htanalysts

Fetal alcohol spectrum disorder (FASD)

Exploratory economic analysis of different prevention strategies in Australia and New Zealand

Prepared by Health Technology Analysts Pty Ltd
For Food Standards Australia New Zealand

May, 2010

Executive Summary

OVERVIEW

This report describes a literature-based cost-effectiveness analysis of four different prevention scenarios for Fetal Alcohol Spectrum Disorder (FASD) in Australia and in New Zealand. Two of the scenarios represent primary prevention strategies (warning labels on alcoholic beverages, and a public media campaign), one scenario represents a secondary prevention strategy (education sessions targeted at all pregnant women), and one scenario represents a tertiary prevention strategy (residential care for pregnant women who are at high risk of giving birth to an infant with FASD). Separate analyses have been undertaken for Australia and New Zealand because of differences in the conventions applied in each country to economic analyses (eg, discount rates), government structure, and the type of health professionals who deliver maternal healthcare.

For each of the identified prevention strategies evidence has been found of their impact on maternal alcohol consumption. Reasonable assumptions have then been made regarding the likely reduction in FASD cases that would ensue following such reductions in maternal alcohol consumption. Each economic scenario has then been based on the description of each strategy in the relevant literature, with costs taken from recognised sources, and with additional input sought from key stakeholders. The cost of managing individual cases of FASD has been derived from the literature. For the primary and secondary prevention scenarios an incremental cost effectiveness ratio has been calculated based on the net cost of each strategy divided by the number of FASD cases avoided. For the tertiary prevention scenario a more conservative incremental cost effectiveness ratio has been calculated based on the net cost of the strategy divided by the number of FASD cases downgraded from severe to mild. All of these ICERs have then been interpreted in the context of whether or not each scenario would achieve cost-neutrality within the expected range of effectiveness.

In Australia all four prevention scenarios were found to be cost-saving within the range of expected effectiveness, and the secondary prevention scenario of education sessions for pregnant women was found to be the most cost-effective. The cost-effectiveness of alcohol warning labels and the public media campaign were found to be comparable.

Similarly, in New Zealand the education sessions for pregnant women were found to be the most cost-effective prevention strategy. However, unlike Australia, the cost-effectiveness of the alcohol

warning labels was greater than that for the public media campaign. For the latter two strategies the point of cost-neutrality was at or just above the upper limit of expected effectiveness.

Although expressed in terms of FASD cases downgraded rather than avoided, the inpatient residential programme for pregnant women who are high-risk drinkers was found to be cost-saving in both countries at a point well below the expected effectiveness of the programme. Thus, although such programmes are resource-intensive and high cost, they represent value for money for the small minority of pregnant women (0.5%) who require them.

Overall, when interpreting the results presented in this report it should be remembered that the most effective overall prevention programme is likely to be one which incorporates primary, secondary and tertiary prevention strategies. It is reasonable to assume that the different strategies will reinforce each other, and that the combined effectiveness of the programmes will be greater than the sum of the individual strategies, yielding lower ICERs than those presented herein.

Separate analyses were undertaken of the potential lost revenue to industry as a consequence of reduced alcohol sales to women who are pregnant. These analyses found that the long-term health benefits and costs savings to society of avoiding FASD far outweigh any potential short-term revenue loss to industry.

A supplementary analysis was conducted in order examine the impact of extending the base-case time horizon from five years to 10 years. The results of the 10-year analysis were generally similar to those of the five year time horizon: the education sessions remained the most cost-effective strategy in Australia and New Zealand. However, unlike with the five year time horizon, in the 10 year time horizon analyses alcohol labels are clearly the second most cost-effective option for Australia and New Zealand.

OBJECTIVE OF THIS REPORT

Food Standards Australia New Zealand (FSANZ) has commissioned a cost-effectiveness analysis of prevention strategies aimed at reducing the incidence of Fetal Alcohol Spectrum Disorder (FASD) via a reduction in the alcohol intake of pregnant women in Australia and New Zealand. The need for this analysis arose as a consequence of an application lodged by the Alcohol Advisory Council of New Zealand to FSANZ seeking a variation to Standard 2.7.1 of the

FSANZ code. Specifically, the application requested that an advisory statement be added to alcoholic beverage containers advising of the risks of consuming alcohol when pregnant or planning to become pregnant. The FSANZ Initial Assessment Report (p29-30) has concluded that the application warrants further consideration, of which cost-effectiveness is one component.

DEFINITION AND BURDEN OF FASD

FASD is an umbrella term used to describe the spectrum of disabilities associated with prenatal exposure to alcohol (Public Health Agency of Canada, 2005). This group of disorders encompasses fetal alcohol syndrome (FAS), fetal alcohol effects (FAE), alcohol-related birth defects (ARBD) and alcohol-related neurodevelopmental disorders (ARND; Striessguth and O'Malley, 2000). The most clinically recognisable form of FASD, FAS, is the leading cause of non-genetic intellectual disability in the Western world (British Medical Association, 2007). FAS consists of measurable deficits including characteristic facial malformations, brain and central nervous system disorders, and growth retardation. Other associated conditions can include heart and kidney defects, hearing and eyesight impairments, skeletal defects and immune system deficiencies.

Although there are no reliable estimates of the incidence of FASD in Australia or New Zealand, current international estimates are that 1% of all pregnant women deliver a child with FASD (Stade *et al*, 2009 and personal communication). In Australia this translates to 2,599 children per year, whilst in New Zealand this translates to 581 children per year. These cases would conservatively be costing Australian and New Zealand taxpayers an extra AU$66 million and NZ$16 million per annum respectively. This represents a significant health and cost burden to society in both countries.

The teratogenic actions of alcohol can occur at any stage during pregnancy, although exposure at different stages of pregnancy is associated with different outcomes. Although the link between alcohol consumption during pregnancy and FASD is well established, quantifying a specific dose-response relationship is difficult.

However, FASD is completely preventable if a woman abstains from alcohol use during pregnancy. This fact is reflected in the recent Guidance from the Australian NHMRC which recommends that "For women who are pregnant or planning a pregnancy, not drinking is the safest option (Australian guidelines to reduce health risk from drinking alcohol, 2009). It is well

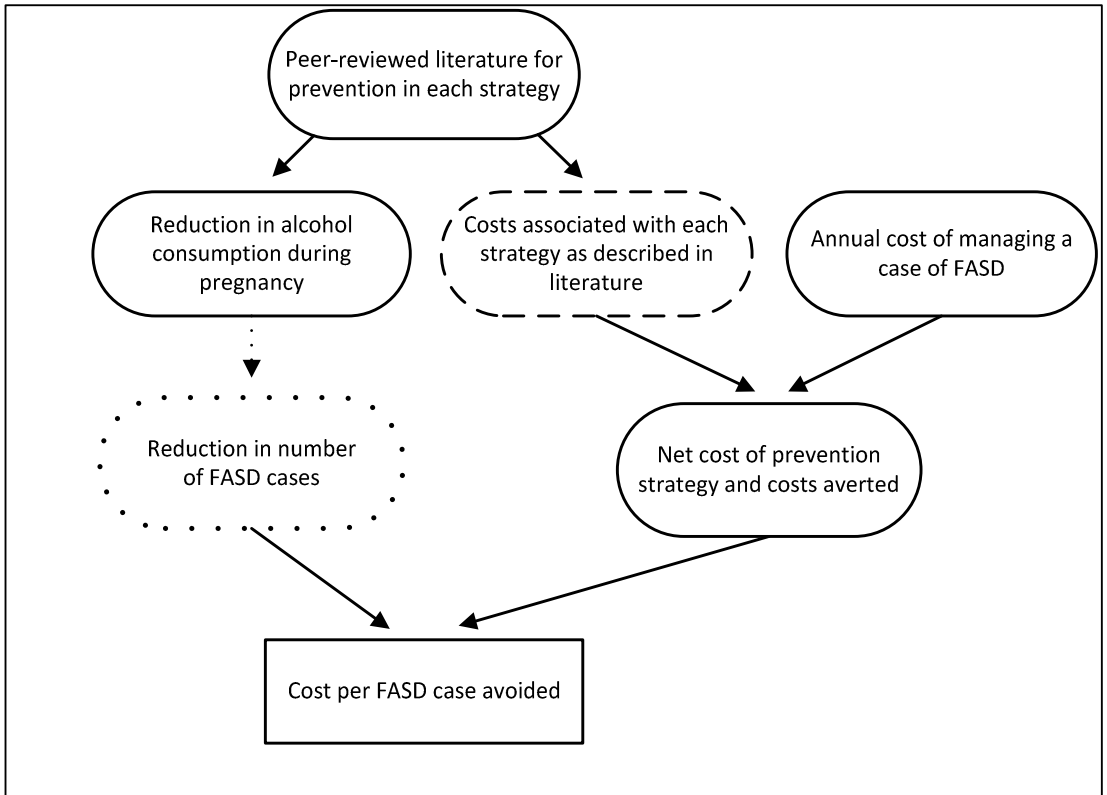
accepted that a comprehensive preventative approach should consist of a universal prevention strategy targeted at the general population, as well as a more selective approaches aimed at all pregnant women and sub-populations of women considered to be at high-risk of delivering a child with FASD.

METHODOLOGY APPLIED IN THIS REPORT

A diagrammatic representation of the overall approach taken in this report is shown in **Figure 1** below. Wherever possible an evidence-based approach has been taken. As described in more detail below, information on the effectiveness of different FASD prevention strategies at reducing maternal alcohol consumption has been taken from systematic reviews of the literature. This evidence has then been used to make assumptions regarding the effectiveness of the same prevention strategies at reducing the number of subsequent FASD cases. This two-step approach was necessary because no evidence has been found which *directly* links any prevention strategy with a reduction in FASD incidence.

The strategies described in the literature were then costed using the descriptions of the strategies reported in that literature. Costs were taken from a variety of recognised sources, with full referencing. A mixture of bottom-up and top-down costing has been used, with care taken to avoid double-counting. Where data gaps were found, additional cost information was sought from key stakeholders including organisations representing alcohol manufacturers in Australia and New Zealand.

Figure 1 Overall approach to the analyses



The annual costs associated with managing individuals with FASD were taken from the best quality cost study available (Stade *et al* 2009). The 2007 Canadian costs reported in this publication were converted to 2009 Australian and New Zealand dollars using standard methods. For each scenario in the economic analyses, the net cost was calculated as the difference between the cost of implementing a particular prevention strategy and the FASD management costs averted by that prevention strategy. The incremental cost-effectiveness ratio for each scenario was then calculated as the net cost divided by the number of FASD cases avoided for each country. For the tertiary prevention strategy of residential programmes for pregnant women who are at high risk of delivering a child with FASD the incremental cost-effectiveness ratio was calculated as the net cost divided by the number of FASD cases downgraded from severe to mild for each country.

Given the expected effectiveness of the different prevention strategies it is fair to expect that alcohol sales would decline in women who are pregnant or planning to become pregnant. This would result in lost revenue to government (via reduced taxes) and lost revenue to industry. The impact of the different prevention strategies on revenue is most appropriately considered as a financial (or budget impact) analysis rather than a cost-effectiveness analysis, and is calculated separately herein.

Identification of the clinical evidence base

The citations identified in a recent systematic review of FASD prevention strategies (Elliott *et al* 2008) and a detailed review of alcohol warning labels (Wilkinson *et al* 2009) were used as the basis of the evidence summary tables. In addition, a brief literature search was conducted to identify any additional relevant evidence published since the Elliott *et al* (2008) review.

A total of 26 studies evaluating an FASD prevention programme were identified. Based on this evidence, a total of four strategies were selected for inclusion in the eight economic scenarios herein. The first two scenarios are the introduction of mandatory alcohol warning labels in Australia and New Zealand. The third and fourth scenarios are the introduction of a public media campaign in Australia and New Zealand. The fifth and sixth scenarios are education sessions for

pregnant women in Australia and New Zealand, and the seventh and eighth scenarios are inpatient alcohol programs for high risk women in Australia and New Zealand.

Where possible, the assumptions used for each scenario were taken directly from the literature. The mandatory alcohol labelling scenario was based on one study (Hankin 1993a and 1993b), which evaluated the impact of the introduction of mandatory labels in the USA. The scenario involving a public media campaign was based on Olsen 1989, which described a multi-faceted health campaign that aimed to reduce alcohol consumption during pregnancy. This scenario included media print-outs such as pamphlets or posters, a television campaign, and a radio campaign. The education sessions for pregnant women scenario was based on the design of Reynolds 1995 and O'Conner & Whaley 2007, although these studies only included pregnant women who were drinking alcohol. The scenario included training all health professionals involved in the provision of prenatal care through distribution of an education booklet. All pregnant women would receive a small pamphlet and a brief education session with their prenatal care provider. The inpatient alcohol programme scenario was based on one study (Whiteside-Mansell *et al* 1998) which described a 15 week programme. It consists of maintaining a residential care home, providing therapy to the pregnant woman, and supplying an onsite childcare service.

Estimation of effectiveness from the clinical evidence base

A major limitation of the evidence base is the lack of evidence directly linking an intervention-related decrease in maternal alcohol consumption with a reduction in FASD incidence. A specific dose-relationship between a reduction in alcohol consumption and a reduction in FASD severity or the prevention of FASD has not been quantified. Nonetheless, in order to conduct an economic analysis it has been assumed that any strategy which reduces alcohol consumption in pregnant women by a particular percentage would reduce the number of children with FASD or the severity of FASD by the same percentage (if the link between intervention and risk reduction is the same for all levels of maternal alcohol exposure). In absence of any further evidence this is considered to be a reasonable assumption given that the link between alcohol consumption during pregnancy and cases of FASD is well established.

The effectiveness of the inpatient alcohol programme is expressed in terms of the number of cases of FASD downgraded from severe to mild, as pregnant women who are identified as high risk drinkers are likely to have already consumed significant levels of alcohol during the early stages of their pregnancy.

Based on the evidence, a plausible range for the percentage of FASD cases avoided or downgraded with each strategy was derived for this report (see **Table 1**). These percentages are then applied to the different population bases in each country to derive the likely range in the number of cases avoided or downgraded in Australia and New Zealand for each strategy. Because of the substantial assumptions that would be required, the analysis does not attempt to quantify the improvement in quality of life that might be gained with the different prevention scenarios. However, it should be kept in mind that such benefits would accrue to all members of society, not just individuals with FASD.

Table 1 Number of FASD cases avoided or downgraded based on the incidence rate of 1 in 100 live births

No.	Scenario	% of individuals with FASD avoided		Number of FASD avoided	
		Lower estimate	Upper estimate	Lower estimate	Upper estimate
1	Alcohol warning labels in Australia	1%	3%	25	77
2	Alcohol warning labels in New Zealand	1%	3%	5	17
3	A public media campaign in Australia	1%	3%	25	77
4	A public media campaign in New Zealand	1%	3%	5	17
5	Education sessions for pregnant women in Australia	19%	29%	493	753
6	Education sessions for pregnant women in New Zealand	19%	29%	110	168
7	An inpatient alcohol programme in Australia	-	20% [a]	-	519 [a]
8	An inpatient alcohol programme in New Zealand	-	20% [a]	-	116 [a]

Abbreviation: FASD = Fetal Alcohol Spectrum Disorder

[a] The review found no evidence that an inpatient alcohol programme can prevent any case of FASD. The study, however, found the evidence that there were significantly less pregnant women in the programme that consumed alcohol at delivery when compared with women not participating in the programme. For this reason, the analysis hypothesised that the programme would result in a reduction in severity of FASD, rather than preventing cases of FASD. The effectiveness of these scenarios is, therefore, expressed in terms of cases of FASD downgraded.

Approach to the economic analysis

A search of the economic and cost-of-illness literature identified Stade *et al* 2009 as the most relevant and recent cost study. This publication reported the adjusted annual cost of FASD per individual with FASD by age range as well as annual costs by FASD severity (ie, mild, moderate and severe). This study provided a basis for the determination of the (averted) cost of FASD.

The analysis takes a societal perspective with all costs measured in 2009 prices. From this perspective, the analysis includes direct costs to the healthcare system and other relevant government agencies and direct costs to industry, as well as indirect costs such as productivity loss, and out-of-pocket expenses to individuals and their families. The estimated costs of FASD do not include costs to the legal system.

Separate analyses have been undertaken for Australia and New Zealand because of differences in the conventions applied in each country to economic analyses (eg, discount rates), differences in

government structure (one national government in New Zealand versus one federal and eight state or territory governments in Australia), and the type of health professionals who deliver maternal healthcare (eg, a higher proportion of obstetricians as primary maternal carers in Australia).

The costs and outcome, where applicable, are distributed over a time horizon of five years and discounted at an annual rate of 3.5% for New Zealand and 5% for Australia. The timeframe of five years is appropriate for this type of economic analysis, given the uncertainty associated with FASD costs over the longer term. This timeframe is also consistent with that typically used by governments for their budget projections.

The economic model is based on a number of necessary assumptions that represent best estimates of the likely costs and outcomes associated with the proposed FASD prevention scenarios. **Key assumptions** are listed below (with a more comprehensive list included within the body of this report):

- The incidence of FASD is 1 in 100 live births for Australia and New Zealand
- The reduction in the proportion of cases of FASD associated with a particular prevention strategy is equivalent to the proportional reduction in maternal alcohol consumption observed for that strategy. This assumes that the link between intervention and risk reduction is the same for all levels of maternal alcohol exposure.
- Appropriate referral pathways are in place in Australia and New Zealand, and all women who require particular healthcare resources have timely access to those resources.
- All one-off costs to government and industry associated with a particular prevention strategy are accrued in the first year of its introduction
- Approximately 40% of the alcoholic beverages produced in Australia and New Zealand are destined for the domestic market, and hence within the jurisdiction of FSANZ.
- Any alcohol labelling changes introduced by FSANZ would allow for a transition period, and the label changes would apply only to new stock produced after that time (ie, there would be no requirement for the recall and relabelling of stock already on shelves at the end of the transition period).
- The costs to industry of labelling changes for each stock keeping unit (SKU) are over-estimated, as not all of the component costs listed in the source report by

PriceWaterhourseCoopers (PWC) will apply in the scenarios under examination (eg, the text and/or schematic would be supplied by FSANZ with little requirement for proof-reading or graphic design by industry, there would be economies of scale across all of the SKUs produced by a single manufacturer, and there would be efficiencies associated with harmonising domestic and export labels).

Alcohol prohibition and increasing taxes on alcoholic drinks were not included for evaluation as there are numerous challenges associated with these options. Firstly, prohibition is extremely difficult to effectively enforce. Though the systematic review found alcohol prohibition to have some effect on alcohol consumption, the practicality of implementing prohibition is limited. Additionally, if alcohol prohibition was implemented, effectively maintaining this policy would have significant resource and financial implications. These costs could disproportionally outweigh the benefits created by alcohol prohibition. Although there is evidence relating an increased tax on alcohol to a reduction in alcohol consumption, it is important to note that no evidence specific to FASD was identified. From an economic perspective, this type of tax could indirectly reduce the economic competitiveness of Australia and New Zealand in the global market, which could create efficiency distortions in the economy, and create overall welfare losses. Further, there is also an ongoing issue of the optimal tax rate to achieve desirable cost-effectiveness results, and there is little information on how best to deal with this matter. Finally, changes to tax rates for alcoholic beverages are the responsibility of other parts of government and not within the remit of FSANZ. This was therefore considered to be outside the scope of this report.

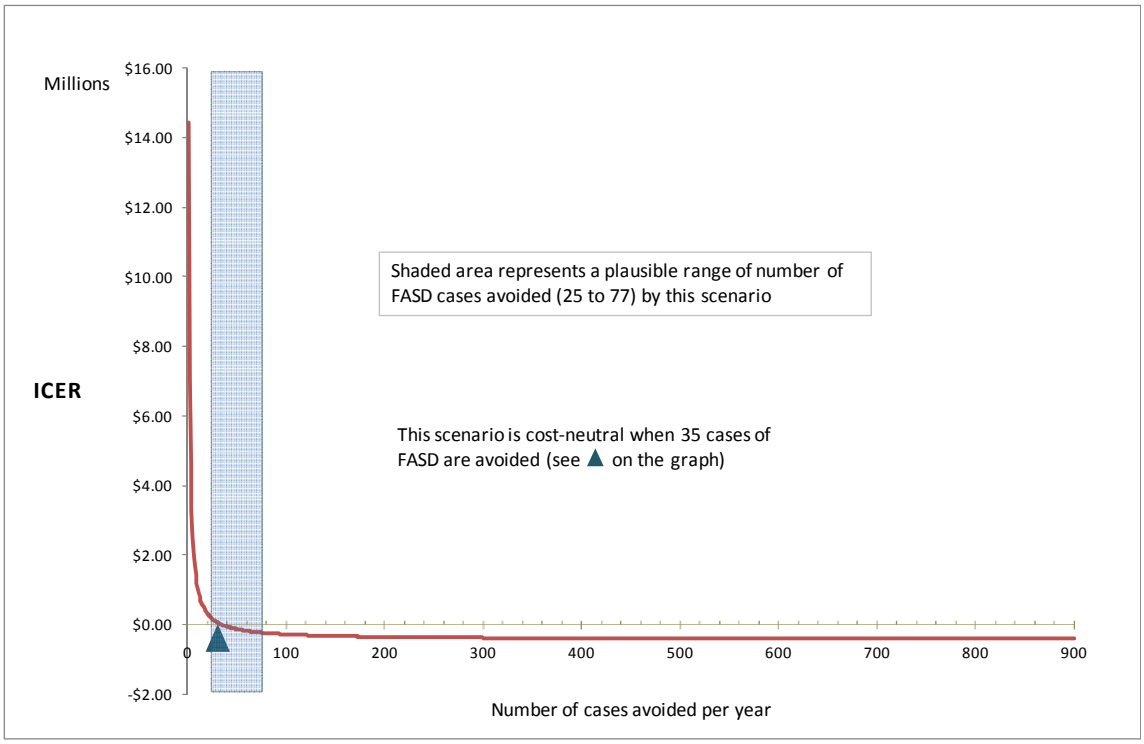
RESULTS

Cost-effectiveness analyses using a 5-year time horizon

For each scenario a range of ICERs has been calculated based on increasing numbers of FASD cases avoided or downgraded per year. As shown in **Figure 2** and **Figure 3** for the alcohol warning labelling scenarios, these ICERs are plotted against the number of cases of avoided. As anticipated, the ICERs for all of the different prevention scenarios decrease as the number of FASD cases avoided or downgraded per annum increases. For each scenario, the plot of ICER versus cases avoided or downgraded also shows the expected effectiveness of the prevention strategy underpinning that scenario. For example it is expected that the introduction of alcohol warning labels in Australia would avoid 25 to 77 cases of FASD per annum (indicated by the shaded area in **Figure 2**). The x-intercept of the plot (indicated by the filled triangle) shows the point at which this scenario achieves cost-neutrality (ie, becomes cost-saving). For alcohol

warning labels in Australia this occurs when 35 cases of FASD are avoided. As this point lies within the expected range of effectiveness for this strategy, it is possible that this strategy is cost-effective. That said, the ICER at the lowest limit of the expected effectiveness is high for a public health intervention (ie, AU$164,000 per FASD case avoided; cf row two, column two in **Table 2**). However, it should be kept in mind that a key driver of the costs associated with the alcohol warning labels is the estimated costs to industry, which have been over-estimated in this analysis (by including all component costs from the PWC report, and by accrual of all costs in year 1 of the analysis when such costs would more likely be spread over more than one year).

Figure 2 Incremental cost per FASD case avoided per year for alcohol warning labels in Australia, over a 5-year time horizon



In the case of New Zealand, it is expected that the introduction of alcohol warning labels would avoid 5 to 17 cases of FASD per annum (indicated by the shaded area in **Figure 3**). For alcohol warning labels in New Zealand this scenario becomes cost-saving when 19 cases of FASD are avoided. This point lies just outside the expected range of effectiveness for this strategy.

Figure 3 **Incremental cost per FASD case avoided per year for alcohol warning labels in New Zealand, over a 5-year time horizon**

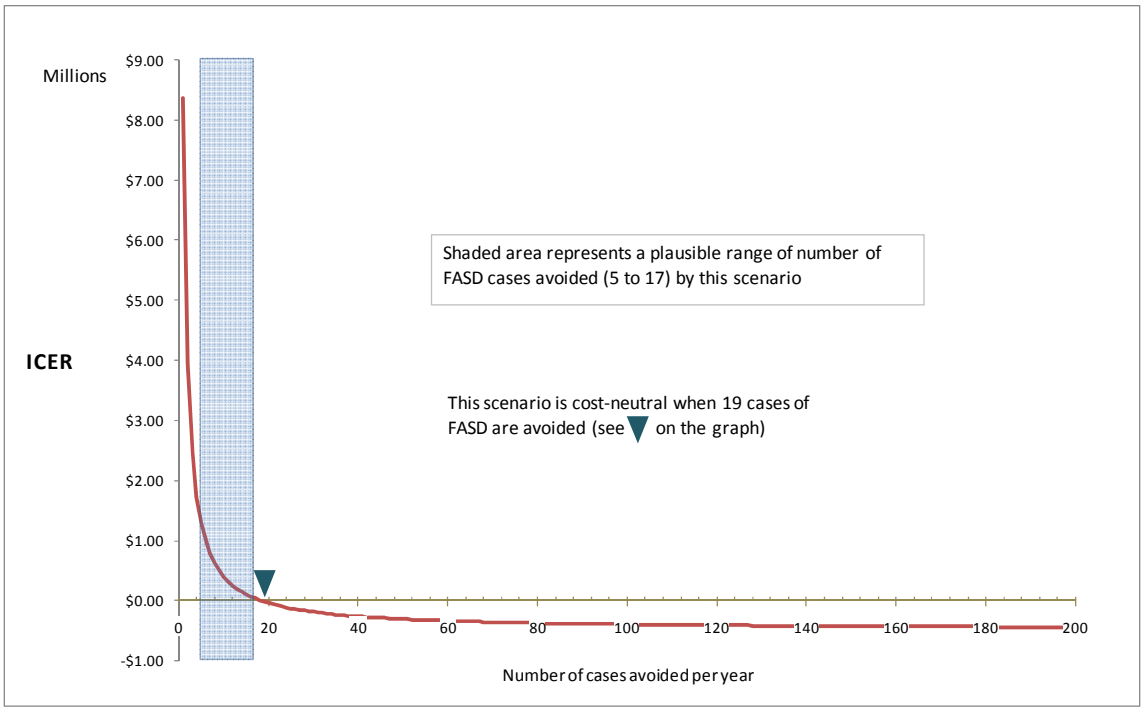


Table 2 shows the ICERs for each scenario at the lower and upper limits of the expected range of effectiveness for each prevention strategy. This table has been constructed from the data derived from the figures above, and from the corresponding figures for the remaining scenarios presented in the body of this report.

In Australia all four scenarios are dominant (ie, cost-saving) at the upper limit of expected effectiveness. In the case of scenario 5, the education sessions for pregnant women, the ICER is also dominant at the lower limit of the expected range of effectiveness. This demonstrates that the secondary prevention strategy of education sessions for pregnant women is the most cost-effective of the four strategies examined. The table also shows that the alcohol warning labels and a public media campaign have comparable cost-effectiveness (with high, but possibly still acceptable ICERs at the lower limits of expected effectiveness).

In New Zealand, education sessions for pregnant women are also clearly the most cost-effective prevention scenario of the four scenarios evaluated herein. However, neither the alcohol warning label scenario nor the public media campaign scenario is dominant at the upper limit of expected effectiveness, although alcohol warning labels appear more cost-effective than the public media

campaign (NZ$38,000 per FASD case avoided versus NZ$181,000 per FASD case avoided at the upper estimate of effectiveness for each). However, both of these scenarios yielded extremely high ratios at the lower limits of effectiveness (NZ$1.3 million and NZ$1.8 million per FASD case avoided). That said, lowest estimation of effectiveness for these two scenarios was very low (1%) and if, for example, the format of the labels was optimised as per the report by Wilkinson *et al* 2009, then a higher level of effectiveness is far more likely.

Table 2 ICERs at limits of expected effectiveness ranges for each scenario using a 5-year time horizon

Number of FASD cases avoided/downgraded per annum	Australia (AU$)		New Zealand (NZ$)	
	Lower estimate	Upper estimate	Lower estimate	Upper estimate
Scenario 1/2 Alcohol warning labels	$164,000	-$237,000	$1.3 million	$38,000
Scenario 3/4 Public media campaign	$158,000	-$239,000	$1.8 million	$181,000
Scenario 5/6 Education sessions	-$400,000	-$410,000	-$456,000	-$465,000
Scenario 7/8 Inpatient programme	-	-$130,000 [a]	-	-$194,000 [a]

[a] The effectiveness of these scenarios is expressed as FASD cases downgraded.
Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorder; ICER = Incremental cost-effectiveness ratio, NZ = New Zealand

Although expressed in terms of FASD cases downgraded rather than avoided, the inpatient residential programme for pregnant women who are at high risk of delivering a child with FASD was found to be cost-saving in both countries at a point well below the expected effectiveness of the programme. For this programme, only a point estimate (not a range) of effectiveness could be derived from the literature.

The information from the analyses of the eight scenarios is presented again in **Table 3** below. This table shows the number of FASD cases avoided or downgraded for each scenario at three points: the point of cost-neutrality for the scenario, the lower limit of effectiveness, and the upper limit of effectiveness. For scenarios where the point of cost-neutrality falls below the upper estimate of effectiveness, the cost-neutral points are highlighted in bold. As shown in the table, the cost-neutral points for six out of the eight scenarios are highlighted in bold.

Table 3 Cases avoided or downgraded at the limits of the range of expected effectiveness for each scenario using a 5-year time horizon

	Australia		New Zealand	
	Cost neutral point	**Lower and upper estimate**	**Cost neutral point**	**Lower and upper estimate**
Scenario 1/2 Alcohol warning labels	**35** (within estimates)	25 and 77	19 (above upper estimate)	5 and 17
Scenario 3/4 Public media campaign	**35** (within estimates)	25 and 77	24 (above upper estimate)	5 and 17
Scenario 5/6 Education sessions	**34** (below lower estimate)	493 and 753	**7** (below lower estimate)	110 and 168
Scenario 7/8 Inpatient programme	**313** (below point estimate)	519 [a]	**55** (below point estimate)	116 [a]

[a] Point estimate only available from the literature.

Financial impact analyses

Separate analyses were undertaken of the potential lost revenue to industry as a consequence of reduced alcohol sales to women who are pregnant. Assuming a prevention programme evoked a 29% reduction in alcohol consumption in pregnant women in any one year, this would be associated with losses of AU$16.6 million in Australia and NZ$1.0 million in New Zealand to the alcohol industry.

However, if that 29% reduction in maternal alcohol consumption did not occur then in that year there would be 2,599 individuals born with FASD in Australia and 581 born in New Zealand. For these cases, the life-time costs associated with managing them would then be AU$498.3 million in Australia and NZ$159.4 million in New Zealand

Consequently, these analyses found that the health benefits and costs savings to society of avoiding FASD far outweigh any potential revenue loss to industry.

Supplementary analyses: a 10-year time horizon

Initially, a conservative time horizon of five years was selected for the base case. Following an external review of the completed analysis, FSANZ requested that a supplementary analysis with a time horizon ten years be conducted. This is to reflect the long-term impact of maternal alcohol consumption on the individual born with FASD.

Table 42 shows the ICERs using a 10-year time horizon. Education sessions were clearly the most cost-effective strategy (ICER of -$1.3 million in Australia and -$1.6 million in New

Zealand), with the alcohol labelling scenario being the second most cost-effective (ICER ranging from -$747,000 to -$1.2 million in Australia and $179,000 to -$1.1 million in New Zealand). The ICERs for a public media campaign ranged from -$376,000 to -$1.0 million in Australia and $2.4 million to -$440,000 million in New Zealand. The upper estimate of an ICER for inpatient alcohol programs was -$674,000 in Australia and -$886,000 in New Zealand.

