HSAC Health Services Assessment Collaboration

A systematic review of the literature

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Fetal Alcohol Spectrum Disorders (FASD)

Systematic reviews of prevention, diagnosis and management

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Executive Summary

Introduction

Fetal Alcohol Spectrum Disorder (FASD) is an umbrella term used to describe the spectrum of disabilities (and diagnoses) 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.

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).

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.

The true extent of the incidence and prevalence of FASD in New Zealand is unknown. There are no nationally consistent definitions or diagnostic criteria for FASD and children are not routinely screened in infancy or early childhood. Alcohol Healthwatch estimate that based on overseas incidence rates of 3 per 1000 live births, at least 173 babies are born with FASD every year in New Zealand (Alcohol Healthwatch, 2007). This can be compared to 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). However other studies have estimated higher FASD incidence rates in New Zealand, with Curtis et al., (1994) estimating that 360 babies are born with FASD each year, and Leversha and Marks (1995) estimating that there are between 200 and 3540 babies born with FASD each year. The New Zealand Paediatric Surveillance Unit (NZPSU) collected data on the incidence and prevalence of FAS in New Zealand from July 1999 to December 2001. In 2000, 29 cases of suspected or definite FAS were reported. The 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). By comparison, 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).

FASD is associated with irreversible damage to neural development and leads to lifelong consequences for the individual, their family and society. FASD is therefore a significant contributor to the burden of disease, to the burden of social costs and to health inequalities. Both primary disabilities (resulting from organ and central nervous system deficits) and secondary disabilities (developed over time because of the lack of interventions) associated with FASD are 100% preventable if women abstain from alcohol use during pregnancy.

The financial implications of FAS and FASD have never been assessed in New Zealand but anecdotal evidence and financial estimates from overseas suggest it is a significant financial burden (Alcohol Healthwatch, 2007). Using a prevalence rate of 3 cases per 1000 live births (using the incidence rate as a proxy), these cases would conservatively be costing New Zealand taxpayers an extra $3.46 million per annum. If lifetime care costs for FAS and FASD were calculated together with a higher estimated prevalence rate (which is likely given the current drinking culture in New Zealand), then it can be assumed that FASD is costing New Zealand a substantial amount of avoidable expenditure.

There are a number of strategies that may be utilised to help reduce the burden of FASD. These include the use of effective screening, prevention and management programs, and accurate methods of diagnosing FASD.

Objectives

This report was requested by the New Zealand Ministry of Health's Population Health Directorate. This report contains a systematic review of the evidence pertaining to the relative effectiveness of various strategies to reduce the burden of Fetal Alcohol Spectrum Disorders (FASD). A top level review of diagnosis and management has also been included. In order to meet these objectives, the following research questions were defined:

Prevention and prenatal screening

- Do primary, secondary or tertiary prevention strategies aimed at reducing FASD reduce the incidence of FASD?
- Do primary, secondary or tertiary prevention strategies aimed at reducing FASD result in a reduction of the amount of alcohol consumed by women during pregnancy?
- Do secondary or tertiary prevention strategies aimed at reducing FASD result in a decreased number of pregnancies in groups or individual women known to be high users of alcohol?
- Are screening tools able to identify women at increased risk of having a child with FASD?

Postnatal screening and diagnosis

- Are postnatal screening tools (aimed at an individual or the mother of an individual suspected of having FASD) effective at identifying individuals who should undergo a full diagnostic FASD evaluation?
- Do diagnostic tools increase the accuracy of FASD identification?

Management

- Do management strategies improve clinical outcomes in individuals with FASD?

In addition to the reviews of effectiveness of various strategies to reduce the burden of FASD, this report also contains a review of the economics of FASD, in terms of the cost and cost-effectiveness of strategies targeting FASD, as well as studies examining the financial burden of FASD.

Methods

A systematic method of literature searching, study selection, data extraction and appraisal was employed. The literature was searched using the Medline, EMBASE, Scopus and PsychInfo databases and the Cochrane Library. The bibliographies of included papers were also examined for relevant studies. NHMRC dimensions of evidence, levels of evidence and quality assessment criteria were used to evaluate each of the included studies. Data was extracted onto standardised data extraction forms by one reviewer.

Publications were included in the systematic review of prenatal screening and prevention studies if they described a prevention strategy that aimed to reduce the incidence of FASD in the general population (primary prevention), pregnant women (secondary prevention) or women at high risk of having a child with FASD (tertiary prevention). Publications were included in the systematic review of screening tools if they evaluated an alcohol screening tool in pregnant women. The key outcomes were a reduction in the incidence of FASD, a reduction in alcohol use during pregnancy and the sensitivity and specificity of the screening tool.

Publications were included in the review of FASD diagnosis and management literature if they aimed to identify or diagnose an individual with FASD, or if they aimed to improve clinical outcomes in individuals with FASD. Only systematic reviews and published guidelines were eligible for inclusion in the review. The key outcomes were the sensitivity and specificity of FASD diagnosis and a reduction in the severity of primary and/or secondary disabilities or deficits associated with FASD.

Publications were included in the review of the economics of FASD if they reported any costing information or information on the cost-effectiveness of strategies to reduce FASD, or if they estimated the financial burden of FASD.

Key findings

Results of literature search

The literature search for prenatal screening and prevention strategies identified 3,655 publications. All publications were reviewed using the pre-defined study selection criteria and subsequently 67 publications were identified as being eligible for inclusion. This comprised of two systematic reviews, six primary prevention publications, 13 secondary prevention publications, 13 tertiary prevention publications, 27 screening publications and six guidelines.

The literature search for level I evidence for postnatal screening, diagnosis and management publications identified 812 publications. All publications were reviewed using the pre-defined study selection criteria and subsequently six publications (all guidelines) were identified as being eligible for inclusion in the postnatal screening and diagnosis review and six publications (two systematic reviews and four guidelines) were identified as being eligible for inclusion in the review of management strategies. Because few citations met the inclusion criteria, key narrative review articles were also included. One article which reviewed FASD diagnosis strategies and two articles which reviewed FASD management strategies were summarised.

The literature search for studies examining the economics of FASD identified six relevant studies. One of these represented a cost-effectiveness analysis of a universal or targeted screening tool for identifying FASD in children, three estimated the economic burden of FASD and two estimated the cost of specific strategies to reduce the burden of FASD.

Prenatal screening and prevention strategies

Prevention of FASD should consist of a primary prevention strategy (aimed at the general population), as well as more focussed strategies directed at specific subgroups of women. Primary prevention strategies aim to educate the general public about the risks of drinking during pregnancy and can include wide ranging, population interventions such as mass media campaigns, pregnancy health advisory labels and increased taxes. Secondary prevention strategies are aimed at pregnant women and include screening, early detection and treatment of pregnant women or women with an increased risk of having a child with FASD. Tertiary prevention strategies are targeted to women considered to be at a higher risk of having a child with FASD and aim to change their drinking behaviour.

The key outcome in all identified studies was a reduction in alcohol consumption during pregnancy. This has been used as a proxy outcome for a reduction in the number of children born with FASD. This outcome must be interpreted with care: although a study may report a small reduction in alcohol consumption, this may not be a meaningful, clinically relevant effect. For example, an intervention which reduces alcohol consumption by $1/10^{th}$ of a standard drink per week is unlikely to reduce the number of children born with FASD, even though this reduction may be statistically significant when compared with a control group. Although a small number of studies reported the number of children born with FAS or FASD, none were powered to detect a statistically significant difference

There are a number of screening tools that could be used to identify women who would benefit from a secondary/tertiary prevention strategy. The advantage of screening tools is that they are quick to administer and can be easily incorporated into a prenatal visit.

Primary prevention strategies

The characteristics and results of the identified primary prevention studies are summarised in **Table A**. There have been few papers published which evaluate the effect of primary prevention strategies on drinking behaviour during pregnancy. Three papers evaluated the effect of warning labels on alcohol bottles, one evaluated the effect of an educational campaign and one evaluated the effect of an alcohol ban. An additional paper assessed the impact of multiple sources of information. The studies were generally poor to fair quality. It is difficult to draw meaningful and reliable conclusions from such a small and varied body of evidence.

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, although this reduction was unlikely to be clinically significant. 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.

From the publications identified in the literature search, there is no strong evidence that any one primary prevention strategy is more effective in reducing alcohol consumption during pregnancy. This result should be considered in the context of the small number of published studies and the low-level of evidence available.

Table A Summary of primary prevention studies

Citation	Study characteristics / quality	Strength of evidence			Clinically relevant effect? [b]
		Intervention / comparator	Comparison	Statistical precision [a]	
Intervention Level III-2					
Bowerman 1997	Interrupted time series with a control group USA (Alaska) N=348 Fair	Alcohol ban in the town of Barrow (Nov 1994-Mar 1995) No alcohol ban in the town of Barrow (Jan 1992-April 1994)	Difference in alcohol consumption during pregnancy pre and post intervention.	Significant reduction in alcohol abuse (RR 0.21, 95% CI 0.08, 0.55).	Probably
Hankin 1993a,b	Interrupted time series with a control group USA (African American women) 1993a:N=12,026 1993b:N=4,379 1996:N=8,105 Fair	Warning labels on alcohol bottles (June 1990-1993) No warning labels on alcohol bottles (1986-June 1990)	Difference in alcohol consumption during pregnancy pre and post intervention.	1993ab: Modest reduction in alcohol consumption in light drinkers ($p<0.009$) but not heavy drinkers. 1996: Significant correlation between label and reduced alcohol consumption in nulliparae ($p<0.04$) but not multiparae women.	Unlikely
Intervention Level III-3					
Kaskutas 1998	Interrupted time series with a control group USA N=365 Poor	Exposure to a warning label, sign, ad or personal conversation about drinking during pregnancy Different level of message exposure	Correlation between number of warning labels seen by subjects and alcohol consumption during pregnancy.	No significant correlation.	No
Olsen 1989	Non randomised experimental trial Denmark N=27,630 Fair	Educational campaign in the town of Odense No educational campaign in the town of Aalborg	Alcohol consumption in the town which received the intervention compared with a control town.	No significant change.	No

Abbreviations: CI=confidence interval, RR=relative risk

[a] True effect rather than a chance finding?

[b] 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)

Secondary prevention strategies

The characteristics and results of the identified secondary prevention studies are summarised in **Table B**. The studies were generally poor to fair quality. 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 and Whaley 2007, Reynolds 1995 and Waterson and 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 program (Allan and Ries 1985, Cziezel 1999, Drinkard 2001, Eisen 2000 and Sarvela and Ford 1993). Women enrolled in these programs received information about alcohol consumption during pregnancy in addition to information about other behaviour (e.g. smoking, illicit drug use, nutrition, general prenatal care).

Three publications reported that pregnant women receiving an 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, O'Conner and 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 benefit from the intervention.

Table B Summary of secondary prevention studies

Citation	Study characteristics/ quality	Strength of evidence			Clinically relevant effect? [b]
		Intervention / comparator	Comparison	Statistical precision [a.]	
Intervention Level II					
Handmaker 1998	Randomised controlled trial USA N=42 Poor	Motivational intervention Letter with information about the risk of drinking during pregnancy	Intervention vs comparator arm	Significant reduction in blood alcohol concentration ($p<0.01$). No significant change in abstinent days or total consumption.	Possibly
Reynolds 1995	Randomised controlled trial USA N=40 Poor	Self-help intervention. Standard care.	Intervention vs comparator arm	Significant increase in subjects who quit drinking ($p<0.058$)	Yes
O'Conner and Whaley 2007	Cluster randomised controlled trial USA N=345 Fair	Brief intervention (with assessment of alcohol use and advice). Assessment of alcohol use and advice only.	Intervention vs comparator arm	Significant increase in proportion of women who were abstinent by the third trimester (OR=5.39, $p<0.058$)	Yes
Intervention Level III-1					
Waterson and Murray-Lyon 1990	Pseudo-randomised controlled trial UK N=75 Poor	Advice, reinforcement with and without an educational video, leaflet about alcohol use. A leaflet about alcohol use only.	Intervention vs comparator arm	No change in alcohol consumption	No
Intervention Level III-2					
Eisen 2000	Non randomised, experimental trial USA N=212 Poor	Drug prevention, education and treatment program. No intervention.	Intervention vs comparator arm	Significant increase in abstinence ($p=0.0001$) and significant decrease in using alcohol to intoxication ($p=0.0001$)	Yes
Meberg 1986	Case control study Norway N=132 Fair	Supportive counselling. Standard care.	Intervention vs comparator arm	No change in alcohol consumption	No
Sarvela and Ford 1993	Non randomised, experimental trial USA (teenagers) N=212 Fair	Prenatal care education program. Standard care.	Intervention vs comparator arm	No change in alcohol consumption	No

Table B Summary of secondary prevention studies (continued)

Citation	Study characteristics/ quality	Strength of evidence			Clinically relevant effect? [b]
		Intervention / comparator	Comparison	Statistical precision [a.]	
Intervention Level IV					
Drinkard 2001	Case series with post-test outcomes USA N=1,115 Poor	A healthy pregnancy program	Alcohol consumption pre vs post intervention	72% attributed reduction in drinking to intervention (significance not stated)	Unclear
Cziezel 1999	Case series with post-test outcomes Hungary N=75 Poor	Periconceptional care program.	Alcohol consumption pre vs post intervention	Reduction in proportion of women who drank >1 drink per week (significance not stated)	Unclear
Allen and Ries 1985	Case series with post-test outcomes USA N=75 Poor	Prenatal education class.	Alcohol consumption pre vs post intervention	No change in alcohol consumption	No
Little 1984 and Little 1985	Case series with post-test outcomes USA N=304 Poor	Interventional counselling.	Alcohol consumption pre vs post intervention	Significant downward trend drinking before and after the intervention ($p<0.001$).	Unclear
Larsson 1983	Case series with post-test outcomes Sweden N=464 Fair	Early detection and treatment program.	Alcohol consumption pre vs post intervention	>74% reported a reduction in alcohol consumption (significance not stated)	Unclear

Abbreviations: OR=odds ratio

[a] True effect rather than a chance finding?

[b] 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)

Tertiary prevention strategies

The characteristics and results of the nine identified tertiary prevention studies are summarised in **Table C**. The studies were generally poor to fair quality. Reduction of alcohol consumption was the primary aim in three of the studies (Chang 1999 and Chang 2000, Chang 2005 and Chang 2006 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 program (Belizán 1995, Corrarino 2000, Grant and Ernst 2003 and Grant 2005, Glor 1987, Halmesmaki 1998 and Whiteside-Mansell 1998). Women enrolled in these programs received

information about alcohol consumption during pregnancy in addition to information about other behaviour (e.g. smoking, illicit drug use, nutrition, general prenatal care).

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 program, which evolved from a 4-5 hour per day, 5 days a week outpatient service to a 7-8 hours per day, 5 days a week onsite residential support service program. The study was considered of poor quality due to significant methodological concerns. The effect of a second intervention was unclear.

Table C Summary of tertiary prevention studies

Citation	Study characteristics/ quality	Strength of evidence			Clinically relevant effect? [b]
		Intervention / comparator	Comparison	Statistical precision [a.]	
Intervention Level II					
Chang 2005 and Chang 2006	Randomised controlled trial USA N=304 Good	Brief intervention with a partner Diagnostic intervention only	Intervention vs comparator	Significant interaction between the brief intervention and alcohol consumption (p=0.01)	Possibly
Chang 1999 and Chang 2000	Randomised controlled trial USA N=250 Good	Brief intervention Alcohol assessment only	Intervention vs comparator	No change in alcohol consumption	No
Belizán 1995	Randomised controlled trial Argentina, Cuba Brazil and Mexico N=2,230 Fair	Home visits Routine antenatal care	Intervention vs comparator	No change in alcohol consumption	No
Intervention Level III-2					
Whiteside-Mansell 1998	Non randomised experimental trial USA N=95 Poor	Alcohol and drug prevention treatment program Women who refused to use the service	Intervention vs comparator	Significantly less drinking at delivery in intervention group (4%) vs control group (33%, p<0.05)	Yes
Intervention Level III-3					
Glor 1987	Three single arm studies Canada N=98 (intervention) Poor	Prenatal care Alcohol consumption in the average population and a high-risk population	Comparison between three groups	19% consumed alcohol at the end of the intervention compared with 63% in the average population (p<0.05)	Unclear

Table C Summary of tertiary prevention studies (continued)

Citation	Study characteristics/ quality	Strength of evidence			Clinically relevant effect? [b]
		Intervention / comparator	Comparison	Statistical precision [a.]	
Level IV					
Grant and Ernst 2003 and Grant 2005	Case series with post-test outcomes USA N=261 Poor	Home visitation program Substance abuse during a prior pregnancy	Alcohol consumption pre vs post intervention	No change in alcohol consumption	No
Corrarino 2000	Case series with post-test outcomes USA N=10 Poor	Linking subjects to drug treatment programs	Alcohol consumption pre vs post intervention	Reduction of the proportion of women with an 'extreme' alcohol severity score (significance not stated)	Unclear
Halmesmaki 1988	Case series with post-test outcomes Finland N=85 Fair	Counselling	Alcohol consumption pre vs post intervention	85% of moderate drinkers reduced consumption, compared with 55% of alcoholics and 57% of heavy drinkers (significance not stated)	Unclear
Rosett 1980 and Rosett 1983	Case series with post-test outcomes USA N=118 Poor	Counselling and prenatal care	Alcohol consumption pre vs post intervention	36% abstained / significant reduction in alcohol consumption prior to third trimester (significance not stated)	Unclear

Abbreviations: CI=confidence interval, RR=relative risk

[a] True effect rather than a chance finding?

[b] 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)

Prenatal screening tools

The literature search identified five publications which evaluated the ability of biomarkers to detect prenatal alcohol consumption (such as serum gamma-glutamyltransferase, aspartate aminotransferases and alanine aminotransferases). All publications reported that these measures were ineffective.

The pregnancy specific screening tools TWEAK and T-ACE were evaluated in seven publications (shown in **Table D**). Unlike general alcohol screening tools which were designed to detect harmful alcohol use in the general population, the TWEAK and T-ACE were specifically designed to detect the lower levels of alcohol consumption that may affect fetal development in pregnant women. All identified publications reported that the T-ACE and TWEAK were at least as effective as other general screening

tools and were generally shorter and easier to administer. The combined evidence from the literature indicates that these are the most appropriate screening tools to use in the clinical setting.

An additional twelve publications were identified in the literature search, however they were considered poor quality and no significant conclusions could be drawn from their results.

Table D Summary of prenatal screening studies

Citation	Study characteristics/ quality	Strength of evidence		
		Test / reference standard	Comparison	Key finding
Diagnostic Level III-2				
Sokol 1989	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence USA (African American women) N=971 Fair	T-ACE, CAGE, MAST Consuming ≥1 ounce of absolute alcohol per day (determined by interview)	Test vs reference standard	T-ACE was at least as effective as CAGE and MAST
Russell 1994, 1996	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence USA (African American women) 1994: N=4.743 1996: N=2,717 Fair	TWEAK, T-ACE, MAST, CAGE, NET Consuming ≥1 ounce of absolute alcohol per day (determined by Timeline Follow Back method)	Test vs reference standard	T-ACE and TWEAK were at least as effective as CAGE, MAST and NET
Chang 1998, 1999a, 1999b	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence USA 1998: N=350 1999a: N=350 1999b: N=135 Poor - Fair	TWEAK, T-ACE, SMAST, AUDIT, Medical record, Clinical predictors, 1998, 1999b: DSM-III-R, More than two drinks/day 1998, 1999a, 1999b: current alcohol consumption (all determined by Timeline Follow Back method, AUDIT and survey)	Test vs reference standard	T-ACE and TWEAK were comparable to other tests but sensitivity and specificity depended on the chosen cut-points
Dawson 2001	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence USA N=404 Poor	TWEAK, TWEAK in combination with additional questions Low risk, moderate risk, high risk consumption of alcohol (determined by interview)	Test vs reference standard	None of the additional items significantly improved the TWEAK

Abbreviations: DSM-III-R= Diagnostic and Statistical Manual of Mental Disorders, revised

One additional publication was identified which did not strictly meet the inclusion criteria, but which was considered to be of interest. Alvik 2005 compared the effect of administering the T-ACE confidentially (i.e. the clinician knew which patient completed the questionnaire) or anonymously (i.e. women did not identify themselves and left the questionnaire in a locked box in the waiting room). There was no significant difference in the proportion of subjects who were T-ACE positive, the proportion of subjects who reported binge drinking or usually drinking more than one drink on one drinking occasion. There was also no difference in the reported number of standard units consumed at different points throughout pregnancy. The self reported number of standard units per week was slightly higher in women who completed the questionnaires anonymously.

Post-natal screening and diagnosis

Postnatal screening is used to identify individuals who may have FASD. Individuals who are positive after postnatal screening should be referred for a full FASD diagnosis. A screening strategy should be broad and identify all individuals who may potentially have FASD. A full diagnostic evaluation should only be performed by a trained specialist, and often requires a multi-disciplinary team.

The literature search identified three articles describing FASD or FAS postnatal diagnostic criteria: Institute of Medicine, 4-Digit Diagnostic Code and Hoyme Updated Institute of Medicine Criteria. In addition, two screening guidelines (Canadian FASD Referral Guidelines and Centre for Disease Control FAS Referral Guidelines) and three diagnostic guidelines (Canadian Guidelines, Centre for Disease Control Guidelines and British Medical Association Guidelines) were identified.

The two screening guidelines recommend that screening should occur based on identification of facial features, known exposure to alcohol or learning and/or behavioural difficulties. The CDC guidelines state that the screening should provide assistance in making the referral decision, rather than be used as a definitive screening tool. All evaluations should be made on an individual basis and individuals should be referred for a full diagnostic evaluation if there is any concern about the results of the postnatal screen.

The five diagnostic approaches were broadly similar, evaluating maternal prenatal alcohol exposure, characteristic facial abnormalities, growth retardation and CNS abnormalities. All publications discussed the significant problems associated with diagnosing the less severe forms of FASD (i.e. children who did not meet the definition of FAS but had significant disabilities as a result of prenatal alcohol exposure). The diagnostic criteria and guidelines are widely used internationally, however there is no consensus on which criteria are most appropriate in the clinical setting.

Management

Clinical management of individuals diagnosed with FASD aims to minimise both primary and secondary disabilities. Primary disabilities are inherent functional problems directly caused by alcohol exposure *in utero* (such as mental retardation, learning disabilities, sensory impairments and speech and language difficulties). Secondary disabilities are acquired as individuals develop and can include mental

health diagnoses, criminal activities, inappropriate sexual behaviour, alcohol or drug abuse and difficulty obtaining and maintaining employment. The specific disabilities experienced by individuals with FASD can vary significantly.

The literature search identified two systematic reviews of FASD management strategies: Caley 2006 and Premji 2007. Caley 2006 did not identify any publications that met their inclusion criteria. Premji 2007 identified three publications: one found no significant difference in neuropsychological or intelligence tests after Cognitive Control Therapy while two publications found a significant improvement in hyperactivity when children received psychostimulant medications. The authors stated that no conclusions could be drawn with regards to effective interventions.

The literature search identified three guidelines (Alcohol Healthwatch New Zealand, British Medical Association, Canadian Government and Centre for Disease Control), and two review articles (Green 2007 and Kalberg and Buckley 2007) which discussed the importance of early intervention and effective management strategies to minimise the effect of primary disabilities and prevent secondary disabilities. Generally, individuals with FASD benefit from a broad management plan, which requires the support of clinical staff, caregivers and teachers. Individuals need access to multiple services (e.g. physical, occupational, speech, behavioural, mental health). Older children need practical interventions, such as improving skills of daily living, specific job skills and money management. There was insufficient evidence in the literature to recommend any specific management strategies.

Economic implications

FASD adversely impacts physical, behavioural, and cognitive functions of the sufferers. As such, FASD does not only create burden on the healthcare system, but also on social services, the education system, the judiciary system, and the family. The impact that FASD has on these segments of the economy is widely accepted, but there is little good-quality quantitative information.

The literature search identified one Canadian study which examined the cost effectiveness of universal or targeted meconium testing as a screening tool for fetal alcohol exposure, compared with usual care (Hopkins et al, 2008). Universal testing was performed on all infants while targeted screening was performed only on infants who had an older sibling diagnosed with FASD. The overall incremental cost per quality adjusted life year (QALY) was CA$65,875 (approximately equivalent to NZ$92,1330 for universal screening, with the QALY sensitive to a number of variables including discount rate, probability of no disease, cost of treatment and health utility gain). Targeted screening was dominant over usual care, resulting in an overall cost saving of CA$3,000 (NZ$4,196). The QALY was robust to changes of most variables with the exception of cost of early education training and the financial benefit of improved literacy. While the authors concluded that meconium screening for FASD represented good value for money, the study has limitations such as untested assumptions and its generalisability.

Three studies were identified which assessed the economic burden of FASD. Stade 2006 estimated the average adjusted annual costs associated with FASD in Canada. The cost was CA$14,342 (NZ$20,059) per child with FASD aged between 1 and 21 years of age. Costs varied depending on age of the child (and were highest for those

aged 6-16 years), severity (highest for those who were severely disabled). The primary components of the total costs were direct educational care (33%), direct medical costs (30%), social services (22%) and loss of productivity (8%).

Lupton 2004 performed a systematic review of the costs associated with FASD; however, the ten studies included in that review assessed the costs of FAS only. Adjusted estimates of the annual cost of FAS were calculated from eight studies; estimates ranged from US$3.6 billion to US$11 billion (NZ$5.9-17.9 billion). Two studies contributed towards the estimated lifetime cost of FAS, with the estimates being between US$1 million and US$1.5 million per child (NZ$1.6-2.4 million).

Klug and Burd 2003 examined the potential cost saving if a case of FAS was prevented in the state of North Dakota, USA. Based on estimated annual direct healthcare costs of a child with FAS (US$2,840 [NZ$4,628]) and without (US$500 [NZ$815]), the cost saving was estimated to be US$2,340 (NZ$3,813) per annum. It should be noted that this is likely to be an underestimate given it only includes healthcare costs, and not other costs to society such as educational or judicial costs.

Two studies costed specific strategies aimed at reducing the burden of FASD. Little 1984 costed a comprehensive programme that included public education, professional training, a telephone helpline, adult treatment and education services, and child assessment services. On average, US$2,429 (NZ$3,958) was spent on each child during the two year programme. The bulk of the total expenditure on the programme of US$1.487 million (NZ$2.4 million) was spent on direct medical services (approximately two thirds of that was spent on adults), 30% on education and professional training and 5% of the telephone information/helpline.

Burd 1999 estimated the cost per child of administration of a paper-based questionnaire, used as a screening tool to identify early cases of FAS who may need intervention services. The authors claimed that this tool had a sensitivity of 100% and a specificity of 94.1% and that it cost US$13 (NZ$21) per child and US$4,100 (NZ$6,681) per case identified. A particular limitation of this study was that it included only children with FAS, and only Native American children; hence, it is unclear how generalisable these results would be to a broader population of children at risk.

Conclusions

The review conclusions are based on the current evidence available from this report's critical appraisal of literature published on the effectiveness of FASD prevention strategies, screening tools, diagnostic systems and management strategies.

A detailed evaluation of FASD prevention programs and prenatal screening was performed. However, the interventions assessed varied widely, and the studies were generally of poor to fair methodological quality. While a small number of prevention strategies appear to have shown a beneficial effect on the reduction of alcohol consumption in pregnant women (e.g., alcohol prohibition and intensive alcohol rehabilitation), there are issues surrounding the interpretation of these results with regards to potential biases and the implementation of these strategies to the New Zealand setting. However, although many of the reviewed studies did not detect a

significant difference between the intervention of interest and a control group (who were typically given information about drinking during pregnancy), a reduction in alcohol consumption was commonly observed in women in the control group. A valid interpretation may be that simple interventions are effective, but that more intensive interventions do not necessarily add to that effectiveness. The simple interventions described in the literature involved the women being told about the effects of alcohol during pregnancy by their health care provider or via a letter or pamphlet.

Two screening tools, the TWEAK and T-ACE have been specifically designed for use in the prenatal setting. All identified publications reported that the T-ACE and TWEAK were at least as effective as other general screening tools and were generally shorter and easier to administer. The combined evidence from the literature indicates that these are the most appropriate screening tools to use in the clinical setting.

A limited review of high level evidence was carried out for postnatal screening and diagnosis, and management of FASD. There was very little high level evidence available for these strategies and as such it was not possible to identify which may be suitable for implementation in New Zealand. A review by Peadon 2008 found that the 4-Digit Diagnostic code was the most commonly used diagnostic criteria worldwide. There was broad agreement in the literature of the need for a multidisciplinary team (comprising of paediatricians, psychologists, psychiatrists, occupational therapists, speech therapists etc) in order to ensure optimal management of individuals with FASD. The specific disabilities experienced by individuals with FASD can vary significantly and consequently each individual requires a personalised management programme.

The assessment of the published economic evidence suggests that FASD represents a significant economic burden (NZ$1.6-2.4 million per child over their lifetime); however, it is not appropriate to comment on the costs of the individual strategies assessed in the identified studies as the effectiveness of these strategies was not formally assessed in this review. That said, given the extent of the economic burden of FASD, it is more than likely that simple, relatively low cost prevention strategies would represent significant value for money from a societal perspective.

Table of Contents

List of Tables and Figures

List of Abbreviations and Acronyms

ALT	Alanine aminotransferases
ARBD	Alcohol-related birth defects
ARND	Alcohol-related neurodevelopmental disorders
APSU	Australian Paediatric Surveillance Unit
AST	Aspartate aminotransferases
AUDIT	Alcohol Use Disorders Identification Test
BAC	Blood alcohol concentration
BMA	British Medical Association
CDT	Carbohydrate-deficient transferrin
CI	Confidence interval
FAE	Fetal alcohol effects
FAS	Fetal Alcohol Syndrome
FASD	Fetal Alcohol Spectrum Disorder
GGT	Gamma-glutamyltransferase
LSA	Lysergic acid amide
MAST	Michigan Alcoholism Screening Test
MCV	Mean corpuscular volume
N	Number
N/A	Not applicable
NICE	National Institute for Health and Clinical Excellence
NR	Not reported
NS	Not significant
NHMRC	National Health and Medical Research Council
NZPSU	New Zealand Paediatric Surveillance Unit
OR	Odds ratio
PAUL	Prenatal alcohol use interview
RCT	Randomised controlled trial
RR	Relative risk
SE	Standard error
WBAA	Whole blood associated acetaldehyde

Introduction

What is FASD?

Fetal Alcohol Spectrum Disorder (FASD) is an umbrella term used to describe the spectrum of disabilities (and diagnoses) 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 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.

The small molecular size of alcohol allows it to freely cross the placenta, attaining nearly equal concentrations in the mother and fetus (O'Leary, 2002). The damage caused by alcohol depends on the level of maternal alcohol consumption, the pattern of alcohol exposure and the stage of pregnancy during which the fetus is exposed. The teratogenic actions of alcohol can occur at any stage during the pregnancy. 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. Alcohol exposure can result in organ malformations, microcephaly or a normal-sized brain with a reduced number of brain cells. Growth and central nervous system (CNS) disturbances can result from exposure to alcohol during any time in pregnancy. 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).

Prenatal alcohol exposure

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). This may be explained by the variability of the definitions of consumption levels, methodological problems in study design and data analysis, and determining the importance of confounding factors (such as genetic predisposition). Alcohol is a teratogen and produces a range of outcomes with variable severity. The level of alcohol required to produce the milder forms of FASD has been difficult to establish and remains controversial. Not all children exposed to heavy alcohol consumption during pregnancy are affected or are affected to the same degree (O'Leary, 2002). It appears that a range of cofactors, such as the pattern and quantity of alcohol consumption, stage of fetal development and socio-economic risk factors such as poverty and smoking are important. Data on the rates of drinking during pregnancy are often based on self reporting and therefore are often unreliable.

Although a number of literature reviews have found that there is no consistent evidence of adverse health effects from low level prenatal alcohol exposure, evidence from animal experiments suggest that CNS damage may occur after low level exposure to alcohol (BMA Board of Science, 2007). Other studies have shown that acute exposure to alcohol can influence fetal behaviour, including a rapid decrease in fetal breathing and short term changes to the fetal nervous system (Akay and Mulder, 1996; McLeod *et al.*, 1983; Fox *et al.*, 1978).

As a result of this inconclusive evidence, there is some variation in national guidelines on alcohol consumption during pregnancy. The United States was the first country to recommend that women who are pregnant or considering pregnancy should not drink alcohol. This health warning was issued by the Surgeon General in 1981. The Canadian Government recommended abstinence in 1996. Guidelines released in France, Spain, the Netherlands, Switzerland and Ireland recommends that pregnant women avoid drinking alcohol (French Ministry of Health, 2002; Spanish Ministry of Health; Netherlands Institute for Health Promotion and Disease Prevention; Swiss Institute for the Prevention of Alcohol and Drug Addiction; Little Book of Women and Alcohol, 2003).

The Australian Alcohol Guidelines (2001) state that women who are pregnant or might soon become pregnant may consider not drinking at all, but if they choose to drink should have less than seven standard drinks over a week and no more than two standard drinks on any one day. These guidelines are being reviewed by the Australian National Health and Medical Research Council (NHMRC) and draft guidelines were released for public consultation in October 2007. The draft guidelines recommend that "For women who are pregnant, are planning a pregnancy or are breastfeeding: Not drinking is the safest option" (Australian Alcohol Guidelines for Low-Risk Drinking, 2007). These guidelines are expected to be finalised in 2008.

The National Institute for Health and Clinical Excellent (NICE) in the United Kingdom published updated Antenatal Care guidelines in March 2008. These guidelines state the following:

- Pregnant women and women planning a pregnancy should be advised to avoid drinking alcohol in the first 3 months of pregnancy if possible because it may be associated with an increased risk of miscarriage
- If women choose to drink alcohol during pregnancy they should be advised to drink no more than 1 to 2 UK units once or twice a week. Although there is uncertainty regarding a safe level of alcohol consumption in pregnancy, at this low level there is no evidence of harm to the unborn baby
- Women should be informed that getting drunk or binge drinking during pregnancy (defined as more than 5 standard drinks or 7.5 UK units on a single occasion) may be harmful to the unborn baby

The UK Department of Health guidelines (UK Department of Health Alcohol and Pregnancy Guidelines) state:

- When you drink, alcohol reaches your baby through the placenta. But the baby can't process it as fast as you can, so it is exposed to greater amounts of alcohol for longer than you are, which can seriously affect the baby's development.

- Pregnant women or women trying to conceive should avoid drinking alcohol. If they do choose to drink, to protect the baby, they should not drink more than 1-2 units of alcohol once or twice a week and should not get drunk. Additional advice from the National Institute for Health and Clinical Excellence (NICE) advises women to avoid alcohol in the first three months in particular, because of the increased risk of miscarriage.

The New Zealand Ministry of Health released guidelines in 2006 which recommended that "It is best not to drink alcohol during pregnancy" (New Zealand Ministry of Health, 2006). They state that "There is no known safe level for alcohol consumption at any stage during pregnancy. The lower limit of alcohol intake at which it is certain that no adverse effect will occur for any developing fetus has not as yet been determined, and may not exist".

Epidemiology of FASD

Worldwide

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. FASD diagnoses are rarely collected routinely, and when they are, data is often restricted to FAS only. Accurate reporting is further complicated by the lack of a uniformly accepted diagnostic criteria and poor knowledge of FASD among primary care providers.

A critique of published FAS and ARND incidence rates estimated that the overall worldwide incidence rate was at least 9.1 cases per 1000 live births (Sampson *et al*., 1997). The authors note that incidence rates varied significantly between different socio-economic groups.

The Australian Paediatric Surveillance Unit (APSU) included FAS in its surveillance program from 2001-2004 (Bower *et al.*, 2005). Of the 76 cases reported to the APSU, 25 had FAS, 49 had partial FAS and two had suspected FAS. The surveillance program only detected new diagnoses of FAS as seen by a paediatrician and therefore incidence rates were not reported. The incidence of FAS in 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).

There were approximately 0.21 cases of FAS per 1000 live births in 2004 in the United Kingdom. There is currently no reliable evidence on the incidence of FASD (British Medical Association, 2007). The Canadian government estimate that the rate of FASD is 9 cases per 1000 births (FASD: A framework for action, 2005).

In the United States, the incidence of FAS is reported to be between 0.5 and 2 per 1000 live births (British Medical Association, 2007). Other prenatal alcohol-related conditions, such as ARND and ARBD, are believed to occur approximately three times as often as FAS. Indigenous populations have a higher incidence and prevalence

of FAS due to higher rates of alcohol consumption. Prevalence rates as high as 20.5/1000 births have been reported in some Native American cultural groups (May *et al.,* 1991).

One of the highest FAS incidence rates has been reported in the Western Cape Providence of South Africa. In a study of children aged 5-9 years, 46.2 cases of FAS were diagnosed per 1000 children (May *et al.,* 2000). Rates of FASD would be significantly higher.

A prospective Italian study evaluated the prevalence of FAS and FASD in primary school aged children (May *et al*., 2006). The rate of FAS was estimated to be between 3.7 and 7.4 cases per 1000 children, while the FASD prevalence rate was estimated to be between 20.3 and 40.5 per 1000 children.

New Zealand

The true extent of the incidence and prevalence of FASD in New Zealand is unknown. There are no nationally consistent definitions or diagnostic criteria for FASD and children are not routinely screened in infancy or early childhood. Alcohol Healthwatch estimate that based on overseas incidence rates of 3 per 1000 live births, at least 173 babies are born with FASD every year in New Zealand (Alcohol Healthwatch, 2007). This can be compared to 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). However other studies have estimated higher FASD incidence rates in New Zealand, with Curtis *et al.,* (1994) estimating that 360 babies are born with FASD each year, and Leversha and Marks (1995) estimating that there are between 200 and 3540 babies born with FASD each year.

The New Zealand Paediatric Surveillance Unit (NZPSU) collected data on the incidence and prevalence of FAS in New Zealand from July 1999 to December 2001. In 2000, 29 cases of suspected or definite FAS were reported. The 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).

Burden of FASD

FASD is associated with irreversible damage to neural development and leads to lifelong consequences for the individual, their family and society. FASD is therefore a significant contributor to the burden of disease, to the burden of social costs and to health inequalities. Both primary disabilities (resulting from organ and central nervous system deficits) and secondary disabilities (developed over time because of the lack of interventions) associated with FASD are 100% preventable if women abstain from alcohol use during pregnancy.

A study by Salmon 2008 described the experience of New Zealand mothers and their biological children with FASD. The mothers described a range of issues of concern for their disabled offspring and themselves relating to health, social, educational, judicial systems, lack of knowledge by professionals and problems in diagnosis, to

being oppressed and stigmatized. Cognitive concerns for the offspring included attention-deficit, absence of fear, diminished memory and comprehension and inability to acknowledge and understand consequences. Behavioural issues included excessive crying or no crying as a baby, lying, stealing, hyper-activity, aggressiveness, destructiveness, sexual promiscuity and few friends. Other issues of concern were delayed milestones and numerous health problems.

A study of New Zealand caregivers raising children with FASD (Symes, 2004) reported the following:

- 58% reported mental health problems such as serious depression, suicide attempts, panic attacks and attention deficit disorders
- 93% lied frequently
- 75% had problems with theft
- 76% damaged property
- 26% lit fires
- 70% were violent
- 96% had anger problems
- 56% had sexuality problems
- 50% needed regular supervision in adulthood

These findings are similar to a longitudinal study of secondary disabilities in a population affected by FASD in the USA (Streissguth *et al.*, 1996). This study reported that:

- 90% had diagnosed mental health problems
- 80% of adults were dependent for their daily needs
- 80% had employment problems
- 60% were expelled from or dropped out of school
- 60% had been in trouble with the law
- 50% had inappropriate sexual behaviour
- 50% had been confined for mental health reasons, alcohol and drug treatment or as a consequence of law violations
- 30% had alcohol and drug problems (prevented from being more significant due to family intervention and control)

A Swedish study compared adult outcomes in children born to young mothers who fell pregnant during a period in which a state monopoly on alcohol sales was restricted in selected counties (Nilsson, 2008). The experiment was terminated early after investigators found that there was a sharp increase of alcohol consumption in the experimental counties, especially among youths. Both counties reported a more than ten-fold increase in beer consumption during the experimental period. Children who were *in utero* during the study had significantly reduced earnings, higher welfare dependence rates, and lower educational attainments compared with children who were *in utero* in the periods before and after the experiment.

The financial implications of FAS and FASD have never been assessed in New Zealand but anecdotal evidence and financial estimates from overseas suggest it a significant financial burden (Alcohol Healthwatch, 2007). Using a prevalence rate of 3/1000 live births, these cases would conservatively be costing New Zealand

taxpayers an extra $3.46 million per annum. If lifetime care costs for FAS and FASD were calculated together with a higher estimated prevalence rate (which is likely given the current drinking culture in New Zealand), then it can be assumed that FASD is costing New Zealand a substantial amount of avoidable expenditure.

Without appropriate knowledge and services to manage the needs of people with FASD appropriately, the unmet need of individuals will inevitably result in increased costs and duplication of ineffective services across lifetimes and generations. The cost of diagnosis, early intervention and ongoing support by appropriately trained personnel would likely be much less than the cost of not identifying and treating FASD affected individuals appropriately and would be far less traumatic and dysfunctional for families (Alcohol Healthwatch, 2007).

Potential strategies to reduce the burden of FASD

There are a number of strategies that may be utilised to help reduce the burden of FASD. These include the use of effective screening, prevention and management programs, and accurate methods of diagnosing FASD. Each of these strategies is briefly described below.

Screening

In the context of FASD, screening can refer to any of the following situations:

1. Prenatal screening
    - screening of women prior to conception or birth to identify women at high risk of having a child with FASD (e.g., screening by a GP)
2. Postnatal screening
    - Screening of mothers to trigger referral of children considered likely to have FASD to a paediatrician for formal diagnosis of FASD (e.g., asking mothers retrospective questions about alcohol consumption during that child's pregnancy)
    - Screening of children to trigger referral of children considered to be at risk of FASD to a paediatrician for formal diagnosis of FASD (e.g., through the health system, education system, the mental health system, the judicial system or social services)

In this report, prenatal screening will be discussed as a possible first step in secondary and tertiary prevention strategies. Postnatal screening of the mother or child will be discussed in the context of diagnosis.

Prevention

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. 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 treatment 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 drinking before pregnancy starts) is needed for most of the female population who are of childbearing age, secondary prevention (early detection and treatment) 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, including preventing further harm in current and subsequent pregnancies, finding and identifying children like to have FASD and reducing 'trans-generational' FASD (Alcohol Healthwatch, 2007).

The need for prevention strategies in New Zealand

FASD is 100% preventable if a woman abstains from alcohol use during pregnancy. In New Zealand, 81% of women of childbearing age consume alcohol (Statistics NZ, 1998 and New Zealand Health Survey, 2008). 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 2000 National Alcohol Survey and the 1995 National Alcohol Survey found that women of all ages increased the 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). High rates of drinking in these age groups, combined with a risk of unplanned pregnancies, suggests that many fetuses are likely to be inadvertently exposed (Elliott and Bower, 2008).

Secondary and tertiary prevention strategies also play a key role in reducing the incidence of FASD. New Zealand research indicates that 25% to 42% of women drink during pregnancy (McLeod et al 2002; Watson and McDonald 1999; Counsell et al 1994) and about 10% drink to intoxicating levels (Watson and McDonald 1999). This is similar to results of an Australian survey, which reported 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 New Zealand women of childbearing age about alcohol consumption in pregnancy is an important preventive measure.

There is no nationally consistent definition or diagnostic criterion for FASD in New Zealand. In addition, there is no comprehensive approach to FASD education, prevention or the management of FASD-affected individuals. As discussed previously, this is partially a result of the lack of scientific information and consensus within the medical community (e.g. the amount, frequency and timing of alcohol consumption during pregnancy that leads to FASD remains unclear). A recent

Australian study reported that almost half of surveyed obstetricians (42.9%) said that they did not routinely ask about alcohol in pregnancy and only 4.8% gave advice that was entirely consistent with the Australian National Health and Medical Research Council guidelines (Elliott and Bower, 2008). Only a small proportion (15.9%) routinely provided information about the consequences of alcohol in pregnancy. This may reflect a lack of knowledge. Only 17.5% of obstetricians surveyed could identify the diagnostic features of FAS and 57.1% thought they were not sufficiently aware of FAS.

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. This is particularly Alcohol Healthwatch recommend that 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 suggestion 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 (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 and 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 and 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 and 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, 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 tool (see following section for more information on 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.

Prenatal screening tools

Screening tools are often used to identify women who would benefit from secondary and tertiary prevention strategies. A screening program can be universal (all pregnant women are screened) or targeted (only women at high risk of having a child with FASD are screened). Universal screening reduces the risk of clinicians making ad hoc judgements about which women are likely to be at risk and reduces stereotyping and stigma.

There are currently no laboratory tests that can detect regular alcohol use during pregnancy. Breath analysis or urinalysis can be ineffective as alcohol is metabolised rapidly and it is unlikely that women will drink immediately prior to a clinical appointment. A number of biomarkers such as serum gamma-glutamyltransferase, aspartate aminotransferases and alanine aminotransferases have been assessed for their ability to detect alcohol consumption during pregnancy; however, no strong correlations have been reported.

There are several hundred screening instruments available which aim to identify patients with alcohol problems. Most screening tools involve an interview or questionnaire and use self-reported measures of alcohol consumption during pregnancy, which are often unreliable. Drinking behaviour is often poorly estimated due to the variation in alcohol concentration in different drinks and variation in the size of drinks (particularly between drinks served in bars and restaurants compared with drinks served at home). Self-reporting is prone to recall bias, particularly if questions are asked postnatally. The period between conception and pregnancy recognition is particularly prone to recall bias. Women may deliberately under-report alcohol consumption due to the stigma associated with drinking during pregnancy.

As a result of these factors, there is a considerable risk of underestimating alcohol consumption when relying on self-reported information. This can result in systematic misclassification, with women who drink heavily reporting their consumption as moderate, and those who drink moderately reporting light or no consumption. This contributes to inaccurate risk estimates and difficulties in studying the association between alcohol consumption and health outcomes.

Screening tools which average weekly amounts of drinking can mask episodes of binge drinking and fetal exposure to peak levels of alcohol. Evaluating an average level of drinking over longer time periods might obscure risks related to particular timing of the exposure (e.g. during the month of pregnancy). Ideally, screening should be performed prospectively and evaluate the timing, frequency, amount, duration, pattern and variability of drinking across the course of the pregnancy. However, this is often not feasible in the clinical setting as clinicians do not have time to make detailed assessments (particularly if the aim is to have every woman undergo the screening process). Therefore, screening tools use questions (or items) which aim to identify drinking in a rapid and easy to administer format.

Two of the most frequently used screening tools in the general population (i.e. not specifically pregnant women) are the AUDIT and CAGE questionnaires (**Table 1**). They are designed to identify individuals with hazardous or risky drinking behaviour. AUDIT is considered to be a more sensitive screening tool, while CAGE is more accurate in detection of lifetime and current harmful alcohol use (Whitlock, 2004). The key complication with these standard screening tools is that they are less effective at detecting problem drinking among women than men (Chang, 2001). This is attributable to the fact that these instruments are typically developed for men, who have different drinking patterns and different thresholds for problem drinking. They are designed to detect levels of alcohol consumption which will adversely affect an adult, although these levels may be significantly different to the alcohol consumption that places a fetus at risk of FASD.

Table 1 Screening tools designed for use in the general population

AUDIT	The AUDIT is a 10-item screening instrument developed by the World Health Organization to detect problem alcohol use and risk drinking among primary care patients. It includes 3 dimensions of alcohol-related risk/problems: (1) hazardous alcohol use—frequency of drinking, typical quantity, frequency of heavy drinking, (2) dependence symptoms—impaired control over drinking, increased salience of drinking, morning drinking, and (3) harmful alcohol use—guilt after drinking, blackouts, alcohol-related injuries, others concerned about drinking.
CAGE	The CAGE is a 4-item screening instrument designed to detect lifetime history of alcoholism that can be modified to detect recent/current alcoholism. The CAGE acronym reflects the following: "C" for feeling the need to cut down on drinking, "A" for people annoying you by criticizing your drinking, "G" for feeling bad or guilty about your drinking, and "E" for having an "eye-opener" (a drink upon arising in the morning).

Abbreviations: AUDIT=Alcohol Use Disorders Identification Test

As a result of the issues discussed above, specific screening tools for pregnant women have been developed. Two common tools are the T-ACE (a modification of the CAGE questionnaire) and the TWEAK (**Table 2**). Rather than identifying women with an alcohol abuse problem, they are typically used to identify women who would benefit from further information on the risks of drinking during pregnancy. These screening tools are specific and sensitive when used in the prenatal setting, and are considered the most appropriate screening tools for detecting potentially harmful prenatal alcohol consumption.

Table 2 Screening tools designed for use in the pregnant woman

T-ACE	The T-ACE is a modified version of the CAGE, designed to detect drinking and alcohol use disorders among pregnant women. "T" stands for tolerance, "A" for people annoying you by criticizing your drinking, "C" for feeling like you should cut down on your drinking and "E" for having an "eye-opener" (a drink upon arising in the morning).
TWEAK	The TWEAK is a 5-item scale developed to screen for alcohol problems and risk drinking during pregnancy. "T" stands for tolerance, "W" stands for close friends/relatives worrying or complaining about your drinking, "E" for eye-openers, "A" for amnesia (blackouts), and "K" for feeling the need to cut down on drinking.

Other screening tools are used in research. The Michigan Alcoholism Screening Test (MAST) is a detailed, 25-item questionnaire that is designed for use in the general population. The Timeline Follow Back method is an interview technique that assists

research participants and treatment clients in recalling past drinking. Both of these methods are considered too time consuming for use in the clinical setting. They are commonly used in the validation of shorter screening tools.

There are significant methodological issues surrounding the evaluation of screening tools in the prenatal setting. These are discussed in more detail on page 100. Briefly, there is no 'gold standard', or test which can detect a risk drinker and a non risk drinker with 100% accuracy. Therefore all screening tools are evaluated against a comparator which itself is not necessarily valid. Any screening tool must be considered in the context of its sensitivity and specificity, which changes depending on the definition of a 'positive response'. A perfect screening tool would be 100% sensitive and 100% specific, but in practice an increase in sensitivity is typically associated with a decrease in specificity. A balance between these two outcomes must be achieved. The importance of sensitivity and specificity must be assessed in the context of the intervention that pregnant women will receive if they are selected using a particular screening tool. It is therefore difficult to evaluate screening tools for prenatal alcohol consumption in isolation.

In New Zealand, all midwives routinely screen women for alcohol use as part of the first prenatal visit. Midwives ask women about their alcohol consumption prior to pregnancy and during pregnancy as part of an extensive prenatal assessment.

Diagnosis

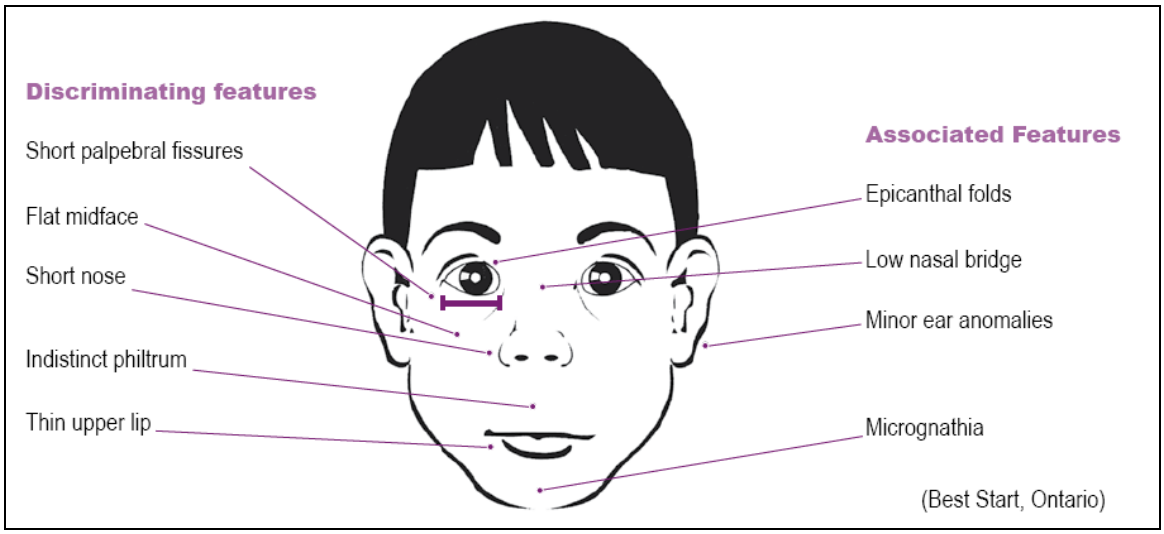
FASD is often described as a hidden or invisible disability as the disorders associated with FASD are difficult to diagnose. Early and accurate diagnosis is critical as it allows access to interventions and resources that aim to prevent the development of secondary disabilities (e.g., unemployment, mental health problems, trouble with the law, inappropriate sexual behaviour and a disrupted school experience). An early diagnosis will also allow appropriate intervention, counselling and treatment for the mother and may prevent the birth of affected children in the future.

Diagnosis of FAS occurs more frequently than a diagnosis of other components of FASD. Children with FAS develop distinctive facial characteristics included a flat elongated philtrum, a thin upper lip, small wide set eyes and a small head circumference. In the absence of full presenting features of FAS, the link between cognitive disorders and prenatal alcohol exposure is often not made at the clinical level because clinicians are not trained in FASD identification. Diagnosis is further complicated as many of the symptoms of FASD (such as growth impairment, cognitive impairment and learning disabilities) can have a range of causes. Some of these causes have a higher visibility and recognition than FASD (such as attention deficit hyperactivity disorders) and consequently clinicians may not link attention disorders to FASD. A general physical and neurologic examination, including appropriate measurements of growth and head size, assessment of characteristic findings and documentation of anomalies (e.g., cleft palate, congenital heart defects, epicanthic folds, high arched palate, poorly aligned or abnormal teeth, hypertelorism, micrognathia, abnormal hair patterning, abnormal palmar creases, skin lesions) is required to exclude the presence of other genetic disorders or multifactorial disorders that could lead to features mimicking FAS or partial FAS (such as Aarskog syndrome, Dubowitz syndrome, Maternal phenylketonuria fetal effects and Toluene embryopathy); (Chudley *et al*., 2005).

There are a range of screening and diagnostic tools that identify children who should undergo a full FAS or FASD diagnosis by a trained specialist (typically a paediatrician). Screening involves assessing a range of features such as physical defects, cognitive defects, CNS abnormalities and the presence of characteristic facial features. As part of the screening process an assessment of maternal alcohol consumption during pregnancy will often be conducted. This can involve the clinician asking the mother about her alcohol use during that child's pregnancy or by using an alcohol use screening tool. Screening must be approached with cautions as there is often a social stigma attached with any evaluation concerning prenatal alcohol exposure (National Centre on Birth Defects and Developmental Disabilities, 2004). In other families, direct information about alcohol use during pregnancy may not be available or only suspected.

There are a number of commonly used diagnostic tools. These include criteria published by the Institute of Medicine, updated Institute of Medicine criteria, the 4-Digit Diagnostic Code and guidelines published by the Canadian Government and the Centre for Disease Control. The diagnostic criteria are broadly comparable, and use an assessment of physical characteristics and maternal prenatal alcohol consumption to diagnose FASD or FAS. Key diagnostic features of FASD and FAS are characteristic facial abnormalities (such as flat upper lip, flattened philtrum and flat midface, shown in Figure 1), growth retardation an neurodevelopmental abnormalities including decreased cranial size, structural brain abnormalities, impaired fine motor skills and poor hand-eye coordination. Some diagnostic criteria also present criteria for alcohol related birth defects and alcohol related neurodevelopmental disorders, neither of which are designed to be used in the clinical setting.

Figure 1 Characteristic facial features associated with FAS



There are a number of issues which must be considered when assessing the feasibility of introducing an FASD diagnostic service. Although these issues will not be discussed further in this report, they include:

- The significant amount of time that it takes to make a diagnosis
- The need to use a multidisciplinary team

- The possibility of an increased rate of an abortion if a pregnant women is screened for alcohol use and told the risks of consuming alcohol during pregnancy
- The opposing views around the ethics of diagnosis, including the argument that it is unethical to diagnose a child because it has the potential to elicit guilt and shame for the mother and family, and the argument that a child must be diagnosed so that they can undergo early intervention and reduce the effect of secondary disabilities

Adult diagnoses

Diagnosis of adults creates special challenges in all aspects of the diagnosis. Physical features may change over time, there may be catch-up growth, and cumulative environmental influences may distort the evaluation of brain function. The characteristic craniofacial malformations of FASD diminish over time, however microcephaly, a poorly developed philtrum and a thin upper lip and, to a lesser degree, short stature persist (Sphor et al., 2007). The adult's history may include additional traumatic head injury, alcohol and drug abuse, and mental health problems. Although tests for the various domains are readily available, clinicians working with the adult FASD population find that the tests are often not sensitive to real-life issues. Reliable prenatal alcohol exposure history and informative birth records may be unavailable, making assessment more complicated (Chudley *et al*., 2007). In addition to the data required for the diagnosis, an assessment must include additional components such as functional literacy and numeracy, employability and quality of life, which fall within the domain of adaptive skills. The clinician should not rely solely on the self-report of the individual who is alcohol-affected; the history and abilities of the individual must be verified by a reliable source (Chudley *et al*., 2005). A further challenge is educating primary care physicians about the recognition and possibility of FASD so that they may be referred for a diagnostic evaluation (Chudley *et al*., 2007).

Although adults may have developed significant secondary disabilities, a diagnosis of FASD can mitigate progression. Individuals can receive appropriate interventions and reduce the effect of their secondary disabilities. It can also provide an individual with a reason for their disabilities and improve their connections to FASD services (Chudley *et al.,* 2007).

Management

The types of services required for individuals with FASD and their families vary according to the areas of the brain which have been affected, the age or level of maturation of the person, the health or function of the family and the overall environment in which the person is living. Management strategies should therefore be individually tailored to each child and their current social status as well as their specific cognitive, behavioural, physical and CNS deficits. It should be noted that individuals with undiagnosed FASD or those who are not specifically being managed for FASD are likely to be utilising a variety of healthcare services, however their delivery may be less than optimal. Therefore the introduction of specialised FASD services may result in a more appropriate utilisation of existing services rather than a significant additional burden to the healthcare system,

Early intervention programs improve developmental outcomes of primary disabilities and are critical factors in preventing secondary disabilities from developing. (Motz *et al.,* 2006; Steissguth *et al.,* 1996). Primary disabilities are the result of direct damage to the central nervous system as a result of prenatal alcohol exposure. These include developmental delay, hearing and eyesight problems, memory problems, epilepsy, physical birth defects and organ damage. In general, major disabilities are detected when the child presents to a clinician, although the disability is often not linked to prenatal alcohol exposure. Secondary disabilities are those that develop over time, and are predominately due to a lack of appropriate and timely protective interventions (Steissguth *et al.,* 1996).

Typical interventions for children with FASD may include physical therapy, speech and language therapy, occupational therapy, social skills training, vocational training (including basic skills required for daily living), training for specific job skills and education programs for parents, caregivers and teachers.

There are a number of practical issues which must be considered when assessing the feasibility of introducing an FASD management plan. These issues will not be discussed further in this report. The development of an FASD diagnostic and management plan must be performed in parallel as there are ethical issues to consider when diagnosing an individual with FASD but not providing adequate treatment. There is currently a lack of expertise and workforce capacity to management the problems associated with FASD, and these problems must be addressed as party of an overall strategic approach.

The effect of other drugs during pregnancy

Research investigating the effects of alcohol and other non-pharmaceutical drugs on pregnancy is generally segregated by the type of substance (O'Leary, 2002). There have been few longitudinal studies analysing the interactive effects of prenatal polydrug exposure. There is evidence that tobacco, marijuana and cocaine individually reduce fetal oxygenation by restricting uterine blood flow, while smoking and caffeine may reduce the level of certain nutrients. These effects may enhance the teratogenic effects of alcohol (Young, 1997). However, a prospective study found no increased risk of FAS with prenatal drug exposures including cigarettes, opiates, cannabis and cocaine (Sokol *et al.,* 1993).

Alcohol is a legal and socially acceptable drug. In contrast, most other non-pharmaceutical drugs which place the fetus at risk are illicit and result in different adverse outcomes. Cocaine use is associated with an increased risk of placental abruption, preterm birth and developmental and cognitive defects. Women who take heroin during pregnancy risk preterm birth, fetal death, stunted fetal growth and behavioural problems. Fetal exposure to amphetamines increases the risk of placental abruption, restricted fetal growth, developmental and behavioural defects and fetal death, while the use of ecstasy is associated with long-term learning and memory problems. Other drugs such as phencyclidine, ketamine, lysergic acid amide, glues and solvents can cause adverse outcomes including poor muscle control, behavioural and learning deficits, low birth weight, limb defects and heart defects. Infants who are exposed to drugs of addiction *in utero* can experience severe withdrawal symptoms

after delivery. The severity and onset of the withdrawal symptoms varies depending on the drug and the level of substance abuse during pregnancy.

Strategies to reduce the harm caused by non-pharmaceutical drugs other than alcohol are quite distinct from those used in FASD screening, prevention, diagnosis and management. Consequently, literature evaluating the effectiveness of strategies to reduce the use of drugs other than alcohol in pregnancy (e.g. cannabis and opiates) is not evaluated as part of this report. Studies including women with alcohol and other drug addictions will be included in this review if they report an appropriate FASD outcome. Only information related to alcohol use has been extracted from the publication and included in this report. However, studies in women with alcohol and other drug addictions which do not report FASD outcomes are excluded from this review, as are studies in women with other drug addictions only.

General Methods

As discussed, there are a number of different strategies that can be used to reduce the burden of FASD - including screening, prevention, diagnosis and management. While each of these strategies will be addressed in this systematic review, the level of detail assessed for each strategy will vary. As prevention is considered to be the most beneficial method of reducing FASD, this will be assessed in the greatest detail, with a full systematic review of all levels of the available evidence included for assessment. As such, all levels of evidence including existing systematic reviews and clinical practice guidelines, as well as different types of original studies will be eligible for inclusion. It should be noted that prenatal screening to identify women at risk of having a child with FASD will also be included in this section.

Post-natal screening/diagnosis and management of FASD will also be evaluated; however, the review of these strategies is limited to a 'top-level' review of existing systematic reviews and clinical practice guidelines. A brief narrative discussion of non-systematic but high quality, comprehensive reviews is also included in the report.

In addition, a Level 1 economic evaluation is included as part of this systematic review. In the case of this review this will encompass an estimate of the economic burden of FASD in New Zealand, an assessment of existing published economic evaluations of strategies to reduce FASD, and a qualitative (and if possible quantitative) discussion of the cost implications of implementing strategies that have been identified by the systematic review of the literature that are considered to be of potential value in New Zealand.

Research questions

The clinical questions to be answered by this review were defined by staff from the Population Health Directorate of the Ministry of Health. In general, the aim of this review was to evaluate the four main strategies for reducing the burden of FASD: prevention, screening, diagnosis and management.

The specific research questions for each strategy are listed in each appropriate section.

Literature search

A systematic method of literature searching and selection was employed in the preparation of this review. Searches were limited to English language material published from <1966 onwards. The searches for the different strategies were conducted between 17 March 2008 and 9 July 2008. Therefore, studies published after 9 July 2008 were not eligible for inclusion in the systematic review. Separate searches were conducted for each of the FASD strategies under review, as well as for the economic analysis.

The following databases/websites were searched:

Bibliographic databases

- EMBASE
- Medline
- Scopus
- PsychInfo

Review databases

- Cochrane Database of Systematic Reviews
- Cochrane Central Register of Controlled Trials
- Database of Abstracts of Reviews of Effectiveness
- Health Technology Assessment database
- NHS Economic Evaluation database

HTA Groups

- 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

Clinical Practice Guidelines

- National Guideline Clearing House database: http://www.guideline.gov/
- Agency for Healthcare Research and Quality: http://www.arhq.gov
- US Preventative Services Task Force: http://www.ahrq.gov/clinic/uspstfix.htm
- Scottish Intercollegiate Guidelines Network: http://www.sign.ac.uk

The reference lists of included papers were scanned to identify any peer-reviewed evidence that may have been missed in the literature search. Hand searching of a selection of relevant journals was also conducted. Contacting of authors for unpublished research was not undertaken in this review. A review of specific conference abstracts, selected by staff from the Population Health Directorate of the Ministry of Health was also undertaken.

Search terms were searched for as keywords, exploded where possible, and as free text within the title and/or abstract, in the EMBASE and Medline databases. Variations on these terms were used for Cochrane library and HTA websites modified to suit their keywords and descriptors. The search terms, search strategy and citations identified are presented separately for each strategy in the relevant section of this report.

The specific literature searches conducted for each strategy and the economic evaluation are listed in each appropriate section.

Assessment of study eligibility

Studies were selected for appraisal using a two-stage process. First, titles and abstracts (where available) identified from the search strategy were scanned and excluded as appropriate. Second, the full text articles were retrieved for the remaining studies and selected for inclusion and appraisal in the review if they fulfilled the study selection criteria outlined below. Double-checking of the eligibility of studies by a second reviewer was not undertaken.

The assessment of eligibility for each strategy is listed in each appropriate section.

Appraisal of included studies

Dimensions of evidence

The aim of this review was to find the highest quality evidence to answer the clinical questions being asked. In accordance with NHMRC guidance, the following dimensions of evidence were reviewed for each of the included studies (**Table 3**). It is important to recognise that the value of a piece of evidence is determined by all of these dimensions, not just the level of evidence.

Table 3 NHMRC Dimensions of evidence

Dimension	Reviewers definition
Strength of the evidence Level (see Table 4 below)	The study design used, as an indication of the degree to which bias has been eliminated by the design alone. The levels reflect the effectiveness of the study design to answer the research question.
Quality	The methods used to minimise bias within an individual study (i.e., other than design per se)
Statistical precision	An indication of the precision of the estimate of effect reflecting the degree of certainty about the existence of a true effect, as opposed to an effect due to chance
Size of effect	Determines the magnitude of effect and whether this is of clinical importance
Relevance of evidence	The considers the relevance of the study to the specific research question and the context in which the information is likely to be applied, with regard to a) the nature of the intervention, b) the nature of the population and c) the definition of the outcomes.

The evidence was assessed according to the dimensions outlined in **Table 3** above**.** Each study was also assigned a level of evidence in accordance with the NHMRC (2005) interim levels of evidence (see **Table 4**).

The highest level of evidence available is a systematic review of randomised controlled trials, which are considered the study type least subject to bias. Individual randomised controlled trials also represent good evidence. However, comparative observational studies such as cohort and case-control studies or non-comparative case series may often be more readily available. However, these lower levels of evidence remain subject to considerable bias.

Table 4 NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention and Diagnostic accuracy Studies

Level	Intervention	Diagnostic accuracy
I *	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial [a] • Cohort study • Case-control study • Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study [b] • Interrupted time series without a parallel control group	Diagnostic case-control study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)

Table notes

* A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence.