Table 4 ICER at limit of plausible ranges for each scenario, over a 10-year time horizon

Number of FASD cases avoided/downgraded per annum	Australia (AU$)		New Zealand (NZ$)	
	Lower estimate	Upper estimate	Lower estimate	Upper estimate
Scenario 1/2 Alcohol warning labels	-$747,000	-$1.2 million	$179,000	-$1.1 million
Scenario 3/4 A public media campaign	-$367,000	-$1.0 million	$2.4 million	-$440,000
Scenario 5/6 Education sessions for pregnant women [a]	-$1.3 million	-$1.3 million	-$1.6 million	-$1.6 million
Scenario 7/8 An inpatient alcohol programme	-	-$674,000 [b]	-	-$886,000 [b]

[a] In writing these numbers in full, the lower estimate was AU$1,314,932 and the upper estimate was AU$1,333,019 for Australia and in New Zealand, the lower estimate was NZ$1,557,016 and the upper estimate was NZ$1,574,414.
[b] The effectiveness of these scenarios is expressed as FASD cases downgraded.
Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorder; ICER = Incremental cost-effectiveness ratio, NZ = New Zealand

As anticipated, the points at which all scenarios became cost neutral were lower in the 10-year time horizon when compared to the 5-year time horizon (see Table 5). In Australia, all scenarios were cost neutral at a point below the lower limits of expected cases avoided or downgraded. In contrast, the cost neutral point was only below the expected range of cases avoided for education sessions. The cost neutral point for alcohol warning labels and a public media campaigns was within the expected range of cases avoided. The cost neutral point for both inpatient programme scenarios were below the upper limit of expected cases downgraded.

Table 5 Cases avoided or cases downgraded at limit of plausible ranges for each scenario, over a 10-year time horizon

	Australia		New Zealand	
	Cost neutral point	Lower and upper estimate	Cost neutral point	Lower and upper estimate
Scenario 1/2 Alcohol warning labels	**12 (below lower estimate)**	25 and 77	6 (within estimates)	5 and 17
Scenario 3/4 A public media campaign	**19 (below lower estimate)**	25 and 77	13 (within estimates)	5 and 17
Scenario 5/6 Education sessions	**19 (below lower estimate)**	493 and 753	**4 (below lower estimate)**	110 and 168
Scenario 7/8 Inpatient programme	**179 (below upper estimate)**	- and 519 [a]	**31 (below upper estimate)**	- and 116 [a]

[a] No lower estimate.

These results were consistent with the results for the 5-year time horizon. In both analyses the education sessions were the most cost effective. However, using a 5-year time horizon, alcohol warning labels and the defined public media campaign were found to have similar cost

effectiveness. In contrast, alcohol warning labels were more cost effective than a public media campaign using a 10-year time horizon.

DISCUSSION AND CONCLUSIONS

In Australia all four prevention scenarios were found to be cost-saving within the range of expected effectiveness, and the secondary prevention scenario of education sessions for pregnant women was found to be the most cost-effective. The cost-effectiveness of alcohol warning labels and the public media campaign were found to be comparable when analysed using a 5-year time horizon. However in a 10-year time horizon, the alcohol warning labels were found to be more cost effective than public media campaigns.

Similarly, in New Zealand the education sessions for pregnant women were found to be the most cost-effective prevention strategy. However, unlike Australia, the cost-effectiveness of the alcohol warning labels was greater than that for the public media campaign. For the latter two strategies the point of cost-neutrality was at or just above the upper limit of expected effectiveness in the 5-year time horizon, but in the 10-year time horizon they were well within the expected range.

Although expressed in terms of FASD cases downgraded rather than avoided, the inpatient residential programme for pregnant women who are at high risk of delivering a child with FASD was found to be cost-saving in both countries at a point well below the expected effectiveness of the programme. Thus, although such programmes are resource-intensive and high cost, they represent value for money for the small minority of pregnant women (0.5%) who require them.

Overall, when interpreting the results presented in this report it should be remembered that the most effective overall prevention programme is likely to be one which incorporates primary, secondary and tertiary prevention strategies. It is reasonable to assume that the different strategies will reinforce each other, and that the combined effectiveness of the programmes will be greater than the sum of the individual strategies, yielding lower ICERs than those presented herein.

Moreover, it should be noted that the benefits of preventing cases of FASD have been captured only in monetary terms. In practice, substantial quality of life benefits would accrue to the individuals who would otherwise be born with FASD, and to their families and the community which cares for them.

Table of Contents

List of Tables

List of Figures

Introduction

OVERVIEW OF FASD

Fetal Alcohol Spectrum Disorders (FASD) is an umbrella term used to describe the spectrum of disabilities associated with prenatal exposure to alcohol (Public Health Agency of Canada, 2005). This group of disorders encompasses fetal alcohol syndrome (FAS), fetal alcohol effects (FAE), alcohol-related birth defects (ARBD) and alcohol-related neurodevelopmental disorders (ARND) (Striessguth & O'Malley 2000). The most clinically recognisable and most severe form of FASD, FAS, is reported to be the leading known cause of non-genetic intellectual disability in the Western world (British Medical Association 2007). FAS consists of measurable deficits; including characteristic facial malformations, brain and central nervous system disorders, and growth retardation. Other associated conditions can include heart and kidney defects, hearing and eyesight impairments, skeletal defects and immune system deficiencies.

The teratogenic actions of alcohol can occur at any stage during pregnancy. In particular, exposure to alcohol during the first three weeks post conception can damage early development and neural tube elaboration (O'Leary, 2002). Exposure between the fourth and nine weeks is the critical period for malformations of the brain and other cranial structures. The pattern of drinking is critical; binge drinking is associated with an increased rate of FAS-related abnormalities compared with drinking the same about of alcohol over an extended period of time (BMA Board of Science, 2007). Existing evidence on the adverse irreversible effects of low to moderate prenatal alcohol exposure is inconclusive and there is currently no consensus on the level of risk or whether there is a clear threshold below which alcohol is non-teratogenic (BMA Board of Science, 2007). Although the link between alcohol consumption during pregnancy and FASD is well established, quantifying a specific dose-response relationship is difficult. The same absolute reduction in alcohol consumption may result in different reductions in FASD severity in different women, depending on a number of factors including the timing and pattern of alcohol consumption. This is reflected in the latest NHMRC guidelines (Australian Guidelines to reduce health risks from drinking alcohol, NHMRC 2009)[a], which also note that a dose-response between alcohol consumption and FASD has not been established.

[a] http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/ds10-alcohol.pdf

EPIDEMIOLOGY OF FASD

Estimates of FAS and FASD incidence and prevalence rates vary between countries. FASD is more common in populations that experience high degrees of social deprivation and poverty, such as indigenous groups. The difficulty in determining the incidence of FASD is due to the lack of accurate and routine data collection. Accurate reporting is further complicated by the lack of uniformly accepted diagnostic criteria and poor knowledge of FASD among primary care providers.

As part of the systematic review of FASD conducted by Elliott *et al* (2008), the epidemiology of FASD in Australia and New Zealand was investigated; however, the true extent of the incidence and prevalence of FASD in these countries is unknown. There are no nationally consistent definitions or diagnostic criteria for FASD and children are not routinely screened in infancy or early childhood. The most recent estimates from Stade (personal communication) relied on by Alcohol Healthwatch in NZ state an incidence rate of 10 per 1000 live births. This can be compared with NZ estimates of cystic fibrosis at 0.3 per 1000 live births, Down Syndrome at 1 per 1000 and cerebral palsy at 1-2.6 per 1000 (Alcohol Advisory Council and Ministry of Health, 2001).

The New Zealand Paediatric Surveillance Unit (NZPSU) collected data on the incidence and prevalence of FAS (the most severe form of FASD) in New Zealand from July 1999 to December 2001. In 2000, 29 cases of suspected or definite FAS were reported. The annual incidence of FAS was found to be 2.9 per 100,000 children below 15 years of age, per year. The report notes that the incidence of FAS was low compared to other countries, possibly because only a small number of New Zealand paediatricians were diagnosing children with FAS (NZPSU, 2000). For Australia, the incidence of FAS in the state of Western Australia has been reported as 0.18 cases per 1000 births (Bower *et al* 2000). Significantly higher incidence rates have been reported in Aboriginal children (2.76/1000 births) compared with non-Aboriginal children (0.02/1000 births). Based on the Australian Paediatric Surveillance Unit (APSU) data, 92 out of 169 cases were reported have the fulfilled criteria of FAS between January 2001 and December 2004.

PREVENTION OF FASD

A comprehensive preventative approach should consist of a universal prevention strategy targeted at the general population, as well as a more selective approach aimed at sub-populations

considered to be at high-risk (Wilkinson *et al* 2009). Prevention strategies are often categorised as primary (or universal), secondary or tertiary. In the case of FASD, primary prevention strategies aim to educate the general public about the risks of drinking during pregnancy. Secondary prevention includes screening, early detection and management of pregnant women or women with an increased risk of having a child with FASD, whilst tertiary prevention aims to change behaviours of women who are considered to be at very high risk of having a child with FASD (May, 1995). May (1995) suggests that primary prevention (stopping maternal alcohol consumption before pregnancy) is needed for most of the female population who are of childbearing age, secondary prevention (early detection and management) may be necessary for 14 to 25 percent of women of childbearing potential, and tertiary prevention (changing the behaviour of women who are at very high risk) is appropriate for only 2 to 6 percent women of childbearing potential. Early appropriate intervention provides substantial benefits for individuals, families and the population as a whole (Alcohol Healthwatch, 2007).

The need for prevention strategies

FASD is 100% preventable if a woman abstains from alcohol consumption during pregnancy. Evidence suggests that there has been an increase in the prevalence of excessive drinking amongst women, especially young women. Historically young men consumed more than young women, however there is now a smaller difference between the amount of alcohol consumed by young men and young women (Alcohol Advisory Council of New Zealand and the Ministry of Health, 2001). The New Zealand Health Survey (2008) reported men were twice as likely to have a potentially hazardous drinking pattern when compared to women (28% vs 12%). Hazardous drinking was most common in those aged 18-24 years, and was reported by 50% of men and 33% of women in this age group. Comparison between the NZ 2000 National Alcohol Survey and the NZ 1995 National Alcohol Survey found that women of all ages increased the overall quantity of alcohol that they consume, with the increase most prominent among those ages 16-17, 18-19 and 20-24 years (Alcohol and Public Health Research Unit, 2001). Risk levels of drinking in these age groups, combined with a risk of unplanned pregnancies, suggest that many fetuses are likely to be inadvertently exposed (Elliott & Bower, 2008).

Secondary and tertiary prevention strategies may also play a key role in reducing the incidence of FASD. The most recent New Zealand research indicates that 25% to 42% of women drink during pregnancy (McLeod *et al* 2002; Watson & McDonald 1999; Counsell *et al* 1994) and about 10% drink to intoxicating levels (Watson & McDonald 1999). Australian research found that 59%

of women drank alcohol during their pregnancy (Colvin *et al* 2007). A 2006 survey found that more than 50% of New Zealand women believed that if a pregnant woman wanted to drink, then some alcohol was safe in pregnancy (Parackal *et al* 2006). Furthermore, nearly 20% of all women had binged on at least one occasion in pregnancy, most having done so before they realised that they were pregnant. Therefore, providing education to women of childbearing age about alcohol consumption in pregnancy is an important preventive measure.

Primary prevention strategies

Universal prevention programs aim to educate the broader public about the risks of drinking during pregnancy (Alcohol Healthwatch, 2007). The critical time of development is usually before a woman recognises that she is pregnant and seeks advice from a health practitioner. Greater emphasis needs to be placed on preconception care to focus public attention toward alcohol and drug avoidance before pregnancy is detected. Advice should also be given to women at the time their pregnancy is confirmed to ensure that the greatest number of opportunities to reduce risk are taken. This is particularly relevant for teenage pregnancies, with studies suggesting that one or both parents had been drinking alcohol during as many as 50% of teen pregnancies (Burke 1998).

Pregnancy health advisory labels have become a growing trend internationally and are one of the most common primary prevention strategies. The United States, South Korea, Columbia, France, Finland and South Africa require warning labels for alcoholic beverages that advise consumers about the risk of drinking alcohol during pregnancy. As of 1 January 2007, 22 US states have also mandated that in every place where alcoholic beverages are sold (ie, stores, bars, restaurants etc.) there are to be posted signs recommending that women avoid alcohol during pregnancy or when planning a pregnancy. These signs must include referral numbers to an alcohol and drug help line or an FASD information line.

The United States has required that warning labels be placed on all alcoholic beverages since 1989, however there is still debate about the effectiveness of this prevention strategy. Awareness has been relatively high among the adult public as a whole (Dufour *et al* 1994; Greenfield, 1997), with awareness rates as high as 80% in inner city African American pregnant women (Hankin *et al* 1996). However, awareness levels are not consistent across populations. Men, 18-29 year olds, heavy drinkers and those with a higher education level were more likely to report having seen the labels (Graves, 1993). Awareness is high among those at most risk, with a study finding that shortly after the appearance of the labels, 39% of the women aged 18 to 29 years classified as 'heavy' drinkers (those drinking five or more drinks at least once a week) were aware of the

warning label, compared to 12% for abstainers (Kaskutas & Greenfield, 1992). However there is little evidence that awareness of a warning label leads to a change in behaviour. The frequency of drinking among pregnant women increased four-fold between 1991 and 1995 (Centers for Disease Control, 1997) and there has been no change in the percentage of adults who regard drinking during pregnancy as being 'very harmful' (Mayer *et al* 1991; Mazis *et al* 1991; Scammon *et al* 1991; Graves, 1993; Hankin *et al* 1993a, *b).* A study of pregnant Native Americans and African Americans found that although there was a high level of awareness of warning labels, only one-fifth were aware that FAS was related to alcohol consumption (Kaskutas, 2000). The women did not understand that abstinence at any time during the pregnancy was beneficial and believed that wine coolers were safer to drink during pregnancy than liquor. Other studies have found a high rate of false positive responses (responses incorrectly identified as positive) when women were asked if they were aware of alcohol warning labels, with 35% of pregnant women stating that they had seen a warning label on alcohol bottles prior to their introduction (Hankin *et al* 1993).

Studies have also shown that warning labels had only a small and transient impact on drinking during pregnancy among inner city African American women, with the effect confined to 'light' drinkers (i.e. those with the lowest risk; Hankin *et al* 1993a,b,1996 cf. also, Scammon *et al* 1991; Kaskutas & Greenfield, 1992; Graves, 1993). The deterrent effect among heavier drinkers and women with high parity has been minimal (Hankin *et al* 1993a, b, 1996). Heavy drinkers may be more likely than occasional drinkers to be aware of the warning label (Kaskutas & Greenfield, 1992), but they are also less inclined to act on that knowledge than are women whose risk for birth defects is very low. It is only the drinkers whose consumption is not yet at the compulsive stage that have altered their drinking behaviour in response to these public education efforts (Hankin *et al* 1993a,b*).* Therefore women 'at-risk' (e.g. women who have previously abused alcohol or women who have already had a child diagnosed with FASD) should be additionally targeted by intervention protocols by health practitioners and referral to specialist alcohol services as part of a comprehensive approach to FASD (British Medical Association, 2007).

Research suggests that there are familiarity effects associated with labels, whereby less attention is paid to label messages over time as people become used to their presence. This has been shown in studies that report that awareness of the alcohol beverage warning label has attenuated over time (Hankin *et al* 2002).

Mass education campaigns, such as TV advertisements, newspaper articles and pamphlets have also been used as primary prevention strategies. However, there is little evidence that these strategies are successful. In Saskatchewan, Canada, the incidence of FAS has remained

unchanged over a 20-year period, despite intensive provincial and national education campaigns raising public awareness of the potential dangers of excessive drinking during pregnancy (Habbick *et al* 1996).

Abel (1998) suggests that primary prevention strategies need to target harmful alcohol use rather than alcohol consumption. A more effective policy may be a combination of targeted prevention strategies and higher taxes on alcohol beverages. Studies have shown that heavy drinking and binge drinking are sensitive to alcohol price changes. Consumers of alcoholic beverages (including heavy drinkers) increase their drinking when prices are low and decrease their drinking when prices are high (Babor *et al* 2003). Although there is strong evidence that increasing alcohol beverage taxes and prices results in a reduction in alcohol related problems, the real price of alcoholic beverages has decreased in many countries over the last 50 years. A major reason for the price decline has been the failure of governments to increase tax levels in accordance with inflation. The British Medical Association stated that there is strong and consistent evidence that alcohol consumption and rates of alcohol-related problems are responsive to price (BMA, 2007). It has been estimated that a 10 per cent increase in alcohol prices in the UK would lead to a 10 per cent fall in consumption. Heavy drinkers and young drinkers are particularly responsive to price changes. The BMA concludes that there is a clear relationship between the affordability of alcohol and the level of consumption. This relationship provides an effective tool for controlling levels of consumption and reducing levels of alcohol related harm.

A review by Deshpande *et al* (2005) suggested that social change strategies may also be effective in promoting abstinence during pregnancy. These include alternative alcohol-free socialisation (such as alcohol free clubs), educational posters at point of sale and encouraging male partners of pregnant women to engage in responsible drinking.

Secondary and tertiary prevention strategies

Secondary and tertiary prevention strategies are interventions directed at a specific subgroup of women. They can be targeted to a broad population (such as any pregnant women) or a well defined population (such as women who have abused alcohol during a previous pregnancy). The exact nature of the intervention depends on the risk status of the targeted population. Women are typically selected for a secondary or tertiary intervention using a screening tools.

A common targeted prevention strategy is a brief intervention (Chang, 2002). This typically consists of assessment, direct feedback, establishing contracts, setting goals, behavioural

modification techniques and written materials such as self help manuals. They can be given by a variety of providers in a broad range of clinical settings. Brief interventions are most appropriate for individuals with mild to moderate alcohol problems. They are therefore most suitable for use in a broad population, such as all pregnant women attending an antenatal clinical, as only a small proportion of pregnant women have severe alcohol problems. The time required to administer a brief intervention is variable, but typically takes a single session of 1-2 hours and one or more brief follow-up sessions.

Brief interventions can take different approaches, such as motivational or confrontational. Motivational interventions are the most common and aim to enhance a patient's motivation to change their drinking behaviour by exploring and resolving the reason for their ambivalence. The provider giving the motivational intervention should express empathy, avoid argumentation and support the patient's self-efficacy.

Extended interventions are most suitable for targeted populations of high-risk women. As with brief interventions, there are a large number of strategies which take a variety of forms. Extended interventions will often require patients to attend multiple sessions over a number of weeks or months. Depending on the targeted population, patients may be seen by a team of providers such as clinicians, social workers or specialists in substance abuse.

Other targeted prevention strategies include providing brief advice (such as verbally advising a pregnant woman not to drink alcohol or providing a pamphlet), other forms of counselling (such as directive-confrontational counselling), educational intervention, skill-based counselling and cognitive behavioural treatment.

OBJECTIVE OF THIS REPORT

Food Standards Australia New Zealand (FSANZ) has commissioned a cost-effectiveness analysis of prevention strategies aimed at reducing the prevalence of FASD via reduction in the alcohol intake of pregnant women in Australia and New Zealand. The need for such analysis arose in response to an application lodged by the Alcohol Advisory Council of New Zealand to FSANZ seeking a variation to Standard 2.7.1 of the FSANZ code. Specifically, the application requested that an advisory statement be added to alcoholic beverage containers advising of the risks of consuming alcohol when pregnant or planning to become pregnant. The FSANZ Initial Assessment Report concluded that the application warrants further consideration, of which cost-effectiveness is one component. For this reason, the current cost-effectiveness analysis has been

undertaken. The aim of this analysis was to determine the value of different strategies which aim to reduce the prevalence of FASD through reducing the alcohol intake of pregnant women in Australia and New Zealand.

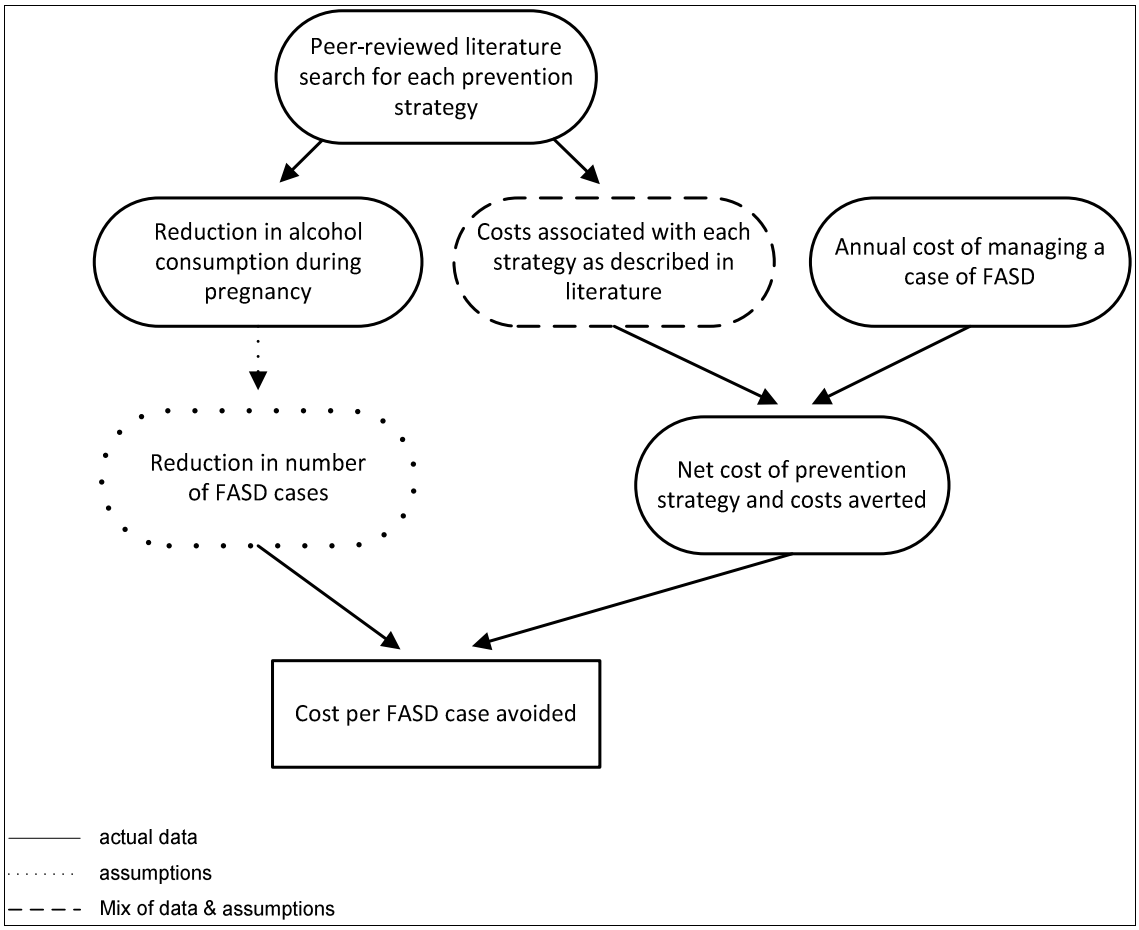
Methodology applied in this report

A flow chart summarising the methodology in this report is shown in **Figure 4**. Wherever possible an evidence-based approach has been taken. As described in more detail below, information on the effectiveness of different FASD prevention strategies at reducing maternal alcohol consumption has been taken from systematic reviews of the literature. This evidence has then been used to make assumptions regarding the effectiveness of the same prevention strategies at reducing the number of subsequent FASD cases. This two-step approach was necessary because no evidence has been found which *directly* links any prevention strategy with a reduction in FASD incidence.

For each prevention strategy one peer-reviewed publication has been chosen (on the basis of quality and/or applicability), and the particular strategy described in that publication has been costed. Costs were taken from a variety of recognised sources, with full referencing. A mixture of bottom-up and top-down costing has been used, with care taken to avoid double-counting. A societal perspective has been taken in order to best capture the costs and benefits to individuals, government and industry that will be associated with the introduction of each of the identified prevention strategies.

As typically occurs in the conduct of cost-effectiveness analyses in healthcare, a number of assumptions have been required where data gaps remain. Sensitivity analyses have been conducted around key assumptions.

Figure 4 Flow chat of methodology used in this report



Identification of the evidence base

LITERATURE SEARCH METHODOLOGY

A systematic review of FASD strategies has previously been undertaken for the New Zealand Ministry of Health (Elliott *et al* 2008). A detailed review of alcohol warning labels has also been conducted on behalf of FSANZ by the National Drug Research Institute in collaboration with the Drug and Alcohol Office, National Drug and Alcohol Research Centre and the Public Health Advocacy Institute (Wilkinson *et al* 2009). The citations identified in these reviews were used as the basis of the evidence summary tables. In addition, a brief literature search was conducted to identify any additional relevant evidence published since the Elliott *et al* (2008) review.

The literature search conducted for the New Zealand Ministry of Health included searches of bibliographic databases (EMBASE, Medline, Scopus and PsycInfo) as well as online review databases (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effectiveness, Health Technology Assessment database and NHS Economic Evaluation database). A literature search was also conducted using the websites from a number of HTA groups (INAHTA, MSAC, ANZHSN, NZHTA, NICE, AHRQ/USPSTF, CADTH, SBU and KCE, see Appendix 1 for website details). It should be noted that these websites capture an extensive body of grey literature, including government documents and other reports not captured by a systematic review of bibliographic databases.

Details of the updated literature search are shown in Appendix 1. Details of the literature search performed in Elliott *et al* 2008 can be found on page 27-37 of that full report[b].

EVIDENCE SUMMARY TABLES

A total of 26 studies evaluating an FASD prevention programme were identified following the literature searches. Of these, 25 studies were identified in the literature search conducted by Elliott *et al* 2008 and one study was identified in the updated literature search.

A summary of the 26 publications identified in both literature searches is shown in **Table 6**. The results are briefly summarised below. The use of the evidence base to estimate the effectiveness of each of the eight scenarios is discussed in detail in the 'Possible effectiveness of different

[b] http://www.healthsac.net/downloads/publications/HSAC07_FASD_FINALv3.pdf.

prevention scenarios' on page 53. This includes a detailed description of the results from each study specifically used in this report.

It should be noted that the evidence base is broad, and few interventions have been assessed in more than one publication or more than one setting. This is particularly true for the primary prevention programs such as mandatory alcohol warning labels and public media campaigns, which were each assessed in a single study or country. Although the individual study results may be robust, they may not reflect the likely impact of any strategy if it were applied in the Australian or New Zealand context. Furthermore, it should not be assumed that strategies which have not been identified in this literature search are ineffective.

The major limitation of the evidence base is the absolute lack of evidence which *directly* linked an intervention-related decrease in alcohol consumption with a subsequent reduction in FASD incidence. However, given the clear correlation between increased alcohol consumption and increased FASD incidence, it is reasonable to assume that a decrease in alcohol consumption is associated with a decrease in FASD incidence. The exact dose-response relationship is, however, unknown.

Primary prevention

Four publications evaluated a primary prevention strategy. Bowerman 1997 reported that alcohol prohibition can reduce alcohol use during pregnancy. Hankin 1993a,b reported that there was no significant difference in alcohol consumption rates in pregnant women after the introduction of warning labels on alcohol bottles. A small decrease in alcohol consumption was observed in low-risk, but not high-risk, women. Kaskutas 1998 reported that exposure to multiple sources of information did not correlate with a decrease in alcohol consumption during pregnancy. Olsen 1989 found that a large-scale, multi-faceted education campaign had no effect on the rates of alcohol consumption during pregnancy.

Secondary prevention

Twelve publications evaluated a secondary prevention strategy. Two publications (Little 1984 and Little 1985) described the same intervention. All other publications described different secondary prevention strategies; however, all can be broadly characterised as one-on-one, education-based interventions. Reduction of alcohol consumption was the primary aim in eight of the interventions (Handmaker 1998, Meberg 1986, Larsson 1983, Little 1984, Little 1985, O'Conner & Whaley 2007, Reynolds 1995, and Waterson & Murray-Lyons 1990). Women enrolled in these

programs received only information about alcohol consumption in pregnancy. The other five interventions included information about alcohol as one component of a broader educational programme including smoking, illicit drug use, nutrition, and general prenatal care (Allan & Ries 1985, Cziezel 1999, Drinkard 2001, Eisen 2000 and Sarvela & Ford 1993).

Three publications reported that pregnant women receiving an education intervention had a significant reduction in alcohol consumption compared to a control group. The intervention described in Reynolds 1995 included an education session and self help manual, while O'Conner & Whaley 2007 required women to undergo an assessment of alcohol use and complete a workbook. Eisen 2000 described pooled results from nine drug treatment programs. It is difficult to identify factors critical to the success of these three interventions as many of the features of these interventions were also present in studies which reported no significant benefit from the intervention.

Tertiary prevention

Ten publications evaluated a tertiary prevention strategy. Reduction of alcohol consumption was the primary aim in four of the studies (Chang 1999 and Chang 2000, Chang 2005 and Chang 2006, May 2009, and Rosett 1980 and Rosett 1983). Women enrolled in these programs received only information about alcohol consumption in pregnancy. The other six studies employed interventions that included information about alcohol as one component of a broader educational programme (Belizán 1995, Corrarino 2000, Grant and Ernst 2003 and Grant 2005, Glor 1987, Halmesmaki 1998 and Whiteside-Mansell 1998).

Whiteside-Mansell 1998 was the only publication which reported that the intervention significantly reduced prenatal alcohol consumption relative to the control group. This intervention was an intensive drug and alcohol prevention programme, which evolved from a 4-5 hours per day, 5 days a week outpatient service to a 7-8 hours per day, 5 days a week onsite residential support service programme. The study was considered of poor quality due to significant methodological concerns. All other publications reported that the intervention being assessed was ineffective, or only partially effective.

Table 6 Summary of primary, secondary and tertiary prevention of FASD studies identified in the literature searches

Intervention	Comparator	NHMRC Level of evidence	Result	Clinical relevant effect? [a]	Citation
Primary prevention					
Alcohol ban in intervention town in Alaska	No alcohol ban in control town in Alaska	Level III-2	Significant reduction in alcohol abuse (RR 0.21, 95% CI 0.08, 0.55).	Probably	Bowerman 1997
Warning labels on alcohol bottles	No warning labels on alcohol labels	Level III-2	Significant correlation between label and reduced alcohol consumption in nulliparae ($p<0.04$) but not multiparae women. Modest reduction in alcohol consumption in light drinkers ($p<0.009$) but not heavy drinkers.	Possibly	Hankin 1993a,b and 1996
Exposure to a warning label, advertisement or conversation about drinking during pregnancy	Correlation between number of labels seen by subjects and alcohol consumption during pregnancy	Level III-3	No significant correlation.	No	Kaskutuas 1998
Educational campaign in intervention town in Denmark	No educational campaign in control town in Denmark	Level III-3	No significant change	No	Olsen 1989
Secondary prevention					
Motivational intervention	Letter with information about the risk of drinking during pregnancy	Level II	Significant reduction in blood alcohol concentration ($p<0.01$). No significant change in abstinent days or total alcohol consumption.	Possibly	Handmaker 1999
Self-help intervention	Standard care	Level II	Significant increase in proportion of women who quit drinking ($p<0.058$)	Yes	Reynolds 1995
Brief intervention with assessment of alcohol use and advice	Assessment of alcohol use and advice	Level II	Significant increase in proportion of women who were abstinent by the third trimester (OR=5.39, $p<0.058$)	Yes	O'Connor and Whaley 2007
Advice, reinforcement, with and without an educational video, leaflet about alcohol use	Leaflet about alcohol use	Level III-1	No change in alcohol consumption	No	Waterson and Murray-Lyon 1990
Drug prevention, education and treatment programme	No intervention	Level III-2	Significant increase in proportion of women abstinent within 30 days of birth ($p=0.0001$) and significant decrease in women who used alcohol to intoxication within 30 days of birth ($p=0.0001$)	Yes	Eisen 2000
Supportive counselling	Standard care	Level III-2	No change in alcohol consumption	No	Meberg 1986
Prenatal care and education programme	Standard care	Level III-2	No change in alcohol consumption	No	Sarvela and Ford 1993
Healthy pregnancy programme	Pre vs post	Level IV	72% of women attributed reduction in drinking to the intervention (significance not stated)	Unclear	Drinkard 2001

Intervention	Comparator	NHMRC Level of evidence	Result	Clinical relevant effect? [a]	Citation
Periconceptional care programme	Pre vs post	Level IV	Reduction in proportion of women who drank >1 drink per week (significance not stated)	Unclear	Cziezel 1999
Prenatal education class	Pre vs post	Level IV	No change in alcohol consumption	No	Allen and Ries 1985
Interventional counselling	Pre vs post	Level IV	Significant downward trend drinking before and after the intervention ($p<0.001$).	Unclear	Little 1984, 1985
Early detection and treatment programme	Pre vs post	Level IV	>74% reported a reduction in alcohol consumption (significance not stated)	Unclear	Larsson 1983
Tertiary prevention					
Brief intervention with a partner	Diagnostic intervention only	Level II	Significant interaction between the brief intervention and alcohol consumption ($p=0.01$)	Possibly	Chang 2005, 2006
Brief intervention	Alcohol assessment only	Level II	No change in alcohol consumption	No	Change 1999, 2000
Home visits	Routine antenatal care	Level II	No change in alcohol consumption	No	Belizán 1995
Alcohol and drug prevention treatment programme	Women who refused to use the service	Level III-2	Significantly less women drank at delivery in the intervention group (4%) vs the control group (33%, $p<0.05$)	Yes	Whiteside-Mansell 1998
Prenatal care	Average population and high-risk population	Level III-3	19% of subjects consumed alcohol at the end of the intervention compared with 63% in the average population ($p<0.05$)	Unclear	Glor 1987
Home visitation programme	Pre vs post	Level IV	No change in alcohol consumption	No	Grant and Ernst 2003, Grant 2005
Linking subjects to drug treatment programs	Pre vs post	Level IV	Reduction of the proportion of women with an 'extreme' alcohol severity score (significance not stated)	Unclear	Corrarino 2000
Counselling	Pre vs post	Level IV	The intervention was most effective in moderate drinkers (85% reduced consumption) compared with alcoholics (55%) and heavy drinkers (57%) (significance not stated)	Unclear	Halmesmaki 1988
Case management [b]	Pre vs post	Level IV	No change in number of drinks consumed or average blood alcohol concentrations. Proportion of subjects who did not drink increased from baseline (69.5%) to 6 months (80.0%), but dropped to 12 months (40.0%).	Unlikely	May 2009 [b]
Counselling and prenatal care	Pre vs post	Level IV	36% of subjects abstained or had a significant reduction in alcohol consumption prior to their third trimester (significance not stated)	Unclear	Rosett 1980, 1983

[a] Is the magnitude of the reduction in alcohol consumption likely to lead to clinically meaningful outcomes? (ie reduction in the number of children born with FASD)
[b] Identified in the updated literature search

LITERATURE SEARCH FOR ECONOMIC AND COST-OF-ILLNESS STUDIES

A literature search was conducted to identify any published economic evaluations or cost-of-illness studies for FASD. Details of the literature search are shown in **Appendix 1**.

No relevant economic evaluations were identified but four cost-of-illness studies were identified (Stade *et al* 2006; Stade *et al* 2007; Stade *et al* 2009; and Thanh *et al* 2009). Stade *et al* 2006 included a sample of children with FASD aged between 1 and 21 years from Canada. Stade *et al* 2007 is a brief update of Stade *et al* 2006. The study by Stade *et al* 2009 describes an expanded subject group (including those described in Stade *et al* 2006), with a sample of 250 individuals from birth to the age of 53 years.

Thanh 2009 is a cost-of-illness study which estimated the long-term and short-term cost of FASD in Alberta, Canada. Since this study narrowly focused on one province in Canada, the generalisability of the findings is somewhat limited. Additionally, Thanh 2009 obtained the cost of FASD per child from Stade *et al* 2006, which has been considered in our review. As a result, Stade *et al* 2009 is considered the most relevant up-to-date cost study, providing a basis for the analysis of the (averted) cost of FASD. The results have been discussed on page 46.

Scenario Selection

A total of eight scenarios were selected for inclusion in the economic analysis (as shown in **Table 7**). The prevention scenarios were examined separately for Australia and New Zealand as there are a number of differences in the healthcare systems, modelling techniques, and government structure between the two countries. For instance, the recommended discount rate of 5% is applied in Australia, while a lower discount rate of 3.5% is used for New Zealand. The discount rate reflects collective preference of future costs and outcome, and it is important that such preferences are accurately captured in an economic analysis. Differences in the healthcare systems between the two countries arise predominantly from differences in the health professionals delivering maternity care. In New Zealand lead maternity carers are predominately midwives or GPs, whereas in Australia a significant proportion of females see an obstetrician as their primary maternity carer. Differences in government structure between the two countries are also notable. New Zealand has one national government, whereas Australia has a national government plus eight state and territory governments. These differences could have a profound impact on the cost estimates and hence the cost-effectiveness ratio. It is therefore important that these differences are captured in an economic evaluation.

The first two scenarios considered in the economic analysis are the introduction of mandatory alcohol warning labels in Australia and New Zealand, respectively. The third and fourth scenarios are the introduction of a public media campaign. The fifth and sixth scenarios are education sessions for pregnant women, and the seventh and eighth scenarios are inpatient alcohol programmes for high risk women. These are shown in **Table 7**.

Table 7 Scenarios selected for inclusion in the economic analysis

Number	Scenario
1	Alcohol warning labels in Australia
2	Alcohol warning labels in New Zealand
3	A public media campaign in Australia
4	A public media campaign in New Zealand
5	Education sessions to pregnant women in Australia
6	Education sessions to pregnant women in New Zealand
7	An inpatient alcohol programme in Australia
8	An inpatient alcohol programme in New Zealand

DETAILS OF SELECTED SCENARIOS

Further details of the eight selected scenarios are shown in **Table 8**. A brief description of each scenario is presented below.

Scenario one and two: Alcohol warning labels in Australia and New Zealand

The introduction of mandatory alcohol warming labels is a primary prevention strategy as it is aimed at the general population. The literature search identified one publication (Hankin 1993a,b) which evaluated the effectiveness of introducing alcohol warning labels in the USA. This requires amending the Food Standards Code to require all alcoholic beverage containers to include a warning about the risks of drinking during pregnancy.

The application to FSANZ by the Alcohol Advisory Council of New Zealand did not specify the type of warning statement, nor did it include proposed wording or type of pictorial message. A review of international warning labels was therefore conducted in order to identify the type of label that would hypothetically be introduced. The transition arrangements are yet to be determined and if required would be subject to further consultation. However for the purpose of this analyses it is assumed that a two year transition period applies and labelling changes would only be required to new stock produced after the transition period (in order to minimise costs for industry). In recognition of the long shelf life of many (but not all) alcoholic beverages, it was assumed that the labelling change would apply only to new product produced after the transition period, consequently there would be no requirement that products already on shelves be relabelled.

Scenario three and four: Public media campaign in Australia and New Zealand

A public media campaign is a primary prevention strategy as it is targeted at the general population. The literature search identified one publication (Olsen 1989) which evaluated the effectiveness of an educational campaign in Denmark. Media campaigns were one component of this strategy.

The hypothetical public media campaign evaluated in this scenario is based on that described by Olsen 1989. It is multi-faceted and included printed materials such as posters and pamphlets inclusive of PR agency time, a television campaign, and a radio campaign.

Scenario five and six: Education sessions in Australia and New Zealand

Education sessions for pregnant women are secondary prevention strategies as they are aimed at a selected group (pregnant women). The literature search identified two publications (Reynolds 1995 and O'Conner & Whaley 2007) which reported that educational sessions for pregnant women were effective.

In the proposed scenario, all pregnant women would receive a brief information pamphlet which contains concise information about the risks and adverse impacts of consumption of alcohol to the unborn child. The hypothetical pamphlets evaluated in this scenario are approximately two pages in length. In order to ensure maximum effectiveness, the pamphlets would be concise and written in every-day language. In New Zealand the pamphlets would be available in five languages – English, Māori, Samoan, Tongan, and Cook Islands Maori. In Australia, it was assumed that the pamphlets would be available in the nine most frequently spoken languages.

It is proposed that the pamphlets would be distributed to pregnant women on two occasions: when pregnancy is confirmed (likely to be during a GP visit), and at the first prenatal visit with the chosen maternal health professional. In New Zealand, this is the lead maternity carer (LMC). In contrast, pregnant women in Australia generally receive one of two types of prenatal care. The first type is shared care provided alternately by a community GP and a midwife, and the second type is by an obstetrician at a hospital. Women would also have a brief discussion with their maternal health professional.

As a crucial part of this scenario, the training of health professionals is included in the first year of the programme. The purpose of training health professionals is to increase their knowledge of FASD and to improve their ability to identify women at risk, and identify infants who may have FASD. Training would occur via booklets distributed to all health professionals directly involved in the care of women in the perinatal period e.g., GPs, midwives, obstetricians. For the purpose of this analysis, it is assumed that the training booklets would be similar to those developed by the Telethon Institute for Child Health Research (ICHR)[c] in Australia, "Alcohol and Pregnancy: Health professionals making difference". The ICHR booklet was developed to support West

[c] http://www.ichr.uwa.edu.au/alcoholandpregnancy/resources

Australian health professionals to address the issue of alcohol use in pregnancy with women. Unlike the booklets for pregnant women, which are brief and concise, it is anticipated that the booklet would be more technical, cover more areas and be longer (38 pages). Additional training was not considered in this analysis.

The ICHR is currently evaluating the acceptability of the booklet and impact on patient care. There may be the potential for national adoption of the booklet in Australia and for New Zealand to localise the booklet, with the agreement of its developers at the ICHR.

Scenario seven and eight: Inpatient alcohol programme in Australia and New Zealand

Inpatient programmes are aimed at women with a high risk of having a child with FASD. The goal of the intensive programme is to reduce excessive or abusive drinking in pregnant women through a multifaceted education and treatment programme. The literature search identified one publication (Whiteside-Mansell 1998) which reported that an inpatient programme for high risk women was effective at reducing alcohol consumption. However, given that these programmes are aimed at women who are already pregnant, the current report assumes that reductions in alcohol consumption during pregnancy would be associated with a reduced severity of FASD cases, but not necessarily associated with a complete avoidance of FASD cases. This is a conservative assumption as it is unlikely that women who had already consumed alcohol during pregnancy may be able to prevent FASD even if they become stop drinking immediately after entering a treatment program.

The hypothetical programme evaluated in this scenario provides residential care services, with all women staying onsite from Monday to Friday. The length of the programme is 15 weeks. The programme services are delivered by a multi-disciplinary team, but managed primarily by a full-time GP. When required, the residential care programme also provides an onsite childcare service to look after young children of women participating in the programme. For the purpose of this analysis it is assumed that such residential care facilitates are available to all women in Australia and New Zealand who are assessed as requiring them. In reality, this is unlikely to be the case, and additional facilities may need to be established. This report does not consider the costs associated with establishing additional residential care facilities. Furthermore, the feasibility of a pregnant woman spending this length of time away from work and family is not explored. Rather, this analysis simply adopts the intensive programme as it was described in the evidence base.

Table 8 Details of possible national prevention strategies for FASD

Scenario	Description	Type	Target population	Timing
1 Alcohol warning labels in Australia	Mandating alcohol warning labels on alcoholic beverage containers in Australia	Primary prevention	General population	Ongoing
2 Alcohol warning labels in New Zealand	Mandating alcohol warning labels on alcoholic beverage containers in New Zealand	Primary prevention	General population	Ongoing
3 A public media campaign in Australia	Distributing print-out materials, broadcasting television campaign, and radio campaign in Australia	Primary prevention	General population	Ongoing
4 A public media campaign in New Zealand	Distributing print-out materials, broadcasting television campaign, and radio campaign in New Zealand	Primary prevention	General population	Ongoing
5 Education sessions to pregnant women in Australia	Training of health professionals (health professional booklets) about the risks of FASD and pamphlet to pregnant women warning them of the risks associated with alcohol consumption during pregnancy in Australia	Secondary prevention	All pregnant women	When pregnancy confirmed (GP visit) and first prenatal visit
6 Education sessions to pregnant women in New Zealand	Training of health professionals (health professional booklets) about the risks of FASD and pamphlet to pregnant women warning them of the risks associated with alcohol consumption during pregnancy in New Zealand	Secondary prevention	All pregnant women	When pregnancy confirmed (GP visit) and first prenatal visit
7 An inpatient alcohol programme in Australia	Intensive intervention for women considered to be at high risk of having a child with FASD, comprised of the following: Alcohol and drug prevention programme composed of 8 hours a day, 5 days a week onsite residential support service for 15 weeks, implemented by a multidisciplinary team, with an onsite childcare service	Tertiary prevention	Pregnant women identified as drinking at high risk level	During pregnancy
8 An inpatient alcohol programme in New Zealand	Intensive intervention for women considered to be at high risk of having a child with FASD, comprised of the following: Alcohol and drug prevention programme composed of 8 hours a day, 5 days a week onsite residential support service for 15 weeks, implemented by a multidisciplinary team, with an onsite childcare service	Tertiary prevention	Pregnant women identified as drinking at high risk level	During pregnancy

Approach to the Economic Analysis

The objective of this exploratory economic analysis was to examine the cost-effectiveness of eight prevention scenarios for FASD in Australia and New Zealand, compared to the current situation (i.e., no additional actions taken to prevent FASD).

This exploratory economic analysis is considered a supplementary report to an existing FASD systematic review (Elliott *et al* 2008), and should be considered in conjunction with this review. The content of this economic analysis alone does not constitute clinical advice or policy recommendations. It should only be viewed as a 'what if' analysis, and not as a commitment by the FSANZ, or any other organisation, to implement the scenarios described herein.

The effectiveness of the hypothetical prevention scenarios included in this analysis is captured through the number of FASD cases avoided or downgraded (where appropriate). Combining this with the incremental cost, the analysis presents the final results in the form of an incremental cost-effectiveness ratio (ICER). The ICER is expressed here as the incremental cost per case of FASD avoided, or per case of FASD downgraded. As discussed later in this report, the inpatient alcohol programme is more likely to reduce the severity of FASD, rather than totally prevent a case of FASD. For this reason, it is more appropriate to express the outcome of scenarios 7 and 8 in terms of the number of cases downgraded.

As noted in the introduction, a specific dose-relationship between a reduction in alcohol consumption and a reduction in FASD severity or the prevention of FASD has not been quantified. Nonetheless, in order to conduct an economic analysis it has been assumed that any strategy which reduces alcohol consumption in pregnant women would reduce the number of children with FASD or the severity of FASD. This is a reasonable assumption given that the link between alcohol consumption and cases of FASD is well established. However, the magnitude of this effect has been estimated purely for the purpose of exploration, based loosely on the findings of the systematic review by Elliott *et al* 2008.

Where possible, a 'bottom-up' approach has been undertaken to estimate the incremental cost of the prevention scenarios for FASD. The analysis takes the societal perspective with all costs measured in 2009 prices. From this perspective, the analysis includes direct costs to the healthcare system and other relevant government agencies and indirect costs such productivity loss, out-of-pocket expenses, and costs to affected industry. The analysis, however, excludes the indirect cost of possible lost revenue. This type of cost is often not appropriate for economic

evaluation. This cost is excluded from the base-case analysis, however it is addressed in the discussion (see page 86).

The costs, where applicable, are distributed over a time horizon of five years and discounted at an annual rate of 3.5% for New Zealand (based on current PHARMAC recommendations) and 5% for Australia (based on current PBAC recommendations). The timeframe of five years is appropriate for this type of economic analysis. Given the great uncertainty associated with FASD costs over a longer timeframe, extending the analysis beyond five years may introduce an unacceptable level of uncertainty to the analysis. A time horizon of five years is also consistent with other government studies of similar types, allowing for comparison, if appropriate. Nonetheless, a supplementary analysis extending the time horizon to ten years was conducted and is discussed herein.

This economic analysis presents the incremental costs of implementing a prevention scenario per case of FASD avoided or downgraded per annum, over the five-year time horizon. The analysis does not attempt to quantify the improvement in quality of life that might be gained with the different prevention strategies. The analysis considers a number of results based on different hypothetical reductions in the number of children born with FASD or different number of FASD cases downgraded. The results are presented in two ways:

- incremental cost of the national prevention scenarios, over a five-year horizon.
- incremental cost per case avoided or downgraded per annum, over a five-year horizon.

The economic model is based on a number of necessary assumptions that represent best estimates of the likely costs and outcomes associated with the proposed FASD prevention scenarios. The list of assumptions underpinning the economic model is shown on page 81.

Incremental cost of the different scenarios

The incremental costs of the eight scenarios evaluated in this economic analysis are presented in **Table 10** to **Table 17.** In general, the costs are classified into two categories – the first year set-up costs and the ongoing costs in each subsequent year.

While the general cost structure for New Zealand and Australia are comparable, the crucial difference between the two countries (and hence between scenarios one and two) is the government body responsible for enforcing labelling regulation and auditing compliance. This difference creates significant financial differentials. In New Zealand, the New Zealand Food Safety Authority (NZFSA) is the responsible organisation (see scenario two). Conversely, in Australia, state and territory governments are responsible for enforcing regulation set by FSANZ on locally produced food and beverages, while the Australian Quarantine and Inspection Service (AQIS) is responsible for imported food and beverages. Further, in Australia there are six state and two major territory governments[d] that govern themselves and set their own legislation to implement, enforce and audit the labelling regulation change. The associated costs could then vary considerably from government to government as they vary in size. Note that AQIS is part of the federal government, which is regulatory and financially separate from state and territory governments. They, however, fall under the general category of government. For more information on this matter, refer to the FSANZ website[e].

Excluded from the economic analysis is the indirect cost to the government, such as loss in Goods and Services Tax (GST) revenue due to a possible decrease in the volume of alcohol sales. In addition, mandatory labelling could result in an increase in the price of alcoholic beverages, which could lead to a decrease in the demand for alcohol and hence a decrease in the alcoholic beverage sales. The magnitude of the loss is, however, unclear. Any loss is dependent upon a number of factors such as demand and supply elasticity of the targeted market, and the consumption behaviour of the affected individuals and the time cost to industry (which is not likely to be very high).

[d] These are Australia Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria, and Western Australia.
[e] http://www.foodstandards.gov.au/

SCENARIO ONE: ALCOHOL WARNING LABELS IN AUSTRALIA

Table 10 presents the expected costs associated with mandatory labelling of alcoholic beverage containers for Australia. From the societal perspective, the total cost in Year 1 was estimated to be approximately AU$14.2 million with an annual ongoing incremental cost of AU$0.19 million for the duration of the model.

The transition arrangements are yet to be determined and if required would be subject to further consultation. However for the purpose of this analyses it is assumed that a two year transition period applies and labelling changes would only be required to new stock produced after the transition period (in order to minimise costs for industry). It is also recognised that the majority of wine labels are changed annually by vintage – the exceptions being fortified and sparkling wines. Consequently, it is important that the current analysis captures the *incremental* cost of the proposed new standard, and not the cost of labelling changes that would otherwise be made in the absence of the new standard.

The costs in Year 1 are associated with enforcing the amendment of the code, general administration, and one-off cost of the alcohol labelling to industry. The costs beyond Year 1 include the continuing costs associated with general administrating, auditing the labelling, costs associated with dealing with complaints/enquiries, and the cost of further research. Note that the time estimates shown in **Table 10** do not imply the actual length of time associated with the change in the Code, they rather represent the accumulated additional time the government agencies would directly devote toward such work. It should also be noted that although industry may be granted a two year transition period, all of the estimated incremental costs to industry have been accrued in Year 1 of the current analysis (and hence not subject to discounting). This is to ensure uniformity in the handling of cost to government and industry within the analysis.

The number of basic hours per government officer required to complete the specified tasks is assumed to be identical for Australia and New Zealand. Given that there are eight states and major territory governments independently completing these tasks in Australia, it is not unreasonable to anticipate that the number of basic hours could be up to eight times the number of hours allowed for New Zealand. However, in practice there is likely to be a working body with overarching responsibilities across both countries, which would reduce the total number of hours required in each jurisdiction. Nevertheless, for simplicity the analysis assumes that the number of hours required for Australia to be eight times those for New Zealand.

For the first year, this economic analysis assumes that it takes an equivalent of one full-time analyst for a period of six months (960 hours) to implement and enforce any changes. An additional one month (160 hours) was allowed for general administration in the first year. These tasks would be the responsibilities of relevant state and territory governments.

The unit costs were obtained from the Survey of Employee Earnings and Hours (August 2008 quarter) published by Australian Bureau of Statistics (ABS). The estimates on the number of units required are assumptions based on similar economic analyses conducted for FSANZ (Access Economics 2006, NZIER 2005).

The most significant first year cost is the financial impact to industry of implementing the labelling changes. It is estimated that this would cost industry approximately AU$14 million in Year 1, and it is assumed that there are no ongoing costs. The total cost was derived based on the cost of labelling change per SKU and the number of alcoholic beverage SKUs that are likely to be affected by the alcohol label change.

The cost to industry of mandatory labelling changes was taken from a PriceWaterhouseCoopers (PWC) report commissioned by FSANZ in 2008. This report describes three types of label changes: minor, medium and major, for a range of different containers and packages. The cost is presented per SKU. In order to determine which change was most appropriate to use in the economics analysis, a comprehensive review of international alcohol warning labels (Wilkinson *et al* 2009) was evaluated. This report identified 19 countries with mandatory alcohol warning labels. Of these, six also required a pregnancy related warning label (Colombia, France, South Africa, South Korea, the United States and the United Kingdom). The majority of pregnancy warning labels were a single, text based sentence (black and white only). France and the United Kingdom had the option of either a short sentence OR a small silhouette of a pregnant woman drinking alcohol with a cross through it. This picture is small, and in black and white. Although FSANZ has not yet made any decision regarding the exact label that would be introduced if labelling was to be recommended, it is unlikely to be significantly different to those that are currently used internationally. With this in mind, the PWC definitions of minor, medium and major label changes were reviewed. The label change which best reflects the current international mandated warning labels (including a silhouette of a woman) is considered to represent a minor change, defined as a change which required only text changes, changes to one colour only, no proofing and no package redesign. The minor label change for glass bottles was therefore used in the base-case. This was AU$3,967 per glass bottle SKU. A medium change in the PWC report was defined as changes to text and label layout, a change in three colours and no change to package shape or

size. Although this reflects a more detailed label than those currently in use worldwide, the cost for a medium change to a glass bottle label has been tested in a sensitivity analysis as the upper limit of the likely cost per SKU.

As shown in **Table 9**, information on the number of wine and non-wine SKUs produced in Australia and New Zealand were provided by FSANZ after industry consultation. The total number of affected SKUs was calculated first for wine SKUs, and then for non-wine SKUs. Cask wine and beer were excluded from the current analysis as such products have a shelf life less than two years and would be expected to change their labels within two years.

Based on information from industry, it was assumed that any labelling changes would only apply to wine SKUs destined for the domestic market, which was estimated as 40% of all wine SKUs.

Industry also estimated that approximately 80-90% of wine SKUs change their labels at least once every two years. It was therefore assumed that 20% of wine SKUs would require a label change as a direct result of the introduction of mandatory alcohol warning labels. Assuming that all SKUs would require a labelling change was tested in a sensitivity analysis. Therefore, the total number of affected wine SKUs was calculated as 1,400 for Australia and 800 for New Zealand.

The total number of non-wine SKUs was obtained for New Zealand based on data provided to FSANZ by industry. As no estimates could be obtained for Australia, it was assumed that the proportion of wine SKUs to non-wine SKUs would be equivalent for Australia and New Zealand. Advice from industry indicated that none of the non-wine SKUs would be expected to change their label within a two year period. Therefore, it was assumed that all non-wine SKUs would be affected by the introduction of mandatory alcohol labels. Therefore, the total number of affected non-wine SKUs was calculated as 2,101 for Australia and 1,200 for New Zealand.

Therefore, the total number of affected SKUs was estimated to be 3,501 in Australia and 2,000 in New Zealand.

Table 9 Calculation of affected SKUs for Australia and New Zealand

Ref		Australia (AU$)	New Zealand (NZ$)	Source
Wine SKUs				
A	Number of wine SKUs produced by country	17,500	10,000	Industry representatives (via FSANZ)
B	Proportion of wine SKUs for domestic market	40%	40%	Industry representatives (via FSANZ)
C	Number of wine SKUs for domestic market	7,000	4,000	Row A x Row B
D	Proportion of wine SKU affected by the labelling change	20%	20%	Industry representatives (via FSANZ)
E	**Number of affected wine SKUs**	**1,400**	**800**	**Row C x Row D**
Non-wine SKUs				
H	Number of non-wine SKUs for domestic market	2,101	1,200	New Zealand: Industry representatives (via FSANZ) Australia: derived from NZ data (ie 10,000/1,200=0.12, applied to Australian data)
I	Proportion of non-wine SKU affected by the labelling change	100%	100%	Industry representatives (via FSANZ)
J	**Number of affected non-wine SKUs**	**2,101**	**1,200**	**Row H x Row I**
K	**Overall number of affected SKUs**	**3,501**	**2,000**	**Row E + Row J**

Abbreviations: A = Australian; ABS = Australian Bureau of Statistics; FSANZ = Food Standard Australia New Zealand; NZ = New Zealand; SKU = stock-keeping unit;

[a] The exchange rate of 1.1025 was applied to convert the cost into New Zealand dollars. The rate was taken from Reserve Bank of Australia, recorded as at June 2009.

The costs beyond Year 1 are associated with the time spent auditing the manufacturers and retailers in order to ensure industry compliance. The analysis assumes that such tasks would take a total of two months (320 hours) annually. Additionally, a total of 40 hours, 160 hours and 160 hours per annum have been allocated for general administration, further research, and time spent dealing with complaints/enquiries, respectively.

The current analysis only considers the impact of mandatory labelling changes on the domestic alcohol market. However, changes to Australian and New Zealand regulatory requirements may impact wine producers who export their product. Potential cost considerations include wasted space on international template labels and increased stock control costs given that a wine which is labelled in a way that it can only be used in one or two specific markets will require separate warehouse space and it cannot be easily diverted between markets. However, as noted in Wilkinson *et al* 2009, Australian winemakers are currently required to meet international labelling requirements, and are required to include alcohol warning labels when exporting to 19 countries. Six countries (including France and the USA) require pregnancy warning labels on all imported products. Therefore, the introduction of pregnancy warning labels may actually bring Australian labelling requirements in line with key global markets, and minimise the need for significant differences in label design across markets. It is recognised by FSANZ that any Australian and

New Zealand regulatory changes should take into consideration issues of global harmonisation of wine labels.

It should also be noted that imported wine will need to comply with Australian and New Zealand regulatory requirements. However, as the current analysis only captures the costs and benefits from an Australian and New Zealand societal perspective, the costs borne by international manufacturers have not been considered here. It is acknowledged that these costs may ultimately be passed on to the consumer in Australia and New Zealand.

Table 10 Costs of alcohol pregnancy warning labels in Australia

Item	Australia (AU$)					
	Unit cost (cost per hour)	Source	No. of unit (number of hours required)	Source	Modifier	Total cost
Cost in Year 1						
Implementation and enforcement	$34.40 per hour [a]	ABS	960 hours per state and territory government	Assumption	8 state and territory governments	$264,192.00
Administration	$32.90 per hour [b]	ABS	160 hours per state and territory government	Assumption	8 state and territory governments	$42,112.00
Impact to the industry	$3,967.00 per SKU	PWC report	3,501 domestic SKUs	**Table 9**	1	$13,888,467.00
Total cost in Year 1						**$14,194,771.00**
Cost post Year 1 (ongoing)						
Administration	$32.90 per hour	ABS	40 hours per state and territory government	Assumption	8 state and territory governments	$10,528.00
Auditing	$34.40 per hour	ABS	320 hours per state and territory government	Assumption	8 state and territory governments	$88,064.00
Complaints/enquiry	$34.40 per hour	ABS	160 hours per state and territory government	Assumption	8 state and territory governments	$44,032.00
Further research	$34.40 per hour	ABS	160 hours per state and territory government	Assumption	8 state and territory governments	$44,032.00
Total cost in a subsequent years						**$186,656.00**
Total cost over 5 years, undiscounted						**$14,941,395.00**
Total cost over 5 years, discounted						**$14,856,643.94**

Abbreviations: A = Australian; ABS = Australian Bureau of Statistics, PWC = PricewaterhouseCoopers; SKU = stock-keeping unit

[a] The average hourly earnings of $34.40 for the occupation group of public order, safety and regulatory services was used as a proxy. The estimate was obtained from the Survey of Employee Earnings and Hours, the August 2008 quarter publication.

[b] The average hourly earnings of $32.90 for the occupation group of public administration was used as a proxy. The estimate was obtained from the Survey of Employee Earnings and Hours, the August 2008 quarter publication.

SCENARIO TWO: ALCOHOL WARNING LABELS IN NEW ZEALAND

Table 11 presents the costs associated with mandatory labelling of alcoholic beverage glass bottles for New Zealand. From the societal perspective, the total cost in Year 1 was estimated to be approximately NZ$8.8 million with an ongoing incremental cost of NZ$20,000 per year after that.

Similar to the case of alcohol warning labels in Australia, the total cost in **Table 11** is driven primarily by the cost of implementing and enforcing the Code in the first year, and the cost of auditing in the subsequent years. As mentioned earlier, the process of amending the Food Standards Code could involve a number of government agencies, however the primary agency would be FSANZ. In contrast to Australia, the enforcing and implementing process is undertaken solely by a single agency (NZFSA).

The unit costs were obtained from New Zealand Income Survey (June 2009 quarter) published by Statistics New Zealand (SNZ). The estimates on the number of units required are the analysis assumptions, based on a similar economic analyses conducted for FSANZ (Access Economics 2006, NZIER 2005).

This economic analysis assumes that it takes a full-time analyst six months (960 hours) to implement and enforce such changes. An addition of one month (160 hours) is allowed for general administration in the first year, see **Table 11**.

In each subsequent year, most of the ongoing cost is accounted for by the time spent auditing the affected manufacturers, importers, and retailers, and ensuring compliance. The analysis assumed that such tasks would take a total of two months (320 hours in total) annually. Additionally, a total of 40 hours, 160 hours and 160 hours per annum have been allocated for general administration, further research, and time spent dealing with complaints/enquiries respectively.

In terms of calculating the cost of labelling change to industry in New Zealand, the approach is identical to that described previously for Australia, with the following differences. The key change is that all the cost per SKU was converted in New Zealand dollars using the exchange rate of 1.1025 recorded at June 2009 (obtained from Reserve Bank of Australia).

Table 11 Costs of alcohol warning labels in New Zealand

Item	New Zealand (NZ$)					
	Unit cost (cost per hour)	Source	No. of unit (number of hours required)	Source	Modifier	Total cost
Cost in Year 1						
Implementation and enforcement	$30.45 per hour [a]	SNZ	960 hours	Assumption	1	$29,232.00
Administration	$20.58 per hour [b]	SNZ	160 hours	Assumption	1	$3,292.80
Impact to the industry	$4,373.62 per SKU [c]	PWC report	2,000 domestic SKUs	**Table 9**	1	$8,747,235.00
Total cost in Year 1						**$8,779,759.80**
Cost post Year 1 (ongoing)						
Administration	$20.58 per hour	SNZ	40 hours	Assumption	1	$823.20
Auditing	$30.45 per hour	SNZ	320 hours	Assumption	1	$9,744.00
Complaints/enquiry	$30.45 per hour	SNZ	160 hours	Assumption	1	$4,872.00
Further research	$30.45 per hour	SNZ	160 hours	Assumption	1	$4,872.00
Total cost a subsequent years						**$20,311.20**
Total cost over 5 years, undiscounted						**$8,861,004.60**
Total cost over 5 years, discounted						**$8,854,364.45**

Abbreviations: NZ= New Zealand; SNZ = Statistics New Zealand; PWC = PricewaterhouseCoopers; SKU = stock-keeping unit

[a] The average hourly earnings of $30.45 for the occupation group of legislators, administrators, and managers was used as a proxy. The estimate was obtained from New Zealand Income Survey, the June 2009 quarter publication.

[b] The average hourly earnings of $20.58 for the occupation group of clerks was used as a proxy. The estimate was obtained from New Zealand Income Survey, the June 2009 quarter publication.

[c] The cost of AU$3,967 * exchange rate of 1.1025 = NZ$4,374

SCENARIO THREE: A PUBLIC MEDIA CAMPAIGN IN AUSTRALIA

Table 12 presents the annual costs of a public media campaign in Australia. The total cost is estimated at approximately AU$14.7 million (discounted) over five years with a cost of AU$4.4 million in Year 1 and an annual ongoing cost of AU$2.9 million post Year 1.

In the first year, there are costs associated with producing and running the multi-faceted public media campaign consisting of (1) media print-outs such as pamphlets or posters, (2) a television campaign, and (3) a radio campaign. The costs of running the campaigns are inclusive of any costs associated with engaging a public relations (PR) agency. The cost estimates were obtained from personal communication with an Australian PR agency.