[a] This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (i.e. utilise A vs B and B vs C, to determine A vs C).

[b] Comparing single arm studies i.e. case series from two studies.

Note: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question e.g. level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence.

Source: National Health and Medical Research Council (2005)

Even within the levels of evidence stated above there is considerable variability in the quality of evidence. In accordance with NHMRC guidelines, it was necessary to consider the quality of each of the included studies. NHMRC quality checklists (1999) have been employed to appraise included articles (**Appendix C**). The characteristics and quality of each included study were assessed using a number of quality criteria, as shown in **Table 5**, with studies rated as good, fair or poor quality.

Table 5 Quality criteria for different levels of evidence (NHMRC, 2000b)

Study type	Quality criteria
Systematic review	Was a clinical question clearly defined? Was an adequate search strategy used? Were the inclusion criteria appropriate and applied in an unbiased way? Was a quality assessment of included studies undertaken? Were the characteristics and results of the individual studies appropriately summarised? Were the methods for pooling the data appropriate? Were sources of heterogeneity explored?
Randomised controlled trials	Was allocation to treatment groups concealed from those responsible for recruiting subjects? Was the study double-blinded? Were patient characteristics and demographics similar between treatment arms at baseline? Were all randomised participants included in the analysis? Were the statistical methods appropriate? Were any subgroup analyses carried out?
Screening articles (using diagnostic criteria)	Were patients selected consecutively? Is the decision to perform the reference standard independent of the test results? Was there a valid reference standard? Are the test and reference standard measured independently Has confounding been avoided? If the reference standard is a later event that the test aims to predict, is any intervention decision blind to the result?
Other trials	Has selection bias been minimised? Have adequate adjustments been made for residual confounding? Was follow-up for final outcomes adequate? Has measurement or misclassification bias been minimised?

Adapted from NHMRC (2000)

Data extraction

Data was extracted onto specifically designed data extraction forms, and included information regarding study design, patient characteristics, details of the intervention, relevant outcomes, study quality and relevant results. Data was extracted by one reviewer and checked by another.

Unless otherwise specified, the data that was most adjusted for confounders and/or multiple comparisons is reported. Furthermore, where subgroup analyses are available, these were reported if they are deemed relevant.

Completed data extraction forms containing detailed information regarding study characteristics and quality, together with a brief summary of study results, can be found in **Appendix D**.

Data synthesis

In addition to the level and quality of evidence of individual studies, the review will consider the body of evidence in total. This will involve consideration of the volume of evidence and its consistency.

For systematic reviews with analyses involving evidence from RCTs, a meta-analysis should be performed when appropriate using the methodology of the Cochrane Collaboration (Mulrow & Oxman, 1997). However, this should only be undertaken if the trial characteristics and patient characteristics are sufficiently homogeneous in order to justify a meta-analysis. Quantitative pooling may not be possible for other research questions or levels of evidence. Data from observational studies is subject to considerable heterogeneity and to biases that vary between studies.

The review will present the statistical precision of the estimated effect size (pooled if possible), together with a discussion of its clinical significance. Finally, the review will consider the relevance of the evidence, both with regard to the applicability of the patient population and the intervention, as well as the relevance to the New Zealand health care setting.

Limitations of the review methodology

This review used a structured approach to review the literature. However, there were some inherent limitations with this approach. All types of study are subject to bias, with systematic reviews, such as the one conducted here, being subject to the same biases seen in the original studies they include, as well as biases specifically related to the systematic review process. Reporting biases are a particular problem related to systematic reviews and include publication bias, time-lag bias, multiple publication bias, language bias and outcome reporting bias (Egger *et al.,* 2001). A brief summary of the different types of reporting bias is shown in **Table 6.** Other biases can result if the methodology to be used in a review is not defined *a priori* (i.e., before the review commences). Detailed knowledge of studies performed in the area of interest may influence the eligibility criteria for inclusion of studies in the review and may therefore result in biased results. For example, studies with more positive results may be preferentially included in a review, thus biasing the results and overestimating treatment effect.

*Table 6 Reporting biases in systematic reviews**

Type of bias	Definition and effect on results of review
Publication bias	The publication or non-publication of research findings. Small, negative trials tend not to be published and this may lead to an overestimate of results of a review if only published studies are included.
Time-lag bias	The rapid or delayed publication of research findings. Studies with positive results tend to be published sooner than studies with negative findings and hence results may be overestimated until the negative trials 'catch up'.
Multiple publication bias	The multiple or singular publication of research findings. Studies with significant results tend to be published multiple times which increases the chance of duplication of the same data and may bias the results of a review.
Citation bias	The citation or non-citation of research. Citing of trials in publications is not objective so retrieving studies using this method alone may result in biased results. Unsupported studies tend to be cited often which may also bias results.
Language bias	The publication of research findings in a particular language. Significant results are more likely to be published in English so a search limited to English-language journals may result in an overestimation of effect.
Outcome reporting bias	The selective reporting of some outcomes but not others. Outcomes with favourable findings may be reported more. For example, adverse events have been found to be reported more often in unpublished studies. This may result in more favourable results for published studies.

* Adapted from Egger *et al.* (2001).

Some of these biases are potentially present in this review. Only data published in peer-reviewed journals is included. No attempt was made to include unpublished material, as such material typically has insufficient information upon which to base quality assessment, and it has not been subject to the scrutiny of the peer-review process. In addition, the search was limited to English-language publications only so language bias is also potential problem. Outcome reporting bias and inclusion criteria bias are unlikely as the reviewers had no detailed knowledge of the topic literature, and the methodology used in the review and the scope of the review was defined *a priori*.

The review scope was developed with the assistance of Ministry of Health staff to support policy and purchasing relevant to New Zealand. The majority of studies included in this review were conducted outside New Zealand, and therefore, their generalisability to the New Zealand population and context may be limited and needs to be considered. This review was confined to an examination of the efficacy and safety of the interventions and did not consider ethical or legal considerations associated with those interventions.

The studies were initially selected by examining the abstracts of these articles. Therefore, it is possible that some studies were inappropriately excluded prior to examination of the full text article. However, where detail was lacking, ambiguous papers were retrieved as full text to minimise this possibility. Reasons for exclusion for every article included in the review are presented in **Appendix B** for transparency. Data extraction, critical appraisal and report preparation was performed by one reviewer and double-checked by another.

The review was conducted over a limited timeframe (March, 2008 – September, 2008).

For a detailed description of interventions and evaluation methods, and results used in the studies appraised, the reader is referred to the original papers cited.

Full Systematic Review of Prenatal Screening and Prevention Literature

Introduction

Prevention of FASD should consist of a primary prevention strategy (aimed at the general population), as well as more focussed strategies directed at specific subgroups of women. Secondary prevention strategies are aimed at pregnant women, while tertiary prevention strategies are aimed at women considered to be at a higher risk of having a child with FASD. There are a number of screening tools that could be used to identify women who would benefit from a tertiary prevention strategy. The advantage of screening tools is that they are quick to administer and can be easily incorporated into a prenatal visit. This report evaluates the effectiveness of interventions and screening tools in the prenatal setting.

As noted previously, the assessment of prenatal screening and prevention was conducted as a full systematic review, assessing all available levels of evidence. Therefore, both controlled and non-controlled evidence was eligible for inclusion in the review. It should be noted that the results of many of the included controlled studies showed that the majority of women reduce their alcohol intake as a result of their pregnancy, even without the introduction of a preventative intervention aimed at getting women to reduce their alcohol intake. As such, the value of evidence from non-controlled studies to this review is questionable. While such studies have been identified and assessed, the results of these studies are only briefly summarised, and their results should be interpreted with these issues in mind.

Methods

Research questions

The clinical questions to be answered by this review were defined by staff from the Population Health Directorate of the Ministry of Health in conjunction with the reviewers. In general, the aim of this section of the review was to comprehensively evaluate prenatal screening and prevention in FASD.

The primary research questions to be addressed within this section of the review were:

- Do primary, secondary or tertiary prevention strategies aimed at reducing FASD reduce the incidence of FASD?
- Do primary, secondary or tertiary prevention strategies aimed at reducing FASD result in a reduction of the amount of alcohol consumed by women during pregnancy?
- Do secondary or tertiary prevention strategies aimed at reducing FASD result in a decreased number of pregnancies in groups or individual women known to be high users of alcohol?
- Are screening tools able to identify women at increased risk of having a child with FASD?

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 developed *a priori* and described in the scoping protocol prepared prior to commencement of the review proper.

Table 7 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 2. Any alcohol screening tool that has been: a) designed for use in pregnant women or designed to evaluate a woman's risk of having a child with FASD or a) designed for use in the general population but has been evaluated in pregnant women or used to determine if women are at increased risk of having a child with 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 3. Sensitivity and specificity of the screening tool

With regards to the population, this review will examine primary, secondary and tertiary prevention strategies that aim to reduce the incidence of FASD. As primary prevention strategies are implemented at the population level, it is not possible to restrict the population for this review. Prevention programs aimed at pregnant women will be classified as a secondary prevention strategy. Prevention programs which only include women with an increased risk of having a child with FASD will be classified as a tertiary prevention strategy.

With regards to the intervention, this review will look at any prevention strategy that aims to reduce the incidence of FASD. Three broad categories of prevention studies have been identified: primary, secondary and tertiary. As such, the type of intervention has not been limited to any one type; any prevention strategy that aims to reduce the incidence of FASD (either explicitly or via a reduction in alcohol intake) is eligible for inclusion in the review.

Studies which evaluate alcohol screening tools will be included in this report if they:

(a) are designed for use in pregnant women,

(b) are designed to identify women with an increased risk of having a child with FASD,

(c) are designed to identify problem drinking in the general population but have been evaluated in pregnant women, or

(d) are designed to identify problem drinking in the general population but have been used to identify women with an increased risk of having a child with FASD

In order to identify as many types of prevention strategies as possible, the review will not be limited to studies comparing prevention strategies to any particular comparator strategy.

The aim of a preventive strategy is to reduce the occurrence of a particular event in time. Therefore, the preferred outcome measurement is a reduction in the incidence of that event. However, it is not always possible or feasible to measure such an outcome. Therefore, in cases where a surrogate measure has been shown to have a causative link with the outcome of interest, this can be used as a proxy outcome. In the case of this review, the primary outcome is a reduction in the incidence of FASD. However, as alcohol exposure during fetal development is known to be a cause of FASD, reduction in alcohol intake during pregnancy will be included as a surrogate outcome. Preliminary examination of the available evidence also suggests that in addition to reducing alcohol intake during pregnancy, increasing contraception in women of childbearing age who are know to be high alcohol users is another potential strategy in reducing FASD. However, it should be noted that this outcome is not relevant for primary prevention strategies and will only be assessed for secondary and tertiary prevention strategies.

This review will also evaluate the sensitivity and specificity of screening tools used to identify women at increased risk of having a child with FASD.

Literature search

A literature search was conducted as described in the 'General methods' section. The search terms, search strategy and citations identified for this section of the review are presented in **Table 8**.

Table 8 Prenatal screening and prevention search strategy

Database	Date searched	Search no.	Search terms	Citations
EMBASE + MEDLINE	<1966 – 17 April 2008	1	('prevention'/exp OR 'prevention') OR preventing OR prevent	1,489,543
		2	intervent*	373,329
		3	('fetal alcohol syndrome'/exp OR 'fetal alcohol syndrome') OR 'fetal alcohol syndrome' OR 'fetal alcohol spectrum disorder' OR 'fetal alcohol spectrum disorder' OR fasd	3,902
		4	(#1 OR #2) AND #3 AND [English]/lim AND [humans]/lim	540
		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')	132,672
		6	('pregnancy complication'/exp OR 'pregnancy complication') OR ('high risk pregnancy'/exp OR 'high risk pregnancy') OR ('pregnant woman'/exp OR 'pregnant woman')	96,464
		7	#5 AND #6	771
		8	pregnancy AND alcohol	8,680
		9	#7 OR #8	8,861
		10	('mass screening'/exp OR 'mass screening') OR ('screening'/exp OR 'screening') OR ('questionnaire'/exp OR 'questionnaire') OR ('developmental screening'/exp OR 'developmental screening')	634,421
		11	't ace' OR ('audit'/de OR 'audit') OR ('cage'/de OR 'cage') OR tweak	37,289
		12	#10 OR #11	667,279
		13	(#9 OR #3) AND #12	1,002
		14	#4 OR #9 OR #13	**2,890**
Scopus Psychology and Social Science search	<1966 – 5 May 2008	1	prevention OR preventing OR prevent OR intervent*	1,181,459
		2	fetal alcohol syndrome" OR "fetal alcohol syndrome" OR "fetal alcohol spectrum disorder" OR "fetal alcohol spectrum disorder" OR fasd	4,348
		3	alcohol intoxication" OR "alcohol abuse" OR "alcohol consumption" OR "alcoholism" OR "drinking behaviour" OR "alcohol rehabilitation program")	124,411
		4	pregnancy complication" OR "high risk pregnancy" OR "pregnant woman"	68,681
		5	pregnancy AND alcohol	11,163
		6	#3 AND #4	646
		7	#5 OR #6	11,299
		8	#7 OR (#1 AND #2)	11,433
		9	#8 LIMIT TO SUBJECT AREA "PSYC" OR "MULT"	685
		10	#8 LIMIT TO SUBJECT AREA "SOCI" OR "MULT"	571
		11	#9 OR #10	1,165
		12	exp PREVENTION/	30039
		13	(prevention or preventing or prevent or intervent$).ti,ab.	180130
		14	#12 OR #13	185925
		15	exp Fetal Alcohol Syndrome/	677
		16	(fetal alcohol syndrome or fetal alcohol syndrome or fetal alcohol spectrum disorder or fetal alcohol spectrum disorder or fasd).ti,ab.	709
		17	#15 OR #16	870
		18	exp Alcohol Intoxication/	2101
		19	exp Alcohol Abuse/	31291
		20	exp ALCOHOLISM/	21995
		21	exp Alcohol Rehabilitation/	8036
		22	exp Alcohol Drinking Patterns/	42365
		23	(alcohol intoxication or alcohol abuse or alcohol consumption or alcoholism or drinking behaviour or alcohol rehabilitation program).ti,ab.	28256
		24	#18 OR #19 OR #20 OR #21 OR #22 OR #23	53219
		25	(pregnancy complication or high risk pregnancy or pregnant woman).ti,ab.	299
		26	exp PREGNANCY/	11159
		27	exp ALCOHOLS/	10525
		28	#26 AND #27	123
		29	#24 AND #25	12
		30	(#28 OR #29) OR (#14 AND #17)	346
		31	#11 OR #30	**1,511**

Table 8 Prenatal screening and prevention search strategy (continued)

Database	Date searched	Search no.	Search terms	Citations
Scopus Psychology and Social Science search for screening articles	<1966 – 9 July 2008	1	(pregnancy complication or high risk pregnancy or pregnant woman).ti,ab.	304
		2	exp Alcohol Intoxication/	2122
		3	exp Alcohol Abuse/	31676
		4	exp ALCOHOLISM/	22225
		5	exp Alcohol Rehabilitation/	8121
		6	exp Alcohol Drinking Patterns/	42903
		7	(alcohol intoxication or alcohol abuse or alcohol consumption or alcoholism or drinking behaviour or alcohol rehabilitation program).ti,ab.	28621
		8	#2 or #3 or #4 or #5 or #6 or #7	53892
		9	#1 and #8	12
		10	exp PREGNANCY/	11364
		11	exp ALCOHOLS/	10701
		12	#10 and #11	124
		13	#9 or #12	135
		14	exp Fetal Alcohol Syndrome/	696
		15	(fetal alcohol syndrome or fetal alcohol syndrome or fetal alcohol spectrum disorder or fetal alcohol spectrum disorder or fasd).ti,ab.	730
		16	#14 or #15	893
		17	#13 or #16	1006
		18	exp screening/	9449
		19	exp screening tests/	3582
		20	exp QUESTIONNAIRES/	11050
		21	screening.ti,ab.	24690
		22	#18 or #19 or #20 or #21	39444
		23	(t ace or audit or cage or tweak).ti,ab.	6903
		24	#22 or #23	45808
		25	#17 and #24	**34**
Cochrane	<1966 – 17 March 2008	1	fetal alcohol spectrum disorder OR fetal alcohol spectrum disorder OR fetal alcohol syndrome OR fetal alcohol syndrome	**64**
Manual searching of HTA site				**53**
Total citations identified				**4,552**
Total citations after removal of duplicate citations				**3,655**

Assessment of study eligibility

The assessment of study eligibility was conducted as described in the 'General methods' section. Citations were excluded for the following reasons:

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.

Literature evaluating the effectiveness of strategies to reduce the use of drugs other than alcohol in pregnancy (e.g. cannabis and opiates) was not evaluated as part of this report. Studies including women with alcohol and other drug addictions will be

included in this review if they report one of the predefined outcomes. However, only information related to alcohol use will be extracted from the publication.

There were 3,655 non-duplicate studies identified by the search strategy. As detailed in **Table 9**, 185 full text articles were eligible for retrieval after excluding studies from the search titles and abstracts. Of the full papers retrieved, 118 did not fulfil the inclusion criteria. Therefore, 65 prevention and screening articles were fully appraised and are included in this report (listed in **Table 10** and **Appendix A**). All excluded articles are presented in **Appendix B**, annotated by reason for exclusion based on the exclusion criteria detailed above. Reasons are presented hierarchically such that the first reason in the list that applied is reported.

Table 9 Application of selection criteria to citations

Exclusion criteria	**Number**
Total citations	3,655
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	1,677
Wrong intervention: study did include an intervention which aims to reduce the incidence of FASD or an appropriate alcohol screening tool	1,774
Wrong outcome: study did not measure one of the four defined outcomes	19
Total citations excluded after review of abstract/title	3,470
Full papers reviewed:	185
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	50
Wrong intervention: study did include an intervention which aims to reduce the incidence of FASD or an appropriate alcohol screening tool	38
Wrong outcome: study did not measure one of the four defined outcomes	28
Not in English, article could not be retrieved	1
Insufficient details provided in article	1
Total citations excluded after review of full publication	118
Total included citations	67

The details of the 67 included prenatal screening and prevention citations are provided in **Table 10**.

Table 10 Included citations for prenatal screening and prevention of FASD

Citation ID	Citation
Systematic reviews	
Schorling 1993	Schorling JB. The prevention of prenatal alcohol use: A critical analysis of intervention studies. J Stud Alcohol 1993; 54(3):261-267.
Whitlock 2004	Whitlock EP, Polen MR, Green CA, Orleans C, Klein J. Behavoral Counseling Interventions in Primary Care to Reduce Risky/harmful Alcohol Use by Adults: A Summary of the Evidence for the U.S Preventitive Services Task Force. 1-46. 1-4-2004. Agency for Health Care Research.
Primary prevention studies	
Bowerman 1997	Bowerman RJ. The effect of a community-supported alcohol ban on prenatal alcohol and other substance abuse. Am J Public Health 1997; 87(8):1378-1379.
Hankin 1993a	Hankin JR, Firestone IJ, Sloan JJ, Ager JW, Martier SS. The impact of the alcohol warning label on drinking during pregnancy. J Pub Pol Mark 1993; 12(1):10-18.
Hankin 1993b	Hankin JR, Sloan JJ, Firestone IJ, Ager JW, Sokol RJ, Martier SS. A time series analysis of the impact of the alcohol warning label on antenatal drinking. Alcohol Clin Exp Res 1993; 17(2):284-289.
Hankin 1996	Hankin JR, Firestone IJ, Sloan JJ, Ager JW, Sokol RJ, Martier SS. Heeding the alcoholic beverage warning label during pregnancy: Multiparae versus nulliparae. J Stud Alcohol 1996; 57(2):171-177.
Kaskutas 1998	Kaskutas L, Greenfield L, Lee M, Cote J. Reach and effects of health messages on drinking during pregnancy. J Hea Ed 1998; 29(1):11-19.
Olsen 1989	Olsen J, Frische G, Poulsen AO, Kirchheiner H. Changing smoking, drinking, and eating behaviour among pregnant women in Denmark. Evaluation of a health campaign in a local region. Scand J Soc Med 1989; 17(4):277-280.
Secondary prevention studies	
Allan and Ries 1985	Allen CD, Ries CP. Smoking, alcohol, and dietary practices during pregnancy: Comparison before and after prenatal education. J Am Diet Assoc 1985; 85(5):605-606.
Czeizel 1999	Czeizel AE. Ten years of experience in periconceptional care. Eur J Obstet Gynecol Reprod Biol 1999; 84(1):43-49.
Drinkard 2001	Drinkard CR, Shatin D, Luo D, Heinen MJ, Hawkins MM, Harmon RG. Healthy Pregnancy Program in a national managed care organization: Evaluation of satisfaction and health behavior outcomes. Am J Managed Care 2001; 7(4):377-386.
Eisen 2000	Eisen M, Keyser-Smith J, Dampeer J, Sambrano S. Evaluation of substance use outcomes in demonstration projects for pregnant and postpartum women and their infants: Findings from a quasi-experiment. Addict Behav 2000; 25(1):123-129.
Handmaker 1999	Handmaker NS, Miller WR, Manicke M. Findings of a pilot study of motivational interviewing with pregnant drinkers. J Stud Alcohol 1999; 60:285-287.
Larsson 1983	Larsson G. Prevention of fetal alcohol effects. An antenatal program for early detection of pregnancies at risk. Acta Obsete Gynecol Scand 1983; 62(2):171-178.
Little 1984	Little RE, Young A, Streissguth AP, Uhl CN. Preventing fetal alcohol effects: effectiveness of a demonstration project. Ciba Found Symp 1984; 105(-):254-274.
Little 1985	Little RE, Streissguth AP, Guzinski GM, Uhl CN, Paulozzi L, Mann SL et al. An evaluation of the pregnancy and health program. Alcohol Health Res World 1985; 10(1):44-53, 71, 75.
Meberg 1986	Meberg A, Halvorsen B, Holter B. Moderate alcohol consumption - Need for intervention programs in pregnancy? Acta Obsete Gynecol Scand 1986; 65(8):861-864.

Table 10 Included citations for prenatal screening and prevention of FASD (continued)

Citation ID	Citation
O'Conner and Whaley 2007	O'Connor MJ, Whaley SE. Brief intervention for alcohol use by pregnant women. Am J Public Health 2007; 97(2):252-258.
Reynolds 1995	Reynolds KD, Coombs DW, Lowe JB, Peterson PL, Gayoso E. Evaluation of a self-help program to reduce alcohol consumption among pregnant women. Int J Addict 1995; 30(4):427-443.
Sarvela and Ford 1993	Sarvela PD, Ford TD. An evaluation of a substance abuse education program for Mississippi delta pregnant adolescents. J Sch Health 1993; 63(3):147-152.
Waterson and Murray-Lyons 1990	Waterson EJ, Murray-Lyon IM. Preventing fetal alcohol effects; A trial of three methods of giving information in the antenatal clinic. Health Edu Res 1990; 5(1):53-61.
Tertiary prevention studies	
Belizan 1995	Belizan JM, Barros F, Langer A, Farnot U, Victora C, Villar J. Impact of health education during pregnancy on behavior and utilization of health resources. Am J Obstet Gynecol 1995; 173(3 I):894-899.
Chang 1999	Chang G, Wilkins-Haug L, Berman S, Goetz MA. Brief intervention for alcohol use in pregnancy: A randomized trial. Addiction 1999; 94(10):1499-1508.
Chang 2000	Chang G, Goetz MA, Wilkins HL, Berman S. A brief intervention for prenatal alcohol use: an in-depth look. J Subst Abuse Treat 2000; 18:365-369.
Chang 2005	Chang G, McNamara TK, Orav EJ, Koby D, Lavigne A, Ludman B et al. Brief intervention for prenatal alcohol use: A randomized trial. Obstet Gynecol 2005; 105(5 I):991-998.
Chang 2006	Chang G, McNamara TK, Orav EJ, Wilkins-Haug L. Brief intervention for prenatal alcohol use: The role of drinking goal selection. J Subst Abuse Treat 2006; 31(4):419-424.
Corriarino 2000	Corrarino JE, Williams C, Campbell 3rd. WS, Amrhein E, LoPiano L, Kalachik D. Linking substance-abusing pregnant women to drug treatment services: a pilot program. J Obstet Gynecol Neonatal Nurs 2000; 29(4):369-376.
Glor 1987	Glor ED. Impacts of a prenatal program for native women. Can J Public Health 1987; 78(4):249-254.
Grant 2003	Grant T, Ernst CC, Pagalilauan G, Streissguth A. Postprogram follow-up effects of paraprofessional intervention with high-risk women who abused alcohol and drugs during pregnancy. J Comm Psy 2003; 31(3):211-222.
Grant and Ernst 2005	Grant TM, Ernst CC, Streissguth A, Stark K. Preventing alcohol and drug exposed births in Washington State: Intervention findings from three parent-child assistance program sites. Am J Drug Alcohol Abuse 2005; 31(3):471-490.
Halmesmaki 1988	Halmesmaki E. Alcohol counselling of 85 pregnant problem drinkers: Effect on drinking and fetal outcome. Br J Obstet Gynaecol 1988; 95(3):243-247.
Rosett 1980	Rosett HL, Weiner L, Zuckerman B. Reduction of alcohol consumption during pregnancy with benefits to the newborn. Alcohol Clin Exp Res 1980; 4(2):178-184.
Rosett 1983	Rosett HL, Weiner L, Edelin KC. Treatment experience with pregnant problem drinkers. J Am Med Assoc 1983; 249(15):2029-2033.
Whiteside-Mansell 1999	Whiteside-Mansell L, Crone CC, Conners NA. The development and evaluation of an alcohol and drug prevention and treatment program for women and children: The AR-CARES program. J Subst Abuse Treat 1999; 16(3):265-275.

Table 10 Included citations for prenatal screening and prevention of FASD (continued)

Citation ID	Citation
Screening studies	
Alvik 2005	Alvik A, Haldorsen T, Lindemann R. Consistency of reported alcohol use by pregnant women: Anonymous versus confidential questionnaires with item nonresponse differences. Alcohol Clin Exp Res 2005; 29(8):1444-1449.
Aros 2006	Aros S, Mills JL, Torres C, Henriquez C, Fuentes A, Capurro T et al. Prospective identification of pregnant women drinking four or more standard drinks ((greater-than or equal to)48 g) of alcohol per day. Subst Use Misuse 2006; 41(2):183-197.
Bad Heart Bull 1999	Bad Heart Bull L, Kvigne VL, Leonardson GR, Lacina L, Welty TK. Validation of a self-administered questionnaire to screen for prenatal alcohol use in Northern Plains Indian women. Am J Prev Med 1999; 16(3):240-243.
Budd 2000	Budd KW, Ross-Alaolmolki K, Zeller RA. Two prenatal alcohol use screening instruments compared with a physiologic measure. J Obstet Gynecol Neonatal Nurs 2000; 29(2):129-136.
Burd 2006	Burd L, Klug MG, Martsolf JT, Martsolf C, Deal E, Kerbeshian J. A staged screening strategy for prenatal alcohol exposure and maternal risk stratification. J R Soc Promot Health 2006; 126(2):86-94.
Chang 1998	Chang G, Wilkins-Haug L, Berman S, Goetz MA, Behr H, Hiley A. Alcohol use and pregnancy: Improving identification. Obstet Gynecol 1998; 91(6):892-898.
Chang 1999a	Chang G, Wilkins-Haug L, Berman S, Goetz MA. The TWEAK: Application in a prenatal setting. J Stud Alcohol 1999; 60(3):306-309.
Chang 1999b	Chang G, Goetz MA, Wilkins-Haug L, Berman S. Identifying prenatal alcohol use: Screening instruments versus clinical predictors. Am J Addict 1999; 8(2):87-93.
Chasnoff 2001	Chasnoff IJ, Neuman K, Thornton C, Callaghan MA. Screening for substance use in pregnancy: A practical approach for the primary care physician. Am J Obstet Gynecol 2001; 184(4):752-758.
Chasnoff 2007	Chasnoff IJ, Wells AM, McGourty RF, Bailey LK. Validation of the 4P's Plus(copyright) screen for substance use in pregnancy validation of the 4P's Plus. J Perinatol 2007; 27(12):744-748.
Christmas 1992	Christmas JT, Knisely JS, Dawson KS, Dinsmoor MJ, Weber SE, Schnoll SH. Comparison of questionnaire screening and urine toxicology for detection of pregnancy complicated by substance use. Obstet Gynecol 1992; 80(5):750-754.
Clark 1999	Clark KA, Dawson S, Martin SL. The effect of implementing a more comprehensive screening for substance use among pregnant women in North Carolina. Matern Child Health J 1999; 3(3):161-166.
Dawson 2001	Dawson DA, Das A, Faden VB, Bhaskar B, Krulewitch CJ, Wesley B. Screening for high- and moderate-risk drinking during pregnancy: A comparison of several tweak-based screeners. Alcohol Clin Exp Res 2001; 25(9):1342-1349.
Fabbri 2007	Fabbri CE, Furtado EF, Laprega MR. Alcohol consumption in pregnancy: Performance of the Brazilian version of the questionnaire T-ACE. Rev Saude Publica 2007; 41(6):979-984.
Goransson 2005	Goransson M, Magnusson A, Heilig M. Identifying hazardous alcohol consumption during pregnancy: implementing a research-based model in real life. Acta Obsete Gyn 2005; 85:657-662.
Kesmodel 2001	Kesmodel U, Olsen SF. Self reported alcohol intake in pregnancy: Comparison between four methods. Journal of epidemiology and community health 2001; 55(10):738-745.
Lapham 1993	Lapham SC, Henley E, Kleyboecker K. Prenatal behavioral risk screening by computer among native Americans. Fam Med 1993; 25(3):197-202.

Table 10 Included citations for prenatal screening and prevention of FASD (continued)

Citation ID	Citation
Larsson 1983	Larsson G, Ottenblad C, Hagenfeldt L. Evaluation of serum (gamma)-glutamyl transferase as a screening method for excessive alcohol consumption during pregnancy. Am J Obstet Gynecol 1983; 147(6):654-657.
Magnusson 2005	Magnusson A, Goransson M, Heilig M. Unexpectedly high prevalence of alcohol use among pregnant Swedish women: Failed detection by antenatal care and simple tools that improve detection. J Stud Alcohol 2005; 66(2):157-164.
Midanik 1998	Midanik LT, Zahnd EG, Klein D. Alcohol and drug CAGE screeners for pregnant, low-income women: The California perinatal needs assessment. Alcohol Clin Exp Res 1998; 22(1):121-125.
Moraes 2005	Moraes CL, Viellas EF, Reichenheim ME. Assessing alcohol misuse during pregnancy: Evaluating psychometric properties of the CAGE, T-ACE and TWEAK in a Brazilian setting. J Stud Alcohol 2005; 66(2):165-173.
Russell 1994	Russell M, Martier SS, Sokol RJ, Mudar P, Bottoms S, Jacobson S et al. Screening for pregnancy risk-drinking. Alcohol Clin Exp Res 1994; 18(5):1156-1161.
Russell 1996	Russell M, Martier SS, Sokol RJ, Mudar P, Jacobson S, Jacobson J. Detecting risk drinking during pregnancy: A comparison of four screening questionnaires. Am J Public Health 1996; 86(10):1435-1439.
Sokol 1989	Sokol RJ, Martier SS, Ager JW. The T-ACE questions: Practical prenatal detection of risk-drinking. Am J Obstet Gynecol 1989; 160(4):863-870.
Stoler 1998	Stoler JM, Huntington KS, Peterson CM, Peterson KP, Daniel P, Aboagye KK et al. The prenatal detection of significant alcohol exposure with maternal blood markers. J Pediatr 1998; 133(3):346-352.
Waterson and Murray-Lyon 1988	Waterson EJ, Murray-Lyon IM. Asking about alcohol: A comparison of three methods used in an antenatal clinic. J Obstet Gynaecol 1988; 8(4):303-306.
Waterson and Murray-Lyon 1989	Waterson EJ, Murray-Lyon IM. Screening for alcohol related problems in the antenatal clinic; An assessment of different methods. Alc Alc 1989; 24(1):21-30.
Guidelines	
Barcelona Department of Health	Anderson P, Gual A, Colom J. Alcohol and primary health care: Clinical guidelines on identification and brief identification. 2005. Department of Health of Cataolia: Barcelona.
British Medical Association	BMA Board of Science. Fetal alcohol spectrum disorders: A guide for healthcare professionals. 2007. British Library Cataloguing-in-Publication.
Canadian Government	Chudley A, Conry J, Cook J, Loock C, Rosales T, LeBlanc N. Fetal alcohol spectrum disorder: Canadian guidelines for diagnosis. Can Med Assoc J 2005; 172(Suppl):Mar05-S21.
CDC	National Centre on Birth Defects and Developmental Disabilities. Fetal Alcohol Syndrome: Guidelines for Referral and Diagnosis. 2004. Centre for Disease Control.
NSW Department of Health	Bell J. National clinical guidelines for the management of drug use during pregnancy, birth and the early development years of the newborn. 2006. Commonwealth of Australia, NSW Department of Health
SIGN	Scottish Intercollegiate Guidelines Network. The management of harmful drinking and alcohol dependence in primary care: A national clinical guideline. 2003. Scottish Intercollegiate Guidelines Network.

Results

Overview

The following section is organised in the following manner: (i) the results of existing systematic reviews of prevention will be presented and discussed; (ii) the results of original studies will be organised by type of prevention strategy (i.e., primary, secondary or tertiary) and discussed; it should be noted that there is significant overlap between the secondary and tertiary sections, and some studies provide data relevant to both; (iii) the findings of existing clinical practice guidelines for the prevention of the FASD will be presented and discussed; (iv) data will be presented on prenatal screening tools that can be used to identify women who may benefit from participation in secondary or tertiary prevention programs; and (v) the findings of existing clinical practice guidelines for screening to identify women at risk of having children with FASD will be presented and discussed. Finally, an overall summary and discussion of the available evidence will be presented and recommendations will be made regarding strategies that may be of value to the New Zealand setting.

More detailed information on each individual study included in the review is available in the data extraction tables in **Appendix D** or in the original papers. Only data directly relevant to the current review is presented in this section.

Systematic reviews and meta-analyses

Characteristics of included studies

The search strategy identified two relevant systematic reviews. The main characteristics of these reviews are described in **Table 11.** The first systematic review, by the U.S. Department of Health and Human Services Agency for Healthcare Research and Quality (Whitlock 2004), evaluated behavioural counselling interventions in primary care to reduce risky/harmful alcohol use. The review defined seven key research questions, all of which were aimed at the general population. A subgroup analysis of studies in pregnant women was performed as part of the evaluation for the research question “Does behavioural counselling intervention in primary care reduce risky or harmful alcohol use?” A total of 16 trials met the inclusion criteria, of which three were targeted at pregnant women. Only the results from the three trials targeted at pregnant women are included in this report.

Schorling (1991) published a systematic review of any intervention that aimed to reduce prenatal alcohol use. Studies were included if they 1) prospectively determined alcohol use in a cohort of pregnant women; 2) employed any intervention; and 3) measured alcohol use in individual women after the intervention. All studies which met these criteria were included (i.e., studies did not have to have a control arm). Only one study had an adequate concurrent control group, where subjects were allocated to the intervention or control group based on the day of their presentation to the clinic. All studies had poor compliance to eight methodological standards defined in the review. Five studies were identified: three included women with a range of drinking levels and two included only "heavy" drinkers.

Table 11 Prenatal screening and prevention: Systematic review characteristics

Author & year [Level of evidence]	Study type	Population	Screening	Intervention	Comparator	Outcomes of relevance
Whitlock 2004 [Level I]	**All trials**: Randomised, parallel-design trials **Chang 1999**: N=250 **Reynolds 1996**: N=78 **Handmaker 1999**: N=42	**All trials**: Pregnant women	**Chang 1999**: Score ≥2 using T-ACE **Reynolds 1996**: Consumed alcohol within the past month **Handmaker 1999**: Consumed alcohol within the past month	**Chang 1999**: 45 minute brief intervention followed by 2 hour assessment. Received take home manual. Follow up interview 2 months postpartum **Reynolds 1996**: 10 minute session with an educator and a self help manual to be completed over 9 days. Subjects completed a self-reported questionnaire (duration after intervention not specified in systematic review) **Handmaker 1999**: 1 hour alcohol assessment, 1 hour motivational interview. Drinking assessed at 2 months follow-up.	**Chang 1999**: Standard care **Reynolds 1996**: Standard care (including routine discussion on alcohol's fetal effects) **Handmaker 1999**: Received a letter informing them about risks of drinking during pregnancy	**Chang 1999**: Change in DR/drinking day and episodes of drinking **Reynolds 1996**: Quit rate and change in DR/month **Handmaker 1999**: Total drinks in past 2 months, peak BAC and total days abstinent

Table 11 Prenatal screening and prevention: Systematic review characteristics (continued)

Author & year [Level of evidence]	Study type	Population	Screening	Intervention	Comparator	Outcomes of relevance
Schorling 1992 [Level I/III]	**Meberg 1986:** Non-concurrent control group N=139 **Waterson 1990:** Concurrent but nonrandomised control group N=2100 **Larsson 1983:** Single arm N=464 **Rosett 1983:** Single arm N=162 **Halmesmaki 1988:** Single arm N=85	**Meberg 1986:** Pregnant women **Waterson 1990:** Pregnant women **Larsson 1983:** Pregnant women **Rosett 1983:** Pregnant women who were heavy drinkers **Halmesmaki 1988:** Pregnant women who were heavy drinkers	**Meberg 1986:** None **Waterson 1990:** None **Larsson 1983:** None **Rosett 1983:** >45 drinks/month, ≥5 on some days **Halmesmaki 1988:** >1 drink/day, ≥10 on some days	**Meberg 1986:** Two 1 hour visits with midwife. Follow-up post partum. **Waterson 1990:** Written information and verbal reinforcement video. Follow-up post partum **Larsson 1983:** 1 hour with midwife and social worker. More if subject drank > 30g / day. Follow-up post partum **Rosett 1983:** 3 ore more counselling sessions at 1-4 week intervals. Follow-up at each visit. **Halmesmaki 1988:** Counselling at 2-4 week intervals. Follow-up at each visit.	**Meberg 1986:** Intervention in control group unclear **Waterson 1990:** Received a pamphlet informing them about risks of drinking during pregnancy **Larsson 1983:** No control group **Rosett 1983:** No control group **Halmesmaki 1988:** No control group	**All trials**: Abstinence or reduction in alcohol intake

Abbreviations: bac=blood alcohol concentration, dr=drinking rate

Results

The main results of the studies assessed by the identified systematic reviews are described in **Table 12**.

The Whitlock (2004) systematic review reported the change in alcohol consumption results from the three included studies. Chang 1999 and Handmaker 1999 failed to show significant intervention impacts on indicators of average alcohol consumption. Reynolds 1995 reported marginally statistically significant differences favouring the intervention group on mean total drinks in the previous month (0.36 versus 1.14 in intervention and control groups, respectively, $p<.06$), and on percent abstinent (88% versus 69% in intervention and control groups, respectively, $p<0.058$). The review concluded that the few randomised controlled trials of interventions in prenatal care settings to eliminate or reduce drinking among pregnant women tended to show small or negligible effects. In comparison to the studies of adults (which are not presented here), these trials tended to include much lighter drinkers, to be smaller, and to have much shorter follow-up periods. Relatively long screening and screening-related assessments as part of the recruitment in two of the trials may have mitigated potential intervention effects. The authors note that a strength of these studies, however, was their inclusion of larger numbers of minority and poor patients than in the general adult studies. Given the importance of reducing the risk of fetal harm from exposure to alcohol, further research among pregnant women and women considering pregnancy is a high priority. As only three randomised trials were identified in the systematic review and all reported different outcomes, it is not appropriate to meta-analyse the results.

The Schorling (1992) systematic review reported the proportion of subjects who abstained from drinking alcohol or had a reduction in alcohol consumption. In each of the five studies that were reviewed, a majority of women reduced or eliminated alcohol consumption by the end of their pregnancies. However, similar reductions were also noted among women in the control groups of the two studies with control arms. The maximum difference in proportions between control and intervention groups (upper 95% confidence interval) was 14%, at best indicating a relatively small effect. Subjects enrolled in the control arm of Waterson 1990 received a pamphlet that discussed the risk of alcohol use during pregnancy. It is unclear if women in the control arm of Meberg 1986 received any specific information. The author notes that perhaps a simple message may be sufficient to lead to behaviour change for the majority of women.

Table 12 Prenatal screening and prevention: Systematic reviews results

Author & year [Level of evidence]	Key findings, change in alcohol consumption
Whitlock 2004 [Level I]	**Chang 1999** Decrease in DR/day: Intervention -0.3, control -0.4 Episodes of drinking: Intervention 0.7, control 1.0 (P=0.12) **Reynolds 1996** Quit rate: Intervention 88%, control 69% (P=0.058) DR/month: Intervention 0.36, control 1.14 (P=0.06) **Handmaker 1999** Total number of drinks: Intervention 0.46, control 0.40 Change in BAC: Intervention 0.77, control 0.46 Change in abstinent days: Intervention 0.69, control 0.2
Schorling 1992 [Level I/III]	**Meberg 1986** Control: 61% abstained Intervention: 53% abstained 95% CI for difference in proportions: -27% to 11% **Waterson 1990** [a] Control Trial 1: 63% abstained. Trial 2: 68% abstained Intervention Trial 1: 69% abstained. Trial 2: 66% abstained 95% CI for difference in proportions Trial 1: -4% to 14%. Trial 2: -15% to 9% **Larsson 1983** 70% abstained or reduced intake **Rosett 1983** 39% abstained, 28% reduced intake to less than 45g/month prior to third trimester **Halmesmaki 1988** 65% reduced intake by at least 50%

Abbreviations: bac=blood alcohol concentration, dr=drinking rate

[a] The Schorling 1992 systematic review does not explain the difference between trial 1 and trial 2 in the waterson 1990 publication

Discussion

The two systematic review identified in the literature search reported the results of eight studies which evaluated interventions which aimed to reduce prenatal alcohol use. Only three randomised controlled trials were identified. Both reviews concluded that there was insufficient evidence to recommend any specific intervention.

All of the eight studies described in the systematic reviews were identified in the literature search conducted for this review. Therefore the results of these studies will be discussed in more detail in the following sections.

Primary prevention strategies

Characteristics of included studies

The literature search identified six eligible primary research studies. The main characteristics of the included studies are summarised in **Table 13.**

A variety of primary prevention strategies were evaluated in the identified studies. These included: the effect of warning labels on alcohol bottles in pregnant women attending a prenatal clinic in the United States (Hankin 1993a, Hankin 1993b and Hankin 1996); the effect of alcohol prohibition in remote villages in Alaska (Bowerman 1997); a comprehensive, multi-faceted prevention campaign in a town in Denmark (Olsen 1989) and the effect of any type of alcohol reduction campaign on the level of drinking during pregnancy (Kaskutas 1998).

Table 13 Primary prevention: Study characteristics

Citation	Study type Study quality	Population	Intervention	Comparator	Outcomes
Intervention Level III-2 evidence					
Bowerman 1997	Interrupted time series with a control group. Poor	Pregnant women from remote villages in arctic Alaska N=348.	Alcohol prohibition in the town of Barrow (introduced in 1994). Women attending prenatal care between Nov 1994 – Mar 1995 N=73.	No alcohol prohibition in the town of Barrow. Women attending prenatal care between Jan 1992 – Apr 1994 N=275.	Reduction in regional alcohol abuse during pregnancy Reduction in first trimester alcohol abuse Reduction in second trimester alcohol abuse Reduction in third trimester alcohol abuse
Hankin 1996	Interrupted time series with a control group. Fair	Consecutive African American women attending a prenatal clinic between 1986 and 1993. N=8,105	Warning labels on alcohol bottles Women who attended a prenatal clinic after the introduction of the alcohol warning label (defined as after June 1990).	No warning labels on alcohol bottles Women who attended a prenatal clinic prior to the introduction of the alcohol warning label (defined as prior to June 1990).	Difference in drinking behaviour pre and post label using a simple time series analysis Difference in drinking behaviour pre and post label using OLS regression Effect of the warning label by nulliparae and multiparae
Hankin 1993a and Hankin 1993b	Interrupted time series with a control group. Fair	Consecutive African American women attending a prenatal clinic. Hankin 1993a: 1986 to 1991 N=12,026 Hankin 1993b: May 1989 to May 1992. N=4,379	Warning labels on alcohol bottles Women who attended a prenatal clinic after the introduction of the alcohol warning label (defined as after June 1990).	No warning labels on alcohol bottles Women who attended a prenatal clinic prior to the introduction of the alcohol warning label (defined as prior to June 1990).	Difference in drinking behaviour pre and post label using a simple time series analysis Difference in drinking behaviour pre and post label using an interventional model Mean alcohol consumption at the time of conception Mean alcohol consumption during pregnancy Predictors of in-pregnancy drinking Effect of the warning label by light drinkers and risk drinkers

Table 13 Primary prevention: Study characteristics (continued)

Citation	Study type Study quality	Population	Intervention	Comparator	Outcomes
Intervention Level III-3 evidence					
Kaskutas 1998	Interrupted time series without a parallel control group. Poor	Pregnant women who participated in telephone surveys N=365	Exposure to a warning label, a sign, or an ad about drinking during pregnancy or having a personal conversation about the risk of drinking during pregnancy.	Women who reported different levels of message exposure.	Proportion of women who had 2 or more drinks while pregnant Relationship between message exposure and alcohol consumption
Olsen 1989	Non-randomised, experimental trial. Fair	Pregnant women from two towns in Denmark between April 1984 and April 1987. N=27,630	An educational campaign which included education strategies aimed at health care providers, brochures, a TV show and stickers a. Pregnant women from the town of Odense N=13,815.	No educational campaign. Pregnant women from the town of Aalborg N=13,815.	Percentage of pregnant women who did not consume alcohol Average alcohol consumption per week Proportion of women who drank more than 8 or more drinks on a given occasion

[a] This intervention included both primary and secondary prevention strategies

Results

Level III-2 studies

BOWERMAN 1997

The study by Bowerman 1997 describes the effect of an alcohol ban, implemented in the town of Barrow in northern Alaska in 1994. The rate of alcohol abuse during pregnancy prior to the alcohol ban was compared to the rate of alcohol abuse during pregnancy after the alcohol ban. The study was considered to be of fair methodological quality, although the term 'alcohol abuse' was not defined and the method of evaluating alcohol consumption was not stated. The authors stated that the trial recruited all known women with viable pregnancies during the study period, although some women may have been missed.

Bowerman 1997 reported that there was a significant decrease in alcohol abuse during pregnancy (relative risk (RR) 0.21, 95% CI 0.08, 0.55) and during the first trimester (RR 0.25, 95% CI 0.07, 0.95) after an alcohol ban was introduced in a town in Alaska (**Table 14**). There was also a reduction in second trimester (15% to 7%) and third trimester (14% to 5%) alcohol abuse, although the authors noted that this was not significant. No adjustment for potential confounders was performed.

Table 14 Primary prevention: Level III-2 evidence (Bowerman 1997)

Outcome	Pre intervention	Post intervention	Statistics
Bowerman 1997			
Regional alcohol abuse during pregnancy	42%	9%	RR 0.21 (95% CI 0.08, 0.55)
Alcohol abuse during the first trimester	43%	11%	RR 0.25 (95% CI 0.07, 0.95)
Alcohol abuse during the second trimester	17%	7%	NS [a]
Alcohol abuse during the third trimester	14%	5%	NS [a]

Abbreviations: CI=confidence interval, RR=relative risk

HANKIN 1993A,B AND 1996

Hankin 1993a, Hankin 1993b and Hankin 1996 reported the impact of legislation introduced in the United States in November 1989 which required all alcohol bottles to carry labels warning of the danger of drinking during pregnancy. There was a delay between the implementation of the law and increased knowledge of the label due to the time required for the newly labelled bottles to appear on retailers' shelves. 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 three publications recruited consecutive women from the same hospital and analysed data from overlapping time periods, although the degree of overlap is not clearly stated. All publications performed sub-group analyses. Hankin 1993a and Hankin 1993b evaluated the effect of alcohol warning labels on light drinkers compared with heavy drinkers. They describe a similar cohort of women and the results of these two publications have been presented, analysed and discussed together. Hankin 1996 assessed the different impact of the warning label on women who had previously

given birth (multiparae) compared with women who had not previously given birth (nulliparae). All studies were considered to be of fair methodological quality. The studies enrolled consecutive women and used validated questionnaires to evaluate alcohol consumption. Analyses were performed using adjustments for potentially confounding variables.

Three publications reported pre and post intervention data, as shown in **Table 15**. 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). 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 addition, 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 15 Primary prevention: Level III-2 evidence (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

Level III-3 studies

KASKUTAS 1998

Kaskutas 1998 evaluated the correlation between exposure to any type of health message related to the dangers of prenatal alcohol consumption and changes in drinking behaviour during pregnancy. Women between 18 and 40 were randomly selected to participate in a telephone survey. Only the analyses performed on women who reported that they had been pregnant in the last 12 months are included in this report. Women were asked if they had been exposed to a warning label, a sign or an ad about drinking during pregnancy, and if they had had a personal conversation about drinking during pregnancy. The quality of the study was considered to be of poor methodological quality.

Following a telephone survey, Kaskutas evaluated the effect of exposure to multiple types of warning messages (as shown **Table 16)**. A similar proportion of pregnant women who reported drinking at least two drinks while pregnant had seen at least one warning message (35%) compared to women who had not seen any warning messages (38%). No significant correlation was found between exposure to any type of warning message or the cumulative count of message exposures and a reduction in drinking during pregnancy.

Table 16 Primary prevention: Results from interrupted time series without a parallel control arm

Outcome	Other analyses	Statistics
Kaskutas 1998		
Proportion of pregnant women who had 2 or more drinks at least once while pregnant	Women who reported seeing at least one warning messages vs women who had not seen any warning messages: 35% vs 38%	NS
Relationship between message exposure and decreased alcohol consumption during pregnancy	No statistically significant relationship was found between exposure to any type of warning label, sign, ad, conversation or the cumulative count of message exposure.	NS

Abbreviations: NS=not significant

OLSEN 1989

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 17**, 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.

Table 17 Primary prevention: Results from non-randomised, controlled studies

Outcome	Intervention group	Control group	Statistics
Olsen 1989			
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

Discussion

In an attempt to illustrate the entire body of primary prevention evidence directly relevant to the current review, **Table 18** summarises the evidence presented in accordance with the NHMRC dimensions of evidence.

There have been few papers published which evaluate the effect of primary prevention strategies on drinking behaviour during pregnancy. Three papers evaluated the effect of warning labels on alcohol bottles, one evaluated the effect of an educational campaign and one evaluated the effect of an alcohol ban. An additional paper assessed the impact of multiple sources of information. It is difficult to draw meaningful and reliable conclusions from such a small and varied body of evidence.

In addition to the paucity of included publications, the level of evidence is weak. All of the identified studies were Level III-2 or Level III-3 evidence and had a quality rating of fair or poor. Given that primary prevention strategies are implemented at the population level it can be difficult to design and conduct trials with a parallel control arm; consequently, five of the studies evaluated drinking behaviour prior to and after an intervention. A disadvantage of these types of studies is that other factors unrelated to the intervention can change over time and influence the defined outcome. This occurred in the three studies by Hankin, which reported increased periconceptional drinking over time due to changes in the demographics of patients attending the hospital. The studies by Hankin adjusted for confounding factors; however, no adjustments were performed in Bowerman 1997 or Kaskutas 1998.

A further limitation of these studies is that they do not adequately evaluate drinking behaviour at different points during pregnancy; i.e., prior to the women knowing she is pregnant or during first, second or third trimesters. It is also relevant to distinguish between a woman consuming one drink per day and a woman consuming seven

drinks on a single day each week. Binge drinking is associated with an increased rate of abnormalities compared with drinking the same amount of alcohol over an extended period of time. Olsen 1998 was the only publication to evaluate both average alcohol consumption and binge drinking.

A validated questionnaire was used to assess levels of alcohol consumption in three studies (Hankin 1993a,b and Hankin 1996). The other publications used broad terms that were poorly defined or not defined at all (e.g. 'alcohol abuse' and 'increased drinking'). All publications used self-reporting to evaluate alcohol consumption, which is associated with recall bias and under-reporting (see the introduction for a more detailed discussion). These issues were not adequately discussed in the publications.

As discussed in the introduction, there is a strong correlation between the level of alcohol consumption during pregnancy and the risk of having a child with FASD. However a range of cofactors, such as the pattern and quantity of alcohol consumption, stage of fetal development and socio-economic risk factors such as poverty and smoking, increase the risk of having a child with FASD. In addition, there is currently no consensus in the medical community regarding the adverse irreversible effects of low to moderate prenatal alcohol exposure or whether there is a clear threshold below which alcohol is non-teratogenic. Consequently, it is difficult to define what constitutes a 'clinically relevant effect'. Bowerman 1997 reported that the percent of women who abused alcohol dropped from 42% to 9% after the introduction of an alcohol ban. As the publication did not define alcohol abuse it is difficult to determine if this reduction is clinically relevant. Hankin 1993b reported a significant correlation between warning labels on alcohol bottles and a reduction in alcohol consumption in low-risk drinkers, however the equivalent reduction in alcohol consumption was only 0.03 ounces per week. Although a reduction in alcohol consumption reduces the risk of having a child with FASD, it unclear if such a small reduction in consumption is clinically meaningful. Hankin 1996 reported a similar significant correlation between warning labels on alcohol bottles and a reduction in alcohol consumption in nulliparae women, however the paper did not report on the magnitude of the reduction. It is therefore difficult to evaluate the clinical relevance of this result.

Synthesising the body of evidence as a whole is problematic for several reasons; (i) the research covers a broad range of primary prevention strategies; (ii) only warning labels on alcohol bottles are evaluated in more than one publication and all of these publications used the same patient population and (iii) the outcomes reported in each study are different and often poorly defined As a result it is not appropriate to meta-analyse the results.

It is worth reiterating that this systematic review only included publications which evaluated the effect of a primary prevention strategy on alcohol consumption during pregnancy. Publications which evaluated a change in knowledge about the dangers of alcohol consumption during pregnancy were excluded. Despite the fact that these studies are often cited as evidence to support the effectiveness of primary interventions, they do not meet the evidence requirements for this systematic review. A reduction in alcohol consumption during pregnancy has been used as a proxy outcome for a reduction in the number of children born with FASD as a strong

causative link has been shown between alcohol consumption during pregnancy and having a child with FASD. As discussed in the introduction, there is little evidence to show that an increase in knowledge about the risks of drinking during pregnancy results in any change to alcohol consumption during pregnancy or a reduction in the number of children born with FASD. Therefore these studies do not provide adequate evidence to evaluate the effectiveness of primary prevention strategies.

Table 18 Primary prevention: Body of evidence summary

Citation	Strength of evidence				Clinically relevant effect?
	Intervention	Comparison	Quality of evidence	Statistical precision [a.]	
Level I					
none available					
Level II					
none available					
Level III-1					
none available					
Level III-2					
Bowerman 1997	Alcohol ban	Difference in alcohol consumption during pregnancy pre and post intervention.	Fair	Significant reduction in alcohol abuse (RR 0.21, 95% CI 0.08, 0.55).	Probably
Hankin 1996	Warning labels on alcohol bottles	Difference in alcohol consumption during pregnancy pre and post intervention.	Fair	Significant correlation between label and reduced alcohol consumption in nulliparae ($p<0.04$) but not multiparae women.	Unlikely
Hankin 1993a,b	Warning labels on alcohol bottles	Difference in alcohol consumption during pregnancy pre and post intervention.	Fair	Modest reduction in alcohol consumption in light drinkers ($p<0.009$) but not heavy drinkers.	Unlikely
Level III-3					
Kaskutas 1998	Warning label, sign, ad or personal conversation about drinking during pregnancy	Correlation between number of warning labels seen by subjects and alcohol consumption during pregnancy.	Poor	No significant correlation.	No
Olsen 1989	Educational campaign	Alcohol consumption in the town which received the intervention compared with a control town.	Poor	No significant change.	No
Level IV					
none available					

Abbreviations: CI=confidence interval, RR=relative risk

[a] True effect rather than a chance finding?

From the publications reviewed here, the most effective primary prevention strategy was alcohol prohibition. The alcohol ban in the town of Barrow resulted in a significant reduction in alcohol abuse during pregnancy (42% pre ban vs 9% post ban, RR 0.21, 95% CI 0.08, 0.55). Although the article did not define 'alcohol abuse', the alcohol ban resulted in a clear reduction in alcohol consumption during pregnancy. The ban occurred in a remote borough of Alaska, in an area with a significant substance abuse problem. Other villages in the borough had been alcohol free for a number of years, and the decision to become totally alcohol free was decided by a referendum. This type of prevention strategy would require a significant degree of public support if it were implemented on a large scale in New Zealand.

Despite the fact that it has been a legal requirement for all alcohol bottles to carry labels warning of the dangers of drinking during pregnancy in the United States since 1989, there is no evidence that they have a significant impact on alcohol consumption during pregnancy. Hankin 1993 reported that a 1% increase in the probability of a light drinker being seen at the antenatal clinic after the alcohol warning label was introduced was associated with a 0.144% decrease in alcohol consumption. This is equivalent to an average reduction of 0.03 ounces (0.85g) of absolute alcohol per week, or less than $1/10^{th}$ of a standard drink (10g of absolute alcohol) per week. Although any reduction in alcohol consumption is beneficial, it is unlikely that such a small reduction is clinically relevant. Hankin 1996 found that the alcohol warning label was associated with a reduction in drinking during pregnancy in nulliparae women, although the magnitude of this reduction was not stated. The warning label had no effect on those at most risk of having a child with FASD: women who are high-risk drinkers (more than 1.4 standard drinks per day) and multiparae women (who were on average consuming three times as much alcohol at their first prenatal visit when compared with nulliparae women). The women were aware of the alcohol warning label but did not change their drinking behaviour during pregnancy. The authors note 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.

A large-scale, multi-faceted education campaign had no effect on the rates of alcohol consumption during pregnancy. The campaign, run in a town in Denmark, included both primary prevention strategies (television advertisements and shows, logos on shopping bags and other public locations) and secondary prevention strategies (brochures given to all pregnant women and available at several public outlets). It also included education strategies aimed at midwives and GPs. The authors noted that the campaign was well received, well known and that pregnant women were motivated to change their behaviour. Despite this, the campaign was ineffective. Kaskutas 1998 also found that exposure to multiple sources of information did not correlate with a decrease in alcohol consumption during pregnancy.

In summary, the results presented here indicate that there is no strong evidence that any primary prevention strategy is effective in reducing alcohol consumption during pregnancy or reducing the number of children born with FASD. This result should be considered in the context of the small number of published studies and the low-level of evidence available.

Secondary prevention strategies

Characteristics of included studies

The search identified 13 eligible secondary prevention studies. Publications were classified as secondary if (i) they were conducted in pregnant women and did not apply any inclusion or exclusion criteria based on alcohol consumption (N=8) or (ii) included pregnant women who consumed alcohol during pregnancy (N=5).

The main characteristics of the included studies are summarised in **Table 19.**

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 and Whaley 2007, Reynolds 1995 and Waterson and 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 program (Allan and Ries 1985, Cziezel 1999, Drinkard 2001, Eisen 2000 and Sarvela and Ford 1993). Women enrolled in these programs received information about alcohol consumption during pregnancy in addition to information about other behaviour (e.g. smoking, illicit drug use, nutrition, general prenatal care).

Generally, the quality of the identified studies was poor. Few publications clearly described the intervention, the exact information given to the participants and the manner in which it was delivered. All publications used self-reported alcohol consumption and it was often unclear how the data had been collected and if the method had been validated. Few publications adjusted for confounding variables, which was of particular relevance in studies without a control arm. Poor reporting of alcohol related outcomes was common. Results were often reported as proportion of subjects who became abstinent after an intervention, which is the ultimate goal of any prevention strategy. However, this does not capture women who drank heavily prior to the intervention and were able to dramatically reduce their alcohol consumption, but were not abstinent after the intervention. Such reductions would be considered clinically meaningful.

Table 19 Secondary prevention: Study characteristics

Citation	Study type Study quality	Population and inclusion criteria	Intervention	Comparator	Outcomes
Intervention Level II evidence					
O'Conner and Whaley 2007	Cluster-randomised controlled trial Fair	Pregnant women. N=345 Inclusion criteria: Any alcohol consumption after conception.	Brief intervention (including a comprehensive assessment of alcohol use and advice). N=162	Comprehensive assessment of alcohol use and advice only. N=183	Correlation between intervention and abstinence.
Handmaker 1998	Randomised controlled trial. Poor	Pregnant women attending an obstetrics clinic. N=42 Inclusion criteria: Any alcohol consumption in the month prior to study enrolment.	Motivational intervention. N=22	Letters with information about the risk of drinking during pregnancy. N=22	Correlation between intervention and alcohol consumption. Analysis of the effect size.
Reynolds 1995	Randomised controlled trial. Poor	Pregnant women. N=40 Inclusion criteria: Any alcohol consumption during pregnancy.	Self-help intervention. N=20	Standard care. N=20	Proportion of women who quit drinking in the intervention vs control group Proportion of women who drank <7 drinks at study entry and who quit drinking at follow-up in the intervention vs control group Proportion of women who drank >7 drinks at study entry and who quit drinking at follow-up in the intervention vs control group Correlation between quitting drinking and the intervention

Table 19 Secondary prevention: Study characteristics (continued)

Citation	Study type Study quality	Population and inclusion criteria	Intervention	Comparator	Outcomes
Intervention Level III-1 evidence					
Waterson and Murray-Lyon 1990	Pseudo-randomised controlled trial Poor	Pregnant women attending a prenatal clinic. N=75 Inclusion criteria: None	Personal advice and reinforcement by a doctor with and without an educational video. All women also received a leaflet about alcohol use in pregnancy. N=2,100	A leaflet about alcohol use in pregnancy only. N=1,059	Change in alcohol consumption in mothers who were drinking >7 units of alcohol per week before pregnancy
Intervention Level III-2 evidence					
Eisen 2000	A non-randomised, experimental trial Poor	Pregnant women. N=212 Inclusion criteria: Any alcohol consumption or drug use during pregnancy.	Drug prevention, education and treatment program. N=370	No intervention. N=288	Used alcohol in the last 30 days Used alcohol to intoxication in the last 30 days
Sarvela and Ford 1993	A non-randomised, experimental trial Fair	Pregnant teenagers attending a prenatal clinic. N=212 Inclusion criteria: Aged less than 20	Prenatal care education program. N=113	Standard care. N=99	Alcohol use in the last 5 months at pre-test vs post-test.
Meberg 1986	A case-control study Fair	Pregnant women. N=132 Inclusion criteria: None	Supportive counselling. N=58	Standard care. N=74	Changes in alcohol consumption during pregnancy Teetolers prepregnancy vs during pregnancy Alcohol consumption prepregnancy vs during pregnancy

Table 19 Secondary prevention: Study characteristics (continued)

Citation	Study type Study quality	Population and inclusion criteria	Intervention	Comparator	Outcomes
Intervention Level IV evidence					
Drinkard 2001	Case series with post-test outcomes Poor	Pregnant women. N=1,155 Inclusion criteria: None	A healthy pregnancy program.	Alcohol consumption prior to the intervention.	Proportion of mothers who reported using alcohol who said that the program helped them quit or reduce their alcohol use
Cziezel 1999	Case series with pre-test/post-test outcomes Poor	Pregnant women attending periconceptional care. N=75 Inclusion criteria: None	Periconceptional care program.	Alcohol consumption prior to the intervention.	Proportion of women who drank daily prior to periconceptional care vs after the 3 month preparation course and in pregnancy Proportion of women who drank more than one drink per week prior to periconceptional care vs after the 3 month preparation course and in pregnancy
Allen and Ries 1985	Case series with pre-test/post-test outcomes Poor	Pregnant women attending a prenatal clinic. N=75 Inclusion criteria: None	Prenatal education class.	Alcohol consumption prior to the intervention.	Average alcohol consumption per day before pregnancy vs during pregnancy Average alcohol consumption per day before prenatal education vs after prenatal education
Little 1984 and Little 1985	Case series with pre-test/post-test outcomes Poor	Pregnant women attending a pregnancy and health program N=304 Inclusion criteria: None	Interventional counselling.	Alcohol consumption prior to the intervention.	Proportion of women who reported drinking prior to contacting the pregnancy health program vs after contacting the pregnancy health program Correlation between fetal alcohol effects and maternal drinking Relationship between intervention and alcohol consumption Proportion of women who reported heavy drinking pre vs post pregnancy and health Percent of clients judged to have a problem at the time of initiation vs termination of contact
Larsson 1983	Case series with pre-test/post-test outcomes Fair	Pregnant women attending a maternal health clinic. N=464 Inclusion criteria: None	Early detection and treatment program.	Alcohol consumption prior to the intervention.	Proportion of women who reported a reduction in alcohol intake or abstinence

Results

Level II evidence

Three Level II studies (randomised controlled trials [RCTs]) were identified by the literature search (O'Connor and Whaley, 2007; Handmaker, 1998; Reynolds, 1995). While two of these were standard RCTs in which individual women were randomised to the intervention or control, one study was a cluster-randomised trial in which centres were randomised.

O'Conner and Whaley 2007

Women enrolled in O'Conner and 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 and 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 20**). In addition, this study reported a number of infant-related outcomes including birth weight and birth length. The results of these analyses showed that there was a trend to increased birth weight in infants of women in the brief intervention group compared with the control group ($p<0.06$). When stratified by level of alcohol consumption, birth weight was substantially greater in the intervention group compared with the control group in infants born to women considered to be high consumers of alcohol (180g). However, birth weights were slightly lower in the intervention versus control group for infants born to women in the low consumption group (-65g). There was a statistically significant difference in birth length in infants born to women in the intervention and control groups ($p<0.03$). Once again, stratification of the results based on alcohol intake showed a greater effect in the high consumption group (intervention – control = 1.67cm) compared with the low consumption group (intervention – control = 0.08cm).

Table 20 Secondary prevention: Level II evidence (O'Conner and Whaley, 2007)

Outcome	Intervention group	Control group	Statistics
O'Conner and Whaley 2007			
Abstinence rate	Women in the intervention group were 5 times more likely to be abstinent by the third trimester		OR=5.39; 95% CI 1.59, 18.25, p<0.05
Birth weight High consumption group Low consumption group	 3486g 3357g	 3306g 3422g	 P<0.06
Birth length High consumption group Low consumption group	 50.35cm 49.98cm	 48.68cm 49.90cm	 P<0.03

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

HANDMAKER 1998

In the study by Handmaker 1998, all participants had to have consumed at least one drink in the month prior to study enrolment. Pregnant women in the intervention arm received a 1 hour motivational interview, which aimed to increase the mother's perceptions of the health risks of drinking and increase her perceived ability to chance her drinking behaviour. Women in the control arm received a letter informing them about the potential risks of drinking during pregnancy. A follow-up assessment was completed 2 months after the intervention. Self-reported alcohol consumption was corroborated by interviewing significant others. This study was considered to be of poor methodological quality.