As there are currently no media campaigns specifically for FASD, an original media campaign would be required. The production costs for a media campaign would be incurred once, and would require maintenance and updating each year in order to insure that it is still relevant to the target audience. A total of AU$2 million was allocated for the initial campaign production. Maintenance and updating is anticipated to cost approximately 25% of the total production cost, contributing an additional AU$0.5 million in each subsequent year.

In each year, there are also ongoing costs associated with running the campaign. The average annual cost of running such campaigns is approximately AU$2 million, plus an additional 20% for PR agency fees (ie,AU$2.4 million annually). This figure includes the significant costs associated with buying advertising time on television and radio.

Table 12 Costs of a public media campaign in Australia

Item	Australia (AU$)					
	Unit cost	Source	No. of unit	Source	Modifier	Total cost
Cost in Year 1						
Preparing and producing a multi-faceted public media campaign	$2,000,000 for the whole campaign	Personal communication with Australian PR agency	1	-	1	$2,000,000.00
Running the media campaign: Print-out materials, TV campaign, radio campaign as well as PR agency time	$2,400,000	Personal communication with Australian PR agency	1	-	1	$2,400,000.00
Total cost in Year 1						**$4,400,000.00**
Cost post Year 1 (ongoing)						
Running the media campaign: Print-out materials, TV campaign, radio campaign as well as PR agency time	$2,400,000	Personal communication with Australian PR agency	1	-	1	$2,400,000.00
Maintaining and updating the campaign	$500,000	Personal communication with Australian PR agency	1	-	1	$500,000.00
Total cost in a subsequent year						**$2,900,00.00**
Total cost over 5 years, undiscounted						**$16,000,000.00**
Total cost over 5 years, discounted						**$14,683,256.46**

Abbreviations: A = Australian; ABS = Australian Bureau of Statistics: TV = television, PR = Public relation

SCENARIO FOUR: A PUBLIC MEDIA CAMPAIGN IN NEW ZEALAND

Table 13 presents the costs of a public media campaign in New Zealand. The total cost is estimated at approximately NZ$11.3 million (discounted) over five years with a cost of NZ$3.3 million in Year 1 and an ongoing cost of NZ$2.2 million annually in the subsequent years.

Similar to the scenario for Australia, in the first year, there are costs associated with preparing and producing the multi-faceted media campaign comprising; print-outs such as pamphlets or posters, a television campaign, and a radio campaign.

The cost estimates were obtained based on personal communication with the Alcohol Advisory Council of New Zealand (ALAC). The total of preparing and producing the campaigns is anticipated to cost approximately NZ$1.5 million in Year 1. Similar to Australia, there is a cost associated with maintaining and updating the campaign, which is estimated to be about 25% of the total New Zealand production costs, translating to NZ$0.38 million annually.

There are additional costs associated with running the campaign in each of the five years. The average cost of running such multi-faceted campaign was estimated to be NZ$1.5 million each year with an additional 20% for PR agency fee, totalling to NZ$1.8 million in each year.

Table 13 Costs of a public media campaign in New Zealand

Item	New Zealand (NZ$)					
	Unit cost	Source	No. of unit	Source	Modifier	Total cost
Cost in Year 1						
Preparing and producing a multi-faceted media campaign	$1.5 million for the whole campaign	Personal communication with ALAC	1	-	1	$1,500,000.00
Running media campaign: Print-out materials, TV campaign, radio campaign as well as PR agency time	$1,800,000	Personal communication with ALAC	1	-	1	$1,800,000.00
Total cost in Year 1						**$3,300,00.00**
Cost post Year 1 (ongoing)						
Running media campaign: Print-out materials, TV campaign, radio campaign as well as PR agency time	$1,800,000	Personal communication with ALAC	1	-	1	$1,800,000.00
Maintaining and updating the campaign	$375,000	Personal communication with ALAC	1	-	1	$375,000.00
Total cost in a subsequent year						**$2,175,000.00**
Total cost over 5 years, undiscounted						**$12,000,000.00**
Total cost over 5 years, discounted						**$11,288,947.28**

Abbreviations: ALAC = Alcohol Advisory Council of New Zealand; DHB = District Health Board; NZ= New Zealand; SNZ = Statistics New Zealand; TV = television

SCENARIO FIVE: EDUCATION SESSIONS FOR PREGNANT WOMEN IN AUSTRALIA

As shown in **Table 14**, the total cost of providing education sessions for pregnant women in Australia was estimated to be approximately AU$3.3 million in the first year with an annual ongoing cost of AU$3.2 million. Over five years, the total cost accumulated to AU$14.5 million (discounted). The total amount includes the cost of training health professionals, preparing pamphlets, printing pamphlets, distributing pamphlets, translation costs, and discussion time between the woman and her health professional.

In the first year, there are three one-off costs: training health professionals, preparing the pamphlet for women, and translating the pamphlets. The training of health professionals involves the provision of booklets to all health professionals who might be involved with the provision of prenatal care. In Australia, these are midwives, GPs, and specialists in obstetrics and gynaecology. It was estimated there are approximately 37,828 health professionals providing prenatal care in Australia: 24,122 are GPs, 12,000 are midwives, and 1,706 are specialists. These statistics were drawn from the health professional workforce reports by the Australian Institute of Health and Welfare (AIHW). Note that the ongoing costs associated with training the health professionals were not captured in the analysis as these incremental costs are likely to be relatively minimal. Should the governments however, decide to instigate an ongoing training programme for such professionals, the associated costs should be considered.

The per booklet cost of printing (AU$2.13) was derived from personal communications with experts at ICHR. This average cost was based on a print run of 1,500. It is anticipated that the cost per print will be reduced below AU$2.13 with increasing volume of prints. The analysis further assumes an additional 50% of this cost to account for the costs associated with distributing these booklets to health professionals. This assumption is not anticipated to have a significant impact on the results.

Since the information on the professional booklets is primarily drawn from the ICHR booklet, it was considered reasonable to assume that there would be minimal work involved in developing the booklets, and consequently this cost was not included in the analysis.

The second one-off cost in year 1 is the time required to prepare the template for the pamphlet for pregnant women. As the pamphlet will be aimed at pregnant women, the information in the pamphlets should be brief and in everyday language. It is assumed that the pamphlet would be two pages long, and that it would require 160 hours of a health communication expert's time to

develop the pamphlet. The pamphlets would then be distributed to all pregnant women on two occasions. The first distribution is assumed to occur when the pregnancy is confirmed (ie, during a GP visit) and the second distribution occurs during the first prenatal visit with the chosen health professional.

The third one-off cost in the first year is associated with translating the pamphlets into 8 languages. The translation cost per pamphlet (AU$497) was derived by multiplying a typical commercial translation rate of US$400 per 1,000 words by the exchange rate of US$0.805:AU$1 (obtained from Reserve Bank of Australia).

In each year, there are ongoing costs associated with printing the pamphlets (twice a year), distributing the pamphlets, and discussion time with a GP (approximately 5 minutes per woman). The cost associated with discussion with the GP reflects additional time (5 minutes) the GP has to spend addressing concerns around the danger of consuming alcohol during pregnancy. Such discussion is assumed to take place during the initial prenatal visit when pregnancy is confirmed. The number of pregnant women in Australia each year was derived from the average number of live births in Australia recorded between 1998 and 2008 with adjustments for multiple births and still births. The average number of pregnant women in Australia was estimated at 258,884 per year.

The unit cost of a GP consultation was obtained from the Medicare Benefits Schedule (MBS) item number 16500 (AU$40.45). A typical consultation of MBS item 16500 is assumed to be 30 minutes in duration. This MBS fee represents only the subsidised amount to the GP, rather than the full cost of a consultation, which include out-of-pocket part paid by individuals. The amount contributed by individuals varies greatly. For simplicity, the analysis assumes additional AU$15 per consultation. To finally derive the cost of additional 5 minutes discussion time with a GP, the total cost of a GP consultation (AU$50.45) was multiplied by one sixth.

Table 14 Costs of education sessions for pregnant women in Australia

Item	Australia (AU$)				
	Unit cost	Source	No. of unit	Source	Total cost
Cost in Year 1					
Providing booklets to healthcare professionals	$3.20 per booklet [a]	Personal communication with ICHR	37,282 health professionals [b]	AIHW	$119,227.84
Preparing pamphlets for pregnant women	$36.40 per hour [c]	ABS	160 hours	Assumption	$5,824.00
Translating pamphlets (cost per booklet)	$496.89 per language [d]	Commercial rate	8 languages	Assumption	$3,975.16
Printing pamphlets at the time of pregnancy confirmed	$0.4 per pamphlet [e]	Assumption	258,884 pamphlets	ABS	$207,107.31
Printing pamphlets at the time of first visit with LMC	$0.4 per pamphlet	Assumption	258,884 pamphlets	ABS	
Distributing pamphlets	$1.10 per pamphlet	Australia Post	517,768 pamphlets	ABS	$569,545.11
Discussion time with GP at time pregnancy confirmed	$9.24 (for 5 minutes) per woman [f]	MBS item 16500 + out-of-pocket expense of $15	259,884 number of pregnant women	ABS	$2,392,520.92
Total cost in Year 1					**$3,298,200.33**
Cost post Year 1 (ongoing)					
Printing pamphlets	*As above*				$207,107.31
Distributing pamphlets	*As above*				$569,545.11
Discussion time with GP at time pregnancy confirmed	*As above*				$2,392,520.92
Total cost in a subsequent year					**$3,169,173.34**
Total cost over 5 years, undiscounted					**$15,974,893.68**
Total cost over 5 years, discounted					**$14,535,932.13**

Abbreviations: ABS = Australian Bureau of Statistics; AIHW = Australian Institute of Health and Welfare; GP = general practitioner; LMC = Lead maternity Carer; MBS = Medicare Benefits Schedule

[a] $32.30 per booklet = $0.85 per page based on current commercial rate multiplied by 38 pages.

[b] A total of 37,282 health professionals include 12,000 midwives, 24,122 GPs, and 1,160 specialists in obstetrics and gynaecology.

[c] The average hourly earnings of $36.40 for the occupation group of professional was used as a proxy. The estimate was obtained from the Survey of Employee Earnings and Hours, the August 2008 quarter publication.

[d] The translation cost of $496.89 per language was derived from the commercial rate of US$400 per 1,000 words multiplied by the exchange rate of 0.805 as at 01/06/09 (Reserve Bank of Australia).

[e] $1.70 per booklet = $0.85 per page based on current commercial rate multiplied by 2 pages.

[f] $9.24 is a cost of 5 minutes discussion time with a GP, which was calculated as 5/30 * ($55.45 of 30 minutes of a GP consultation).

SCENARIO SIX: EDUCATION SESSIONS FOR PREGNANT WOMEN IN NEW ZEALAND

The total cost of providing education sessions for pregnant women in New Zealand was estimated to be approximately NZ$0.67 million in the first year and NZ$0.64 million annually in the subsequent years, as shown in **Table 15**. Over five years, the total cost accumulated to AU$3.0 million (discounted). The components of this scenario are identical to scenario five, with the following exceptions.

The number of health professionals involved in providing prenatal care is markedly lower in New Zealand compared with Australia. Based on the reports published by New Zealand Health Information Services (NZHIS), there are 3,222 GPs, 2,875 midwives, and 199 obstetricians in New Zealand, totalling 6,265 health professionals. The cost of printing per ICHR booklet for New Zealand was calculated by converting the Australian cost (AU$3.20) into New Zealand dollars using the exchange rate of 1.1025 (obtained from Reserve Bank of Australia).

The number of pregnant women in New Zealand is lower than in Australia, with 57,540 women pregnant each year. The annual number of pregnant women was derived from the average number of live births in New Zealand between 1993 and 2009. Adjustments were made for multiple births and still births.

Lastly, the average cost of a GP consultation of 30 minutes (NZ$50) was obtained from PHARMAC. Given that the analysis takes the societal perspective, the cost of a GP consultation must consistently include the government subsidy and patient contribution. Similar to the case of Australia, in deriving the cost of additional 5 minutes discussion time with a GP, the total cost of a GP consultation (NZ$50.00) was multiplied by one sixth.

Table 15 Costs of education sessions for pregnant women in New Zealand

Item	New Zealand (NZ$)				
	Unit cost	Source	No. of unit	Source	Total cost
Cost in Year 1					
Providing booklets to healthcare professionals	$3.52 per booklet [a]	Assumption	6,265 health professionals [b]	NZHIS	$22,068.38
Preparing pamphlets for pregnant women	$30.38 per hour [c]	SNZ	160 hours	Assumption	$4,860.80
Translating pamphlets (cost per booklet)	$627.55 per language [d]	Commercial rate	4 languages	Assumption	$2,510.20
Pamphlets at the time of pregnancy confirmed	$0.4 per pamphlet [e]	Assumption	57,540 pamphlets	SNZ	$46,031.58
Pamphlets at the time of first visit with LMC	$0.4 per pamphlet	Assumption	57,540 pamphlets	SNZ	
Distributing pamphlets	$1.00 per pamphlet	NZ Post	115,079 pamphlets	SNZ	$115,078.96
Discussion time with GP at time pregnancy confirmed	$8.33 (for 5 minutes) per woman [f]	PHARMAC	57,540 number of pregnant women	SNZ	$479,495.66
Total cost in Year 1					**$670,045.58**
Cost post Year 1 (ongoing)					
Cost of printing pamphlets	*As above*				$46,031.58
Distributing pamphlets	*As above*				$115,078.96
Discussion time with GP at time pregnancy confirmed	*As above*				$479,495.66
Total cost in a subsequent year					**$640,606.20**
Total cost over 5 years, undiscounted					**$3,232,470.39**
Total cost over 5 years, discounted					**$3,023,042.91**

Abbreviations: GP = general practitioner; LMC = lead maternal carer; MoH = Ministry of Health; NZHIS = New Zealand Health Information Services; SNZ = Statistics New Zealand

[a] $32.30 per booklet = $0.85 per page based on current commercial rate multiplied by 38 pages.

[b] A total of 6,265 health professionals include 2,875 midwives, 3,222 GPs, and 199 obstetricians.

[c] The average hourly earnings of $30.38 for the occupation group of professional was used as a proxy. The estimate was obtained from New Zealand Income Survey, the June 2009 quarter publication.

[d] The translation cost of $627.55 per language was derived from the commercial rate of US$400 per 1,000 words multiplied the exchange rate of 0.6374 as at 06/09 (Reserve Bank of New Zealand).

[e] $1.70 per booklet = $0.85 per page based on current commercial rate multiplied by 2 pages.

[f] $8.33 is a cost of 5 minutes discussion time with a GP, which was calculated as 5/30 * ($50.00 of 30 minutes of a GP consultation).

SCENARIO SEVEN: AN INPATIENT ALCOHOL PROGRAMME IN AUSTRALIA

It is estimated that the annual cost of providing an inpatient alcohol programme in Australia would be AU$22.54 million, assuming that all eligible women participate in the programme (shown in **Table 16)**. Over five years, the total cost would accumulate to AU$102.45 million (discounted). It is assumed that pregnant women identified as being at high risk (based on alcohol consumption) would be eligible for the intensive intervention. Based on Elliott *et al* 2008, it was assumed that 0.5% of pregnant women are high risk. This yields a total of 1,294 high-risk pregnant women in Australia.

The total cost of this programme consists of maintaining a residential care home, providing therapy, and supplying an onsite childcare service. The structure of the proposed intensive alcohol reduction programme for women at high risk was drawn from the descriptions in Whiteside-Mansell *et al* 1998.

The cost of a residential care facility is estimated at AU$150 per day per woman. This includes the basic cost of running the facility, the cost of a bed, and the costs associated with maintaining one full-time member of staff.

The admitted women are required to stay at the residential home five days a week from Monday to Friday for 15 weeks. Based on Whiteside-Mansell *et al* 1998, one residential care centre is assumed to accommodate up to 13 women. Given that 1,294 women are identified at high risk, each year approximately 100 residential homes would be required. The analysis assumes there are sufficient existing residential care facilities to accommodate all these high risk women. This is a significant assumption as there is no information to suggest that this many facilities are available in Australia. The cost of building additional centres has not been considered in this analysis.

There are also a number of health professionals involved in service delivery. These health professionals are assumed to be available on a casual basis (as contractors) including GPs, nurse practitioners, obstetricians, paediatricians, psychiatrists, psychologists and social workers. The model assumes that on average they are each required for 30 minutes per day per woman for five days a week, for the whole course of treatment. The total hours spent by a health professional is 40 hours in total per woman for 15 weeks.

The programme also provides an onsite childcare service for those women who might require it. It is assumed that three full-time childcare workers are available for the whole course of treatment. The analysis assumes there are on average six children cared for in each residential site.

Table 16 Costs of an inpatient alcohol programme in Australia

Item	Unit cost	Source	No. of unit	Modifier	Cost
Cost in Year 1					
8 hours a day, 5 days a week, 15 weeks onsite residential programme (13 women per site):					
Cost of running a residential care (per day)	$150 per day per woman	Assumption	75 day/women	1,294 women	$14,562,232.84
Multidisciplinary team of health professionals: On average, 30 min per health professional per day delivered to a group of 6 or 7 women					
GP (hourly rate)	$89.38	Preliminary result from MABEL report	40 hours/woman	1,294 women	
Nurse practitioner (hourly rate)	$34.80 [a]	ABS	40 hours/woman	1,294 women	
Obstetrician (hourly rate)	$104.57	HMA 2000 report on remuneration rates	40 hours/woman	1,294 women	
Paediatrician (hourly rate)	$104.57	HMA 2000 report on remuneration rates	40 hours/woman	1,294 women	
Psychiatrist (hourly rate)	$105.47	HMA 2000 report on remuneration rates	40 hours/woman	1,294 women	
Psychologist (hourly rate)	$34.80 [a]	ABS	40 hours/woman	1,294 women	
Social worker (hourly rate)	$21.10 [b]	ABS	40 hours/woman	1,294 women	
Subtotal					$3,940,595.77
Onsite childcare services: (3 childcare workers for 15 weeks):					
3 x trained childcare worker (hourly rate)	$22.50 [c]	ABS	600 hours/site/worker	100 sites & 3 workers	$4,032,618.32
Total cost in Year 1					$22,535,446.92
Cost post Year 1 (ongoing)	**As above**				$22,535,446.92
Total cost over 5 years, undiscounted					**$112,677,234.62**
Total cost over 5 years, discounted					**$102,445,026.31**

Abbreviations: ABS = Australian Bureau of Statistics; GP = General practitioner; HMA = Healthcare Management Advisors; MABEL = Medicine in Australia: Balancing Employment and Life

[a] The average hourly earnings of $34.80 for the occupation group of other healthcare services was used as a proxy. The estimate was obtained from the Survey of Employee Earnings and Hours, the August 2008 quarter publication.

[b] The average hourly earnings of $21.10 for the occupation group of social assistance services was used as a proxy. The estimate was obtained from the Survey of Employee Earnings and Hours, the August 2008 quarter publication.

[b] The average hourly earnings of $22.50 for the occupation group of childcare services was used as a proxy. The estimate was obtained from the Survey of Employee Earnings and Hours, the August 2008 quarter publication.

SCENARIO EIGHT: AN INPATIENT ALCOHOL PROGRAMME IN NEW ZEALAND

It is estimated that the annual cost of an inpatient alcohol programme in New Zealand would be NZ$4.32 million if all eligible women participated in the programme, see **Table 17**. Over five years, the cost would accumulate to approximately NZ$20.20 million (discounted). It is assumed that all pregnant women identified as being at high risk of delivering a child with FASD would be eligible for the intensive intervention. As for the Australian scenario, it is assumed that 0.5% of all pregnant women would be at high risk. This equates to 288 pregnant women in New Zealand.

As for the Australian economic analysis, the structure of the programme for women at high risk was drawn from the descriptions in Whiteside-Mansell *et al* (1998) with the details described earlier in scenario seven.

Table 17 Costs of an inpatient alcohol programme in New Zealand

Item	Unit cost	Source	No. of unit	Modifier	Cost
Cost in Year 1					
8 hours a day, 5 days a week, 15 weeks onsite residential programme (13 women per site):					
Cost of running a residential care (per day)	$120 per day per woman	Assumption	75 days/women	288 women	$2,589,276.57
Multidisciplinary team of health professionals: On average, 30 min per health professional per day delivered to a group of 6 or 7 women					
GP (hourly rate)	$50.00	PHARMAC	40 hours/woman	288 women	
Nurse practitioner (hourly rate)	$22.40 [a]	Campbell *et al* 2008	40 hours/woman	288 women	
Obstetrician (hourly rate)	$83.58 [b]	MECA [c]	40 hours/woman	288 women	
Paediatrician (hourly rate)	$83.58	MECA	40 hours/woman	288 women	
Psychiatrist (hourly rate)	$83.58	MECA	40 hours/woman	288 women	
Psychologist (hourly rate)	$40.00	Campbell *et al* 2008	40 hours/woman	288 women	
Social worker (hourly rate)	$26.20	SNZ [d]	40 hours/woman	288 women	
Cost of health professionals					$689,293.13
Onsite childcare services: (3 childcare workers for 15 weeks):					
3 x trained childcare worker (hourly rate)	$26.20	SNZ	600 hours/site/worker	23 sites & 3 workers	$1,043,677.63
Total cost in Year 1					$4,322,247.33
Cost post Year 2	***As above***				*$4,322,247.33*
Total cost over 5 years, undiscounted					**$21,611,236.66**
Total cost over 5 years, discounted					**$20,198,204.14**

Abbreviations: MoH = Ministry of Health; MECA = Multi Employer Collective Agreement; GP = General practitioner; SNZ = Statistics New Zealand

[a] Registered nurse rate as a proxy.

[b] Hourly rate is calculated by dividing annual salary by number of working weeks (46) and number of working hour per week (40).

[c] Step 8 salary (median step) is applied in the model.

[d] The average hourly earnings of $26.20 for the industry of healthcare and social assistance was used as a proxy. The estimate was obtained from Quarterly Employment Survey, the September 2009 quarter publication.

Potential costs averted by preventing or downgrading cases of FASD

This section presents estimates on the potential costs avoided (ie cost-offsets) from (1) complete prevention of an FASD case and (2) downgrading the severity of the disability. The cost of managing and caring for individuals with FASD was obtained from Stade *et al* 2009. The results of Stade *et al* 2009 are discussed here.

COSTS AVERTED BY PREVENTING A CASE OF FASD

Stade *et al* 2009 estimated the average annual cost of FASD per individual with FASD, valued in 2007 prices. Their analysis was based on a sample of 250 individuals diagnosed with FASD aged between 0 and 53 years in Canada. The overall adjusted annual societal costs was estimated at CAU$21,642 per individual with FASD. The annual cost per individual peaked at CAU$30,222 during the first two years after birth, and then decreased slightly over the next three years before rising to CAU$28,666 in the 7-12 age group. The annual cost rapidly decreased to CAU$14,810 in the 46 - 53 age group. The high cost in young children largely reflects significant medical care and social service needs (see **Table 18**).

Table 18 Adjusted annual cost of FASD per individual with FASD by age range from Stade *et al* 2009 (CAU$)

Ref	Age range (years)	Number of individuals with FASD	Mean annual cost CAU$ (95% CI)
A	0 – 2	20	$30,222 ($26,302, $38,222)
B	3 – 6	36	$26,544 ($23,666, $30,328)
C	7 – 12	60	$28,666 ($25,446, $32,832)
D	13 – 17	48	$20,201 ($16,997, $24,885)
E	18 – 21	36	$16,544 ($14,888, $18,234)
F	22 – 25	18	$16,232 ($14,666, $18,002)
G	26 – 35	12	$15,998 ($14,021, $18,112)
H	36 – 45	10	$14,689 ($12,888, $16,681)
I	46 – 53	10	$14,810 ($12,664, $16,988)
J	**Overall**	**250**	**$21,642 ($19,842, $24,041)**

Abbreviations: CA = Canadian; CI= confidence interval; FASD = Fetal Alcohol Spectrum Disorder

The total costs of FASD include direct medical care, direct non-medical care, and productivity loss. The largest proportion of the total costs (33%) are medical, as shown in **Table 19**. The direct costs of educational activities such as special schooling and residential programmes also contributed substantially (26%) to the annual cost. Social services such as legal aid, and foster care contributed 20% to the total costs. Losses in productivity comprised 7%. Note that the

analysis captured productivity loss by measuring parents' lost work time due to caring for their disabled child. The productivity loss from the disabled children was not captured. After removing productivity loss, a large proportion (75%) of the annual direct costs was paid for by the government. This information provides an insight as to how the burden of FASD is shared, and who would benefit from avoiding the burden.

Table 19 Distribution of per individual cost of FASD from Stade *et al* 2009

Ref	Item	Proportion of cost of FASD per individual with FASD
A	Total cost of FASD	100%
	Total cost ascribable to	
B	Healthcare	33%
C	Education activities	26%
D	Social services	20%
E	Out-of-pocket	14%
F	Productivity loss	7%
	Total direct cost (total cost excluding productivity loss) ascribable to	
G	Government sector	75%
H	Patients and families	25%

Abbreviations: FASD = Fetal Alcohol Spectrum Disorder

In addition to the age of the individual with FASD, the other two key determinants of the average adjusted annual cost were the severity of FASD, and the relationship between caretakers and the individual with FASD.

The annual costs increased with the level of severity, as shown in **Table 20**. The annual cost for a mildly disabled individual was CAU$10,009. This increased to CAU$17,345 for a moderately disabled individual and CAU$31,234 for a severely disabled individual. As anticipated, an individual with more severe physical and mental conditions required more medical attention and more specialised educational services, hence resulting in a greater cost to society.

Table 20 Adjusted annual cost of FASD per individual with FASD by severity

Disease severity	n	Mean cost CAU$ (95% CI)
Mild	122	$10,009 ($5,445, $15,221)
Moderate	84	$17,345 ($15,012, $19,432)
Severe	44	$31,234 ($22,341, $40,368)
Overall	250	$21,642 ($19,842, $24,041)

Stade *et al* 2009 reported that the average cost was dependent upon the relationship between caretakers and individual with FASD. Costs were lowest if an individual with FASD was in the

care of biological parents, estimated to be approximately CAU$8,800 annually[f]. If the individual with FASD was being looked after by foster or adoptive parents, it was estimated to cost approximately CAU$16,355 or CAU$10,886 per individual with FASD respectively.

The costs reported in Stade's 2009 paper are considered conservative. Their analysis excludes the burden that individuals with FASD place on the legal or criminal justice system. Youth with FASD have been linked to criminal behaviour (Alcohol Healthwatch, 2007) and Fast *et al* 1999 found that 23% of all youth remanded to a forensic psychiatric inpatient assessment unit were diagnosed with FAS or FAE. The literature search did not identify any well-documented reports of the costs associated with these behaviours.

Given the scenarios were costed for the first five years of analysis and taken from the societal perspective, the averted cost of FASD must be consistent with this time interval and perspective. The average annual cost of FASD from this perspective during the first five years was calculated using the data presented in **Table 18** and **Table 19**. The calculation is a two-step process as shown in **Table 21**. The final annual cost of FASD to society was estimated to be approximately AU$32,584 and NZ$35,267 per child during the first five years of analysis for Australia and New Zealand respectively (See Row H and I of **Table 21**). Firstly the cost was calculated by averaging the costs for the 0-2 and 3-6 age ranges, then weighting these by the number of children with FASD (Row A of **Table 21**). Given the perspective of interest is societal, consistent with the Stade *et al* (2009), no further adjustment was therefore required. That is 100% of the cost was applied in the analysis (Row B of **Table 21**). Then the estimate was converted to Australian or New Zealand dollars (Row D and E of **Table 21**) before inflating them to 2009 prices (Row F and G of **Table 21**) using appropriate healthcare Consumer Price Indices (CPI).

[f] There appears to be a typographical mistake in the mean cost estimate for an individual with FASD raised by biological parents in Stade *et al* (2009;see Table 7). The table states the mean cost of $8,8225. Based on our back-calculation using the estimate of the 95% confidence interval, the actual estimate should be approximately CAU$8,800. This has no material impact on the current analysis as this cost estimate was not used.

Table 21 Adjusted annual cost of FASD per individual with FASD for Australia and New Zealand based Stade *et al* 2009

Ref	Description	Cost of FASD	Note
A	Total adjusted annual cost of FASD, per child	CAU$30,222 * (20/56) + CAU$26,544 * (36/56) = CAU$27,858	See Row A and B of **Table 18**
	Out of the total cost estimated by Stade *et al* 2009:		
B	Proportion to the perspective of interest (societal perspective)	100%	See Row A of **Table 19**
C	Total cost of FASD to society	CAU$27,858	Row A * Row B
D	Exchange rate CAU$: AU$	0.8977	Sourced from RBA
E	Exchange rate CAU$: NZ	0.8057	Sourced RBNZ
F	Healthcare inflation: Australia	5%	Sourced from ABS
G	Healthcare inflation: New Zealand	2%	Sourced from SNZ
H	**Total annual cost of FASD for Australia, per child**	**AU$32,584**	**(Row C / Row D) * (1 + Row F)**
I	**Total annual cost of FASD for New Zealand, per child**	**NZ$35,267**	**(Row C / Row E) * (1 + Row G)**

Abbreviations: ABS = Australian Bureau of Statistics; CA= Canadian; FASD = Fetal Alcohol Spectrum Disorder; NZ = New Zealand; RBA = Reserve Bank of Australia; RBNZ = Reserve Bank of New Zealand

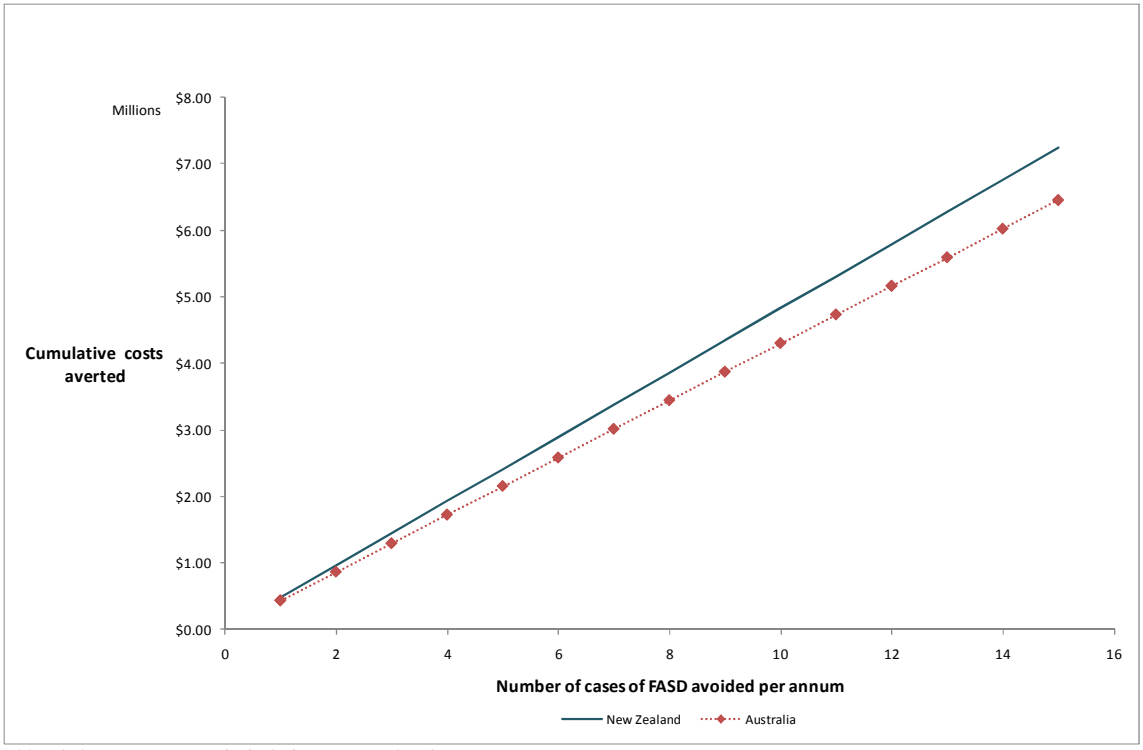
The estimates imply that if a prevention scenario avoids a single new case of FASD each year, the government would avert a cost of AU$32,584 in the first year for Australia and NZ$35,267 for New Zealand. If the scenario continues for a second year, the accumulated costs averted (discounted) would be AU$94,648 and NZ$103,416 in total - that is a two-year saving from a child without FASD plus a one-year saving from a new case avoided in the second year. After five years, the accumulated cost averted would be AU$429,934 and NZ$483,085 from avoiding a single new case of FASD each year. If the scenario continues for five years and prevents ten new cases per year, it was estimated that costs of AU$4.3 million and NZ$4.8 million would be averted. **Figure 5** presents the accumulated costs averted from preventing cases of FASD for five consecutive years (not including the actual costs incurred from implementing the different prevention scenarios). A detailed example of the calculation of the accumulated averted cost for Australia for the first three years is tabulated in **Table 22**. By applying the sequence explained in **Table 22**, one could calculate the accumulated cost over 5 years.