Handmaker 1998 reported that there was no significant difference in total alcohol consumption or abstinent days at follow-up in the intervention group compared with the control group (p=0.94 and 0.27 respectively; **Table 21**). There was a significant difference in homogeneity of regression of post-peak blood alcohol concentration (BAC) and pre-peak BAC (p=0.04). Women with the highest initial intoxication levels in the intervention arm had significantly lower blood alcohol concentrations during the follow-up period than did corresponding controls. The definition of 'highest initial intoxication level' was not stated. An analysis of overall change on the dependant measure using matched pairs showed a significant reduction from pre to post intoxication levels (p<0.01) and a significant increase in total abstinent days (p=0.015). Limited details of this analysis were provided. At follow-up, 44% of subjects in the intervention group were abstinent, compared with 33% in the control group, which was not significant. The authors compared the comparative effect sizes for the intervention and control groups of change in consumption (θ=0.46 vs 0.40), BAC (θ=0.77 vs 0.46) and abstinence (θ=0.69 vs 0.20). The authors provided limited details about this analysis and it is unclear how results in the treatment and control arms should be compared and what conclusions can be made.

Table 21 Secondary prevention: Level II evidence (Handmaker 1998)

Outcome	Intervention group	Control group	Statistics
Handmaker 1998			
Total alcohol consumption (ANVOCA analysis)	NR	NR	p=0.94
Abstinent days (ANVOCA analysis)	NR	NR	p=0.27
Homogeneity of regression between post-peak and pre-peak BAC	NR	NR	p=0.043
Reduction in pre to post BAC intoxication levels [a]	NR	NR	p<0.01
Increase in total abstinent days [a]	NR	NR	p=0.015
Total abstinence during follow-up	44%	33%	p>0.05
Reduction in total drinks consumed	NR	NR	p>0.05
Blood alcohol concentration	Among women with the highest initial intoxication levels, those who had received motivational interviewing showed significantly lower BAC during the follow-up period than did corresponding controls.		
Effect size	Change in consumption (θ=0.46) BAC (θ=0.77) Abstinence (θ=0.69)	Change in consumption (θ=0.40) BAC (θ=0.46) Abstinence (θ=0.20)	NR

Abbreviations: BAC=blood alcohol concentration, NR=not reported

[a] Analysis of overall change on the dependent measures using matched pairs t-tests

REYNOLDS 1995

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 22**, 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 is <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 22 Secondary prevention: Level II (Reynolds 1995)

Outcome	Intervention group	Control group	Statistics
Reynolds 1995			
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 (χ^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.		

Level III-1 evidence

One trial was identified which has been classified as a pseudorandomised trial (Waterson and Murray-Lyon, 1990).

WATERSON AND MURRAY-LYON 1990

In this trial, four antenatal booking clinics conducted each week at West London Hospital were allocated to administer either the intervention or control information/advice; two clinics administered the intervention and two clinics were used as the control. The exact method of allocation has not been reported. The publication described two controlled trials: Trial 1 was run between May 1982 and January 1983, and Trial 2 was run between February 1983 and October 1983. Subjects in Trial 1 received a leaflet about alcohol use in pregnancy and personal advice and reinforcement from a doctor. Subjects in Trial 2 received the same leaflet and personal advice, but also viewed a 4 minute video which encouraged mothers to reduce their drinking and gave advice on how they could do this. Subjects in the control arms of both trials only received the leaflet. Alcohol consumption was assessed by a questionnaire that had been previously validated. The study was considered to be of poor methodological quality.

The results of the two trials are presented in **Table 23**. There was no significant difference in the proportion of the subgroup of women who were drinking > 7 units of alcohol per week prior to pregnancy who reduced their alcohol consumption in either the intervention or control groups. Similar results were obtained for both Trial 1 and Trial 2. An additional analysis was performed on the subgroup of women who consumed < 7 drinks per week prior to pregnancy. This analysis showed that similar proportions of women in the intervention and control groups across the two trials increased their alcohol consumption during their pregnancy (~5-8%); there were no significant differences between treatment and control groups or between the two trials.

Table 23 Secondary prevention: Level III-1 (Waterson and Murray-Lyon, 1990)

Outcome	Intervention group	Control group	Statistics
Waterson and Murray-Lyon 1990			
Change in alcohol consumption in mothers who were drinking >7 units of alcohol per week before pregnancy	Trial 1 [a] Success 68% Partial success 12% No change 13% Failure 8% Trial 2 [a] Success 66% Partial success 19% No change 7% Failure 8%	Trial 1 [a] Success 63% Partial success 22% No change 9% Failure 6% Trial 2 [a] Success 69% Partial success 14% No change 12% Failure 5%	NS
Increase in alcohol consumption in mothers who were drinking <7 units of alcohol per week before pregnancy	Trial 1 7% Trial 2 7%	Trial 1 8% Trial 2 5%	NS

Abbreviations: NS=not significant

[a] Success: Drinking <7 units of alcohol per week at both stages of pregnancy, Partial success: Some reduction in intake but still drinking >7 units per week at one or both stages of pregnancy, No change: No change in number of units of alcohol per week, Failure: An increase in the number of units of alcohol per week from pre-pregnancy levels

Level III-2 evidence

Three studies considered to provide level III-2 evidence were identified by the literature search. All three of these studies were classified as non-randomised, controlled trials (Eisen, 2000; Sarvela and Ford, 1993; Meberg, 1986).

EISEN 2000

Eisen 2000 presented pooled results from nine non-randomised, experimental interventions which represented a convenience sample of 147 Center for Abuse and Prevention Pregnant and Postpartum Women and their Infants grantees. To be eligible for the programs, women must have used drugs or alcohol during pregnancy. The programs employed either (a) case management with provision or referral to individual and group counselling and other services or (b) day treatment with direct provision of services such as individual and group counselling. In general, case management programs linked clients to other service providers, whereas day treatment programs required clients to attend on-site services for 10-20 hours per week. Five programs were primarily case management, four were primarily day treatment. Due to the range of programs included in the analyses, the interventions are poorly described. Women in the control arm did not receive any interventions as a result of the study, however many were independently referred to substance abuse related education sessions. The methods of evaluating alcohol consumption were not described. The study was considered to be of poor methodological quality.

Eisen 2000 reported that significantly less people allocated to the intervention used alcohol within 30 days of delivery compared to prior to the intervention (14% at delivery compared with 33% at study entry, p=0.0001; **Table 24**). There was no change in the proportion of women consuming alcohol allocated to the control group (23% used alcohol at both time points). The reduction in alcohol consumption was not maintained after delivery, with 34% of the intervention arm reporting alcohol

consumption 6 months after delivery (compared with 32% at study entry). The proportion of subjects in the control group consuming alcohol was 23% prior to the study and 35% 6 months after delivery. There was a significant reduction in the proportion of women in the treatment group who drank to intoxication (19% at study entry vs 4% within 30 days of delivery, p=0.0001). There was a small, but not significant reduction, in the proportion of the control group who drank to intoxication (10% at study entry vs 6% within 30 days of delivery). The authors did not directly compare the intervention and control arms, all analyses were done within these groups. The intervention and control groups were not well matched at baseline, with a significantly greater of proportion drinking to intoxication in the intervention group compared with the control group (17% vs 11%). The degree of exposure to drug abuse prevention and education sessions was significantly associated with a reduction in alcohol consumption (p<0.02).

Table 24 Secondary prevention: Level III-2 evidence (Eisen 2000)

Outcome	Intervention group	Control group	Statistics
Eisen 2000			
Used alcohol prior to the intervention vs within 30 days of birth	33% vs 14% (p<0.001)	23% vs 23% (p=NS)	NR
Used alcohol prior to the intervention vs 6 months after birth	32% vs 34% (p=NS)	23% vs 35% (p=NS)	NR
Used alcohol to intoxication prior to the intervention vs within 30 days of birth	19% vs 4% (p<0.001)	10% vs 6% (p=NS)	NR
Used alcohol to intoxication prior to the intervention vs 6 months after birth	14% vs 7% (p=NS)	10% vs 8% (p=NS)	NR
Treatment effect	The amount of exposure to drug abuse prevention and education sessions appeared to mediate a positive treatment effect for alcohol (p<0.02) in a multivariate analysis at delivery vs 30days of birth, but not delivery vs 6 months after birth		

Abbreviations: NR=not reported, NS=not significant

SARVELA AND FORD 1993

Sarvela and Ford 1993 recruited pregnant adolescent teenagers into a non-randomised, experimental trial. Subjects were allocated to the intervention or control group based on the county of residence. The intervention was a prenatal care program which aimed to reduce substance abuse during and after pregnancy. Subjects completed one module of the 8-model ASPEN educational program during each prenatal care visit. The modules were self-administered and conducted in private. Subjects were asked questions regarding the module by a trained health care worked in a brief, private session following the completion of each module. One module, 'You, Your Baby and Alcohol' specifically referred to alcohol consumption during pregnancy. The questions used to assess alcohol consumption were not described; however, sensitivity and specificity analyses had been performed previously. The study was considered to be of fair methodological quality.

As shown in **Table 25**, Sarvela and Ford 1993 reported a significant reduction in the proportion of subjects using alcohol in the intervention group (22% at study entry vs 4% after delivery). However, a similar reduction was observed in the control arm (15% at study entry vs 4% after delivery), suggesting that the change in alcohol consumption occurred independently of the intervention.

Table 25 Secondary prevention: Level III-2 evidence (Sarvela and Ford, 1993)

Outcome	Intervention group	Control group	Statistics
Sarvela and Ford 1993			
Alcohol use in the last 5 months at pre-test vs post-test	22% vs 4%	15% vs 4%	NR

Abbreviations: NR=not reported

MEBERG 1986

Meberg 1986 describes a non-randomised controlled study conducted in a hospital in Norway. Women receiving prenatal care (who were consecutively enrolled following referral from a single large general practitioners office) received two consultations lasting one hour each, the first soon after pregnancy was verified and the second during the end of the second or beginning of the third trimester. During the consultation women received supportive counselling focused on reduction of alcohol consumption. A follow-up interview was performed after delivery. The control arm consisted of women who were admitted for delivery to the same hospital, but who had not received the intervention. An interview was conducted after delivery and the women were retrospectively asked about their alcohol consumption over the course of the pregnancy. Alcohol consumption was assessed using a validated screening tool, the Cahalan method. The study was considered to be of fair methodological quality.

Meberg 1986 reported that there was no significant difference between the changes in alcohol consumption in the intervention group compared with the control group. A similar proportion of prepregnancy alcohol users decreased their alcohol consumption (41% in the intervention group vs 32% in the control group) and reported abstinence (53% in the intervention group vs 61% in the control group). There was no significant difference in the amount of alcohol consumed per day in the intervention group compared with the control group. There were some differences in type of alcohol used prepregnancy in the intervention versus control group, with a significant greater proportion of women in the intervention group reporting use of beer, wine or liquor (~65% vs ~36%). However, the authors note that the retrospective nature of data collection in the control group may have led to differences in the ability of intervention and control participants to recall more detailed information regarding types of alcohol consumed. During pregnancy, consumption of these alcohol types was similar between the two groups.

Table 26 Secondary prevention: Level III-2 evidence (Meberg 1986)

Outcome	Intervention group	Control group	Statistics
Meberg 1986			
Teetotaller prepregnancy vs during pregnancy	16% vs 60% (p<0.01)	24% vs 70% (p<0.01)	NS
Used alcohol prepregnancy vs during pregnancy	84% vs 40% (NR)	76% vs 30% (NR)	NS
Proportion of women who used alcohol prepregnancy who abstained following confirmation of pregnancy	100% vs 53% (p<0.001)	100% vs 61% (p<0.001)	NS
Changes in alcohol consumption during pregnancy among alcohol users	Increased 0% Unchanged 6% Decreased 41% Abstinence 53%	Increased 0% Unchanged 7% Decreased 32% Abstinence 61%	NS
Alcohol consumption prepregnancy vs during pregnancy	<5g/day 62% vs 34% 5-10g/day 12% vs 5% 10-20g/day 10% vs 0%	<5g/day 64% vs 27% 5-10g/day 8% vs 3% 10-20 g/day 4% vs 0%	NS
Type of alcohol consumed prepregnancy vs during pregnancy	Beer: 60% vs 21% Wine: 68% vs 21% Liquor: 66% vs 2%	Beer: 31% vs 15% Wine: 42% vs 18% Liquor: 37% vs 3%	P<0.05 at prepregnancy only

Abbreviations: NR=not reported, NS=not significant

Level IV evidence

Five studies were considered to provide level IV evidence. None of these studies included a control group; the effect of the intervention was measured in a single population of women by comparing alcohol-related behaviour (i) prior to the intervention and (ii) post introduction of the intervention. With this study type it is difficult to determine if a change in alcohol consumption is related to the intervention without the presence of a control arm; any reported changes may have occurred purely as a result of the pregnancy. As such, the results provided by these level IV studies should be interpreted with this in mind (shown in **Table 27**).

DRINKARD 2001

Drinkard 2001 describes a case series with pre-test outcomes. A healthy pregnancy program was run as part of three large health plans at multiple hospital sites. The program was designed to reduce the incidence of low-birth-weight infants and the number of neonatal intensive care unit days by improving prenatal education, promoting safe health behaviours and enhancing the management of maternity care. Reducing prenatal alcohol consumption was one component of the program; however, the exact nature of the information given was not described in the publication. The exact question/s used to evaluate alcohol consumption were not included in the publication. The study was considered to be of poor methodological quality.

Drinkard 2001 reported that of the 123 mothers (18%) who reported using alcohol, 89 (72%) considered that the program helped them quit or decrease their use of alcohol. An assessment of potential predictors of reduction in alcohol use showed that both age (< 30 years) and identification of a high-risk pregnancy were statistically significant predictors.

CZEIZEL 1999

A comprehensive periconceptional care program was developed in Hungary and is described in Czeizel 1999. The program was designed to follow couples from pregnancy planning through to the 10-12th week of gestation. Women were then referred to an antenatal clinic. A follow-up interview was conducted after delivery. At the second periconceptional visit, couples were advised to avoid alcohol as part of a comprehensive 'preparation for conception' session. The exact nature of the advice and the method of delivery was not described in the publication. The questions used to assess alcohol consumption were not described. The study was considered to be of poor methodological quality.

Cziezel 1999 reported that there was no significant change in the proportion of women who drank one drink per day prior to the intervention compared with after the intervention (0.2% vs 0%). The proportion of women who consumed more than one drink per week was lower after the intervention compared with prior to the intervention (5.4% vs 0.8%), although the authors did not state if this was significant. The authors note that this information could not be checked.

ALLEN AND RIES 1985

Alan and Ries 1995 present data from a case series with pre-test/post-test outcomes. Women attended a prenatal education class which included information on alcohol, smoking and dietary practices. The information given about alcohol consumption was not stated in the publication. A follow-up interview was conducted by telephone four weeks after the class. The questions used to assess alcohol consumption were not described. The study was considered to be of poor methodological quality.

Allen and Ries 1985 reported that women significantly reduced their daily alcohol consumption from 0.35 drinks per day prior to pregnancy to 0.04 drinks per day during pregnancy ($p<0.01$). There was no significant change in the number of drinks per day following the intervention (0.03 drinks per day), as alcohol consumption was already very low prior to the intervention.

LITTLE 1984 AND 1985

Little 1984 and Little 1985 described a case series with pre-test/post-test outcomes. Women were offered individual counselling. During the first meeting a drinking history was taken, and the risk to the fetus after maternal alcohol consumption was described and discussed. If a pregnant woman did not appear to have a drinking problem, she was encouraged to remain abstinent throughout pregnancy and lactation and to visit the pregnancy and health program as often as needed. Women with a drinking problem were given individual counselling by trained, certified alcoholism therapists using an eclectic approach compatible with the philosophy of Alcoholics Anonymous. Home and hospital visits were made by counsellors when needed. Support groups were formed when sufficient patients were available. Family counselling was offered. The questions used to evaluate alcohol consumption were described, however it was unclear how they had been developed and if they had been validated. The study was considered to be of poor methodological quality.

Little 1984 and Little 1985 reported that there was a significant downward trend in drinking levels before and after the intervention ($p<0.001$). The proportion of women who reported drinking prior to receiving the intervention was 85% 9 months prior to

the intervention, and declined to 55% 1 month prior to the intervention. This decline continued after women received the intervention, with 40% reporting alcohol consumption 1 month after the intervention and 20% reporting alcohol consumption 5 months after the intervention. The proportion of women who reported heavy drinking was 20% prior to pregnancy, 8% one month after the intervention and 2% 4-6 months after the intervention. This was not a significant decrease. There was a non-significant reduction in the proportion of women who had a drinking problem at the start of the intervention (62%) compared with the end of the intervention (44%).

LARSSON 1983

Larsson 1983 presents data from a case series with pre-test/post-test outcomes. Women attended a prenatal alcohol use, early detection and treatment program. The intervention lasted an hour and included a structured interview and information about the adverse effects of alcohol on fetal development. Alcohol consumption was assessed by Calahan's method. Based on their responses to the questionnaire, women were classified as occasional drinkers (< 30 g pure alcohol per day), excessive drinkers (30-125 g pure alcohol per day) or alcohol abusers (> 125 g pure alcohol per day). Women classified as excessive drinkers and alcohol abusers were offered various kinds of support; for example, more frequent visits to the maternal health clinic and visits by a social worker and psychiatrist. The study was considered to be of fair methodological quality.

The majority of women in Larsson 1983 reported a reduction in alcohol intake or abstinence. The proportion was similar in occasional drinkers (74%), excessive drinkers (100%) and alcohol abusers (78%). With regards to newborn outcomes, approximately 33% of newborn infants in the excessive drinkers and alcohol abusers categories were transferred to a neonatal ward, compared with 12% in the occasional drinkers group. One infant was diagnosed with FAS and another baby was diagnosed with partial FAS in the alcohol abusers group. Mean birth weight was slightly greater in the occasional drinkers group compared with the excessive drinkers and alcohol abusers groups.

While the results of this study suggest that the majority of women in all three categories reduced their alcohol intake following the intervention, it is unclear to what degree consumption was reduced, and whether the reduction was specifically linked to the intervention, or whether similar reductions would have been seen without the intervention (i.e., due to confirmation of the pregnancy alone).

Table 27 Secondary prevention: Results from case-series with post-test outcomes or pre-test/post-test outcomes

Outcome	Analyses	Statistics
Drinkard 2001		
Proportion of mothers who reported using alcohol who said that the program helped them quit or reduce their alcohol use	89/123 (72%)	NR
Statistically significant predictors for quitting or reducing alcohol intake	< 30 years Identified as a high-risk pregnancy	P=0.01 P=0.02
Cziezel 1999		
One drink per day	Prior to periconceptional care vs after the 3 month preparation course and in pregnancy: 0.2% vs 0%	NR
More than one drink per week	Prior to periconceptional care vs after the 3 month preparation course and in pregnancy: 5.4% vs 0.8%	NR
Allen and Ries 1985		
Average alcohol consumption (drinks per day)	Before pregnancy vs during pregnancy: 0.35 vs 0.04	p<0.01
Average alcohol consumption (drinks per day)	Prior to prenatal education vs after prenatal education: 0.04 vs 0.03	NS
Larsson 1983		
Proportion of women who reported a reduction in alcohol intake or abstinence	Occasional drinkers 266/360 (74%) Excessive drinkers 30/30 (100%) Alcohol abusers 7/9 (78%)	NS
Incidence of fetal alcohol syndrome	Occasional drinkers 0/360 (0%) Excessive drinkers 0/30 (0%) Alcohol abusers 2/9 (22%)	NR
Birth weight (g)	Occasional drinkers 3400 Excessive drinkers 3200 Alcohol abusers 3040	NS
Little 1984 and Little 1985		
Proportion of women who reported drinking prior to contacting the pregnancy health program a	9 months 85% 7 months 69% 5 months 67% 3 months 69% 1 month 55%	There was a statistically significant (p<0.001) downward trend drinking before and after the intervention
Proportion of women who reported drinking after contacting the pregnancy health program a	1 month 40% 3 months 35% 5 months 20%	
Change in proportion of drinkers	There was a drop in the percentage of drinkers from the last month prior to contact to the first month after contact (p<0.01).	
Proportion of women who reported heavy drinking (at least five drinks on one occasion or at least twice as many drinks on one occasion as in regular drinking)	Pre vs post pregnancy: 20% vs 8% (one month after contact) and 2% (4-6 months after contact)	NR
Percent of clients judged to have drinking problem	Time of initiation vs termination of contact: 62% vs 44%	NR
Average alcohol consumption	Among clients who continued to drink, average alcohol consumption declined before and after contact (although fewer women drank at all as their pregnancies progressed).	

Abbreviations: NR=not reported, NS=not significant

[a] Results read off a graph

Discussion

In an attempt to illustrate the entire body of evidence directly relevant to the current review, **Table 28** summarises the evidence presented in accordance with the NHMRC dimensions of evidence.

The interventions described in the 13 publications identified were broadly comparable: all involved an assessment of alcohol consumption and provided subjects with information about the risks of drinking during pregnancy. However, there were significant variations in the interventions. Some interventions were run over a single session, while others required subjects to attend multiple meetings throughout their pregnancy. The level of support given to subjects ranged from providing an opportunity to ask questions about the effect of alcohol on the fetus, to comprehensive programs designed to assist women in making significant behavioural changes. Some programs were only designed to reduce alcohol consumption, while others included this as part of a broader program which aimed to improve a variety of pregnancy related outcomes (such as nutrition, smoking, illicit drug use and prenatal care). Many studies did not provide an adequate description of the intervention. It is difficult to draw conclusions from such a varied body of evidence.

The level of evidence of the publications was varied. Two publications were Level II, two were Level III-1, three were Level III-2 and six were Level IV. Handmaker 1989, Reynolds 1995, Sarvela and Ford 1993 and Larsson 1983 had a quality rating of fair, while the other publications had a quality rating of poor. Larsson 1983 and Sarvela and Ford 1993 were the only two publications to adjust for confounding variables. The lack of adjustment for confounding variables was a particular problem in the Level IV studies (which did not include a control arm). As seen in the controlled studies described here, women often dramatically reduce their alcohol intake during pregnancy independent of any specific intervention. Women often report feeling unwell after consuming small amounts of alcohol while pregnant, which may be an innate protective mechanism. It is therefore difficult to draw any conclusions from the Level IV studies which reported a reduction in alcohol consumption, as this change in behaviour may be unrelated to the intervention under investigation. Some of these publications erroneously stated that it was unethical to conduct a study in which one arm does not receive information about the risks of alcohol consumption during pregnancy. However, as an intervention which is under investigation is unlikely to be part of standard practice, there should be no ethical concerns with providing a group of women with *additional* information or support and comparing them to women receiving standard care. Alternatively, a comparator group could be women who declined to receive the intervention (such as in Eisen 2000) or women who delivered at the same site at which the study was being run, but who did not receive prenatal care at that site (such as Meberg 1986). Although there are problems associated with these types of control groups, they do provide a framework in which to evaluate the intervention being studied.

A validated questionnaire was used to assess levels of alcohol consumption in seven studies: one used the TWEAK in combination with other questions (O'Conner and Whaley 2007), two used the Calahan method (Meberg 1986 and Larsson 1983), one used the brief drinker profile (Handmaker 1998) and three did not describe the questions used but noted that they had been previously validated (Sarvela and Ford 1993, Reynolds 1995 and Waterson and Murray-Lyon 1990). The other publications

did not adequately describe the method used to evaluate alcohol consumption. All publications used self-reporting to evaluate alcohol consumption, which is associated with recall bias and under-reporting (see the introduction for a more detailed discussion). The problems with self-reported alcohol consumption were discussed in Handmaker 1999, in which there was significant discrepancy in self-reported alcohol consumption in different settings. On self-administered screening questionnaires, women reported consuming a mean of 9 ± 21 drinks in the month prior to study entry. These same women reported an average of 17 ± 37 drinks in the month prior to study entry during subsequent non judgmental personal interviews. Yet, when asked by their health care providers just before delivery, 74% of the participants denied drinking even once during their *entire* pregnancies. These figures highlight the difficulties in accurately calculating alcohol consumption and the methodological problems in pooling data from studies that used different methods.

The publications do not adequately evaluate drinking behaviour at different points during pregnancy i.e. prior to the women knowing she is pregnant or during first, second or third trimesters (the importance of which was discussed in the introduction). It is also relevant to distinguish between a woman consuming one drink per day and a woman consuming seven drinks on a single day each week. Binge drinking is associated with an increased rate of abnormalities compared with drinking the same amount of alcohol over an extended period of time. Little 1984, Little 1985 and Eisen 2000 were the only publications to evaluate a measure of alcohol use and binge drinking ('drinking to intoxication' and 'drinking five drinks in one night or more than twice as many drinks on one occasion as in regular drinking').

As discussed for primary prevention strategies, there is currently no consensus in the medical community regarding the adverse irreversible effects of low to moderate prenatal alcohol exposure or whether there is a clear threshold below which alcohol is non-teratogenic. Consequently, it is difficult to define what constitutes a 'clinically relevant effect'. Some publications only reported the proportion of women who were abstinent. It may be that subjects reduced their alcohol consumption from a very high level to a very low level as a result of the intervention. However, this clinically relevant outcome would not be detected by evaluating abstinence alone. It is therefore important that publications quantify the reduction in alcohol consumption in order to evaluate the effectiveness of the intervention. Abstinence was the only outcome reported in Reynolds 1995, O'Conner and Whaley 2007, Sarvela and Ford 1993, and Drinkard 2001. Other publications used outcomes such as the proportion of subjects who were 'heavy drinkers', had a 'reduction in alcohol intake' or reported a 'change in alcohol consumption', which were often difficult to interpret. Allen and Ries 1985 was the only publication to report the absolute reduction in alcohol consumption (0.04 drinks/day prior to the intervention and 0.03 drinks per day after the intervention).

Some publications, typically those which evaluated a multi-faceted intervention, only provided minimal descriptions of the alcohol component of the program and limited analyses. Drinkard 2001, Larsson 1983, O'Conner and Whaley 2007 and Sarvela and Ford 1993 reported a single alcohol-related outcome. It is therefore difficult to evaluate the effectiveness of the intervention.

Two publications assessed the change in knowledge about the effects of alcohol consumption during pregnancy. Waterson and Murray-Lyon 1990 reported that

women who received the intervention were significantly more likely to correctly identify a ‘safe’ daily intake of alcohol (as defined by the authors). Despite this, the same proportion of women in the intervention group and in the control group reduced their alcohol consumption. Conversely, Reynolds 1995 reported that a significantly higher proportion of women quit drinking in the intervention arm when compared with women who received standard care. However, women in both arms scored the same result on a knowledge test at study entry and at follow-up, indicating that the intervention did not increase knowledge. These results confirm the findings discussed in the introduction: an increase in knowledge about the effects of prenatal alcohol consumption does not necessarily result in behavioural changes.

Synthesising the body of evidence as a whole is problematic for several reasons; (i) the research covers a broad range of secondary prevention strategies and (ii) the outcomes reported in each study are different and often poorly defined As a result it is not appropriate to statistically meta-analyse the results.

Table 28 Secondary prevention: Body of evidence

Citation	Strength of evidence				Clinically relevant effect?
	Intervention	Comparison	Quality of evidence	Statistical precision [a.]	
Level I					
None available					
Level II					
Handmaker 1998	Motivational intervention.	Letters with information about the risk of drinking during pregnancy.	Poor	Significant reduction in blood alcohol concentration ($p<0.01$). No significant change in abstinent days or total alcohol consumption.	Possibly
Reynolds 1995	Self-help intervention.	Standard care.	Poor	Significant increase in proportion of women who quit drinking ($p<0.058$)	Yes
Level III-1					
O'Conner and Whaley 2007	Brief intervention (including a comprehensive assessment of alcohol use and advice).	Comprehensive assessment of alcohol use and advice only.	Fair	Significant increase in proportion of women who were abstinent by the third trimester (OR=5.39, $p<0.058$)	Yes
Waterson and Murray-Lyon 1990	Personal advice and reinforcement by a doctor with and without an educational video. All women also received a leaflet about alcohol use in pregnancy.	A leaflet about alcohol use in pregnancy only.	Poor	No change in alcohol consumption	No
Level III-2					
Eisen 2000	Drug prevention, education and treatment program.	No intervention.	Poor	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
Meberg 1986	Supportive counselling.	Standard care.	Fair	No change in alcohol consumption	No
Sarvela and Ford 1993	Prenatal care education program.	Standard care.	Fair	No change in alcohol consumption	No

Table 28 Secondary prevention: Body of evidence (continued)

Citation	Strength of evidence				Clinically relevant effect?
	Intervention	Comparison	Quality of evidence	Statistical precision [a.]	
Level III-3					
None available					
Level IV					
Drinkard 2001	A healthy pregnancy program.	Alcohol consumption prior to the intervention.	Poor	72% of women attributed reduction in drinking to the intervention (significance not stated)	Unclear
Cziezel 1999	Periconceptional care program.	Alcohol consumption prior to the intervention.	Poor	Reduction in proportion of women who drank >1 drink per week (significance not stated)	Unclear
Allen and Ries 1985	Prenatal education class.	Alcohol consumption prior to the intervention.	Poor	No change in alcohol consumption	No
Little 1984 and Little 1985	Interventional counselling.	Alcohol consumption prior to the intervention.	Poor	Significant downward trend drinking before and after the intervention ($p<0.001$).	Unclear
Larsson 1983	Early detection and treatment program.	Alcohol consumption prior to the intervention.	Fair	>74% reported a reduction in alcohol consumption (significance not stated)	Unclear

Abbreviations: OR=odds ratio

[a] True effect rather than a chance finding?

From the data evaluated, three secondary interventions significantly reduced prenatal alcohol consumption. Reynolds 1995 described a 10 minute education session (including information on the effects of alcohol on the fetus) coupled with a nine-step self-help manual that was completed by women at home in 9 days. The manual included 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 allocated to the control arm received standard clinical care. Despite the small sample size (20 subjects in each arm), a significant difference in the proportion of abstinent women was detected (88% in the intervention arm vs 69% in the control arm, $p<0.058$). Subgroup analysis found that the intervention was significantly associated with abstinence in women who 'drank <7 drinks' at study entry ($p<0.01$), but not in women who 'drank >7 drinks' at study entry. As previously noted, the publication does not state if this outcome was 7 drinks per day, week or month. The authors note that the treatment effect was stronger among light to moderate drinkers (<8 drinks per month).

A significant treatment effect was also reported in O'Conner and Whaley 2007. Subjects allocated to the intervention received a comprehensive assessment of alcohol use and were advised to stop drinking during pregnancy. Women also received a standardised workbook-driven brief intervention, designed specifically to help women reduce alcohol consumption during pregnancy. The workbook consisted of traditional brief intervention techniques, including education and feedback, cognitive behavioural procedures, goal setting, and contracting. Subjects in the control arm were advised to stop drinking. Women who received the intervention were five times more likely to report abstinence by the third trimester compared with women in the control group (OR=5.39; 95% CI 1.59, 18.25, $p<0.05$). This was the only alcohol-related outcome reported. The publication described a number of infant health and developmental markers (e.g. birth weight and length), however none could be used as a proxy for FASD.

Eisen 2000 described pooled results from nine drug treatment programs. The interventions employed either (a) case management with provision or referral to other individual and group counselling programs and other services or (b) day treatment with direct provision of services such as individual and group counselling, which were typically on-site for 10-20 hours per week. Five programs were primarily case management, four were primarily day treatment. Women in the control arm received a mean of 3.22 substance abuse related education and prevention sessions between entry to the study and delivery (compared with 12.87 for women in the treatment arm). Subjects who entered a drug prevention, education and treatment program were significantly less likely to have used alcohol and used alcohol to intoxication in the 30 days prior to delivery when compared with study entry (33% vs 14%, $p=0.0001$ and 19% vs 4%, $p=0.0001$ respectively). The reduction in alcohol consumption was not maintained in the 6 months after delivery. There was no significant reduction in the proportion of subjects in the control group who used alcohol and used alcohol to intoxication in the 30 days prior to delivery, when compared with study entry (23% vs 23%, $p=0.0001$ and 10% vs 6%, $p=0.0001$ respectively). The treatment and control groups were not well matched at baseline and statistical analyses were only performed within arms, rather than between the intervention and control groups. Due to the range of treatment programs included in analyses the publication did not clearly describe what occurred during the intervention and it is unclear what information was given

about drinking during pregnancy, and how this information was delivered. The authors do not report results for individual programs and it is therefore difficult to evaluate their effectiveness.

No significant difference was found between the intervention and control group in any other publication. Four of the level IV studies reported that subjects reduced their alcohol intake after receiving an intervention (the fifth, Alan and Ries 1985 showed no reduction in alcohol consumption after the intervention). However, without a control group it is difficult to attribute any of the behavioural changes to the interventions studied.

It is difficult to identify factors critical to the success of Reynolds 1995, O'Conner and Whaley 2007 and Eisen 2000, as many of the features of these interventions were also present in studies which found no benefit from the intervention. Reynolds 1995 and O'Conner and Whaley 2007 focussed on behavioural modification rather than just increasing knowledge. However, a similar approach was described in Meberg 1986 yet no treatment-related change in alcohol consumption was observed in the latter study.

In summary, the results presented here indicate that some secondary prevention strategies can be effective in reducing alcohol consumption during pregnancy. However, there is insufficient evidence to determine which elements of a treatment program are most effective. This result should be considered in the context of the small number of published studies and the low-level of evidence available.

Tertiary prevention strategies

Characteristics of included studies

The search identified 13 eligible tertiary prevention studies. Publications were classified as tertiary if they were conducted in high-risk women.

Different aspects of the same intervention were described in Chang 1999 and Chang 2000, Chang 2005 and Chang 2006, Grant and Ernst 2003 and Grant 2005 and Rosett 1980 and Rosett 1983. The other seven publications described different tertiary prevention strategies. Reduction of alcohol consumption was the primary aim in four of the interventions (Chang 1999 and Chang 2000, Chang 2005 and Chang 2006 and Rosett 1980 and Rosett 1983). Women enrolled in these programs received only information about alcohol consumption in pregnancy. The other six interventions included information about alcohol as one component of a broader educational program (Belizán 1995, Corrarino 2000, Grant and Ernst 2003 and Grant 2005, Glor 1987, Halmesmaki 1998 and Whiteside-Mansell 1998). Women enrolled in these programs received information about alcohol consumption during pregnancy in addition to information about other behaviour (e.g. smoking, illicit drug use, nutrition, general prenatal care).

The quality of the evidence was variable; although the five included RCTs were considered to be of fair to good methodological quality. Generally, the publications did not clearly describe the intervention, the exact nature of the information given to the participants and the manner in which it was delivered. All publications used self-reported alcohol consumption, which is often unreliable. Few of the publications

discussed the problems with self-reported alcohol consumption or made any attempt to use alternative sources of information to improve accuracy (such as interviewing partners or family members). Reporting of alcohol-related outcomes was often limited. Some publications only reported the proportion of abstinent subjects, which fails to capture women who may have significantly reduced their alcohol consumption but were still drinking at very low levels. As discussed for secondary prevention strategies, it was difficult to interpret data from tertiary prevention studies without a control arm.

Table 29 Tertiary prevention: Study characteristics

Citation	Study type Study quality	Population and inclusion criteria	Intervention	Comparator	Relevant outcomes
Intervention Level II evidence					
Chang 2005, Chang 2006	Randomised controlled trial. Good	Women attending an obstetrics clinic N=304 Inclusion criteria: ≥2 using the T-ACE questionnaire and any alcohol consumption in the 3 months prior to the pregnancy, or drinking during a previous pregnancy	Brief intervention with a partner N=152	Diagnostic intervention only N=152	Drinking days in control vs intervention group Drinks per drinking episodes in control vs intervention group Effect of partner involvement Effect of drinking goal selection (assessed in brief intervention group only)
Chang 1999, Chang 2000	Randomised controlled trial. Good	Women attending an obstetrics clinic N=250 Inclusion criteria: ≥2 using the T-ACE questionnaire	Brief intervention N=123	Alcohol assessment only N=127	Drinks per drinking day in control vs intervention group Regression analysis Abstinence in control vs intervention group Drinking episodes in early study vs late study entry Effect of drinking goal selection (assessed in brief intervention group only)
Belizán 1995	Randomised controlled trial. Fair	Pregnant women attending prenatal care N=2,230 Inclusion criteria: Multiple, one of which was smoking or heavy alcohol consumption	Home visits N=1,110	Routine antenatal care N=1,120	Proportion of women who drank alcohol daily

Table 29 Tertiary prevention: Study characteristics (continued)

Citation	Study type Study quality	Population and inclusion criteria	Intervention	Comparator	Relevant outcomes
Intervention Level III-2 evidence					
Whiteside-Mansell 1998	Non-randomised, experimental trial Poor	Pregnant women referred to an evolving alcohol and drug treatment prevention program N=95 Inclusion criteria: None, however it can be assumed that all women were abusing drugs and/or alcohol at the time of study entry.	Participants in the alcohol and drug prevention treatment program N=72	Non-participants in the alcohol and drug prevention program N=23	Proportion of women who used alcohol at intake vs delivery
Intervention Level III-3 evidence					
Glor 1987	Two or more single arm studies Poor	Pregnant women attending a prenatal program N=98 Inclusion criteria: Native Indian	Prenatal care	Alcohol consumption in the average population and a high-risk population	Alcohol use in the three groups
Intervention Level IV evidence					
Grant and Ernst 2003 and Grant 2005	Case series with pre-test/post-test outcomes Poor	Women enrolled in a Parent-Child Assistance Program N=45 (Grant and Ernst 2003) N=216 (Grant 2005) Inclusion criteria: pregnant or postpartum and reported heavy alcohol or illicit drug use during pregnancy (≥ 5 alcoholic drinks/occasion ≥once/month and/or use of any illicit substance ≥once/week during pregnancy).	Home visitation program	Substance abuse during a prior pregnancy	Children unexposed to alcohol or drugs at exit from program vs follow-up Proportion who reported alcohol abuse during index pregnancy vs Proportion of women who had given birth during the program who had an alcohol exposed pregnancy.

Table 29 Tertiary prevention: Study characteristics (continued)

Citation	Study type Study quality	Population and inclusion criteria	Intervention	Comparator	Relevant outcomes
Corrarino 2000	Case series with pre-test/post-test outcomes Poor	Substance abusing pregnant women who were not currently in a treatment program. N=10 Inclusion criteria: Abuse of alcohol or illicit substances	Linking subjects to drug treatment programs	Alcohol consumption prior to the intervention.	Alcohol severity index score
Halmesmaki 1988	Case series with pre-test/post-test outcomes Fair	Pregnant women attending an outpatient clinic N=85 Inclusion criteria: alcohol abuse	Counselling	Alcohol consumption prior to the intervention.	Proportion of subjects who had no change in alcohol consumption vs reduced their alcohol consumption Proportion of women who reduced their drinking who booked between 12 and 20 weeks of gestation vs those who booked later Proportion of infants with FAS and FAE Proportion of infants with FAS born to women who had no change in consumption vs women who reduced drinking Proportion of infants with FAE born to women who had no change in consumption vs women who reduced drinking
Rosett 1980 and Rosett 1983	Case series with pre-test/post-test outcomes Poor	Pregnant women attending prenatal care N=69 (Rosett 1980 N=49 (Rosett 1983) Inclusion criteria: heavy drinking, defined as at least 45 drinks per month, with at least 5 drinks on some occasions.	Counselling and prenatal care	Alcohol consumption prior to the intervention.	Proportion of women who abstained or had a significant reduction of alcohol consumption prior to their third trimester which was sustained throughout delivery Proportion of heavy drinkers who abstained or markedly reduced alcohol consumption before the third trimester Differences between women who reduced alcohol consumption and those who didn't

Results

Level II studies

Three Level II studies (RCTs) were identified by the literature search (Belizan 1995, Change 1999 and Chang 2000, and Chang 2005 and Chang 2006). The results from the three randomised controlled trials are summarised in **Table 32** and discussed below.

CHANG 2005 AND CHANG 2006

Women were eligible for Chang 2005 and Chang 2006 if they scored ≥2 using the T-ACE questionnaire and had consumed any alcohol in the 3 months prior to study enrolment (while pregnant), or if they had drunk during a previous pregnancy. Subjects randomised to the brief intervention received the following: (i) knowledge assessment with feedback; (ii) contracting and goal setting; (iii) behavioural modification; and (iv) a summary of the intervention. The brief intervention included the woman's partner. The intervention was a single-session, and took an average of 25 minutes to complete. Subjects randomised to the control group received a diagnostic interview only. Alcohol consumption was assessed using the Alcohol Timeline Follow Back, method and the Alcohol Abstinence Self-Efficacy scale. The study was considered to be of good methodological quality.

The results of this study are summarised in **Table 30**. The results reported in Chang (2005) comparing the brief intervention and the control suggest that there is no significant benefit of the brief intervention over the control group in terms of reduction in drinking behaviour (% days drinking and drinks per drinking episode) during pregnancy. Women in the two groups had similar alcohol consumption levels prior to pregnancy, at the time of study enrolment during pregnancy and during the prenatal period post-enrolment. Of note, there was a substantial reduction in drinking of approximately the same magnitude from the time of enrolment into the study to the post-enrolment period in both the intervention and control groups. This may suggest that administering the diagnostic interview alone had a substantial impact on drinking behaviour. In addition, the authors note that the women in this study may have been particularly motivated given their agreement to participate in the study and the involvement of the partners of the majority of women, indicating they may be in a very stable and supportive environment.

A regression analysis showed that the interaction between the brief intervention and prenatal alcohol consumption was significant (regression coefficient, b = –0.163, SE = 0.063, p = 0.01) and that the brief intervention was more effective for the heavier-drinking subjects when the subjects partner was involved; however, given the study failed to show any difference between the intervention and control the value of this finding is questionable. The follow-up report by Chang (2006) assessing women in the intervention group only suggests that subjects who were abstinent at enrolment were more likely to be abstinent at follow-up if they reported abstinence as their drinking goal compared with cutting down (50% vs 0%). Subjects who were drinking at enrolment were more likely to have reduced their drinking at follow-up if they reported abstinence as their drinking goal compared with cutting down (25% vs 16%).

Table 30 Tertiary prevention: Results from randomised, controlled studies (Chang 2005; Chang, 2006)

Outcome	Intervention group N=152	Control group N=152	Statistics
Chang 2005			
Mean average drinking days (%) prepregnancy	20.9%	20.3%	NS[a]
Mean average drinking days (%) prenatal at study enrolment	5.4%	5.0%	NS[a]
Mean average drinking days (%) after study enrolment	1.9%	2.0%	NS[a]
Mean number of drinks per episode prepregnancy	1.85	1.82	NS[a]
Mean number of drinks per episode at study enrolment	1.6	1.6	NS[a]
Mean number of drinks per episode after study enrolment	0.39	0.40	NS[a]
Chang 2006			
Impact of the brief intervention on different levels of prenatal consumption at enrolment	Significant interaction between the brief intervention and prenatal alcohol consumption (regression coefficient, b = –0.163, SE = 0.063, p = 0.01).		
Effect of partner involvement	More effective for the heavier-drinking subjects when her partner was involved, when drinking was measure by percentage of days drinking (b=–0.867, SE=0.419, p=0.05) and the combined measure of drinking (b=–0.932, SE=0.468, p=0.05).		
Subjects drinking at enrolment who were abstinent at follow-up	Reported abstinence as their drinking goal vs those who reported cutting down as their drinking goal 50% vs 0%		
Subjects drinking at enrolment who had cut down on drinking at follow-up	Reported abstinence as their drinking goal vs those who reported cutting down as their drinking goal 25% vs 16%		

Abbreviations: NS=not significant, SE=Standard Error

[a] Post-hoc analysis conducted for this review using Fisher's Exact test and t-test (NS = p>0.05).

CHANG 1999 AND CHANG 2000

Pregnant women were eligible for the study described in Chang 1999 and Chang 2000 if they scored ≥2 using the T-ACE questionnaire. All included women completed a comprehensive alcohol assessment which took approximately 2 hours. In addition to this, women randomised to the intervention group received a brief intervention. The brief intervention was structured as follows: (1) review the subject's general health and course of pregnancy to date, (2) review the subject's life-style changes made since pregnancy, including work schedule, exercise, diet, cigarette smoking and alcohol consumption, (3) request that the subject articulate her drinking goals while pregnant and their reason, (4) have the subject identify circumstances when she might be tempted to drink, (5) identify alternatives to drinking when she is tempted to drink, and (6) summarize the session by emphasizing four key points (drinking goal, motivation, risk situations for drinking and alternatives to alcohol) and noting them in the take-home manual, "How to prevent alcohol-related problems", given to the subject. This manual was based on materials provided by the WHO Amethyst Project. All subjects receiving the brief intervention were informed of the recommendation of the US Surgeon General, with prenatal abstinence being the most prudent drinking

goal. The brief intervention required approximately 45 minutes to complete. A follow-up interview was performed at the first post-partum visit. Alcohol consumption was evaluated using a number of screening tools, including the alcohol and drug abuse modules from the Structured Clinical Interview for DSM-III-R, the ASI, AUDIT, SMAST, the Timeline Follow Back method and the Alcohol Craving Scale. The study was considered to be of good methodological quality.

The results of the Chang (1999) study are summarised in **Table 33**. Pregnant women who received the intervention decreased their alcohol consumption by 0.4 drinks per drinking day, similar to the decrease of 0.3 drinks per drinking day reported by women in the control group. There was no significant difference in the mean number of antepartum drinking episodes (0.7 in the intervention group and 1.0 in the control group). The brief intervention was not contributory to the relative risk of prenatal drinking (RR=0.80, p=0.33). Subgroup analyses showed that women who were abstinent pre-assessment were significantly more likely to remain abstinent throughout the pregnancy if they were randomised to the intervention group compared with the control group (86% vs 72%, p=0.04). Subjects who were abstinent at study entry had significantly fewer drinking episodes if they had early study entry (0.3 in the intervention arm compared with 0.6 in the control arm, p=0.02). The definition of 'early study entry' was not given. In women who drank pre-assessment, there was no difference between the intervention and control groups in the change in drinks per day or drinking episodes over the duration of the study.

Assessment of infant outcomes showed no differences in birth weight or 1- and 5-minute APGAR scores between the intervention and control groups.

Overall, those who drank pre-assessment had an average decrease of 1.2 drinks per drinking day, 49% were abstinent after assessment and 20% reduced their alcohol consumption. Alcohol consumption increased in 12% of women and 19% made no change. Women who received the intervention averaged about half a drink per drinking day, with most drinking no more than once a week. Subjects who did not choose abstinence as their antepartum goal were more likely to be currently drinking (p=0.001) and 83% of current drinkers who chose abstinence reduced their subsequent prenatal alcohol use (p=0.002). Those who were initially abstinent and stated that there were no risk situations for antepartum alcohol consumption were less likely to drink (p=0.027). The number of risks, number of reasons, and Beck Depression Index scores were not related to antepartum alcohol consumption (p=NS).

Table 31 Tertiary prevention: Results from randomised, controlled studies

Outcome	Intervention group	Control group	Statistics
Chang 1999			
Alcohol outcomes			
Decrease in drinking between the time of assessment and delivery (drinks per drinking day)	**0.4**	**0.3**	**NS**
Number of antepartum drinking episodes	**0.7**	**1.0**	**NS**
Proportional hazards regression analysis	The brief intervention was not contributory to the relative risk of prenatal drinking (RR=0.80, p=0.33). Any drinking while pregnant prior to study entry was identified as a predictor variable (RR=2.96, p=0.0001).		
Abstinent at pre-assessment and maintained abstinence during pregnancy	86%	72%	p=0.04
Drinking episodes in abstinent pre-assessment subjects who had early study entry	0.3	0.6	p=0.02
Other outcomes in women who drank pre-assessment	There was no difference between the intervention and control groups in the change in drinks per day or drinking episodes over the duration of the study. There was an average decrease of 1.2 drinks per drinking day. Overall, 49% were abstinent, 20% reduced their alcohol consumption, 12% increased their alcohol consumption and 19% made no change.		
Infant outcomes			
Birth weight	3360g	3406g	NS
1-minute APGAR scores	8.1	7.8	NS
5-minute APGAR scores	8.9	8.7	NS
Chang 2000			
Results from subjects in the intervention group only	Subjects who did not choose abstinence as their antepartum goal were more likely to be currently drinking (p=0.001). 83% of the 30 current drinkers who chose abstinence reduced their subsequent prenatal alcohol use (p=0.002). The 15 current drinkers who cited awareness of fetal alcohol effects and syndrome as a reason to modify prenatal alcohol use drank less after the brief intervention (p=0.001). The number of risks, number of reasons, and Beck Depression Index scores were not related to antepartum alcohol consumption (p=NS). Those who were initially abstinent and stated that there were no risk situations for antepartum alcohol consumption were less likely to drink (p=0.027).		

Abbreviations: NR=not reported, NS=not significant, SE=standard error

BELIZÁN 1995

The objective of the study by Belizán (1995) was to assess whether an intervention aimed at increasing the education of mothers and support persons results in changes in health-related behaviours and use of health facilities. As part of this intervention, suggestions regarding reduction in alcohol use were given and changes in alcohol use were assessed. Women were included in the trial if they were considered to be at risk;

one of the risk criteria was heavy alcohol consumption. This criterion was met by approximately 19% of study participants.

Women were randomised to either an intervention or control group. Women in the intervention group received four home visits at 22, 26, 30 and 34 weeks of gestation, with two additional visits conducted if required. Each visit lasted 1-2 hours and involved discussing the pregnancy situation, changes, worries and doubts and then focussing on information relevant to the women. Information provided included health education and suggestions about reducing alcohol consumption were given. The intervention and control groups both received standard prenatal care. The study was considered to be of fair methodological quality.

The results of the Belizán (1995) study are summarised in **Table 32**. There was no significant difference in the proportion of pregnant women who drank alcohol daily at 36 weeks of gestation (19.1% in the intervention group compared with 21.8% in the control group). Similar proportions of subjects reported drinking daily at study entry (20.4% in the intervention group compared with 17.6% in the control group). The results suggest a slight reduction in the proportion of women drinking daily in the intervention group (1.3%) and a slight increase in the proportion of women drinking daily in the control group (4.2%). The authors report there was no difference in maternal morbidity at 36 weeks gestation between the two groups.

Table 32 Tertiary prevention: Results from randomised, controlled studies

Outcome	Intervention group	Control group	Statistics
Belizán 1995			
Proportion of women who drank alcohol daily at randomisation	20.4%	17.6%	NS
Proportion of women who drank alcohol daily at 36 weeks of gestation	19.1%	21.8%	NS

Abbreviations: NS=not significant

Level III-2 evidence

One trial was identified that was considered to provide Level III-2 evidence; a non-randomised, experimental trial (Whiteside-Mansell 1998).

WHITESIDE-MANSELL 1998

The publication by Whiteside-Mansell (1998) describes an assessment of an evolving alcohol and drug prevention and treatment program 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 program and are therefore assumed to have been abusing drugs and/or alcohol at study entry. Over a five-year period the program 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 program. As much as possible, the program 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 program. As the

program 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 program 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 33**. Significantly less pregnant women participating in the program consumed alcohol at delivery when compared with women not participating in the program (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 33 Tertiary prevention: Results from non-randomised, experimental trials (Whiteside-Mansell, 1998)

Outcome	Intervention group	Control group	Statistics
Whiteside-Mansell 1998			
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

Level III-3 evidence

One trial was identified which has been classified as a historical control study, as it is unclear if data for the control groups was collected within the same timeframe as the intervention group (Glor 1997).

GLOR 1997

Women were eligible for the study if they were Native Americans residing in the Regina region of Saskatchewan, Canada. The intervention involved prenatal education, birth coaching, postnatal counselling and any other assistance the counsellor could reasonably provide. Alcohol consumption in the study group was compared with alcohol consumption rates in an average population (data from a prenatal nutrition project) and a high-risk population (data from a nutrition counselling project). The questions used to evaluate alcohol consumption were not described. Data on maternal and infant outcomes was also reported. The study was considered to be of poor methodological quality.

After the intervention, 19% of the intervention subjects reported alcohol consumption (**Table 34**). This was significantly less than the average population, in which 63% of women consumed alcohol during pregnancy. A similar proportion of high-risk pregnant women (15%) reported alcohol consumption after participating in a nutrition counselling project. The authors conclude that the program 'maybe' had an impact on high alcohol consumption.

A number of additional outcomes were reported including birth weight and infant mortality rate. These were similar for the intervention group compared with the historical controls which included the general Saskatchewan population as well as selected Indian populations.

Table 34 Tertiary prevention: Results from Level III-3 studies (Glor, 1987)

Outcome	Intervention group	Control groups	Statistics
Glor 1997			
Alcohol outcomes			
Alcohol use	19%	Average population: 63% High-risk population: 15%	p<0.05 for intervention vs average population
Infant outcomes			
Birth weight	3302 g	Saskatchewan population: 3405 g British Columbia Indians: 3410 g Saskatchewan Indians: 3382 g Saskatchewan Reserve Indians: 3568 g	p<0.05 vs Saskatchewan Reserve Indians
Infant mortality rate	0.03	Saskatchewan population: 0.01 Saskatchewan Indians: 0.02	NS

Abbreviations: NS=not significant

Level IV evidence

Six studies were considered to provide level IV evidence (Grant and Ernst 2003 and Grant 2005, Corrarino 2000, Halmesmaki 1998 and Rosett 1980 and Rosett 1983). None of these studies included a control group; the effect of the intervention was measured in a single population of women by comparing alcohol-related behaviour i) prior to the intervention and ii) post intervention. With this study type it is difficult to determine if a change in alcohol consumption is related to the intervention without the presence of a control arm, as any reported changes may have occurred purely as a result of the pregnancy. As such, the results provided by these level IV studies should be interpreted with this in mind. The results of these studies are summarised in **Table 35** and discussed below.

GRANT AND ERNST 2003 AND GRANT 2005

Women were eligible for the study if they were pregnant or postpartum and reported heavy alcohol or illicit drug use during pregnancy (≥5 alcoholic drinks/occasion ≥once/month and/or use of any illicit substance ≥once/week during pregnancy). The intervention was a home visitation program. Case managers assisted women in obtaining alcohol and drug treatment and staying in recovery, and linked them with comprehensive community resources that helped them build healthy, independent lives. They worked individually with families, helped mothers identify personal goals and steps necessary to achieve them, and monitored progress. They facilitated integrated service delivery among providers, offered regular home visitation, transported clients and children to important appointments and worked actively within the context of the extended family. Grant and Ernst 2003 discussed the results from one site over a single year. Grant 2005 discussed the results from this same site, but over a four year period, as well as results from an additional two sites. Alcohol consumption was self-reported. Initially, subjects were interviewed using a 50 minute structured interview. The Addiction Severity Index (ASI) was used later in the

program. A follow-up interview was performed when subjects exited the program, and again approximately 3 years after completing the intervention. The study was of considered to be of poor quality.

None of the children born during the initial period were unexposed to alcohol or drugs. In contrast, 67% of children born during the follow-up period were unexposed. Statistical analysis was not performed due to the same sample size (0/12 children during the intervention and 4/6 children during follow-up). There was no difference in the proportion of women who abused alcohol during their previous pregnancy and the proportion of women who abused alcohol during a pregnancy which occurred during the intervention at either the original site (78% vs 82%), the first additional site (63% vs 68%) or the second additional site (78% vs 60%).

CORRARINO 2000

Women were eligible for the study if they abused alcohol or illicit substances. The intervention was a program to link substance abusing pregnant women to drug treatment services. A specialised outreach program, home visits, and other services were provided to pregnant women who were identified upon entry into prenatal care as having a problem with substance abuse (alcohol or illicit drug use). Only those women not currently in treatment for their substance abuse were eligible for the project. A public health nurse visited the woman at home to conduct an assessment. The nurse and the woman jointly agreed to a plan of care. The nurse focused on building a trusting relationship with the woman. Substance abuse was discussed during the course of treatment. The plan of care was targeted to the woman's needs, with an emphasis on the woman's readiness for change. The number of visits during the prenatal period ranged from five to nine, with an average of seven visits each. The frequency of visits was individually determined by the woman and nurse. Some key features of the program were: (i) assignment of a primary public health nurse; (ii) a flexible home visit plan that allowed for more frequent visiting as needed; (iii) health education at each contact; (iv) the services of a substance abuse counsellor who assessed substance abuse patterns and developed strategies to help the woman enter treatment. A medical social worker was also available for social needs; (v) follow-up at each contact; (vi) referral to community and social services as needed; (vii) referral to substance abuse treatment when the woman was ready and agreed to this part of the plan and (viii) monthly meeting of an interdisciplinary team. Alcohol consumption was assessed using the addiction severity index, which was administered during the counsellor's second home visit and every 3 months thereafter. The study was considered to be of poor methodological quality.

The proportion of pregnant women who reported an extreme alcohol severity score (8-9) dropped from 44% pre-intervention to 11% post-intervention. The proportion of subjects classified a considerable alcohol severity score (6-7) dropped from 44% to 22%; those with a moderate score (4-5) increased from 11% to 22% and those with both slight (2-3) and none (0-1) scores increased from 0% to 22%.

HALMESMAKI 1988

Pregnant women were eligible for the study if they abused alcohol. Women were4 classified into the following categories based on alcohol consumption: alcoholics (10-20 drinks per day and had several alcohol-related social problems); (ii) heavy drinkers (1-10 drinks daily but relatively normal social lives in terms of family and employment); and (iii) moderate drinkers (consumed alcohol only on weekends but

then up to 10 drinks at a time). Women were counselled at 2-4 week intervals about the effects of alcohol and cigarettes upon the fetus. They were encouraged to abstain totally, or if that was impossible, to decrease their drinking as much as possible. Consultations with social workers and psychiatrists were freely available. Infants were examined at 5 days and 4, 6 and 12 months of age. The questions used to evaluate alcohol consumption were not described. Infants were assessed for evidence of FAE using the following criteria: presence of at least one of the following characteristics including (i) growth retardation (low birth weight, short length and small head circumference; all below the normal 10^{th} percentile at birth or below the mean -2SD at follow-up visit), (ii) distinctive facial features (low nasal bridge and short upturned nose, short palpebral fissures, indistinct philtrum, thin upper lip) or (iii) neurological aberrations and/or developmental delays. The criteria for FAS were fulfilled if they infant showed growth retardation, distinctive facial features, neurological aberrations and/or developmental delay. The study was considered to be of fair methodological quality.

The proportion of subjects who reduced their alcohol consumption in Halmesmaki 1988 was similar for alcoholics (55%) and heavy drinkers (57%). The intervention was more effective in moderate drinkers (85%). Women who booked into the intervention between 12 and 20 weeks were significantly more likely to reduce their alcohol consumption when compared to women who booked in later (94% vs 54%, $p<0.0005$). The proportion of children born with FAS and FAE was highest in alcoholics (62% FAS and 38% FAE in those who did not change their alcohol consumption and 31% FAS and 63% FAE in those who reduced their alcohol consumption). The proportion of children born with FAS and FAE was 38% and 46% in heavy drinkers who had no change in alcohol consumption, and 12% and 0% in heavy drinkers who reduced their alcohol consumption. The lowest rates of FAS and FAE were in moderate drinkers (no cases of FAS or FAE in those who did not change their alcohol consumption and 0% FAS and 5% FAE in those who reduced their alcohol consumption). Overall, FAS was reported more commonly in women who did not change their alcohol consumption when compared with women who reduced their alcohol consumption (48% vs 16%). Similarly, FAE was reported more commonly in women who did not change their alcohol consumption when compared with women who reduced their alcohol consumption (41% vs 24%).

ROSETT 1980 AND ROSETT 1983

Women were eligible for the study if they drank at least 45 drinks per month, with at least 5 drinks on some occasions. Women participated in individual counselling sessions conducted in the prenatal Clinic at the time of their routine visits. The first counselling session included a diagnostic interview and an assessment of drinking history. Women were advised that they would have a better chance of having a healthy baby if they stopped drinking. During the session the alcoholic content of beer, wine and whisky were defined. Women were advised that substitution of one beverage for another did not constitute reduction. Myths that beer and wine were not as harmful as whiskey were dispelled. Abstinence was the goal of therapy and when achieved, the achievement was praised. When a woman reported that she had continued or resumed drinking, she was again told of the potential benefits of abstinence. Criticism and provocation of guilt were avoided, particularly among patients who ceased drinking heavily but had the occasional drink. Information was also given about diet, smoking, use of drugs and general prenatal care. The frequency

of counselling sessions varied with the schedule of routine visits, increasing from every 3 weeks to weekly as the pregnancy progressed. When indicated, supplementary appointments were scheduled. Women who had previous success with Alcoholics Anonymous or other community groups were encouraged to re-establish these relationships. Women were referred to social workers and alcoholism counsellors at the hospital. Women were encouraged to meet with the project psychiatrist during their next prenatal clinic appointment, who employed an unstructured interview format to independently evaluate drinking patterns and other behaviour. Women who had a physiological tolerance to alcohol and were drinking about 0.5L or more or its equivalent daily were advised to taper consumption to achieve abstinence. Withdrawal by two women who had been drinking more than 1L/day and were hospitalised demonstrated no adverse effects on mother or fetus when alcohol dosage was reduced during four days. Follow-up sessions averaged half an hour and occurred between 1 and 4 times a month. Consumption of beer, wine and liquor was evaluated using Cahalan's Volume-Variability Index. Absolute alcohol consumption was calculated by Jessors method. The study was considered to be of poor methodological quality.

The publications reported that 36% of subjects abstained or had a significant reduction in alcohol consumption prior to their third trimester (22% abstained totally, 7% had an occasional drink but never more than 2, 6% had 4 or more drinks on several occasions but did not consume more than 45 drinks a month). The proportion of heavy drinkers who abstained or reduced their alcohol consumption before the third trimester was 67% (39% were abstinent and 28% reduced their consumption). A reduction in alcohol consumption was associated with being younger ($p<0.05$) and nulliparous ($p<0.05$).

Table 35 Tertiary prevention: Results from case-series with post-test outcomes or pre-test/post-test outcomes

Outcome	Analyses	Statistics
Grant and Ernst 2003 and Grant 2005		
Children unexposed to alcohol or drugs at exit from program vs follow-up	Original Seattle site: 0% vs 67%	NR
Proportion who reported alcohol abuse during index pregnancy vs proportion who had given birth during the program who had an alcohol exposed pregnancy.	Original Seattle site: 78% vs 82% Seattle replication site: 63% vs 68% Tacoma site: 78% vs 60%	NR
Corrarino 2000		
Alcohol severity score at study entry vs after intervention	None: 0% vs 22% Slight: 0% vs 22% Moderate: 11% vs 22% Considerable: 44% vs 22% Extreme: 44% vs 11%	NR
Halmesmaki 1988		
Proportion of subjects who reduced their alcohol consumption	Alcoholics: 55% Heavy drinkers: 57% Moderate drinkers: 85%	NR
Proportion of women who reduced their drinking who booked between 12 and 20 weeks of gestation vs those who booked later	94% vs 54%	p<0.0005
Proportion of infants with FAS and FAE	Alcoholics who had no change in consumption: 62% FAS and 38% FAE Alcoholics who reduced consumption: 31% FAS and 63% FAE Heavy drinkers who had no change in consumption: 38% FAS and 46% FAE Heavy drinkers who reduced consumption: 12% FAS and 0% FAE Moderate drinkers who had no change in consumption: 0% FAS and 0% FAE Moderate drinkers who reduced consumption: 0% FAS and 5% FAE	NR
Proportion of infants with FAS born to women who had no change in consumption vs women who reduced drinking	48% vs 16%	NR
Proportion of infants with FAE born to women who had no change in consumption vs women who reduced drinking	41% vs 24%	NR
Rosett 1980 and Rosett 1983		
Proportion of women who abstained or had a significant reduction of alcohol consumption prior to their third trimester which was sustained throughout delivery	36% (22% abstained totally, 7% had an occasional drink but never more than 2, 6% had 4 or more drinks on several occasions but did not consume more than 45 drinks a month).	NR
Proportion of heavy drinkers who abstained or markedly reduced alcohol consumption before the third trimester	67% (39% were abstinent and 28% reduced their consumption)	NR
Differences between women who reduced alcohol consumption and those who didn't	Younger (p<0.05) and nulliparous (p<0.05)	

ABBREVIATIONS: NR=NOT REPORTED, NS=NOT SIGNIFICANT

[A] RESULTS READ OFF A GRAPH

Discussion

In an attempt to illustrate the entire body of tertiary prevention evidence directly relevant to the current review, **Table 36** summarises the evidence presented in accordance with the NHMRC dimensions of evidence.

The interventions described in the 14 publications identified were broadly comparable: all involved an assessment of alcohol consumption and provided subjects with information about the risks of drinking during pregnancy. However, there were significant variations in the interventions. Some interventions were run over a single session, while others involved an intensive 8 hour a day, 5 days a week outpatient program. The level of support given to subjects varied, however as the programs were designed for high-risk women the interventions typically involved comprehensive programs designed to assist women in making significant behavioural changes. Some programs were only designed to reduce alcohol consumption, while others included this as part of a broader program which aimed to improve a variety of pregnancy related outcomes (such as nutrition and prenatal care), other addictions (such as smoking and drugs) and/or other social skills. Many studies did not provide a detailed description of the intervention. It is difficult to draw conclusions from such a varied body of evidence.

The level of evidence of the publications was varied. Three publications were Level II, one was Level III-2, one was Level III-3 and six were Level IV. Two had a quality rating of good and two had a quality rating of poor, while the other publications had a quality rating of poor. Chang 2005 and Chang 2006 were the only publications to adjust for confounding variables. The lack of adjustment for confounding variable was a particular problem in the Level IV studies (which did not include a control arm). The problems associated with Level IV studies were discussed in detail for secondary prevention studies (page 69). Briefly, women often dramatically reduce their alcohol intake during pregnancy independent of any specific intervention. It is therefore difficult to draw any conclusions from the Level IV studies which reported a reduction in alcohol consumption, as this change in behaviour may be unrelated to the intervention under investigation.

A validated questionnaire was used to assess levels of alcohol consumption in seven studies: one used the ASI (Corrarino 2000), two used the ASI in combination with a structured interview (Grant and Ernst 2003 and Grant 2005), two used the Calahan method (Rosett 1980 and Rosett 1983), and four used the ASI, AUDIT, Timeline Follow Back method and other questionnaires (Chang 1999, Chang 2000, Chang 2005 and Chang 2006). The other publications did not adequately describe the method used to evaluate alcohol consumption. All publications used self-reporting to evaluate alcohol consumption, which is associated with recall bias and under-reporting (see the introduction for a more detailed discussion). The problems with self-reported alcohol consumption were discussed in Chang 1999, Chang 2000, Grant and Ernst 2003, Grant 2005, Rosett 1980 and Rosett 1983.

As for secondary prevention strategies, alcohol related outcomes were generally poorly reported (see page 69 for a more detailed discussion). No publication adequately evaluated drinking behaviour at different points during pregnancy or the pattern of drinking behaviour (regular low level consumption vs infrequent binge drinking). No publication reported the absolute reduction in alcohol consumption and

it was therefore difficult to evaluate the effectiveness of the interventions. Abstinence was the only outcome reported in Whiteside-Mansell 1998 and Glor 1997. Other publications used outcomes such as the proportion of subjects who 'drank heavily', had a 'reduction in alcohol intake' or reported a 'change in alcohol consumption', which were often difficult to interpret. Some publications, typically those which evaluated a multi-faceted intervention, only provided minimal descriptions of the alcohol component of the program and limited analyses. Corrarino 2000, Belizan 1995, Whiteside-Mansell 1998 and Glor 1987 reported a single alcohol-related outcome. It is therefore difficult to evaluate the effectiveness of the interventions.