Table 22 Example calculation of the accumulated cost averted from avoiding FASD cases

Ref	Calculation step	Cost averted from avoiding 1 case	Cost averted from avoiding 10 cases	Note
A	Year 1 – Base year	$32,584 * 1 case =$32,584	$32,584 * 10 cases = $0.33 million	$32,584 was taken from Row H of **Table 21**
B	Year 2 – Undiscounted	($32,584 * 1 case from Year 1) + ($32,584 * a new case in Year 2) = $65,168	($32,584 * 10 case from Year 1) + ($32,584 * 10 new case in Year 2) = $0.65 million	$32,584 was taken from Row H of **Table 21**
C	Year 2 – Discounted	$65,168 / (1+5%)^(1) = $62,064	$0.6 million / (1+5%)^(1) = $0.62 million	Cost in Year 2 / (1+discount rate)^(# of years since Year 1)
D	Accumulated cost over the first 2 years	$32,584 + $62,064 = $94,648	$0.33 million + $0.62 million = $0.95 million	Row A + C
E	Year 3 – Undiscounted	($32,584 * 1 case from Year 1) + ($32,584 * 1 case from Year 2) + ($32,584 * a new case in Year 3) = $97,751	($32,584 * 10 cases from Year 1) + ($32,584 * 10 cases from Year 2) + ($32,584 * 10 new cases in Year 3) = $0.98 million	$32,584 was taken from Row H of **Table 21**
F	Year 3 – Discounted	$97,751 / (1+5%)^(2) = $88,663	$0.98 million / (1+5%)^(2) = $0.89 million	$X / (1+discount rate)^(# of years since Year 1)
G	Accumulated cost over the first 3 years	$183,311	$1.84 million	Row A + C + F

Abbreviations: FASD = Fetal Alcohol Spectrum Disorder

Figure 5 Accumulated costs averted by preventing cases of FASD per year, over a 5-year time horizon



Abbreviations: FASD= Fetal Alcohol Spectrum Disorder

COSTS AVERTED BY DOWNGRADING A CASE OF FASD

Stade *et al* 2009 reported that the cost of FASD was dependent upon the severity of the disability. Specifically, a severely-disabled individual (eg, one with severe FAS) created the most significant financial burden, estimated at CAU$31,234 per individual per annum. This is materially higher than a moderately or mildly-disabled individual with costs of CAU$17,345 and CAU$10,009 respectively.

Based on the same method outlined in **Table 21** (Also see **Table 22**), the cost of FASD by severity was derived and inflated to 2009 Australia and New Zealand prices with the results presented in **Table 23**.

Table 23 Adjusted annual cost of FASD per individual with FASD by severity of disability for New Zealand and Australia based on Stade *et al* 2009

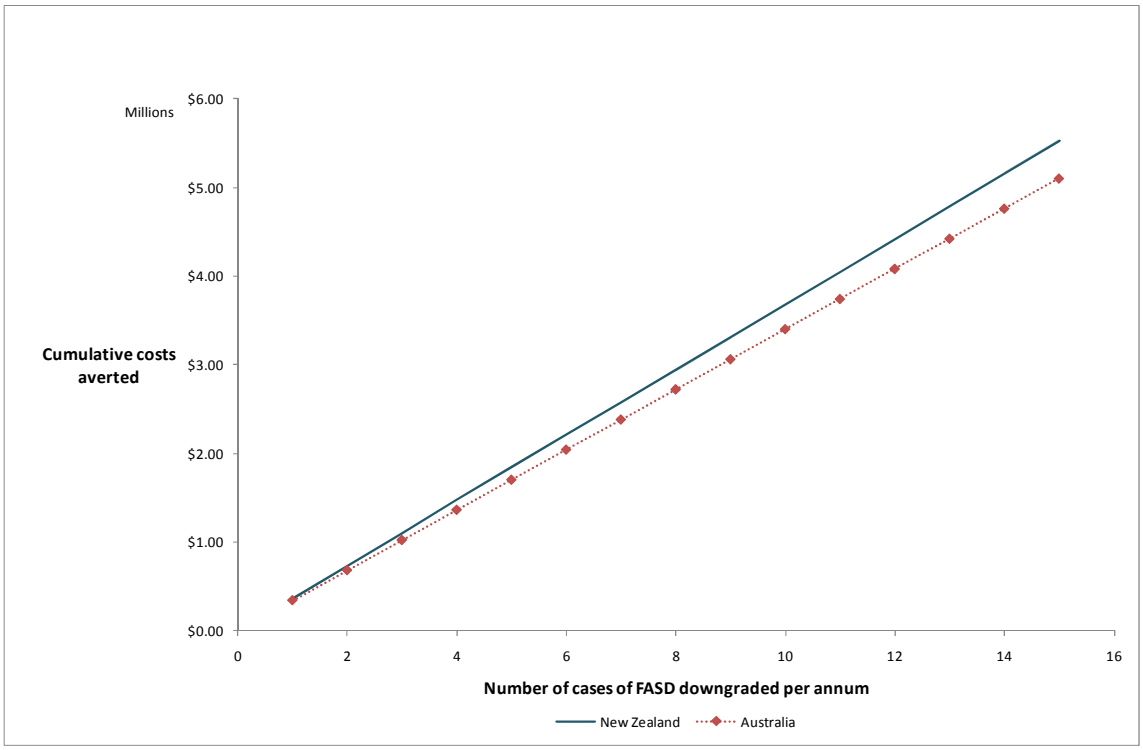
Disease severity	Number of individuals with FASD	Mean cost	
		Australia	New Zealand
Mild	122	$11,707.08	$12,671.19
Moderate	84	$20,287.68	$21,958.42
Severe	44	$36,533.03	$39,541.62

Abbreviations: CI = confidence interval; FASD= Fetal Alcohol Spectrum Disorder

This implies that if a prevention scenario downgrades one case of FASD from severe to mild, there would be an averted annual cost of AU$24,826 ($36,533 - $11,707) for Australia or NZ$26,870 ($39,541 - $12,671) for New Zealand. If one severe case is downgraded to mild each year, over five years the total averted cost would accumulate to $AU0.33 and $NZ0.37 million for Australia and New Zealand respectively. **Figure 6** presents the accumulated costs averted from downgrading severe cases to mild cases per year, over a 5-year time horizon.

A multi-step analysis considering the proportion of subjects who changed from severe-moderate, moderate-mild and mild-none was not undertaken due to the difficulty in estimating these proportions based on the limited evidence available.

Figure 6 Cumulative costs averted from downgrading cases of FASD from severe to mild per year, over a 5-year time horizon



Abbreviations: FASD= Fetal Alcohol Spectrum Disorder

Possible effectiveness of different prevention strategies

As discussed above, the true effectiveness of the considered prevention scenarios on FASD incidence is unknown. The systematic literature review found no evidence which directly linked any intervention with a reduction in the number of cases of FASD. It is well recognised that the amount of alcohol consumed is positively related to the severity of FASD. It is, however, postulated that prevention scenarios one to six could reduce the number of individuals with FASD given that they have been shown to reduce the amount of alcohol consumed by pregnant women.

By contrast, scenarios seven and eight, which are inpatient alcohol programmes, are more sensibly postulated to reduce the level of severity of FASD. Pregnant women who are identified as high risk due to their excessive alcohol consumption are likely to have already consumed significant levels of alcohol during the early stages of their pregnancy. Even the most effective programme can not reverse damage which occurs prior to its implementation. For this reason, the outcome of scenarios seven and eight are most conservatively expressed in terms of FASD cases downgraded. Given that Stade *et al* 2009 reports costs by FASD severity (severe, moderate and mild), our estimates of effectiveness assume a 'best case' of downgrading from severe to mild, and a 'worst case' of downgrading from severe to moderate.

CASES OF FASD AVOIDED OR DOWNGRADED

Estimating effectiveness

Table 30 presents the plausible range of percentage of FASD cases avoided and the number of FASD cases avoided utilised in this economic model. Note that the percentages for the inpatient alcohol programmes for Australia and New Zealand (scenarios seven and eight) represent the percentage of FASD cases downgraded. In attempting to quantify the number of FASD cases avoided or downgraded, it is assumed that proportional reductions in alcohol consumption during pregnancy are associated with the same proportional reduction in FASD cases. This is considered to be a reasonable assumption as any changes in alcohol intake prior to pregnancy will have an immediate effect on FASD risk.

The reductions in alcohol consumption associated with each prevention strategy were derived from the available evidence shown in the systematic review of Elliott *et al* 2008. The range of effectiveness with regard to FASD explored in this economic analysis is based on plausible lower and upper limits of effectiveness from the literature.

Table 24 Range of effectiveness considered in the economic analysis

No.	Scenario	% effectiveness		Source
		Lower estimate	Upper estimate	
1	Alcohol warning labels in Australia	1%	3%	Hankin 1993a,b and 1996
2	Alcohol warning labels in New Zealand	1%	3%	Hankin 1993a,b and 1996
3	A public media campaign in Australia	1%	3%	Olsen 1989
4	A public media campaign in New Zealand	1%	3%	Olsen 1989
5	Education sessions for pregnant women in Australia	19%	29%	Reynolds 1995 and O'Conner & Whaley 2007
6	Education sessions for pregnant women in New Zealand	19%	29%	Reynolds 1995 and O'Conner & Whaley 2007
7	An inpatient alcohol programme in Australia	-	20% [a]	Whiteside-Mansell 1998
8	An inpatient alcohol programme in New Zealand	-	20% [a]	Whiteside-Mansell 1998

Abbreviation: FASD = Fetal Alcohol Spectrum Disorder

[a] The review found no evidence that an inpatient alcohol programme can prevent any case of FASD. The study, however, found the evidence that there were significantly less pregnant women in the programme that consumed alcohol at delivery when compared with women not participating in the programme. For this reason, the analysis hypothesised that the programme would result in a reduction in severity of FASD, rather than preventing cases of FASD. The effectiveness of these scenarios is, therefore, expressed in terms of cases of FASD downgraded.

Alcohol warning labels

The literature search identified one study which evaluated the alcohol consumption in pregnant women prior to, and after, the introduction of mandatory alcohol warning labels in the USA (reported in three separate publications, Hankin 1993a,b and 1996). The first significant increase in knowledge of the warning labels occurred in June 1990, therefore the studies compared drinking behaviour prior to and after this date. The results are summarised in **Table 25**. Hankin 1993a,b reported that there was no significant change in mean alcohol consumption during conception or pregnancy after the introduction of a compulsory alcohol warning label in the United States. The proportion of women who drank less than 0.5 ounces of alcohol per day during pregnancy did not change significantly (17.5% prior to the introduction of the warning label vs 16.4% after the introduction of the warning label; ie a reduction of 1.1%). A similar proportion of women reported drinking at least 0.5 ounces of alcohol during pregnancy prior to the introduction of the warning label (2.2%) when compared with after the introduction of the warning label (1.9%). Drinking at the time of the first prenatal visit did not correlate with awareness of the warning label. Hankin 1993a reported the change in antenatal drinking score, which was calculated using an OLS regression. It is unclear how the antenatal drinking score correlated with alcohol consumption. The authors noted that light drinkers decreased their drinking score by 0.68, which equivalent to about 1 ounce of beer/week. They noted that this small decrease would not be expected to make a difference to pregnancy outcomes as they were drinking below risk levels at the time of conception. No change in drinking behaviour was found

in risk drinkers. In Hankin 1993b, seeking prenatal care after the label was introduced correlated with a reduction in drinking behaviour in light drinkers ($p<0.009$), but not in heavy drinkers. However the effective reduction in alcohol consumption was modest. A 1% increase in the probability of a light drinker being aware of a warning label resulted in an average decrease of 0.03 ounces of alcohol consumed each week.

Hankin 1996 also found that there was no overall change in alcohol consumption during pregnancy after the introduction of the alcohol warning label. However, a significant decline in drinking during pregnancy was observed in nulliparae women ($p<0.04$) but not in multiparae women. Nulliparae consumed less alcohol than multiparae around the time of conception (1.19 vs 2.38 ounces of alcohol per week) and at their first prenatal visit (0.14 vs 0.42 ounces of alcohol per week). The authors stated that this could be a result of the difficulty in overcoming alcohol addiction, the belief that their fetus is invulnerable due to prior experience, impulsive behaviour or enjoying taking risks. Although a significant decline in alcohol consumption was reported, the paper does not state the magnitude of the decline. It is therefore difficult to evaluate the clinical relevance of this finding.

Table 25 Results from Hankin 1993a,b; 1996

Outcome	Pre intervention	Post intervention	Statistics
Hankin 1993a,b			
Mean alcohol consumed at conception (ounces of absolute alcohol/day)	0.281	0.272	NR
Mean alcohol consumed during pregnancy (ounces of absolute alcohol/day)	0.047	0.048	NR
Proportion of women who abstained during pregnancy	80.4%	81.7%	NR
Proportion of women who drank less than 0.5 ounces of alcohol/day during pregnancy (light drinkers)	17.5%	16.4%	NR
Proportion of women who drank at least 0.5 ounces of alcohol/day during pregnancy (risk drinkers)	2.2%	1.9%	NR
Predicting in-pregnancy drinking	Drinking at the time of the first prenatal visit did not correlate with post-label time period or awareness of the warning label.		
Simple time series analysis	There was no difference in alcohol consumption pre and post label		
Effect of warning label by light drinkers/abstainers and risk drinkers	Hankin 1993b There was a significant increase in drinking at the end of the year and during the summer months in both non risk and risk drinkers There was an overall decrease of 0.28 in the monthly mean of the antenatal drinking score. Light drinkers had a decrease in antenatal drinking score of 0.68. There was no change in alcohol intake in risk drinkers. Hankin 1993b Awareness of the warning label did not correlate with drinking behaviour in either group. Seeking prenatal care after 1990 correlated with a reduction in drinking behaviour in light drinkers ($p<0.009$) but not risk drinkers. A 1% increase in the probability of a light drinker attending the antenatal clinic after June 1990 resulted in a 0.144% decrease in the amount of alcohol consumed during pregnancy (equivalent to an average decrease of 0.03 ounces per week). A 1% increase in the probability of a risk drinker attending the antenatal clinic after June 1990 resulted in a 0.007% decrease in the amount of alcohol consumed during pregnancy (equivalent to an average decrease of 0.05 ounces per week).		
Hankin 1996			
Simple time series analysis of antenatal drinking	There was no change in alcohol consumption during pregnancy after the introduction of the alcohol warning label.		
OLS regression using periconceptional drinking as a control variable	Nulliparae: antenatal drinking score decreased in June 1990 ($T=2.00$, 82 df, $p<0.04$) Multiparae: antenatal drinking scores did not change (possibility of seasonal changes e.g. increased at the end of each year and during summer)		

Abbreviations: NR=not reported

Based on this evidence, it was concluded that the plausible range of effectiveness for this strategy was a 1-3% reduction in the number of FASD cases. The Hankin publications reported that there was small reduction in alcohol consumption in some groups of women (ie, 1.1%), and it is possible that this reduction may be greater in Australia and New Zealand if the mandatory warning labels were optimised for local conditions. It is plausible that mandatory alcohol labelling could reduce up to 3% of FASD cases, akin to what was observed with the introduction of

explicit graphic warnings on cigarette packages[g].In the case of smoking warning labels, tobacco consumption was reduced by a mean of 3%. The current analysis recognises the very limited generalisability of the tobacco study to the case of alcohol. The reader should bear in mind that the upper limit of effectiveness of 3% is indicative only.

Public media campaigns

The literature search identified one publication which evaluated a public media campaign. The study by Olsen 1989 reported on the effect of a broad, multi-faceted health campaign run in the town of Odense in Denmark between 1985 and 1987. The campaign, "Health Habits for Two" aimed to reduce drinking and smoking during pregnancy and improve healthy eating habits. Both primary and secondary prevention strategies were used in the programme. These included education campaigns for midwives and GPs and brochures about smoking and drinking (which included a cookbook) which were offered to all pregnant women in Odense and were available to the public in a number of outlets (including public offices, libraries, hospitals etc). A television programme featured the recipes in the cookbook and the campaign logo was shown in cinemas and newspapers, and stickers were placed in public areas. Media outlets (newspapers and local radio) ran information about the campaign. The change in alcohol consumption during pregnancy in Odense was compared with any changes observed in the control town of Aalborg. The study was considered to be of fair methodological quality. More than 95% of all pregnant women in both towns were enrolled in the study.

As shown in **Table 26** , there was no change in the percentage of pregnant women who reported any alcohol consumption or consumed more than 8 drinks on any occasion during pregnancy. The average alcohol consumption in the intervention town was 1.9 drinks/week at baseline and 1.8 drinks/week during the campaign. No statistical analysis of the results was included in the publication, although the authors stated that there was no change in drinking habits.

[g] Commonwealth Department of Health and Ageing's (2003) Cost-Benefit Analyses of Proposed New Health Warning on Tobacco Products

Table 26 Results from Olsen 1989

Outcome	Intervention group	Control group	Statistics
Percentage of pregnant women who did not drink	Baseline: 18% Year 1: 16% Year 2: 18%	Baseline: 20% Year 1: 19% Year 2: 20%	NR
Average alcohol consumption during pregnancy (drinks/week)	Baseline: 1.9 Year 1: 1.8 Year 2: 1.8	Baseline: 1.4 Year 1: 1.5 Year 2: 1.5	NR
Drinking 8 or more drinks on a given occasion during pregnancy	Baseline: <20% Year 1: 18% Year 2: 19%	Baseline: <20% Year 1: 19% Year 2: 18%	NR

Abbreviations: NR=not reported

Based on this evidence, it was concluded that the plausible range of effectiveness for this strategy was a 1-5% reduction in the number of FASD cases. Olsen 1989 did not find that women exposed to the public media campaign significantly reduced their alcohol consumption compared to a control group. However, they did have a small reduction in alcohol consumption (from a mean of 1.9 drinks in the first year to 1.8 drinks in the second and third years), and it is plausible that a campaign specifically tailored to Australia and New Zealand could reduce up to 5% of FASD cases.

Education sessions for pregnant women

The literature search identified two publications which reported that education sessions for pregnant women were effective at reducing alcohol consumption (Reynolds 1995 and O'Conner & Whaley 2007). It should be noted that some publications did not find an effect, although all publications evaluated slightly different interventions (eg different form of education, timing, intensity) and it is therefore difficult to evaluate the body of evidence as a whole.

In the Reynolds 1995 study, pregnant women were eligible for the trial if they had consumed any alcohol during pregnancy. The intervention was a 10 minute educational session which included information about the effects of alcohol consumption during pregnancy. Women received a nine-step, self-help manual which was completed at home over nine days. The manual contained information on FAS, identification of drinking patterns, using social support, self-monitoring and self-reward to help in quitting, resisting pressure to drink, coping with stress and maintaining abstinence. Women in the control arm received standard care, which included information on the effects of alcohol and pregnancy. A follow-up assessment was completed 2 months after the intervention. Alcohol consumption was assessed with a questionnaire which was developed and validated by the authors. The study was of considered to be of poor methodological quality.

As shown in **Table 27**, women randomised to the intervention group in Reynolds 1995 were significantly more likely to quit drinking when compared with women in the control group (88%

vs 69%, p<0.058). Women who 'drank <7 drinks' at study entry were significantly more likely to quit drinking if they received the intervention (100% in the treatment arm vs 71% in the control arm, p<0.01). The publication does not state if this outcome was <7 drinks per day, week or month. There was no significant difference in the proportion of women who drank >7 drinks at study entry and quit drinking (73% in the intervention arm vs 68% in the control arm). The treatment effect was stronger among light to moderate drinkers (<8 drinks per month), African-Americans and non-Protestants. The treatment effect was significant in women with an annual family income greater than $5000, teenage women and women not recruited on their first clinic visit.

Table 27 Results from Reynolds 1995

Outcome	Intervention group	Control group	Statistics
Women who quit drinking	88%	69%	P=0.06
Women who drank <7 drinks at study entry and who quit drinking at follow-up	100%	71%	p<0.01
Women who drank >7 drinks at study entry and who quit drinking at follow-up	73%	68%	p>0.05
Logistic regression	Participation in the self-help intervention increased the likelihood that a women would quit drinking ($\chi 2=4.62$, p<0.03).		
Other outcomes	The treatment effect was stronger among light to moderate drinkers (<8 drinks per month), African-Americans and non-Protestants. The treatment effect was significant in women with an annual family income greater than $5000, teenage women and women not recruited on their first clinic visit.		

Women enrolled in O'Conner & Whaley 2007 were allocated to an intervention or control arm based on the site at which they received prenatal care. Pregnant women who reported drinking after conception were included in the study. The intervention consisted of a workbook-driven brief intervention. The workbook consisted of traditional brief intervention techniques, including education and feedback, cognitive behavioural procedures, goal setting, and contracting. The publication does not clearly state what information was given about drinking during pregnancy. Women were screened at every monthly prenatal visit and provided with the brief intervention again if they were still drinking. Subjects in the control arm were advised to stop drinking during pregnancy. Alcohol consumption was assessed using multiple questionnaires, including the TWEAK and the Health Interview for Women. This study was considered to be of fair methodological quality.

O'Conner & Whaley 2007 reported that women who received the intervention were five times more likely to be abstinent by the third trimester compared with women in the control group (odds ratio (OR)=5.39; 95% CI 1.59, 18.25, p<0.05; **Table 28**).

Table 28 Results for O'Conner & Whaley, 2007

Outcome	OR
Abstinence rate by the third trimester	OR=5.39; 95% CI 1.59, 18.25, p<0.05

Abbreviations: CI = confidence interval; OR = odds ratio.

It was difficult to derive an estimate of the effectiveness of the intervention described in O'Conner & Whaley as the results were presented as an odds ratio. The range of plausible effectiveness was therefore assumed to be 19-29% based on the evidence from Reynolds 1995. Overall, 19% more women in the intervention group quit drinking when compared with the control group (88% vs 69%). This was then assumed to be the lower limit of effectiveness. The upper limit of effectiveness (29%) was taken from the difference in drinking rates in the subgroup of women who consumed more than seven drinks at study entry (73% vs 68%). This is an appropriate upper estimate as interventions are generally more effective in low vs high risk drinkers.

Inpatient alcohol programme

The literature search identified one publication which evaluated an inpatient alcohol programme. Whiteside-Mansell 1998 describes an assessment of an evolving alcohol and drug prevention and treatment programme for women and children in Little Rock, Arkansas. Although there was no specific inclusion criteria listed, the included women were referred to the alcohol and drug prevention programme and are therefore assumed to have been abusing drugs and/or alcohol at study entry. Over a five-year period the programme evolved from a 4-5 hour per day, 5 day per week outpatient service to a 7-8 hour per day, 5 days per week, onsite residential support service programme. As much as possible, the programme was to be a "one stop shopping" model implemented by a multidisciplinary team and guided by an individualized treatment plan. Biweekly group sessions were to be held with the mother's family member of choice regarding recovery issues for pregnant and parenting women and focusing on issues ranging from communication skills to the 12-step recovery programme. As the programme developed a number of additional services were provided, including residential facilities, mental health counselling, child care, early intervention for children, and transportation. Women who elected to participate in the programme made up the intervention group, while women who refused to participate in the service made up the control group. Due to significant concerns regarding selection bias, the study was considered to be of poor methodological quality.

The results of the study are summarised in **Table 29**. Significantly fewer pregnant women participating in the programme consumed alcohol at delivery when compared with women not participating in the programme (4.0% vs 33.3%, $p<0.05$). Both groups had a significant reduction in alcohol consumption from study entry to delivery (83.6% to 4.0% in the intervention arm and 90.5% to 33.3% in the control arm. $p<0.05$ in both arms). It is unclear if the assessment of alcohol use at delivery includes all 95 included women, or only the 37 women who were noted as providing delivery assessments. It should be noted that obstetric/neonatal complications and maternal and infant health marker outcomes were also reported; however, due to the small proportion of women supplying follow-up data this has not been presented here.

Table 29 Tertiary prevention: Results from non-randomised, experimental trials (Whiteside-Mansell, 1998)

Outcome	Intervention group	Control group	Statistics
Alcohol use at intake	83.6%	90.5%	NS
Alcohol use at delivery	4.0%	33.3%	p<0.05
Statistics	p<0.05	p<0.05	

Abbreviations: NS=not significant

As noted elsewhere, it was conservatively assumed that an inpatient alcohol programme for high risk women would not prevent any cases of FASD as women would have already consumed significant levels of alcohol prior to commencing any intervention. It was concluded that it was reasonable to assume that this type of strategy would downgrade a case of FASD from severe to either moderate or mild. Based on this evidence, it was concluded that the plausible range of effectiveness for this strategy was a downgrade in FASD severity for 0-20% of participants. The upper limit was based on the different in alcohol use at delivery between the intervention and control arms (4.0% vs 33.3%).

Estimating number of cases avoided or downgraded

In deriving the number of FASD cases avoided or downgraded, the percentage of FASD cases avoided or downgraded was multiplied by the prevalence of FASD in Australia and New Zealand.

As discussed earlier, the economic analysis assumes an incidence of 1 per 100 live births for Australia and New Zealand. This is the most up-to-date estimate reported by Stade *et al* 2009. Based on this, the annual number of FASD cases was estimated to be 2,599 in Australia and 581 in New Zealand. These cases would conservatively be costing Australian and New Zealand taxpayers an extra AU$66 million and NZ$16 million per annum respectively. This represents a significant health and cost burden to society in both countries. Using these annual incidence

estimates, the number of FASD cases avoided or downgraded for each scenario could be estimated (see **Table 30**).

Table 30 Number of FASD cases avoided or downgraded based on the incidence rate of 1 in 100 live births

No.	Scenario	Proportion of FASD cases avoided		Number of FASD cases avoided per year	
		Lower estimate	Upper estimate	Lower estimate	Upper estimate
1	Alcohol warning labels in Australia	1%	3%	25	77
2	Alcohol warning labels in New Zealand	1%	3%	5	17
3	A public media campaign in Australia	1%	3%	25	77
4	A public media campaign in New Zealand	1%	3%	5	17
5	Education sessions for pregnant women in Australia	19%	29%	493	753
6	Education sessions for pregnant women in New Zealand	19%	29%	110	168
7	An inpatient alcohol programme in Australia	-	20% [a]	-	519 [a]
8	An inpatient alcohol programme in New Zealand	-	20% [a]	-	116 [a]

Abbreviation: FASD = Fetal Alcohol Spectrum Disorder

[a] The review found no evidence that an inpatient alcohol programme can prevent any case of FASD. The study, however, found the evidence that there were significantly less pregnant women in the programme that consumed alcohol at delivery when compared with women not participating in the programme. For this reason, the analysis hypothesised that the programme would result in a reduction in severity of FASD, rather than preventing cases of FASD. The effectiveness of these scenarios is, therefore, expressed in terms of cases of FASD downgraded.

Results

INCREMENTAL COST OVER A 5-YEAR TIME HORIZON

For each scenario, **Table 31** presents (1) the accumulated incremental cost of the scenarios, (2) the accumulated cost averted at 1, 10 and 50 FASD cases avoided, and finally (3) the net accumulated incremental cost, over the period of five years. A similar analysis for scenario seven and eight, which is measured in terms of cases downgraded, is presented in **Table 33**.

As an example of how the figures in **Table 31** were derived, the steps of calculation are shown as follows.

Row A of **Table 31** (accumulated incremental cost) was taken from **Table 10** to **Table 15** presented earlier in the report. For example, the accumulated increment cost of alcohol warning labels in Australia is AU$14.2 million over five years.

The calculation of figures in Row B of **Table 31** (accumulated cost averted) was described in the 'Potential costs averted by preventing and downgrading cases of FASD' section. For example, the accumulated averted cost from avoiding 1 case annually for 5 years is AU$0.43 million. Similar calculations were then applied to Row C and D.

Row E of **Table 31** (net accumulated cost) was calculated by subtracting the accumulated cost averted (Row B) from the accumulated incremental cost (Row A). For the example, the net accumulated incremental cost of alcohol warning labels in Australia from avoiding 1 case annually, over a 5-year horizon is then AU$14.2 - AU$0.43 = AU$13.7 million. Similar calculations were then applied to the row F and G.

Table 33 shows the equivalent analysis for scenarios seven and eight, which were measured in terms of cases downgraded.

INCREMENTAL COST-EFFECTIVENESS RATIO (ICER)

As discussed above, the actual effectiveness of each of the hypothetical prevention scenarios on FASD is unknown. This economic analysis, therefore, presents a hypothetical, but plausible, range of FASD cases that could be avoided. **Table 32** presents (net) incremental cost per FASD case avoided per annum, over a 5-year time horizon. **Table 34** shows the equivalent analysis for scenarios seven and eight, which were measured in terms of cases downgraded. The ICERs are

also represented graphically in **Figure 7** to **Figure 14**, with a summarised description of each result. Additionally, a summary of ICERs at the limits of plausible ranges for each scenario is tabulated in **Table 35** and **Table 36**. Notice the ICERs are plotted in the graphs against a wide range of FASD cases avoided or downgraded with, when applicable, the plausible range implied by Elliott *et al* 2008 highlighted by shading. Any point on the ICER line above the x-axis (number of cases avoided or downgraded per year) represents a cost to the government, whereas any point on the ICER below the x-axis means a cost-saving to the government. A point where the ICER intercepts the x-axis represents cost-neutrality to the government.

The calculation of the overall incremental cost per FASD case avoided is the summation of the discounted net incremental cost per FASD case avoided. Specifically, the formula can be written as following.