Two publications reported outcomes in infants born to mothers receiving an intervention. Grant and Ernst 2003 reported that none of the 12 children born during the intervention were exposed to alcohol or drug. However, 4/6 (67%) of children born during the follow-up period (mean of 2.5 years post intervention) were exposed to drugs or alcohol. This suggests that this intervention does not have a mid to long-term effect. Halmesmaki 1988 was the only publication to report the number of infants born with FAE or FAS. Although it was difficult to compare results given the small numbers of mothers in each group analysed (ranging from n=4 to n=22), FAE and FAS was more common in children born to alcoholics and heavy drinkers than children born to moderate drinkers. A 'change in consumption' did not appear to be associated with a reduction in the number of children born with FAS or FAE in alcoholics. However these results must be interpreted with caution given the small sample size (n=29 alcoholics) and the variability in the term 'change in consumption'. A 'change in consumption' may have been associated with fewer children born with FAS or FAE in heavy drinkers, although the same caveats must be considered.

Synthesising the body of evidence as a whole is problematic for several reasons; (i) the research covers a broad range of tertiary prevention strategies and (ii) the outcomes reported in each study are different and often poorly defined As a result it is not appropriate to statistically meta-analyse the results.

Table 36 Tertiary prevention: Body of evidence - Efficacy of interventions

Citation	Strength of evidence				Clinically relevant effect?
	Intervention	Comparison	Quality of evidence	Statistical precision [a.]	
Level I					
none available	-	-	-	-	-
Level II					
Chang 2005 and Chang 2006	Brief intervention with a partner	Diagnostic intervention only	Good	Significant interaction between the brief intervention and alcohol consumption (p=0.01)	Possibly
Chang 1999 and Chang 2000	Brief intervention	Alcohol assessment only	Good	No change in alcohol consumption	No
Belizan 1995	Home visits	Routine antenatal care	Fair	No change in alcohol consumption	No
Level III-1					
none available	-	-	-	-	-
Level III-2					
Whiteside-Mansell 1998	Alcohol and drug prevention treatment program	Pregnant women who refused to use the service	Poor	Significantly less women drank at delivery in the intervention group (4%) vs the control group (33%, p<0.05)	Yes
Level III-3					
Glor 1987	Prenatal care	Alcohol consumption in the average population and a high-risk population	Poor	19% of subjects consumed alcohol at the end of the intervention compared with 63% in the average population (p<0.05)	Unclear

Table 36 Tertiary prevention: Body of evidence - Efficacy of interventions (continued)

Citation	Strength of evidence				Clinically relevant effect?
	Intervention	Comparison	Quality of evidence	Statistical precision [a.]	
Level IV					
Grant and Ernst 2003 and Grant 2005	Home visitation program	Substance abuse during a prior pregnancy	Poor	No change in alcohol consumption	No
Corrarino 2000	Linking subjects to drug treatment programs	Alcohol consumption prior to the intervention.	Poor	Reduction of the proportion of women with an 'extreme' alcohol severity score (significance not stated)	Unclear
Halmesmaki 1988	Counselling	Alcohol consumption prior to the intervention.	Fair	The intervention was most effective in moderate drinkers (85% reduced consumption) compared with alcoholics (55%) and heavy drinkers (57%) (significance not stated)	Unclear
Rosett 1980 and Rosett 1983	Counselling and prenatal care	Alcohol consumption prior to the intervention.	Poor	The publications reported that 36% of subjects abstained or had a significant reduction in alcohol consumption prior to their third trimester (significance not stated)	Unclear

Abbreviations: CI=confidence interval, RR=relative risk

a True effect rather than a chance finding?

From the data evaluated, one tertiary intervention significantly reduced prenatal alcohol consumption. Whiteside-Mansell 1998 described an intensive drug and alcohol prevention program, which evolved from a 4-5 hour per day, 5 days a week outpatient service to a 7-8 hours per day, 5 days a week onsite residential support service program. The intervention group was comprised of women who elected to take part in the program; the control group was comprised of women who refused. The study was considered of poor quality due to significant methodological concerns. Significantly fewer women in the intervention group consumed alcohol at the time of delivery compared with women in the control group (4% vs 33%, $p<0.05$).

The effect of a second intervention was unclear. Glor 1987 described an intervention involving prenatal education, birth coaching, postnatal counselling and any other assistance the counsellor could reasonably provide. All women invited to participate in the program were Native Americans. Alcohol consumption in the study group was compared with alcohol consumption rates in an average population (data from a prenatal nutrition project) and a high-risk population (data from a nutrition counselling project). The authors did not describe the socio-demographics of the two comparator cohorts and it is therefore difficult to evaluate if is methodologically appropriate to compare these groups. After the intervention, 19% of the intervention subjects reported alcohol consumption, which was significantly less than the average population (63%). A similar proportion of high-risk pregnant women (15%) reported alcohol consumption after participating in a nutrition counselling project. The authors conclude that the program 'maybe' had an impact on high alcohol consumption.

No significant difference was found between the intervention and control group in any other publication. All of the Level IV studies reported that subjects reduced their alcohol intake after receiving an intervention. However, without a control group it is difficult to attribute any of the behavioural changes to the interventions studied.

It is difficult to identify factors critical to the success of Whiteside-Mansell 1998. The tertiary prevention studies were generally more intensive than the secondary prevention studies, involving multiple sessions and a more holistic approach (such as the inclusion of social workers and substance abuse councillors and the focus on other areas of the women life such as her social support and parenting skills). The intervention described by Whiteside-Mansell 1998 was the most intensive intervention, comprising of a 7-8 hour, 5 day a week program. It was individualised, included counselling sessions with members of the subject's family and focussed on a range of issues including communication skills. The program also included mental health counselling, child care, early intervention and transportation. It is likely that the success of the program was a result of the comprehensive nature of the intervention.

In summary, the results presented here indicate that some tertiary prevention strategies can be effective in reducing alcohol consumption during pregnancy. There is insufficient evidence to determine which elements of a treatment program are most effective. This result should be considered in the context of the small number of published studies and the low-level of evidence available.

Prevention guidelines

Prevention programs

The literature search identified four clinical practice guidelines which discussed prevention programs.

CENTRE FOR DISEASE CONTROL (CDC), UNITED STATES 2004

The CDC guidelines, which were developed after consultation with clinical experts, did not recommend any specific intervention. The guidelines noted that there is evidence to suggest that pregnant women are motivated to stop drinking even if the intervention includes only an assessment of alcohol use with simple advice to stop or reduce drinking. Interventions are effective with pregnant women who are light as well as high-risk drinkers.

BRITISH MEDICAL ASSOCIATION 2007

These recommendations were prepared under the auspices of the Board of Science of the British Medical Association (BMA). The BMA guidelines note that there have been no universal strategies which specifically focus on FASD prevention in the United Kingdom. The current strategy for reducing alcohol-related harm focuses on health promotion through effective communication of the sensible drinking message; school-based educational programmes; responsible advertising and service policies; and enforcement of licensing laws. Research examining these types of alcohol control policy has consistently concluded that they are not effective measures for altering drinking behaviour or reducing alcohol related harm in a population. Controlling the price and availability of alcoholic drinks has been shown to be effective at reducing alcohol-related problems and population mean alcohol consumption level. These measures could potentially be effective in reducing alcohol consumption during pregnancy. These policies, however, have proved unpopular politically in the UK, and have not been used as part of the strategy to reduce alcohol-related harm. The key recommendations for primary prevention strategies are shown in **Table 37**.

Table 37 BMA recommendations for primary prevention

The UK government should review existing alcohol control policies in the UK to ensure that they are evidence-based and effective. This should include the introduction of increased taxation on alcohol products and the implementation of policies limiting the availability of alcohol. Any changes to existing alcohol control policies should be regularly reviewed and evaluated.
Health promotion, and public and school-based educational programmes aimed at preventing FASD should only be used as part of a wider alcohol-related harm reduction strategy to support other policies that are effective at altering drinking behaviour.
Research should be undertaken to establish current public attitudes and levels of awareness of FASD in the UK and the risks of alcohol consumption during pregnancy among the general public.
Further research should be undertaken to identify the most effective ways to educate the public about the range of FASD and to alter drinking behaviour. This requires systematic studies that compare various universal prevention strategies and their impacts across the different social groups.

The BMA guidelines state that there is no specific guidance on the use of brief interventions in the prenatal setting. Further guidance is required on the referral for, and provision of, brief interventions in the antenatal setting. Indeed, the first recommendation from the guidelines is that the UK Health Department should develop specific guidelines on the use of brief interventions (see **Table 38**). The guidelines include a general discussion on the efficacy of brief intervention and note

that they are a low-cost and effective method of reducing or stopping alcohol consumption during pregnancy in women who are nondependent and who consume alcohol at low-to-moderate levels. The type of brief intervention provided is dependent on the level of maternal alcohol consumption, the stage of pregnancy and the severity of dependence on alcohol.

Table 38 BMA recommendations for referring women to an intervention

The UK health departments should produce specific guidance on the referral for, and provision of, brief interventions for women who are pregnant, or who are considering a pregnancy.
Any woman who is pregnant, or who is planning a pregnancy, and who has a suspected or confirmed history of alcohol consumption at low-to-moderate levels should be offered brief intervention counselling. This should occur at the earliest possible stage and be considered a part of routine antenatal care where required.
All healthcare professionals providing antenatal care should be trained in the delivery of brief interventions within this setting, as well as having appropriate resources to ensure this is carried out effectively.

The guidelines state there is no specific guidance on the referral of women who are at high-risk of prenatal alcohol exposure. Further guidance is required on the referral of women at high-risk of prenatal alcohol exposure to specialist alcohol services (see **Table 39**).

Table 39 BMA recommendations for high-risk women

The UK health departments should produce specific guidance for the implementation of targeted interventions and referral to specialist alcohol services for women at high-risk of prenatal alcohol exposure, including those with a history of alcohol misuse, those with severe alcohol problems, and women who have previously had a child affected by alcohol.
Any woman who is identified as being at high-risk of prenatal alcohol exposure should be offered referral to specialist alcohol services for appropriate treatment. Any referral should be followed up and assessed at regular intervals.

BARCELONA DEPARTMENT OF HEALTH 2005

Guidelines published by the Barcelona Department of Health, and developed by a task force of clinical experts, state that the evidence to date suggests that interventions during pregnancy are ineffective (Anderson 2005). Three good-quality publications describing behavioural counselling interventions that targeted pregnant women were identified. Two of the publications found no evidence of any reduction in on alcohol consumption (Handmaker 1999 and Chang 1999). The third publication reported a possible effect which may have failed to reach statistical significance (Reynolds 1995).

SIGN 2003

The Scottish Intercollegiate Guidelines Network (SIGN) recommend that routine antenatal care provides a useful opportunity to deliver a brief intervention for reducing alcohol consumption (SIGN 2003). The guidelines cite two studies: Manwell, 2000 and Chang, 1999. This recommendation was graded B (from a body of evidence including studies rated as high quality systematic reviews of case control or cohort studies and high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship was causal). No specific brief interventions were recommended.

Prenatal screening

Introduction

There are several hundred screening instruments available which aim to identify patients with alcohol problems, ranging from multi-question, validated instruments to single questions. The majority of these have been designed and/or validated in the general population, or in populations known to have a higher than average alcohol intake. A number of issues surrounding their use have been discussed in the Introduction, including issues surrounding the utilisation of these screening tools in pregnant women; a population generally associated with a low alcohol intake. Prenatal screening in pregnant women can be used to quickly identify women with an alcohol intake that may put them at risk of having a child with FASD; i.e., a positive screening test result can lead to application of an appropriate intervention. Consequently, screening tools have been developed specifically for the prenatal setting.

The use of biological markers as a screening tool

The most accurate screening tool (or 'gold standard') would be a biological marker that would indicate the level of recent past alcohol use. However, there are currently no laboratory tests that can detect regular alcohol use during pregnancy. Breath analysis or urinalysis can detect the metabolites of alcohol, however both are ineffective as alcohol is metabolised rapidly and these test can only detect alcohol consumption immediately prior to a clinical appointment. A number of biomarkers such as serum gamma-glutamyltransferase, (GGT) aspartate aminotransferases (AST) and alanine aminotransferases (ALT) have been assessed for their ability to detect alcohol consumption during pregnancy, however no strong correlations have been reported.

Screening tools designed for use in pregnant women

Two screening tools have been developed specifically for use in pregnant women: the T-ACE and TWEAK. Rather than identifying women with an alcohol abuse problem (as is the aim with alcohol screening tools designed for use in the general population), they are typically used to identify women who would benefit from further information on the risks of drinking during pregnancy. They are therefore able to detect much lower levels of alcohol consumption.

The T-ACE screening tool (Tolerance/Annoyed/Cut-down/Eye-opener) is a modified version of the CAGE screening tool (Cut-down/Annoyed/Guilty/Eye-opener; see Sokol 1989 pg 108 for details of how the tool was developed). The T-ACE includes a question about the subjects 'tolerance' to alcohol, which is more effective in the prenatal setting. This question is not as likely to be perceived as an indication of the level of alcohol consumption and women are therefore more likely to answer the question honestly.

The TWEAK contains the same T, E and K (C) items as the T-ACE. It also uses the 'amnesia' and 'worry' items from the AUDIT. Details of the questions used and the scoring of the T-ACE and TWEAK screening tools are shown in **Table 40**.

Table 40 Screening tools: The T-ACE and TWEAK

Tool	Questions in standard version	Scoring in standard version
T-ACE	T: How many drinks does it take to make you feel high? (Tolerance) A: Have people Annoyed you by criticising your drinking? C: Have you ever felt that you should Cut down on your drinking? E: Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (Eye-opener?)	T: positive if 3 or more drinks. A, C, E: positive if answered yes. Overall score: 2 points if positive to T, 1 point if positive to A, C, E.
TWEAK	T: How many drinks does it take to make you feel high? (Tolerance) W: Does your spouse or parent ever Worry or complain about your drinking? E: Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (Eye-opener?) A: Have you ever awakened the morning after some drinking the night before and found that you could not remember a part of the evening before? (Amnesia) K(C): Have you ever felt that you should Cut down on your drinking?	T: positive if 3 or more drinks. W, E, A, K: positive if answered yes. Overall score: 2 points if positive to T, 1 point if positive to E, A, K.

Other screening tools

There are a number of other screening tools that have been developed for use in the general population, but are often used in the prenatal population. The Michigan Alcohol Screening Test (MAST) is a detailed, 25 item questionnaire that is often used in research settings. However, it is time consuming and hence clinically impractical (Sokol 1989). The Alcohol Use Disorders Identification Test (AUDIT) is a shorter, 10 item screening tool designed by the World Health Organisation. Both the AUDIT and the MAST have a complicated scoring system. The CAGE is a brief, 4 item screening tool. The NET screening tool (Normal/Eye-opener/Tolerance) is a 3 item screening tool which uses items from the CAGE and T-ACE. The CAGE and NET have been designed for use in a clinical setting. A summary of these screening tools is shown in **Table 41**.

The Timeline Follow Back method is an interview technique that assists research participants and treatment clients in recalling past drinking. This method can be time intensive and requires the subject to work with an interviewer to recall their past drinking behaviour. It is not designed to be used as a screening tool in a clinical setting. The Timeline Follow Back method is often used as the comparator when developing or evaluating screening tools.

Table 41 Screening tools: General alcohol screening tools

Tool	Questions in standard version	Scoring in standard version
MAST	The Michigan Alcoholism Screening Test (MAST) consists of 25 yes/no questions about the subjects' alcohol consumption.	Each item is weighted 0, 1, 2 or 5. Overall score: Sum of all of the individual scores. It can range from 0 – 53.
AUDIT	1. How often do you have a drink containing alcohol? 2. How many drinks containing alcohol do you have on a typical day when you are drinking? 3. How often do you have six or more drinks on one occasion? 4. How often during the last year have you found that you were not able to stop drinking once you had started? 5. How often during the last year have you failed to do what was normally expected from you because of drinking? 6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session? 7. How often during the last year have you had a feeling of guilt or remorse after drinking? 8. How often during the last year have you been unable to remember what happened the night before because you had been drinking? 9. Have you or someone else been injured as a result of your drinking? 10. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?	Subjects choose the most appropriate answer from the questionnaire. Each answer has a score from 0-4. Overall score: Sum of all individual items
CAGE	C: Have you ever felt that you should Cut down on your drinking? A: Have people Annoyed you by criticising your drinking? G: Have you ever felt bad or Guilty about your drinking? E: Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (Eye-opener?)	C, A, G, E: positive if answered yes. Overall score: 1 point if positive to C, A, G, E
NET	N: Do you feel you are a Normal drinker? E: Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (Eye-opener?) T: How many drinks does it take to make you feel high? (Tolerance)	T: positive if 3 or more drinks. N, E: positive if answered yes. Overall score: 2 points if positive to T, 1 point if positive to A, C, E.
Timeline Follow Back	The interviewer and respondent look at a calendar marked with dates that are memorable for the community (e.g., local college homecoming) or the individual (e.g., a birthday). Respondents are asked to report the amount of alcohol consumed on each day, recorded as the number of standard drinks.	There is no scoring; the alcohol measures of interest are taken directly from the subjects response.

Issues surrounding the evaluation of prenatal screening tools

Assessing the impact of a health outcome is ideally performed by evaluating a screening tool in conjunction with any subsequent action that may be taken (i.e. treating it as an intervention). However, since this approach is rarely practical and

requires a very large sample size to negotiate all confounding factors the evaluation of screening tools are typically undertaken in isolation from subsequent management (i.e. evaluated as a diagnostic tool). When evaluating a screening tool in this way it is important to consider the technical features of the test such as its reproducibility, test-retest and intra-operator variability. It is also necessary to consider the practicality and applicability of the screening tool.

In order to determine the ability of a screening tool to correctly identify the target population (in this case, pregnant women at risk of having a child with FASD), the diagnostic accuracy (i.e., sensitivity and specificity) of the screening tool must be compared with a 'gold standard' or reference standard. A reference standard refers to the commonly accepted 'proof' that an individual does or does not have the disorder in question (in this case alcohol consumption of a particular level during pregnancy). The reference standard provides objective criteria or a current clinical standard for diagnosis. As there is no true reference standard (an objective, unbiased marker of alcohol consumption), individual screening tools must be validated against other 'reference' screening tools. This type of comparison is problematic as the true diagnostic accuracy of the reference screening tool may also be unknown. As such, the results of such comparisons must be interpreted with caution.

Prenatal screening tools are designed to identify women who consume alcohol at levels considered to be a risk factor for FASD. As discussed throughout this systematic review, there remains debate in the medical community about the definition of 'risk drinking' during pregnancy. Therefore the thresholds used to evaluate each screening tool must be considered. A screening tool which has been validated using a definition of 1 drink/day for 'risk drinking' would have different results if it were validated using a definition of 1 drink/month for 'risk drinking'.

In an ideal setting, all women who consumed alcohol would be identified by a screening tool and would receive an appropriate intervention. Consequently, the key focus when evaluating screening tools is sensitivity. This can be defined as the proportion of subjects with a condition who are detected by the screening tool. This can be best seen by considering 100 pregnant women, 80 who consume no alcohol during pregnancy and 20 who consume alcohol at risk levels. A screening tool with 100% sensitivity will correctly identify the 20 risk drinkers as positive. However, an increase in sensitivity is often associated with a decrease in specificity (defined as the proportion of subjects who do not have the condition and are correctly detected as negative by the screening tool). Therefore, the hypothetical screening tool with 100% sensitivity only may have a specificity of 80%, meaning that 16 subjects who are not consuming alcohol will test positive using the screening tool. Therefore, of the 36 subjects who are positive using the screening tool, only 20/36 (55%) are actually risk drinkers (this is also known as the positive predictive value).

The importance of the relationship between sensitivity and specificity can vary depending on consequence of testing positive. If an intervention is inexpensive, non-invasive, effective and not overly time consuming, the unnecessary treatment of 16 subjects who are not actually at risk of having a child with FASD may be acceptable, given that all true risk subjects will receive the intervention. However, if the intervention is an expensive and intensive intervention, then this number of unnecessary interventions may be unacceptable. In this situation, the definition of a

positive response using this screening tool would have to be modified so that the specificity was increased, although this would almost certainly result in a decrease in sensitivity. Although some risk drinkers would not be detected by the modified screening tool, a larger proportion of subjects receiving the intervention would be true risk drinkers. This would represent a more efficient use of time and resources, but may not be socially acceptable if treatment positives are not identified. It is also relevant to consider if the diagnosis may have a psycho-social or physical implication to the patient. For example, an incorrect positive diagnosis (due to poor specificity) might result in unnecessary medication, treatment or psychological distress.

An important consideration when evaluating screening tools is the time they take to administer. An ideal FASD screening tool should be given to every pregnant woman as part of their routine prenatal care. However, screening tools with the highest sensitivity, specificity and positive predictive value are often the most time consuming and most complicated to score. As discussed previously, the MAST is often used in research settings but is considered too long and difficult to use in a clinical setting. Therefore the aim of studies evaluating screening tools is often to identify questions that quickly identify risk drinkers in a structured format.

To summarise, the ideal screening tool is a simple questionnaire that can be administered rapidly and has a high sensitivity, specificity and positive predictive value. The test should be reproducible.

It should be noted that in addition to the issues surrounding the assessment of diagnostic accuracy of prenatal screening tools, there are also problems associated with self-reported alcohol consumption, particularly in the prenatal setting where women are more likely to underreport their alcohol intake.

The following sections assess the available published evidence surrounding the diagnostic accuracy of various screening tools available for use in pregnant women. These include objective biomarkers and pregnancy-specific tools. In addition, a brief summary of the evidence available for other general screening tools will be presented.

Biomarkers

The literature search identified five publications which evaluated the ability of biomarkers to detect alcohol consumption in pregnant women (see **Table 42**). As discussed in the introduction to this section, there is no evidence that biomarkers are appropriate either as a screening tool in a clinical setting or as a comparator. Therefore these publications will only be briefly summarised below.

Table 42 Screening tools: Characteristics of studies evaluating biomarkers

Citation	Population	Intervention	Reference standard	Outcome
Magnusson 2004	Pregnant women N=147	AST ALT MCV GGT CDT Combination of all biomarkers	AUDIT Timeline Follow Back	Sensitivity
Budd 2000	Pregnant women N=56	PAUI ACOG antepartum record	CDT	Sensitivity Specificity
Stoler 1998	Pregnant women N=529	CDT GGT MCV WBAA	TWEAK Timeline Follow Back	Correlation between biomarkers, TWEAK score, and infant outcome
Christmas 1992	Pregnant women N=302	Urine analysis	Structured questionnaire	Proportion of subjects who were positive
Larsson 1982	Pregnant women N=669	Serum GGT ALT AST	Self-reported alcohol consumption	Sensitivity Specificity

Abbreviations: ALT= Alanine aminotransferase, AST=Aspartate aminotransferase, CDT=Carbohydrate-deficient transferrin, MCV=mean corpuscular volume, GGT= γ-glutamyl transferase, PAUI=prenatal alcohol use interview, WBAA=whole blood associated acetaldehyde

MAGNUSSON 2004

Five biomarkers were evaluated (AST, ALT, MCV, GGT and CDT) in pregnant women. MCV is increased after alcohol consumption, but can also increase independently during pregnancy. GGT is elevated after liver damage, which can be caused by excess alcohol consumption but also by numerous other factors. AST and ALT are non specific markers of liver damage which can also be elevated in a number of conditions. CDT is elevated after high alcohol intake, although levels are increased during pregnancy and are significantly higher in the third trimester than in the first.

None of the women with the highest alcohol consumption as determined using the Timeline Follow Back method (defined as alcohol consumption more than once a week) had positive biomarkers. The authors note the difficulties of calculating a true sensitivity given the lack of a true gold standard; however, they provide an approximate sensitivity of 4% for AST, 9% for ALT, 4% for MCV, 0% for GGT and 0% for CDT. The sensitivity of all biomarkers combined was 4%. The authors conclude that elevated laboratory markers are likely a result of somatic illness rather than harmful drinking.

BUDD 2000

Two general screening tools, the PAUI and ACOG antepartum record, were compared with CDT, which is elevated during periods of heavy alcohol consumption. However, CDT levels are only elevated for 2 weeks after alcohol abuse. CDT can not be used to detect the lower levels of alcohol consumption relevant to FASD prevention.

Women who were identified as heavy drinkers using CDT were more likely to be detected by the PAUI (59%) than the ACOG antepartum record (19%). The PAUI also had a lower false negative rate (41%) than the ACOG (80%).

STOLER 1998

Four biomarkers were evaluated against self-reported alcohol consumption using the TWEAK and Timeline Follow Back method. WBAA was the most effective, identifying 40% of women who drank daily, 37% of women who drank weekly and 33% of women who drank occasionally. The mean TWEAK score increased with increasing number of positive markers. The authors' state that the positive predictive value of 2 biomarkers was higher than the self-reporting measures in identifying affected infants. However, the authors do not report either the sensitivity or specificity of the biomarkers. It is therefore unclear if the reported high positive predictive value is a consequence of a very low specificity, which would be inappropriate in the prenatal setting.

CHRISTMAS 1992

The authors note that urine toxicology can be limited due to the rapid clearance of most substances, although the length of time that alcohol can be detected in the urine after alcohol consumption was not stated. Overall, 22 women reported alcohol consumption using the questionnaire. None of the urine samples showed any evidence of alcohol consumption.

LARSSON 1992

Pregnant women were asked about their alcohol consumption during their first trimester. The ability of three biomarkers (Serum GGT, ALT and AST) to detect women who consumed more than 30 grams of alcohol per day (as determined by interview) was assessed. At a sensitivity of 95%, the specificity was 26% for serum GGT, 19% for ALT and 15% for AST. The authors conclude that a brief interview is superior to a laboratory screening test for excessive consumption of alcohol.

Pregnancy-specific screening tools: T-ACE and TWEAK

The literature search identified 10 publications which evaluated the T-ACE and/or TWEAK in pregnant women. One publication (Alvik 2005) did not evaluate a screening tool against a reference standard. However, it was included in this report as it evaluated the effect of women completing a screening tool anonymously as compared to confidentially. This was considered a relevant study as it addressed the accuracy of self-reported alcohol consumption. Two publications evaluated the Brazilian versions of the T-ACE and TWEAK (Moraes 2004 and Fabbri 2007) and were therefore not included in this report. The main characteristics of these included studies are summarised in **Table 43**. The results of these publications are then discussed in more detail below.

It would be inappropriate to evaluate the studies described in this section using the NHMRC levels of evidence and quality criteria for screening interventions. This is because the studies assessed screening tools independently of any subsequent intervention (i.e. they have been evaluated as a diagnostic test in isolation). As will be explained in more detail in the discussion below, the efficacy of a screening tool must be considered in the context of the intervention that will be applied as a result of the screening tool. The publications identified here used the screening tool in the same

manner as a diagnostic test. Women were classified as risk drinkers using the most effective tool available (the reference standard). The screening tool was then assessed for its ability to identify (or diagnose) risk drinkers relative to the assignment made by the reference standard. Therefore, the NHMRC level of evidence and quality criteria for a *diagnostic test* are the most appropriate in this context.

All studies were Level III-2, as a comparison was not made with a valid reference standard (as there is no true gold standard). A quality assessment was performed on six studies: four were rated as fair and two were rated as poor. Alvik 2005 was not given a quality rating as it did not evaluate a screening tool (as discussed above).

Table 43 Screening tools: Characteristics of studies evaluating the T-ACE and TWEAK

Citation	Study type Study quality	Population	Intervention	Reference standard	Outcome
Diagnostic Level III-2					
Sokol 1989	Level III-2 Fair	Consecutive pregnant African American women who reported any alcohol consumption in their lifetime N=971	**T-ACE** CAGE MAST	Consuming ≥1 ounces of absolute alcohol/day (determined by Interview)	Sensitivity Specificity PPV Efficiency
Russell 1994	Level III-2 Fair	Consecutive pregnant African American women who reported any alcohol consumption in their lifetime N=4,743	**TWEAK** **T-ACE** MAST CAGE NET	Consuming ≥1 ounces of absolute alcohol/day (determined by Timeline Follow Back method)	Sensitivity Specificity PPV Efficiency Follow-up rate ROC curve
Russell 1996	Level III-2 Fair	Pregnant African American women who reported any alcohol consumption in their lifetime N=2,717 N=1,420 (T-ACE only)	**TWEAK** **T-ACE** MAST CAGE	Consuming ≥1 ounces of absolute alcohol/day (determined by Timeline Follow Back method)	Sensitivity Specificity PPV Efficiency ROC curve
Chang 1998	Level III-2 Poor	Pregnant women attending prenatal care N=350 (250 T-ACE positive and 100 T-ACE negative)	**T-ACE** SMAST AUDIT Medical record	DSM-III-R More than two drinks per drinking day (as determined by Timeline Follow Back, AUDIT and response to a health and habits survey) Current alcohol consumption (as above)	Sensitivity Specificity ROC curve

Table 43 Screening tools: Characteristics of studies evaluating the T-ACE and TWEAK (continued)

Citation	Study type Study quality	Population	Intervention	Reference standard	Outcome
Chang 1999a	Level III-2 Poor	Pregnant women attending prenatal care N=350 (250 T-ACE positive and 100 T-ACE negative)	**T-ACE** AUDIT SMAST Clinical predictors **T-ACE plus clinical predictors** AUDIT plus clinical predictors	Current alcohol consumption (as determined by Timeline Follow Back, AUDIT and response to a health and habits survey)	Sensitivity Specificity ROC curve
Chang 1999b	Level III-2 Fair	Consecutive pregnant women attending prenatal care N=135	**TWEAK (T1≥2)** **TWEAK (T1>2)** **TWEAK (T2>5)** Medical records	DSM-III-R More than two drinks per drinking day (as determined by Timeline Follow Back, AUDIT and response to a health and habits survey) Current alcohol consumption (as above)	Predictive ability
Dawson 2001	Level III-2 Poor	Pregnant women who reported any alcohol consumption in their lifetime N=404	**TWEAK** **TWEAK + HIGH4** **TWEAK + KEPTFROM** **TWEAK +INJURE** **TWEAK +ALCTRT** **TWEAK +PARTNER** **TWEAK +SMOKER** **TWEAK +ASSIST** **TWEAK +UNWANTED** **TWEAK +ASSALT**	Low-risk (no alcohol consumption during pregnancy) Moderate-risk (consumed some alcohol, but an average daily consumption of ≤1 drink and drank 3 or more drinks less than once a month) High-risk (average daily consumption of >1 drink or drank 3+ drinks once a month or more). (all determined by interview)	Sensitivity Specificity False positives
Alvik 2005	N/A [A]	Pregnant women receiving ultrasound screening N=1,940	**T-ACE** [A] Multiple questions about alcohol consumption (questionnaire) (all measures completed confidentially)	**T-ACE** [A] Multiple questions about alcohol consumption (questionnaire) (all measures completed anonymously)	Completing the questionnaire anonymously vs confidentially

Abbreviations: AUDIT= Alcohol Use Disorders Identification Test, DSM-III-R= Diagnostic and Statistical Manual of Mental Disorders, revised, N/A=not applicable, PPV=positive predictive value, ROC=receiver operator curve, SMAST=Short Michigan Alcoholism Screening Test, T-ACE =tolerance, annoyed, cut-down, eye-opener.

a This publication did not evaluate a screening tool and it was therefore not given a quality rating. It compared measures of alcohol consumption when questionnaires were completed anonymously vs confidentially, therefore there is technically no 'intervention' or 'reference standard'

SOKOL 1989

The development of the T-ACE was described in Sokol 1989. Pregnant African-American women who had previously consumed alcohol completed the MAST and CAGE questionnaires. Women were also interviewed and asked a question about tolerance, "How many drinks does it take you to get high?", and to recall their average drinking around the time of conception and a recent, 2-week drinking history. Subjects were classified as 'risk drinkers' if they reported consuming a mean of more than 1 ounce of absolute alcohol per day.

The four CAGE questions (C=cut down, A=annoyed, G=guilt and E=eye opener) and the tolerance question were included in a stepwise linear discriminant analysis. Four items (C, A, E and tolerance) were found to be significantly related to dichotomised absolute alcohol intake. The 'guilt' item did not add significantly to the prediction of risk-drinking (F to remove <1.00). A logistic regression was used to obtain fitted probabilities and odds ratios for risk-drinking for each of the four items, both as singular questions and in combination. The results are shown in Table 44. The tolerance question was the strongest predictor of risk drinking (11.7% of subjects who answered yes to this question were a 'risk drinker' as defined by the interview). As a screening tool needs to be usable in a clinical setting, statistical weighting for each response was considered too complicated. Therefore, a score of 2 was assigned to the tolerance question and a score of 1 was assigned to the A, C and E questions. This combination of questions was called the T-ACE screening tool.

Table 44 Screening tools: results of logistic regression as a function of the T-ACE questions (Sokol 1989)

	Probability of being a risk-drinker (%)	Odds ratio
None	1.5	1.0
T	11.7	8.5
A	2.8	1.8
C	5.1	3.5
E	3.0	2.0
All	62.7	107.1

The performance of the T-ACE, CAGE and MAST was then compared with the reference standard (self-reported alcohol consumption of >1 ounce of alcohol per day), as shown in **Table 45**. The T-ACE achieved greater sensitivity, specificity, positive predictive value and efficiency than the MAST when comparable cut-points were compared. For example, the highest sensitivity (76%) was achieved at a cut-point (the overall score defined as being positive) of ≥1 for both the T-ACE and the MAST. At this cut-point the results for the T-ACE vs MAST were as follows: specificity 79% vs 76%, positive predictive value 14% vs 13% and efficiency 79% vs 76%. The T-ACE was superior to the CAGE as it had a higher maximum sensitivity (76% for the T-ACE vs 59% for the CAGE). At the same sensitivity (38%), the positive predictive value of the T-ACE was more than two times higher than that of the CAGE.

Table 45 Screening tools: Comparison of T-ACE, CAGE and MAST (Sokol 1989)

	T-ACE			MAST		CAGE	
	≥ 1	≥ 2	≥ 3	≥ 1	≥ 5	≥ 1	≥ 2
Predicted to be a risk drinker [a]	23	13	4	26	5	20	9
Sensitivity	76	69	38	76	36	59	38
Specificity	79	89	97	76	96	82	92
PPV	14	23	40	13	29	13	18
Efficiency	79	88	95	76	94	80	90

Abbreviations: PPV=positive predictive value

[a] 'Risk drinker' was defined as >1 ounce of absolute alcohol per day as self-reported by interview

RUSSELL 1994 AND RUSSELL 1996

Subjects in Russell 1994 were pregnant African-American women who had previously consumed alcohol. The women completed the MAST, CAGE and Timeline Follow Back questionnaires and answered the 'tolerance' question from the T-ACE questionnaire (due to low literacy levels in the cohort, interviewers administered the questions). The TWEAK, T-ACE and NET were not administered as separate screening instruments; they were calculated from the items embedded in the MAST, CAGE, Timeline Follow Back and tolerance questions. Subjects were classified as 'risk drinkers' if they reported consuming more than 1 ounce of absolute alcohol per day (as determined by the Timeline Follow Back method).

The women in Russell 1996 were recruited from the same site as the women in Russell 1994, although it is unclear if the publications described the same cohort. Screening questionnaires were administered in the same format as Russell 1994, although the NET was not used. A separate cohort of women was screened with the T-ACE alone in order to evaluate the impact of using a separate screening tool rather than evaluating the T-ACE from questions embedded in the CAGE. Subjects were classified as 'risk drinkers' if they reported consuming more than 1 ounce of absolute alcohol per day (as determined by the Timeline Follow Back method).

In both publications the questionnaires were assessed using a cut-point of 1, 2 and 3 for the screening tools. A comparison was made with 'risk drinkers' (as determined by the Timeline Follow Back method). Accuracy indices for the area under the receiver operating characteristics (ROC) curves are shown in **Table 46**. In Russell 1994 the area under the ROC curve was largest for the TWEAK and lowest for the NET and CAGE. The optimal combination of sensitivity and specificity for the TWEAK and T-ACE was a cut-point of 2. The optimal cut-point was not stated for the MAST, NET or CAGE. Results from Russell 1996 were similar, with the TWEAK and T-ACE associated with a significantly larger area under the ROC curve than the MAST and CAGE.

Table 46 Screening tools: Accuracy indices for ROC curves for TWEAK, T-ACE, MAST, NET and CAGE (Russell 1994 and Russell 1996)

Screening questionnaire	Accuracy Index
Russell 1994 [a]	
TWEAK	0.865 (SD=0.0014)
T-ACE	0.840 (SD=0.015)
MAST	0.833 (SD=0.016)
NET	0.793 (SD=0.017)
CAGE	0.776 (SD=0.013)
Russell 1996 [a]	
TWEAK	0.894 (95% CI 0.867, 0.921)
T-ACE	0.887 (95% CI 0.858, 0.916)
MAST	0.821 (95% CI 0.782, 0.860)
CAGE	0.763 (95% CI 0.720, 0.806)

Abbreviations: CI = confidence interval; SD = standard deviation.

[a] Comparison with 'risk drinkers'

Table 47 shows the sensitivity, specificity, positive predictive value, efficiency and follow-up rates for the questionnaires at cut-points ranging from 1 to 3. Russell 1994 reported that at every cut-point the five item TWEAK was more sensitive than the four item T-ACE, while the T-ACE was more sensitive than the NET. Despite having 25 items, the MAST was less sensitive to risk drinking than the TWEAK and T-ACE at a cut point of 1 and 2. At a cut-point of 3, the MAST was more sensitive than the TWEAK but less specific, however at this cut-point the sensitivity is considerably lower than it is at lower cut-points.

Russell 1996 reported that the TWEAK was more sensitive than the T-ACE at all cut-points. At cut-point 1 and 2 the TWEAK and T-ACE were more sensitive than the MAST and CAGE, however at cut-point 3 the MAST was comparable to the TWEAK and T-ACE.

Both publications reported that the CAGE did not perform well at any cut-point.

Russell 1996 evaluated the performance of the T-ACE when it was calculated from items administered in other screening tools, and when it was performance as a stand-alone screening tool. The Timeline Follow Back method was used as a reference standard. When administered as a separate screening tool, the sensitivity was 67%, the specificity was 86%, the positive predictive value was 33% and the efficiency was 85%. However, caution must be taken when comparing results as there were significant differences between the cohort of women given the T-ACE as a separate screening tool and the cohort of women who completed the T-ACE embedded in the other screening tools. A key difference between the cohorts was the mean alcohol consumption: women who received the T-ACE alone reported higher alcohol consumption (mean of 0.4 ± 1.3 ounces per day and 9.1% classified as risk drinkers vs 0.2 ± 0.8 ounces per day and 6.5% classified as risk drinkers in the embedded group).

Table 47 Screening tools: Comparison of TWEAK, T-ACE, MAST, NET and CAGE (Russell 1994 and Russell 1996)

	TWEAK			**T-ACE**			**MAST**			**NET**			CAGE		
	≥ 1	≥ 2	≥ 3	≥ 1	≥ 2	≥ 3	≥ 1	≥ 2	≥ 3	≥ 1	≥ 2	≥ 3	≥ 1	≥ 2	≥ 3
Russell 1994 [a]															
Sensitivity	87	79	59	83	70	45	80	69	61	71	61	24	68	49	30
Specificity	72	83	94	75	85	97	75	85	92	86	87	99	82	93	98
PPV	16	22	39	17	22	46	16	21	32	23	22	58	18	30	52
Efficiency	72	83	92	75	85	94	75	84	90	85	85	95	81	91	94
Follow-up rate	32	21	9	28	18	6	28	18	11	18	16	2	21	9	3
Russell 1996 [a]															
Sensitivity	92	91	67	91	88	61	80	69	61	NR	NR	NR	66	46	27
Specificity	67	77	92	70	79	95	73	84	91	NR	NR	NR	81	93	99
PPV	17	22	39	18	23	47	17	23	32	NR	NR	NR	20	32	56
Efficiency	69	78	91	71	80	93	73	83	89	NR	NR	NR	80	90	94

Abbreviations: NR=not reported, PPV=positive predictive value

[a] Comparison with 'risk drinkers', defined as consumption of >1 ounce of absolute alcohol per day

CHANG 1998, CHANG 1999A AND CHANG 1999B

The three publications by Chang described a cohort of patients recruited from the same prenatal clinic. All patients attending the clinic were asked to complete the T-ACE prior to their first prenatal visit. Chang 1998 and Chang 1999a recruited a consecutive sample of 250 T-ACE positive subjects (defined as a T-ACE score of ≥2) and 100 T-ACE negative subjects. It should be noted that the selection of subjects based on their T-ACE score limits the applicability of these results to the general population. The publications do not clearly state if the same 350 subjects were included in each article. Chang 1999b described a subset of 135 women who also completed the six item TWEAK.

Chang 1998 and Chang 1999a stated that subjects completed the following: 1) alcohol and drug abuse modules from the structured clinical interview in the Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R); 2) ASI; 3) AUDIT; 4) SMAST; 5) an estimate of alcohol consumption in the 90 day period prior to study enrolment using the Timeline Follow Back method and; 6) Alcohol Craving Scale. A review of each patient's medical records was also performed. All subjects completed a general health and habits survey.

Chang 1999b stated that women completed the 1) alcohol and drug abuse modules from the structured clinical interview in the DSM-III-R; 2) AUDIT; 3) an estimate of alcohol consumption in the 90 day period prior to study enrolment using the Timeline Follow Back method and; 4) the six item TWEAK. The six-item TWEAK differs from the standard five item TWEAK as it contains a second 'tolerance' item: "How many drinks does it take before the alcohol makes you fall asleep or pass out? Or, if you never drink until you pass out, what is the largest number of drinks you have?" Three different versions of the TWEAK were evaluated:

1. subjects had to give an answer of ≥2 to be positive for the first tolerance question (T1≥2)
2. subjects had to give an answer of >2 to be positive for the first tolerance question (T1>2)
3. subjects had to give an answer of >5 to be positive for the second tolerance question (T2>5).

In all versions, subjects were considered positive if their overall score was ≥2.

Chang 1998 and Chang 1999b classified subjects as having a 'lifetime alcohol diagnosis' if they met the criteria in the DSM-III-R, 'risk drinking' if they consumed more than two drinks per drinking day and a 'current alcohol consumption if they currently consumed alcohol. 'Risk drinkers' and 'current alcohol consumers' were defined based on the Timeline Follow Back data, response to the AUDIT question 'how many drinks do you have on a typical day when you are drinking?' and response to a health and habits survey question about the number of drinks per drinking day. Only the classification 'current alcohol consumption' was used in the analyses in Chang 1999a. This publication also assessed five clinical predictors: age greater than 30, receiving routine obstetric care, early pregnancy recognition and alcohol craving in the last week.

In Chang 1998, the ROC curve analyses for the T-ACE. AUDIT and SMAST as an independent predictor of DSM-III-R diagnoses, risk drinking, and current drinking are shown in **Table 48**. The AUDIT performed significantly better than the T-ACE ($p<0.005$) and the SMAST ($p<0.005$) as a predictor of lifetime alcohol diagnoses. The AUDIT also performed significantly better than the T-ACE ($p=0.04$) and the SMAST ($p<0.001$) as a predictor of current drinking. The difference between the predictive abilities of the T-ACE and the SMAST for risk drinking was not significant. The AUDIT was not analysed with 'risk drinking' because the definition of risk drinking was based on a question from the AUDIT.

All ROC curves in Chang 1999a were calculated using 'current alcohol consumption'. Consequently, results for the T-ACE, AUDIT and SMAST alone were the same as those reported in Chang 1989. The five clinical predictors had a greater predictive value than the T-ACE, but not the AUDIT. Both the AUDIT and T-ACE were enhanced by the addition of the clinical predictors, although this was only significant for the T-ACE ($p=0.001$).

Chang 1999b compared the three versions of the TWEAK with 'life time alcohol diagnosis', 'risk drinking' and 'current alcohol consumption'. The TWEAK ($T1\geq2$) was the most sensitive, but least specific for all three categories of alcohol use. A review of the subjects' medical records was the least sensitive, but most specific tool.

Table 48 Screening tools: Accuracy indices for ROC curves for T-ACE, AUDIT and SMAST compared with 'lifetime alcohol diagnosis', 'risk drinker' and 'current drinker' (Chang 1998 and Chang 1999a)

Screening questionnaire	Accuracy Index (SE)
Chang 1998	
T-ACE vs 'life time alcohol diagnosis'	0.644 (0.030)
AUDIT vs 'life time alcohol diagnosis'	0.763 (0.028)
SMAST vs 'life time alcohol diagnosis'	0.624 (0.032)
T-ACE vs 'risk drinking' [a]	0.687 (0.029)
SMAST vs 'risk drinking' [a]	0.551 (0.034)
T-ACE vs 'current alcohol consumption'	0.647 (0.029)
AUDIT vs 'current alcohol consumption'	0.708 (0.028)
SMAST vs 'current alcohol consumption'	0.518 (0.032)
Chang 1999a	
T-ACE vs 'current alcohol consumption'	0.647 (0.029)
AUDIT vs 'current alcohol consumption'	0.708 (0.028)
SMAST vs 'current alcohol consumption'	0.518 (0.032)
Clinical predictors vs 'current alcohol consumption'	0.688 (0.030)
T-ACE plus clinical predictors vs 'current alcohol consumption'	0.747 (0.026)
AUDIT plus clinical predictors vs 'current alcohol consumption'	0.752 (0.036)
Chang 1999b	
TWEAK (T1≥2) vs 'life time alcohol diagnosis'	0.653 (0.030)
TWEAK (T1>2) vs 'life time alcohol diagnosis'	0.712 (0.028)
TWEAK (T2>5) vs 'life time alcohol diagnosis'	0.677 (0.032)
TWEAK (T1≥2) vs 'risk drinking' [a]	0.678 (0.029)
TWEAK (T1>2) vs 'risk drinking' [a]	0.787 (0.034)
TWEAK (T2>5) vs 'risk drinking' [a]	0.734 (0.029)
TWEAK (T1≥2) vs 'current alcohol consumption'	0.645 (0.029)
TWEAK (T1>2) vs 'current alcohol consumption'	0.644 (0.028)
TWEAK (T2>5) vs 'current alcohol consumption'	0.644 (0.032)

Abbreviations: SE = standard error.

[a] 'risk drinking' was defined as >2 drinks/drinking day

Table 49 compares the sensitivity and specificity of screening instruments with various cut-points defining a positive test as described in Chang 1998. The T-ACE was assessed by scoring a women as positive for the 'tolerance' question if she reported intoxication after >2 drinks, or if she reported intoxication after ≥2 drinks. The most sensitive screening tool for was the T-ACE with tolerance of two drinks or more, with a sensitivity of 88% for detecting lifetime alcohol diagnoses, 92% for risk drinking and 89% for current drinking. However, it was also the least specific. The T-ACE outperformed medical staff assessment of medical records, although 96% of women were asked about drinking when they enrolled in prenatal care.

Table 49 Screening tools: Comparison of T-ACE, AUDIT, SMAST and medical records compared with 'lifetime alcohol diagnosis', 'risk drinker' and 'current drinker' (Chang 1998)

	T-ACE		AUDIT			SMAST	Medical record
Cut-point	Tolerance > 2	Tolerance ≥ 2	≥ 8	≥ 10	≥ 11	NA	NA
Sensitivity vs 'lifetime alcohol diagnoses'	87.8	60.0	22.6	11.0	7.0	14.8	15.6
Specificity vs 'lifetime alcohol diagnoses'	36.6	64.4	97.4	99.0	99.6	97.9	93.6
Sensitivity vs 'risk drinking' [a]	92.4	74.3	NR	NR	NR	11.4	6.7
Specificity vs 'risk drinking' [a]	37.6	71.4	NR	NR	NR	95.9	89.4
Sensitivity vs 'current alcohol consumption'	89.2	60.0	15.0	6.7	3.3	7.5	20.0
Specificity vs 'current alcohol consumption'	37.8	66.9	93.9	96.9	97.8	94.3	96.1

Abbreviations: NR=not reported

[a] 'risk drinking' was defined as >2 drinks/drinking day

The sensitivity and specificity of the three variations of the TWEAK and a review of subject's medical records, as described in Chang 1999b, are shown in **Table 50**. The TWEAK ≥2 was the most sensitive, but least specific screening tool. In contrast, the medical records review was the least specific, but most sensitive.

Table 50 Screening tools: Comparison of three versions of the TWEAK and medical records compared with 'lifetime alcohol diagnosis', 'risk drinker' and 'current drinker' (Chang 1999b)

	TWEAK T1 >2	TWEAK T1≥2	TWEAK T2>5	Medical record
Sensitivity compared with 'lifetime alcohol diagnoses'	84.1	58.7	57.1	15.9
Specificity compared with 'lifetime alcohol diagnoses'	25.0	77.8	70.8	94.4
Sensitivity compared with 'risk drinking' [a]	92.3	71.2	67.9	7.5
Specificity compared with 'risk drinking' [a]	28.9	80.7	74.4	87.8
Sensitivity compared with 'current alcohol consumption'	87.8	55.1	57.1	22.4
Specificity compared with 'current alcohol consumption	25.6	69.8	66.3	95.6

Abbreviations: NR=not reported

[a] 'risk drinking' was defined as >2 drinks/drinking day

DAWSON 2001

A total of 404 women attending a prenatal clinic were recruited into the study. All women reported consuming at least one alcoholic drink in their life. Subjects completed the 5-item TWEAK and nine variations of the TWEAK which included an additional question (shown in **Table 51**). An interview was also conducted, and women were classified as low-risk (no alcohol consumption during pregnancy), moderate-risk (consumed some alcohol, but an average daily consumption of ≤1 drink

and drank ≥3 drinks less than once a month) or high-risk (average daily consumption of >1 drink or drank ≥3 drinks once a month or more). These definitions were used as the reference standard.

Table 51 Screening tools: Variations on the TWEAK (Dawson 2001)

Modified screening tool	Details of additional question
TWEAK + HIGH4	Do you require 4 or more drinks to get high? (modified from T-ACE)
TWEAK + KEPTFROM	Has alcohol kept you from doing something you had to do? (taken from the AUDIT)
TWEAK +INJURE	Have you injured yourself or someone else as a result of drinking? (taken from the AUDIT)
TWEAK +ALCTRT	Have you ever received treatment for your own problems with alcohol?
TWEAK +PARTNER	Do you have a partner with alcohol problems?
TWEAK +SMOKER	Are you a current smoker?
TWEAK +ASSIST	Are you a recipient of public assistance?
TWEAK +UNWANTED	Is your pregnancy not wanted?
TWEAK +ASSALT	Have you been injured in a fight or assault?

Using the standard TWEAK, moderate-risk drinking was classified as a score ≥1 and high-risk drinking as a score of ≥2. Three different cut-points were evaluated for the modified TWEAK questionnaires:

Scoring option 1: 0=low-risk, 1=moderate-risk, ≥2=high-risk
Scoring option 2: 0-1=low-risk, 2=moderate-risk, ≥3=high-risk
Scoring option 3: 0=low-risk, 1-2=moderate-risk, ≥3=high-risk

The TWEAK demonstrated a sensitivity of 70.6% in predicting high-risk drinking relative to the interview result. It was less sensitive when predicting any risk drinking (65.6%) or moderate-risk drinking (57.6%). Specificity for the TWEAK was 73.2% with respect to high-risk drinking and 63.7% with respect to any risk drinking. Of the false positives for any risk drinking, 40.2% were estimated as being at moderate as opposed to high-risk, meaning that nearly half of the false positives would be assigned to a moderate rather than an intensive intervention.

Relative to the basic TWEAK, alternative screeners based on the first scoring option generally showed an increase in sensitivity at the cost of reduced specificity, but few of the differences were statistically significant. Adding ASSIST or UNWANTED significantly increased the sensitivity for moderate-risk drinking to 71.8% and 74.1%, respectively. The addition of SMOKER significantly decreased specificity for high-risk drinking (59.3%), and SMOKER, ASSIST, and UNWANTED all reduced the specificity of the TWEAK in predicting any risk drinking (52.7%, 50.2%, and 48.4%). The addition of SMOKER significantly reduced the proportion of false positives classified as moderate-risk (24.8%), but the addition of UNWANTED significantly increased this proportion (51.7%).

Use of the second scoring option resulted in significant increases in specificity at the cost of consistent but non significant reductions in sensitivity. This held true for high-risk, moderate-risk, and any risk drinking across eight of the nine alternative screening instruments. The use of the third scoring option tended to have the same

effect, but only the parameters for high-risk drinking were affected. The third scoring option also significantly increased the proportion of false positives classified as moderate-risk, a benefit in terms of reducing the cost of false positives.

The one alternative screening instrument that showed promise for improvement over the basic TWEAK was the TWEAK + SMOKER screener when the second scoring option was used. It appeared to increase both specificity and sensitivity for high-risk drinking, although neither of these differences was statistically significant. This was accomplished without any apparent adverse effect on the sensitivity and specificity for any risk or moderate-risk drinking. When the third scoring option was used with the TWEAK + SMOKER, it additionally improved sensitivity for moderate-risk drinking but significantly decreased specificity for any risk drinking.

Table 52 Screening tools: Comparison of TWEAK and nine alternative TWEAK screening tools (Dawson 2001)

	TWEAK	TWEAK +HIGH4	TWEAK +KEPTFROM	TWEAK +INJURE	TWEAK +ALCTRT	TWEAK +PARTNER	TWEAK +SMOKER	TWEAK +ASSIST	TWEAK +UNWANTED	TWEAK +ASSALT
Standard TWEAK scoring										
Sensitivity for 'high-risk'	70.6	NA	NA	NA	NA	NA	NA	NA	NA	NA
Sensitivity for 'moderate-risk' [a]	57.6	NA	NA	NA	NA	NA	NA	NA	NA	NA
Sensitivity for 'any risk	65.6	NA	NA	NA	NA	NA	NA	NA	NA	NA
Sensitivity for 'high-risk'	73.2	NA	NA	NA	NA	NA	NA	NA	NA	NA
Sensitivity for 'any risk	63.7	NA	NA	NA	NA	NA	NA	NA	NA	NA
% false positives classified as moderate-risk	40.2	NA	NA	NA	NA	NA	NA	NA	NA	NA
Scoring option 1: 0, 1, ≥2										
Sensitivity for 'high-risk'	NA	76..5	70.6	76.5	73.5	70.6	82.4	76.5	82.3	73.5
Sensitivity for 'moderate-risk' [a]	NA	61.2	57.6	57.6	57.6	61.1	69.4	71.8 *	74.1 *	63.5
Sensitivity for 'any risk	NA	68.1	65.6	66.4	65.6	68.9	75.6	76.5	78.7 *	71.4
Sensitivity for 'high-risk'	NA	71.6	71.6	72.1	73.0	70.8	59.3 *	68.3	69.4	71.0
Sensitivity for 'any risk	NA	61.3	63.0	63.3	63.3	59.4	52.7 *	50.2 *	48.4 *	60.9
% false positives classified as moderate-risk	NA	40.7	38.5	27.7	39.8	40.3	24.8 *	46.4	51.7 *	39.1
Scoring option 2: 0-1, 2, ≥3										
Sensitivity for 'high-risk'	NA	64.7	58.8	64.7	58.8	61.8	76.4	67.7	64.7	58.8
Sensitivity for 'moderate-risk' [a]	NA	44.7	47.1	44.7	43.5	45.9	57.6	48.2	49.4	45.9
Sensitivity for 'any risk	NA	53.8	53.8	53.8	52.1 *	52.9 *	64.7	56.3	58.8	53.8
Specificity for 'high-risk'	NA	78.7	80.9 *	81.1 *	82.2 *	81.1 *	78.4	79.5 *	79.5 *	80.9 *
Specificity for 'any risk	NA	77.1 *	77.2 *	77.2 *	77.9 *	75.8 *	64.4	73.3 *	75.1 *	76.2 *
% false positives classified as moderate-risk	NA	25.0 *	32.8	33.4	33.8	36.8	51.0 *	41.3	35.7	37.3

Table 52 Screening tools: Comparison of TWEAK and nine alternative TWEAK screening tools (Dawson 2001) (continued)

	TWEAK	TWEAK +HIGH4	TWEAK +KEPTFROM	TWEAK +INJURE	TWEAK +ALCTRT	TWEAK +PARTNER	TWEAK +SMOKER	TWEAK +ASSIST	TWEAK +UNWANTED	TWEAK +ASSALT
Scoring option 3: 0, 1-2, ≥3										
Sensitivity for 'high-risk'	NA	64.7	58.5	64.7	58.8	61.8	76.4	67.7	64.7	58.8
Sensitivity for 'moderate-risk' [a]	NA	61.2	57.6	57.6	57.6	61.2	69.4	71.8 *	74.1 *	43.5
Sensitivity for 'any risk	NA	68.1	65.6	66.4	65.6	68.9	75.6	76.5	78.1 *	71.4
Specificity for 'high-risk'	NA	78.7	80.9 *	81.1 *	82.2 *	81.1 *	78.4	79.5 *	79.5 *	80.9 *
Specificity for 'any risk	NA	61.3	63.0	63.3	63.3	59.4	52.7 *	50.2 *	48.4 *	60.9
% false positives classified as moderate-risk	NA	55.6 *	58.7 *	59.2 *	60.2 *	62.3 *	63.2 *	68.6 *	69.0 *	61.8 *

Abbreviations: NA=not applicable

[a] Percentage of individuals at moderate-risk classified as being at moderate or high-risk

* Significantly different ($p<0.05$) from the value from the TWEAK alone

ALVIK 2005

Alvik 2005 compared the effect of asking pregnant women to completed the T-ACE and a questionnaire either confidentially (i.e. the clinician knew which patient completed the questionnaire N=1,749) or anonymously (i.e. women did not identify themselves and left the questionnaire in a locked box in the waiting room N=191). The 'tolerance' question in the T-ACE was considered positive if the subject consumed more than two Standard Units. All other questions were scored out of 1, and a woman was considered positive if she scored ≥2. The questionnaire included items about civil status, education, income, physical and mental health, smoking habits, and alcohol use. Direct alcohol questions included items on binge drinking and usual quantity and frequency consumed for the following time periods: the six months before pregnancy, pregnancy week zero to six, seven to 12, and 13 to the time of the questionnaire.

As shown in **Table 53**, there was no significant difference in the proportion of subjects who were T-ACE positive, the proportion of subjects who reported binge drinking or usually drinking more than one drink on a drinking occasion. There was also no difference in the reported number of standard units consumed at different points throughout the pregnancy. There was a small difference ($p<0.10$) in reported alcohol consumption prior to pregnancy, the reported number of standard unit of alcohol consumed prior to pregnancy and after 13 weeks. The self-reported number of standard units per week was slightly higher in women who completed the questionnaires anonymously.

Table 53 Screening tools: Comparison of confidential and anonymous completion of the T-ACE and other alcohol outcomes (Alvik 2005)

Measure	Confidential	Anonymous	Significance
T-ACE positive	40.5	34.3	NS
T-ACE tolerance positive	41.8	35.1	NS
T-ACE annoyed positive	1.3	1.7	NS
T-ACE considered reduce positive	4.7	4.0	NS
T-ACE eye opener positive	0.7	1.1	NS
≥8 SU in one sitting prior to pregnancy	58.6	60.7	NS
≥8 SU in one sitting between week 0-6	21.9	24.7	NS
≥8 SU in one sitting between week 7-12	1.6	1.7	NS
≥8 SU in one sitting after week 13	1.1	1.1	NS
Any alcohol consumption before pregnancy	89.8	85.3	p≤0.1
Any alcohol consumption between week 0-6	44.7	49.7	NS
Any alcohol consumption between week 7-12	22.6	22.5	NS
Any alcohol consumption between week 13+	23.3	25.8	NS
Usually ≥1 drink per occasion before pregnancy	87.7	84.2	NS
Usually ≥1 drink per occasion week 0-6	31.3	30.3	NS
Usually ≥1 drink per occasion week 7-12	9.6	7.4	NS
Usually ≥1 drink per occasion week 13+	10.2	8.6	NS
SU before pregnancy	2.2 (SD=3.0)	2.7 (SD=4.7)	p≤0.1
SU week 0-6	0.74 (SD=2.7)	0.70 (SD=1.8)	NS
SU week 7-12	0.11 (SD=0.6)	0.09 (SD=0.3)	NS
SU week 13+	0.10 (SD=0.3)	0.14 (SD=0.6)	p≤0.1
Did not drink prior to pregnancy	10.4	14.8	NS
Drank <3.5 SU/week prior to pregnancy	65.3	55.7	NS
Drank 3.5-6.9 SU/week prior to pregnancy	17.4	19.9	NS
Drank 7-13.9 SU/week prior to pregnancy	6.3	8.0	NS
Drank ≥14 SU/week prior to pregnancy	0.7	1.7	NS
Did not drink between weeks 0-6	56.7	51.9	NS
Drank <3.5 SU/week between weeks 0-6	37.1	40.7	NS
Drank 3.5-6.9 SU/week between weeks 0-6	3.9	4.9	NS
Drank 7-13.9 SU/week between weeks 0-6	1.8	2.5	NS
Did not drink between weeks 7-12	77.8	78.0	NS

Table 53 Screening tools: Comparison of confidential and anonymous completion of the T-ACE and other alcohol outcomes (Alvik 2005) (continued)

Measure	Confidential	Anonymous	Significance
Drank <3.5 SU/week between weeks 7-12	22.0	22.0	NS
Drank 3.5-6.9 SU/week between weeks 7-12	0.1	0	NS
Drank 7-13.9 SU/week between weeks 7-12	0.1	0	NS
Did not drink after week 13	77.0	74.7	NS
Drank <3.5 SU/week after week 13	23.0	24.1	NS
Drank 3.5-6.9 SU/week after week 13	0	1.3	NS

Abbreviations: SD=standard definition, SU=standard units, NS=not significant

A subgroup analysis was performed on women who attended university and those who did not. Only measures which were significantly different in these groups are shown in **Table 54**. University educated women were significantly more likely to report alcohol consumption during pregnancy if they were asked anonymously. Conversely, women without a university education were significantly less likely to report alcohol consumption both prior and during pregnancy when the questions were anonymous. They were also significantly less likely to report that they consumed ≥1 drinks on a drinking occasion if the answer was anonymous.

Table 54 Screening tools: Comparison of effect of university education on confidential and anonymous reporting of alcohol outcomes (Alvik 2005)

	University educated			Not university educated		
Measure	**Confidential**	**Anonymous**	**Sig**	**Confidential**	**Anonymous**	**Sig**
Any alcohol consumption between pregnancy	91.6	93.5	NS	86.4	66.0	p≤0.001
Any alcohol consumption between weeks 0-6	47.5	60.7	p≤0.01	38.8	22.4	p≤0.01
Any alcohol consumption between weeks 7-12	22.5	30.7	p≤0.05	22.7	2.2	p≤0.001
Any alcohol consumption after week 13	24.2	34.8	p≤0.05	21.3	4.3	p≤0.05
Usually ≥1 drink per occasion before pregnancy	89.5	90.3	NS	84.3	69.2	p≤0.0 5

Abbreviations: sig=significance

Other screening tools identified in the literature search

The literature search identified 12 other publications (see **Table 55**) which are briefly described in Appendix E. The publications were generally of poor quality with poorly reported outcomes. Although these studies have been fully appraised as part of this review, their poor design and quality renders them of negligible clinical importance. Hence, they are listed here and described briefly in Appendix E, but are not considered within the body of evidence.

Typically, authors arbitrarily selected items for evaluation and reported how many subjects were detected using each item. Some items, or combination of items, detected a large proportion of 'at risk' subjects, however few publications described the specificity of the selected items. Other publications (Chasnoff 2001, Chasnoff 2007, Clark 1999 and Midanik 1998) evaluated screening strategies for both alcohol and illicit drug use. These types of tools are not as sensitive or specific as tools designed for detecting alcohol use alone.

There was no evidence that any of the screening tools in **Table 55** were appropriate for use in the prenatal setting.

Table 55 Screening tools: Characteristics of studies evaluating biomarkers

Citation	Population	Intervention	Reference standard	Outcome
Aros 2006	Pregnant women N=834	Author defined items	Self-reported consumption of >48g alcohol/day	Author defined item which identified the highest proportion of women who drank >48g alcohol/day
Bad Heart Bull 1999	Pregnant Native Indians N=208	Author defined items (based on the T-ACE and quantity / frequency questions)	Structured interview Medical records review	Sensitivity Specificity
Burd 2006	Pregnant women N=697	Author defined items	Children with and without FASD (registry data)	Sensitivity Specificity Accuracy
Chasnoff 2001	Pregnant women N=2,002	Author defined items	Self-reported drug and alcohol consumption	Items which best predicted drug and alcohol use
Chasnoff 2007	Pregnant women N=228	4P's plus	Self-reported substance use	Sensitivity Specificity PPV NPV
Clark 1999	Pregnant women N=400	Author defined items (shorter form) Author develop items (longer form)	Self-reported substance use	Proportion of subjects reporting substance use
Goransson 2006	Pregnant women N=315	AUDIT Timeline Follow Back	Review of medical records	Proportion of subjects reporting alcohol use
Kesmodel and Olsen 2001	Pregnant women N=441	Interview (average weekly intake) Interview (current intake) Diary (prior 2 weeks) Questionnaire	All items were compared with each other	Proportion of subjects reporting alcohol use
Lapham 1991	Pregnant women N=201	Author defined items delivered by computer questionnaire	Author defined items delivered by a paper questionnaire	Proportion of subjects reporting substance abuse
Midanik 1998	Pregnant women N=1,147	Drug CAGE Alcohol CAGE	Self-reported substance use	Sensitivity Specificity ROC
Waterson and Murray-Lyon 1988	Pregnant women N=1,122	Quantity/frequency questions Author defined items CAGE BMAST	Self-reported alcohol consumption	Sensitivity Specificity
Waterson and Murray-Lyon 1989	Pregnant women N=1,117	Quantity/frequency questions Author defined items CAGE	Self-reported alcohol consumption	Proportion of subjects reporting alcohol use

Abbreviations: BMAST=Brief Michigan Alcoholism Screening Test, NPV=negative predictive value, PPV=positive predictive value

Discussion

Sokol 1989 reported that modifying the CAGE to include a 'tolerance' item (the T-ACE) improved the specificity of the screening tool. The increased efficacy of the T-ACE may be a result of women being less likely to deny a 'tolerance' to alcohol. The tolerance question is less likely to be recognised as an indication of the level of alcohol consumption and women are therefore more likely to answer the question honestly.