Overall ICER =

Summation of {[((Cost-Cost averted)/No. of cases avoided)]*Discount factor *at Year 1*,
[((Cost-Cost averted)/ No. of cases avoided)]*Discount factor *at Year 2*,
[((Cost-Cost averted)/ No. of cases avoided)]*Discount factor *at Year 3*
[((Cost-Cost averted)/ No. of cases avoided)]*Discount factor *at Year 4*
[((Cost-Cost averted)/ No. of cases avoided)]*Discount factor at *Year 5*},

where

Discount factor *at Year X* = 1/ [(1+discount rate) ^ (# of years since Year 1)]

Table 31 Accumulated incremental cost of scenarios for FASD cases avoided, over a 5-year time horizon

	Item	Alcohol warning labels in Australia (AU$)	Alcohol warning labels in New Zealand (NZ$)	Public media campaign in Australia (AU$)	Public media campaign in New Zealand (NZ$)	Education sessions in Australia (AU$)	Education sessions in New Zealand (NZ$)
A	Accumulated incremental cost	$14,856,644	$8,854,364	$14,683,256	$11,288,947	$14,535,932	$3,023,043
Accumulated cost averted if preventing FASD cases:							
B	1 case annually	$429,933	$483,085	$429,933	$483,085	$429,933	$483,085
C	10 cases annually	$4,299,335	$4,830,849	$4,299,335	$4,830,849	$4,299,335	$4,830,849
D	50 cases annually	$21,496,675	$24,154,245	$21,496,675	$24,154,245	$21,496,675	$24,154,245
Net accumulated incremental cost if preventing FASD cases:							
E	1 case annually	$14,426,710	$8,371,280	$14,253,323	$10,805,862	$14,105,999	$2,539,958
F	10 cases annually	$10,557,309	$4,023,516	$10,383,922	$6,458,098	$10,236,597	-$1,807,806
G	50 cases annually	-$6,640,031	-$15,299,880	-$6,813,418	-$12,865,297	-$6,960,742	-$21,131,202

Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorder; NZ = New Zealand

Table 32 Overall incremental cost per FASD case avoided, over a 5-year time horizon

FASD cases avoided/annum	Alcohol warning labels in Australia (AU$)	Alcohol warning labels in New Zealand (NZ$)	Public media campaign in Australia (AU$)	Public media campaign in New Zealand (NZ$)	Education sessions in Australia (AU$)	Education sessions in New Zealand (NZ$)
1 case annually	$14,426,710	$8,371,280	$14,253,323	$10,805,862	$14,105,999	$2,539,958
10 cases annually	$1,055,731	$402,352	$1,038,392	$645,810	$1,023,660	-$180,781
50 cases annually	-$132,801	-$305,998	-$136,268	-$257,306	-$139,215	-$422,624

Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorders; NZ = New Zealand

Table 33 Accumulated incremental cost of scenarios for cases downgraded, over a 5-year time horizon

Item	Inpatient alcohol programme in Australia (AU$)	Inpatient alcohol programme in New Zealand (NZ$)
Accumulated incremental cost	$102,445,026	$20,198,204
Cost averted if downgrading FASD cases:		
1 case annually	$327,571	$368,068
10 cases annually	$3,275,712	$3,680,679
50 cases annually	$16,378,560	$18,403,393
Net accumulated incremental cost if downgrading FASD cases:		
1 case annually	$102,117,455	$19,830,136
10 cases annually	$99,169,314	$16,517,525
50 cases annually	$86,066,466	$1,794,811

Abbreviations: A = Australian; NZ = New Zealand

Table 34 Incremental cost per FASD case downgraded, over a 5-year time horizon

Number of FASD cases downgraded per annum	Inpatient alcohol programme in Australia (AU$)	Inpatient alcohol programme in New Zealand (NZ$)
1 case annually	$102,117,455	$19,830,136
10 cases annually	$9,916,931	$1,651,753
50 cases annually	$1,721,329	$35,896

Abbreviations: A = Australia; FASD = Fetal Alcohol Spectrum Disorders; NZ = New Zealand

For each scenario a range of ICERs has been calculated based on increasing numbers of FASD cases avoided or downgraded per year. As shown in the following figures, these ICERs are plotted against the number of cases of avoided. As anticipated, the ICERs for all of the different prevention scenarios decrease as the number of FASD cases avoided or downgraded per annum increases. For each scenario, the plot of ICER versus cases avoided or downgraded also shows the expected effectiveness of the prevention strategy underpinning that scenario. For example it is expected that the introduction of alcohol warning labels in Australia would avoid 25 to 77 cases of FASD per annum (indicated by the shaded area in **Figure 7**). The x-intercept of the plot (indicated by the filled triangle) shows the point at which this scenario achieves cost-neutrality (ie, becomes cost-saving). For alcohol warning labels in Australia this occurs when 35 cases of FASD are avoided. As this point lies within the estimated range of effectiveness for this strategy, it is possible that this strategy is cost-effective. That said, the ICER at the lowest limit of the expected effectiveness is high for a public health intervention (ie, $164,000 per FASD case avoided).

Figure 7 and **Figure 8** show the plausible range of FASD cases avoided for mandatory alcohol warning labels in Australia and New Zealand, respectively. The ICER ranged from $164,000 to -$237,000 for Australia, and from $1.3 million to $38,000 for New Zealand. This scenario is cost-

neutral in Australia when 35 cases are avoided (plausible range of cases avoided 25-77). This scenario is cost-neutral in New Zealand when 19 cases are avoided (plausible range of cases avoided 5-17). Therefore, the cost-neutrality point falls within the plausible range for Australia, and just outside the plausible range for New Zealand.

Figure 7 Incremental cost per FASD case avoided per year for mandatory alcohol warning labels in Australia, over a 5-year time horizon

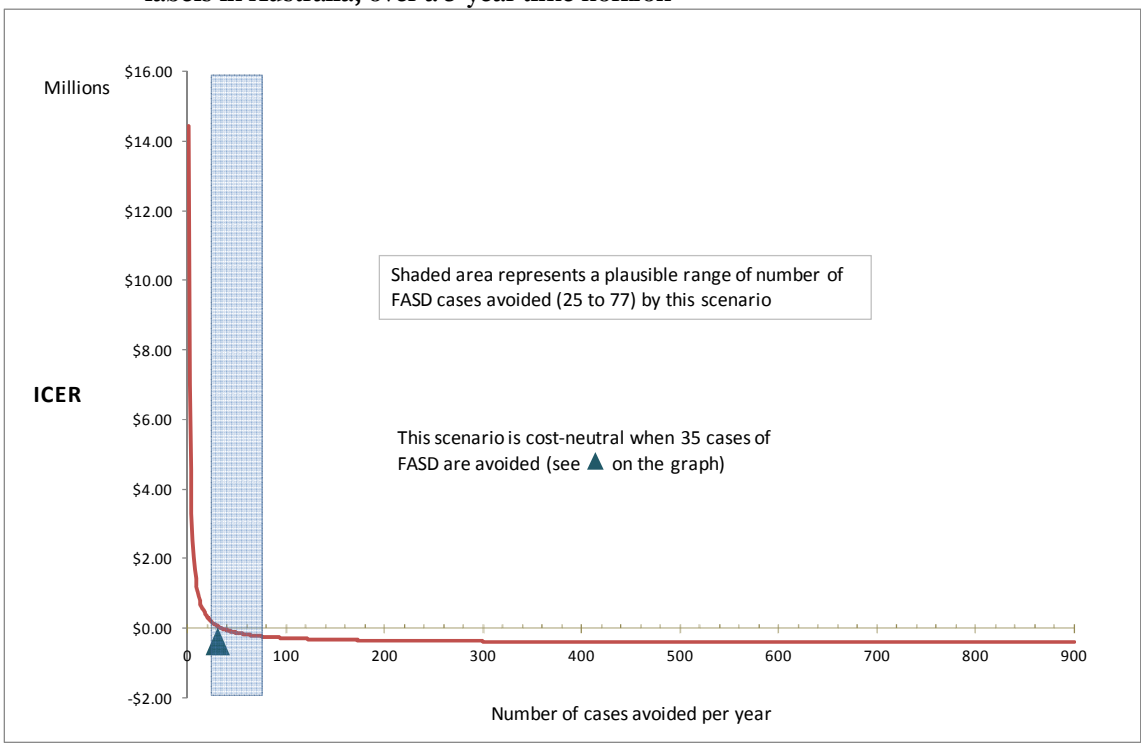


Figure 8 Incremental cost per FASD case avoided per year for mandatory alcohol warning labels in New Zealand, over a 5-year time horizon

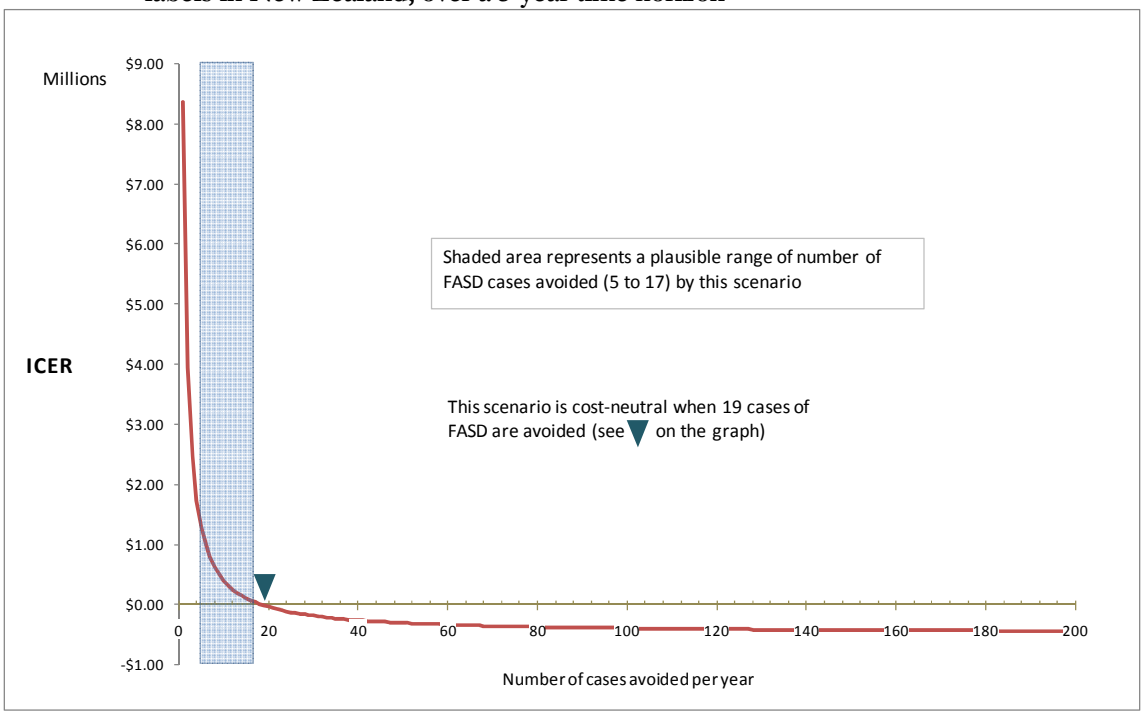


Figure 9 and **Figure 10** show the plausible range of FASD cases avoided for a public media campaign. The ICER for the public media campaign ranged from $158,000 to -$239,000 for Australia, and from $1.8 million to $181,000 for New Zealand. This scenario is cost-neutral in Australia when 35 cases are avoided (plausible range of cases avoided 25-77). These scenarios are cost-neutral in New Zealand when 24 cases are avoided (plausible range of cases avoided 5-17). Therefore, the cost-neutrality point falls within the plausible range for Australia, and just outside the plausible range for New Zealand.

Figure 9 Incremental cost per FASD case avoided per year for a public media campaign in Australia, over a 5-year time horizon

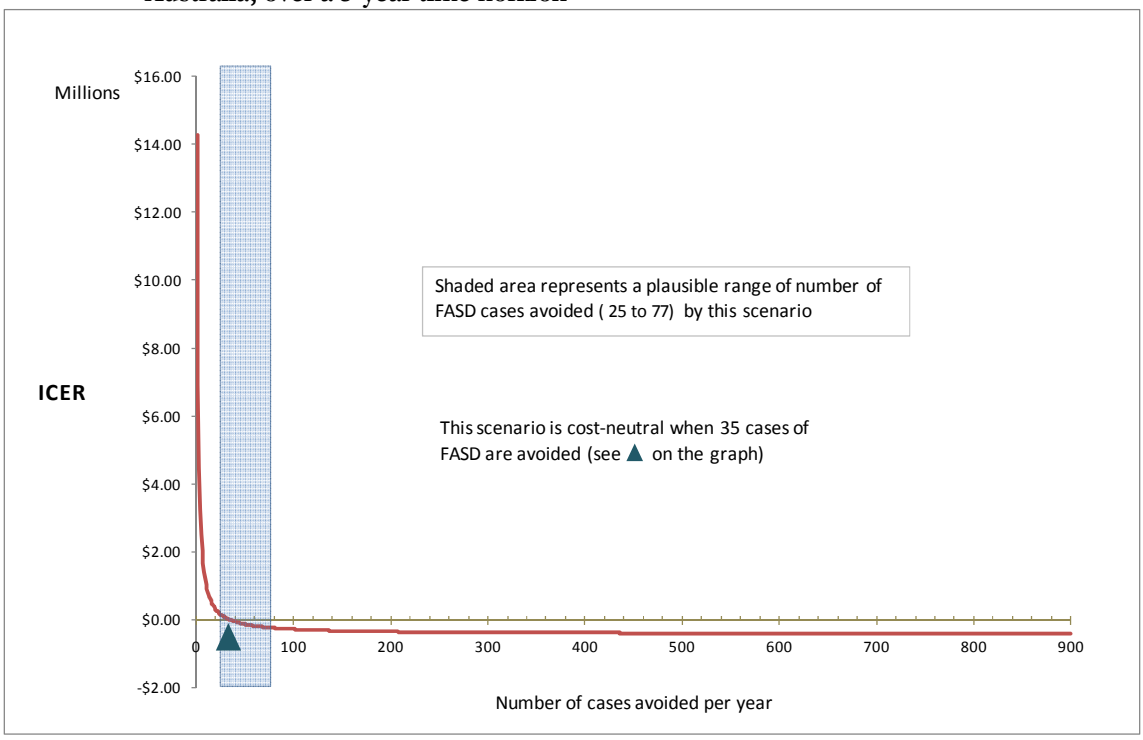


Figure 10 Incremental cost per FASD case avoided per year for a public media campaign in New Zealand, over a 5-year time horizon

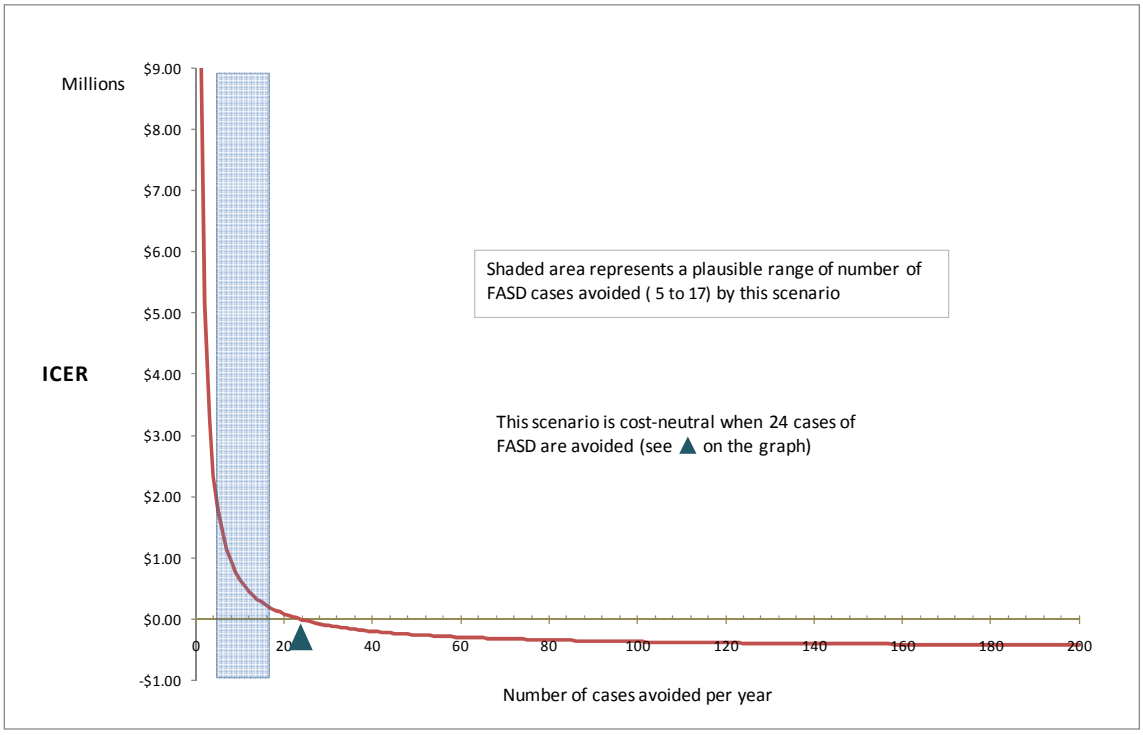


Figure 11 and **Figure 12** show the plausible range of FASD cases avoided for education sessions. The ICER ranged from -$0.40 million to -$0.41 million for Australia, and from -$0.46 million to -$0.47 for New Zealand. These scenarios are dominant within the identified ranges for Australia and New Zealand. These scenarios are cost-neutral in Australia when 34 cases are avoided (plausible range of avoided cases 493-753). This scenario is cost-neutral in New Zealand when 7 cases are avoided (plausible range of avoided cases 110-168). Therefore, the cost-neutrality point falls well under the lower estimate of the plausible range for Australia and New Zealand.

Figure 11 Incremental cost per FASD case avoided per year for education sessions for pregnant women in Australia, over a 5-year time horizon

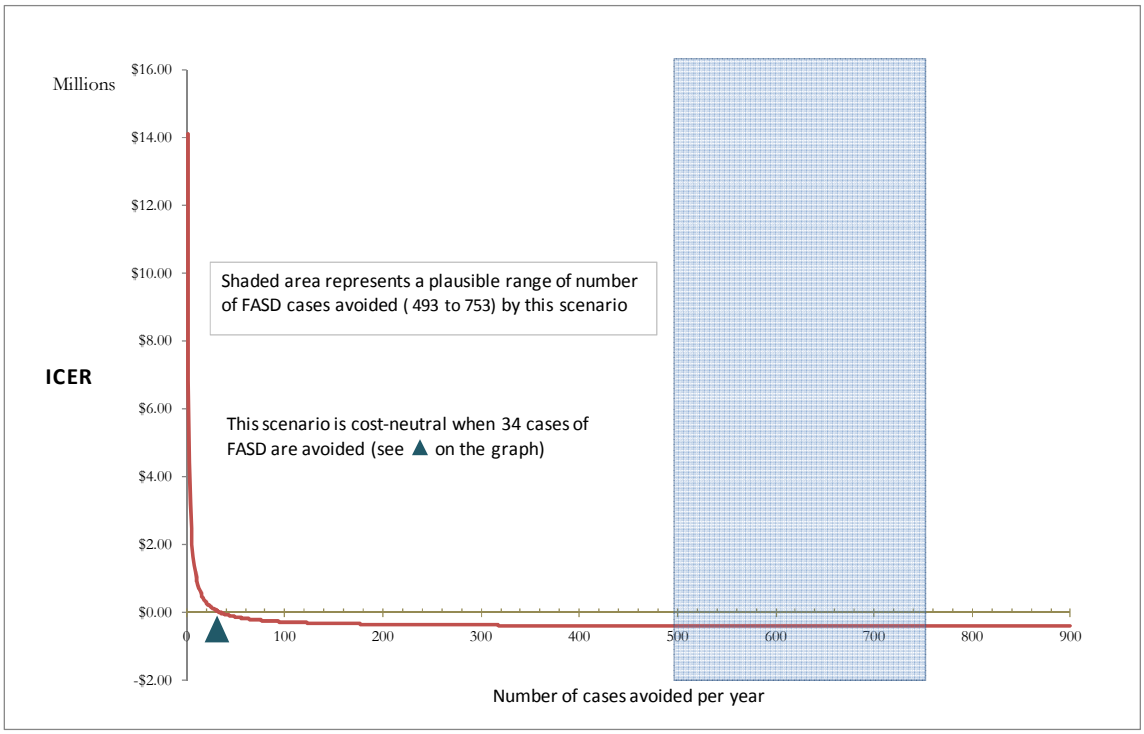


Figure 12 Incremental cost per FASD case avoided per year for education sessions for pregnant women in New Zealand, over a 5-year time horizon

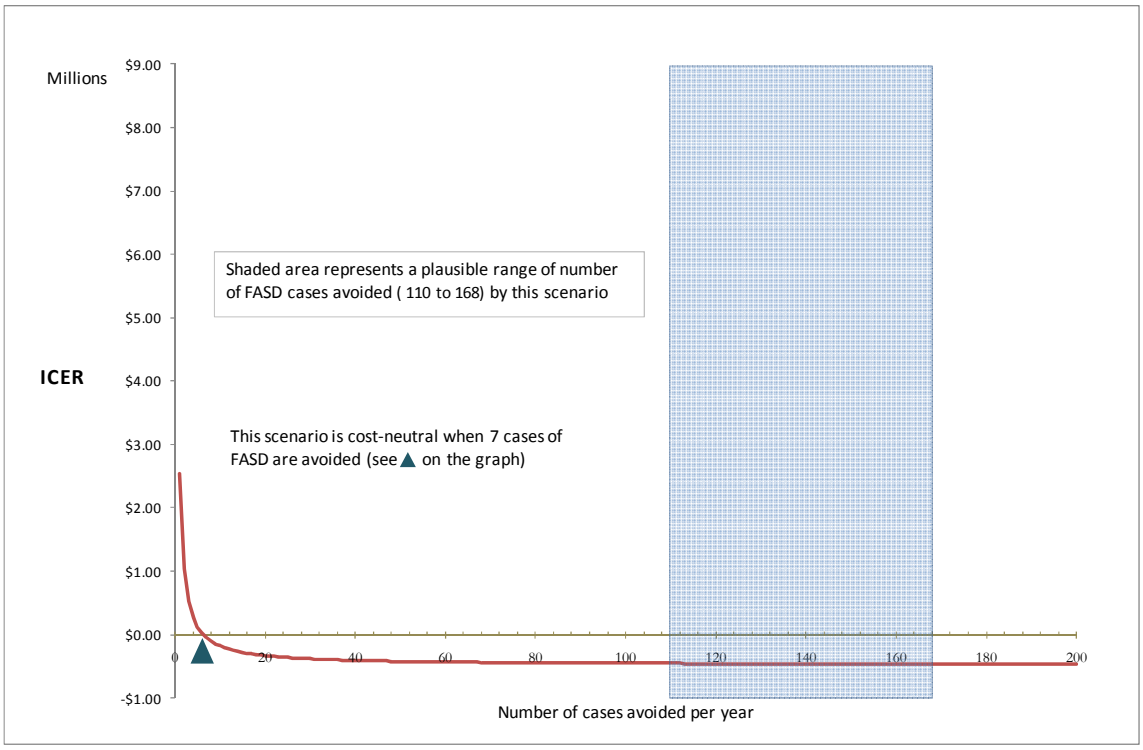


Figure 13 and **Figure 14** show the point estimate of FASD cases avoided for inpatient alcohol programmes. The ICER was estimated to be -$0.13 million for Australia, and -$0.19 million for New Zealand. This scenario is cost-neutral in Australia when 313 cases are avoided (plausible upper estimate 519). This scenario is cost-neutral in New Zealand when 55 cases are avoided (plausible upper estimate 116). Therefore, the cost-neutrality point falls well under the lower estimate of the plausible range for Australia and New Zealand.

Figure 13 Incremental cost per FASD case downgraded per year for an inpatient alcohol programme in Australia, over a 5-year time horizon

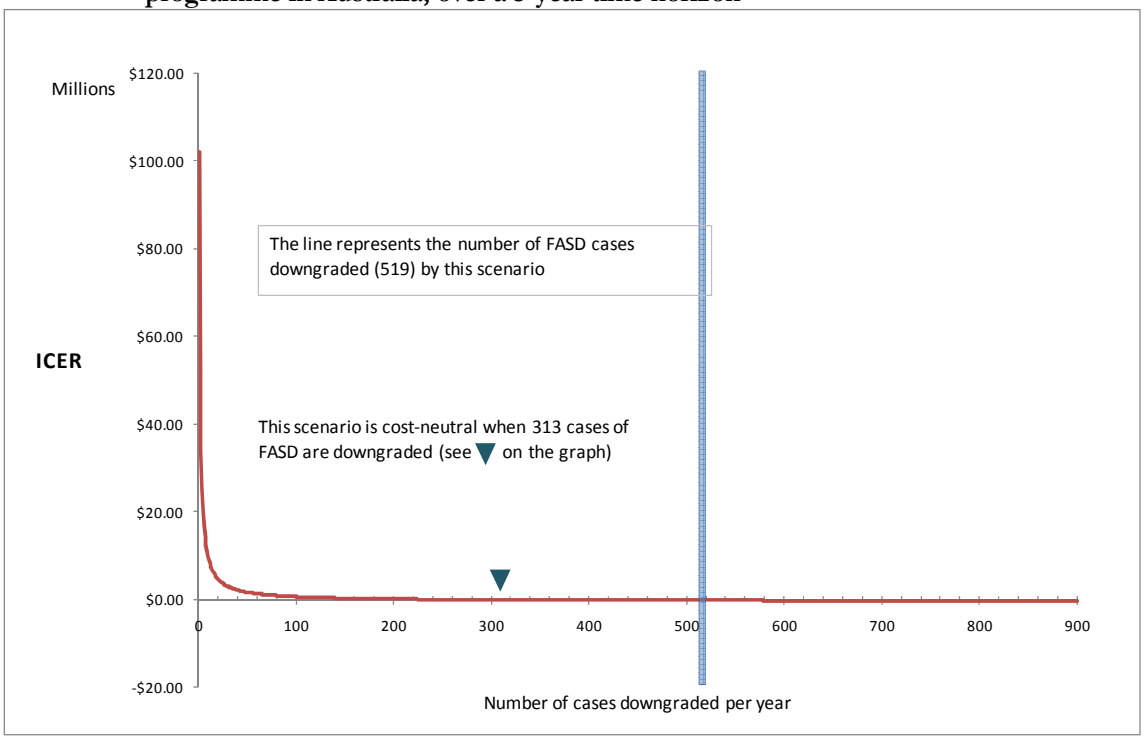


Figure 14 Incremental cost per FASD case downgraded per year for an inpatient alcohol programme in New Zealand, over a 5-year time horizon

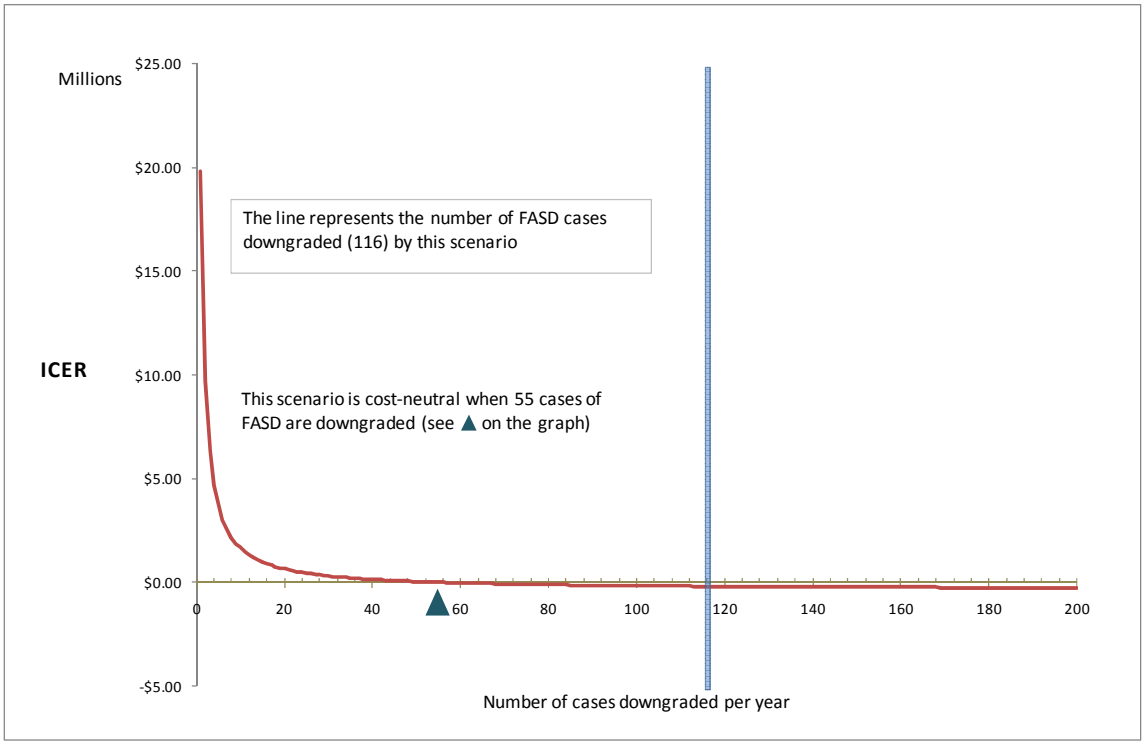


Table 35 shows the ICERs for each scenario at the lower and upper limits of the expected range of effectiveness for each prevention strategy. This table has been constructed from the data derived from the figures above, and from the corresponding figures for the remaining scenarios presented in the body of this report.

In Australia all four scenarios are dominant (ie, cost-saving) at the upper limit of expected effectiveness. In the case of scenario 5, the education sessions for pregnant women, the ICER is also dominant at the lower limit of the expected range of effectiveness. This demonstrates that the secondary prevention strategy of education sessions for pregnant women is the most cost-effective of the four strategies examined. The table also shows that the alcohol warning labels and a public media campaign have comparable cost-effectiveness (with high, but possibly still acceptable ICERs at the lower limits of expected effectiveness).

In New Zealand, education sessions for pregnant women are also clearly the most cost-effective prevention strategy of the four strategies evaluated herein. However, neither the alcohol warning label strategy nor the public media campaign strategy is dominant at the upper limit of expected effectiveness, although alcohol warning labels appear more cost-effective than the public media campaign.

Although expressed in terms of FASD cases downgraded rather than avoided, the inpatient residential programme for pregnant women who are high-risk drinkers was found to be cost-saving in both countries at a point well below the expected effectiveness of the programme

Table 35 ICER at limit of plausible ranges for each scenario, over a 5-year time horizon

Number of FASD cases avoided/downgraded per annum	Australia (AU$)		New Zealand (NZ$)	
	Lower estimate	Upper estimate	Lower estimate	Upper estimate
Scenario 1/2 Alcohol warning labels	$164,000 (Figure 7)	-$237,000 (Figure 7)	$1.3 million (Figure 8)	$38,000 (Figure 8)
Scenario 3/4 A public media campaign	$158,000 (Figure 9)	-$239,000 (Figure 9)	$1.8 million (Figure 10)	$181,000 (Figure 10)
Scenario 5/6 Education sessions for pregnant women	-$400,000 (Figure 11)	-$410,000 (Figure 11)	-$456,000 (Figure 12)	-$465,000 (Figure 12)
Scenario 7/8 An inpatient alcohol programme	-	-$130,000 [a] (Figure 13)	-	-$194,000 [a] (Figure 14)

[a] The effectiveness of these scenarios is expressed as FASD cases downgraded.
Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorder; ICER = Incremental cost-effectiveness ratio, NZ = New Zealand

Table 36 shows the ICERs for each scenario at the lower and upper limits of the expected range of cases avoided or downgraded for each prevention strategy. This table has been constructed from the data derived from the figures above, and from the corresponding figures for the remaining scenarios presented in the body of this report.

In Australia all four scenarios are cost-neutral when the number of cases avoided or downgraded is below the upper limit of the expected effectiveness (based on the evidence available in the literature). For education sessions, the cost-neutral point is below the lower limit of expected effectiveness, indicating that this scenario is cost-effective across the range of expected outcomes. In New Zealand, education sessions were also cost-neutral well below the lower estimate of effectiveness, indicating that this scenario is cost-effective across the range of expected outcomes. The cost-neutral point for alcohol warning labels and public media campaigns was slightly higher than the upper limit of effectiveness, indicating that these scenarios are unlikely to be cost neutral if implemented. The inpatient alcohol programme was cost-neutral when the number of cases avoided was below the upper limit of expected effectiveness in both Australia and New Zealand.

Table 36 Cases avoided or cases downgraded at limit of plausible ranges for each scenario, over a 5-year time horizon

	Australia		New Zealand	
	Cost neutral point	**Lower and upper estimate**	**Cost neutral point**	**Lower and upper estimate**
Scenario 1/2 Alcohol warning labels	35 (within estimates)	25 and 77	19 (above upper estimate)	5 and 17
Scenario 3/4 A Public media campaign	35 (within estimates)	25 and 77	24 (above upper estimate)	5 and 17
Scenario 5/6 Education sessions	**34 (below lower estimate)**	493 and 753	**7 (below lower estimate)**	110 and 168
Scenario 7/8 Inpatient programme	**313 (below upper estimate)**	- and 519 [a]	**55 (below upper estimate)**	- and 116 [a]

[a] No lower estimate.

ESTIMATES OF LOST REVENUE

The amount of lost revenue due to the introduction of the prevention scenarios was not included in the cost-effectiveness analysis. However, it is hypothesised that the introduction of one or more FASD prevention scenarios could result in revenue losses to the alcohol industry through a decline in alcohol sales. In reality, it is difficult to accurately attribute the revenue losses due to the FASD prevention scenarios because the alcohol sales revenue is influenced by several economic factors along with the changing drinking culture. A crude estimate of the lost revenue is, nonetheless, calculated based on advice received from FSANZ. This is shown in **Table 37.** First, the expenditure on alcoholic beverages by pregnant women from the surveys of household expenditures was estimated. For Australia, this information was drawn from the Australian Bureau of Statistics Household Expenditure Survey (2003-2004) and for New Zealand from Statistics New Zealand Household Economic Survey (2007). FSANZ estimated that pregnant women spend approximately AU$57.1 million on alcoholic beverages in Australia and NZ$3.3 in

New Zealand. If 29% of pregnant women abstained from consuming alcohol for an entire year, the total value of lost revenue to the alcohol industry would be approximately AU$16.6 and NZ$1.0 million for Australia and New Zealand respectively. However, some of this loss may be offset by gains to other industry such as an increase in soft drink consumption. Note the break-down of revenue loss by the make-up of the industry is not possible given the simplicity of the calculation.

Table 37 Estimated lost revenue to industry associated with prevention strategies

	Australia	New Zealand	Source
Average amount spent on alcohol by pregnant women annually	AU$57.1 million	NZ$3.3 million	FSANZ
Maximum effectiveness of scenarios	29% reduction in consumption	29% reduction in consumption	Maximum effectiveness identified in the literature search (for Education sessions)
Annual lost revenue	AU$16.6 million	NZ$1.0 million	Calculated

These potential annual losses to industry should be compared to the corresponding life-time savings to the rest of society that would accrue with the assumed 29% reduction in the incidence of FASD: AU$161.2 million in Australia and NZ$132.5 million in New Zealand over the lifetime (assuming 70 years) of the individuals born with FASD.

Supplementary analysis: A 10-year time horizon

Initially, a conservative time horizon of five years was selected for the base case. Following an external review of the completed analysis, FSANZ requested that the time horizon be extended to ten years in order. These analyses are presented in **Table 38** to **Table 43**.

INCREMENTAL COST OVER A 10-YEAR TIME HORIZON

Table 38 presents (1) the accumulated incremental cost of the scenario, (2) the accumulated cost averted at 1, 10 and 50 FASD cases avoided, and finally (3) the net accumulated incremental cost, over the period of ten years. A similar analysis for scenario seven and eight, which expressed the outcome in terms of cases downgraded in presented in **Table 40**.

INCREMENTAL COST-EFFECTIVENESS RATIO (ICER)

Table 39 presents the incremental cost per FASD avoided per annum, over a 10-year time horizon, while **Table 41** presents the equivalent analysis for scenario seven and eight.

Table 38 Accumulated incremental cost of scenarios for FASD cases avoided, over a 10-year time horizon

	Item	Alcohol warning labels in Australia (AU$)	Alcohol warning labels in New Zealand (NZ$)	Public media campaign in Australia (AU$)	Public media campaign in New Zealand (NZ$)	Education sessions in Australia (AU$)	Education sessions in New Zealand (NZ$)
A	Accumulated incremental cost	$15,521,489	$8,934,281	$25,012,683	$19,846,718	$25,824,119	$5,543,577
Accumulated cost averted if preventing FASD cases:							
B	1 case annually	$1,367,314	$1,607,412	$1,367,314	$1,607,412	$1,367,314	$1,607,412
C	10 cases annually	$13,673,140	$16,074,119	$13,673,140	$16,074,119	$13,673,140	$16,074,119
D	50 cases annually	$68,365,698	$80,370,595	$68,365,698	$80,370,595	$68,365,698	$80,370,595
Net accumulated incremental cost if preventing FASD cases:							
E	1 case annually	$14,154,175	$7,326,869	$23,645,369	$18,239,306	$24,456,805	$3,936,165
F	10 cases annually	$1,848,349	-$7,139,838	$11,339,543	$3,772,599	$12,150,980	-$10,530,542
G	50 cases annually	-$52,844,210	-$71,436,314	-$43,353,016	-$60,523,877	-$42,541,579	-$74,827,018

Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorder; NZ = New Zealand

Table 39 Overall incremental cost per FASD case avoided, over a 10-year time horizon

FASD cases avoided/annum	Alcohol warning labels in Australia (AU$)	Alcohol warning labels in New Zealand (NZ$)	Public media campaign in Australia (AU$)	Public media campaign in New Zealand (NZ$)	Education sessions in Australia (AU$)	Education sessions in New Zealand (NZ$)
1 case annually	$14,154,175	$7,326,869	$23,645,369	$18,239,306	$24,456,805	$3,936,165
10 cases annually	$184,835	-$713,984	$1,133,954	$377,260	$1,215,098	-$1,053,054
50 cases annually	-$1,056,884	-$1,428,726	-$867,060	-$1,210,478	-$850,832	-$1,496,540

Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorders; NZ = New Zealand

Table 40 Accumulated incremental cost of scenarios for cases downgraded, over a 10-year time horizon

Item	Inpatient alcohol programme in Australia (AU$)	Inpatient alcohol programme in New Zealand (NZ$)
Accumulated incremental cost	$182,713,385	$37,204,550
Cost averted if downgrading FASD cases:		
1 case annually	$1,026,366	$1,206,594
10 cases annually	$10,263,659	$12,065,939
50 cases annually	$51,318,295	$60,329,697
Net accumulated incremental cost if downgrading FASD cases:		
1 case annually	$181,687,019	$35,997,956
10 cases annually	$172,449,726	$25,138,611
50 cases annually	$131,395,090	-$23,125,147

Abbreviations: A = Australian; NZ = New Zealand

Table 41 Incremental cost per FASD case downgraded, over a 10-year time horizon

Number of FASD cases downgraded per annum	Inpatient alcohol programme in Australia (AU$)	Inpatient alcohol programme in New Zealand (NZ$)
1 case annually	$181,687,019	$35,997,956
10 cases annually	$17,244,973	$2,513,861
50 cases annually	$2,627,902	-$462,503

Abbreviations: A = Australia; FASD = Fetal Alcohol Spectrum Disorders; NZ = New Zealand

Table 42 shows the ICERs at the lower and upper limits of the expected range of effectiveness for each scenario, over the 10-year time horizon. The analysis has shown that all prevention strategies for Australia are dominant (cost-saving) throughout the entire ranges. In Australia, the education sessions strategy is clearly the best value for money at the lower and upper limits of the effectiveness range (-$1.3 million and -$1.3 million). At the lower limit, the second best strategy is alcohol labelling (-$747,000) with a public media campaign being the third best option (-AU$367,000). However at the upper limit, the cost-effectiveness of a public media campaign (-AU$1.0 million) and alcohol labelling (-AU$1.2 million) are comparable with the education sessions strategy being a marginally more cost-effective option (-AU$1.3 million)).

Similar to Australia, in New Zealand the provision of education sessions to pregnant women is consistently the most cost-effective scenario at the lower and upper limits of the expected ranges (-$1.6 million and -$1.6 million). At the lower limit, only the education sessions strategy is dominant. The alcohol warning scenario is the second most cost-effective option, but the ICER (NZ$179,000) is high. The lower estimate for a public media campaign was NZ$2.4 million. At the upper limit, education sessions (-NZ$1.6 million) and alcohol labelling are dominant (-NZ$1.1 million).

The inpatient alcohol programme, whose outcome is expressed in terms of cases downgraded, is dominant at the upper limits of the expected effectiveness (-$674,000 for Australia and -$886,000 for New Zealand). As discussed previously, it is not appropriate to directly compare this strategy with the other strategies mentioned earlier as their outcomes are expressed differently (ie cases avoided vs cases downgraded).

Table 42 ICER at limit of plausible ranges for each scenario, over a 10-year time horizon

Number of FASD cases avoided/downgraded per annum	Australia (AU$)		New Zealand (NZ$)	
	Lower estimate	Upper estimate	Lower estimate	Upper estimate
Scenario 1/2 Alcohol warning labels	-$747,000	-$1.2 million	$179,000	-$1.1 million
Scenario 3/4 A public media campaign	-$367,000	-$1.0 million	$2.4 million	-$440,000
Scenario 5/6 Education sessions for pregnant women [a]	-$1.3 million	-$1.3 million	-$1.6 million	-$1.6 million
Scenario 7/8 An inpatient alcohol programme	-	-$674,000 [b]	-	-$886,000 [b]

[a] In writing these numbers in full, the lower estimate was AU$1,314,932 and the upper estimate was AU$1,333,019 for Australia and in New Zealand, the lower estimate was NZ$1,557,016 and the upper estimate was NZ$1,574,414.
[b] The effectiveness of these scenarios is expressed as FASD cases downgraded.
Abbreviations: A = Australian; FASD = Fetal Alcohol Spectrum Disorder; ICER = Incremental cost-effectiveness ratio, NZ = New Zealand

Table 43 shows the required number of FASD cases avoided or downgraded for each strategy to become cost neutral. It also shows the lower and upper limits for the expected ranges of cases avoided or downgraded. In Australia, the point of cost neutrality is well below the lower limit of expected cases avoided for alcohol labelling, the public media campaign and the education sessions. Alcohol labelling requires the least number of FASD cases avoided (12 cases annually for 10 years consecutively) for each of the 10 years to achieve cost neutrality.

In New Zealand the point of cost neutrality is below the lower of limit of expected cases avoided for education sessions, and below the upper limit for alcohol labelling and public media campaign.

The inpatient alcohol programme was cost-neutral when the number of cases avoided was below the upper limit of expected effectiveness in both Australia and New Zealand.

Table 43 Cases avoided or cases downgraded at limit of plausible ranges for each scenario, over a 10-year time horizon

	Australia		New Zealand	
	Cost neutral point	**Lower and upper estimate**	**Cost neutral point**	**Lower and upper estimate**
Scenario 1/2 Alcohol warning labels	**12 (below lower estimate)**	25 and 77	6 (within estimates)	5 and 17
Scenario 3/4 A Public media campaign	**19 (below lower estimate)**	25 and 77	13 (within estimates)	5 and 17
Scenario 5/6 Education sessions	**19 (below lower estimate)**	493 and 753	**4 (below lower estimate)**	110 and 168
Scenario 7/8 Inpatient programme	**179 (below upper estimate)**	- and 519 [a]	**31 (below upper estimate)**	- and 116 [a]

[a] No lower estimate.

When comparing the 10-year results to the 5-year (base-case) results, the following patterns emerged. In Australia and New Zealand, the education session scenario remains the most cost-effective option at the lower and upper end of the expected range of effectiveness. This scenario presents a substantial cost-saving over both the 5 and 10-year time horizons.

In Australia, over 10 years the alcohol labelling scenario is clearly a more cost-effective option than the public media campaign scenario, owning mainly to the relatively low ongoing costs of alcohol labelling. In contrast, over a 5-year period, the alcohol warning labels and public media campaign scenarios were comparable. This change reflects the difference in the cost structure of these two scenarios. The alcohol labelling scenario has high fixed costs in the first year with minimal ongoing costs. In contrast, the public media campaign scenario has relatively low fixed costs, but with more substantial ongoing cost. Given this, the alcohol labelling scenario is highly likely to remain a more cost-effective option than the public media campaign over the longer timeframe. In New Zealand, the relative ranking of the considered scenarios remains identical in the 5 and 10-year time horizon at the lower and upper end of the range. As anticipated, the points at which all the scenarios in Australia and New Zealand become cost neutral are lower in the 10-year time horizon than in the 5-year time horizon.

Assumptions

- The incidence of FASD is 1 in 100 live births for Australia and New Zealand
- The reduction in the proportion of cases of FASD associated with a particular prevention strategy is equivalent to the proportional reduction in maternal alcohol consumption observed for that strategy [ie, a one-to-one relationship between the reduction in alcohol consumption and the reduction in the number of children born with FASD or the severity of FASD (eg a 1% reduction in alcohol consumption equates to an equal (1%) reduction in the number of children born with FASD or the severity of FASD].
- Appropriate referral pathways are in place in Australia and New Zealand, and all women who require particular healthcare resources have timely access to those resources.
- There are sufficient healthcare resources to support eligible pregnant women who require an intervention. That is, there are enough residential care facilities and health care practitioners for high risk women.
- All one-off costs to government and industry associated with a particular prevention strategy are accrued in the first year of its introduction
- Approximately 40% of the alcoholic beverages produced in Australia and New Zealand are destined for the domestic market, and hence subject to domestic labelling requirements
- Any alcohol labelling changes introduced by FSANZ would allow for a transition period, and the label changes would apply only to new stock produced after that time (ie, there would be no requirement for the recall and relabelling of stock already on shelves at the end of the transition period).
- The costs to industry of labelling changes for each SKU are over-estimated, as not all of the component costs listed in the PWC report will apply in the scenarios under examination (eg, the text and/or schematic would be supplied by FSANZ with little requirement for proof-reading or graphic design by industry, there would be economies of scale across all of the SKUs produced by a single manufacturer, and there would be efficiencies associated with harmonising domestic and export labels).
- Cost of printing education pamphlet is $0.4 per page.
- Cost of translating a booklet is AU$497 and NZ$628 per booklet for New Zealand and Australia respectively.

- An average basic cost of running a residential care per bed is $120 per day for New Zealand and $150 for Australia.

Sensitivity analyses

A number of one-way sensitivity analyses have been conducted around the key assumptions and parameters. The results of the sensitivity analyses are tabulated in **Table 44**.

Table 44 Sensitivity analyses, assuming 50 cases of FASD are avoided annually

Scenarios	Australia	New Zealand
Base-case analysis		
Alcohol warning labels	-$132,801	-$305,998
Public media campaign	-$136,268	-$257,306
Education sessions	-$139,215	-$422,624
Inpatient alcohol programme	$1,721,329	$35,896
The cost of labelling per SKU is equivalent to a medium change (minor change in base case)		
Alcohol warning labels	$266,103	-$54,760
Public media campaign	NC	NC
Education sessions	NC	NC
Inpatient alcohol programme	NC	NC
100% of domestic SKU labels will be modified due to mandatory labelling changes (20% in base case)		
Alcohol warning labels	$311,503	-$26,086
Public media campaign	NC	NC
Education sessions	NC	NC
Inpatient alcohol programme	NC	NC
The cost of printing booklets and pamphlets is halved		
Alcohol warning labels	NC	NC
Public media campaign	NC	NC
Education sessions	-$149,822	-$424,996
Inpatient alcohol programme	NC	NC
The proportion of women considered high-risk is doubled to 1.0% (0.5% in base case)		
Alcohol warning labels	NC	NC
Public media campaign	NC	NC
Education sessions	NC	NC
Inpatient alcohol programme	$3,770,230	$439,860
The discount rate is decreased by 100 percentage points		
Alcohol warning labels	-$143,306	-$318,408
Public media campaign	-$142,219	-$265,886
Education sessions	-$144,713	-$433,932
Inpatient alcohol programme	$1,750,921	$34,097
The discount rate is increased by 100 percentage points		
Alcohol warning labels	-$122,709	-$294,083
Public media campaign	-$130,564	-$249,078
Education sessions	-$133,945	-$411,771
Inpatient alcohol programme	$1,692,811	$37,605
The cost of FASD is decreased by one standard deviation		
Alcohol warning labels	-$82,640	-$249,636
Public media campaign	-$86,108	-$200,944
Education sessions	-$89,055	-$366,263
Inpatient alcohol programme	$1,788,140	$110,966
The cost of FASD is increased by one standard deviation		
Alcohol warning labels	-$214,438	-$397,728
Public media campaign	-$217,906	-$349,036
Education sessions	-$220,852	-$514,354
Inpatient alcohol programme	$1,660,800	-$32,116

Scenarios	Australia	New Zealand
Base-case analysis		
Alcohol warning labels	-$132,801	-$305,998
Public media campaign	-$136,268	-$257,306
Education sessions	-$139,215	-$422,624
Inpatient alcohol programme	$1,721,329	$35,896
1% cent reduction in alcohol consumption equates to a 0.5% reduction in number of children born with FASD or in the severity of FASD		
Alcohol warning labels	$164,332	-$128,910
Public media campaign	$157,397	-$31,527
Education sessions	$151,504	-$362,163
Inpatient alcohol programme	$3,770,230	$439,860

Abbreviations: FASD = Fetal Alcohol Spectrum Disorder; NC = no change

The base-case represents the ICER for avoiding 50 cases of FASD annually. This is presented for each prevention scenario. Eight sensitivity analyses were performed: changing the cost to industry of labelling changes, changing the proportion of labels affected by labelling changes, changing the cost of printing booklets and pamphlets for the education sessions with pregnant women, changing the proportion of women considered to be at high risk of delivering a child with FASD, changing the discount rate (both increasing and decreasing), changing the cost of FASD (both increasing and decreasing), and altering the one-to-one relationship between the reduction in alcohol consumption and the reduction in number of children with FASD or in the severity of FASD.

In the base-case, the cost to industry of changing labels was considered to be equivalent to a minor change as defined by PwC. The sensitivity analysis assumed that the cost of each label change was equivalent to a medium change as defined by PWC. There was a large increase in the ICER, from -AU$133,000 in the base case to AU$266,000 in the sensitivity analysis for Australia, and from -NZ$306,000 in the base case to -$55,000 for New Zealand in the sensitivity analysis.

The base-case assumes that 20% of domestic wine SKUs will be required to change their labels as a direct result of the introduction of mandatory labelling changes (ie the label would not have been modified if the labelling changes were not introduced). This was increased to 100% in a sensitivity analysis. There was a large increase in the ICER, from -AU$133,000 in the base-case to AU$312,000 in the sensitivity analysis for Australia, and from -NZ$306,000 in the base case to -NZ$26,000 for New Zealand in the sensitivity analysis. These results indicated that the mandatory alcohol warning label scenarios are sensitive to the cost of labelling to industry.

Halving the cost of printing educational booklets and pamphlets was evaluated in another sensitivity analysis. The base-case results of the education sessions scenario were relatively insensitive to the change in printing costs. The ICERs decreased slightly by 8% and 1% for

Australia and New Zealand respectively. The ICER changed from -AU$139,000 in the base case to -AU$150,000 in the sensitivity analysis for Australia, and from -NZ$423,000 in the base case to -$425,000 for New Zealand in the sensitivity analysis.

The proportion of women considered to be at high-risk of delivering a child with FASD was increased from 0.5% to 1.0% in a sensitivity analysis. As per the base-case, it was assumed that all high-risk women would enter an inpatient alcohol programme. The ICERs increased considerably from AU$1.7 in the base case to AU$3.9 million in the sensitivity analysis for Australia, and from $36,000 in the base case to NZ$440,000 in the sensitivity analysis for New Zealand.

A decrease and increase in the discount rate of 100 percentage points, and the cost of FASD by one standard deviation was evaluated. The results of these sensitivity analyses showed that the impact of these changes was relatively minor: there was as a small increase in the ICER when the discount rate was decreased, and when the cost of FASD was increased; there was a small decrease in the ICER when the discount rate was increased, and when the cost of FASD was decreased.

The base-case assumes that a 1% reduction in alcohol consumption leads to a 1% reduction in the number of FASD cases or in the severity of FASD. The impact of altering these assumptions was explored in a sensitivity analysis. The base-case results were found to be highly sensitive to this assumption. If this assumption was changed to assume that a 1% reduction in alcohol leads a 0.5% reduction in the number of FASD cases avoided or in the severity of FASD, the ICERs of all scenarios increased substantially. For example, the ICERs for the alcohol labelling scenario increased from -AU$133,000 to AU$164,000 for Australia, and for New Zealand from -NZ$306,000 to -NZ$129,000.

Discussion and limitations

This exploratory economic analysis examined the cost-effectiveness of four possible national prevention scenarios for FASD in Australia and the same four scenarios for New Zealand, compared to no additional action to prevent FASD. The four scenarios were: mandatory alcohol labelling, a public media campaign, education sessions for all pregnant women, and an inpatient alcohol programme for high risk women. The effectiveness of these prevention strategies is expressed as the incremental cost per case of FASD avoided or, in the case of the inpatient programme from high-risk women, the incremental cost per case of FASD downgraded, over a five-year period. It is important to note that the analysis does not attempt to quantity the outcomes in terms of quality of life. Although the benefit of expressing outcomes in terms of utility would allow the results to be compared against other interventions and public health programs, it was the authors' opinion that this would introduce an unacceptable level of uncertainty to the analysis: not only has the magnitude of the impact of maternal alcohol consumption on FASD be assumed, but deriving relevant preference-based utility scores for FASD is known to be difficult. .. .

In the base-case analysis over a 5-year time horizon, the most cost-effective scenario was education sessions for pregnant women (scenarios five and six). This was found to be are dominant (cost-saving) for Australia and New Zealand, presenting the best value for money. Within range of effectiveness considered, the ICERs ranged from -$400,000 to -$410,000 for Australia and from -$456,000 to -$465,000 for New Zealand. In Australia, mandatory alcohol warning labels and a public media campaign were found to be similarly cost-effective. The ICER for mandatory warning labels ranged from $164,000 to -$237,000, and the ICER for public media campaigns ranged $158,000 to -$239,000. In New Zealand, the second most cost-effective scenario was mandatory alcohol warning labels, followed by public media campaigns. The ICER for mandatory warning labels ranged from $1.3 million to $38,000, and for public media campaigns the ICER ranged from ranged $158,000 to -$239,000. Inpatient alcohol programs could not be directly compared with the other scenarios as they were evaluated using different outcomes (cases downgraded rather than cases avoided). However, inpatient alcohol programme were found to be cost saving in both Australia and New Zealand.

In Australia all four prevention scenarios were found to be cost-neutral within or below the range of expected effectiveness. Education sessions were cost neutral at 34 cases avoided, with the range of expected effectiveness between 493 and 753 cases avoided. The cost neutral point was

well below the lower estimate of expected effectiveness. Both alcohol warning labels and public media campaigns were cost-neutral at 35 cases avoided, with the range of expected effectiveness between 25 and 77 cases avoided. The cost neutral point was therefore within the range of expected effectiveness. Inpatient alcohol programs were cost neutral at 313 cases downgraded, with an upper estimate of 519 cases avoided. The cost neutral point was therefore below the upper estimate of the number of cases avoided.

In New Zealand, education sessions were cost neutral at 7 cases avoided, with the range of expected effectiveness between 110 and 168 cases avoided. The cost neutral point was well below the lower estimate of expected effectiveness. Alcohol warning labels and public media campaigns were cost-neutral at 19 and 24 cases avoided respectively. The range of expected effectiveness for both of these scenarios was between 5 and 17 cases avoided. Therefore both cost neutral points fell outside the range of expected effectiveness. Inpatient alcohol programs were cost neutral at 55 cases downgraded, with an upper estimate of 116 cases avoided. The cost neutral point was therefore below the upper estimate of the number of cases avoided.

The supplementary analysis using a 10-year time horizon found that the education sessions remained the most cost-effective scenario for Australia and New Zealand. The scenario is consistently dominant throughout the entire range of expected effectiveness in Australia and in New Zealand, presenting the best value for money. Over the period of ten years, the ICERs were approximately -$1.3 million for Australia and approximately -$1.6 for New Zealand. In contrast to the 5-year analysis, the mandatory alcohol labelling is clearly the second most cost-effective scenario in Australia and in New Zealand. Within the expected range of effectiveness, the ICERs for alcohol labelling ranged from -AU$747,000 to -AU$1.2 million for Australia, and from NZ$179,000 to -$1.1 million for New Zealand. The ICERs for a public media campaign ranged from -AU$367,000 to -AU$1.0 million for Australia, and from NZ$2.4 million to -$440,000 for New Zealand.

In the analysis over the 10-year time horizon, all scenarios for Australia were cost neutral at a point well below the lower limit of expected effectiveness range. The alcohol labelling scenario was cost neutral at 12 cases avoided annually (expected range of effectiveness 25-77 cases avoided) and the public media campaign and education session scenarios were cost neutral at 19 cases avoided annually (expected range of effectiveness 25-77 cases avoided). The inpatient programs were cost neutral at 179 cases avoided (expected range of effectiveness up to 519). In New Zealand, The alcohol labelling scenario was cost neutral at 6 cases avoided annually (expected effectiveness 5-17 cases avoided) and the public media campaign and education session

scenarios were cost neutral at 13 cases avoided annually (expected range of effectiveness 5-17 cases avoided). The inpatient programs were cost neutral at 31 cases avoided (expected effectiveness up to 116). As anticipated, the points at which all the scenarios in Australia and New Zealand become cost neutrality are lower in the 10-year time horizon than in the 5-year time horizon.

Based on these analyses, it can be concluded that for Australia and New Zealand, the education sessions scenario is the most cost-effective option with the alcohol labelling scenario being the second most cost-effective option.

The sensitivity analyses were conducted for the base-case analysis around the key assumptions and parameters. In summary, the ICERs of mandatory alcohol warning labels were most sensitive to a change in the cost of mandatory labelling to industry, while the inpatient programmes were most sensitive to the proportion of eligible women taking up the programme. A change in the cost of managing a case of FASD has a modest impact on the ICERs.

It should be noted that the evidence for the effectiveness of each scenario was limited, often to a single publication, none of which were conducted in Australia or New Zealand. It is therefore plausible that the effect extrapolated from these publications may be different if it were optimised to the Australian or New Zealand setting. For example, the Wilkinson *et al* 2009 review discusses the importance of optimising warning labels for alcohol bottles. It is unclear if the Hankin studies, which were used as the basis for estimating the effect size, assessed the most effective form of warning labels. Similar caveats apply to the other selected strategies (public media campaigns, education sessions for pregnant women and inpatient alcohol programmes). Nevertheless, these estimates were made based on the available evidence from the literature.

Note that the cost per case of FASD downgraded was specifically examined in scenario seven and scenario eight as it was postulated that the scenarios are more likely to result in a reduction in severity of FASD rather than complete avoidance of FASD. As these inpatient treatment programmes are aimed at high-risk women who are already pregnant, it is assumed that any reduction in alcohol consumption during pregnancy would be associated with a reduced severity of FASD cases, but not necessarily a complete avoidance of FASD cases. This is based on the assumption that high-risk women are likely to have consumed significant amounts of alcohol prior to entering the inpatient programme, the effects of which cannot be reversed. This is a conservative assumption.

The results should also be considered in the context of unknown link between any intervention and a reduction in the number of cases of FASD. Although the link between alcohol consumption during pregnancy and FASD is well established, quantifying a specific dose-response relationship is difficult. This is reflected in the latest NHMRC guidelines (Australian Guidelines to reduce health risks from drinking alcohol, NHMRC 2009)[h], which also noted that a dose-response between alcohol consumption and FASD has not been established. For this reason, it was recommended that not drinking during pregnancy was the safest option, although it was acknowledged that the evidence linking very low levels of alcohol consumption with FASD was unclear. Nevertheless, it is postulated that strategies shown to be effective at reducing alcohol consumption in pregnant women would reduce the number of FASD cases. The effectiveness of each strategy on the number of FASD cases was therefore estimated purely for the purpose of exploration.

Note that the evidence base for high-risk female drinkers was limited to pregnant women as these were the studies most likely to report effects on fetal outcomes. The original systematic review by Elliott *et al* 2008 excluded generic alcohol programmes (eg in non-pregnant women) as the evidence would have been very broad and not informative with respect to FASD incidence. However, it could well be the case that strategies exist for high-risk female drinkers who are not pregnant, and that such strategies may avoid cases of FASD. It should also be noted that women who consumed alcohol prior to being aware of their pregnancy will not receive the full benefit from the interventions described here as some alcohol related damage may already have occurred.

It is important to note that there are significant limitations and uncertainty associated with this economic analysis. The result has been derived based on a number of necessary assumptions (see 'assumptions' section). There is currently insufficient reliable data and information to verify these assumptions. While all the effort was made to ensure the robustness of the analysis, readers are encouraged to exercise caution while interpreting the results.

The scope of this analysis was defined as the full spectrum of alcohol related disorders, ie FASD and not just the most severe form (FAS). Consequently, FAS only literature was not considered herein as it does not reflect the full range of FASD. A broader approach, incorporating separate FAS and FASD data, could be undertaken as part of a further analysis.

This economic analysis has taken the societal perspective, including costs to government agencies, and indirect costs such as productivity loss, out-of-pocket expenses and financial impact

[h] http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/ds10-alcohol.pdf

to industry. The cost of developing the standard has been excluded in order to be consistent with prior FSANZ reports.

It is important to note that the cost of an FASD case avoided or downgraded applied in the economic analysis is based on Stade *et al* 2009, which was conducted for Canada. The applicability of these estimates to the Australian or New Zealand setting depends on a number of variables, including service costs and the similarity of healthcare practices between Canada and Australia or New Zealand. While recognising that there are differences in managing children with FASD between the countries, the analysis used these estimates as there is a paucity of studies reporting the cost of FASD. Similar studies such as Lupton *et al* 2004 and Klug and Burd 2003 related only to FAS. The impact of the uncertainty around the cost of FASD was examined further in the sensitivity analyses.

The burden of FASD is not only limited to the healthcare sector, but it also affects social services, the education system, the judicial system, and society in general. Youth with FASD have also been linked to criminal behaviour (Alcohol Healthwatch, 2007). The Stade study, however, did not include the cost to the justice system. Fast *et al* 1999 found 23% of all youth remanded to forensic psychiatric inpatient assessment unit were diagnosed with FAS or FAE. Additionally, Streissguth *et al* 1996 reported that 60% of FASD individuals in the USA had been in trouble with the law. These costs are not likely to incur until the children with FASD reach adolescence. Over a long period of time, this could add further burden to the criminal justice system. This suggests that, when extending the analysis to a longer time horizon (lifetime for instance), the potential annual costs averted to the government from avoidance of FASD could be larger than Stades' estimates.

Alcohol prohibition and increasing taxes on alcoholic drinks were not included for evaluation as there are numerous challenges associated with these options. Firstly, prohibition is extremely difficult to effectively enforce. Though the systematic review found alcohol prohibition to have some effect on alcohol consumption, the practicality of implementing prohibition is limited. Additionally, if alcohol prohibition were implemented, effectively maintaining this policy would have significant resource and financial implications. These costs could disproportionally outweigh the benefits created by alcohol prohibition. Although there is evidence relating an increased tax on alcohol to a reduction in alcohol consumption, it is important to note that no evidence specific to FASD was identified. The generalisability of such evidence in the general population is somewhat limited to pregnant women. From an economic perspective, this type of tax could indirectly reduce the economic competitiveness of Australia and New Zealand in the global

market, which could create efficiency distortions in the economy, and create overall welfare losses. Further, there is also an ongoing issue of the optimal tax rate to achieve the desirable cost-effectiveness result, there is little information how this matter should be dealt with.

The amount of lost revenue due to the introduction of the prevention scenarios was not included in the base-case analysis; it is however briefly discussed below. It is hypothesised that, given all else remains constant, the introduction of FASD prevention scenarios could result in revenue losses to the alcohol industry through decline in the alcohol sales. In reality, it is difficult to accurately attribute the revenue losses due to the FASD prevention scenarios because the alcohol sale revenue is influenced by several economic factors along with the changing drinking culture. The total value of lost revenue to the alcohol industry would be approximately AU$17.13 million and NZ$1.0 million for Australia and New Zealand respectively. Note the break-down of the loss by the make-up of the industry is not possible given the simplicity of the calculation.

Finally, this economic analysis does not include costs associated with evaluating any national FASD prevention programme. The cost of monitoring and evaluating each scenario could range between 5% and 10% of the total cost (ALAC, personal communication). Such measurement is critical if the government is to assess the true value for money of such a programme, and specific evaluation should be incorporated in the total costs of the programme. Importantly, there are no reliable estimates of FASD incidence or costs in Australia and New Zealand, and priority should be given to collecting such data.

References

Access Economics. (2006). "Cost benefit analysis of fortifying the food supply with iodine".

Alcohol Advisory Council of New Zealand and Ministry of Health. (2001). National Alcohol Strategy 2000-2003. Alcohol Advisory Council of New Zealand and Ministry of Health: Wellington.

Alcohol and Public Health Research Unit. (2001). Drinking in New Zealand, National Surveys Comparison 1995 & 2000. Auckland: University of Auckland.

Alcohol Healthwatch. (2007). Fetal Alcohol Spectrum Disorder in New Zealand: Activating the Awareness and Intervention Continuum. Alcohol Healthwatch: Auckland

Abel, E. (1998). Prevention of alcohol abuse-related birth effects – II: Targeting and pricing. Alcohol and Alcoholism. 33 (4): 417-420.

Australian Bureau of Statistics (ABS), http://www.abs.gov.au/

Babor TF, Caetano R, Casswell S, Edwards G, Giesbrecht N, Graham K, Grube J, Gruenewald P, Hill L, Holder H, Homel R, Österberg E, Rehm J, Room R, Rossow, I. (2003). Alcohol: No Ordinary Commodity—Research and Public Policy . Oxford and London: Oxford University Press.

British Medical Association Board of Science. (2007). Fetal alcohol spectrum disorders: a guide for healthcare professionals. British Medical Association

Bower C, Silva D, Henderson TR, Ryan A, Rudy E. (2000). Ascertainment of birth defects: The effect on completeness of adding a new source of data. Journal of Paediatric Child Health. 36: 574-576.

Burd L, Cox C, Poitra B, Wentx T, Ebertowski M, Martsolf JT, Kerbeshian J, Klug MG. (1999). The FAS screen: a rapid screening tool for fetal alcohol syndrome. Add Biol 4:329-336.