Russell 1994 compared the TWEAK, T-ACE, CAGE, MAST and NET. The TWEAK compared favourably with the T-ACE, combining a high sensitivity with reasonable specificity levels. This highlighted the importance of including a 'tolerance item', as both tools performed substantially better then the CAGE despite sharing multiple items. As the TWEAK outperformed the NET, the 'worry' item from the TWEAK may be more sensitive than the 'annoy' item from the NET because some women may not be annoyed if others worry or complain about their drinking. Although the MAST performed well, it was considered too long and too difficult to score to be used for screening in clinical practice. The authors note several areas that warrant further investigation. The MAST questionnaire asked questions more typical of males (e.g. prior treatment for alcoholism, number of fights after drinking, arrests for drink driving) and it is possible that these questions desensitised or sensitised obstetric patients. The questions were administered by an interviewer and results may have been different if they were self-administered. The TWEAK, T-ACE and NET were not administered independently; they were embedded in the MAST and CAGE. This question was evaluated in Russell 1996, which reported that that the sensitivity of the T-ACE decreased when it was administered alone rather than as part of an interview that included the MAST and CAGE. Although this loss of sensitivity was accompanied by an increase in specificity, sensitivity is generally given priority when validating a screening tool.

Russell 1994 evaluated several potential cut-points. As sensitivity is usually the key outcome for screening, a case can be made for selecting a cut-off of 1 for the TWEAK or T-ACE. However, when a condition is relatively rare, small decreases in the specificity can greatly increase the false-positive rate. Therefore, both Russell 1994 and Russell 1996 recommended that a cut-point of 2 be used for the TWEAK and the T-ACE in order to maximise the sensitivity while maintaining an adequate specificity.

Chang 1998 compared the predictive ability of the T-ACE, AUDIT, and SMAST. Analysis of ROC curves found that the AUDIT had the best overall accuracy for DSM-III-R lifetime alcohol diagnoses and current drinking when cut-points were not considered. However, the superior performance of the AUDIT must be balanced against the requirements of its administration (asking ten core clinical questions, with responses scored from 0 to 4 and then summing results to achieve a total score ranging from 0 to 40) and, more importantly, the necessity of establishing an appropriate cut-point for the prenatal patient. Previously established cut-points resulted in unacceptable sensitivity for all three types of drinking in this study. In contrast, the T-ACE was shorter and simpler to score. With tolerance defined as two or more drinks to feel intoxicated, it was the most sensitive instrument to identify current alcohol consumption, risk drinking and lifetime alcohol diagnoses, but it was also the least specific. The specificity of the T-ACE could be increased at the expense of the sensitivity by using its original definition of tolerance (more than two drinks).

However, in the case of risk for prenatal exposure to alcohol, the authors noted that it is preferable to have more false positives than false negatives, particularly if the T-ACE sparks discussion about prenatal alcohol use between a patient and her doctor.

Chang 1999a reported that the predictive value of the T-ACE could be improved by the addition of clinical variables: the patients' age, alcohol craving in the past week and specific obstetrics data (early recognition of pregnancy and routine care). This exploratory study also demonstrated the importance of clinical variables when assessing prenatal alcohol use, since their predictive ability was comparable to that of either the T-ACE or AUDIT and superior to the SMAST.

Chang 1999b compared three variations of the six item TWEAK, using different cut-points for the tolerance questions. The TWEAK had the best predictive value when the first tolerance question (number of drinks before feeling the first effects of alcohol) was considered positive at more than two drinks. The sensitivity could be increased if this was lowered to two or more drinks; however it was associated with some loss in specificity and predictive value. A review of the medical records was the least sensitive but most specific method for identifying alcohol use during pregnancy.

Dawson 2001 evaluated nine variations on the TWEAK. None of the additional items significantly improved the TWEAK as a screening tool. The most effective addition item was 'current smoking', which increased both sensitivity and specificity for high-risk drinking (using a cut-point of 2 points for moderate/any risk drinking and 3 points for high-risk drinking). Smoking during pregnancy might reflect the kind of risk-taking behaviour and disregard for medical advice that is indicative of episodic heavy drinking, or it may reflect a general tendency toward substance addiction that identifies women with alcohol dependence and the sustained heavy drinking style that often accompanies this disorder. A key finding of the study is that the TWEAK scoring can be modified to screen for moderate-risk drinking, albeit at the cost of erroneously including a substantial proportion of low-risk women in this category. A TWEAK score of one is recommended for identifying moderate-risk women, with a score of two or more continuing to represent the threshold for high-risk drinking.

The authors note that the statistical significance in sensitivity and specificity need to be interpreted with caution due to the multiple comparisons made between screening tools. The sensitivity and specificity for the standard TWEAK was lower than that reported in Russell 1994 and Russell 1996. This may reflect poor reporting of alcohol consumption, or the different definition of high-risk drinking. The definition applied in Dawson 2001 was more conservative and also defined risk drinking in terms of episodic heavy drinking. When a definition of high-risk drinking based solely on an average daily ethanol intake of ≥1 ounce of ethanol was applied (as used in Russell 1994 and 1996), the resulting sensitivity and specificity for high-risk drinking increased to 87.5% and 72.0%, respectively, similar to what was reported in the publications by Russell *et al*.

Alvik 2005 reported that there was no significant difference in the T-ACE when it was completed confidentially compared with completed anonymously. In contrast, there was evidence that women underreported their alcohol consumption when asked direct questions about their drinking behaviour. University educated women were significantly more likely to report alcohol consumption during pregnancy if they were

asked anonymously. Conversely, women without a university education were significantly less likely to report alcohol consumption both prior and during pregnancy when the questions were anonymous. These results must be interpreted with caution due to the relatively few participants in the anonymous group without university education (N=53). In the confidential group, the women with lower education had close to twice as high item non-response on the direct alcohol questions during pregnancy, compared with those with higher education. This may partly explain why pregnant women with higher education have reported more alcohol use than those with lower education.

The importance of using screening tools was highlighted in Chang 1999a. In this cohort, 96% of subjects had discussed their alcohol consumption with their obstetric provider in a non-structured format. However, only 20% of women who had consumed alcohol during their pregnancy had this documented in their obstetric record. As discussed in the introduction, pregnant women may deliberately under-report alcohol consumption due to the stigma associated with drinking during pregnancy. The T-ACE and TWEAK are designed to overcome this problem by asking indirect questions about alcohol consumption that women are more likely to answer truthfully (such as the 'tolerance' item). This was shown in the Alvik 2005, in which women reported a significantly higher level of alcohol consumption when direct questions were asked anonymously compared with confidentially. However there was no significant difference in any of the T-ACE items.

All publications which compared the TWEAK and T-ACE with other screening tools reported that these two screening tools had the highest sensitivity and specificity. The MAST (Russell 1994 and Russell 1996) and AUDIT (Chang 1998, Chang 1999a and Chang 1999b) were comparable to the T-ACE and TWEAK in terms of effectiveness, however their length and complicated scoring system makes them less appropriate in a clinical setting.

As discussed in the introduction to this section, the desire to use a highly sensitive screening tool must be considered in the context of its specificity. This is clearly shown in Russell 1994. This cohort included 270 risk-drinkers and 4437 non-risk drinkers. Using the standard TWEAK, a subject was considered a risk drinker if they scored ≥2. If the cut-point was lowered to ≥1, the sensitivity increased by 8%, which in this cohort was equivalent to correctly identifying an additional 22 risk-drinkers. However, reducing the cut-point decreased the specificity by 11%, which resulted in an additional 533 non risk-drinkers incorrectly identified as risk drinkers. Similarly, lowering the cut point for the T-ACE from 2 to 1 identified an additional 36 risk-drinkers at the cost of incorrectly identifying an additional 500 non risk-drinkers. Therefore, a small increase in the number of true positives was associated with a significant increase in the number of false positives (and therefore unnecessary interventions). Any negative implications of this unnecessary intervention will be dependent upon the nature of the intervention (i.e. less important if the intervention is inexpensive and easy to administer).

The evaluation of a screening tool must also be considered in the context of the population being studied. As discussed above, an increase in sensitivity is often associated with a decrease in specificity. In the example given, risk drinkers made up a small proportion of the population (270/4437, 6%). However, if the same screening

tool were evaluated in a clinic in which a much larger proportion of women were risk drinkers, the results would be quite different. As an example, if 270 women were risk drinkers and only 1000 women were not risk drinkers, the proportion of risk drinkers would be 21%. As in Russell 1994, an increase in specificity of 8% would still be equivalent to correctly identifying an additional 22 risk-drinkers. However, the same decrease in specificity of 11% would only incorrectly identify an additional 140 subjects, rather than the 533 subjects in the lower risk cohort described in Russell 1994. In the hypothetic cohort with a large proportion of high-risk women, it may be appropriate to use the modified screening tool with the higher specificity. It may also be more critical to identify women in a higher risk population. Screening tools generally give a dichotomous outcome (i.e. high-risk or not high-risk) and do not quantify the level of alcohol use. In a clinic where more women drink at very high-risk levels, it may become more important to identify them. Therefore, within this context the increase in false positives may be justified given the increased importance of identifying high-risk women.

Subjects in Sokol 1989, Russell 1994 and Russell 1996 were African American women who reported any alcohol consumption in their lifetime. The majority (96%) of subjects in Dawson 2001 were African American women who had previously consumed alcohol. In contrast, the majority of subjects (71%) in the publications by Chang *et al.* were Caucasian and received a positive score when they completed the T-ACE (250/350). The women in Alvik 2005 were Scandinavian and were not selected on the basis of alcohol consumption. Due to the significant variation in the populations described in these publications, it is not appropriate to directly compare results between publications or meta-analyse the results.

Any comparisons must also be considered in the context of the different reference standards used. Sokol 1989, Russell 1994 and Russell 1996 evaluated the ability of the screening tools to detect women who consumed a mean of ≥1 ounce of absolute alcohol per day. The publications by Chang evaluated the ability of the screening tools to detect women who met the DSM-III-R lifetime alcohol diagnosis criteria, women who drank ≥2 drinks per drinking day and women who consumed any alcohol. Dawson 2001 compared the ability of screening tools to detect low-risk women (no alcohol consumption during pregnancy), moderate-risk women (average daily consumption of ≤1 drink and drank ≥3 drinks less than once a month) and high-risk women (average daily consumption of >1 drink or drank ≥3 drinks once a month or more). Alvik 2005 evaluated 20 different direct measures of alcohol use, including frequency of alcohol consumption, binge drinking and level of alcohol consumption.

In all publications, the reference standard outcomes were evaluated by interviewing subjects and asking direct questions about alcohol use. As discussed in the Introduction, self-reported measures of alcohol consumption are often unreliable. Drinking behaviour is often poorly estimated and is prone to recall bias. In addition, women may deliberately under-report alcohol consumption due to the stigma associated with drinking during pregnancy. Therefore the diagnostic accuracy of the reference standard must also be considered when evaluating the results of these publications. In reality, the reference standards used are likely to be imperfect themselves.

A range of cut-points were evaluated in the identified publications. Sokol 1989 recommended using the T-ACE with a cut-point of ≥2 (sensitivity 69%, specificity 89%, PPV 23%). Both Russell 1994 and Russell 1996 recommended that a cut-point of ≥2 be used for the standard TWEAK and T-ACE in order to optimise the sensitivity and specificity. Chang 1998 evaluated the T-ACE when two different scoring systems were used for the 'tolerance' item (>2 and ≥2). The sensitivity was higher when a positive response to the 'tolerance' item was defined as ≥2, however the specificity was lower. The authors do not recommend either scoring system, but note that it is probably better to have more false positives than false negatives if the T-ACE sparks discussion about prenatal alcohol use between a patient and her doctor. Chang 1999b evaluated three scoring systems for the 6 item TWEAK: ≥2 for the first 'tolerance' item, >2 for the first 'tolerance' item and >5 for the second 'tolerance' item. The authors concluded that the best scoring system was defining a positive response as >2 for the first 'tolerance' item. Dawson 2001 evaluated the ability of 10 different screening tools (the standard TWEAK and nine variations of the TWEAK) to identify low-risk, moderate-risk, and high-risk women using alternative 3 scoring systems. The authors concluded that none of the variations significantly improved the standard TWEAK. A cut-point of 1 could be used to as the threshold for moderate-risk women and a cut point of ≥2 could be used as the threshold for high-risk drinking.

It is also relevant to consider what a positive response means in the clinical setting. As discussed above, the publications used a variety of direct measures of alcohol consumption to validate the screening tools. Using a cut-point of ≥2, the T-ACE detected 69% (Sokol 1989), 70% (Russell 1994) and 88% (Russell 1996) of subjects who reported consuming a mean of ≥1 ounce of absolute alcohol per day, 60% of subjects who met the DMS-III-R criteria, 74% of subjects who drank ≥2 drinks per drinking day and 60% of women who consumed any alcohol during pregnancy (Chang 1998). Using a cut-point of ≥2, the TWEAK detected 79% (Russell 1994) and 91% (Russell 1996) of subjects who reported consuming a mean of ≥1 ounce of absolute alcohol per day, 70% of subjects who consumed a mean of ≥1 drink per day and ≥3 drinks once a month or more, and 57% of subjects who had mean daily consumption of <1 drink and drank ≥3 drinks less than once a month (Dawson 2001). This large variation in sensitivities and definitions makes it difficult to accurately assess the level of risk of women who are positive using this screening tool. This must be taken into consideration when using these tools to screen women for involvement in an intervention. The T-ACE detects 69-88% of women who consume a mean of ≥1 ounce of absolute alcohol per day (approximately 1 standard drink), which could be considered a quite high-risk group. Therefore, the T-ACE with a cut-point of ≥2 may not be an appropriate way of determine which women receive a detailed pamphlet about the risks of drinking during pregnancy as an unacceptable proportion of women who consume alcohol during pregnancy will be T-ACE negative.

The literature search did not identify any publications that specifically evaluated the standard questions asked by midwives in New Zealand as part of their prenatal evaluation ('How often did you drink alcohol before you knew you were pregnant, and how often do you drink alcohol currently?'). Unlike many other countries, women in New Zealand are managed by the same midwife throughout their pregnancy. This high level of continuity of care results in a strong relationship between patient and midwife. It is likely that women feel more comfortable disclosing alcohol

consumption, reducing the need for questionnaires such as the TWEAK and T-ACE which ask indirect questions about alcohol consumption in order to identify risk behaviour. However, it would be beneficial to validate these questions against the TWEAK and T-ACE.

In summary, the results presented here indicate that the most appropriate screening tool for use in the prenatal setting is the TWEAK or T-ACE. The standard cut-point for 'risk drinking' is a score of ≥2 using either test, however a score of ≥1 or ≥3 may be appropriate in a clinic with an unusually high or low-risk population. Alternatively, cut-points may also be appropriate if the consequence of a positive TWEAK or T-ACE is an short, low cost intervention (in which case a higher proportion of false positives may be acceptable) or an intensive, expensive intervention (in which case it may be of more importance that all treated women are true positives). This result should be considered in the context of the methodological constraints discussed above and the small number of published studies available.

Screening guidelines

Screening tools

The literature search identified 5 clinical practice guidelines which discussed relevant screening tools. These publications have based their discussions on the opinion of a panel of clinicians or the opinion of one or more authors. These types of publications represent the lowest level of evidence available and must be interpreted with caution.

NSW Department of Health 2006

The recommendations were developed after consultation with clinical experts. The NSW Department of Health recommended that all pregnant women be asked about their level of alcohol consumption (NSW Department of Health, 2006). Pregnant women who drank at levels over those recommended by the NHMRC should have a full assessment of alcohol intake and be referred for further management where appropriate. The guidelines recommended that screening tools be validated and reliable, but do not recommend any specific tool. They note that T-ACE and TWEAK have been developed for use with pregnant women, although they may be unable to detect low level drinking that is still risky in pregnancy (as defined in the Australian Alcohol Guidelines). The AUDIT is a validated tool, but it has not been designed specifically for use during pregnancy.

Centre for Disease Control (CDC), United States 2004

The guidelines published by the Centre for Disease Control (CDC) in the USA contain a detailed discussion of the different screening tools available (National Centre on Birth Defects and Developmental Disabilities, 2004). The recommendations were developed after consultation with clinical experts. These guidelines recommend that all women of childbearing age are screened for alcohol use, including women who are pregnant or nursing, women who are planning a pregnancy, and women who are sexually active and not using contraception (such as teens and college-aged women).

The CDC guidelines discuss the use of biomarkers as a screening tool, specifically gamma glutamyltransferase, carbohydrate-deficient transferrin and fatty acid ethyl esters synthase (which can be detected in the hair). The guidelines do not recommend

their use as they have a low sensitivity in non alcoholic women and are expensive to administer. They were therefore not considered feasible for use as a universal screening tool.

The CDC guidelines do not specifically recommend any one screening tool. They discuss research which shows that there is significant variation in the results depending on the population studied and note that it is therefore difficult to recommend a single tool for all populations. Simple screening techniques that include measures of quantity, frequency, and heavy episodic drinking, as well as behavioural manifestations of risk drinking, have proven to be most beneficial. Some of the key conclusions from the discussion about screening tools are shown in **Table 56**. The guidelines state that the 5-item TWEAK and the T-ACE are the recommended screening tools. No screening tools have been validated for use in pregnant adolescent women.

Table 56 Key conclusions about screening tools from the CDC guidelines

The 5-item TWEAK and T-ACE	For pregnant women, the T-ACE and the TWEAK are the recommended screening tools of choice The TWEAK is the optimal screening questionnaire for identifying heavy drinking or harmful alcohol use and dependence in racially mixed populations of non pregnant and pregnant women. With a cut point score of ≥2, the specificity of the TWEAK is high for all ethnic groups studied; however sensitivity was high for White non-Hispanic women but low for African-American non-Hispanic and Hispanic women. The TWEAK is a practical screening tool in a busy clinic setting. However the variable sensitivity in women of different ethnic backgrounds suggests that additional methods of screening should be employed.
Screening tools in adolescents	Standard screening tools are not as appropriate in adolescents and college students. The CAGE is not appropriate for screening adolescents and that a much lower cut point of two (rather than the eight recommended for adults) on the AUDIT is optimal for identifying alcohol use problems in this population. The CRAFFT shows promise as an alcohol and other drug screener for female adolescents.

BRITISH MEDICAL ASSOCIATION GUIDELINES 2007

These recommendations were prepared under the auspices of the Board of Science of the British Medical Association (BMA). The BMA guidelines note that there is no routine screening system for specifically monitoring alcohol consumption during pregnancy. Screening for alcohol use and misuse should be considered as part of the routine antenatal screening tests provided to pregnant women as a part of National Health Service (NHS) care. The guidelines recommend screening tools such as the T-ACE and TWEAK and state that it is important that the T-ACE and TWEAK screening questionnaires are used as part of routine antenatal screening. Further research is required into the most effective screening method for maternal alcohol consumption in the UK.

Table 57 BMA recommendations for screening tools

Screening for maternal alcohol consumption via objective screening techniques such as T-ACE and TWEAK should be considered as part of routine antenatal care in the NHS. The UK health departments together with relevant NHS bodies should ensure appropriate training, resources, guidance and incentives for this routine screening are provided.
All healthcare professionals involved in the provision of antenatal care should ensure that alcohol use among pregnant women is monitored and recorded appropriately.
Further research should be undertaken to examine the: use and validity of biological markers for detecting maternal alcohol consumption, ethical considerations for the use of biological markers of maternal alcohol consumption and most effective screening method for maternal alcohol consumption.

CANADIAN GOVERNMENT 2005

The Canadian Government (2005) recommended that any screening tool used in pregnant women should be validated and reliable. However, the guidelines do not recommend any specific tool. The guidelines were developed by a subcommittee of the Public Health Agency of Canada's National Advisory Committee on Fetal Alcohol Spectrum Disorder after reviewing, analysing and integrating current approaches to diagnosis.

SIGN 2003

The Scottish Intercollegiate Guidelines Network (SIGN) recommended that the TWEAK, T-ACE or shortened versions of the AUDIT questionnaire be used in the antenatal and preconception setting (SIGN, 2003). This recommendation was based on evidence from high quality systematic reviews, case control or cohort studies.

Summary and conclusions

Summary of evidence for evidence review

This section of the report systematically reviewed the international published evidence for prenatal screening and prevention strategies.

The most effective primary prevention strategy evaluated was alcohol prohibition. There was no evidence that warning labels on alcohol bottles or mass education campaigns reduce alcohol consumption in pregnant women.

Of the 13 identified secondary prevention programs, three significantly reduced prenatal alcohol consumption. Two programs were a brief intervention and involved education and behavioural modification components. The third publication described pooled results from nine different drug treatment programs. It is difficult to identify factors critical to the success of these three interventions as many of the features of these programs were also present in studies which found no benefit from the intervention.

Of the 14 identified tertiary prevention programs, one significantly reduced prenatal alcohol consumption. The intervention was an intensive drug and alcohol prevention program, which evolved from a 4-5 hour per day, 5 days a week outpatient program to a 7-8 hours per day, 5 days a week onsite residential program. The program included a range of support services, including social workers, substance abuse counsellors, mental health counselling, child care, early intervention and transportation. It is likely that this success of this program was related to its comprehensive nature.

Interventions were generally more effective in women who consumed low levels of alcohol at study entry. High-risk women were less able to change their drinking behaviour, which reflects the fact that women who consume high levels of alcohol are more likely to abuse alcohol. Therefore, interventions in high-risk women need to provide both information about alcohol use in pregnancy and alcohol addiction.

There was some evidence that providing pregnant women with any information about the risks of alcohol consumption during pregnancy resulted in reduced alcohol consumption. This occurred in controlled studies, in which women in the control arm were advised not to drink during pregnancy, received a short pamphlet or were given a brief alcohol assessment by a medical provider were able to significantly reduce their alcohol consumption. It may be that these simple procedures, conducted one-on-one with a medical provider, are the most appropriate interventions in the majority of low-risk women.

The T-ACE and TWEAK are the most appropriate screening tools for use in the prenatal setting. Pregnant women are generally considered 'risk drinkers' if they score ≥ 2 using either of these tools, however an alternative definition may be appropriate if the population being screening is very high-risk or very low-risk. The use of screening tools must also be considered in the context of the intervention that women classified as 'risk drinkers' will receive.

All of these results must be considered in the context of the small number of published studies identified and the low-level of evidence available.

Limitations of evidence base

The evidence considered in this review exhibited methodological limitations which are summarised below. Systematic reviews are only as good as the quality of the information contained within the included studies. There are many biases that may impact on the internal validity of individual clinical trials such as selection bias, performance bias, detection bias and attrition bias (Egger, 2001).

The studies identified in the literature search were generally of limited quality and had a number of key limitations:

- Insufficient detail provided about the intervention.
- Poor evaluation of drinking behaviour at different points during pregnancy (e.g. prior to the woman knowing she is pregnant or during first, second or third trimesters).
- Poor differentiation between binge drinking and regular, low level alcohol consumption.
- Limited acknowledgement of the problems associated with self-reported alcohol consumption.
- Limited use of validated questionnaires.
- Poorly defined outcomes (e.g. "alcohol abuse" and "increased drinking") or reporting only abstinence.
- Limited discussion of the clinical relevance of outcomes (e.g. small but statistically significant differences may not be of clinical relevance).
- Lack of a control arm or comparison group.

In addition, many studies suffer from small patient numbers and therefore are susceptible to type II error (i.e. failure to detect a true difference).

Conclusions

There is no strong evidence to suggest that any particular type of intervention is effective at reducing prenatal alcohol consumption. Women who consume low levels of alcohol during pregnancy may reduce their alcohol consumption after relatively simple interventions such as being informed about the risks of drinking during pregnancy. High-risk women are more likely to be abusing alcohol, and therefore may require more intensive interventions.

The most appropriate screening tools are the pregnancy-specific T-ACE and TWEAK questionnaires.

Top Level Review of Postnatal Screening and Diagnosis Literature

Introduction

Postnatal screening is used to identify individuals who may have FASD. Individuals who are positive after postnatal screening should be referred for a full FASD diagnosis. A screening strategy should be broad and identify all individuals who may potentially have FASD. A full diagnostic evaluation should only be performed by a trained specialist, and often requires a multi-disciplinary team. This section of the report evaluates the screening and diagnostic criteria for individuals with suspected FASD.

As noted previously, the assessment of postnatal screening and diagnosis literature was conducted as a top level review. Therefore, only systematic reviews and published guidelines were eligible for inclusion.

Methods

Research questions

The clinical questions to be answered by this review were defined by staff from the Population Health Directorate of the Ministry of in conjunction with the reviewers. In general, the aim of this section of the review was to comprehensively evaluate postnatal screening and diagnosis in FASD.

The primary research questions to be addressed within this section of the review were:

- Are postnatal screening tools (aimed at an individual suspected of having FASD and/or their mother) effective at identifying individuals who should undergo a full diagnostic FASD evaluation?
- Do diagnostic tools increase the accuracy of FASD identification?

For inclusion in the current review, the evidence had to fulfil the criteria outlined in **Table 58**. These criteria were developed *a priori* and were described in the scoping protocol prepared prior to commencement of the review proper.

Table 58 Criteria for determining study eligibility

Patient population	Individuals who may have FASD or mothers of individuals who may have FASD [A]
Intervention	Any strategy that aims to identify an individual who may have FASD or diagnose an individual with FASD
Comparator	Any comparator
Outcomes	Sensitivity and specificity of FASD diagnosis

[a] Screening can occur in an individual suspected of having FASD and/or the mother of an individual suspected of having FASD.

The population for this review will be any individual who may have FASD. Any strategy that aims to identify an individual who may have FASD or clinically diagnose an individual with FASD will be included in the review. In order to identify as many types of diagnosis strategies as possible, the review was not limited to studies comparing screening or diagnosis guidelines to any particular comparator. Only systematic reviews that include studies that measure the sensitivity and specificity of FASD diagnosis have been included.

Literature search

A literature search was conducted as described in the 'General methods' section. A search was performed in EMBASE.com, which include EMBASE and MEDLINE. A manual search of HTA websites was also undertaken. The search terms, search strategy and citations identified for this section of the review are presented in **Table 59.**

Table 59 Postnatal screening and diagnosis search strategy

Database	Date searched	Search no.	Search terms	Citations
EMBASE + MEDLINE	<1966 – 13 April 2008	1	('fetal alcohol syndrome'/exp OR 'fetal alcohol syndrome') OR ('fetal alcohol syndrome'/exp OR 'fetal alcohol syndrome') OR 'fetal alcohol syndrome' OR 'fetal alcohol spectrum disorder' OR 'fetal alcohol spectrum disorder' OR fasd	3,911
		2	('meta analysis'/exp OR 'meta analysis') OR ('systematic review'/exp OR 'systematic review') OR 'pooled analysis' OR ('review'/exp OR 'review') OR ('meta analysis'/exp OR 'meta analysis') OR systemat* OR pool*	2,160,272
		3	#1 AND #2	746
Cochrane	<1966 – 17 March 2008	1	fetal alcohol spectrum disorder OR fetal alcohol spectrum disorder OR fetal alcohol syndrome OR fetal alcohol syndrome	64
Manual searching of HTA sites				11
Total citations identified				**821**
Total citations after removal of duplicate citations				**812**

Assessment of study eligibility

The assessment of study eligibility was conducted as described in the 'General methods' section. As mentioned earlier, non-English publications were excluded at the database searching stage. Citations were excluded for the following reasons:

Not a systematic review, diagnostic criteria or guideline: including journal articles, case reports, animal studies, short notes, letters, editorials, conference abstracts, *in-vitro* studies, studies not deemed appropriate to the research question or nature of review

Not a systematic review, diagnostic criteria or guideline for postnatal screening or diagnosis of FASD

There were 812 non-duplicate studies identified by the search strategy. As detailed in **Table 60**, 16 full text articles were eligible for retrieval after excluding studies from the search titles and abstracts. Of the full papers retrieved, six were eligible for inclusion in this report (listed in **Table 61** and **Appendix A**) and 10 did not fulfil the inclusion criteria. No relevant systematic reviews of postnatal screening or diagnosis were identified. The citation details of all excluded articles are presented in **Appendix B**, annotated by reason for exclusion based on the exclusion criteria detailed above. Reasons are presented hierarchically such that the first reason in the list that applied is reported.

Table 60 Application of selection criteria to citations

Exclusion criteria	Number
Total citations	812
Citations excluded after review of abstract/title	
Not a systematic review, diagnostic criteria or guideline	778
Not a systematic review, diagnostic criteria or guideline of postnatal screening or diagnosis	18
Total number of excluded citations after review of abstract/title	796
Full papers reviewed:	16
Citations excluded after review of full paper	
Not a systematic review, diagnostic criteria or guideline	0
Not a systematic review, diagnostic criteria or guideline of postnatal screening or diagnosis	10
Total number of excluded citations after review of full paper	10
Total included citations	**6**

Due to the low number of citations that met the inclusion criteria, it was decided that key narrative review articles should also be included. One such review article was identified in the literature search.

The details of the seven included citations for postnatal screening and diagnosis are provided in **Table 61**.

Table 61 Included citations for postnatal screening and diagnosis

Citation ID	Citation
Diagnostic Criteria and Guidelines	
4-Digit Diagnostic Code	Astley, S. 2004. Diagnostic Guide for Fetal Alcohol Spectrum Disorders: The 4-Digit Diagnostic Code. University of Washington Publication Services. http://www.depts.washington.edu/fasdpn
British Medical Association	BMA Board of Science. Fetal alcohol spectrum disorders: A guide for healthcare professionals. 2007. British Library Cataloguing-in-Publication.
Canadian Guidelines	Chudley A, Conry J, Cook J, Loock C, Rosales T, LeBlanc N. Fetal alcohol spectrum disorder: Canadian guidelines for diagnosis. Can Med Assoc J 2005; 172(Suppl):Mar05-S21.
CDC	National Centre on Birth Defects and Developmental Disabilities. Fetal Alcohol Syndrome: Guidelines for Referral and Diagnosis. 2004. Centre for Disease Control.
Institute of Medicine	Stratton K, Howe C, Battaglia FC. 1996. Fetal alcohol syndrome: diagnosis, epidemiology, prevention, and treatment. Washington: Institute of Medicine and National Academy Press. http://www.nap.edu/books/0309052920/html/index.html
Hoyme Updated Institute of Medicine	Hoyme HE, Trujillo PM, Buckley D, Miller JH, Arango P, Khaole B et al. A practical clinical approach to diagnosis of fetal alcohol spectrum disorders: Clarification of the 1996 Institute of Medicine Criteria. Paediatrics 2005; 115(39):47.
Review articles	
Peadon 2008	Peadon E, Fremantle E, Bower C and Elliott, EJ. (2008). International survey of diagnostic services for children with Fetal Alcohol Spectrum Disorders. BMC Paed; 8:12-20.

Results

Overview

The following section is organised in the following manner: (i) a summary of any identified diagnostic criteria; (ii) a summary of any identified diagnosis guidelines and; (iii) a summary of any key review articles. Finally, an overall summary and discussion of the available evidence is presented.

More detailed information on each individual study included in the review is available in the data extraction tables in **Appendix D** or in the original papers. Only data directly relevant to the current review is presented in this section.

Published postnatal screening or diagnostic criteria

The search identified three articles describing FASD or FAS postnatal diagnostic criteria. No screening criteria were identified.

INSTITUTE OF MEDICINE 1996

The first diagnostic criteria for FAS were published by the Institute of Medicine after consultation with a panel of experts (Stratton *et al* 1996). The panel developed five diagnostic categories: FAS with and without a confirmed history of alcohol exposure, partial FAS, alcohol-related birth defects (ARBD), and alcohol-related neurodevelopmental disorder (ARND).

The diagnostic criteria are shown in **Table 62**. Any alcohol consumption during pregnancy was defined as confirmed maternal alcohol exposure. Characteristic facial

abnormalities were defined as palpebral fissures and abnormalities in the premaxillary zone (e.g., flat upper lip, flattened philtrum and flat midface). Growth retardation was defined as either low birth weight, decelerating weight over time not due to nutrition or disproportional low weight-to-height ratio. CNS neurodevelopmental abnormalities were defined as either decreased cranial size at birth, structural brain abnormalities (such as microcephaly, partial or complete agenesis of the corpus callosum, cerebellar hypoplasia) or neurologic hard or soft signs (such as impaired fine motor skills, neurosensory hearing loss, poor tandem gait, poor eye-hand coordination). An individual was defined as having FAS if they had known maternal alcohol exposure, characteristic facial abnormalities, growth retardation and CNS neurodevelopment abnormalities. Partial FAS was defined as known maternal alcohol exposure, some facial abnormalities and either growth retardation, CNS neurodevelopment abnormalities or behavioural or cognitive abnormalities.

The term ‘alcohol related effects’ (covering ARBD and ARND) was not intended to be used in individual patients, but to refer to the range of abnormalities that occur in individuals who were exposed to alcohol *in utero* but who did not have FAS. These diagnostic categories included clinical conditions for which clinical or animal research linked maternal alcohol ingestion to an observed outcome. The panel noted that if further research found that lower quantities or variable patterns of alcohol use was associated with ARBD or ARND, then these patterns of alcohol use should be incorporated into the diagnostic criteria. These two diagnostic categories (ARBD and ARND) were intended to convey some degree of uncertainty regarding whether prenatal alcohol exposure caused the adverse effects documented in an individual patient, or whether other factors were causative. They are therefore not appropriate for use in the clinical setting.

Table 62 Institute of Medicine diagnostic criteria

Fetal alcohol syndrome (FAS)

1. FAS with confirmed maternal alcohol exposure

A. Confirmed maternal alcohol exposure

B. Evidence of a characteristic pattern of facial abnormalities that includes features such as short palpebral fissures and abnormalities in the premaxillary zone (e.g., flat upper lip, flattened philtrum and flat midface)

C. Evidence of growth retardation, as in at least one of the following:

• low birth weight for gestational age

• decelerating weight over time not due to nutrition

• disproportional low weight-to-height ratio

D. Evidence of central nervous system neurodevelopmental abnormalities, as in at least one of the following:

• decreased cranial size at birth

• structural brain abnormalities (e.g., microcephaly, partial or complete agenesis of the corpus callosum, cerebellar hypoplasia)

• neurologic hard or soft signs (as age appropriate), such as impaired fine motor skills, neurosensory hearing loss, poor tandem gait, poor eye-hand coordination

2. FAS without confirmed maternal alcohol exposure

B, C, and D as above

3. Partial FAS with confirmed maternal alcohol exposure

A. Confirmed maternal alcohol exposure

B. Evidence of some components of the pattern of characteristic facial anomalies

Either C or D or E

C. Evidence of growth retardation, as in at least one of the following:

• low birth weight for gestational age

• decelerating weight over time not due to nutrition

• disproportionally low weight-to-height ratio

D. Evidence of CNS neurodevelopmental abnormalities, e.g.,

• decreased cranial size at birth

• structural brain abnormalities (e.g., microcephaly, partial or complete agenesis of the corpus callosum, cerebellar hypoplasia)

• neurologic hard or soft signs (as age appropriate) such as impaired fine motor skills, neurosensory hearing loss, poor tandem gait, poor eye–hand coordination

E. Evidence of a complex pattern of behaviour or cognitive abnormalities that are inconsistent with developmental level and cannot be explained by familial background or environment alone: e.g., learning difficulties; deficits in school performance; poor impulse control; problems in social perception; deficits in higher level receptive and expressive language; poor capacity for abstraction or metacognition; specific deficits in mathematical skills; or problems in memory, attention or judgment.

Table 62 Institute of Medicine diagnostic criteria (continued)

Alcohol-related effects

Clinical conditions in which there is a history of maternal alcohol exposure and where clinical or animal research has linked maternal alcohol ingestion to an observed outcome. There are 2 categories, which may co-occur. If both diagnoses are present, then both diagnoses should be rendered.

4. Alcohol-related birth defects (ARBD)

Congenital anomalies, including malformations and dysplasias

Cardiac: Atrial septal defects, Ventricular septal defects, Aberrant great vessels, Tetralogy of Fallot

Skeletal: Hypoplastic nails, Shortened fifth digits, Radioulnar synostosis, Flexion contractures, Camptodactyly, Clinodactyly, Pectus excavatum and carinatum, Klippel-Feil syndrome, Hemivertebrae, Scoliosis

Renal: Aplastic, dysplastic, hypoplastic kidneys, Horseshoe kidneys, Ureteral duplications, Hydronephrosis

Ocular: Strabismus, Retinal vascular anomalies, Refractive problems secondary to small globes

Auditory: Conductive hearing loss, Neurosensory hearing loss

Other: Virtually every malformation has been described in some patient with FAS. The etiologic specificity of most of these anomalies to alcohol, teratogenesis remains uncertain.

5. Alcohol-related neurodevelopmental disorder (ARND)

Presence of A or B or both.

A. Evidence of CNS neurodevelopmental abnormalities, as in any one of the following:

• decreased cranial size at birth

• structural brain abnormalities (e.g., microcephaly, partial or complete agenesis of the corpus callosum, cerebellar hypoplasia)

• neurologic hard or soft signs (as age appropriate), such as impaired fine motor skills, neurosensory hearing loss, poor tandem gait, poor eye-hand coordination

B. Evidence of a complex pattern of behaviour or cognitive abnormalities that are inconsistent with developmental level and cannot be explained by familial background or environment alone; e.g., learning difficulties; deficits in school performance; poor impulse control; problems in social perception; deficits in higher level receptive and expressive language; poor capacity for abstraction or metacognition; specific deficits in mathematical skills; or problems in memory, attention or judgment.

4-DIGIT DIAGNOSTIC CODE 2004

The University of Washington developed the 4-Digit Diagnostic Code for FASD, which uses quantitative, objective measurement scales and specific case definitions (Astley *et al.*, 2004). The 4-Digit Diagnostic Code was developed in response to concerns that guidelines such as those developed by the Institute of Medicine were not sufficiently specific to assure diagnostic accuracy or precision. For example, the Institute of Medicine criteria for CNS abnormalities do not address how many areas of deficit must be present, how severe the deficits must be, or what level of documentation must exist to substantiate the presence of the deficit. Unlike the Institute of Medicine diagnostic criteria, the 4-Digit Diagnostic Code can be used to diagnose both FAS and other FASD related diagnoses. Using this diagnostic criteria, the term FASD refers to the range of disorders associated with prenatal alcohol use and was not intended for use as a clinical diagnosis.

The 4 digits in the code reflect the magnitude of expression or severity of the 4 key diagnostic features of FAS: growth deficiency; the FAS facial phenotype; central nervous system damage or dysfunction; gestational exposure to alcohol (shown in **Table 63**). The magnitude of expression of each feature is ranked independently on a 4-point Likert scale with 1 reflecting complete absence of the feature and 4 reflecting its extreme expression. As an example, the 4-Digit Code 4444 reflects the most severe expression of FAS (significant growth deficiency, all three FAS facial features, structural/neurological evidence of CNS damage, and confirmed prenatal exposure to high levels of alcohol). At the opposite end of the scale is the 4-Digit Code 1111 reflecting normal growth, none of the three FAS facial features, no evidence of CNS abnormalities, and confirmed absence of prenatal alcohol exposure. Using these codes the clinician is able to diagnoses the full spectrum of outcomes classified under the umbrella term FASD.

Table 63 4-Digit Diagnostic Code criteria for FASD

Rank	Growth deficiency	FAS facial phenotype	CNS damage or dysfunction	Gestational exposure to alcohol
4	**Significant** Height and weight below 3rd percentile	**Severe** All 3 features: PFL 2 or more SDs below mean, Thin lip: rank 4 or 5 and smooth philtrum: rank 4 or 5	**Definite** Structural or neurologic evidence	**High risk** Confirmed exposure to high levels
3	**Moderate** Height and weight below 10th percentile	**Moderate** Generally 2 of the 3 features	**Probable** Significant dysfunction across 3 or more domains	**Some risk** Confirmed exposure. Level of exposure unknown or less than rank 4
2	**Mild** Height or weight below 10th percentile	**Mild** Generally 1 of the 3 features	**Possible** Evidence of dysfunction, but less than rank 3	**Unknown** Exposure not confirmed present or absent
1	**None** Height and weight at or above 10th percentile	**Absent** None of the 3 features	**Unlikely** No structural, neurologic or functional evidence of impairment	**No risk** Confirmed absence of exposure from conception to birth

Abbreviations: PFL= palpebral fissure lengths, SD=standard deviation

HOYME UPDATED INSTITUTE OF MEDICINE CRITERIA 2005

The 1996 Institute of Medicine diagnostic criteria was updated by Hoyme and colleagues on the basis of their extensive experience with alcohol-exposed children (Hoyme *et al.*, 2005). The authors state that the Institute of Medicine criteria is vague, with no specific parameters being set forth for diagnosis in each category. The degree of growth deficiency, facial dysmorphic features, behavioural and cognitive deficits are not clearly defined. Assessment of the family and genetic history of each affected child is not addressed adequately. The updated criteria also allow for ARBN and ARND to be used as a diagnostic term.

The updated criteria are shown in **Table 64**. Children with FAS (with or without confirmed maternal alcohol exposure) must have abnormalities in all domains (facial dysmorphic features, growth, and brain growth or structure). In the partial FAS category (with or without confirmed maternal alcohol exposure), children must display typical facial dysmorphic features and abnormalities in one of the other domains (growth or central nervous system structure or function).

For the two diagnoses characterised as alcohol-related effects, maternal alcohol exposure must be documented. The term ARBD is meant to apply to affected children in the FASD continuum who have typical facial features, normal growth and development, and specific structural anomalies (either major malformations or a pattern of minor malformations). ARND is meant to apply to children with normal growth and structural development who display a characteristic pattern of behavioural or cognitive abnormalities typical of prenatal alcohol exposure. In this latter category, it is imperative that the neurobehavioral abnormalities not be typical of other individuals in the family who were not exposed prenatally to alcohol. In addition, the abnormalities should not be explained by postnatal environmental influences alone.

Table 64 Hoyme Updated Institute of Medicine diagnostic criteria

FAS With Confirmed Maternal Alcohol Exposure (requires all features A–D)
A. Confirmed maternal alcohol exposure
B. Evidence of a characteristic pattern of minor facial anomalies, including ≥2 of the following
1. Short palpebral fissures (≤10th percentile)
2. Thin vermilion border of the upper lip (score 4 or 5 with the lip/philtrum guide)
3. Smooth philtrum (score 4 or 5 with the lip/philtrum guide)
C. Evidence of prenatal and/or postnatal growth retardation
1. Height or weight ≤10th percentile, corrected for racial norms, if possible
D. Evidence of deficient brain growth or abnormal morphogenesis, including ≥1 of the following
1. Structural brain abnormalities
2. Head circumference ≤10th percentile
FAS Without Confirmed Maternal Alcohol Exposure
IB, IC, and ID, as above
III. Partial FAS With Confirmed Maternal Alcohol Exposure (requires all features, A–C)
A. Confirmed maternal alcohol exposure
B. Evidence of a characteristic pattern of minor facial anomalies, including ≥2 of the following
1. Short palpebral fissures (≤10th percentile)
2. Thin vermilion border of the upper lip (score 4 or 5 with the lip/philtrum guide)
3. Smooth philtrum (score 4 or 5 with the lip/philtrum guide)
C. One of the following other characteristics
1. Evidence of prenatal and/or postnatal growth retardation
a. Height or weight ≤10th percentile corrected for racial norms, if possible
2. Evidence of deficient brain growth or abnormal morphogenesis, including ≥1 of the following
a. Structural brain abnormalities
b. Head circumference ≤10th percentile
3. Evidence of a complex pattern of behavioural or cognitive abnormalities inconsistent with developmental level that cannot be explained by genetic predisposition, family background, or environment alone
a. This pattern includes marked impairment in the performance of complex tasks (complex problem solving, planning, judgment, abstraction, metacognition, and arithmetic tasks); higher-level receptive and expressive language deficits; and disordered behavior (difficulties in personal manner, emotional lability, motor dysfunction, poor academic performance, and deficient social interaction)
Partial FAS Without Confirmed Maternal Alcohol Exposure
IIIB and IIIC, as above
ARBD (requires all features, A–C)
A. Confirmed maternal alcohol exposure
B. Evidence of a characteristic pattern of minor facial anomalies, including ≥2 of the following
1. Short palpebral fissures (≤10th percentile)
2. Thin vermilion border of the upper lip (score 4 or 5 with the lip/philtrum guide)
3. Smooth philtrum (score 4 or 5 with the lip/philtrum guide)
C. Congenital structural defects in ≥1 of the following categories, including malformations and dysplasias (if the patient displays minor anomalies only, ≥2 must be present): *cardiac*: atrial septal defects, aberrant great vessels, ventricular septal defects, conotruncal heart defects; *skeletal*: radioulnar synostosis, vertebral segmentation defects, large joint contractures, scoliosis; *renal*: aplastic/hypoplastic/dysplastic kidneys, “horseshoe” kidneys/ureteral duplications; *eyes*: strabismus, ptosis, retinal vascular anomalies, optic nerve hypoplasia; *ears*: conductive hearing loss, neurosensory hearing loss; *minor anomalies*: hypoplastic nails, short fifth digits, clinodactyly of fifth fingers, pectus carinatum/excavatum, camptodactyly, “hockey stick” palmar creases, refractive errors, “railroad track” ears

Table 64 Hoyme Updated Institute of Medicine diagnostic criteria (continued)

ARND (requires both A and B)
A. Confirmed maternal alcohol exposure
B. At least 1 of the following
1. Evidence of deficient brain growth or abnormal morphogenesis, including ≥1 of the following
a. Structural brain abnormalities
b. Head circumference ≤10th percentile
2. Evidence of a complex pattern of behavioural or cognitive abnormalities inconsistent with developmental level that cannot be explained by genetic predisposition, family background, or environment alone.
a. This pattern includes marked impairment in the performance of complex tasks (complex problem solving, planning, judgment, abstraction, metacognition, and arithmetic tasks); higher-level receptive and expressive language deficits; and disordered behaviour (difficulties in personal manner, emotional lability, motor dysfunction, poor academic performance, and deficient social interaction)

Published postnatal screening and diagnostic guidelines

The literature search identified two screening guidelines and three diagnostic guidelines.

Postnatal screening or referral guidelines

PUBLIC HEALTH AGENCY OF CANADA 2005

FASD referral guidelines published by the Canadian government are shown in **Table 65** (Public Health Agency of Canada, 2005). These were developed by a subcommittee of the Public Health Agency of Canada's National Advisory Committee on FASD. They reviewed, analysed and integrated current diagnostic approaches to reach agreement on a standard for Canada. The guidelines recommend that screening be based on identification of facial features, known exposure to alcohol or learning and/or behavioural difficulties. Individuals should be referred to a speciality clinic and treated by a trained professional.

Table 65 Canadian FASD referral guidelines

Referral of individuals for a possible FASD-related diagnosis should be made in the following situations:
a. Presence of 3 characteristic facial features (short palpebral fissures, smooth or flattened philtrum, thin vermilion border).
b. Evidence of significant prenatal exposure to alcohol at levels known to be associated with physical or developmental effects, or both.
c. Presence of 1 or more facial features with growth deficits plus known or probable significant prenatal alcohol exposure.
d. Presence of 1 or more facial features with 1 or more central nervous system deficits plus known or probable significant prenatal alcohol exposure.
e. Presence of 1 or more facial features with pre- or postnatal growth deficits, or both (at the 10th percentile or below [1.5 standard deviations below the mean]) and 1 or more central nervous system deficits plus known or probable significant prenatal alcohol exposure.
Individuals with learning or behavioural difficulties, or both, without physical or dysmorphic features and without known or likely prenatal alcohol exposure should be assessed by appropriate professionals or specialty clinics (i.e., developmental paediatrics, clinical genetics, psychiatry, psychology) to identify and treat their problems.

CENTRE FOR DISEASE CONTROL (CDC), UNITED STATES 2004

The CDC guidelines for referral of children with suspected FAS (i.e. not FASD) are shown in **Table 66** (National Centre on Birth Defects and Developmental Disabilities, CDC 2004). If it is known that a mother consumed high levels of alcohol during pregnancy but there is no other positive screening criteria, the primary healthcare provider should document this exposure and closely monitor the child's ongoing growth and development. If prenatal alcohol exposure is unknown, individuals should be referred for full FAS evaluation if they have characteristic facial features and/or growth deficits and CNS abnormalities. The guidelines note that they have been developed to provide assistance in making the referral decision, rather than as a definitive screening tool. They recommend that evaluation should occur on a case by case basis and that an individual should be referred for a full diagnostic evaluation if there is any doubt about the screening result.

Table 66 CDC FAS referral guidelines

For situations with known prenatal alcohol exposure
A child or individual should be referred for full FAS evaluation when there is confirmed significant prenatal alcohol use (i.e., 7 or more drinks per week or 3 or more drinks on multiple occasions, or both).
If prenatal alcohol exposure in the high-risk range is known in the absence of any other positive screening criteria, the primary healthcare provider should document this exposure and closely monitor the child's ongoing growth and development.
For situations with unknown prenatal alcohol exposure
A child or individual should be referred for full FAS evaluation when:
– there is any report of concern by a parent or caregiver (foster or adoptive parent) that his or her child has or might possibly have FAS.
– all three facial features are present (smooth philtrum, thin vermillion border, and small palpebral fissures).
– one or more facial features are present in addition to growth deficits in height or weight, or both.
– one or more facial features are present, along with one or more CNS abnormalities.
– one or more facial features are present, along with growth deficits and one or more CNS abnormalities.

Diagnostic guidelines

CANADIAN GUIDELINES 2005

In 2005 Canada published guidelines for the diagnosis of FAS and its related disabilities, which were developed after broad-based consultation among experts in diagnosis (Chudley *et al.*, 2005). FASD was defined as an umbrella term describing the range of effects that can occur in an individual whose mother drank alcohol during pregnancy. The term FASD was not intended for use as a clinical diagnosis.

The Canadian guidelines aimed to combine the descriptive terminology of the Institute of Medicine criteria and the objective measures described in the 4-Digit Diagnostic Code (see **Table 67**). For example, the categories from the Institute of Medicine criteria were used for growth impairment with the objective measures (below the 10th percentile for age) from the 4-Digit Diagnostic Code. The diagnostic process consists of screening and referral, physical examination and differential diagnosis, neurobehavioural assessment and treatment and follow-up. Due to the complexity and the range of expression of dysfunction related to prenatal alcohol exposure, a multidisciplinary team is essential for an accurate and comprehensive diagnosis and treatment recommendations.

Table 67 Canadian diagnostic criteria for FAS, partial FAS and ARBD

The criteria for the diagnosis of fetal alcohol syndrome, after excluding other diagnoses, are:
A. Evidence of prenatal or postnatal growth impairment, as in at least 1 of the following:
a. Birth weight or birth length at or below the 10th percentile for gestational age.
b. Height or weight at or below the 10th percentile for age.
c. Disproportionately low weight-to-height ratio (= 10th percentile).
B. Simultaneous presentation of all 3 of the following facial anomalies at any age:
a. Short palpebral fissure length (2 or more standard deviations below the mean).
b. Smooth or flattened philtrum (rank 4 or 5 on the lip-philtrum guide).
c. Thin upper lip (rank 4 or 5 on the lip-philtrum guide).
C. Evidence of impairment in 3 or more of the following central nervous system domains: hard and soft neurologic signs; brain structure; cognition; communication; academic achievement; memory; executive functioning and abstract reasoning; attention deficit/hyperactivity; adaptive behaviour, social skills, social communication.
D. Confirmed (or unconfirmed) maternal alcohol exposure.
The diagnostic criteria for partial fetal alcohol syndrome, after excluding other diagnoses, are:
A. Simultaneous presentation of 2 of the following facial anomalies at any age:
a. Short palpebral fissure length (2 or more standard deviations below the mean).
b. Smooth or flattened philtrum (rank 4 or 5 on the lip-philtrum guide).
c. Thin upper lip (rank 4 or 5 on the lip-philtrum guide).
B. Evidence of impairment in 3 or more of the following central nervous system domains: hard and soft neurologic signs; brain structure; cognition; communication; academic achievement; memory; executive functioning and abstract reasoning; attention deficit/hyperactivity; adaptive behaviour, social skills, social communication.
C. Confirmed maternal alcohol exposure.
The diagnostic criteria for alcohol-related neurodevelopmental disorder, after excluding other diagnoses, are:
A. Evidence of impairment in 3 or more of the following central nervous system domains: hard and soft neurologic signs; brain structure; cognition; communication; academic achievement; memory; executive functioning and abstract reasoning; attention deficit/hyperactivity; adaptive behaviour, social skills, social communication.
B. Confirmed maternal alcohol exposure.
Alcohol-related birth defects (ARBD)
The term ARBD should not be used as an umbrella or diagnostic term, for the spectrum of alcohol effects. ARBD constitutes a list of congenital anomalies, including malformations and dysplasias and should be used with caution.

The Canadian report also provides a method for harmonisation of the Institute of Medicine and 4-Digit Diagnostic Code. The report suggests that the approach identified in the 4-Digit Diagnostic Code should be used to describe, assess and measure objectively alcohol exposure, growth, facial features and brain damage. The 4-Digit Diagnostic Code should be recorded for each assessment and may be useful for surveillance and research purposes. The terminology in the Institute of Medicine criteria should be used to describe the diagnosis. The recommendations for using the Institute of Medicine terminology with the 4-Digit Diagnostic Code are shown in **Table 68.**

Table 68 Harmonization of IOM nomenclature and 4-Digit Diagnostic Code ranks for growth, face, brain and alcohol history

	4-Digit Diagnostic Code ranks			
IOM nomenclature	**Growth deficiency**	**FAS facial phenotype**	**CNS damage or dysfunction**	**Gestational exposure to alcohol**
FAS (with confirmed exposure)	2, 3 or 4	3 or 4	3 or 4	3 or 4
FAS (without confirmed exposure)	2, 3 or 4	3 or 4	3 or 4	2
Partial FAS (with confirmed exposure)*	1, 2, 3 or 4	2, 3 or 4	3 or 4	3 or 4
ARND (with confirmed exposure)	1, 2, 3 or 4	1 or 2	3 or 4 (2 for < 6 years)	3 or 4

* Any final 4-Digit code that can be made with these combinations of numbers and that is not also an FAS code signifies partial FAS. Combinations of face 2 that include two significant facial features also meet criteria for partial FAS.

CENTRE FOR DISEASE CONTROL (CDC), UNITED STATES 2004

The CDC guidelines for the diagnosis of FAS (i.e. not FASD) are shown in **Table 69** (National Centre on Birth Defects and Developmental Disabilities, CDC, 2004). The guidelines state that consensus was not reached by the scientific working group convened to develop the guidelines, or the scientific and clinical community at large regarding evidence-based diagnostic criteria for any prenatal alcohol-related condition other than FAS. At the time the guidelines were developed, it was the opinion of the CDC that the only diagnostic category with scientific evidence to support clinical criteria was FAS.

Table 69 Summary of the CDC diagnostic criteria for FAS

Facial dysmorphia
Based on racial norms, individual exhibits all three characteristic facial features:
Smooth philtrum (University of Washington Lip-Philtrum Guide rank 4 or 5)
Thin vermillion border (University of Washington Lip-Philtrum Guide rank 4 or 5)
Small palpebral fissures (at or below 10th percentile)
Growth problems
Confirmed prenatal or postnatal height or weight, or both, at or below the 10th percentile, documented at any one point in time (adjusted for age, sex, gestational age, and race or ethnicity).
Central Nervous System Abnormalities
I. Structural
1) Head circumference (OFC) at or below the 10th percentile adjusted for age and sex.
2) Clinically significant brain abnormalities observable through imaging.
II. Neurological problems not due to a postnatal insult or fever, or other soft neurological signs outside normal limits.
III. Functional Performance substantially below that expected for an individual's age, schooling, or circumstances, as evidenced by:
1) Global cognitive or intellectual deficits representing multiple domains of deficit (or significant developmental delay in younger children) with performance below the 3rd percentile (2 standard deviations below the mean for standardized testing)
or
2) Functional deficits below the 16th percentile (1 standard deviation below the mean for standardized testing) in at least three of the following domains: a) cognitive or developmental deficits or discrepancies b) executive functioning deficits c) motor functioning delays d) problems with attention or hyperactivity e) social skills f) other, such as sensory problems, pragmatic language problems, memory deficits, etc.
Maternal Alcohol Exposure
I. Confirmed prenatal alcohol exposure
II. Unknown prenatal alcohol exposure
Criteria for FAS Diagnosis
Requires all three of the following findings:
1. Documentation of all three facial abnormalities (smooth philtrum, thin vermillion border, and small palpebral fissures);
2. Documentation of growth deficits
3. Documentation of CNS abnormality

BRITISH MEDICAL ASSOCIATION 2007

There is no guidance in the UK on FASD diagnosis and referral (BMA Board of Science, 2007). Several sets of diagnostic criteria are currently used in clinics for the evaluation of FASD: the Institute of Medicine criteria, the 4-Digit Diagnostic Code and the Canadian FASD guidelines.

Formal diagnosis at the earliest possible stage is considered paramount as it permits the implementation of early intervention and treatment programmes. Early diagnosis can also decrease the risk of additional problems commonly found in individuals affected by these disorders that result from the neurocognitive deficits (e.g. psychiatric problems, disrupted school experience, alcohol and drug problems). Within the UK, specific skills in diagnosing and managing neurodevelopmental conditions already exist and could be enhanced to provide FASD services, for example Child Learning Disability services with links to local or regional genetics clinics.

General recommendations made by the BMA are shown in **Table 70**.

Table 70 BMA recommendations for FASD diagnosis

The UK health departments should produce guidance for healthcare professionals in the UK on the identification, referral and diagnosis for the full range of FASD.
The UK health departments should ensure appropriate diagnostic and referral services for FASD are adequately provided and resourced throughout the UK. There should be adequate funding for the development, training and maintenance of multidisciplinary diagnostic teams.

Summary of key review articles

The search did not identify any articles that reviewed FASD or FAS postnatal screening or diagnostic criteria. However, one article (Peadon *et al.*, 2008) surveyed FASD clinics and discussed their choice of diagnostic criteria.

Peadon 2008

Peadon and colleagues conducted an international survey of diagnostic services for children with FASD. Clinics which provided a dedicated specialist service for the assessment of children exposed to alcohol *in utero* were included in the survey. Clinics were identified by searching literature databases and online search engines. In countries in which no clinic was identified in the initial search, researchers identified clinics through publications about FASD, on the internet or by contacting organisations involved with people with a FASD and asking for information regarding diagnostic services in their country. A total of 34 clinics were identified worldwide. There authors were unable to identify any specialist clinics in Australia or New Zealand.

All 34 clinics offered a diagnostic service. Sixteen were also involved in screening for at risk children. Referral criteria varied between clinics. Eight had no specific referral criteria. Of the clinics with referral criteria, some required only a history of prenatal alcohol exposure, whereas others had more specific criteria mirroring the diagnostic features of FAS (i.e. prenatal alcohol exposure, central nervous system disorder and growth deficiency).

Clinics had different approaches to the assessment process. Twenty-three reported that they routinely carried out a physical assessment of the child. Twenty-five clinics took facial photographs and seventeen clinics used facial analysis software. Other routine assessments included audiology (N=7), genetic testing (N=7), vision assessment (N=6) and neuro-imaging (N=5). Thirty-two clinics carried out some form of neurobehavioural assessment. One clinic did not respond to this question, and one did not carry out any neurobehavioural assessment. Neurobehavioural assessments included: behavioural assessment (N=28); motor or visual-motor or perception tests (N=28); sensory function (N=22); cognitive or developmental testing (n = 19); neuropsychometric tests (N=17); adaptive behaviour or social skills or social communication (N=17); communication assessment (N=13); educational or academic assessment (N=12); and neurological examination (N=12).

The diagnosis of FASD is complicated by the debate about the most appropriate diagnostic criteria, with multiple guidelines published since 1996. This complexity was reflected in this survey, with centres using a variety of diagnostic criteria (see **Table 71)**. A single criteria was used at 23 sites, the most common of which were the

4-Digit Diagnostic Code (N=14 sites) and the Hoyme Updated Institute of Medicine (N=8 sites). Notably, 11 clinics used more than one set of diagnostic criteria or their own adaptations of published criteria. There was a significant variation in the specific criteria used at these sites. The CDC guidelines only define diagnostic criteria for FAS. Services which use these criteria would need to use another set of diagnostic criteria for other FASD diagnoses. Only two of the clinics using a combination of criteria, were using the same combination of criteria. This lack of agreement in diagnosis reduces the potential for comparison of data about FASD across clinics and countries. It also highlights the potential for confusion for health professionals around the diagnosis of FASD.

Table 71 Diagnostic criteria used in FASD diagnostic clinics (Peadon 2008)

Criteria	Number of centres
Sites using a single criteria	**N=23**
4-Digit Diagnostic code	N=14
Hoyme Updated Institute of Medicine	N=8
Institute of Medicine	N=1
Sites using more than one published criteria or an adaptation of published criteria	**N=11**
An adaptation of the 4-Digit Diagnostic code	N=2
4-Digit Diagnostic code, CDC criteria and Institute of Medicine	N=2
Hoyme Updated Institute of Medicine, Canadian guidelines, 4-Digit Diagnostic Code and Institute of Medicine	N=1
Hoyme Updated Institute of Medicine, 4-Digit Diagnostic Code and Institute of Medicine	N=1
Canadian guidelines and 4-Digit Diagnostic code	N=1
4-Digit Diagnostic Code and Institute of Medicine	N=1
Hoyme Updated Institute of Medicine and Institute of Medicine	N=1
CDC and Institute of Medicine	N=1
Institute of Medicine and other criteria	N=1

Discussion

Developing diagnostic criteria for FASD is particularly challenging. As the name indicates, FASD describes a spectrum of disorders. The pattern and severity of outcome is dependent on the timing, frequency, and quantity of prenatal alcohol exposure (which is rarely known with any level of accuracy), and is frequently confounded by other adverse prenatal and postnatal exposures and events. Consequently, individuals with prenatal alcohol exposure present with a wide range of outcomes, most of which are not specific to FASD. For example, individuals with FASD often exhibit behavioural disabilities which appear similar to attention deficit hyperactivity disorder (ADHD), or they may have comorbid ADHD. Clinicians may diagnose a child with ADHD and not evaluate them for FASD. This can lead to other FASD-related neurocognitive and behavioural disabilities remaining undetected and unmanaged. It should be noted that in this example the individual would be undergoing management for their FASD-related behavioural and learning problems, even if they had not specifically diagnosed with FASD. These problems are magnified when children have mild forms of FASD, or their primary symptoms are behavioural problems which are attributed to outside factors such as poor parenting. Individuals

with FASD may have an IQ which falls within the lower limit of normal range and have a high degree of expressive language. However, their level of comprehension may be very poor and detailed neurocognitive assessment is needed to detect the impairment. It is therefore important that diagnostic criteria are broad and assesses a wide range of potential FASD-related outcomes. It is also critical that health professionals are aware of FASD and its typical manifestations.

Diagnosis is further complicated by the difficulty in evaluating prenatal alcohol consumption. Some of these problems have been discussed in the introduction (e.g. poor estimation of alcohol content, difference in standard drinks sizes and recall bias). Admitting alcohol use during pregnancy can be confronting for some mothers, particularly when this results in a diagnosis that will acknowledge that their behaviour caused their child's illness, although most birth mothers find the diagnosis of FASD a positive starting point for themselves and their child (Alcohol Healthwatch 2007). The situation can be further complicated if the woman is still using or abusing alcohol, especially if the women is in denial about her alcohol use. Therefore, it is often prudent to obtain information about prenatal alcohol use from other reliable informants, such as a relative. However, as a significant proportion of individuals with suspected FASD are in foster care or have been adopted, this information if often not available. It may be possible to obtain information about alcohol consumption during pregnancy (e.g. from medical records or case files), but the lack of confirmation of alcohol use during pregnancy should not prevent an FASD diagnosis if all other criteria are present.

Some healthcare providers are reluctant to diagnose FASD out of fear of causing anxiety and guilt in the mother, child and family (Alcohol Healthwatch, 2007). However, early and accurate diagnosis results in significant benefits for an individual with FASD and their family which outweigh any perceived or real barriers to the health or wellbeing of the child, mother or family. Following a diagnosis, the individual with FASD can access interventions and resources that aim to prevent the development of secondary disabilities (e.g., unemployment, mental health problems, trouble with the law, inappropriate sexual behaviour and a disrupted school experience). A diagnosis of FASD can benefit the family as it provides an understanding and explanation of the reason for the child's behaviour problems and the family can learn to compensate for the dysfunction and be proactive rather than reactive (Alcohol Healthwatch, 2007). An early diagnosis can also benefit the diagnosed individual's birth mother as she may have access to appropriate interventions, counselling and treatment programs. This can be particularly important as it may prevent the birth of affected children in the future.

Two postnatal screening guidelines were identified in the literature search. According to the guidelines, screening should occur based on identification of facial features, known exposure to alcohol or learning and/or behavioural difficulties. The CDC guidelines state that the screening should provide assistance in making the referral decision, rather than be used as a definitive screening tool. All evaluations should be made on an individual basis and individuals should be referred for a full diagnostic evaluation if there is any concern about the results of the postnatal screen.

Five diagnostic criteria and guidelines were identified in the literature search. These publications have based their discussions on the opinion of a panel of clinicians or the

opinion of one or more authors. These types of publications represent the lowest level of evidence available and must be interpreted with caution. They all base diagnosis on an assessment of growth, facial features, CNS abnormalities and alcohol consumption during pregnancy. The first diagnostic criteria developed by the Institute of Medicine in 1996 used general definitions (e.g. low weight, flat upper lip, abnormal CNS function). Subsequent diagnostic criteria further defined these features in order to improve the diagnostic accuracy (e.g. weight $\leq 10^{th}$ percentile or the development of a standardised ranking for upper lip flatness).

The four criteria published after the Institute of Medicine diagnostic criteria have defined similar FAS diagnostic criteria. The individual must have poor growth (either weight or height $\leq 10^{th}$ percentile), three characteristic facial features (with the exception of the updated Institute of Medicine criteria, which only requires two), and evidence of CNS developmental abnormalities. FAS can be diagnosed in the absence of known prenatal alcohol exposure in all of the diagnostic criteria.

It is clear that there is now strong evidence to link lower levels of prenatal alcohol exposure to the less severe forms of FASD. However, only two publications (Hoyme Updated Institute of Medicine criteria and the 4-Digit Diagnostic Code) can be used to diagnose ARND and ARBD (or equivalent diagnostic terms). However the authors state that these terms must be used with caution and discuss the difficulties of diagnosing a condition which has a spectrum of outcomes, alternative diagnoses and comorbidities.

The Institute of Medicine criteria describes diagnostic criteria for alcohol-related effects (the term FASD was not in common usage at the time that the criteria was developed). However, the authors noted that this term was not intended to be used in the clinical setting as there was insufficient evidence to link lower levels of prenatal alcohol consumption to less severe clinical outcome. The panel stated that it may be appropriate to diagnose individuals with alcohol-related effects in the future if more evidence became available, and the diagnostic criteria should be updated accordingly. In contrast, the 4-Digit Diagnostic Code was designed to identify both FAS and the spectrum of FASD. Individuals can be ranked from 4444 (full FAS) to 1111 (normal). However, the authors state that "The term FASD is not intended for use as a clinical diagnosis. A patient would not receive a diagnosis of FASD, for the term is too broadly defined to be of clinical value. FAS, on the other hand, is a clinical diagnosis and is one of several alcohol-related diagnoses that fall under the umbrella of FASD." The 4-Digit Diagnostic Code can be used to diagnose alcohol related effects, classified as partial FAS, neurobehavioural disorders or sentinel physical findings. The Hoyme Updated Institute of Medicine diagnostic guidelines were modified so that the two categories of alcohol related effects (ARND and ARBD) could be used as a clinical diagnosis. In both cases, maternal alcohol consumption during pregnancy must be documented and all other genetic or malformation syndromes must be excluded prior to the diagnosis being made. The authors stress that a diagnosis in the FASD continuum (i.e. ARND or ARBD) must not be made merely because a child with disabilities had confirmed prenatal alcohol exposure.

The Public Health Agency of Canada guidelines describe diagnostic criteria for FAS, partial FAS and ARBD. They defined FASD as an umbrella term for the range of effects that can occur in an individual whose mother drank alcohol during pregnancy.

The term FASD was not intended for use as a clinical diagnosis. They authors also note that ARBD should not be used as an umbrella or diagnostic term, and that it should be used with caution. The CDC guidelines state that there is currently no evidence-base to develop diagnostic criteria for any for any prenatal alcohol-related condition other than FAS

Four of the five diagnostic criteria clearly state that FASD (or equivalent terms) should not be used as a clinical diagnostic term. This is a contrast to the broader medical community, which often uses the term FASD in a diagnostic context, rather than to describe individuals with FAS, partial FAS, ARND or ARBD as recommended by the diagnostic criteria and guidelines.

The FAS and FASD diagnostic criteria described here can be used with both paediatric and adult patients. The Canadian Guidelines briefly discuss the additional challenges faced in an adult diagnosis. The patient's physical features may have changed over time, they may have experienced 'catch-up' growth and their cognitive function may have been significantly influenced by environment factors (e.g. increased function due to educational interventions or decreased function due to alcohol or drug abuse). Diagnosis can also be complicated by other clinical findings, such as additional traumatic head injury or mental health problems. These guidelines recommend that evaluation in the adult population also include additional components such as functional literacy and numeracy, employability and quality of life.

This top level review of the postnatal screening and diagnostic literature did not identify any publications that evaluated the accuracy of the diagnostic criteria. Therefore, there is no evidence that any one criterion is the most appropriate. An international survey of FASD diagnostic clinics found significant variation in the diagnostic criteria used worldwide. Of the 34 clinics identified, 23 (68%) used a single diagnostic criteria, with the most common criteria the 4-Digit Diagnostic Code (N=14) and the Hoyme Updated Institute of Medicine criteria (N=8). The complexity of the diagnostic criteria was reflected in the finding that 11 sites (32%) used their own adaptation of existing criteria, or a combination of multiple criteria. This suggests that there is no international consensus on the most appropriate diagnostic criteria.

Summary and conclusions

Summary of evidence for evidence review

This section of the report presented a top level review of the international published evidence for postnatal screening and diagnosis strategies.

The literature search did not identify any systematic reviews of screening or diagnostic criteria.

Two screening guidelines were identified. Screening should be based on the same criteria as used for diagnosis (prenatal alcohol exposure, characteristic facial abnormalities, growth retardation and CNS abnormalities), but be less restrictive. Screening criteria should be used as a tool rather than as a definitive test, and a full diagnostic evaluation should be performed if there are any concerns about the results of the screening evaluation.

A total of three FASD or FAS diagnostic criteria and two diagnostic guidelines were identified. The five diagnostic approaches were broadly similar, evaluating maternal prenatal alcohol exposure, characteristic facial abnormalities, growth retardation and CNS abnormalities. All publications discussed the significant problems associated with diagnosing the less severe forms of FASD (i.e. children who did not meet the definition of FAS but had significant disabilities as a result of prenatal alcohol exposure). Although four publications described diagnostic criteria for these individuals, two stated that there was insufficient evidence to use these terms as a clinical diagnosis.

There are significant difficulties applying a single diagnostic framework to a spectrum of disorders. The diagnostic criteria and guidelines identified in the literature search are widely used internationally; however there is no consensus on which criteria are most appropriate in the clinical setting.

Limitations of evidence base

The evidence considered in this review exhibited limitations. The studies identified in the literature search were generally of limited quality and had a number of key limitations:

No systematic reviews of the postnatal screening and diagnosis literature were identified

No key review articles were identified

Conclusions

There is no evidence to suggest that any one set of screening or diagnostic criteria is the most appropriate for use in the New Zealand population.

Top Level Review of Management Literature

Introduction

Clinical management of individuals diagnosed with FASD aims to minimise both primary and secondary disabilities. Primary disabilities are inherent functional problems directly caused by alcohol exposure *in utero* (such as mental retardation, learning disabilities, sensory impairments and speech and language difficulties). Secondary disabilities are acquired as individuals develop and can include mental health diagnoses, criminal activities, inappropriate sexual behaviour, alcohol or drug abuse and difficulty obtaining and maintaining employment. The specific disabilities experienced by individuals with FASD can vary significantly.

As noted previously, the assessment of management of FASD literature was conducted as a top level review. Therefore, only systematic reviews and published guidelines were eligible for inclusion.

Methods

Research questions

The clinical questions to be answered by this review were defined by staff from the Population Health Directorate of the Ministry of in conjunction with the reviewers. In general, the aim of this section of the review was to comprehensively evaluate management of FASD.

The primary research question to be addressed within this section of the review was:

- Do management strategies improve clinical outcomes in individuals with FASD?

For inclusion in the current review, the evidence had to fulfil the criteria outlined in **Table 72**. These criteria were developed *a priori* and described in the scoping protocol prepared prior to commencement of the review proper.

Table 72 Criteria for determining study eligibility

Patient population	Individuals with FASD
Intervention	Any strategy that aims to identify improve clinical outcomes in individuals with FASD
Comparator	Any comparator
Outcomes	Reduction in the severity of primary and/or secondary disabilities or deficits associated with FASD

The population for this review was any individual with FASD. Any strategy that aims to improve any clinical outcome was included in the review. In order to identify as many types of diagnosis strategies as possible, the review was not limited to studies comparing management strategies to any particular comparator. Only systematic reviews that include studies that measure a reduction in severity of primary or secondary disabilities or deficits have been included.

Literature search

A literature search was conducted as described in the 'General methods' section. A search was performed in EMBASE.com, which include EMBASE and MEDLINE. A manual search of HTA websites was also undertaken. The search terms, search strategy and citations identified for this section of the review are presented in **Table 73.**

Table 73 FASD management search strategy

Database	Date searched	Search no.	Search terms	Citations
EMBASE + MEDLINE	<1966 – 13 April 2008	1	('fetal alcohol syndrome'/exp OR 'fetal alcohol syndrome') OR ('fetal alcohol syndrome'/exp OR 'fetal alcohol syndrome') OR 'fetal alcohol syndrome' OR 'fetal alcohol spectrum disorder' OR 'fetal alcohol spectrum disorder' OR fasd	3,911
		2	('meta analysis'/exp OR 'meta analysis') OR ('systematic review'/exp OR 'systematic review') OR 'pooled analysis' OR ('review'/exp OR 'review') OR ('meta analysis'/exp OR 'meta analysis') OR systemat* OR pool*	2,160,272
		3	#1 AND #2	746
Cochrane	<1966 – 17 March 2008	1	fetal alcohol spectrum disorder OR fetal alcohol spectrum disorder OR fetal alcohol syndrome OR fetal alcohol syndrome	64
Manual search of HTA sites				11
Total citations identified				**821**
Total citations after removal of duplicate citations				**812**

Assessment of study eligibility

The assessment of study eligibility was conducted as described in the 'General methods' section. Citations were excluded for the following reasons:

As mentioned earlier, non-English publications were excluded at the database searching stage. Citations were excluded for the following reasons:

1. Not a systematic review or guideline: including journal articles, case reports, animal studies, short notes, letters, editorials, conference abstracts, *in-vitro* studies, studies not deemed appropriate to the research question or nature of review
2. Not a systematic review or guideline of management strategies for FASD

There were 812 non-duplicate studies identified by the search strategy. As detailed in **Table 74**, 16 full text articles were eligible for retrieval after excluding studies from the search titles and abstracts. Of full papers retrieved, six were eligible for inclusion in this report (listed in **Table 75** and **Appendix A**) and 10 did not fulfil the inclusion criteria. Two of the six included citations were systematic reviews, which were fully appraised. The full citation of each excluded article is presented in **Appendix B**, annotated by reason for exclusion based on the exclusion criteria detailed above. Reasons are presented hierarchically such that the first reason in the list that applied is reported.

Table 74 Application of selection criteria to citations

Exclusion criteria	Number
Total citations	812
Citations excluded after review of abstract/title	
Not a systematic review, diagnostic criteria or guideline	778
Not a systematic review, diagnostic criteria or guideline of management strategies	18
Total number of excluded citations after review of abstract/title	796
Full papers reviewed:	16
Citations excluded after review of full paper	
Not a systematic review, diagnostic criteria or guideline	0
Not a systematic review, diagnostic criteria or guideline of management strategies	10
Total number of excluded citations after review of full paper	10
Total included citations	**6**

Due to the low number of citations that met the inclusion criteria, it was decided that key narrative review articles should also be included. Two review articles were identified in the literature search.

The details of the eight included citations for management are provided in **Table 75**.

Table 75 Included citations for management

Citation ID	Citation
Systematic reviews	
Caley 2006	Caley LM, Shipkey N, Winkelman T, Dunlap C, Rivera S. Evidence-based review of nursing interventions to prevent secondary disabilities in fetal alcohol spectrum disorder. Pediatr Nurs 2006; 32(2):155-162.
Premji 2007	Premji S, Benzies K, Serrett K, Hayden KA. Research-based interventions for children and youth with a Fetal Alcohol Spectrum Disorder: Revealing the gap. Child Care Health Dev 2007; 33(4):389-397.
Guidelines	
Alcohol Healthwatch	Alcohol Healthwatch, (2007). Fetal Alcohol Spectrum Disorder in New Zealand: Activating the Awareness and Intervention Continuum. Alcohol Healthwatch: Auckland.
British Medical Association	BMA Board of Science. Fetal alcohol spectrum disorders: A guide for healthcare professionals. 2007. British Library Cataloguing-in-Publication.
Canadian Government	Chudley A, Conry J, Cook J, Loock C, Rosales T, LeBlanc N. Fetal alcohol spectrum disorder: Canadian guidelines for diagnosis. Can Med Assoc J 2005; 172(Suppl):Mar05-S21.
CDC	National Centre on Birth Defects and Developmental Disabilities. Fetal Alcohol Syndrome: Guidelines for Referral and Diagnosis. 2004. Centre for Disease Control.
Review articles	
Green 2007	Green JH. Fetal alcohol spectrum disorders: Understanding the effects of prenatal alcohol exposure and supporting students. J Sch Health 2007; 77(3):103-108.
Kalberg and Buckley 2007	Kalberg WO, Buckley D. FASD: What types of intervention and rehabilitation are useful? Neurosci Biobehav Rev 2007; 31(2):278-285.

Results

Overview

The following section is organised in the following manner: (i) the results of any systematic reviews of management strategies; (ii) a summary of any identified management guidelines and; (iii) a summary of any key review articles. Finally, an overall summary and discussion of the available evidence is presented.

More detailed information on each individual study included in the review is available in the data extraction tables in **Appendix D** or in the original papers. Only data directly relevant to the current review is presented in this section.

Systematic reviews and meta-analyses

Characteristics of included studies

The search strategy identified two systematic reviews of management strategies for FASD: Caley 2006 and Premji 2006.

CALEY 2006

Caley 2006 systematically reviewed nursing interventions to prevent secondary disabilities in FASD. Publications were included in Caley 2006 if they described an intervention, or if they recommended an intervention. The Caley 2006 literature search did not identify any publication that evaluated the effectiveness of an FAS or FASD intervention, therefore Caley 2006 will not be discussed further in this section.

However, the Caley 2006 literature search identified 28 publications containing recommendations about management strategies. The conclusions drawn from these publications will be discussed in the summary of key review articles (page 169).

PREMJI 2006

Premji 2006 published a systematic review of research-based interventions for children and youth with FASD. The main characteristics of this systematic review are described in **Table 76.** The search was conducted in 40 peer-reviewed databases and 23 grey literature databases. Foreign language publications were not excluded from the search. The search was restricted to publications published after 1973 as this was the year that FAS was first identified. The search terms were not described, however the authors noted that a group of stakeholders were consulted to clarify the key search terms. Studies were included in the systematic review if they recruited individuals diagnosed with FAS or FASD who were aged between 0-18 years of age. Studies were not restricted on the basis of the intervention used (interventions included early interventions, later interventions, strategies, education and medication). The intervention could target the individual with FASD or FAS, their caregiver or their family. Only randomised controlled trials or quasi-experimental studies were eligible for inclusion in the systematic review.

The literature search identified three publications: two randomised, controlled trials (Osterheld 1998 and Riley 2003) and one quasi-experimental study (Snyder 1997). All three studies were described as randomised, although Premji 2006 noted that the method used to randomise subjects was not described in any of the publications.

Although all studies were described as double-blind, only Snyder 1997 adequately described the concealment of treatment allocation. All studies reported only short-term outcomes. The authors did not evaluate the quality of each study; however they noted that their review was severely limited by the lack of scientific rigour of the three studies included. Riley 2003 evaluated Cognitive Control Therapy, while the remaining two studies (Oesterheld 1998 and Snyder 1997) assessed the effectiveness of psychostimulant medication.

Table 76 Management: Systematic review characteristics

Author year [Level of evidence]	Number of participants Study type	Population Country	Intervention	Comparator	Outcomes of relevance
Premji 2006 [Level I]	**Riley 2003** N=10 Pre-test/post-test controlled intervention **Oesterheld 1998** N=4 Randomised, double-blind crossover **Snyder 1997** N=12 Modified, placebo controlled cross over design	**Riley 2003** Primary school children with FAS. South Africa. **Oesterheld 1998** Naive American children between 5-12 years with FAS, or PFAS and ADHD. United States. **Snyder 1997** Children between 6-16 years with FAS and ADHD who were taking psychostimulant medications. Canada.	**Riley 2003** 5 children attending the intervention school. Cognitive Control Therapy (not described). Two trained therapists administered the Cognitive Control Therapy programme, which consisted of 1-h therapy sessions each week. The duration was 10 months. **Oesterheld 1998** 3 daily doses (7:30 AM ,11 AM, and 2 PM) of Methylphenidate (Ritalin) 0.6 mg/kg per dose. The duration was 5 days for 3 consecutive weeks. Subjects received no treatment for the 2 days between treatment trials. **Snyder 1997** Dosages individualized with each child receiving the previously prescribed dosage by his/her paediatrician. Methylphenidate (Ritalin), pemoline (Cylert) and dextroamphetamine (Dexedrine). The duration was 3 days. There was a one-day washout period before commencing the study and a 3-day washout prior to cross over. Subjects returned to their regular medication during the 3-day washout.	**Riley 2003** 5 children attending the control school received no intervention. **Oesterheld 1998** Placebo and vitamin C **Snyder 1997** Placebo	**Riley 2003** Neuropsychological tests or intelligence quotient. Teacher rated behaviour scores. **Oesterheld 1998** Conners Parent Rating Scale – 48, Conners Teacher Rating Scale – 39, and Barkley Side-Effects Questionnaire completed by teacher and caregiver. **Snyder 1997** Vigilance task to assess attention, a short form of the Underlining Test to assess impulsivity, and Abbreviated Symptom Questionnaire – Parents to assess hyperactivity.

Abbreviations: ADHD=attention deficit/Hyperactivity disorder, FAS=fetal alcohol syndrome, PFAS=Partial fetal alcohol syndrome

Results

The main results of the studies assessed in Premji 2006 are described below. Premji 2006 only described the results qualitatively.

RILEY 2003

Riley 2003 evaluated the effectiveness of Cognitive Control Therapy in five children with FAS. A group of five children attending a different school were recruited as a comparator group. Children in intervention and control groups were matched for age, first language, socio-economic status, grade and locality of school. Cognitive Control Therapy was not described, but the underlying premise of the therapy was described in the publication. Two trained therapists administered the Cognitive Control Therapy programme, which consisted of 1-h therapy sessions each week for a 10-month duration. Children were assessed using neuropsychological tests, intelligence quotient and teacher rated behaviour scores.

There was no significant improvement on neuropsychological tests or intelligence tests after the implementation of a Cognitive Control Therapy programme (see **Table 77**). There were anecdotal reports of an improvement in behaviour, however this must be interpreted with caution as the publication did not adequately describe how assessors were blinded to treatment allocation.

Table 77 Management: Systematic review results (Riley 2003)

Riley 2003
There were no significant differences on neuropsychological tests or intelligence tests after implementation of a Cognitive Control Therapy programme. However, teachers anecdotally reported behavioural improvements following the intervention. Qualitative improvements with a trend towards functionality for children in the intervention group were noted in the therapists, teachers and school reports.

OESTERHELD 1998

Oesterheld 1998 recruited Native American children with FAS and children with partial FAS (PFAS) who were also diagnosed with ADHD. The effectiveness and side-effects of methylphenidate for management of ADHD was assessed in four children aged between 5-12 years of age. The trial was a randomised, double-blind crossover design, with subjects receiving either methylphenidate or placebo and vitamin C for 3 weeks. There was a two day washout period before subjects were crossed over to the alternative arm. The trial was assessed using the Conners Parent Rating Scale – 48, Conners Teacher Rating Scale – 39 and Barkley Side-Effects questionnaires, which were completed by teachers and caregivers.

The publication reported a significant reduction in hyperactivity in children receiving methylphenidate compared with children receiving placebo or vitamin C (see **Table 78**). No significant differences were found on measures of attention.

Table 78 Management: Systematic review results (Oesterheld 1998)

Oesterheld 1998
There were significant reductions in hyperactivity, as measured by behavioural checklists, Conners Parent Rating Scale–48 and Conners Teacher Rating Scale–39, were seen when children were administered methylphenidate versus either placebo or vitamin C. No significant differences were found on measures of attention.

SNYDER 1997

All children in Snyder 1997 were diagnosed with FAS and ADHD, and were taking psychostimulant medications at the time of study entry. A total of 12 children, aged between 6-16 years of age, were recruited. The study aimed to assess the effectiveness of psychostimulant medications (methylphenidate, pemoline and dextroamphetamine) previously prescribed by the child's developmental paediatrician prior to study entry. All children had been positive responders to their prescribed medication. The study was a modified, placebo controlled cross over design. The duration was 3 days, with a one-day washout period before commencing the study and a 3-day washout prior to crossing over to the alternative study arm. Subjects returned to their regular medication during the 3-day washout. This is therefore not a true washout period, as subjects were still receiving medication, and this could have been at as similar dose to the study medication. A vigilance task was used to assess attention, a short form of the Underlining Test was used to assess impulsivity and the Abbreviated Symptom Questionnaire – Parents was used to assess hyperactivity.

There was a significant reduction in hyperactivity in subjects receiving pscyhostimulant medication compared with subjects receiving placebo (see **Table 79**). There was no significant effect of medication on attention or impulsivity.

Table 79 Management: Systematic review results (Synder 1997)

Snyder 1997
There were significant reductions in hyperactivity when subjects were taking pscyhostimulant medication versus placebo. There was no significant effect of medication on measures of attention (Vigilance Task) or impulsivity (short form of the Underlining Test).

SUMMARY OF PREMJI 2006

Premji 2006 identified three publications that evaluated an intervention in children with FAS. One publication described a cognitive behavioural program. Two publications described the use of psychostimulant medications; however there were significant variations in study design. Oesterheld 1998 recruited Native American children who may have been diagnosed with ADHD, while all children recruited in Snyder 1997 were diagnosed with ADHD. Subjects in Oesterheld 1998 received the same dose of methylphenidate for three weeks. Subjects in Synder 1997 received an individualised dose of either methylphenidate, pemoline or dextroamphetamine for three days. Synthesising the body of evidence as a whole is problematic for several reasons; (i) the research covers a range of interventions and study designs, (ii) there were a small number of identified publications, each with a less than 15 subjects and (iii) different outcomes were reported in each study. As a result it is not appropriate to statistically meta-analyse the results.

A Cognitive Control Therapy programme was not associated with a significant improvement in neuropsychological or intelligence testing. The intervention was not clearly described in the publication and only a small number of subjects (N=5) received the intervention. It is therefore difficult to draw conclusions from this publication.

Two publications evaluated the efficacy of psychostimulant medication. The authors of Premji 1998 note that pemoline is no longer considered a first-line therapy for ADHD in the USA because of the serious side effect of hepatotoxicity. They also report that ADHD is a co-morbid condition in approximately 85% of children with FASD. There is limited evidence to suggest that these individuals may be more sensitive to psychostimulant medications, and it is critical to establish the efficacy of medication therapy in this population. Both publications reported a significant decrease in hyperactivity, but no change in attention or impulsitivity, when subjects received psychostimulant medication. This suggests that these medications can be used effectively in children with FAS and ADHD.

Premji 1998 stated that the efficacy of any reviewed interventions for children and youth with FASD was not scientifically substantiated. The authors noted that their review was severely limited by the lack of scientific rigour of the three studies included and no conclusions could be drawn with regards to effective interventions for children with FASD. They conclude that "While interventions are critical to support the optimal development of children affected by prenatal alcohol exposure, it is difficult to discern from the current state of the literature what would constitute an effective intervention".

The results of all studies must be considered in the context of the small sample sizes (ranging from N=4 to N=12). The systematic review was severely limited by the lack of scientific rigour of the three studies identified. It is therefore difficult to draw conclusions from this varied body of evidence.

Published guidelines

The search identified three guidelines that describe FASD or FAS management strategies. These publications have based their discussions on the opinion of a panel of clinicians or the opinion of one or more authors. These types of publications represent the lowest level of evidence available and must be interpreted with caution.

ALCOHOL HEALTHWATCH 2007

Alcohol Healthwatch published a briefing paper in 2007 that included a summary of New Zealand policy and action on FASD (Alcohol Healthwatch, 2007).

FASD is not considered a disability in New Zealand. However, individuals diagnosed with FASD would qualify for disability support if they met the threshold for intellectual disability (an IQ of 70 or less) and had significant deficits in adaptive behaviour. The majority of children with FASD are high functioning and have an IQ within the normal range, and therefore miss out on essential disability services. Mental health services such as Child and Adolescent Mental Health Services may address FASD issues on an ad-hoc basis depending on the interest and knowledge of individual practitioners within these services.

Alcohol Healthwatch recommends that a national guideline for the support and treatment of FASD be developed. This should be based on international best practice models and informed community consultation rather than an arbitrary IQ threshold. The report did not recommend any specific management strategies.

CANADIAN GOVERNMENT 2005

Guidelines released by the Canadian Government (Chudley *et al.*, 2005) include very broad recommendations for treatment and follow-up (shown in **Table 80**). The individual diagnosed with FASD and their family must be educated about the diagnosis and the potential impact on the family. The guidelines recommend that individuals are linked with resources and services, although specific resources and services are not described. The guidelines were developed by a subcommittee of the Public Health Agency of Canada's National Advisory Committee on Fetal Alcohol Spectrum Disorder.

Table 80 Canadian Guidelines for treatment and follow-up

Education of the patient and family members on features of FASD is crucial. The potential psychosocial tensions that might be expected to develop within the family as a result of the diagnosis should also be discussed. This must be done in a culturally sensitive manner using appropriate language.
A member of the diagnostic team should follow-up outcomes of diagnostic assessments and treatment plans within a reasonable length of time to assure that the recommendations have been addressed.
Diagnosed individuals and their families should be linked to resources and services that will improve outcome. However, where services are limited in the community, an individual should not be denied an assessment for diagnosis and treatment. Often the diagnosis in the individual is the impetus that leads to the development of resources.

CENTRE FOR DISEASE CONTROL (CDC), UNITED STATES 2004

These recommendations were developed after consultation with clinical experts. The CDC guidelines (National Centre on Birth Defects and Developmental Disabilities, CDC, 2004) note that the services required for individuals with FAS and their family vary according to what parts of the brain have been affected, the age or level of maturation of the person, the health or function of the family and the overall environment in which the person is living. Despite the need for individualised services, the guidelines recommended some general services which may benefit individuals with FAS. A summary of these services and recommendations are shown in **Table 81**.

Briefly, the CDC guidelines discuss the importance of educating parents and carers about managing and caring for children with FAS. All children with FAS need interventions between birth and three years of age, even if they do not meet all eligibility criteria for state run general services. Early intervention is vital in preventing secondary disabilities. Children with FAS are often in the foster care system and can be at a higher risk of negative attachment disorders due to the increased rate of multiple placements. FAS is most commonly detected in children between three and six years of age. The CDC recommends that all states establish FAS diagnostic centres or trained clinicians. Children should have access to appropriate habilitation and rehabilitation services (physical, occupational, speech, behavioural, mental health, and other related services) and vocational training focussing on skills of daily living (e.g., personal hygiene, money management, and family life education). Families raising preschool and school-aged children continue to need services to promote positive family functioning. Such services might include

behaviour management training, family (or child) counselling, parenting workshops that focus on the unique aspects of parenting a child with FAS, or other types of continuing education. Behavioural and mental health problems typically become more pronounced in adolescence. Vocational and transitional services become essential during this stage and may need to include both specific skills related to a job as well as skills related to being a good employee (e.g., punctuality and minimized socialising). Individuals with FAS are at high risk for involvement with the juvenile and criminal justice systems. Their lack of executive functioning skills, language skills, and naïve social skills make them particularly vulnerable to participating in criminal activity. In addition to all the services mentioned for the preceding age groups, adults with FAS often need support in every area of their lives. These include transportation issues, job assistance, housing assistance, medication reminders, money assistance, living independently in the community, housing, healthcare, and employment.

Table 81 CDC recommended services for individuals with FAS

General needs
Stabilising home placement and parent-child interactions.
Increased understanding of FAS by parents, teachers and other professionals through education courses
Unique management due to difficulty with cause and effect reasoning and other executive functioning skills.
Prenatal services
Physicians, nurses, and other allied health professionals need to be trained to screen patients and to be familiar with treatment services. Families need ongoing support and monitoring.
Services for birth to 3 years of age
The first years of life are an important time for physical, cognitive, and emotional development.
Early inventions are critical.
Clinicians need to familiarise themselves with state services. This is important as only about 25% of children score in the significantly developmentally delayed range and may not be eligible through standard routes.
A stable and nurturing care giving environment is a protective factor for children with FAS.
Disruption in the care giving environment can lead to poor or negative attachment between infant and caregiver.
Children in the foster care system experience multiple placements (due to the nature of the system and the difficulty in parenting a child with FAS) and are at higher risk of disabilities.
Services for children 3 to 6 years of age and school age
It is essential that states establish FAS diagnostic centres or ensure that their child evaluation centres have clinicians who are trained in the diagnostic criteria associated with prenatal exposure.
Children can receive various therapies, including physical therapy (usually most appropriate for very young children), speech and language therapy, occupational therapy, or social skills training.
Children need access to appropriate habilitation and rehabilitation services (physical, occupational, speech, behavioural, mental health, and other related services).
Academic curricula must be balanced with vocational training and skills of daily living (e.g., personal hygiene, money management, and family life education).
It is important that school staff be trained to recognize possible characteristics associated with FAS, as well as appropriate techniques for instructing students with FAS.
Families need services to promote positive family functioning. Such services might include behaviour management training, family (or child) counseling, parenting workshops that focus on the unique aspects of parenting a child with FAS, or other types of continuing education.
Respite care has been shown to significantly reduce family stress and improve family functioning.
Services for adolescents
Depression or anxiety is common as the individual struggles to cope with changes in physical characteristics, cognitive abilities, peer groups and community expectation.
Individual counselling, family counselling, and a strong support network becomes more crucial.
Vocational and transitional services become essential during this stage. This includes daily living skills, employment skills, specific skills that go with a particular job and skills related to being a good employee (e.g., punctuality and minimised socializing).
Sexual behaviour often becomes a critical issue during this stage. The boundaries for appropriate interaction with the opposite sex, the subtle nature of social cues, and impulse issues are problematic.
Individuals with FAS are at high risk for involvement with the juvenile and criminal justice systems. Their lack of executive functioning skills (i.e., poor judgment), fluid language skills, and naïve social skills make them particularly vulnerable to participating in criminal activity. Special rehabilitation programs with staff that are trained to work with adolescents and young adults with FAS should be established.
Services for adults
In addition to all the services mentioned for the preceding age groups, adults with FAS often need support in every area of their lives. Everyday needs such as transportation issues, job assistance, housing assistance, medication reminders, money assistance, and support and living as independently in the community as possible and includes support for housing, healthcare, and employment.

BRITISH MEDICAL ASSOCIATION 2007

These recommendations were prepared under the auspices of the Board of Science of the British Medical Association (BMA). The BMA stated that there has been very little research into the clinical management of FASD and there is no framework for clinical management of FASD in the UK. It is important that diagnosed individuals and their families are linked to appropriate resources and services. Effective clinical management requires the cooperation between a wide range of healthcare professionals including GPs, obstetricians, paediatricians, psychiatrists, psychologists, and speech and language therapists. Further management requires specialist support in the provision of education and social services. The adverse effects of prenatal alcohol exposure on learning and life skills varies significantly among individuals, thus management programmes have to be tailored to the individual and his or her family. The services recommended by the BMA are shown in **Table 82**. Management should include education, social support and vocational training. The BMA guidelines recommended that the UK Health departments develop a framework for the clinical management of individuals affected by the range of FASDs, as well as their birth mothers.

Table 82 BMA recommended services for individuals with FASD

Social services may be required to ensure a supportive and stable home environment and to provide prenatal education. Educational support is essential during schooling years and requires adequately trained school staff. For intervention programmes to be effective, they need to be focused on an individual's developmental level. Intervention strategies for school-age children need to focus on providing specialised educational opportunities; whereas interventions for adolescents should also focus on providing vocational and transitional services (e.g. employment skills).
It is important that healthcare professionals work closely with education and social service providers to ensure that individuals affected by the range of FASD are appropriately assessed in terms of their communication and social skills, emotional maturity, verbal and comprehension abilities, language usage, and healthcare requirements. These assessments should be used to inform the clinical management programme. It is also important that healthcare professionals provide information on the available support services to carers and their families.

Summary of key review articles

A total of two key review articles were identified in the literature search. A third article, Caley 2006, was identified in the systematic review search. A summary of the review portion of this article has been included in this section. The three publications are summarised below.

CALEY 2006

A review of the literature identified 28 publications that recommended nursing interventions to prevent secondary disabilities. The publications were classified by the authors as Level VII evidence (opinion of authorities), which was the lowest level of evidence available. The authors did not define the term 'authority' and it is therefore unclear how the recommendations were developed and substantiated. A quality assessment was not performed on these publications; therefore the results must be interpreted with caution.

Case management was recommended in ten publications, although there was significant variation between the publications. Generally, it was recommended that

case management focus on financial assistance, resources available, medical, educational services, physical therapy, speech, behavioural care and social needs. Nursing interventions included coordination of services, discharge planning and assuring access to care and continuity of services.

Health teaching, counselling and consultation were also recommended in multiple publications. Eleven publications recommended health teaching for patents (including providing a safe environment, behaviour management strategies, appropriate parent-child interaction and sensory integration). Other teaching related to helping parents to learn strategies to help their child maintain control (including developing routines, alerting the child to changes in routines, calming techniques, verbal redirection, eye contact and maintaining a neutral location in the house). Six publications recommended counselling. This included crisis management and group sessions. Consultation was recommended in three publications, and included discussions with experts and consultations for referral to day-care and transportation. Advocacy was recommended by seven publications. Two articles recommended that that nurses advocate for individual patients and families to find information and services.

The publication does not draw any conclusions from the body of evidence identified.

GREEN 2007

Green 2007 reviewed school-based interventions for children with FAS or FASD. The author suggests that interventions focus on using a variety of strategies to teach children new skills using basic behavioural principles such as positive reinforcement and natural consequences. Interventions will only be effective if executive functioning limitations have been addressed. To support children with FASD to function effectively in the classroom, intervention plans should use methods such as Positive Behaviour Support (PBS) programming, cognitive behavioural therapy, and specific interventions for child behaviour disorders such as ADHD. These may include the use of visual cues and schedules, teaching of self-directed speech and problem solving, social skills training, role play, cognitive modelling and coaching to support poor nonverbal memory, internalisation of self-directed speech or verbal working memory, self-regulation of mood, motivation, and level of arousal and problem solving. This type of approach must be collaborative and include all service providers, educators and the individual's family.

In designing interventions, children with FASD need opportunities to learn and build skills that will help them regulate their emotions and behaviours as well as environmental modifications that increase the likelihood of adaptive behaviours. Interventions to support emotional and behavioural regulation must focus on modifying the environment and providing structure and consistency in daily routines and rules. The use of detailed visual schedules and a detailed visual presentation of rules that cue appropriate behaviour are recommended. Visual prompts must be positioned in close proximity to the child, such as on their desk. Environmental modifications with visual prompts might involve placing a sign, made by the child, on a door to remind them that they are not permitted in that room. Moving their desk away from a particular distraction (door, peer, air-conditioning unit) or near to a stimulus that helps with attention (teacher, peer) may be helpful. Positive feedback and praise are imperative for reinforcing desired behaviours. When considering how and whether to provide feedback for negative behaviours, caregivers and educators

will want to first consider how the environment could be modified to assist the child in engaging in an alternative behaviour and what skills the child may need to learn to engage in the alternative behaviour.

Difficulties understanding cause and effect relationships can be addressed through concrete examples using pictures and stories to illustrate abstract relationships. For example, the relationship between cleaning up toys, completing an assignment, or raising one's hand before talking and receiving a reward could be illustrated visually. The use of concrete prompts such as timers and stopwatches can help children understand concepts related to time and waiting. Multiple warnings (verbal, visual) that specify an amount of time before a transition and transitional objects will assist with time concepts and transition difficulties. The use of cognitive-behavioural strategies, such as social skills training, emotion identification, coping skills, anger management, and self-talk, may be helpful for children with FASD.

KALBERG AND BUCKLEY, 2007

Kalberg and Buckley discussed interventions and rehabilitation strategies that could be used in children with FASD. The authors stated that children who have average intelligence benefit most from multiple tests that can best determine specific issues of attention, verbal learning and recall, verbal memory, auditory memory, spatial memory, auditory processing and verbal processing. The authors recommend that children receive a battery of neuropsychological tests targeted at specific areas of functioning. This can lend useful information about the child's learning style, aptitude, and challenges, which can provide valuable information regarding attention, memory, problem-solving and inhibitory control; all of which are extremely useful in tailoring interventions to suit the needs of a child. This type of testing assists the family, medical provider, and classroom teacher with a clearer understanding of the issues that interfere with learning and behaviour.

Children may need an environmental tool to help them stay on track during the routine of an ordinary day. Normal social cues are not easily understood by children with FASD and they should be taught by rote and eventually learned through repetition.

Professionals working with the child must fully evaluate and assess the child's abilities in order to help identify the strengths and challenges of the child, including environmental and academic supports. This is best done by using a combination of tools and assessment processes. Neurocognitive abilities, academic achievement, behavioural profile, and adaptive skills must all be studied to determine the specific areas of need for the child. In addition, an assessment of the learning environment should be included to determine what environmental supports are needed. Once this informal assessment is completed and a functional behavioural assessment is completed, a specific learning profile for the child can be completed. Although there may be similarities among profiles, each profile should reflect the unique picture of the particular child.

The review article specifically discussed six interventions, which have been briefly summarised in **Table 83**.

Table 83 Interventions discussed in Kalberg and Buckley, 2007

Structure and systematic teaching as potentially effective methods for children with FASD
Children with FASD may have lower abilities when compared to their classroom peers. Professionals must understand the child's abilities so that activities are appropriate.
Structuring the teaching environment helps the child know what is expected of them.
Teaching functional routines requires, first, identifying skills, routines or activities that can be taught through routine practice such as dressing, getting ready for bed, bathing, etc. A teaching plan must be created for teaching a functional routine.
Visual structure
External structuring techniques compensate for and aid the child's deficit areas (e.g., executive functioning, set shifting, working memory and attention).
Visual organisation is beneficial (e.g. using containers to separate materials and taping off sections of the room for specific activity centres). Visual clarity is achieved through highlighting relevant and important information, colour coding each content area, and labelling tasks or work centres.
Visual instructions provide the child with a clear visual cue regarding the sequence to complete a task (e.g. placing arrows to direct the student, numbering the steps of a given sequence and providing written steps of an instruction).
Children with FASD benefit from visual schedules in that they help to alleviate anxiety during transitions, give information that helps them anticipate and predict what will happen next and in what sequence.
Environmental structure
Environmental structure helps provide the best conditions for learning. Children with FASD are also often distracted by visual clutter. Therefore, keeping the environment simple with a minimum of decorations can be helpful.
Task structure
A task can be structured so that the child understands what task expectations there are, how many tasks need completing, when one task is finished, and what task comes next. A specific task can be structured in a way that the child can clearly understand the steps of the task.
Cognitive control therapy as a potentially useful intervention process for children with FASD
Cognitive control therapy is a progressive skill-building intervention process that culminates in the child's ability to understand his own learning style and learning challenges. Significant improvements in behaviour are being seen after six months of interventions using cognitive control therapy.
The role of the family
The family of the child is instrumental in defining and guiding the school program for the child with FAS. Professionals provide valuable expertise toward the development of and educational programs, however, professionals move in and out of a child's life over the educational career and are financially compensated for their services.

DISCUSSION

FASD describes a spectrum of disorders, consequently each individual with FASD will have a unique pattern of impairments and disabilities. It is critical that management strategies are specifically tailored for each individual patient. Therefore, it is clinically inappropriate to recommend a single management strategy for all individuals with FASD. However, the literature describes a number of key areas which could be the focus of an FASD management strategy. Although not discussed in detail here, a broad ranging FASD policy should also target the birth mother and family.

The literature search identified two systematic reviews of FASD management strategies. One publication did not identify any relevant publications. The second systematic review identified three publications: one evaluation of Cognitive Control Therapy and two evaluations of psychostimulant medication for the treatment of

ADHD. The Cognitive Control Therapy did not significantly improve outcomes in children with FASD. Psychostimulant medication was associated with a significant decrease in hyperactivity, but no change in attention or impulsitivity. Both publications discussed the lack of literature evaluating management strategies for FASD and the need for further research.

The literature search identified four guidelines and three review articles discussing management strategies. These publications have based their discussions on the opinion of a panel of clinicians or the opinion of one or more authors. These types of publications represent the lowest level of evidence available and must be interpreted with caution. However, some common themes were discussed in multiple publications.

- Effective management of individuals with FASD relies on a comprehensive evaluation of each person's specific primary disabilities. This is most effective if it is carried out by a trained, multi-disciplinary team. This assessment should evaluate both physical and cognitive abilities. Early evaluation of primary disability and implementing appropriate interventions is vital in preventing secondary disabilities.
- It is critical that any management plan include the school system. Teachers should be trained in the identification of children with FASD and basic management strategies. This can include small environmental modifications such as moving a child's desk away from any potential distracters. Teachers can also benefit from knowing the child's specific disabilities. For example, children who have difficulties understanding cause and relationship will not learn from standard punishments as they will be unable to associate the punishment with the undesirable behaviour. The most effective way of preventing the undesirable behaviour may be clearer instructions rather than repeated reprimands. This type of simple management strategy can be quite effective in modifying behavioural patterns.
- Children with FASD are overrepresented in the foster care system and consequently face additional challenges. Interventions are most effective when they are part of a long-term management plan. Children in government care are difficult to look after and are therefore more likely to be moved through multiple placements. This results in disrupted medical treatment and places them at a higher risk of attachment disorders. Individuals with FAS often have poor social skills and find adjusting to new environments particularly difficult. Factors such as these make them more likely to develop secondary disabilities.

As children become adolescents and young adults they continue to need access to neurocognitive and behavioural interventions. However, there needs to be an increasing focus on vocational and transitional services. These might include specific skills related to a job as well as more general skills such as punctuality and socialising with work colleagues. As individuals begin to live independently they may need interventions which improve their skills of daily living, such as money management, hygiene, accessing government support and transportation. It is at this age that individuals with FASD are at most risk of entering the criminal justice system as many have poor executive functioning skills. This results in poor judgement and naïve social skills.

Due to the range and severity of disabilities experience by individuals with FAS, they need access to multiple services (e.g. physical, occupational, speech, behavioural, mental health). Caregivers can benefit from support services, such as a dedicated case manager who organises both clinical bookings and broader services such as access to financial assistance and respite care. Individuals with FASD often have IQs and basic skills within normal ranges are therefore ineligible for disability services. Experienced case managers can help caregivers access these services or identify alternative services.

The literature search identified insufficient good quality literature to recommend any specific interventions for individuals with FASD. Indeed, many publications discussed the lack of research in this field. However, from the literature identified it is apparent that individuals with FASD need early interventions to manage primary disabilities and prevent secondary disabilities. This is most effective when individuals undergo a comprehensive assessment to identify their specific disabilities, and a management plan is developed to meet their individual needs.

Summary and conclusions

Summary of evidence for evidence review

This section of the report presented a top level review of the international published evidence for FASD management strategies.

The literature search identified two systematic reviews. One review did not identify any publications that met their inclusion criteria. The second review identified three publications. One found no significant difference in neuropsychological or intelligence tests after Cognitive Control Therapy. Two publications found a significant improvement in hyperactivity when children received psychostimulant medications. The authors concluded that their review was severely limited by the lack of scientific rigour of the three studies included and that no conclusions could be drawn with regards to effective interventions.

The literature search identified three guidelines and three review articles. However these publications based their recommendations on the opinion of a panel of clinicians or the opinion of one or more authors. These types of publications represent the lowest level of evidence available and must be interpreted with caution. The articles discussed the importance of early intervention and effective management strategies to minimise the effect of primary disabilities and prevent secondary disabilities. It is critical that management strategies are specifically tailed for each individual patient. Therefore, it is clinically inappropriate to recommend a single management strategy for all individuals with FASD. Generally, individuals with FASD benefit from a broad management plan, which requires the support of clinical staff, caregivers and teachers. Individuals need access to multiple services (e.g. physical, occupational, speech, behavioural, mental health) and caregivers may require assistance to ensure that children are able to access all of these services. Older children need practical interventions, such improving skills of daily living, specific job skills and money management.

Limitations of evidence base

The evidence considered in this review exhibited limitations. The studies identified in the literature search had a number of key limitations:

- The low quality of publications identified by the systematic reviews
- The poor evidence base on which recommendations and guidelines were developed

Conclusions

There is no evidence to recommend any specific intervention for individuals with FASD.

Economic Considerations

Introduction

The current review includes (i) a systematic search of the published literature to identify any relevant economic evaluations and (ii) a qualitative discussion of the costs and outcomes likely to be associated with the prevention, diagnosis and management of FASD.

This section presents the results of the economic literature search, discusses the costs of FASD to society in general and presents the cost of strategies to reduce the burden of FASD.

Methods

Research questions

The economic questions to be answered by this review were defined by staff from the Population Health Directorate of the Ministry of Health in conjunction with the reviewers. In general, the aim of this section of the review was to comprehensively evaluate the economic burden of FASD and the economic impact of strategies to reduce the burden of FASD.

Literature search

A literature search was conducted as described in the 'General methods' section. The search was limited to the EMBASE, MEDLINE and Cochrane Library Databases. The search terms, search strategy and citations identified for this section of the review are presented in **Table 84**.

Table 84 Economic search strategy

Database	Date searched	Search no.	Search terms	Citations
EMBASE + MEDLINE	<1966 – 03 November 2008	1	((‘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’)) AND (‘foetal alcohol syndrome’ OR ‘foetal alcohol spectrum disorder’ OR (‘fetal alcohol syndrome’/exp OR ‘fetal alcohol syndrome’) OR ‘fetal alcohol spectrum disorder’ OR ‘fasd’)	37
Cochrane	<1966 – 03 November 2008	1	(Fetal OR foetal) AND alcohol AND (cost OR economic)	40
Manual searching of HTA site				**3**
Total citations identified				**80**
Total citations after removal of duplicate citations				**77**

Assessment of study eligibility

The assessment of study eligibility was conducted as described in the 'General methods' section. Citations were excluded for the following reasons:

- Not examining FASD: The study does not examine FASD
- Not an economic or costing study: The study does not include an economic evaluation or costing of a strategy to reduce the burden of FASD
- Duplicate data: The same data has been included in two publications.

There were 77 non-duplicate studies identified by the search strategy. As detailed in **Table 85**, all publications were retrieved and the full publication reviewed. Of these publications, 71 did not fulfil the inclusion criteria. Therefore, 6 articles were fully appraised and are included in this report (listed in **Table 86** and **Appendix A**). All excluded citations are presented in **Appendix B**, annotated by reason for exclusion based on the exclusion criteria detailed above.

Table 85 Application of selection criteria to citations

Exclusion criteria	Number
Total citations	77
Citations excluded after review of full publication	
Not examining FASD	46
Not an economic evaluation or costing study	23
Duplicate data	2
Total citations excluded after review of full publication	71
Total included citations	6

The full citations of the 6 included economic studies identified by the literature search are provided in **Table 86**.

Table 86 Included citations for economic evaluation

Citation ID	Citation
Burd 1999	Burd L, Cox C, Poitra B, Wentz T, Ebertowski M, Martsolf JT et al. The FAS screen: a rapid screening tool for fetal alcohol syndrome. Addict Biol 1999; 4:329-336.
Hopkins 2008	Hopkins RB, Paradis J, Roshankar T, Bowen J, Tarride JE, Blackhouse G et al. Universal or targeted screening for fetal alcohol exposure: a cost-effectiveness analysis. J Stud Alcohol Drugs 2008; 69(4):510-519.
Klug 2003	Klug MG, Burd L. Fetal alcohol syndrome prevention: Annual and cumulative cost savings. Neurotoxicol Teratol 2003; 25(6):763-765.
Little 1984	Little RE, Young A, Streissguth AP, Uhl CN. (1984). Preventing fetal alcohol effects: effectiveness of a demonstration project. Ciba Found Symp. 105:254-274.
Lupton 2004	Lupton C, Burd L, Harwood R. Cost of Fetal Alcohol Spectrum Disorders. Am J Med Genet Semin Med Genet 2004; 127 C(1):42-50.
Stade 2006	Stade B, Ungar WJ, Stevens B, Beyene J, Koren G. The burden of prenatal exposure to alcohol: measurement of cost. JFAS Int 2006; 4:e5.

Results

The primary objective of the economic literature search was to identify existing published economic evaluations assessing the incremental cost and benefit of FASD strategies. The search identified one economic paper that was relevant for this economic review.

Furthermore, the search identified the following information: (i) three papers that related to the costs of managing FASD and (ii) two papers that assessed the cost of strategies to reduce the burden for FASD. These six papers were summarised and discussed the appropriate sections below. The figures included in this economic section are crudely converted to New Zealand (NZ) dollars, but not inter-temporally adjusted. The following exchange rates were used to convert Canadian and US dollars to New Zealand dollars (0.61 and 0.72 respectively; extracted on 5 November 2008 from Reserve Bank of New Zealand).

Economic evaluation literature review

HOPKINS ET AL 2008

The study by Hopkins and associates examined the cost-effectiveness of meconium testing as a screening tool for fetal alcohol exposure compared with usual care. Meconium testing is a laboratory test, which aims to detect at birth prenatal alcohol exposure. The study analysed both universal meconium testing and targeted meconium testing. Universal testing was performed on all infants born in the province of Ontario, Canada, while targeted screening was performed only on the infants born who had older sibling diagnosed with FASD.

A decision analytic model was constructed to estimate the cost-effectiveness of the two strategies. The analysis compared the incremental cost of testing meconium, with the incremental benefit of reduced societal costs of FASD, and improvement in the quality of life of children born with FASD. The analysis took a societal perspective, which included both direct and indirect costs, and had a lifetime horizon. The analysis also disaggregated the population of interest by disease level: severe disease, mild disease, and no disease. The discount rate applied in the model was 5%, but whether or not the outcome was discounted was not specified.

The cost components included in the analysis were meconium testing (CA$150; approximately equivalent to NZ$210), intervention such as early special schooling (CA$28,800; NZ$40,280 for 5 years), and societal cost of FASD (CA$13,060; NZ$18,266 per year). In addition, a cost saving captured in the analysis was the societal financial benefit of improvement in literacy (CA$26,400; NZ$36,924 per year). The authors argued that early education training would improve the affected children's literacy, which in turn improve their lifetime earnings. Sensitivity analyses were also conducted using maximum and minimum plausible values of these costs.

The utility weights applied in the economic model were obtained from other economic studies. A utility weight of 0.47 was assigned to an infant with FASD regardless of their disease severity. A normal infant was assigned a utility weight of 0.93. It was estimated that an infant with FASD who was diagnosed and received an

early intervention would benefit from the intervention and receive a utility gain of 0.17. Sensitivity analyses were conducted using maximum and minimum plausible values of these utility weights.

A key assumption in the economic model was that all detected cases receive therapy. No sensitivity analyses were conducted to explore this assumption; therefore, it is difficult to estimate the magnitude of the impact of this assumption.

The summary of the results for the universal screening and targeted screening are presented in **Table 87**.

The overall cost per quality-adjusted life year (QALY) in the universal screening analysis was CA$65,875 (NZ$92,133). Over the lifetime of the model, the overall incremental cost of the universal screening strategy was CA$232 (NZ$324) per case with an incremental utility gain of 0.035 per case. The QALY resulted from universal screening analysis was most sensitive to the discount rate, the probability of no disease, the cost of treatment, and the utility gain from receiving treatment.

For the targeted screening analysis, meconium testing dominated over usual care, which presented an overall cost saving of CA$3,000 (NZ$4,196) with a positive health benefit of 0.898. The sensitivity analyses showed the ICER was robust to changes of most variables, with the exception of the cost of early education training and the financial benefit of literacy improvement.

Table 87 Economic evaluation: summary of the results (Hopkins et al. 2008)

(Value/CA$ per case)	Universal screening	Targeted screening
Incremental cost	Overall: $232 Severe disease: $150 Mild disease: $9,682 No disease: $150	Overall: -$3,000 Severe disease: $150 Mild disease: -$8,032 No disease: $150
Incremental utility gain	Overall: 0.0035 Severe disease: 0 Mild disease: 0.41 No disease: 0	Overall: 0.09 Severe disease: 0 Mild disease: 0.23 No disease: 0
Cost-effectiveness result	Overall: $65,875/QALY Severe disease: undefined Mild disease: $23,725 No disease: $0/QALY	Overall: dominant Severe disease: undefined Mild disease: dominant No disease: $0/QALY
Sensitivity analyses	Most sensitive to: Discount rate increasing to 10% from 5% = $130,444/QALY Probability of no disease increasing to 99.9% from 90% = $699,038/QALY Cost of early education increasing to $100,000 from 28,800 = $126,939/QALY QALY gain reducing to 0.05 from 0.17 = $223,974/QALY	Most sensitive to: The targeted screening remains the dominant strategy except when: Cost of early education increasing to $100,000 from 28,800 = $27,674/QALY Financial benefit of literacy reducing from 26,400 to $10,000 = 3,381/QALY

The authors concluded that from a societal perspective both universal and targeted screening for FASD represented good value for money. However, the overall ICER resulting from the universal screening analysis was clearly sensitive to input parameters. The overall result from the targeted screening analysis was robust to a range of parameter changes.

There are some potential limitations with the Hopkins study which should be considered when viewing these results. A positive impact of early education on literacy level has been assumed for all children identified with FASD. This implies that the analysis might have overestimated the lifetime earnings and/or magnitude of a utility gain, and hence have overestimated the cost per QALY. The results from this analysis might not be generalisable to other jurisdictions as the model parameters such as societal burden, probability of disease were country specific.

Published cost data

Cost of FASD

FASD is a well-recognised cause of facial malformations, mental retardation, and neurodevelopmental disorders. It adversely impacts physical, behavioural, and cognitive functions of the sufferers. As such, FASD does not only create burden on the healthcare system, but also on social services, the education system, the judiciary

system, and the family. The impact that FASD has on these segments of the economy is widely accepted, but there is little good-quality quantitative information.

There is a paucity of studies that estimate the costs of adverse effects from prenatal exposure to alcohol. Out of three identified studies, only one was able to report the costs of FASD, while the others related only to FAS. No cost-of-illness analyses that related to other disorders which come under the umbrella of FASD including FAE, ARBD or ARND were identified. All identified analyses were conducted in the US and Canada. No published 'cost of FASD' studies for NZ were identified.

STADE ET AL 2006

In a study conducted in Canada, Stade et al. (2006) estimated average adjusted annual costs associated with FASD at CA$14,342 (approximately equivalent to NZ$20,059) per child with FASD, aged between 1 and 21 years old. The estimate was valued in 2003 prices. The total costs comprised direct medical care, direct non-medical care, and productivity loss. A large proportion of the costs (33%) were accounted for by direct educational activities such as special schooling and residential programmes. The direct medical costs also contributed substantially (30%) to the annual costs per child. About 22% could be ascribed to social services such as legal aid, and foster care. Losses in productivity added to the total only slightly (8.1%). The analysis captured productivity loss by measuring parents' lost work time due to caring for their disabled child. A large proportion (81%) of the annual costs was paid for by the government; therefore, 19% of the annual costs came out of the parents' own pockets. It is important to note that Stade's study included children diagnosed only with FAS and FAE – not with ARND and ARBD.

The two key determinants of the average annual cost were the severity of the child's condition, and the age of the child. The annual costs per child increased with the level of severity. A mildly disabled child cost approximately CA$9,800 (NZ$13,706) annually. The costs increased to CA$14,323 (NZ$20,032), and CA$19,500 (NZ$27,273) for a moderately and severely disabled child respectively. As anticipated, a child with more severe physical and mental conditions required more medical attention and more specialised educational services, and hence resulted in a greater cost to society.

The average annual cost per child steadily increased from the age of one year old at CA$13,000 (NZ$18,182) and peaked at CA$19,000 (NZ$26,573) when reaching the 6-15 age group. The annual cost then rapidly decreased to CA$5,700 (NZ$7,972) as they reached the 18 - 21 age group. The high cost at young ages largely reflects the high need for medical specialists such as psychiatrists, psychologists, and occupational therapists.

Additionally, Stade found the average cost per child to be significantly dependent upon the geographical location of the children or family. The authors linked the different regional costs to resource availability in the areas, rather than the differences in morbidity or utilisation of services.

The costs reported in Stade's paper are considered conservative. Their analysis appeared to exclude the burden that individuals with FASD place on the legal or criminal justice system, and also exclude the costs of residential care due to mental retardation. 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. No well-documented reports were found to quantify the costs of these effects.

LUPTON ET AL 2004

Another cost estimate of FASD is from Lupton and colleagues (Lupton et al. 2004). They conducted a review of studies that estimated the costs of FASD. However, they found no studies that discussed costs associated with FASD. At the time of the review, all cost information existed for FAS only. Lupton and colleagues reviewed 10 papers in total: eight of which related to the annual costs of FAS and two which related to the lifetime costs of FAS.

The original annual cost estimates obtained from these eight papers varied considerably ranging from US$75 million (approximately equivalent to NZ$122 million) in 1984 (Abel and Sokol 1991) to US$4 billion (NZ$7 billion) in 1998 (Harwood 2000). This variation was due to a number of factors such as prevalence rates, included cost components, and inflation. Lupton and colleagues attempted to adjust for the differences by aligning two components. First the prevalence rates were adjusted to 2 per 1,000 live births, and second, they allowed for all estimates to include residential care for persons over the age of 21. Excluding productivity loss, the adjusted estimates ranged between US$3.6 billion (NZ$5.9 billion) and US$11 billion (NZ$17.9 billion) in the year 2002. The cost of FAS remained large, in spite of large variation in the adjusted estimates.

With regard to the lifetime costs of FAS, Lupton found only two papers that calculated the costs (Harwood et al. 1985; Weeks 1989). After accounting for inflation, the discounted lifetime costs were estimated to be between US$1 million (NZ$1.6 million) and US$1.5 million (NZ$2.4 million) per child with FAS based on 2002 prices.

KLUG AND BURD 2003

FAS is argued to be 100% preventable; it is however difficult for any prevention strategies to achieve the perfect outcome. Klug and Burd (2003) examined the potential cost saving if a case of FAS was prevented in the state of North Dakota. They estimated the saving to be US$2,340 (approximately equivalent to NZ$3,813) per annum when preventing a case of FAS. The analysis included only the cost of healthcare for FAS and related co-morbid conditions for children from birth to 21 years of age. The cost-saving is anticipated to be much more substantial if the analysis is expanded to include the cost FASD creates on other segments of the economy.

Klug and Burd conducted their analysis based on the data from the North Dakota Health Claim database. The saving estimate was simply the difference between the average annual costs of healthcare for a child with and without FAS, which were estimated at US$2,840 (NZ$4,628) and US$500 (NZ$815) per year respectively.

Given that no ‘cost of FASD’ studies for NZ were identified, the estimates from Stade’s analysis are used as proxies. The costs of FASD in NZ were estimated approximately at NZ$20,059 per child with FASD aged between 1 and 21. How well Stade’s estimates could be translated to a NZ setting depends on the similarity of the structure of public services and resources provided for children with FASD between NZ and Canada. Combining this NZ unit cost estimate with the prevalence rate of

FASD in NZ gives a rough estimate of the cost of FASD to NZ. Alcohol Healthwatch estimated that there are at least 173 babies born with FASD each year (Alcohol Healthwatch, 2007). This results in the cost of FASD to NZ being at least NZ$3.47 million per annum for children with FASD aged between 1 and 21 years old.

Costs of strategies to reduce the burden of FASD

Two publications were identified that estimated the cost of specific strategies to reduce the burden of FASD (Little et al. 1984; Burd et al. 1999).

LITTLE ET AL 1984

Little et al. (1984) evaluated the Pregnancy and Health Programme (PHP) that was a demonstration project conducted between 1 April 1979 and 30 March 1981 in the US. The programme was established to develop effective methods of preventing fetal alcohol effects by intervening in maternal abuse during pregnancy in the metropolitan US community. PHP was a comprehensive programme whose activities involved public education, professional training, telephone helpline, adult treatment and education services, and child assessment services.

The direct financial expenditure on PHP was reported at US$1.49 million (approximately equivalent to NZ$2.4 million) over two operating years. About US$1 million (NZ$1.6 million) was spent on direct medical services, 62% of which was spent on the adult treatment services, and the other 38% on child services. An additional 14% and 16% of the total spending were accounted for by public education and professional training respectively. A telephone information/helpline (5-HEALTH) cost the least, making up 5% of the total spending.

The services provided per child cost the most compared with the services provided per adult. One hundred and fifty one children were seen over the two years the programme was run and, on average, US$2,429 (NZ$3,958) was spent on each child. Approximately 50% of these children were less than one month old at the first visit, and the other 26% were between one month old and 6 years old. The child services appeared to be available to all children with developmental and behavioural problems, regardless of whether they had been formally diagnosed with FAS.

BURD ET AL 1999

The other strategy to mitigate the burden of FASD was examined by Burd et al. (1999). They developed a population-based screening tool for children with FAS aged between 4 and 18 years old. The screening tool was a paper-based questionnaire, which could be administered by professionals or paraprofessionals. The tool was designed to identify early cases of FAS who may especially need intervention services, with the view that early identification may help prevent the development of secondary disabilities in the children with FAS, as well as help pinpoint high-risk mothers.

The screening tool was tested in six sites in North Dakota and 1,013 children were screened. The authors claimed that the screening tool had a specificity of 94.1% and a sensitivity of 100%.

The cost of screening was estimated at US$13 (NZ$21) per child and US$4,100 (NZ$6,681) per case identified. The cost of screening was based on the cost of

training, staff time, staff travel, and the printing cost of the screening tool, while the cost per case identified included the cost of screening, and scheduling the clinics and the diagnostic evaluation to discuss the results. Each screening took about 10 to 15 minutes per child.

The screening tool was specifically developed for detecting children specifically with FAS; it is unclear how well the screening tool would perform detecting children with broader effects of prenatal exposure to alcohol. The screening tool was also evaluated only on Native American children. The paper did not indicate if similar diagnostic performance could be expected on other ethnic or racial populations.

Discussion

There are a small number of published studies which examine the economics of FASD. The majority of these provide estimates of the economic burden of FASD (or specifically FAS) in Canada or the US. These estimates suggest that FASD causes a substantial economic burden. It is not clear how directly generalisable these estimates are to New Zealand, as it is likely that many of the variables used in these calculations would vary considerably from country to country.

The remaining studies assessed the cost or cost effectiveness of specific strategies aimed at reducing the burden of FASD. However, the clinical effectiveness of these strategies was not assessed during this review: (i) two studies examined postnatal screening strategies which were not identified and assessed due to the review of postnatal screening and diagnosis being limited to top level evidence; and (ii) a comprehensive strategy encompassing prevention, screening and treatment, which was identified during the literature search for this review, but which did not provide clinical effectiveness data. As such, it is difficult to assess whether the cost of these strategies was reasonable in terms of their clinical benefit.

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Appendix A: Included Studies

Prenatal screening and prevention

Prevention systematic reviews
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Postnatal screening and Diagnosis

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Appendix B: Excluded Studies Annotated by Reason for Exclusion

Publications excluded from the prenatal screening and prevention literature search

Aarts MCG, Vingerhoets AJJM. Psychosocial factors and intrauterine fetal growth: A prospective study. Journal of Psychosomatic Obstetrics and Gynaecology 1993; 14(4):249-258.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Aase JM. The fetal alcohol syndrome in American Indians: A high risk group. NEUROBEHAV TOXICOL TERATOL 1981; 3(2):153-156.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abalos E, Duley L, Steyn DW, Henderson-Smart DJ. Antihypertensive drug therapy for mild to moderate hypertension during pregnancy. Abalos E, Duley L, Steyn DW , Henderson Smart DJ Antihypertensive drug therapy for mild to moderate hypertension during pregnancy Cochrane Database of Systematic Reviews: Reviews 2007 Issue 1 John Wiley & Sons , Ltd Chichester, UK DOI : 10 1002 /1465185 2007.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abascal K, Yarnell E. The Many Faces of Silybum marianum (Milk Thistle): Part 2-Clinical Uses, Safety, and Types of Preparations. Altern Complement Ther 2003; 9(5):251-256.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abate P, Pepino MY, Spear NE, Molina JC. Fetal Learning With Ethanol: Correlations Between Maternal Hypothermia During Pregnancy and Neonatal Responsiveness to Chemosensory Cues of the Drug. [References]. Alcoholism: Clinical and Experimental Research Vol 28 (5) May 2004;-815.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abdollah S, Brien JF. Effect of chronic maternal ethanol administration on glutamate and N- methyl-D-aspartate binding sites in the hippocampus of the near-term fetal guinea pig. Alcohol 1995; 12(4):377-382.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Effects of ethanol on pregnant rats and their offspring. Psychopharmacology Vol 57 (1) 1978;-11.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Effects of ethanol exposure during different gestation weeks of pregnancy on maternal weight gain and intrauterine growth retardation in the rat. NEUROBEHAV TOXICOL TERATOL 1979; 1(2):145-151.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Dintcheff BA, Day N. Effects of in utero exposure to alcohol, nicotine, and alcohol plus nicotine, on growth and development in rats. NEUROBEHAV TOXICOL TERATOL 1979; 1(2):153-159.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

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Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, York JL. Absence of effect of prenatal ethanol on adult emotionality and ethanol consumption in rats. J Stud Alcohol 1979; 40(7):547-553.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Prenatal effects of alcohol on adult learning in rats. Pharmacology, Biochemistry and Behavior Vol 10(2) Feb 1979;-243.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Procedural considerations in evaluating prenatal effects of alcohol in animals. NEUROBEHAV TOXICOL TERATOL 1980; 2(3):167-174.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Fetal alcohol syndrome: behavioral teratology. Psychological bulletin 1980; 87(1):29-50.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Bush R, Dintcheff BA. Exposure of rats to alcohol in utero alters drug sensitivity in adulthood. Science 1981; 212(4502):1531-1533.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Dintcheff BA, Bush R. Behavioral teratology of alcoholic beverages compared to ethanol. NEUROBEHAV TOXICOL TERATOL 1981; 3(3):339-342.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Behavioral teratology of alcohol. Psychological bulletin 1981; 90(3):564-581.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Prenatal exposure to beer, wine, whiskey, and ethanol: Effects on postnatal growth and food and water consumption. NEUROBEHAV TOXICOL TERATOL 1981; 3(1):49-51.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. A critical evaluation of the obstetric use of alcohol in preterm labor. Drug Alcohol Depend 1981; 7(4):367-378.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Characteristics of mothers of fetal alcohol syndrome children. NEUROBEHAV TOXICOL TERATOL 1982; 4(1):3-4.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL, Sokol RM. Fetal alcohol syndrome: How good is the criticism? NEUROBEHAV TOXICOL TERATOL 1983; 5(5):491-492.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Jacobson S, Sherwin BT. In utero alcohol exposure: Functional and structural brain damage. NEUROBEHAV TOXICOL TERATOL 1983; 5(3):363-366.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Prenatal effects of alcohol. Drug Alcohol Depend 1984; 14(1):1-10.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Dintcheff BA. Factors affecting the outcome of maternal alcohol exposure: I. Parity. NEUROBEHAV TOXICOL TERATOL 1984; 6(5):373-377.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Dintcheff BA. Factors affecting the outcome of maternal alcohol exposure: II. Maternal age. NEUROBEHAV TOXICOL TERATOL 1985; 7(3):263-266.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Dintcheff BA. Saccharin preference in animals prenatally exposed to alcohol: No evidence of altered sexual dimorphism. NEUROBEHAV TOXICOL TERATOL 1986; 8(5):521-523.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Sokol RJ. Maternal and fetal characteristics affecting alcohol's teratogenicity. NEUROBEHAV TOXICOL TERATOL 1986; 8(4):329-334.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Dintcheff BA. Effects of prenatal alcohol exposure on behavior of aged rats. Drug Alcohol Depend 1986; 16(4):321-330.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Dintcheff BA. Effects of prenatal alcohol exposure on nose poking in year-old rats. Alcohol 1986; 3(3):201-204.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Sokol RJ. Fetal alcohol syndrome is now leading cause of mental retardation. Lancet 1986; 2(8517):1222.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL, Dintcheff BA. Increased marihuana-induced fetotoxicity by a low dose of concomitant alcohol administration. J Stud Alcohol 1986; 47(5):440-443.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL, Welte JW. Publication trends in fetal alcohol, tobacco and narcotic effects. Drug Alcohol Depend 1986; 18(1):107-114.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL, Sokol RJ. Incidence of fetal alcohol syndrome and economic impact of FAS-related anomalies. Drug Alcohol Depend 1987; 19(1):51-70.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL, Sokol RJ. A revised estimate of the economic impact of fetal alcohol syndrome. Recent Dev Alcohol 1991; 9(-):117-125.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL, Berman RF, Church MW. Prenatal alcohol exposure attenuates pentylenetetrazol-induced convulsions in rats. Alcohol 1993; 10(2):155-157.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Martier S, Kruger M, Ager J, Sokol RJ. Ratings of fetal alcohol syndrome facial features by medical providers and biomedical scientists. Alcohol Clin Exp Res 1993; 17(3):717-721.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL. Rat offspring sired by males treated with alcohol. Alcohol 1993; 10(3):237-242.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. A surprising effect of paternal alcohol treatment on rat fetuses. Alcohol 1995; 12(1):1-6.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Effects of prenatal alcohol exposure on birth weight in rats: Is there an inverted U-shaped function? Alcohol 1996; 13(1):99-102.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Alcohol-induced changes in blood gases, glucose, and lactate in pregnant and nonpregnant rats. Alcohol 1996; 13(3):281-285.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Reddy PP. Prenatal high saturated fat diet modifies behavioral effects of prenatal alcohol exposure in rats. Alcohol 1997; 14(1):25-29.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Protecting fetuses from certain harm. Politics Life Sciences 1998; 17(2):113-117.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL. Prevention of alcohol abuse-related birth effects - I. Public education efforts. Alcohol Alcohol 1998; 33(4):411-416.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention (review article)

Abel EL. Prevention of alcohol abuse-related birth effects - II. Targeting and pricing. Alcohol Alcohol 1998; 33(4):417-420.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study (review article)

Abel EL. What really causes FAS: From the sublime to the ridiculous. Teratology 1999; 60(5):250.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. The role of dietary fat in alcohol's prenatal effects. Alcohol 2000; 20(1):83-86.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL, Kruger M. Physician attitudes concerning legal coercion of pregnant alcohol and drug abusers. Am J Obstet Gynecol 2002; 186(4):768-772.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL. Paternal contribution to fetal alcohol syndrome. Addict Biol 2004; 9(2):127-133.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Abel EL, Sokol RJ. Maternal and fetal characteristics affecting alcohol's teratogenicity. Neurobehavioral Toxicology & Teratology Vol 8 (4) Jul -Aug 1986;-334.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abel EL. Paternal and maternal alcohol consumption: Effects on offspring in two strains of rats. Alcoholism: Clinical and Experimental Research Vol 13(4) Aug 1989;-541.
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Abkarian GG. Communication effects of prenatal alcohol exposure. J COMMUN DISORD 1992; 25(4):221-240.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Abraham S. Obstetricians and maternal body weight and eating disorders during pregnancy. J Psychosom Obstet Gynecol 2001; 22(3):159-163.
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Accornero VH, Morrow CE, Bandstra ES, Johnson AL, Anthony JC. Behavioral outcome of preschoolers exposed prenatally to cocaine: Role of maternal behavioral health. J Pediatr Psychol 2002; 27(3):259-269.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Acevedo CG, Huambachano AM, Bravo I, Contreras E. Endogenous nitric oxide attenuates ethanol-induced vasoconstriction in the human placenta. GYNECOL OBSTET INVEST 1997; 44(3):153-156.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Acevedo MC. The role of acculturation in explaining ethnic differences in the prenatal health-risk behaviors, mental health, and parenting beliefs of Mexican American and European American at-risk women. Child Abuse Negl 2000; 24(1):111-127.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Acres L. The foetal alcohol syndrome. Nurs RSA 1987; 2(4):41, 43.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Adam Z. Basics of dysmorphology: A review. Ultrasound Rev Obstet Gynecol 2003; 3(4):227-235.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Adams J, Bittner P, Buttar HS, Chambers CD, Collins TFX, Daston GP et al. Statement of the Public Affairs Committee of the Teratology Society on the Fetal Alcohol Syndrome. Teratology 2002; 66(6):344-347.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Adams MM, Bruce FC, Shulman HB, Kendrick JS, Brogan DJ. Pregnancy planning and pre-conception counseling. Obstet Gynecol 1993; 82(6):955-959.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Addolorato G, Gasbarrini A, Marcoccia S, Simoncini M, Baccarini P, Vagni G et al. Prenatal exposure to ethanol in rats: Effects on liver energy level and antioxidant status in mothers, fetuses, and newborns. Alcohol 1997; 14(6):569-573.
Reason for exclusion: Abstract/Title: Excluded, not a clinical study

Adnams CM, Sorour P, Kalberg WO, Kodituwakku P, Perold MD, Kotze A et al. Language and literacy outcomes from a pilot intervention study for children with fetal alcohol spectrum disorders in South Africa. Alcohol 2007; 41(6):403-414.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Adolph C, Ramos DE, Linton KLP, Grimes DA. Pregnancy among hispanic teenagers: Is good parental communication a deterrent? Contraception 1995; 51(5):303-306.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

Adrian M, Barry SJ. Physical and mental health problems associated with the use of alcohol and drugs. Subst Use Misuse 2003; 38(11-13):1575-1614+1903.
Reason for exclusion: Abstract/Title: Excluded, wrong intervention

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Appendix C: Quality Checklists for Appraising Interventions

Study type	Quality criteria
Systematic review	Was a clinical question clearly defined? Was an adequate search strategy used? Were the inclusion criteria appropriate and applied in an unbiased way? Was a quality assessment of included studies undertaken? Were the characteristics and results of the individual studies appropriately summarised? Were the methods for pooling the data appropriate? Were sources of heterogeneity explored?
RCT	Was allocation to treatment groups concealed from those responsible for recruiting subjects? Was the study double-blinded? Were patient characteristics and demographics similar between treatment arms at baseline? Were all randomised patients included in the analysis? Were the statistical methods appropriate? Were any subgroup analyses carried out?
Cohort	How were subjects selected for the 'new' intervention? How were subjects selected for the comparison or control group? Does the study adequately control for demographic characteristics, clinical features and other potential confounding variables in the study design or analysis? Was the measurement of outcomes unbiased (i.e., blinded to treatment group and comparable across groups)? Was follow-up long enough for outcomes to occur? Was follow-up complete and were there exclusions from analysis?
Other studies	Has selection bias been minimised? Have adequate adjustments been made for residual confounding? Was follow-up for final outcomes adequate? Has measurement or misclassification bias been minimised?
Screening studies	Were patients selected consecutively? Is the decision to perform the reference standard independent of the test results? Was there a valid reference standard? Are the test and reference standard measured independently Has confounding been avoided? If the reference standard is a later event that the test aims to predict, is any intervention decision blind to the result?