Burke, TR. (1998). The economic impact of Alcohol Abuse and Alcoholism. Public Health Reports. 103: 565-569.

Campbell S, Norris S, Standfield L, Suebwongpat A. (2008). Screening for postnatal depression within the Well Child Tamariki Ora Framework. HSAC Report; 1(2)

Centers for Disease Control (CDC). (1997). Alcohol consumption among pregnant and child bearing aged- women — United States, 1991 and 1995. Monthly Mortality and Morbidity Report 46:346- 349.

Chang G. (2002). Brief interventions for problem drinking and women. Journal of Substance Abuse Treatment. 23:1-7.

Colvin L, Payne J, Parsons D, Kurinczuk JJ, Bower C. (2007). Alcohol consumption during pregnancy in non-indigenous West Australian women. Alcohol Clin Exp Res. 31: 276–284.

Curtis J. (1994). Alcohol and Pregnancy: Information for health professionals. Alcohol Advisory Council

Deshpande S, Basil M, Basford L, Thorpe K, Piquette-Tomei N, Droessler J, Cardwell K, Williams RJ, Bureau A. (2005). Promoting alcohol abstinence among pregnant women: Potential social change strategies. Health Marketing Quarterly. 23(2): 45-67.

Dufour MC, Williams GD, Campbell KE, Aitken SS. (1994). Knowledge of FAS and the risks of heavy drinking during pregnancy, 1985 and 1990. Alcohol Health and Research World 18:86-92.

Eisen M, Keyser-Smith J, Dampeer J, Sambrana S. (2000). Evaluation of substance use outcomes in demonstration projects for pregnant and postparteum women and their infants: Findings from a quasi-experiment. Addict Behav. 25(1):123-129.

Elliott E, Bower C. (2008). Alcohol and pregnancy: the pivotal role of the obstetrician. Australian and New Zealand Journal of Obstetrics and Gynaecology. 48:236-239.

Elliott L, Coleman K, Suebwongpat A, Norris S. (2008). Fetal Alcohol Spectrum Disorders (FASD): systematic reviews of prevention, diagnosis and management. HSAC Report 1(9).

Fast DK, Conry J, Loock CA. (1999). Identifying fetal alcohol syndrome among youth in the criminal justice system. Devel Behav Paed 20:5

Food Standards Australia New Zealand (FSANZ), www.foodstands.gov.au

Graves K. (1993). An evaluation of the alcohol warning label: A comparison of the United States and Ontario, Canada in 1990 and 1991. Journal of Public Policy and Marketing. 31:471-490.

Greenfield TK. (1997). Warning labels: evidence on harm reduction from long-term American surveys. In Alcohol: Minimizing the Harm. What Works'! Plant, M., Single, E. and Stockwell, T. eds, pp. 105-125. Free Association Books, New York.

Habbick BF, Nanson JL, Snyder RE, Casey RE, Schulman AL. (1996). Fetal alcohol syndrome in Saskatchewan: Unchanged incidence in a 20-year period. Canadian Journal of Public Health 87:204-207.

Hankin JR, Firestone IJ, Sloan JJ, Ager JW, Martier SS. (1993). The impact of the alcohol warning label on drinking during pregnancy. Journal of Public Policy and marketing. 12(1):10-18.

Hankin JR, Firestone IJ, Sloan JJ, Ager JW, Sokol RJ, Martier SS. (1996). Heeding the alcoholic beverage warning label during pregnancy: Multiparae versus nulliparae. J Stud Alcohol. 57(2):171-177.

Hankin JR, Sloan JJ, Firestone IJ, Ager JW, Sokol RJ, Martier SS. (1993). A time series analysis of the impact of the alcohol warning label on antenatal drinking. Alcohol Clin Exp Res. 17(2):284-289.

Hankin JR, Sloan JJ, Firestone IJ, Ager JW, Sokol RJ, Martier SS. (1996). Has awareness of the alcohol warning label reached its upper limit? Alcoholism: Clinical and Experimental Research 20:440-444

Kaskutas L, Greenfield TK. (1992). First effects of warning labels on alcoholic beverage containers. Drug and Alcohol Dependence 31:1-14.

Klug MG, Burd L. (2003). Fetal alcohol syndrome prevention: annual and cumulative cost saving. Neuro Terat 25:763-765.

Leversha A, Marks RE. (1995). The Prevalence of fetal alcohol syndrome in New Zealand. New Zealand Medical Journal 108:502-505

Little RE, Young A, Steissuth AP, Uhl CN. (1984). Preventing fetal alcohol effects: effectiveness of a demonstration project. Ciba Found Symp. 105:524-274.

Lupton C, Burd L, Harwood R. (2004). Cost of fetal alcohol spectrum disorder. Am J Med Gen Part C. 127C:42-50

McLeod D, Pullon S, Cookson T, Cornford E. (2002). Factors influencing alcohol consumption during pregnancy and after giving birth. The New Zealand Medical Journal. 115:1157.

May PA. (1995). A multiple-level, comprehensive approach to the prevention of Fetal Alcohol Syndrome (FAS) and other alcohol-related birth defects (ARBD). International Journal of the Addictions, 30(12):1549-1602.

Mayer RN, Smith KR, Scammon DL. (1991). Evaluating the impact of alcohol warning labels. Advances in Consumer Research 18:706-714.

Mazis MB, Morris LA, Swasy JL. (1991). An evaluation of the alcohol label: initial survey results. Journal of Public Policy and Marketing 10:229- 241.

New Zealand Food Safety Authority (NZFSA), http://www.nzfsa.govt.nz/

New Zealand Health Information Service (NZHIS), www.nzhis.govt.nz

New Zealand Health Information Service. (2006). Report on Maternity: Maternal and New born Information 2003. Wellington: Ministry of Health.

New Zealand Health Information Service. (2007). Selected Health Professional Workforce in New Zealand 2006. Wellington: Ministry of Health.

New Zealand Institute of Economic Research (NZIER). (2005). "Cool revisited: Benefit cost analysis of Country of Origin Labelling".

New Zealand Paediatric Surveillance Unit. (2000). Annual Report of the New Zealand Paediatric Surveillance Unit.

O'Conner MJ, Whaley SE. (2007). Brief intervention for alcohol use by pregnant women. American Journal of Public Health. 97: 252-258.

O'Leary C. (2002). Fetal Alcohol Syndrome: A Literature Review. Publications Production Unit, Commonwealth Department of Health and Ageing Australia. http://www.alcohol.gov.au/internet/alcohol/publishing.nsf/Content/746BAD892492B586CA2572610010C29A/$File/fetalcsyn.pdf

Parackal S, Parackal M, Ferguson E, Harraway J. 2006. Report on Awareness of the Effects of Alcohol Use During Pregnancy Among New Zealand Women of Childbearing Age. Submitted to the Alcohol Advisory Council & Ministry of Health.

PHARMAC, www.pharmac.co.nz

Public Health Agency of Canada. (2005). Fetal Alcohol Spectrum Disorder (FASD): A Framework for Action. Ottawa: Canada.

Reynolds KD, Coombs DW, Lowe JB, Peterson PL, Gayoso E. (1995). Evaluation of a self-help program to reduce alcohol consumption among pregnant women. The international Journal of the Addictions. 30(4): 427-443.

Scammon DL, Mayer RN, Smith KR. (1991). Alcohol warnings: How do you know when you have had one too many? Journal of Public Policy and Marketing 10:214-218.

Stade B, Ungar WJ, Stevens B, Beyen J, Koren G. (2007). Cost of fetal alcohol spectrum disorder in Canada. Canadian Family Physician. 53(8): 1303-1304

Stade B, Ali A, Bennett D, Campbell D, Johnston M, Lens C, Tran S, Koren G. (2009). The burden of prenatal exposure to alcohol: REVISED measurement of cost. Canadian Journal of Clinical Pharmacology. 16(1): 91-102

Stade B, Ungar WJ, Stevens B, Beyen J, Koren G. (2006). The burden of prenatal exposure to alcohol: measurement of cost. JFAS Int e:E5.

Statistics New Zealand (SNZ), www.stats.govt.nz

Striessguth AP, O'Malley K. (2000). Neuropsychiatric implications and long-term consequences of fetal alcohol spectrum disorders. Seminars in Clinical Neuropsychiatry 5(3): 177-190.

Telethon Institute for Child Health Research (ICHR), www.ichr.uwa.edu.au/alcoholandpregnancy/resources

Thanh NX, Jonsson E. (2009). Costs of fetal alcohol spectrum disorder in alberta, Canada. Canadian Journal of Clinical Pharmacology. 16(1):80-90

Watson PE and McDonald B. (1999). Nutrition during pregnancy: A report to the Ministry of Health. Auckland: Albany campus, Massey University.

Whiteside-Mansell L, Crone CC, Conners NA. (1998). The development of evaluation of an alcohol and drug prevention and treatment program for pregnant women and children: The AR-CARES program. J Subst Abuse Treat. 16(3):265-275.

Wilkinson C, Allsop S, Cail D, Chikritzhs T, Daube M, Kirby G, Mattick R. (2009). Report 2 Alcohol warning labels: Evidence of impact on alcohol consumption amongst women of childbaring age.

Appendix 1: Updated Literature Searches

PREVENTION PROGRAMS LITERATURE SEARCH

Eligibility criteria

For inclusion in this section of the review, the evidence had to fulfil the criteria outlined in Table 1 and Table 2. These criteria were based on the criteria used in Elliott *et al* 2008.

Table 45 Criteria for determining study eligibility

Patient population	1. The general population (to identify primary prevention strategies) 2. Pregnant women (to identify secondary prevention strategies) 3. Women at high risk of having a child with FASD (to identify tertiary prevention strategies)
Intervention	1. Any strategy that aims to reduce the incidence of FASD
Comparator	Any comparator
Outcomes	1. Reduction in the incidence of FASD 2. Reduction in alcohol use during pregnancy or in women of childbearing age

Literature search

The literature search conducted in Elliott *et al* 2008 was updated. The updated search strategy is shown in Table 46. The initial search was run in April 2008, therefore the EMBASE and PsychInfo searches included articles published from the 1st of March 2008 to ensure that no publications were missed. The Scopus and Cochrane searches included all articles published in 2008 and 2009 as searches could not be restricted by month. The following HTA websites were also manually searched.

INAHTA website database: http://www.inahta.org/Search2/?pub=1

MSAC: http://www.msac.gov.au/

ANZHSN: http://www.horizonscanning.gov.au/

NZHTA: http://nzhta.chmeds.ac.nz/

NICE: http://www.nice.org.uk/

AHRQ/USPSTF: http://www.ahrq.gov/

CADTH: http://www.cadth.ca/

SBU: http://www.sbu.se

KCE: http://kce.fgov.be

Table 46 Updated search strategy

Database	Date searched	#	Search terms	Citations
EMBASE + MEDLINE	01 Mar 2009 - 02 Nov 2009	#1	'prevention'/exp OR 'prevention' OR preventing OR prevent	1,921,031
		#2	intervent*	483,042
		#3	'fetal alcohol syndrome'/exp OR 'fetal alcohol syndrome' OR 'fetal alcohol spectrum disorder' OR fasd	4,321
		#4	#1 OR #2 AND #3 AND [english]/lim AND [humans]/lim	649
		#5	'alcohol intoxication'/exp OR 'alcohol intoxication' OR 'alcohol abuse'/exp OR 'alcohol abuse' OR 'alcohol consumption'/exp OR 'alcohol consumption' OR 'alcoholism'/exp OR 'alcoholism' OR 'drinking behaviour' OR 'alcohol rehabilitation program'/exp OR 'alcohol rehabilitation program'	147,741
		#6	'pregnancy complication'/exp OR 'pregnancy complication' OR 'high risk pregnancy'/exp OR 'high risk pregnancy' OR 'pregnant woman'/exp OR 'pregnant woman'	104,862
		#7	#5 AND #6	896
		#8	'alcohol'/exp OR 'alcohol' AND 'pregnancy'/exp	9,156
		#9	#7 OR #8	9,531
		#10	#9 AND (#1 OR #2)	2,178
		#11	#4 OR #10	2,450
		#12	'mass screening'/exp OR 'mass screening' OR 'screening'/exp OR 'screening' OR 'questionnaire'/exp OR 'questionnaire' OR 'developmental screening'/exp OR 'developmental screening'	715,564
		#13	't ace' OR 'audit'/exp OR 'audit' OR 'cage'/exp OR 'cage' OR tweak	43,230
		#14	#12 OR #13	753,630
		#15	#14 AND (#3 OR #9)	1,003
		#16	#11 OR #15	3,027
		#17	#16 AND [1-3-2008]/sd NOT [16-11-2009]/sd	**389**
PsychInfo	01 Jan 2008 – 22 Oct 2009	1	exp PREVENTION/	33,040
		2	(prevention or preventing or prevent or intervent$).ti,ab.	201,731
		3	1 or 2	207,909
		4	exp Fetal Alcohol Syndrome/	766
		5	(fetal alcohol syndrome or fetal alcohol syndrome or fetal alcohol spectrum disorder or fetal alcohol spectrum disorder or fasd).ti,ab.	799
		6	4 or 5	982
		7	exp Alcohol Intoxication/	2,135
		8	exp Alcohol Abuse/	32,302
		9	exp ALCOHOLISM/	22,386
		10	exp Alcohol Rehabilitation/	8,261
		11	exp Alcohol Drinking Patterns/	43,648
		12	(alcohol intoxication or alcohol abuse or alcohol consumption or alcoholism or drinking behaviour or alcohol rehabilitation program).ti,ab.	29,441
		13	7 or 8 or 9 or 10 or 11 or 12	55,099
		14	(pregnancy complication or high risk pregnancy or pregnant woman).ti,ab.	330
		15	exp PREGNANCY/	12,294
		16	exp ALCOHOLS/	11,517
		17	15 and 16	137
		18	13 and 14	12
		19	17 or 18	148
		20	3 and 6	243
		21	19 or 20	388
		22	limit 21 to yr="2008 -Current"	41
		23	limit 21 to up="20080501-20091021"	47
		24	22 or 23	**51**

Database	Date searched	#	Search terms	Citations
Scopus	01 Jan 2008 – 22 Oct 2009	1	TITLE-ABS-KEY(prevention OR preventing OR prevent OR intervent*)	1,365,732
		2	TITLE-ABS-KEY("fetal alcohol syndrome" OR "fetal alcohol syndrome" OR "fetal alcohol spectrum disorder" OR "fetal alcohol spectrum disorder" OR fasd)	4,824
		3	TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")	143,894
		4	TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman")	158,208
		5	TITLE-ABS-KEY(pregnancy AND alcohol)	12,675
		6	(TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")) AND (TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman"))	1,952
		7	(TITLE-ABS-KEY(pregnancy AND alcohol)) OR ((TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")) AND (TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman")))	12,951
		8	((TITLE-ABS-KEY(pregnancy AND alcohol)) OR ((TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")) AND (TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman")))) OR ((TITLE-ABS-KEY(prevention OR preventing OR prevent OR intervent*)) AND (TITLE-ABS-KEY("fetal alcohol syndrome" OR "fetal alcohol syndrome" OR "fetal alcohol spectrum disorder" OR "fetal alcohol spectrum disorder" OR fasd)))	13,084
		9	((TITLE-ABS-KEY(pregnancy AND alcohol)) OR ((TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")) AND (TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman")))) OR ((TITLE-ABS-KEY(prevention OR preventing OR prevent OR intervent*)) AND (TITLE-ABS-KEY("fetal alcohol syndrome" OR "fetal alcohol syndrome" OR "fetal alcohol spectrum disorder" OR "fetal alcohol spectrum disorder" OR fasd))) AND SUBJAREA("PSYC" OR "MULT")	808
		10	((TITLE-ABS-KEY(pregnancy AND alcohol)) OR ((TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")) AND (TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman")))) OR ((TITLE-ABS-KEY(prevention OR preventing OR prevent OR intervent*)) AND (TITLE-ABS-KEY("fetal alcohol syndrome" OR "fetal alcohol syndrome" OR "fetal alcohol spectrum disorder" OR "fetal alcohol spectrum disorder" OR fasd))) AND SUBJAREA("SOCI" OR "MULT")	669

Database	Date searched	#	Search terms	Citations
		11	(((TITLE-ABS-KEY(pregnancy AND alcohol)) OR ((TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")) AND (TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman")))) OR ((TITLE-ABS-KEY(prevention OR preventing OR prevent OR intervent*)) AND (TITLE-ABS-KEY("fetal alcohol syndrome" OR "fetal alcohol syndrome" OR "fetal alcohol spectrum disorder" OR "fetal alcohol spectrum disorder" OR fasd))) AND SUBJAREA("PSYC" OR "MULT")) OR (((TITLE-ABS-KEY(pregnancy AND alcohol)) OR ((TITLE-ABS-KEY("alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")) AND (TITLE-ABS-KEY("pregnancy complication" OR "high risk pregnancy" OR "pregnant woman")))) OR ((TITLE-ABS-KEY(prevention OR preventing OR prevent OR intervent*)) AND (TITLE-ABS-KEY("fetal alcohol syndrome" OR "fetal alcohol syndrome" OR "fetal alcohol spectrum disorder" OR "fetal alcohol spectrum disorder" OR fasd))) AND SUBJAREA("SOCI" OR "MULT"))	1,369
		12	11 AND (LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008))	**117**
Cochrane	2008 – 05 Nov 2009	1	fetal alcohol spectrum disorder OR fetal alcohol spectrum disorder OR fetal alcohol syndrome OR fetal alcohol syndrome	**6**
Manual searching of HTA site				**2**
Total citations identified				**563**
Total citations after removal of duplicate citations				**487**

Assessment of study eligibility

Exclusion criteria, as shown in Table 47, were applied to the publications identified in the updated literature search.

Table 47 Exclusion criteria

Not a clinical study	Excludes non-systematic reviews, case reports, animal studies, short notes, letters, editorials, conference abstracts, in-vitro studies.
Wrong intervention	Does not assess a strategy which ultimately aims to reduce FASD or a screening tool that has been designed for use in pregnant women, designed to evaluates a woman's risk of having a child with FASD or has been designed for use in the general population but has been evaluated in pregnant women or used to evaluate if women are at increased risk of having a child with FASD
Wrong outcomes	Does not measure one of the four defined outcomes (i.e., reduction in incidence of FASD, reduction in alcohol use during pregnancy, increase in contraception/reduction in pregnancies in individual or groups of women known to be high alcohol users or sensitivity and specificity of a screening tool).
Not in English	Due to resource constraints non-English publications will not be included.

There were 487 non-duplicate studies identified by the search strategy. As detailed in Table 48, 18 full text articles were eligible for retrieval after excluding studies from the search titles and abstracts. Reasons are presented hierarchically such that the first reason in the list that applied is

reported. Of the full papers retrieved, 16 did not fulfill the inclusion criteria. Therefore, two articles were fully appraised.

Table 48 Application of selection criteria to citations

Exclusion criteria	Number
Total number of publications	487
Citations excluded after review of abstract/title	
Not a full publication of a clinical study: exclude non-systematic reviews, letters, editorials, notes, *in-vitro* studies and studies not deemed appropriate to the research question	160
Wrong intervention: study did include an intervention which aims to reduce the incidence of FASD or an appropriate alcohol screening tool	309
Wrong outcome: study did not measure one of the four defined outcomes	0
Total citations excluded after review of abstract/title	469
Full papers reviewed:	18
Citations excluded after review of full paper	
Not a full publication of a clinical study: exclude non-systematic reviews, letters, editorials, notes, *in-vitro* studies and studies not deemed appropriate to the research question	7[a]
Wrong intervention: study did include an intervention which aims to reduce the incidence of FASD or an appropriate alcohol screening tool	2
Wrong outcome: study did not measure one of the four defined outcomes	7
Not in English, article could not be retrieved	0
Total citations excluded after review of full publication	16
Total included citations	2

[a] The full text of one publication has not been reviewed, however it appears from the abstract to be a review article. An updated version of this document will be provided to FSANZ if a review of the full text shows that the paper evaluated any FASD reduction strategy.

Studies identified in the updated literature search

Two studies were identified in the updated literature search, the results of which have been described below.

Systematic reviews and meta-analyses

The updated literature search identified one systematic review.

Stade 2009

This Cochrane review identified four studies which evaluated a psychological or educational intervention to reduce alcohol consumption during pregnancy. All four studies (Chang 1999, Handmaker 1999, O'Conner 2007 and Reynolds 1995) were included in Elliott *et al* 2008. No additional studies published after the literature search for Elliott *et al* 2008 were identified.

Primary prevention

The updated literature search did not identify any publications which evaluated primary prevention strategies.

Secondary prevention

The updated literature search did not identify any publications which evaluated secondary prevention strategies.

Tertiary prevention

The literature search identified one publication which evaluated a tertiary prevention strategy. The study characteristics are summarised in Table 49.

Table 49 Study characteristics: Tertiary prevention strategies

Citation	Study type Study quality	Population and inclusion criteria	Intervention	Comparator	Relevant outcomes
Intervention Level IV evidence					
May 2008	Case series with pre-test/post-test outcomes Fair	Women in high risk communities N=137	Case management	Alcohol consumption prior to the intervention.	Stopped drinking completely in past 6 months Intentions to quit drinking Drinks consumed in past 30 days Peak BAC Times "high" or drunk in last 6 months Number of drinks on typical drinking day in last 30 days Number of drinking days in typical week (last 30 days) Number of drinks over last 30 days

May 2008

Case management was evaluated in six American Indian communities in the USA. Women who were identified as being at high-risk for drinking during pregnancy were offered case management, with the emphasis placed on re-organising the subjects life around the health of their unborn child. This involved abstinence from alcohol when pregnant, and abstinence or reduction of drinking when not pregnant. Birth control was also encouraged. Two field staff members (a prevention site manager and a case manager) were hired to work in each of the communities. Ongoing training, supervision and coordination of case management activities were provided by an experienced prevention intervention professional. Site visits, telephone consultations, live observations, and review of audio-taped sessions were used to increase the case management skills of all staff members and to provide specific consultation on specific cases. A total of 172 women were identified as candidates for case management, with 137 (76%) agreeing to take part. The publication included data up to 72 months after enrolment.

Alcohol use at baseline, 6 months and 12 months is shown in Table 50. The authors noted that the proportion of subjects who were not drinking at baseline (67.9%) was high as many subjects entered case management after a period of incarceration, a major period of introspection, or some other event that encouraged a period of abstinence (e.g., a social service threat of child removal). The proportion of subjects who were abstinent at 6 and 12 months did not drop significantly (60.5% and 56.8% respectively). The proportion of drinkers who intended to drop drinking completely increased from 46.2% at baseline to 100% at 12 months, although this was also not significant. The subjects consumed an average of 24.2 drinks at baseline, which did not change at 6 months, but increased at 12 months (36.2). There was also no change in the number of drinks consumed by drinkers in that last 30 days (55.3 at baseline, 45.8 at 6 months and 54.3 at 12 months). Among drinkers at baseline, estimated peak blood alcohol concentration was 0.275, which did not change significant at 6 months (0.234) or 12 months (0.263).

Table 50 Alcohol use at baseline, 6 months and 12 months

	Baseline N=115	6 months N=39	P value Baseline vs 6 months	12 months N=37	P value Baseline vs 12 months
Stopped drinking completely in past 6 months					
Yes, currently not drinking	67.9	60.5	NS	56.8	NS
No	2.8	5.3	NS	21.6	NS
Yes, stopped one or more times	29.4	34.2	NS	21.6	NS
Current drinkers, intentions to quit drinking					
Never intends to quit	15.4	0.0	NS	0.0	NS
May quit in future but not in next 6 months	15.4	75.0	NS	0.0	NS
Plans to quit in next 6 months	23.1	25.0	NS	0.0	NS
Plans to quit in next month	46.2	0.0	NS	100.0	NS
All women, drinks consumed in past 30 days					
Mean (SD)	24.2 (51.79)	23.5 (61.70)	NS	36.2 (65.07)	NS
Drinkers only, drinks consumed in past 30 days					
Mean (SD)	55.3 (66.75)	45.8 (80.83)	NS	54.3 (73.60)	NS
Among drinkers, peak BAC in past 6 months					
Mean (SD)	0.275 (0.151)	0.234 (0.172)	NS	0.263 (0.167)	NS

Abbreviations: BAC=Blood alcohol concentration, NS=Not significant, SD=Standard deviation

Alcohol consumption was also evaluated in pregnant women, as shown in Table 51. The authors noted that there was some transition of subjects in out and out of pregnancy status during the various time points. The proportion of subjects who were considered high risk for being high or drunk in the last 6 months significantly improved from 62.7% at baseline, to 33.3% at 6 month and 12 month follow-ups ($p<0.001$). There was a significant decrease in the proportion of women in at low risk in terms of the number of drinks consumed on a typical drinking day, from

67.6% at baseline to 44.4% at 12 months. When examining the number of drinking days in a typical week over the past 30 days, the percentage of women with no risk (no drinking days) increases from 69.5% at baseline to 80.0% at 6 month follow-up (p<0.001), but decreases to 40.0% at 12 month follow-up (p<0.001). Data about the number of drinks consumed over the past 30 days provided varied results. The number of women at highest risk (consuming eight or more drinks) was 15.4% at baseline, increased modestly to 16.7% at 6 month follow-up, but then dropped to 11.1% at 12 month follow-up (p<0.001). The average estimated peak BAC's of drinking episodes was high at all time points, ranging from 0.223 to 0.318 with no statistically significant change from 6 to 12 months.

Table 51 Risk and protective factors for FASD among pregnant women at baseline, 6 months and 12 months

	Baseline N=115	6 months N=39	P value Baseline vs 6 months	12 months N=37	P value Baseline vs 12 months
Times "high" or drunk in last 6 months (%)					
0 (no risk)	14.9	67.7	0.000	44.4	<0.001
1–2 (some risk)	22.4	0.0		22.4	
3+ (high risk)	62.7	33.3		33.3	
Number of drinks on typical drinking day in last 30 days (%)					
0 (no risk)	67.6	66.7	NS	44.4	0.001
1–2 (some risk)	-	-		-	
3+ (high risk)	32.4	33.3		55.6	
Number of drinking days in typical week (last 30 days) (%)					
0 (no risk)	69.5	80.0	0.000	40.0	<0.001
1–2 (some risk)	23.7	0.0		60.0	
3+ (high risk)	6.8	20.0		0.0	
Number of drinks over last 30 days (%)					
0 (no risk)	67.7	66.7	NS	44.4	<0.001
1–2 (some risk)	16.9	16.7		44.1	
3+ (high risk)	15.4	16.7		11.1	
Peak BAC in highest drinking episode					
Peak (mean)	0.294 (0.156)	0.223 (0.081)	NS	0.318 (0.088)	NS

Abbreviations: BAC=Blood alcohol concentration, NS=Not significant

Of the 119 children born over the study period, only one had been diagnosed with FASD and another may have FAS (final diagnosis was pending at the time of study publication).

The authors concluded that women who are at risk for giving birth to children with FASD in these American Indian are complex individuals with lifestyles and behaviours that are difficult to change. Generally, the drinking data document mixed but significant improvements from baseline through follow-up. For some variables, there was a statistically significant improvement at 6 months, however there was regression at 12 months.

ECONOMICS AND COST-OF-ILLNESS LITERATURE SEARCH

A literature search was conducted with an aim to identify any published economic evaluations and cost-of-illness studies for FASD. The search was conducted using EMBASE.com, which concurrently searched EMBASE and Medline databases. The search string used the literature search is presented in **Table 52**.

Table 52 Search strategy

Database	Date searched	#	Search terms	Citations
EMBASE + MEDLINE	01 Mar 2009 - 29 Oct 2009	#1	fetal OR fetal AND ('alcohol' OR 'alcohol'/exp OR alcohol)	12,462
		#2	'cost effectiveness analysis'/exp OR 'cost effectiveness analysis' OR 'economic evaluation'/exp OR 'economic evaluation' OR 'health economics'/exp OR 'health economics' OR 'cost minimization analysis'/exp OR 'cost minimization analysis' OR 'cost minimisation analysis' OR 'cost utility analysis'/exp OR 'cost utility analysis' OR 'quality adjusted life year'/exp OR 'quality adjusted life year' OR 'qaly'/exp OR 'qaly' OR 'life year saved'	454,541
		#3	'cost of illness'/exp OR 'cost of illness' OR 'cost of illness analysis'/exp OR 'cost of illness analysis' OR 'economic aspects of illness'/exp OR 'economic aspects of illness'	10,370
		#4	#2 AND #3	454,618
		#5	#1 AND #4	86
		#6	#5 AND [english]/lim	84

A total of 84 citations were identified. Initially, the review was performed using the publication title and, when available, the abstract. To further identify relevant studies, the citations were categorised based on the following exclusion criteria (**Table 53**).

Assessment of study eligibility

A citation that is not related to FASD, not an economic evaluation, or not a cost-of-illness study is excluded. Additionally, given that this economic analysis focuses only on prevention strategies during the antenatal period, rather the postnatal period, any economic evaluation that examined postnatal prevention strategies such as early screening is also excluded as they are of limited use in for this analysis. As shown in **Table 53**, the majority of the citations were excluded as they were not related to FASD.

Table 53 Application of selection criteria to citations

Exclusion criteria	Number
Total citations	84
Citations excluded after review of full publication	
Not examining FASD	51
Not an economic evaluation or cost-of-illness study	19
Wrong intervention such as early screening programme [a]	4
Duplicate data	4
Total citations excluded after review of full publication	78
Full papers reviewed (searched through EMBASE):	6
Full papers reviewed (searched through hand-search the included articles identified through EMBASE):	1 [b]
Full paper reviewed:	7
Citations excluded after review of full paper	
Not examining FASD	3
Not an economic evaluation or cost-of-illness study	0
Wrong intervention	0
Not in English, article could not be retrieved	0
Total citations excluded after review of full publication	3
Total included citations	4

Abbreviations: FASD = Fetal Alcohol Spectrum Disorders

a A total of four economic evaluations were identified that examined postnatal strategies to allow for early diagnosis and intervention for children with FASD. They are [1] Burd L, Cox C, Poitra B, Wentz T, Ebertowski M, Martsolf J T, Kerbeshian J, Klug M G. (1999). The FAS Screen: A rapid screening tool for fetal alcohol syndrome. Addiction Biology. 4(3): 329-336; [2] Hopkins R B, Paradis J, Roshankar T, Bowen J, Tarride J E, Blackhouse G, Lim M, O'Reilly D, Goeree R, Longo C J. (2008). Universal or targeted screening for fetal alcohol exposure: A cost-effectiveness analysis. Journal of Studies on and Drugs. 69(4): 510-519; [3] Poitra B A, Marion S, Dionne M, Wilkie E, Dauphinais P, Wilkie-Pepion M, Martsolf J T, Klug M G, Burd L. (2003). A school-based screening program for fetal alcohol syndrome. Neurotoxicology and Teratology. 25(6): 725-729; [4] Zelner I, Koren G. Universal or targeted screening for fetal alcohol exposure: A cost-effectiveness analysis. Therapeutic Drug Monitoring. 31(2): 170-172

[b] Stade B, Ungar W J, Stevens B, Beyene J, Koren G. (2006). The burden of prenatal exposure to alcohol: measurement of cost. J FAS Int. 4:e5

Studies identified

In total, seven articles were included and retrieved in full for review, six of which identified through the EMBASE search and one identified from a hand-searching the included studies (Stade *et al* 2006). Out of the seven reviewed articles, a total of three articles were further excluded from discussion as they were related only FAS, rather than FASD. As a result, a total of four articles were included for review. The full citation details for all four articles are tabulated in **Table 54**.

Table 54 Full citation details for all four articles

Number	Details
1	Stade B, Ungar W J, Stevens B, Beyene J, Koren G. (2006). The burden of prenatal exposure to alcohol: measurement of cost. J FAS Int. 4:e5
2	Stade B, Ungar W J, Stevens B, Beyen J, Koren G. (2007). Cost of fetal alcohol spectrum disorder in Canada. Canadian Family Physician. 53(8): 1303-1304
3	Stade B, Ali A, Bennett D, Campbell D, Johnston M, Lens C, Tran S, Koren G. (2009). The burden of prenatal exposure to alcohol: REVISED measurement of cost. Canadian Journal of Clinical Pharmacology. 16(1): 91-102
4	Thanh N X, Jonsson E. (2009). Costs of fetal alcohol spectrum disorder in alberta, Canada. Canadian Journal of Clinical Pharmacology. 16(1):80-90