Appendix D: Data Extraction Tables

Prevention systematic reviews

Citation	Whitlock 2004
Level of evidence	Level I (Intervention)
Research question/aims	To systematically review evidence for the efficacy of brief behavioural counselling interventions conducted in primary care settings to reduce risky/harmful alcohol consumption or patterns
Study type/design	Systematic review
Search strategy	Searched Cochrane Reviews, Database of Clinical Effectiveness, Medline, PsychInfo, HealthSTAR and CINAHL. Literature from 1994-2002 was included. Appropriate search terms were tailored for individual databases.
Type of included studies	Randomised control trials.
Type of intervention	Brief to extended interventions to reduce risky/harmful alcohol use
Outcome	Three primary outcomes were selected: average consumption, binge use and safe/moderate/recommended use
Quality rating	Good (A) Yes. Seven clinical questions were clearly defined (only one was applicable to this report). (B) Yes. Extensive search of numerous databases with broad search terms. (C) Yes. Appropriate inclusion and exclusion criteria was applied. (D) Yes. Performed based on USPSTF criteria. (E) Yes. Detailed data extraction tables were included. (F) Adequate. Data was not pooled due to the difference in study design. (G) Adequate, heterogeneity between the studies was narratively discussed.
Data analyses & statistics	Narrative synthesis including tables of study characteristics and results. The results were not meta-analysed due to the heterogeneity of the identified publications.
Description of included studies	Note: Three trials targeting pregnant women were identified as part of a larger search which aimed to identify interventions to reduce risky/harmful alcohol use. The three publications reporting outcomes in pregnant women were analysed as a subgroup. Chang 1999: Screening: Score ≥2 using T-ACE. Intervention: 45 minute brief intervention followed by 2 hour assessment. All subjects received a take home manual. Control: Standard care Quality rating: Good Reynolds 1996: Screening: Any alcohol consumption within the past month. Intervention: 10 minute session with an educator and a self help manual to be completed over 9 days. Control: Standard care. Quality rating: Good Handmaker 1999: Screening: Any alcohol consumption within the past month. Intervention: 1 hour alcohol assessment, 1 hour motivational interview. Control: Letter about risks of drinking during pregnancy. Quality rating: Fair

Results (within scope of review)	Chang 1999: Decrease in DR/day: Intervention -0.3, control -0.4. Episodes of drinking: Intervention 0.7, control 1.0 (P=0.12) Reynolds 1996: Quit rate: Intervention 88%, control 69% (P=0.058) DR/month: Intervention 0.36, control 1.14 (P=0.06) Handmaker 1999: Total number of drinks: Intervention 0.46, control 0.40. Change in BAC: Intervention 0.77, control 0.46 Change in abstinent days: Intervention 0.69, control 0.2
Authors conclusions	The few randomised controlled trials of interventions in prenatal care settings that aimed to eliminate or reduce drinking among pregnant women tended to show small or negligible effects. Relatively long screening and screening-related assessments as part of the recruitment in two of the trials may have mitigated potential intervention effects. A strength of these studies, however, was their inclusion of larger numbers of minority and poor patients than in the general adult studies. Given the importance of reducing the risk of fetal harm from exposure to alcohol, further research among pregnant women and women considering pregnancy is a high priority.
Reviewers notes	The systematic review defined seven clinical questions. One question was related to prevention strategies, prenatal interventions was discussed as a subgroup of this clinical aim. All three publications identified in this systematic review have been identified in the literature search conducted for this report. These publications will be described in greater detail in the appropriate sections of this report.
Relevance to study question	This study aims to systematically review the evidence relating to FASD prevention strategies. **This study provides results relevant to questions regarding prenatal screening and prevention.**

ABBREVIATIONS: BAC=BLOOD ALCOHOL CONCENTRATION, DR=DRINKING RATE, USPSTF=UNITED STATES PREVENTATIVE SERVICES TASK FORCE

THE QUALITY OF SYSTEMATIC REVIEWS WERE ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS A CLINICAL QUESTION CLEARLY DEFINED?; (B) WAS AN ADEQUATE SEARCH STRATEGY USED?; (C) WERE THE INCLUSION CRITERIA APPROPRIATE AND APPLIED IN AN UNBIASED WAY?; (D) WAS A QUALITY ASSESSMENT OF INCLUDED STUDIES UNDERTAKEN?; (E) WERE THE CHARACTERISTICS AND RESULTS OF THE INDIVIDUAL STUDIES APPROPRIATELY SUMMARISED? ; (F) WERE THE METHODS FOR POOLING THE DATA APPROPRIATE? AND (G) WERE SOURCES OF HETEROGENEITY EXPLORED?

Citation	Schorling 1992
Level of evidence	Level I / III [A] (Intervention)
Research question/aims	Critical review of investigations that used prenatal education and counselling to reduce alcohol use in pregnancy
Study type/design	Systematic review
Search strategy	Searched Medline (1973-1991), ETOH (the alcohol and alcohol problems science database) and bibliographies of primary sources. The search terms were not stated.
Type of included studies	Any study which: 1) Prospectively determined alcohol use among a cohort of pregnant women 2) Provided a specific intervention 3) Determined alcohol use in individual women following the intervention
Type of intervention	Any intervention that used prenatal education and counselling to reduce alcohol use in pregnancy
Outcome	Proportion of subjects who abstained from alcohol or decreased their alcohol consumption
Quality rating	Fair (A) Yes. The clinical question was clearly defined. (B) Partial. The only two databases searched were Medline and an alcohol database. The search terms used were not reported. (C) Partial. The selection criteria clearly defined, but it was unclear if additional criteria was used. (D) Yes. Methodological standards were clearly defined and applied to all included studies. (E) Partial. Reduction in alcohol use and abstinence was presented, it was unclear if included studies reported other outcomes. (F) Adequate. Data was not pooled due to the difference in study design. (G) Adequate, heterogeneity between the studies was narratively discussed.
Data analyses & statistics	Narrative synthesis including tables of study characteristics and results. The results were not meta-analysed due to the heterogeneity of the identified publications.
Description of included studies	Meberg et al 1986: Study type: Non concurrent control group. Screening: Not stated Intervention: Two 1 hour visits with a midwife. Follow-up post partum. Control: No details given. Waterson and Murray-Lyon 1990: Study type: Non randomised, concurrent control group. Screening: Not stated Intervention: Written information and verbal reinforcement video. Follow-up post partum Control: No details given. Larsson 1983: Study type: Single arm. Screening: Not stated Intervention: 1 hour with midwife and social worker. Subjects received additional support if they drank > 30g / day. Follow-up post partum Rosett et al 1983: Study type: Single arm Screening: Not stated, all subjects were heavy drinkers. Intervention: 3 or more counselling sessions at 1-4 week intervals.

	Halmesmaki 1998: Study type: Single arm. Screening: Not stated, all subjects were heavy drinkers. Intervention: Counselling at 2-4 week intervals.
Results (within scope of review)	Meberg 1986: Control: 61% abstained. Intervention: 53% abstained. 95% CI for difference in proportions: -27% to 11% Waterson 1990: Control: Trial 1: 63% abstained. Trial 2: 68% abstained. Intervention: Trial 1: 69% abstained. Trial 2: 66% abstained. 95% CI for difference in proportions: Trial 1: -4% to 14%. Trial 2: -15% to 9% Larsson 1983: 70% abstained or reduced alcohol intake Rosett 1983: 39% abstained, 28% reduced alcohol intake to less than 45g/month prior to third trimester Halmesmaki 1988: 65% reduced alcohol intake by at least 50%
Authors conclusions	Despite wide variations in the study populations the interventions and the study designs, the results of all five studies were similar: the majority of subjects reduced their alcohol intake or abstained by the end of pregnancy (even among subjects who consumed more than 10 grams of absolute alcohol per day). However, similar reductions also occurred among control subjects in the two studies with a control arm. The 95% confidence intervals around the differences between the control and intervention groups must be interpreted with caution, due to the methodologic limitations of the studies. With this in mind, it is unlikely that any difference between the proportion of successes in the intervention groups compared to the control groups was greater than 14%. It appears that a simple message, or perhaps just the influence of public education campaigns, may be sufficient to lead to behaviour change for a majority of women. The lack of a concurrent control group was a major flaw in the design of four of the five intervention studies. Two studies stated that unethical to identify pregnant women who consumed alcohol and then not provide the same education and counselling to all subjects. However the use of a control group is ethically justified when the superiority of either arm of a trial is unknown.
Reviewers notes	All publications identified in this systematic review have been identified in the literature search conducted for this report. These publications will be described in greater detail in the appropriate sections of this report.
Relevance to study question	This study aims to systematically review the evidence relating to FASD prevention strategies. **This study provides results relevant to questions regarding prenatal screening and prevention.**

ABBREVIATIONS:

[A] A SYSTEMATIC REVIEW OF LEVEL II, III AND IV STUDIES

THE QUALITY OF SYSTEMATIC REVIEWS WERE ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS A CLINICAL QUESTION CLEARLY DEFINED?; (B) WAS AN ADEQUATE SEARCH STRATEGY USED?; (C) WERE THE INCLUSION CRITERIA APPROPRIATE AND APPLIED IN AN UNBIASED WAY?; (D) WAS A QUALITY ASSESSMENT OF INCLUDED STUDIES UNDERTAKEN?; (E) WERE THE CHARACTERISTICS AND RESULTS OF THE INDIVIDUAL STUDIES APPROPRIATELY SUMMARISED? ; (F) WERE THE METHODS FOR POOLING THE DATA APPROPRIATE? AND (G) WERE SOURCES OF HETEROGENEITY EXPLORED?

Primary Prevention original studies

Level III-2

Citation	Bowerman 1997
Level of evidence	III-2 (Intervention)
Country	United States
Research question/aims	To evaluate the effect of alcohol prohibition on the consumption of alcohol during pregnancy in the North Slope Borough in northern Alaska.
Study type/design	Interrupted time series with a control group
Patient group	Pregnant women from remote villages in arctic Alaska (N=348)
Intervention	Alcohol ban. Alaska's most northern municipality, the North Slope Borough has a high incidence of fetal alcohol syndrome. Alcohol was banned in all regional villages except the largest and most central village, Barrow. Despite these measures, alcohol abuse was still commonly encountered in the course of prenatal care. In 1994, Barrow, through a local referendum, became the largest community in Alaska to prohibit the possession of alcohol. All women in the intervention group also received FASD information as part of their prenatal care. N=73 recruited from Nov 1994 – March 1995
Comparator	Women who received FASD information as part of prenatal care prior to the introduction of the alcohol ban. N=275 recruited from Jan 1992 – April 1994
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described or validated. The definition of alcohol abuse was not stated.
Data analyses & statistics	Details of data analyses were not reported. Relative risk and 95% confidence intervals were reported.
Study quality	Fair (A) Probably. All women who were pregnant in any of six remote villages in the Borough were eligible for inclusion in the study. The authors state that “all known women” were recruited, however some women may have been missed. (B) No adjustments were made for potential confounders. (C) Unclear. Women were assessed during first, second and third trimesters. The publication did not state if all women were assessed at all time points. (D) No. Alcohol consumption was self-reported. The method used to determine the level of alcohol consumption was not reported. The authors do not discuss measurement or misclassification bias.
Results (within scope of review)	Reduction in regional alcohol abuse during pregnancy (intervention vs control) • 9% vs 42% (RR 0.21, 95% CI 0.08, 0.55) Reduction in first trimester alcohol abuse • 11% vs 43% (RR 0.25, 95% CI 0.07, 0.95) Reduction in second trimester alcohol abuse • 7% vs 17% (RR and 95% CI not reported) Reduction in third trimester alcohol abuse • 5% vs 14% (RR and 95% CI not reported)
Authors conclusions	The banning of alcohol in Barrow had a regional effect on prenatal alcohol consumption as Barrow is centrally located and is most likely a distribution point for other villages. During this time, no significant change in other prenatal substance abuse was evident. The alcohol ban should be considered as a potential public health intervention in areas where fetal alcohol syndrome incidence is high.

Reviewers notes	This was a brief letter to the editor which provided minimal details about study design and presented limited analyses. The authors did not discuss the potential problems associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the effect of a primary prevention strategy (alcohol prohibition) on the rates of alcohol abuse during pregnancy.

ABBREVIATIONS: CI=CONFIDENCE INTERVAL, FASD=FETAL ALCOHOL SYNDROME DISORDERS, RR=RELATIVE RISK.

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Hankin *et al* 1993a and Hankin *et al* 1993b
Level of evidence	III-2 (Intervention)
Country	United States
Research question/aims	To evaluate the effect of the alcohol beverage warning label on alcohol consumption in pregnant women.
Study type/design	Interrupted time series with a control group
Patient group	Hankin *et al* 1993a Consecutive African American women attending a prenatal clinic from 1986 to 1991. N=12,026 Hankin *et al* 1993b Consecutive African American women attending a prenatal clinic from May 1989 to May 1992. N=4,379
Intervention	Warning label on alcohol bottles. The law requiring warning labels on alcohol bottles was approved by the United States government in 1988 and implemented in November 1989. The article notes that there was a lag between the implementation of the law and increased knowledge of the label due to a delay in the penetration of labelled bottles on retailers' shelves. The intervention group were women who attended a prenatal clinic after the introduction of the alcohol warning label (defined as after June 1990).
Comparator	Women who attended a prenatal clinic prior to the introduction of the alcohol warning label (defined as prior to June 1990).
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. Subjects completed a questionnaire (developed and validated by Sokol et al 1981) and were asked about their drinking around the time of conception and during their pregnancy. Alcohol consumption was reported as average absolute alcohol per day. Drinking at conception was based on the recall of a one week period and in-pregnancy drinking was based on the recall of a two week period prior to the prenatal visit. Light drinkers: consumption of less than 0.5 ounces of alcohol/day (N=596) Risk drinkers: consumption of at least 0.5 ounces of alcohol/day (N=3,786) Note: 0.5 ounces of alcohol is equivalent to 1.4 standard drinks
Data analyses & statistics	Analyses were performed pre and post June 1990 as prior research by these authors has shown that although the labels were introduced in November 1989 the first significant increase in women's awareness of the labels occurred in June 1990. Subgroup analysis was performed on light vs risk drinkers. A multivariate model was used, which estimated in-pregnancy drinking at the time of the first prenatal visit as a function of time (pre- vs post-label) and knowledge of the warning label. The model was also controlled for other variables that have been shown to affect in-pregnancy drinking, including drinking history and maternal characteristics (number of deliveries, maternal age and age of fetus at initiation of prenatal care). The impact of the warning label was tested using the Box-Jenkins Interventional Model. The time series was constructed suing the monthly mean of alcohol consumption for the duration of the study. Hankin *et al* 1993a An antenatal drinking score was calculated using an ordinary least-squares (OLS) regression. The predictive variables included in the OLS regression were the mothers age, gravidity, weeks gestation (which controls for the date of conception) and peri conceptional drinking. The antenatal score for each individual was the difference between the estimated amount of alcohol consumed (from the OLS regression) and the actual amount of alcohol consumed. Hankin *et al* 1993b Multiple tobit regressions were evaluated by calculating elasticises.

Study quality	Fair (A) Yes. Consecutive women were recruited into the study. (B) Yes. Analysis was performed using potentially confounding factors such as age, prior deliveries and peri conceptional drinking. (C) Unclear. Women were assessed during their pregnancy and not followed after delivery. The publication did not state if all women were assessed at all time points. (D) Alcohol consumption was self evaluated using a validated screening questionnaire. The authors do not discuss measurement or misclassification bias.
Results (within scope of review)	Hankin *et al* 1993a Simple time series analysis • No difference in alcohol consumption pre label vs post label Intervention models • 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 the drinking score of 0.68 • There was no change in alcohol intake in risk drinkers. Hankin *et al* 1993b Mean alcohol consumed at conception (ounces of absolute alcohol/day) • Pre label vs post label: 0.281 vs 0.272 Mean alcohol consumed during pregnancy (ounces of absolute alcohol/day) • Pre label vs post label: 0.047 vs 0.048 Proportion of women who abstained during pregnancy • Pre label vs post label: 80.4% vs 81.7% Proportion of women who drank less than 0.5 ounces of alcohol/day during pregnancy (light drinkers) • Pre label vs post label: 17.5% vs 16.4% Proportion of women who drank at least 0.5 ounces of alcohol/day during pregnancy (risk drinkers) • Pre label vs post label: 2.2% vs 1.9% Predicting in-pregnancy drinking • Drinking at the time of the first prenatal visit correlates with drinking around the time of conception, greater age and higher number of deliveries. It does not correlate with post-label time period or awareness of the warning label. Effect of warning label by light drinkers/abstainers and risk drinkers • 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). Note: 0.03 ounces is equivalent to 0.85 standard drinks
Authors conclusions	Hankin *et al* 1993a This social intervention took awhile to make an impact on drinking behaviour. The finding of a 7 month lag of the impact in the label law is consistent with our hypothesis of the gradual diffusion of labelled stock. The decline in drinking occurred only for lighter drinkers. Thus far, the label law has not reduced alcohol consumption for the heavier (i.e. risk) drinkers. As a result, there is no reason to suspect that the warning label has impacted on the incidence of FAS or ARBD. We found a significant impact of the label law on alcohol consumption by lighter drinkers,

	although the effect size was quite small. This small decrease would not be expected to make a difference in pregnancy outcome for these women, because they were drinking below-risk levels at the time of conception. The time series analysis showed seasonal trends in antenatal drinking. Gravidas increased alcohol consumption around the end of the year holidays and during the summer. These results suggest that intervention efforts need to be targeted to these particularly calendar periods, where there is peer pressure and increased opportunities to consume more alcohol Hankin *et al* 1993b Warning labels have a differential effect on risk drinkers and light drinkers. After June 1, 1990 (seven months after the introduction of the warning label) light drinkers reduced their alcohol consumption by a small amount. Among risk drinkers, the label law clearly has not affected drinking behaviour. Risk drinkers were older and had more deliveries than lighter drinkers and abstainers. They were therefore more likely to have been warned about drinking during their previous pregnancy. Despite this, they continued to drink heavily. The study has several limitations: the cohort of inner city, black pregnant women may not be generalisable to the general population, alcohol use was self-reported and the measure of awareness was crude and did not assess understanding of the label. Risk drinkers were exposed to the warning label more often yet seemed to be ignoring the warning label. Multiple mechanisms may be at work: risk drinkers may be more impulsive, feel that their fetus is invulnerable to the effects of alcohol or may enjoy taking risks and gambling the odds.
Reviewers notes	There is likely to be significant overlap between the study population reported in Hankin *et al* 1993a and Hankin *et al* 1993b as consecutive African-American women attending the same prenatal clinic were enrolled over a similar timeframe (1986-1991 for Hankin *et al* 1993a and May 1989 – May 1992 for Hankin *et al* 1993b). Neither article discusses this overlap.The study did not assess the subjects understanding of the alcohol warning label. The questions used to elicit drinking behaviour information have been validated, although the authors did not discuss the potential problems associated with self-reported alcohol consumption. Hankin *et al* 1993b reported that a high proportion of women (25%) reported that they had seen warning labels on alcohol bottles prior to November 1989, indicating a false-positive response.
Relevance to study question	This study aims to evaluate the effect of a primary prevention strategy (warning labels on alcohol bottles) on the rates of alcohol consumption during pregnancy, with emphasis on light and risk drinkers.

ABBREVIATIONS: ARBD=ALCOHOL RELATED BIRTH DISORDERS, FAS=FETAL ALCOHOL SYNDROME

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Hankin *et al* 1996
Level of evidence	III-2 (Intervention)
Country	United States
Research question/aims	To evaluate the effect of the alcohol beverage warning label on alcohol consumption in pregnant women and any difference between women with at least one prior birth and women who had not previously given birth[c]
Study type/design	Interrupted time series with a control group
Patient group	Consecutive African American women attending an prenatal clinic N=8,105
Intervention	Warning label on alcohol bottles. The law requiring warning labels on alcohol bottles was approved by the United States government in 1988 and implemented in November 1989. The article notes that there was a lag between the implementation of the law and increased knowledge of the label due to a delay in the penetration of labelled bottles on retailers' shelves. Prior research by these authors has shown that although the labels were introduced in November 1989 the first significant increase in women's awareness of the labels occurred in June 1990. The intervention group were women who attended a prenatal clinic after the introduction of the alcohol warning label (defined as after June 1990).
Comparator	Women who attended a prenatal clinic prior to the introduction of the alcohol warning label (defined as prior to June 1990).
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. Subjects completed a questionnaire (developed and validated by Sokol et al 1981) and were asked about their drinking around the time of conception and during their pregnancy. Alcohol consumption was reported as average absolute alcohol per day. Drinking at conception was based on the recall of a one week period and in-pregnancy drinking was based on the recall of a two week period prior to the prenatal visit.
Data analyses & statistics	The impact of the alcohol warning label was assessed using a Box-Jenkins Interventional Model. The time series was constructed using the monthly means of AA/D for women initiating prenatal care during each month. Monthly average were calculated from September 1986 to September 1993. Subgroup analysis was performed on nulliparae (n=7,349) and multiparae (n=1,017) women.
Study quality	<u>Fair</u> (A) Yes. Consecutive women were recruited into the study. (B) Yes. Analysis was performed using potentially confounding factors such as age, prior deliveries and periconceptional drinking. The authors note that there may have been some other factors which should be identified and studied. (C) Unclear. Women were assessed during their pregnancy and not followed after delivery. The publication did not state if all women were assessed at all time points. (D) Yes. Alcohol consumption was self-reported using a validated screening questionnaire. The authors do not discuss measurement or misclassification bias.
Results (within scope of review)	Simple time series analysis of antenatal drinking • There was no change in alcohol consumption during pregnancy after the introduction of the alcohol warning label. This could be a result of an upward trend in periconceptional drinking since December 1988 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)
Authors conclusions	The absence of the label impact between 1986 and 1993 using a simple time analysis was attributed in part to changes in the clinic population. The upward trend in periconceptional drinking since 1988, suggests that the clinic population was changing in favour of heavier drinkers. This could be related to changes in eligibility requirements for several welfare programs and more low-risk obstetrical patients being "creamed off" by HMOs. Multiparae were more likely to be exposed to the warning label and drank more at the time of conception, therefore these women may be less likely to respond to the warning label as they feel, based on prior experience,

	that alcohol will not harm their fetus. Data collected on women since May 22, 1989, provide some support for this hypothesis. Multiparae cite slightly higher chances than nulliparae that the baby will be okay if the mother drinks a lot while pregnant (although the difference is not large, 28.1% vs 25.3%, $t = 5.09$, $p < .001$). As well, multiparae are less likely to say that alcohol affects pregnancy (1.987 vs 1.993, $t = 3.03$, $p < .002$; 1 = no, 2 = yes) and are slightly more likely to say that it is safe to drink more often when pregnant (4.54 vs 4.71, $t = 9.68$, $p < .0001$; 1 = daily, 5 = never). There was no evidence that other FASD campaigns were directed towards the subjects. The education programs at the antenatal clinic remained constant throughout the period and there were no signs in bars or major media campaigns in Detroit during this period. Given that multiparae are heavy drinkers and are ignoring warning labels, these data suggest the importance of targeting multiparae for intensive, individualised prevention efforts.
Reviewers notes	Multiparae were at significantly higher risk of having a child with FASD as they consumed twice at much alcohol at conception compared with nulliparae (0.34 oz AA/D vs 0.17 oz AA/D) and consumed three times as much alcohol at their first prenatal visit (0.06 oz AA/D vs 0.02 oz AA/D). This study highlights the importance of directing health messages towards high-risk groups. The effect of interventions may differ significantly between low and high-risk individuals. The authors did not discuss the potential problems associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the effect of a primary prevention strategy (warning labels on alcohol bottles) on the rates of alcohol consumption during pregnancy, with emphasis on nulliparae and multiparae drinkers.

ABBREVIATIONS: OZ AA/D=OUNCES OF ABSOLUTE ALCOHOL CONSUMED/DAY

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Level III-3

Citation	Kaskutas *et al* 1998
Level of evidence	Level III-3 (Intervention)
Country	United States
Research question/aims	To evaluate the effect of alcoholic beverage warning labels on drinking during pregnancy in the United States and Ontario, Canada.
Study type/design	Interrupted time series without a parallel control group (The publication states that the Canadian women were a non-equivalent, non-intervention reference group but the results from this group do not appear in the publication).
Patient group	Women of child bearing age (18-40 years) who participated in a telephone surveys (N=9,800) N=365 had been pregnant in the last 12 months
Intervention	Intervention: Various. Exposure to any health message about the risk of drinking during pregnancy. Message exposure included personal messages (e.g. conversations) and impersonal messages (e.g. point-of-sale warning signs, warning labels on bottles and health advertisements).
Comparator	No exposure to any health messages about the risk of drinking during pregnancy.
Outcome definitions and measurements	Evaluation of alcohol consumption: Self-reported. Women were asked 'during the time that you knew you were pregnant, was the largest number of drinks that you had'. Women were also asked if their drinking had increased, decreased or stayed the same during their pregnancy. The exposure index was created by summing the number of sources each respondent said they had seen about drinking during pregnancy: ranging from 0 for respondents who did not report seeing a warning label, a sign, or an ad about drinking during pregnancy nor having had a personal conversation on the topic. A score of 4 was given to respondents who were exposed to all 4 messages sources. The questionnaire did not evaluate the number of exposures to a given message source, only the number of messages sources seen by each subject. National telephone surveys were conducted in the summer of 1989, 1990, 1991, 1993 and 1994. Longitudinal data was collected on a subset of pregnant women in 1993 (N=62) and 1994 (N=35).
Data analyses & statistics	For longitudinal respondents who had been pregnant during only one of the two 12 month periods (N=41), the maximum number of drinks consumed in the 12 months prior to their index year (the year they were not pregnant) was compared with the maximum number of drinks consumed while pregnant. For the cross sectional samples, maximum drinking in the 12 months prior to the telephone survey was considered a representation of "normal" (i.e. non pregnancy) drinking. Since the period would include at least 3 months when not pregnant, a difference in consumption measure when pregnant versus not pregnant was calculated by comparing the stated maximum while pregnant and the "normal" maximum drinking. The difference was categorised as increased, decreased or remained the same. As periods when not pregnant and pregnant during the prior 12 months would vary between respondents, this measure represents an imperfect categorical assessment of change in maximum drinking. The validity of this measure was assessed by comparing the within-year results with the cross-sectional results and was found to be comparable.
Study quality	<u>Poor</u> (A) Unclear. Telephone numbers were chosen by random digit dialling. The most recent birthday technique was used to select the participant. Response rates were 53% - 65%. No data was collected from women who did not participate. (B) Analysis was performed by comparing drinking outside of pregnancy to drinking during pregnancy. No adjustments were made for potential confounders. (C) Yes. Women were asked about their drinking behaviour during their current pregnancy or a pregnancy in the last 12 months. Follow-up in the longitudinal cohort was 35/62 (56%). (D) Unlikely. Alcohol consumption was evaluated using a series of questions. It is unclear how these questions were developed and if they were validated. The authors do not discuss measurement or misclassification bias.

Results (within scope of review)	Proportion of pregnant women who had 2 or more drinks at least once while pregnant • Women who reported seeing at least one warning label vs women who had not seen any warning labels: 35% vs 38% Relationship between message exposure and decreased alcohol consumption during pregnancy • No statistically significant relationship was found between exposure to any type of warning label, sign, ad, conversation or the cumulative count of message exposure.
Authors conclusions	This study did not assess the frequency of drinking during pregnancy, as a result no statement can be made with regard to the total amount of alcohol to which the fetus is exposed. No information was collected about the trimester in which the maximum drinking occurred, therefore some women may have had their maximum episode of drinking before they knew they were pregnant.
Reviewers notes	This study evaluates a range of primary prevention strategies and does not provide a breakdown of the effect of each type of strategy. It may be that some strategies are more effective than others. The authors did not discuss the potential problems associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the effect of a variety of primary prevention strategy on the rates of alcohol consumption during pregnancy.

ABBREVIATIONS:

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Olsen *et al* 1989
Level of evidence	Level III-3 (Intervention)
Country	Denmark
Research question/aims	To evaluate the effect of a health campaign on pregnant women in a town in Denmark.
Study type/design	Non-randomised, experimental trial
Patient group	Women from the towns of Odense and Aalborg N=27,630
Intervention	Mass education campaign. The "Healthy Habits for Two" program ran in Odense from April 1985 to April 1987. No campaign was run in Aalborg. The two cities were similar in size, structure, number and size of hospitals and number of GPs. The campaign included education strategies aimed at midwives and GPs, brochures about smoking and drinking behaviour during pregnancy (given to all pregnant women in Odense and available in several outlets). A TV show was run and the campaign logo was used on stickers placed on shopping bags. The campaigns included information on alcohol consumption, smoking and healthy eating during pregnancy Intervention: pregnant women from the town of Odense (N=13,815)
Comparator	Pregnant women from the town of Aalborg Control: pregnant women from the town of Aalborg (N=13,815)
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described or validated. 'Alcohol consumption' was not defined.
Data analyses & statistics	Data was collected in both towns from April 1984 to April 1987. The data was descriptive, no analyses were performed on the results.
Study quality	<u>Fair</u> (A) Yes. All pregnant women in the town of Odense were eligible to be in the intervention group. More than 95% of all pregnant women in the town were enrolled in the trial. All pregnant women in the town of Aalborg were eligible to be in the control group. More than 95% of all pregnant women in the town were enrolled in the trial. (B) Yes. The two towns were chosen as they were similar in size, structure, number and size of hospitals and number of GPs. The women in Odense and Aalborg were well matched at baseline. (C) Possibly. Women were followed for the duration of their pregnancy. The number of women excluded from the analysis was not stated. (D) No. Subjects and participants were not blinded to treatment allocation.
Results (within scope of review)	Baseline data • Percentage of pregnant women who did not drink in Odense vs Aalborg: 18% vs 20% • Average alcohol consumption during pregnancy in Odense vs Aalborg: 1.9 drinks/week vs 1.4 drinks/week ($p<0.05$) • Drinking 8 or more drinks on a given occasion during pregnancy in Odense vs Aalborg: <20% in both towns Post campaign data • Percentage of pregnant women who did not drink in Odense vs Aalborg 1985/1986: 16% vs 19% 1986/1987: 18% vs 20% • Average alcohol consumption during pregnancy in Odense vs Aalborg 1985/1986: 1.8 drinks/week vs 1.5 drinks/week 1986/1987: 1.8 drinks/week vs 1.5 drinks/week • Drinking 8 or more drinks on a given occasion during pregnancy in Odense vs Aalborg 1985/1986: 18% vs 19% 1986/1987: 19% vs 18%

Authors conclusions	The campaign was well received and several interviews gave the impression that pregnant women were motivated to change. Yet no change in eating, drinking and smoking habits were noticed. Detailed analysis month by month showed remarkably similar behaviour year after year in the two areas. These findings stress the need for more research in what is important for the success of a mass campaign concerning changes in behaviour, not just programme evaluation.
Reviewers notes	This intervention contains primary prevention strategies (TV shows, education booklets) and secondary prevention strategies (material directed at pregnant women). More than 95% of all pregnant women in each town agreed to participate in this study. The health campaign was comprehensive and included multiple forms of media. The study did not evaluate when during pregnancy the women consumed alcohol. The authors did not discuss the potential problems associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the effect of a variety of primary prevention strategy on the rates of alcohol consumption during pregnancy.

ABBREVIATIONS: GP=GENERAL PRACTITIONER

THE QUALITY OF COHORT STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Secondary prevention original studies

Level II evidence

Citation	Handmaker *et al* 1998
Level of evidence	Level II (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a motivational intervention on alcohol consumption in pregnant women
Study type/design	Randomised controlled trial (pilot study)
Patient group	Pregnant women attending the University of New Mexico obstetrics clinics. Women must have reported consuming at least one drink during pregnancy in the month prior to study enrolment. N=42
Intervention	Motivational intervention. The 1 hour motivational interview typically began by asking the participant what she already knew about the effects of drinking during pregnancy. She was given feedback about the severity of her drinking, and shown a chart of fetal development by gestational week to personalize the potential impact on the fetus. The interview was conducted in the empathetic client-centred by directive style described by Miller and Rollnick (1991)[a]. The goal was to increase the mother's perceptions of the health risks to her unborn baby associated with her current drinking with supporting her perceived ability to change. Women were encouraged that quitting her drinking at any point in the pregnancy could lead to better outcomes. A follow-up assessment was performed after 2 months. N=20 randomised; N=18 available for analysis (2 women miscarried); N=15 analysed (3 unwilling or unavailable to participate)
Comparator	The participants in the control arm did not receive a motivational interview but were sent letters informing them about the potential risks of drinking during pregnancy and referring them to their health care providers. A follow-up assessment was performed after 2 months N=22 randomised; N=19 analysed (3 unwilling or unavailable to participate)
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported: Initial assessment consisted of a structured interview, the Brief Drinker Profile (BDP), supplement by a calendar for timeline reconstruction of drinking during the previous 2 months .For each drinking day, the number and strength of drinks and the duration of drinking episodes were estimated. All drinking was converted into standard ethanol content (SEC) units equal to 0.5 oz (15 ml) of absolute alcohol. Computer projections of peak blood alcohol concentration (BAC) were performed with BACCuS software. To corroborate self-reports: significant others were interview (with the partner's permission) at intake and follow-up using a Collateral Information Form (CIF).
Data analyses & statistics	Data analysis not described in the methodology section. In the results section it states that analysis of covariance (ANCOVA) was carried out. In addition it states that a ANOCOHET analysis was carried out (to accommodate the unequal within-group slopes; Maxwell and Delaney, 1990)[b].

Study quality[c]	Poor (A) No. The interviewer privately opened a prepared envelope to determine randomised group assignment. Randomisation was stratified 2:1 for light/moderate and heavy drinkers. (B) No. Women could not be blinded to their treatment allocation. Single-blind; research assistants were unaware of treatment assignment during all interviews. (C) Not reported. However, article does state that randomised participants were similar to the broader clinic population. (D) No. Two women in the intervention group had a miscarriage and were not included in the analysis. Six women (three from each group) did not participate in the follow-up interview and were not included in the analysis. Article states there were 18 controls and 16 in the intervention group however this does not tally with numbers described in the text. States that there were no differences between patients retained and withdrawn from the study. (E) Unclear. Little detail is given on statistical methods used. (F) Unclear. Article does state that women with a greater alcohol intake at baseline had greater improvements due to the intervention.
Results (within scope of review)	ANCOVAs reflected no differences between treatment and control groups for total alcohol consumption (F=0.01, 1/31 df, p=0.94) and abstinent days (F=1.25, 1/31 df, p=0.27). For the third ANCOVA, the test for homogeneity of regression of postpeak BAC on prepeak BAC between the two groups was significant (F=4.46, 1/30 df, p =0.043). Thus, this analysis was altered to accommodate the unequal within-group slopes. These results indicate the presence of a significant interaction between the covariate (i.e. peak BAC at intake) and the treatment. Among women with the highest initial intoxication levels, those who had received the intervention showed significantly lower BACs during the follow-up period than did corresponding controls. Analyses of overall change on the dependent measures using matched pairs (one-tailed) t- tests showed a significant reduction from pre to post intoxication levels (BAC, t=3.46, 33 df, p<0.01), and a significant increase in total abstinent days(t=-2.18, 33 df, p=0.015). Of participants (38%) reporting total abstinence during the follow-up interval,33% were controls and 44% received the intervention. A reduction in total drinks consumed failed to reach significance by the Bonferroni-protected critical alpha level with this small sample size (t=1.97, 33 df, p=0.025). Effect sizes: intervention group: change in consumption (θ=0.46), BAC (θ=0.77), abstinence (θ=0.69); control group: change in consumption (θ=0.40), BAC (θ=0.46), abstinence (θ=0.20)
Authors conclusions	“Motivational interviewing shows promise as a specific intervention for initiating a reduction in drinking among pregnant women who are at greatest risk. Simpler assessment and advice may suffice for women with lower initial consumption levels”.
Reviewers notes	The authors discussed the potential problems associated with self-reported alcohol consumption and used multiple measures to evaluate the difference in self-reporting under different conditions. The paper clearly described what occurred during the intervention, the information given about drinking during pregnancy and how this information was delivered. The study does not quantify the reduction in alcohol consumption (results are presented as effect sizes which are difficult to interpret) and it is therefore difficult to determine the clinical relevance of this outcome. The authors state that small to medium effects were found for changes in consumption, BAC and abstinence, however it is unclear how clinically relevant these changes are. The authors note that 67% of controls and 56% of the treatment group were still drinking during pregnancy, albeit at very low levels. They do not state the level of alcohol consumption, and it is therefore difficult to evaluate the effectiveness of this intervention.
Relevance to study question	The results of this study suggest there is no additional benefit of motivational interviewing as a secondary prevention tool in women with low/moderate alcohol intake during pregnancy; however, there appears to be a significant benefit as a tertiary prevention tool in women with high alcohol consumption. **Therefore, the results of this study are relevant to questions regarding secondary and tertiary prevention.**

ABBREVIATIONS: ANCOVA=ANALYSIS OF COVARIANCE; BAC=BLOOD ALCOHOL CONCENTRATION.

[A] MILLER AND ROLLNICK (1991) MOTIVATIONAL INTERVIEWING: PREPARING PEOPLE TO CHANGE ADDICTIVE BEHAVIOUR, NEW YORK; GUILFORD PESS, 1991.

[B] MAXELL AND DELANEY (1990) DESIGNING EXPERIMENTS AND ANALYSING DATA, BELMONT, CA: WADSWORTH PUBLISHING CO., 1990.

[C] THE QUALITY OF RCTS WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS ALLOCATION TO TREATMENT GROUPS CONCEALED FROM THOSE RESPONSIBLE FOR RECRUITING SUBJECTS?; (B) WAS THE STUDY DOUBLE-BLINDED; (C) WERE PATIENT CHARACTERISTICS AND DEMOGRAPHICS SIMILAR BETWEEN TREATMENT ARMS AT BASELINE; (D) WERE ALL RANDOMISED PATIENTS INCLUDED IN THE ANALYSIS?; (E) WERE THE STATISTICAL METHODS APPROPRIATE?; (F) WERE ANY SUBGROUP ANALYSES CARRIED OUT?

Citation	Reynolds *et al* 1995
Level of evidence	Level II (Intervention)
Country	United States
Research question/aims	To evaluate the effect of self-help intervention on alcohol consumption during pregnancy
Study type/design	A randomised controlled trial
Patient group	Pregnant women from two public health maternity clinics (Alabama, US). Women must have reported alcohol consumption during pregnancy. N=78 (N=1201 screened, N=101 reported drinking during pregnancy)
Intervention	Self-help intervention. The intervention included a 10 minute education session coupled with a nine-step self-help manual to be completed by women at home in 9 days. During the educational sessions an educator described the effects of alcohol on the fetus and explained the use of the manual. Women then completed the manual at home. The manual included 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. A follow-up assessment was carried out after 2 months. N=42
Comparator	Standard clinical care, which included a brief discussion with clinic staff about the effects of alcohol and pregnancy and a video tape on prenatal care. The article notes that five women in the control group read a portion of the self-help manual. A follow-up assessment was carried out after 2 months. N=36
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. A 15 item self-administered questionnaire was used to assess alcohol consumption at screening. The TACE questionnaire was used to identify problem drinkers (Sokol et al, 1989)[a]. A 47 item self-administered questionnaire was completed by each subject after recruitment. It assessed alcohol consumption, knowledge and psychosocial variables. For each beverage, a woman was asked if she had consumed that beverage in the past month. If yes, she was asked how many days she consumed the beverage and how many cans, bottles or glasses she consumed on average each day. Binge drinking was also assessed. The post-test was identical to the pre-test, except for 9 items assessing threats to internal validity. Women in the intervention group were called 1 week after recruitment to assess their progress. All women completed a post-test 2 months after recruitment.
Data analyses & statistics	Details of the statistical analyses are not reported in the methods section. T-tests and chi-square tests were used to compare groups.
Study quality[b]	Poor (A) Unclear. (B) No. Women could not be blinded to their treatment allocation. Educators were blinded to randomisation status until prior to intervention. (C) The authors state that there was no difference between groups at baseline; however, there was some difference in the mean number of drinks per month in the intervention and usual care groups (44 vs 28) and the types of drinks differed, with more subjects in the intervention group drinking wine (48% vs 39%) and more in the usual care arm drinking beer (75% vs 64%) and liquor (28% vs 19%). (D) Unclear. The number of women included in the analysis is not stated. The article states that 72/78 women completed the post-test questionnaire. The number of steps completed of the intervention is only reported for 32/39 subjects in the intervention arm who completed the study. The article states that protestants and women in the first trimester were less likely to drop out. Dropouts consumed more cans of beer per drinking day at baseline. (E) Unclear. Details of the statistical analyses are not reported. (F) No. However, analyses were stratified by different patients characteristics (e.g., ethnicity, income, age, marital status, religion, drinking level, trimester and visit number.

Results (within scope of review)	Proportion of women who quit drinking in the intervention vs control group: 88% vs 69% (p<0.058) Proportion of women who drank <7 drinks at study entry and who quit drinking at follow-up in the intervention vs control group (note: publication does not clearly state if this is <7 drinks/day, /week or /month; assumed to be /month): 100% vs 71% (p<0.01) Proportion of women who drank >7 drinks at study entry and who quit drinking at follow-up in the intervention vs control group (note: publication does not clearly state if this is <7 drinks/day, /week or /month; assumed to be /month) 73% vs 68% Using logistic regression, participation in the self-help intervention increased the likelihood that a women would quit drinking (χ^2=4.62, p<0.03). Estimated alcohol consumption was 0.36 drinks per person/month for the intervention group and 1.14 drinks per person/month for the control group (p<0.06). It is difficult to compare with baseline levels as these are reported as mean drinks per month and are 44 for the intervention group and 28 for the control group. 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.
Authors conclusions	The self-help intervention produced greater alcohol cessation and greater reductions in the amount of alcohol consumed than the usual prenatal care in the clinics. The intervention was most effective among light to moderate drinkers, African-American women and non-Protestants. The approach may be useful in clinics where staff time is limited.
Reviewers notes	The authors discussed the potential problems associated with self-reported alcohol consumption. There was no change in the number of correct responses to the 10 knowledge questions pre-intervention vs post-intervention in either the intervention or control group.
Relevance to study question	The results of this study suggest a significant reduction in drinking between women taking part in a self-help intervention and women undergoing standard care. All women in the study had received some alcohol during the previous month. **Therefore, this study is relevant to questions regarding both secondary and tertiary prevention strategies.**

ABBREVIATIONS:

[A] SOKOL ET AL (1989) THE T-ACE QUESTIONS: PRACTICAL PRENATAL DETECTION OF RISK DRINKING. AM J OBSTET GYNECOL 160: 863-870.

[B] THE QUALITY OF RCTS WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS ALLOCATION TO TREATMENT GROUPS CONCEALED FROM THOSE RESPONSIBLE FOR RECRUITING SUBJECTS?; (B) WAS THE STUDY DOUBLE-BLINDED; (C) WERE PATIENT CHARACTERISTICS AND DEMOGRAPHICS SIMILAR BETWEEN TREATMENT ARMS AT BASELINE; (D) WERE ALL RANDOMISED PATIENTS INCLUDED IN THE ANALYSIS?; (E) WERE THE STATISTICAL METHODS APPROPRIATE?; (F) WERE ANY SUBGROUP ANALYSES CARRIED OUT?

Citation	O'Connor and Whaley 2007
Level of evidence	Level II (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a brief intervention on alcohol consumption during pregnancy
Study type/design	A cluster-randomised controlled trial
Patient group	Pregnant women attending one of 12 PHFE-WIC centres in Southern California between June 2001 and March 2004. Women were eligible if they reported any drinking after conception N=4980 screened; N=4084 enrolled; N=345 currently drinking and randomised
Intervention	<u>Brief intervention:</u> Women received a comprehensive assessment of alcohol use and were advised to stop drinking during pregnancy. Women also received a standardised workbook-driven brief intervention, designed specifically to help women reduce alcohol consumption during pregnancy. The workbook consisted of traditional brief intervention techniques, including education and feedback, cognitive behavioural procedures, goal setting, and contracting. The intervention was administered by trained nutritionists. N=162 randomised; N=117 followed to third trimester
Comparator	Comprehensive assessment of alcohol use and the advice to stop drinking during pregnancy. The assessment was conducted by trained nutritionists. N=183 randomised; N=138 followed to third trimester
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. Women completed a 2-page alcohol screening questionnaire that incorporated quantity– frequency measures to inquire about typical consumption patterns. Women were also queried about whether or not they had any alcohol during the previous week, the previous weekend, or the previous month. The TWEAK 5-question scale, a measure of alcohol tolerance and physical consequences of alcohol consumption, was included in the questionnaire to assess high-risk drinking. If a woman provided a positive answer on any of the alcohol questions on the screening questionnaire, she was administered the Health Interview for Women. Maximum drinks per drinking occasion (MAX), was selected as the outcome measure on the basis of previous work that demonstrated it is a valid predictor of teratogenic effects. Estimates were taken at the first enrolment visit before the intervention (MAX1) and in the third trimester of pregnancy (MAX3). One drink was considered to be 0.60 ounces of absolute alcohol. Women were screened at every monthly prenatal visit and, if they were still drinking, were provided a brief intervention. **Evaluation of newborn outcomes:** Gestational age identified via due date and birth date. Newborn birth weight and length routinely collected and retrieved via the PHFE-WIC database.
Data analyses & statistics	Differences in demographic and other study variables between the assessment-only and brief intervention groups were assessed using a chi-square and *t* tests for independent samples. Efficacy (i.e., abstinence) was analysed using a logistic regression analysis via a generalized linear mixed effects model, assigning brief intervention or assessment only as the primary fixed effect. The authors included WIC centre as a random design effect and MAX1 (initial alcohol consumption level) as a fixed covariate. All demographic and other baseline study variables were examined as possible covariates. Infant outcome measures were analysed using a mixed-effects ANCOVA in which WIC centre was a random design effect and significant baseline covariates were controlled.

Study quality[a]	Fair (A) Unclear. Centres were randomised to treatment/control. No details of procedure provided. Cluster randomisation used as it was considered to be unfeasible to withhold intervention from women from a random selection of participants within a centre. (B) No. Women could not be blinded to their treatment allocation. (C) Probably. The authors state that there were no differences between women in the intervention and control groups. Visual inspection suggests some small differences in ethnicity. (D) No. 72% of women in intervention group and 75% of women in control group followed to third trimester. Attrition not significantly related to treatment group, alcohol risk or consumption levels but was related to education and race. There were no baseline differences between women who were retained or excluded from the study with the exception of more white, non-Hispanic women being in the dropout group than the follow-up group (10% vs 7.1%). (E) Yes. Analyses took into account cluster randomisation method (via WIC centre as a random design effect) and assessed other significant baseline variables as covariates. (F) No specific subgroups were assessed although results of the infant outcomes were analysed separately for high and low consumption groups.
Results (within scope of review)	Alcohol consumption: Women in the intervention group were 5 times more likely to be abstinent by the third trimester Odds ratio [OR]=5.39; 95% confidence interval [CI]=1.59, 18.25, p<0.05 Newborn outcomes Birth weight: intervention vs control – p<0.06 Birth weight in the high consumption group –intervention vs control group = 180.45g greater. Birth weight in the low consumption group –intervention vs control group = -65.07 g Birth length: intervention vs control – p<0.03 Birth length < 2 drinks per occasion – intervention vs control group = 0.08cm greater Birth length ≥ 2 drinks per occasion – intervention vs control group = 1.67 cm Fetal death – intervention vs control group = 0.9% vs 2.9%
Authors conclusions	"Our results strongly suggest that women who use alcohol during pregnancy are receptive to brief intervention strategies, that brief intervention can be successfully provided by nonmedical professionals, and that negative neonatal consequences of prenatal exposure to alcohol can be prevented through intervention". The authors note that although results suggested that brief intervention was more effective than assessment alone, women in both groups reduced their drinking substantially. This may have been because the women sampled wanted to have healthy pregnancies and because of the time and attention that nutritionists provided for women in both conditions. Because this sample was drawn from women living in Southern California who volunteered to be screened, the authors note that the ability to generalize the results to other populations of women in other parts of California and the United States is limited. Specifically, the sample was highly saturated with low-income Hispanic participants.
Reviewers notes	The authors did not discuss the potential problems associated with self-reported alcohol consumption. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. The publication provides limited analysis of the change in drinking behaviour in women receiving the intervention compared with women in the control arm.
Relevance to study question	The results of this study suggest that the use of a brief intervention has a significant impact in terms of increasing abstinence from alcohol in pregnant women who have drunk alcohol during pregnancy. **Therefore, the results of this study are relevant to questions regarding secondary prevention.**

ABBREVIATIONS:

[A] THE QUALITY OF RCTS WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS ALLOCATION TO TREATMENT GROUPS CONCEALED FROM THOSE RESPONSIBLE FOR RECRUITING SUBJECTS?; (B) WAS THE STUDY DOUBLE-BLINDED; (C) WERE PATIENT CHARACTERISTICS AND DEMOGRAPHICS SIMILAR BETWEEN TREATMENT ARMS AT BASELINE; (D) WERE ALL RANDOMISED PATIENTS INCLUDED IN THE ANALYSIS?; (E) WERE THE STATISTICAL METHODS APPROPRIATE?; (F) WERE ANY SUBGROUP ANALYSES CARRIED OUT?

Level III-1 evidence

Citation	Waterson and Murray-Lyon 1990
Level of evidence	Level III-1 (Intervention)
Country	United Kingdom
Research question/aims	To evaluate the effect of different methods of giving information about prevention of fetal alcohol effects
Study type/design	Pseudorandomised controlled trial
Patient group	Trial 1 Women who booked into a prenatal clinic between May 1982 and January 1983 N=1,036 enrolled Trial 2 Women who booked into a prenatal clinic between February 1983 and October 1983 N=1,064 Both trials The primary analysis was conducted on the subset of women who were drinking > 7 units of alcohol per week before pregnancy Trial 1 N=391 and Trial 2 N=234
Intervention	Trial 1 A leaflet about alcohol use in pregnancy and personal advice and reinforcement by the interviewing doctor N=559 enrolled; N=207 analysed Trial 2 A leaflet about alcohol use in pregnancy, personal advice and reinforcement by the interviewing doctor and viewing a 4 minute video which encouraged mothers to reduce their drinking and gave advice on how they could do this. N=500; N=119 analysed Both trials The doctors were asked to tell the women “Current evidence suggests that drinking regularly in pregnancy may affect your baby. So, we suggest that you try not to drink at all during your pregnancy, or at least try to cut it down to one drink a day”. This message was also contained in the leaflet and the video.
Comparator	Trial 1 and Trial 2 A leaflet about alcohol use in pregnancy only. Medical staff were asked not to give any verbal advice to the women. Trial 1 N=477 enrolled; N=184 analysed; Trial 2 N=564 enrolled; N=115 analysed
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption had been previously described and validated in a previous study by the same authors. Alcohol use assessed at first prenatal visit, at 28-week visit and following birth. Success: Drinking <7 units of alcohol per week at both stages of pregnancy Partial success: Some reduction in intake but still drinking >7 units per week at one or both stages of pregnancy No change: No change in number of units of alcohol per week from pre-pregnancy levels Failure: An increase in the number of units of alcohol per week from pre-pregnancy levels
Data analyses & statistics	Women were given a questionnaire at their first clinic visit, at around week 28 and after delivery. Significance tests were carried out using chi-square analysis when values were nominal and Mann-Whitney U tests when values were ordinal.

Study quality[a]	Poor (A) Unknown. There were four booking clinic per week, each taking new patients are random. Therefore women in two clinics were allocated to the intervention and women in the other two clinics were allocated to the control. (B) No. Clinicians were aware which arm each patient was in so they could give or withhold verbal advice as appropriate. (C) Unclear. The authors note that there were no differences between treatment arms with regards to baseline demographics and alcohol intake. However, there were some differences between trials 1 and 2 regarding social class and parity. (D) No. For trial 1 there was a 55% return rate for the second and third questionnaires. For trial 2 there was a 50% return rate for the second questionnaire and a 34% return rate for the third questionnaire. The authors note that there was no difference within or between trials in terms of pre-pregnancy drinking levels in those mothers who returned one or two questionnaires. In all groups, non-drinkers and light drinkers were least likely to return questionnaires. (E) Significance tests were carried out using chi-square analysis for nominal variables and Mann-Whitney U-tests for ordinal variables. (F) The primary analysis was conducted on a subset of all women included in the study who indicated they had consumed on average > 7 drinks per week pre-pregnancy.
Results (within scope of review)	Trial 1 Change in alcohol consumption in mothers who were drinking >7 units of alcohol per week before pregnancy Reduction in second trimester alcohol abuse • Intervention: Success 63%, Partial success 22%, No change 9%, Failure 6% • Control: Success 68%, Partial success 12%, No change 13%, Failure 8% Trial 2 Change in alcohol consumption in mothers who were drinking >7 units of alcohol per week before pregnancy • Intervention: Success 69%, Partial success 14%, No change 12%, Failure 5% • Control: Success 66%, Partial success 19%, No change 7%, Failure 8%
Authors conclusions	There were no statistically significant differences either within or between trials with regards to change in alcohol consumption. . As there was no change in research policy it is hard to account for the low return rates in the second trial. Although the representative response rates indicate the validity of our findings they must still be interpreted with caution.
Reviewers notes	The authors note the shortcomings of using self-reporting as a method of quantifying levels of alcohol consumption. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. The intervention is clearly described.
Relevance to study question	The results of this study indicate no difference in alcohol consumption during pregnancy compared with pre-pregnancy in women who received two types of intervention (written material + counselling from clinician ± short video) compared with control (written information only. While the overall study population included all women who attended the clinic, the primary results of this study focussed on women with significant alcohol intake prior to pregnancy. **Therefore, this result is more likely to be relevant to questions of tertiary prevention.**

ABBREVIATIONS:

[A] THE QUALITY OF RCTS WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS ALLOCATION TO TREATMENT GROUPS CONCEALED FROM THOSE RESPONSIBLE FOR RECRUITING SUBJECTS?; (B) WAS THE STUDY DOUBLE-BLINDED; (C) WERE PATIENT CHARACTERISTICS AND DEMOGRAPHICS SIMILAR BETWEEN TREATMENT ARMS AT BASELINE; (D) WERE ALL RANDOMISED PATIENTS INCLUDED IN THE ANALYSIS?; (E) WERE THE STATISTICAL METHODS APPROPRIATE?; (F) WERE ANY SUBGROUP ANALYSES CARRIED OUT?

Level III-2 evidence

Citation	Eisen *et al* 2000
Level of evidence	Level III-2 (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a community-based drug prevention, education, and treatment program
Study type/design	Non-randomised, experimental trial
Patient group	Pregnant women offered treatment in a drug prevention, education and treatment program from September 1994- September 1996. Women must have used alcohol or other drugs during their pregnancy N=658
Intervention	Intervention: Drug prevention, education and treatment program. A convenience sample of nine intervention programs was selected from 147 CSAP PPWI grantees. These employed either (a) case management with provision or referral to individual and group counselling and other services or (b) day treatment with direct provision of services such as individual and group counselling. In general, case management programs linked clients to other service providers, whereas day treatment programs required clients to attend on-site services for 10-20 hours per week. Five programs were primarily case management, four were primarily day treatment. N=370
Comparator	Women who did not receive the intervention. N=288
Outcome definitions and measurements	The study evaluated six substances. **Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described. Alcohol consumption was classified as (i) used alcohol in the last 30 days; and (ii) used alcohol to intoxication in the last 30 days. Data were collected by each program using a core set of measures across sites to assess major intervention outcomes for the women and their babies. Data were collected from individual participants (a) prior to a mother's exposure to the intervention and to her delivery (Time 1), (b) within 30 days of the birth (Time 2), and (c) about 6 months after the birth (Time 3).
Data analyses & statistics	Bivariate and multivariate approaches were used to assess outcomes. To determine whether treatment and comparison women decreased their usage from Time 1–Time 2 and from Time 1–Time 3 significantly, repeated measures analyses (Sign Tests) were performed separately for the treatment group and then for the comparison group women They were conducted for the Time 1–Time 2 interval and then for the Time 1– Time 3 interval.
Study quality[a]	Poor (A) Unclear. Investigators were instructed to follow strict guidelines to ensure that the treatment and comparison group member had similar demographic characteristics and drug use histories with the exception of more women drinking to intoxication in the treatment group compared with the control group (17% vs 11%). The time 2 assessment was completed by 73% of treatment subjects and 67% of control subjects. The time 3 assessment was completed by 56% of treatment subjects and 51% of control subjects. No details of similarities between groups at time 2 and time 3. (B) Multivariate analyses adjusting for various potential confounders were conducted however, the results are not clearly reported. (C) No. Time 2 and Time 3 assessments were completed by only ~70% and 53% of women respectively. The timeframe of assessments was sufficient to measure outcomes. (D) No. Alcohol consumption was self-reported. The authors do not discuss measurement or misclassification bias. The study does not examine the degree of reduction in alcohol consumption.

Results (within scope of review)	Used alcohol in the last 30 days time 1 vs time 2 • Intervention: 33% vs 14% (p=0.0001) • Control: 23% vs 23% (p=NS) Used alcohol in the last 30 days time 1 vs time 3 • Intervention: 32% vs 34% (p=NS) • Control: 23% vs 35% (p=NS) Used alcohol to intoxication n the last 30 days time 1 vs time 2 • Intervention: 19% vs 4% (p=0.0001) • Control: 10% vs 6% (p=NS) Used alcohol to intoxication in the last 30 days time 1 vs time 3 • Intervention: 14% vs 7% (p=NS) • Control: 10% vs 8% (p=NS) The amount of exposure to drug abuse prevention and education sessions appeared to mediate a positive treatment effect for alcohol (p<0.02) in a multivariate analysis at time 1 vs time 2, but not time 1 vs time 3.
Authors conclusions	Data showed that project clients had significantly lower 30-day use rates on four of the measures –alcohol, any illicit drug(s), marijuana and crack –from intake to delivery, with preintervention alcohol and other drug use controlled. However, none of these results was maintained from intake through 6 months postpartum.
Reviewers notes	The authors did not discuss the potential problems associated with self-reported alcohol consumption. Due to the range of treatment programs included in analyses the publication did not clearly describe what occurred during the intervention and it is unclear what information was given about drinking during pregnancy, and how this information was delivered. Women in the control arm of the trial received fewer interventions than women in the treatment arm, rather than no interventions. Women in the control arm received a mean of 3.22 substance abuse related education and prevention sessions between Time 1 and Time 2 (compared with 12.87 for women in the treatment arm) and 5.75 between Time 1 and Time 3 (compared with 11.82 for women in the treatment arm). The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. Women were not matched for alcohol consumption at baseline. Women in the treatment group were more likely to have drunk alcohol to intoxication (17%) than comparison women (11%, p=0.05).
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (a drug prevention, education and treatment program) on the rates of alcohol consumption during pregnancy. **This study provides results relevant to questions regarding both secondary and tertiary prevention.**

ABBREVIATIONS: CSAP, CENTER FOR SUBSTANCE ABUSE PREVENTION; PPWI, PREGNANT AND POSTPARTUM WOMEN AND THEIR INFANTS;

[A] THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Sarvela and Ford, 1993
Level of evidence	Level III-2 (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a prenatal care education program on alcohol consumption in pregnant adolescents
Study type/design	Non randomised, experimental trial.
Patient group	Pregnant adolescent teenagers attending a prenatal clinic between 1989-1990. Subjects assigned to treatment based on town of residence to ensure no cross-contamination of information from intervention and control. There were no specific inclusion criteria. N=212
Intervention	Intervention: Prenatal care education program. Subjects completed one module of the program during each prenatal care visit. The modules were self-administered and conducted in private. Subjects were asked questions regarding the module by a trained health care worked in a brief, private session following the completion of each module. One module, 'You, Your Baby and Alcohol' specifically referred to alcohol consumption during pregnancy. N=113
Comparator	Standard care: N=99
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described. The authors note that the behaviour survey had specificity between 91-100% and 100% sensitivity to alcohol using urinalysis. Post-test data was collected as soon after delivery as possible.
Data analyses & statistics	The control and experimental groups were first directly compared. Analyses were also performed using a 'matched' approached, where an equal number of Black and White subjects in the experimental and control groups were matched. This was performed as there was a significantly different proportion of Blacks and Whites within each group. Analyses were also conducted for Blacks only and for Whites only.
Study quality	Fair (A) Unclear. No mention of how many subjects refused to participate or whether there was any difference between those that refused and those that agreed. (B) Unclear. The only difference at baseline between the two treatment groups was race, and analyses were conducted so as to take this into account. (C) Follow-up occurred post delivery so was adequate to measure alcohol use outcomes. Some subjects were lost to follow-up (10/103, 10% in the intervention arm and 14/99, 14% in the control arm). No details of differences between those that were and were not followed up. (D) Alcohol consumption was self-reported. The authors do not discuss measurement or misclassification bias. However, based on urinalysis results in a random sample of participants, the questionnaire used had a high sensitivity and specificity. The study does not examine the degree of reduction in alcohol consumption.
Results (within scope of review)	Alcohol use in the last 5 months at pre-test vs post-test Intervention: 22% vs 4% Control: 15% vs 4%
Authors conclusions	For both the control and experimental groups a decrease occurred in frequency of substance use behaviour from pretest to post-test for alcohol and cigarettes. These data appear to suggest that general prenatal care as experienced by the control group emphasizes the importance of reducing substance abuse during pregnancy.

Reviewers notes	The authors did not discuss the potential problems associated with self-reported alcohol consumption although a random sample of participants did undergo urinalysis and the accuracy of the questionnaire was shown to be high. The paper did not clearly describe what occurred during the intervention and it is unclear what information was given about drinking during pregnancy, and how this information was delivered. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. Subjects were allocated to the intervention or control group based on the county of residence. The authors justified the sample size.
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (prenatal care education program) on the rates of alcohol consumption during pregnancy. **This study provides results relevant to questions regarding both secondary and tertiary prevention.**

ABBREVIATIONS:

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Meberg *et al* 1986
Level of evidence	III-2 (Intervention)
Country	Norway
Research question/aims	To evaluate the effect of supportive counselling on consumption of alcohol during pregnancy
Study type/design	Non-randomised, experimental trial
Patient group	Consecutive pregnant women referred from a larger general practitioners office in Norway who were registered for pre-natal care (intervention group) and women consecutively admitted for delivery at the obstetric department at the same hospital (control group). Women were not included or excluded on the basis of alcohol consumption. N=132
Intervention	Supportive counselling. Women registered for prenatal care were consecutively enrolled. During pregnancy the women met a midwife two times for consultations lasting one hour each. This included a structured interview and supportive counselling focused on reduction of alcohol consumption. The first interview was performed soon after pregnancy was verified, the second during the last part of the second or beginning of the third trimester, and a final interview was performed after delivery. The exact nature of the advice was not described in the publication. N=58
Comparator	Women consecutively admitted for delivery at the obstetrics department. The women were interviewed after delivery and retrospectively asked about their alcohol consumption during pregnancy. N=74
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. Alcohol consumption was assessed using the Cahalan method[a] and calculated as g absolute alcohol per day.
Data analyses & statistics	Differences between the intervention and control group were tested using a chi-square analysis and changes within the same group by the McNemar test.
Study quality[b]	Fair (A) Subjects were consecutively enrolled in the intervention group if they were referred from a single large general practitioners office and registered for prenatal care at Vestfold Central Hospital, Norway. (B) Subjects were consecutively enrolled in the control group if they were admitted for delivery to the obstetrics department of the same hospital. (C) No. The study did not adjust for confounding variables. However, the authors report that the intervention and control groups were well matched for demographic and social characteristics. There were no differences in alcohol consumption prepregnancy between the intervention and control groups with the exception of beer/wine and liquor consumption which was higher in the intervention group. The authors note this may be due to differences in the way alcohol data was collected: prospectively for the intervention group and retrospectively for the control group. (D) No. Patients were allocated to the intervention or control group based on their decision to attend prenatal care. The study was not blinded. (E) Yes. Intervention subjects were followed through the duration of their pregnancy. Control subjects were asked to recall alcohol consumption pre and during pregnancy. (F) Yes. All subjects were included in the analysis.

Results (within scope of review)	<u>Changes in alcohol consumption during pregnancy</u> • Intervention: Increased 0%, Unchanged 6%, Decreased 41%, Abstinence 53% • Control: Increased 0%, Unchanged 7%, Decreased 32%, Abstinence 61% <u>Teetotallers prepregnancy vs during pregnancy</u> • Intervention: 16% vs 60% • Control: 24% vs 70% <u>Alcohol consumption prepregnancy vs during pregnancy</u> • Intervention: <5g/day 62% vs 34%, 5-10g/day 12% vs 5%, 10-20g/day 10% vs 0% • Control: <5g/day 64% vs 27%, 5-10g/day 8% vs 3%, 10-20 g/day 4% vs 0%
Authors conclusions	"Pregnancy considerably reduced alcohol consumption in both groups, 66% abstained for alcohol use during pregnancy and use of liquor nearly ceased. The changes in alcohol consumption occurred independently to the intervention group."
Reviewers notes	It is interesting to note that 35% of subjects in the intervention group reported that the decision to reduce their alcohol consumption was a result of the counselling, despite a similar reduction in alcohol consumption in the control group. This suggests that these women would have reduced their alcohol consumption regardless of the intervention, despite attributing their behavioural change to the counselling. The authors do not discuss measurement or misclassification bias and the problems associated with self-reported alcohol consumption. The data collected from the intervention group in the form of structured interview at three times during pregnancy and following delivery is likely to be more reliable than the retrospective assessment collected after delivery in the control group. This study is one of a few that does quantify the reduction in alcohol consumption and shows that while many women became abstinent, a large proportion of women also decreased consumption. The paper did not clearly describe what occurred during the intervention and it is unclear what information was given about drinking during pregnancy.
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (supportive counselling) on the rates of alcohol consumption during pregnancy. **This study provides results relevant to questions regarding secondary prevention.**

ABBREVIATIONS:

[A] CAHALAN ET AL (1969) AMERICAN DRINKING PRACTICES. A NATIONAL STUDY OF DRINKING BEHAVIOUR AND ATTITUDES. NEW BRUNSWICK, NJ. RUTHERS CENTRE OF ALCOHOL STUDIES.

[B] THE QUALITY OF COHORT STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HOW WERE SUBJECTS SELECTED FOR THE 'NEW' INTERVENTION?; (B) HOW WERE SUBJECTS SELECTED FOR THE COMPARISON OR CONTROL GROUP?; (C) DOES THE STUDY ADEQUATELY CONTROL FOR DEMOGRAPHIC CHARACTERISTICS, CLINICAL FEATURES AND OTHER POTENTIAL CONFOUNDING VARIABLES IN THE STUDY DESIGN OR ANALYSIS?; (D) WAS THE MEASUREMENT OF OUTCOMES UNBIASED (I.E., BLINDED TO TREATMENT GROUP AND COMPARABLE ACROSS GROUPS)?; (E) WAS FOLLOW-UP LONG ENOUGH FOR OUTCOMES TO OCCUR?; (F) WAS FOLLOW-UP COMPLETE AND WERE THERE EXCLUSIONS FROM ANALYSIS?

Level IV evidence

Citation	Drinkard *et al* 2001
Level of evidence	Level IV (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a healthy pregnancy program
Study type/design	Case series with post-test outcomes
Patient group	Women who delivered a baby between April 1997 and March 1998 at a hospital covered by one of three health plans, who completed at least 1 risk assessment survey, who had a working telephone number and who were able to communicate by telephone for completion of an interview. Women were not included or excluded on the basis of alcohol consumption. N=1,155 eligible; N=684 participated
Intervention	A healthy pregnancy program. The program was initiated in 1996 and was designed to reduce the incidence of low-birth-weight infants and the number of neonatal intensive care unit days by improving prenatal education, promoting safe health behaviours and enhancing the management of maternity care. A reduction in alcohol use was one of the health behaviours targeted by the intervention. During 1997, education booklets and questionnaires were sent to pregnant women enrolled through more than 30 sites. A total of 29% returned the questionnaire by mail or completed it over the telephone. The program consisted of the following: (i) a risk assessment survey; (ii) telephone access to an obstetric nurse specialist; (iii) written educational material (including information on substance abuse and the effect on the baby); and (iv) a fridge magnet with the warning signs of early labour).
Comparator	Alcohol consumption prior to pregnancy
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described.
Data analyses & statistics	The results for each question were summarised with frequencies and percentages. The chi-square test was used to compare differences in proportions for statistical significance. Logistic regression was used to identify the most important predictors of satisfaction and reported behaviour changes in multivariate analyses.
Study quality[a]	Poor (A) No. A total of 59% of the women enrolled in the program completed the questionnaire. 123 of these women reported alcohol use. (B) Yes. Potential predictors of changes in health behaviour were examined. Variables assessed in the model included age, trimester of entry, number of telephone contacts, read booklet, identified as high-risk pregnancy and first child. Both age < 30 and identification of a high-risk pregnancy were significant predictors of quitting/decreasing alcohol use. (C) Unclear. Women were asked whether they had decreased or quit alcohol use during pregnancy. There is no quantification of prepregnancy or pre-intervention alcohol use. (D) No. Alcohol consumption was self-reported. The authors do not discuss measurement or misclassification bias. The study does not examine the degree of reduction in alcohol consumption.
Results (within scope of review)	Proportion of mothers who reported using alcohol who said that the program helped them quit or reduce their alcohol use • 89/123 (72%) Women were more likely to quit or decrease alcohol use if they were younger than 30 years of if they reported being told they had a high-risk pregnancy.
Authors conclusions	Most women reported improving their health behaviours, including the 4 targeted behaviours of cigarette use, alcohol use, diet, and stress reduction, because of their participation in the health in pregnancy program. Because women are more likely to be motivated to change behaviours during pregnancy, this is an opportune time to initiate improved health behaviours for the sake of both their infant's health and their own.

Reviewers notes	This paper describes a comprehensive healthy pregnancy program which aimed to improve a vast array of pregnancy outcomes, of which alcohol consumption was one outcome. Therefore there is little data or discussion about the reduction in alcohol consumption. The authors did not discuss the potential problems associated with self-reported alcohol consumption. The study does not evaluate the absolute reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. The questionnaire had a very low response rate. Women who had children with birth defects were excluded from the study, which may have excluded mothers of children with FASD.
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (a healthy pregnancy program) and provides some data on its effect on alcohol reduction. **This study provides results relevant to questions regarding secondary prevention.**

ABBREVIATIONS:

[A] THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Czeizel 1999
Level of evidence	Level IV (Intervention)
Country	Hungary
Research question/aims	To describe 10 years experience of a comprehensive periconceptional care program
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Women who enrolled in a periconceptional care program. Women were eligible if they were not infertile, not currently pregnant and planning a pregnancy. Women were not included or excluded on the basis of alcohol consumption. N=6,060
Intervention	Intervention: Periconceptional care program. Periconceptional care consisted of i) a check-up of reproductive health, ii) a 3-month preparation for conception, iii) a visit to confirm pregnancy and iv) a visit in the 10-12th week of gestation. After the fourth visit women were referred to an antenatal clinic. Data on the pregnancy outcome was collected after delivery. At the second visit couples were advised to avoid alcohol as part of a comprehensive 'preparation for conception' session. The exact nature of the advice and the method of delivery was not described in the publication.
Comparator	Alcohol consumption prior to periconceptional care program
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described.
Data analyses & statistics	Details of data analyses were not reported.
Study quality	Poor (A) Probably. Participants were recruited by the help of physicians, midwives, nurses, social workers in the primary health care and media. A significantly greater proportion of women included in the study had a high level of education compared with the general Hungarian population (~80% vs 20%). May bias results as more highly educated women may be more likely to change health-related behaviours. (B) No. Adjustments were not made for residual confounders. (C) Yes. 99% of women were followed from pre-conception to post delivery. Considerable effort was used to maximise the follow-up of women in the study. (D) No. Alcohol consumption was self-reported. The method used to determine the level of alcohol consumption was not reported. The authors do not discuss measurement or misclassification bias.
Results (within scope of review)	Proportion of women who drank daily prior to periconceptional care vs after the 3 month preparation course and in pregnancy • 0.2% vs 0% Proportion of women who drank more than one drink per week prior to periconceptional care vs after the 3 month preparation course and in pregnancy • 5.4% vs 0.8% Note: Authors state these numbers in the text of the publication but note that they "could not check this information".
Authors conclusions	Our data confirmed the increase of the gestation age specific birth weight due to the avoidance of smoking and alcohol consumption.
Reviewers notes	This paper describes a comprehensive periconceptional care program which aimed to improve a vast array of pregnancy outcomes, of which alcohol consumption was one outcome. Therefore there is little data or discussion about the reduction in alcohol consumption. The paper did not clearly describe what occurred during the 'preparation for conception' session and it is unclear what information was given about drinking during pregnancy, and how this information was delivered. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome.
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (a comprehensive periconceptional program) on the rates of alcohol consumption during pregnancy. **This study provides results relevant to questions regarding secondary prevention.**

ABBREVIATIONS:

[A] THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Allen and Ries 1985
Level of evidence	Level IV (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a prenatal education class on smoking, alcohol and dietary practices during pregnancy
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Pregnant women attending one of three prenatal clinics. Women were not included or excluded on the basis of alcohol consumption.
Intervention	Prenatal education class. The exact nature of the advice and the method of delivery were not described in the publication. N=175 eligible; N=75 enrolled
Comparator	Alcohol consumption prior to prenatal education class
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described. A pre-intervention questionnaire consisted of a 14 item multiple-choice test of prenatal nutrition concepts and questions assessing alcohol consumption, smoking and dietary behaviour before and during pregnancy. A similar questionnaire was administered via telephone approximately 4 weeks after the class.
Data analyses & statistics	Dependent t-tests were used to compare alcohol consumption prior to pregnancy and to compare consumption pre and post postnatal intervention.
Study quality[a]	Poor (A) No. All women attending a prenatal clinic were eligible to enrol in the study, 75/175 (43%) enrolled. No data was collected from women who did not enrol. Characteristics of the included women showed they were not representative of the general population; however, the authors state they do represent those who voluntarily seek prenatal care. This population are likely to be already highly motivated during their pregnancy. (B) No. No adjustments were made for potential confounders. (C) Unclear. Effect of prenatal class assessed after 4 weeks. (D) No. Alcohol consumption was self-reported. The method used to determine the level of alcohol consumption was not reported. The authors do not discuss measurement or misclassification bias.
Results (within scope of review)	Average alcohol consumption per day before pregnancy vs during pregnancy • 0.35 vs 0.04 ($p<0.01$) Average alcohol consumption per day before prenatal education vs after prenatal education • 0.04 vs 0.03
Authors conclusions	The fact that pregnant women significantly decreased smoking and alcohol consumption as a result of their pregnancies supports the belief that women are especially motivated during pregnancy to change behaviour patterns. Although this rather select sample does not represent the general population of pregnant women, it does represent those who voluntarily seek prenatal education.
Reviewers notes	The major factor that influenced drinking behaviour was the pregnancy itself, with women reporting a significant reduction in alcohol consumption after becoming pregnant. The average level of alcohol consumption prior to the intervention was almost negligible (0.04 drinks per day) and it was therefore difficult to assess the impact of the prenatal education class. The authors did not discuss the potential problems associated with self-reported alcohol consumption. The paper did not clearly describe what occurred during the intervention and it is unclear what information was given about drinking during pregnancy, and how this information was delivered.
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (prenatal education class) on the rates of alcohol consumption during pregnancy. **This study provides results relevant to questions regarding secondary prevention.**

ABBREVIATIONS:

[A] THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Little *et al* 1984 and Little *et al* 1985
Level of evidence	Level IV (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a program to reduce maternal alcohol consumption
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Both publications Clients of the pregnancy and health program conducted at the University of Washington. Women were not included or excluded on the basis of alcohol consumption. N=304
Intervention	Both publications Intervention: Individual counselling. All pregnant women received an evaluation of their drinking and information about drinking and fetal risk. Typically, during the first meeting a drinking history was taken, and the risk to the fetus of maternal alcohol consumption was described and discussed. If a pregnant woman did not appear to have a drinking problem she was encouraged to remain abstinent throughout pregnancy and lactation and to visit the pregnancy and health program as often as needed. Women with a drinking problem were given individual counselling by trained, certified alcoholism therapists using an eclectic approach compatible with the philosophy of Alcoholics Anonymous. Home and hospital visits were made by counsellors when needed. Support groups were formed when sufficient patients were available. Family counselling was offered.
Comparator	Both publications Alcohol consumption prior to the program
Outcome definitions and measurements	Evaluation of alcohol consumption: Self-reported. The questions used to evaluate alcohol consumption were described in Little *et al* 1985. It is unclear how the questions were developed and if the questionnaire was validated. Little *et al* 1984 reported the outcome “women who reported drinking”. This is not defined and it is unclear if this refers to abstinence or a pre-defined low level of alcohol consumption.
Data analyses & statistics	Details of data analyses were not reported.
Study quality[a]	Poor (A) Unlikely. Women attended the pregnancy and health program after referrals from clinicians, from a formal screening program at two hospitals, an informal screening program at a third hospital or after self-referral. (B) No. No adjustments were made for potential confounders. (C) Unclear. The publications did not state if all women were assessed at all time points. (D) No. Alcohol consumption was self-reported. The methods used to determine the level of alcohol consumption were reported in Little *et al* 1985.

Results (within scope of review)	Little *et al* 1984 Proportion of women who reported drinking prior to contacting the pregnancy health program [a] • 9 months 85%, 7 months 69%, 5 months 67%, 3 months 69%, 1 month 55% Proportion of women who reported drinking after contacting the pregnancy health program [a] • 1 month 40%, 3 months 35%, 5 months 20% An index of infant abnormalities and neurological finds previously associated with maternal drinking was used as a measure of fetal alcohol effects. There was a significant decreasing linear trend in this index as the length of alcohol exposure decreased. Mean scores for fetal alcohol effects were three times as high for infants of women still drinking above risk levels in the third trimester as for those whose mothers cut down their drinking in the first. Little *et al* 1985 Analysis of the data reveals a statistically significant ($p<0.001$) downward trend in the percentage of clients drinking before and after contact with the pregnancy and health clinic. There was a drop in the percentage of drinkers from the last month prior to contact to the first month after contact ($p<0.01$). Proportion of women who reported heavy drinking (at least five drinks on one occasion or at least twice as many drinks on one occasion as in regular drinking) pre vs post pregnancy and health contact • 20% vs 8% (one month after contact) and 2% (4-6 months after contact) Percent of clients judged to have a problem at the time of initiation vs termination of contact • 62.2% vs 44.4% Average alcohol consumption in women who did not stop drinking were calculated for the month before pregnancy and for every month during pregnancy. Among clients who continued to drink, average alcohol consumption declined before and after contact (although fewer women drank at all as their pregnancies progressed).
Authors conclusions	Little *et al* 1984 Pregnant women seen at the program were not only the expected 'excessive' drinkers and alcohol abusers, but also light and non drinkers who had other drug and/or psychosocial problems. Excessive drinkers and light or non drinkers usually needed only brief contact, but problem drinkers required extensive treatment. The major presenting problems, in addition to alcohol use, were guilt and anxiety over past alcohol use and ignorance of possible fetal effects. Little *et al* 1985 Although there was a significant decrease in drinking, 44% of women were still judged to have an alcohol problem at the end of the pregnancy and health program. Clients displayed a broad spectrum of drinking behaviour and clinical problems. The majority had at most a slight problem with alcohol and drinking did not cause significant disruption in their lives. Early intervention in their risk drinking led to fruitful and gratifying prevention. About one third had an alcohol problem that could be considered moderate or more severe. Secondary prevention in these more advanced cases was facilitated since they were most likely to receive extensive service. Their influence was proportionately greater than their numbers because they had more appointments, occupied a larger proportion of staff time and were often more difficult to treat. Many clients had multiple, serious problems that were secondary to drinking. It is impossible to determine which change to abstinence or reduced drinking was a spontaneous effect of pregnancy, an effector of the pregnancy and health program or the other activities such as improved professional training and public education.

Reviewers notes	The authors did not discuss the potential problems associated with self-reported alcohol consumption. The measures used to determine fetal alcohol effects were not described. Little *et al* 1985 discusses the results of a questionnaire completed by 642 subjects, but this did not evaluate a change in drinking behaviour during pregnancy. It is unclear if there is an overlap between these subjects and the 304 subjects described here. The individual counselling was part of a much larger program which aimed to provide services to women who drank during pregnancy and their children. This included a public education campaign, extensive training of over 6300 professional (teachers, nurses, alcohol counsellors, social workers, psychologists and teachers) who might have encountered a pregnant woman or her child. A 24-hour hotline was made available to women who wanted further information about drinking during pregnancy. Screening and counselling services for women and a child assessment services were set up. It is therefore possible that these other strategies may have influenced any change in drinking behaviour. The potential for confounding is discussed in Little *et al* 1985. It is difficult to evaluate the clinical relevance of the some of the qualitatively described outcomes (e.g. there was a drop in the percentage of drinkers). The intervention varied for different women e.g. a support group was only formed when sufficient patients were available. It should be noted that there was a decline in drinking prior to the program (85% reported drinking 9 months prior to the program and 55% reported drinking 1 month prior to the program). It is therefore difficult to assess the impact of the program on drinking levels as there is no control arm.
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (individual counselling) on the rates of alcohol consumption during pregnancy. **This study provides results relevant to questions regarding secondary and tertiary prevention.**

ABBREVIATIONS:

[A] THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

[B] DATA READ OFF A GRAPH.

Citation	Larsson 1983
Level of evidence	Level IV (Intervention)
Country	Sweden
Research question/aims	To evaluate the effect of a program for early detection of maternal alcohol abuse
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Consecutive pregnant women attending one of four maternal health clinics in Stockholm, Sweden. Women were not included or excluded on the basis of alcohol consumption. N=464
Intervention	Early detection and treatment program for prenatal alcohol use. Women met a midwife and social worker during their first visit to the maternal health clinic. The visit lasted an hour. A structured interview was employed using a questionnaire which included questions about consumption of alcohol. Alcohol consumption was assessed by Calahan's method, which includes a drinking anamnesis of 10 questions. All women were given information about the adverse effects of alcohol on fetal development. The staff at the antenatal clinic met with women with initially high alcohol consumption about twice a week and also made domiciliary visits. The exact nature of the advice was not described in the publication. Women completed a second questionnaire in the week after delivery. Women classified as excessive drinkers were offered various kinds of support e.g. more frequent visits to the maternal health clinic and visits by a social worker and psychiatrist.
Comparator	Alcohol consumption prior to the program
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported, supplemented by information from community programs if available. Alcohol consumption was assessed by Calahan's method. Women were classified as i) Occasional drinkers (average consumption <30g per day ii) Excessive drinkers (average consumption 30 – 125g per day) or iii) alcohol abusers (average consumption >125g per day). Classification was based on consumption in the month prior to the first clinic visit. **Evaluation of newborn outcomes:** All newborn infants were examined by a neonatologist with special emphasis placed on neurological and developmental assessment and the characteristics of FAS.
Data analyses & statistics	Statistical differences between the groups were calculated using the Chi-square or Fishers exact test. The article states that analysis of variance was used to evaluate the effect of confounding factors; however, it is unclear how this was used in relation to the alcohol use and newborn outcomes results.
Study quality[a]	<u>Fair</u> (A) Yes. Patients were recruited consecutively from four maternal health clinics in 1979. According to the article, all eligible women participated in the study. Three of the clinics were located in socially-deprived suburbs in Stockholm and one was in a socioeconomically average region in the city of Stockholm. (B) Unclear. The article states that analysis of variance was used to evaluate the effect of confounding factors; however, it is unclear how this was used in relation to the alcohol use and newborn outcomes results. (C) Yes. Data on the change in alcohol consumption was available from 399/464 women, with the remaining 65 women having an abortion or miscarriage. Outcomes were measured following birth. (D) Yes. Alcohol consumption was self-reported using a validated questionnaire. Alcohol consumption data was supplemented with information from community alcoholism programs and social agencies if available. The reliability of the women's answers were tested by repeating the questionnaire at the second and third visits. There was a good reliability between answers at subsequent visits (89-100%). The authors discuss measurement and misclassification bias.
Results (within scope of review)	Proportion of women who reported a reduction in alcohol intake or abstinence • Occasional drinkers 266/230 (74%) • Excessive drinkers 30/30 (100%) • Alcohol abusers 7/9 (78%)

Authors conclusions	"In our program, therapeutic assistance has resulted in a substantial decline in alcohol intake among mothers who are heavy drinkers." Data on reduction of drinking were obtained at the counselling sessions as well as in an interview after delivery. It is recognised that women who wish to please may exaggerate their reports of reduced alcohol intake. The reliability of such answers must always be checked by studying the records of the social welfare authorities and of the social welfare authorities and of the out-patient units for alcoholics. The social and physical rehabilitation and the discontinuation of alcohol intake were verified in the records. Maternal reports of alcohol abuse to the antenatal staff have proved remarkably reliable, whereas there is a tendency to report moderate drinking as rare drinking. Thus, there was a possible under identification of primarily excessive drinking women in the study. This would diminish observed differences between the groups. The change, however, that a non-alcohol women was incorrectly diagnosed as an abuser is considered negligible. The benefit of this program was that all pregnant women were initially treated in the same way and no one felt discriminated against or accused.
Reviewers notes	The authors discuss the potential problems associated with self-reported alcohol consumption and undertake numerous steps to minimise this effect (incorporating data from other sources and using the same questionnaire on multiple occasions to evaluate internal validity). The paper did not clearly describe what occurred during the information session and it is unclear what information was given about drinking during pregnancy. The support offered to excessive drinkers is not clearly described. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome.
Relevance to study question	This study aims to evaluate the effect of a secondary prevention strategy (an early detection and treatment program for prenatal alcohol use) on the rates of alcohol consumption during pregnancy. **This study provides results relevant to questions regarding secondary prevention.**

ABBREVIATIONS: FAS, FETAL ALCOHOL SYNDROME.

[A] THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Tertiary prevention original studies

Level II studies

Citation	Chang *et al* 2005 (RCT), Chang *et al* 2006 (single-arm only)
Level of evidence	Level II (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a brief intervention including a partner on alcohol consumption during pregnancy
Study type/design	Randomised controlled trial
Patient group	Women attending an obstetric practice (date of study not specified). Women must have scored ≥2 using the T-ACE questionnaire and any alcohol consumption in the 3 months prior to study enrolment (while pregnant) or drinking during a previous pregnancy. N=304
Intervention	Chang *et al* 2005 Brief intervention including a partner. Knowledge assessment with feedback began with a review of the Healthy Pregnancy Facts knowledge measure completed by both the subject and her partner. Questions were answered and any misapprehensions were discussed. The subject's actual alcohol consumption was not discussed in the presence of her partner, unless she volunteered the information. The subject was asked to describe her prenatal drinking goal (e.g., abstinence), and the rationale for her choice was explored. The couple was informed that maternal abstinence from alcohol was the most prudent choice during pregnancy. They were asked if either the subject or the couple had made any lifestyle changes because of her pregnancy (e.g., work schedule). The behavioural modification portion consisted of asking the subject to identify situations or circumstances when she might be tempted to drink alcohol (e.g., at a wedding) and to then list some alternative behaviours (e.g., having some food instead). The partner was asked to describe ways in which he or she had modified or made plans to change behaviours that could offer support to the pregnant woman, such as drinking less, socialising differently, or doing more at home. The content of the brief intervention was summarized and given to the couple. The intervention was a single-session, and took an average of 25 minutes to complete. N=152 Chang *et al* 2006 As above. Some women have been excluded from the data analysis. 34 women did not complete the intervention and 3 had incomplete data. N=115
Comparator	Chang *et al* 2005 Diagnostic interview only N=152
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. At the diagnostic interview given by research assistants, pregnant participants completed the 1) Alcohol Timeline Follow back, to obtain estimates of their daily drinking for the 6 months before study enrolment; 2) Alcohol Abstinence Self-Efficacy scale, to measure their evaluations of their perceived temptation to drink and their efficacy to abstain in 20 common situations; and 3) Healthy Pregnancy Facts, a series of 7 statements about healthy habits during pregnancy that the respondent was asked to judge as true or false, among other instruments. Separately, the partners met with research assistants to complete 1) the Health and Habits Survey, already described; 2) National Institute on Alcohol Abuse and Alcoholism quantity-frequency questions, 9 questions about personal use of beer, wine, whiskey, gin, or other spirits in the previous 30 days; 3) collateral report, the National Institute on Alcohol Abuse and Alcoholism quantity-frequency questions about the partner's alcohol use in the past 90 days; and 4) Healthy Pregnancy Facts, a series of 7 statements about healthy habits during pregnancy that the respondent was asked to judge as true or false. At the postpartum follow-up interview, subjects completed the 1) Alcohol Timeline Follow back for alcohol consumption from the time of study enrolment until delivery, and 2) Alcohol Abstinence

	Self-Efficacy scale, already described. At the postpartum interview, partners provided 1) a collateral report on the subject's use of alcohol since study enrolment using the National Institute on Alcohol Abuse and Alcoholism quantity-frequency questions, 2) follow-up Health and Habits Survey, to assess changes in health habits by the partner since enrolment, and 3) National Institute on Alcohol Abuse and Alcoholism quantity-frequency questions about personal consumption of beer, wine, whiskey, gin, or other spirits since study enrolment.
Data analyses & statistics	Chang *et al* 2005 Data were analysed using univariate and multivariable techniques to compare the treatment (brief intervention) and control (diagnostic interview only) groups before and after study enrolment. Descriptive results are reported as percentages and means. Baseline patient demographic and behavioural characteristics were compared between the 2 study arms using Wilcoxon or Fisher exact tests. Ordinary least-squares regression models were used to evaluate the effect of the brief intervention on 3 dependent variables: drinks per drinking day (quantity), percentage of drinking days (frequency), and a combined quantity-frequency measure subsequent to study enrolment. To control confounding and reduce variability, all regression models included demographic variables, history of prior drinking, temptation and confidence in managing temptation to drink in a variety of circumstances, use of cigarettes, and high-risk pregnancy status, in addition to the primary predictor indicating treatment or control status. Multiple imputation, with 5 imputations, was used to manage missing data. All analyses were replicated with mean substitution to verify the findings from the multiple imputation. Chang *et al* 2006 Data were analysed using univariate and multivariate techniques to compare prenatal drinking by brief intervention goals (abstinence or cut down) chosen by the couples and that by enrolment level of prenatal alcohol consumption. Descriptive results were reported as percentages, means, and medians.
Study quality[a]	Good (A) Probably. Randomisation to treatment was by computer assignment. (B) No. The authors state that this was logistically impossible. (C) Yes. The authors report no differences between the brief intervention and control groups and a table of baseline characteristics suggests they are similar. (D) Yes. All randomised participants were included in the analyses presented in Chang *et al* 2005. 37 (24%) of women from the brief intervention group were excluded from the analyses in Chang *et al* 2006 (E) Yes. Regression analyses were performed to adjust for potential confounders including demographic variable, drinking variables, smoking status and high-risk pregnancy status. (F) Yes. Chang 2006 examines results from the brief intervention for those who were or were not abstinent at study entry and those who did or did not have abstinence as a goal during pregnancy.
Results (within scope of review)	Chang *et al* 2005 Mean average drinking days prepregnancy • Intervention: 29.9%; control: 20.3% Mean average drinking days prenatal at study enrolment • Intervention: 5.4% ; control: 5.0% Mean average drinking days prenatal after study enrolment • Intervention: 1.9%; control: 2.0% Mean number of drinks per episode prepregnancy • Intervention: 1.85; control: 1.82 Mean number of drinks per episode prenatal at study enrolment • Intervention: 1.6; control: 1.6 Mean number of drinks per episode after study enrolment • Intervention: 0.39; control: 0.40 Impact of the brief intervention on different levels of prenatal consumption at enrolment • The interaction between the brief intervention and prenatal alcohol consumption was significant (regression coefficient, b = –0.163, SE = 0.063, p = 0.01), indicating that the brief intervention was more effective in reducing frequency of consumption among women who drank more at the time of study enrolment. For example, a subject who reported drinking on 15% of days when she enrolled in the study would be expected to reduce drinking to 5% of days if she received only the diagnostic interview. If she received the brief intervention, her drinking would be reduced to 3% of days.

	Effect of partner involvement • The brief intervention was more effective for the heavier-drinking subjects when her partner was involved, when drinking was measure by percentage of days drinking (b=–0.867, SE=0.419, p=0.05) and the combined measure of drinking (b=–0.932, SE=0.468, p=0.05). Chang *et al* 2006 Proportion of subjects drinking at enrolment who were abstinent at follow-up and reported abstinence as their drinking goal vs those who reported cutting down as their drinking goal • 50% vs 0% Proportion of subjects drinking at enrolment who had cut down on drinking at follow-up and reported abstinence as their drinking goal vs those who reported cutting down as their drinking goal • 25% vs 16%
Authors conclusions	Chang *et al* 2005 The main findings are that brief interventions for prenatal alcohol use are more effective in reducing subsequent consumption for women who are drinking more often when it is administered (p=0.01). Moreover, the effects of the brief intervention are significantly enhanced when a support partner of the woman's choice also participates in the brief intervention (p=0.05).
Reviewers notes	Chang *et al* 2005 describes the RCT. Chang *et al* 2006 provides more information on the women randomised to receive the brief intervention. While the quality of the trial itself was good, the conclusion drawn by the authors does not relate to the main purpose of the trial. The main conclusion of the authors was that women who drank more at baseline are more likely to benefit from the brief intervention. However, the study showed no significant difference in effect between the brief intervention and the control (diagnostic interview only). As the authors note, the population included in the study may have been particularly motivated and may not be representative of general population of women at risk.
Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (brief intervention including a partner) on the rates of alcohol consumption during pregnancy. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS: RCT=RANDOMISED CONTROLLED TRIAL, SE=STANDARD ERROR

[A] THE QUALITY OF RCTS WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS ALLOCATION TO TREATMENT GROUPS CONCEALED FROM THOSE RESPONSIBLE FOR RECRUITING SUBJECTS?; (B) WAS THE STUDY DOUBLE-BLINDED; (C) WERE PATIENT CHARACTERISTICS AND DEMOGRAPHICS SIMILAR BETWEEN TREATMENT ARMS AT BASELINE; (D) WERE ALL RANDOMISED PATIENTS INCLUDED IN THE ANALYSIS?; (E) WERE THE STATISTICAL METHODS APPROPRIATE?; (F) WERE ANY SUBGROUP ANALYSES CARRIED OUT?

Citation	Chang *et al* 1999, Chang *et al* 2000
Level of evidence	Level II (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a brief intervention on alcohol consumption during pregnancy
Study type/design	Randomised controlled trial
Patient group	Pregnant women attending an obstetric practice from January 1994 (end date not specified). Women were eligible if they scored ≥2 using the T-ACE questionnaire N=250
Intervention	Chang et al (1999) Brief intervention. The brief intervention was structured as follows: (1) review the subject' s general health and course of pregnancy to date, (2) review the subject' s life-style changes made since pregnancy, including work schedule, exercise, diet, cigarette smoking and alcohol consumption, (3) request that the subject articulate her drinking goals while pregnant and their reason, (4) have the subject identify circumstances when she might be tempted to drink, (5) identify alternatives to drinking when she is tempted to drink, and (6) summarize the session by emphasizing four key points (drinking goal, motivation, risk situations for drinking and alternatives to alcohol) and noting them in the take-home manual, "How to prevent alcohol-related problems", given to the subject. This manual was based on materials provided by the WHO Amethyst Project. All subjects receiving the brief intervention were informed of the recommendation of the US Surgeon General, with prenatal abstinence being the most prudent drinking goal. The brief intervention required approximately 45 minutes to complete. The subjects were asked to return for a post-partum follow-up interview. This in-person interview was administered by a second research assistant blind to the results of the initial assessment and usually scheduled to coincide with the first post-partum obstetric visit of each subject. N=123 Chang et al (2000) As above. N=123
Comparator	Women received a comprehensive alcohol assessment only. N=127
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The comprehensive assessment was administered by a research assistant over the course of 2 hours and consisted of: (1) the alcohol and drug abuse modules from the Structured Clinical Interview for DSM-III-R (2) the Addiction Severity Index (ASI) (3) the Alcohol Use Disorders Identification Test (AUDIT) (4) the Short Michigan Alcoholism Screening Test (SMAST); (5) the Timeline Follow back interview for the quantity and frequency of alcohol consumption for the 90 days immediately before study assessment (6) the Alcohol Craving Scale, a visual analogue scale to measure the desire to drink at the moment and in the past week (7) the Global Assessment of Functioning (GAF) and (8) the Situational Confidence Questionnaire, a measure of the subject's confidence in managing drinking situations. Subjects were asked to report any alcohol consumed, even sips, when completing the Timeline Follow back interview. In this study, alcohol consumption was quantified by drinks per drinking day, since few pregnant women drink daily. Drinking episodes, defined with each episode beginning with a drinking day and ending with 7 consecutive days of abstinence, were also calculated. At the follow-up interview subjects completed the Addiction Severity Index, Timeline Follow back interview for the quantity and frequency of alcohol consumption since assessment, Situational Confidence Questionnaire, Alcohol Craving Scale and Collateral Report of antepartum drinking. **Evaluation of infant outcomes:** The birth weight and APGAR scores of infants born to the women in the study were collected.

Data analyses & statistics	Chang *et al* 1999 Data were analysed using univariate and multivariate techniques to compare the intervention and control groups at before and after study enrolment. Group means were compared using chi-squared tests of significance and Wilcoxon rank sum tests for subject data before and after randomisation. Survival analysis was used to evaluate antepartum alcohol consumption, because it is designed for longitudinal data on the occurrence of events and it allows for censoring and time-varying explanatory variables, which other methods such as logistic regression ignore (Allison, 1995). The semi parametric Cox proportional hazards regression was used to model the relative risk of antepartum drinking after the intervention or control. Independent predictor variables included a dichotomous variable reflecting treatment group, current drinking status, prepartum consumption of more than two drinks per drinking day, DSM-III-R life-time alcohol diagnoses, intention to breast feed and cigarette smoking. Influence diagnostics were used to examine outliers, if any, within each model. Chang *et al* 2000 Results are reported as percentages or means with standard deviations. Associations between categorical variables were analysed using the Pearson chi-squared statistic or Fisher's exact test, as appropriate. Associations between continuous variables were analysed using the Pearson product–moment correlation coefficient.
Study quality	Good (A) Probably. Randomisation to treatment was by computer assignment. (B) No. However, follow-up assessment was conducted by a second research assistant blind to results of the initial assessment. (C) Mostly. There were a few differences including (i) the proportion of women having > 2 drinks per day pre-pregnancy which was higher in the control group (32% vs 46%) and (ii) mean number of drinks in women who were not abstainers which was also higher in the control group (1.5 vs 2.1). (D) Yes. All randomised participants were included in the analyses. (E) Yes. Regression analyses were performed to adjust for potential confounders including drinking variables, smoking status and intention to breast feed. (F) Yes. Examines results for those who were or were not abstinent at study entry and those who did or did not have abstinence as a goal during pregnancy. However, these subgroup analyses do not relate to the assessment of intervention versus control.
Results (within scope of review)	Chang *et al* 1999 Decrease in drinking between the time of assessment and delivery in intervention vs control group (drinks per drinking day) • 0.4 vs 0.3 Number of antepartum drinking episodes in intervention vs control group • 0.7 vs 1.0 Proportional hazards regression analysis did not show that the brief intervention was contributory to the relative risk of prenatal drinking (RR=0.80, p=0.33). Any drinking while pregnant prior to study entry was identified as a predictor variable (RR=2.96, p=0.0001). Proportion of subjects who were abstinent at the pre-assessment who maintained their abstinence during pregnancy in intervention vs control group • 86% vs 72% (p=0.04) Drinking episodes in abstinent pre-assessment subjects who had early study entry in intervention vs control group • 0.3 vs 0.6 (p=0.02) In women who drank pre-assessment, there was no difference between the intervention and control groups in the change in drinks per day or drinking episodes over the duration of the study. Overall, women who drank pre-assessment had an average decrease of 1.2 drinks per drinking day, 49% were abstinent after assessment and 20% reduced their alcohol consumption. Alcohol consumption increased in 12% of women and 19% made no change.

	Chang *et al* 2000 (intervention group only) Subjects who did not choose abstinence as their antepartum goal were more likely to be currently drinking (p=0.001). 83% of the 30 current drinkers who chose abstinence reduced their subsequent prenatal alcohol use (p=0.002). The 15 current drinkers who cited awareness of fetal alcohol effects and syndrome as a reason to modify prenatal alcohol use drank less after the brief intervention (p=0.001). The number of risks, number of reasons, and Beck Depression Index scores were not related to antepartum alcohol consumption (p=NS). Those who were initially abstinent and stated that there were no risk situations for antepartum alcohol consumption were less likely to drink (p=0.027).
Authors conclusions	Chang *et al* 1999 Both the intervention and control groups demonstrated declines in antepartum alcohol consumption after assessment, and only 17% reported an increase in their drinking in the period following assessment until delivery. The single-session BI might have been more effective if compared to a more cursory alcohol assessment. After all, a 2-hour alcohol assessment is considered by some as the first step in alcohol treatment.
Reviewers notes	Chang *et al* 1999 describes the RCT. Chang *et al* 2000 provides more information on the women randomised to receive the brief intervention. The authors discuss the potential problems associated with self-reported alcohol consumption. Subjects were asked to identify a collateral reporter who was asked about their health habits at the time of assessment and post-partum follow-up. This provided independent verification of alcohol consumption. Multiple screening tools were used to evaluate alcohol consumption.
Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (brief intervention) on the rates of alcohol consumption during pregnancy. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS: RCT=RANDOMISED CLINICAL TRIAL, RR=RELATIVE RISK

[A] THE QUALITY OF RCTS WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS ALLOCATION TO TREATMENT GROUPS CONCEALED FROM THOSE RESPONSIBLE FOR RECRUITING SUBJECTS?; (B) WAS THE STUDY DOUBLE-BLINDED; (C) WERE PATIENT CHARACTERISTICS AND DEMOGRAPHICS SIMILAR BETWEEN TREATMENT ARMS AT BASELINE; (D) WERE ALL RANDOMISED PATIENTS INCLUDED IN THE ANALYSIS?; (E) WERE THE STATISTICAL METHODS APPROPRIATE?; (F) WERE ANY SUBGROUP ANALYSES CARRIED OUT?

Citation	Belizán *et al* 1995
Level of evidence	Level II (Intervention)
Country	Argentina, Brazil, Cuba and Mexico
Research question/aims	To evaluate the effect of home visits during pregnancy on behaviour and utilisation of health resources
Study type/design	Randomised controlled trial
Patient group	Pregnant women attending prenatal care between January 1989 and March 1991 at one of four hospitals. Women must have met one of the following inclusion criteria (1) previous low-birth-weight or preterm infants; (2) previous fetal, neonatal, or infant death; (3) ≤17 years old; (4) body weight ≤50 kg and height ≤1.50 m; (5) low family income defined by locally adapted cut-off points; (6) < 3 years of schooling; (7) smoking or heavy alcohol consumption; and (8) single, separated, divorced, or widowed. N=2,230
Intervention	Home visits. The intervention aimed to reduce stress and anxiety, inadequate health-related behaviour, untimely or null recognition of pregnancy- and labour-related morbidity and at increasing health services utilisation. Four home visits occurred at 22, 26, 30, and 34 weeks of gestation, with two more optional visits to conducted if needed (as determined by the woman and the study staff). Home visits were planned to last between 1 and 2 hours. Each visit, although flexible, was based on the standardised manual of operations used during the home visitor's training course. The content of the manual and the proposed activities were prepared by use of information obtained from special ethnographic studies conducted in each site before the initiation of the study. The first part of the visit was devoted to encouraging the pregnant woman and her support person to discuss the pregnancy situation, changes, worries, and doubts. By using this information as background, the home visitor adapted the predefined themes, focusing the program on information that could be relevant to each woman. The home visitor discussed the developed strategy with the study supervisor after the first visit, and the final plan of the intervention for that woman, was developed. Changes were made, if needed, during subsequent visits. A special patient support office that did not require a previous appointment, with a hot line, was located at the hospitals only for patients in the intervention group. Education was provided during the home visit; this included education about nutrition, relevance and schedule of prenatal care, recognition of alarm signs, opportunity of hospital attendance, and suggestions about reducing smoking and alcohol or drug use. Educational activities conducted during the home visit were reinforced with a poster simulating a path for a healthy pregnancy and a booklet provided during the first home visit. The intervention group was provided with the routine antenatal care available at each of the participating institutions. N=1,115
Comparator	The control group was provided with the routine antenatal care available at each of the participating institutions. N=1,120
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described. Interviewers unaware of the characteristics of the study met women during the 36th week of gestation, 40 days postpartum and in the hospital immediately after delivery.
Data analyses & statistics	Analyses were conducted comparing the intervention and control groups with a chi-square analysis or t test where appropriate (two-tailed).

Study quality[a]	Fair (A) No. Group assignment was only known to the person responsible for recruitment, the study supervisor and the home visitor. Randomisation was stratified by centre, with block randomisation of 20 women. (B) No. However, personnel who conducted the follow-up interviews were unaware of the characteristics of the study. (C) Yes. The authors state that the women had similar demographic, obstetric and psychological characteristics at baseline. . (D) No. 90% of intervention and 91% of control subjects were included in the analysis. There is a discrepancy in the paper; one section states 1115 subjects were randomised to the intervention group and other states that 1110 women were randomised. (E) The sample size was considered sufficient to show a difference in intrauterine growth retardation. Analyses conducted using chi-square or t-tests. (F) No.
Results (within scope of review)	Proportion of women who drank alcohol daily at the time of study entry vs 36 weeks of gestation • Intervention: 20.4% vs 19.1% • Control: 17.6% vs 21.8%
Authors conclusions	An intervention of psychosocial support and health education during pregnancy failed to show any benefit on perinatal outcome, health-related behaviour *[including reduction in alcohol use]* or utilization of health facilities.
Reviewers notes	Only one of the inclusion criteria related to alcohol use so some women may have consumed no alcohol or low levels of alcohol during pregnancy. The authors did not discuss the potential problems associated with self-reported alcohol consumption. It is unclear what information was given about drinking during pregnancy. The study does not quantify alcohol consumption and it is therefore difficult to determine the clinical relevance of the outcome 'daily drinking'. It may be that some women drank significant amounts of alcohol each day, and as a result of the intervention reduced their drinking to one drink per day. This would be a meaningful clinical outcome but would not be detected by the analyses reported in the publication.
Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (home visits) on the rates of alcohol consumption during pregnancy. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS:

[A] THE QUALITY OF RCTS WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS ALLOCATION TO TREATMENT GROUPS CONCEALED FROM THOSE RESPONSIBLE FOR RECRUITING SUBJECTS?; (B) WAS THE STUDY DOUBLE-BLINDED; (C) WERE PATIENT CHARACTERISTICS AND DEMOGRAPHICS SIMILAR BETWEEN TREATMENT ARMS AT BASELINE; (D) WERE ALL RANDOMISED PATIENTS INCLUDED IN THE ANALYSIS?; (E) WERE THE STATISTICAL METHODS APPROPRIATE?; (F) WERE ANY SUBGROUP ANALYSES CARRIED OUT?

Level III-2 studies

Citation	Whiteside-Mansell *et al* 1998
Level of evidence	Level III-2 (Intervention)
Country	United States (Arkansas)
Research question/aims	To evaluate the effect of an alcohol and drug prevention and treatment program on alcohol and drug use in pregnant women
Study type/design	Non-randomised, experimental trial
Patient group	Pregnant women referred to the alcohol and drug treatment prevention program over a 5 year period (dates not specified). There were no specific inclusion criteria, however it is assumed that all women were abusing drugs and/or alcohol at the time of study entry. N=95
Intervention	Alcohol and drug prevention and treatment program. The intervention is not clearly defined for the subjects included in the study (i.e., pregnant women). The overall program initially offered (to pregnant women and mothers and their children) was a 4-5 hours per day, 5 days per week as an outpatient. By the 5th year the program was a 7-8 hour per day, 5 days per week, onsite residential support program. As much as possible, the program 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 of choice regarding recovery issues for pregnant and parenting women and focusing on issues ranging from communication skills to the 12-step recovery program. As the program developed a number of additional services were provided, including residential facilities, mental health counselling, child care, early intervention for children, and transportation. N=72 pregnant women who were invited or required to use the service and elected to use the service; N=27 at delivery
Comparator	N=23 pregnant women who were invited or required to use the service but elected not to use the service; N=10 at delivery
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described. Women were interviewed at study intake, the delivery of the target child, 6,12 and 18 months of age.
Data analyses & statistics	Outcome data were examined in independent t-tests between participating and on participating women.
Study quality	<u>Poor</u> (A) No. Women were referred to the program from a number of sources. The inclusion criteria for the women are not clearly defined. The comparison groups were made up of participating and non-participating women. Baseline characteristics suggested the two groups of women were mostly similar but follow-up assessment was made in only a small proportion of these women and no comparison of the characteristics of these women is made. (B) No. No adjustments were made for potential confounders. (C) Possibly not. Women were only enrolled for an average of 13.6 weeks prior to delivery (range 2 -26 weeks). (D) Alcohol consumption was self-reported. The authors state that urine toxicology analyses "appear to support the self-report of women concerning their use of substances". 25/72 participating women had urine toxicology analyses. The study does not examine the degree of reduction in alcohol consumption.
Results (within scope of review)	Proportion of women reporting alcohol use at intake vs delivery • Intervention: 83.6% vs 4.0% • Control: 90.5% vs 33.3% ($p<0.05$ both between intake and delivery in both arms and between intervention and control at delivery)
Authors conclusions	The authors state that the "evaluation suggests that the program had an impact on the substance use of study participants, birth outcomes, and the growth and development of children".

Reviewers notes	The lack of any details regarding the small proportion of women who reported outcomes at delivery (i.e., 36% in participating group and 43% in non-participating group) makes it difficult to draw any conclusions regarding the reductions in alcohol use during the study, and in particular between the two groups; significant selection bias cannot be ruled out. The study reports a number of child outcomes however, these have been assessed in so few children that they cannot be used.
Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (an alcohol and drug prevention and treatment program) on the rates of alcohol consumption during pregnancy. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS:

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Level III-3 studies

Citation	Glor 1987
Level of evidence	III-3 (Intervention)
Country	Saskatchewan, Canada
Research question/aims	To evaluate the effect of a prenatal program on various risk factors and outcomes (including alcohol consumption) in Native Indian women residing in Regina.
Study type/design	Historical control study
Patient group	Pregnant Native Indian women attending a prenatal program between January 1982 and March 1983. There were no specific inclusion criteria, however Native Indian women are considered a high-risk group for prenatal alcohol consumption. N=98
Intervention	Prenatal care. Program content included prenatal education, birth coaching, postnatal counselling and any other assistance the counsellor could reasonably provide.
Comparator	Alcohol consumption rates in an average population (data from the North Battleford Prenatal Nutrition Project) and a high-risk population (data from the Toronto Healthiest Babies Possible nutrition counselling project). The number of patients in each of these two groups was not stated.
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described. **Infant outcomes:** Contact was maintained on 61 births and detailed birth data was available for 32 births. Data collected included maternal weight gain, birth weight, infant mortality rate and % breastfeeding.
Data analyses & statistics	Statistical analyses were done by the binomial, normal approximation to the binomial, Fisher's exact test and t-test.
Study quality	<u>Poor</u> (A) Unlikely. This was not discussed in the publication. The publication does not adequately discuss the differences in the study group and data for the 'average population' and the 'high-risk' group. (B) No. No adjustments were made for potential confounders. (C) Possibly. While the length of time was sufficient for the alcohol and infant outcomes, outcomes were not available for all infants. (D) No. Alcohol consumption was self-reported. The authors do not discuss measurement or misclassification bias. The study does not examine the degree of reduction in alcohol consumption.
Results (within scope of review)	Alcohol use in the study group vs the average population vs a high-risk population • 19% vs 63% vs 15%
Authors conclusions	The low level of alcohol and drug consumption may have been due to the impact of the program. Similar results in the two high-risk groups suggest success for both programs in the area of alcohol consumption; they may also reflect low income.
Reviewers notes	The authors do not clearly state what information was obtained from the 'average population' and 'high-risk population'. The questions used to evaluate alcohol consumption in these three groups were not discussed and it is unclear if it is appropriate to compared data across these groups. As the authors note, differences in alcohol consumption may be a result of other factors such as low income in the study and high-risk groups. The authors did not discuss the potential problems associated with self-reported alcohol consumption. The paper did not clearly describe what occurred during the intervention and it is unclear what information was given about drinking during pregnancy, and how this information was delivered. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. The authors do not state when the outcome 'alcohol use' was assessed, it could have been at the beginning, middle or end of the intervention.

Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (prenatal care) on the rates of alcohol consumption during pregnancy. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS:

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Level IV studies

Citation	Grant and Ernst 2003 and Grant *et al* 2005
Level of evidence	Level IV (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a home visitation program on preventing alcohol and drug exposed births
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Women enrolled in a Parent-Child Assistance Program. Women were eligible for the program if they were pregnant or postpartum and reported heavy alcohol or illicit drug use during pregnancy (≥ 5 alcoholic drinks/occasion ≥once/month and/or use of any illicit substance ≥once/week during pregnancy). Women were identified through hospital postpartum screening at urban hospitals and community providers (e.g. social workers, public health nurses). Every third woman recruited in the original Seattle program was allocated to the control arm (Note: the data from the control arm was not included in this publication).
Intervention	Home visitation program The Parent-Child Assistance Program was a three year home visitation program. The primary aim of the intervention was to prevent future alcohol and drug exposed births among high-risk mothers who have already delivered at least one exposed child. Case managers assisted women in obtaining alcohol and drug treatment and staying in recovery, and linked them with comprehensive community resources. They worked individually with families, helped mothers identify personal goals and steps necessary to achieve them, and monitor progress. They facilitated integrated service delivery among providers, offer regular home visitation, transport clients and children to important appointments and worked actively within the context of the extended family.
Comparator	Substance abuse during a pregnancy prior to enrolling in the program.
Outcome definitions and measurements	<u>Grant and Ernst 2003</u> Evaluation of alcohol consumption: Self-reported. Alcohol consumption was evaluated using a 1-hour face-to-face structured interview which included items on demographics, quantity, frequency, and pattern of alcohol and drug use prior to and during pregnancy, problems associated with alcohol and drug use, family history of substance abuse problems, use of family planning and community services during pregnancy. Specialized interview techniques were used to increase the accuracy of self-report, including calendars and reminders of special events. The second interview was at exit from the program, using a structured face-to-face interview instrument modified after the enrolment interview and asking about the 3-year time period from enrolment to exit. The third interview was at post-program follow-up approximately 1.6 to 3.6 years (mean 2.5 years) after subjects had completed the intervention, using a 15-minute scripted telephone interview modified after the 3-year exit interview. Length of post-program follow-up time varied among participants because original enrolment took place over an 18-month period, program exits therefore took place over 18-months, and the follow-up study took place over a 10-month period. Women were interviewed post-program as they were located, and no effort was made to locate women in the order in which they had originally been enrolled. <u>Grant *et al* 2005</u> Evaluation of alcohol consumption: Self-reported. Subjects in the initial Seattle program and the first 50 subjects in the Seattle replication program and Tacoma were interviewed using a 50 minute structured interview. Women recruited after 1996 (n=84) were interviewed using the Addiction Severity Index (ASI), At three year exit, subjects in the initial Seattle program were interviewed by structured interview. At the Seattle replication site and Tacoma subjects were interviewed using the ASI.

Data analyses & statistics	Grant and Ernst 2003 *t* -Tests and chi-square tests were used to compare enrolment and exit characteristics between two independent groups (subjects interviewed versus those not interviewed on follow-up) when variables were measured on continuous or categorical scales respectively. McNemar Test for Correlated Proportions compared outcomes at enrolment versus exit, and at exit versus follow-up, including the 45 clients interviewed at all three points. Chi-square test examined the relationship between length of time to follow-up sample divided into triads based on time since program exit. Grant *et al* 2005 The study used pre-test/post-test comparisons across the three sites. Enrolment and exist characteristics between the two groups were compared using a t test or chi-square. The end point summary variables were compared across the three sites using three-group analysis of covariance adjusting for the baseline variable to test for differences.
Study quality	Poor (A) Unlikely. Women were referred to the program from a variety of sources. (B) No. No adjustments were made for potential confounders. (C) No. 5/65 (8%) of women were lost to follow-up from the original Seattle site and 73/229 (32%) were lost to follow-up or did not completed all interviews at the replication Seattle and Tacoma sites. All of these women were excluded from the analysis. (D) Unclear. Alcohol consumption was self-reported. The authors do not discuss measurement or misclassification bias. The study does not examine the degree of reduction in alcohol consumption. Outcome assessment did involve use of techniques to try to help improve accuracy of self reporting.
Results (within scope of review)	Grant and Ernst 2003 Children unexposed to alcohol or drugs at exit from program vs follow-up 0% vs 67% Grant *et al* 2005 Proportion who reported alcohol abuse during index pregnancy vs Proportion of women who had given birth during the program who had an alcohol exposed pregnancy. • Original Seattle site: 78% vs 82% • Seattle replication site: 63% vs 68% • Tacoma site: 78% vs 60%
Authors conclusions	Grant and Ernst 2003 “At postpartum follow-up we observed a significant increase in abstinence from alcohol and drugs for 6 months or more, and significant decreases in subsequent pregnancies and deliveries.” Grant *et al* 2005 “Outcomes at replication sites were maintained (for regular use of contraception and use of a reliable method; and number of subsequent deliveries), or improved (for alcohol/drug treatment completed; alcohol/drug abstinence; subsequent delivery unexposed to alcohol/drugs).”

Reviewers notes	Both publications The authors discussed the potential problems associated with self-reported alcohol consumption. The outcome reported is 'alcohol exposed pregnancy'. This does not quantify the alcohol consumption during this pregnancy and could presumably mean that women drank a single unit of alcohol on a single occasion. The clinical relevance of this outcome is unclear. Subjects in the treatment arm were connected to a range of community services. It is likely that the range of services accessed by women in the treatment arm varied, and this may have influence the results. Grant and Ernst 2003 The publication reports the change in alcohol consumption at enrolment, at exit from the program and at follow-up. However this is reported for the entire cohort, not for pregnant women alone. Grant *et al* 2005 The authors discussed the potential problems associated with self-reported alcohol consumption. The program provided detailed instruction manuals and intensive training sessions to interviewers. The authors note that the program may not affect the same degree of change among mothers whose baseline profile is not as severe. There are a number of significant confounding factors that may have influenced the results in this study. As noted by the authors, the Washington State Government instituted a number of programs (including an almost three fold increase in the number of dedicated inpatient residential treatment beds for pregnant and postpartum women, which may have increased the effectiveness of the Parent-Child Assistance Program. Although the three programs were relatively well matched at baseline, there were some significant differences in outcomes. These are not clearly explained by the authors. The publication reports the proportion of pregnancies during the program that were unaffected by alcohol/drugs. It may be that the number of pregnancies unaffected by alcohol alone was less than the reported figures.
Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (home visitation program) on the rates of alcohol affected pregnancies and contraception use. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS:

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Corrarino *et al* 2000
Level of evidence	Level IV (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a program to link substance abusing pregnant women to drug treatment services
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Substance abusing pregnant women who were not currently in a treatment program. Women were eligible for the study if they abused alcohol or illicit drugs (substance abuse was self-reported) N=10
Intervention	Intervention: A program to link substance abusing pregnant women to drug treatment services. The Perinatal Outreach Project included the following elements that were designed to maximise the chances of a healthy newborn and assist the woman in entering substance abuse treatment: (1) Assignment of a primary public health nurse who was responsible for a small caseload that included women who were eligible for the project; (2) A flexible home visit plan that allowed for more frequent visiting as needed; (3) Health education at each contact concerning pregnancy-related preventive health care, such as nutrition and signs and symptoms of preterm labour and actions to take if any of these occur; (4) The services of a substance abuse counsellor. The counsellor was available as a consultant to the nurse and for home visits (alone or jointly with the nurse) to assess substance abuse patterns and develop strategies to help the woman enter treatment. The ASI was administered during the counsellor's second home visit and every 3 months thereafter to assess the severity of the woman's addiction; (5) Follow-up at each contact of needs identified by the woman, nurse, or substance abuse counsellor. (6) Referral to community and social services as needed; (7) The availability of a medical social worker for social needs; (8) Referral to substance abuse treatment when the woman was ready and agreed to this part of the plan and (9) Monthly meeting of an interdisciplinary team.
Comparator	Alcohol consumption prior to the program
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. Addiction Severity Index (ASI) was used to evaluate alcohol consumption. Participants completed the ASI at the time of enrolment and 6 months after entry into the study.
Data analyses & statistics	None reported
Study quality	<u>Poor</u> (A) This was not discussed in the publication. (B) No adjustments were made for potential confounders. (C) One woman did not complete the ASI questionnaire and was not included in the analysis. (D) No. Alcohol consumption was self-reported. The authors do not discuss measurement or misclassification bias. The study does not examine the degree of reduction in alcohol consumption.
Results (within scope of review)	ASI alcohol severity score • At study entry: none 0%, slight 0%, moderate 11%, considerable 44%, extreme 44% • After intervention: none 22%, slight 22%, moderate 22%, considerable 22%, extreme 11%
Authors conclusions	After the intervention, there was a marked improvement in all three subscales of the ASI. The study was limited by the nonexperimental design and small sample size. Because pregnancy is known to be a factor that can motivate women to enter drug treatment, it is unknown whether these women would have entered treatment without outreach services and home visiting. Of the participants *(n* = 10), 9 entered treatment for their substance abuse problem. This contrasts with data from other programs that indicate a success rate of approximately 10% when only a referral was made to treatment programs.
Reviewers notes	The authors did not discuss the potential problems associated with self-reported alcohol consumption. It is unclear what information was given about drinking during pregnancy, and how this information was delivered. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome.

Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (a program to link substance abusing pregnant women to drug treatment services) on the rates of alcohol consumption during pregnancy. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS: ASI=ADDICTION SEVERITY INDEX

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Halmesmaki 1988
Level of evidence	Level IV (Intervention)
Country	Finland
Research question/aims	To evaluate the effect counselling on alcohol consumption during pregnancy
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Pregnant women attending an outpatient clinic between 1983 and 1986. All women abused alcohol. N=85
Intervention	Counselling. Women were counselled at 2-4 week intervals about the effects of alcohol and cigarettes upon the fetus. They were encouraged to abstain totally, of if that was impossible, to decrease their drinking as much as possible. Consultations with social workers and psychiatrists were freely available.
Comparator	Alcohol consumption at entry to the program.
Outcome definitions and measurements	**Evaluation of alcohol consumption:** Self-reported. The questions used to evaluate alcohol consumption were not described. Women were classified as follows: Alcoholics: Consumed up to 10-20 drinks daily and had several alcohol-related social problems. (N=29) Heavy drinkers: 1-10 drinks daily, but relatively normal social lives in terms of family and employment. (N=30) Moderate drinkers: Consumed alcohol only during weekends, but then up to 10 drinks at a time. (N=26) **Fetal alcohol effects:** The criteria for fetal alcohol effects (FAE) were the presence of at least one of the following characteristics: growth retardation (low birth weight, short length and small head circumference; all below the normal 10th percentile at birth or below the mean -2SD at follow-up visit), distinctive facial features (low nasal bridge and short upturned nose, short palpebral fissures, indistinct philtrum, thin upper lip) or neurological aberrations and/or developmental delays. The criteria for FAS were fulfilled if they infant showed growth retardation, distinctive facial features, neurological aberrations and/or developmental delay. Infants were examined at 5 days and 4, 6 and 12 months of age.
Data analyses & statistics	The significance of the difference in the mean values and percentages were tested by analysis of variance and binomial test, respectively.
Study quality	<u>Fair</u> (A) This was not discussed in the publication. (B) No. No adjustments were made for potential confounders. (C) Yes. All women were included in the final analysis. (D) No. Alcohol consumption was self-reported. The authors do not discuss measurement or misclassification bias. The study does not examine the degree of reduction in alcohol consumption.

Results (within scope of review)	Proportion of subjects who had no change in alcohol consumption vs reduced their alcohol consumption • Alcoholics: 45% vs 55% • Heavy drinkers: 43% vs 57% • Moderate drinkers: 15% vs 85% Proportion of women who reduced their drinking who booked between 12 and 20 weeks of gestation vs those who booked later • 94% vs 54% (p<0.0005) None of the women who booked after 32 weeks could reduce their drinking (N=10). Proportion of infants with FAS and FAE • Alcoholics who had no change in consumption: 62% FAS and 38% FAE • Alcoholics who reduced consumption: 31% FAS and 63% FAE • Heavy drinkers who had no change in consumption: 38% FAS and 46% FAE • Heavy drinkers who reduced consumption: 12% FAS and 0% FAE • Moderate drinkers who had no change in consumption: 0% FAS and 0% FAE • Moderate drinkers who reduced consumption: 0% FAS and 5% FAE Proportion of infants with FAS born to women who had no change in consumption vs women who reduced drinking • 48% vs 16% Proportion of infants with FAE born to women who had no change in consumption vs women who reduced drinking • 41% vs 24%
Authors conclusions	"In the present study, 65% succeeded in reducing their drinking, apparently as a result of information and/or psychological support received during repeated counselling sessions. This conclusion is supported by the fact that the longer patients took part in counselling, the more effective it was. However, the possibility that patients who registered early were more likely to reduce their drinking even without counselling can not be excluded. " The rate of FAS and FAE were significantly reduced among the women who decreased their drinking. Alcohol abusers are seldom responsive to health education spread by mass media and pregnancy women are no exception to this rule. For ethical reasons all alcohol abusers must be given the same counselling and treatment and it was impossible to form a non-counselled control group.
Reviewers notes	The authors did not discuss the potential problems associated with self-reported alcohol consumption. The paper did not clearly describe what occurred during the intervention and it is unclear what information was given about drinking during pregnancy, and how this information was delivered. The study does not quantify the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. The sample size is small and it is therefore difficult to evaluate the different effect on alcoholics, heavy drinkers and moderate drinkers. The authors provide a detailed description of the classification used to diagnose children with FAS and FAE.
Relevance to study question	This study aims to evaluate the effect of a tertiary prevention strategy (counselling) on the rates of alcohol consumption during pregnancy. **Therefore, it is relevant to the question of tertiary prevention.**

ABBREVIATIONS:

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Citation	Rosett *et al* 1980 and Rosett *et al* 1983
Level of evidence	Level IV (Intervention)
Country	United States
Research question/aims	To evaluate the effect of a counselling and prenatal care on alcohol consumption during pregnancy
Study type/design	Case series with pre-test/post-test outcomes
Patient group	Rosett 1980 Pregnant women attending prenatal care at a Boston Hospital between 1974 and 1977. N=69 Rosett 1983 Pregnant problem drinkers who attended at least three counselling sessions at a Boston Hospital as part of a prenatal care program between 1974 and 1979. N=49 Both publications Women reported heavy drinking, defined as at least 45 drinks per month, with at least 5 drinks on some occasions.
Intervention	Both publications Counselling and prenatal care. Subjects who reported drinking heavily participated in individual counselling sessions conducted in the Prenatal Clinic at the time of their routine visits. The first counselling session included a diagnostic interview and an assessment of drinking history. Women were advised that they would have a better chance of having a healthy baby if they stopped drinking. During the session the alcoholic content of beer, wine and whisky were defined. Women were advised that substitution of one beverage for another did not constitute reduction. Myths that beer or wine is not as harmful as whiskey were dispelled. Abstinence was the goal of therapy and when achieved, the achievement was praised. When a woman reported that she had continued or resumed drinking, she was again told of the potential benefits of abstinence. Criticism and provocation of guilt were avoided, particularly among patients who ceased drinking heavily but had the occasional drink. Information was also given about diet, smoking, use of drugs and general prenatal care. The frequency of counselling sessions varied with the schedule of routine visits, increasing from every 3 weeks to weekly as the pregnancy progressed. When indicated, supplementary appointments were scheduled. Women who had previous success with Alcoholics Anonymous or other community groups were encouraged to re-establish these relationships. Women were referred to social workers and alcoholism counsellors at the hospital. Women were encouraged to meet with the project psychiatrist during their next prenatal clinic appointment, who employed an unstructured interview format to independently evaluate drinking patterns and other behaviour. Follow-up sessions averaged half an hour and occurred between 1 and 4 times a month.
Comparator	Both publications Alcohol consumption at entry to the program.

Outcome definitions and measurements	Rosett 1980 **Evaluation of alcohol consumption:** Self-reported. Consumption of beer, wine and liquor was evaluated separately and combined into Cahalan's Volume-Variability Index. Absolute alcohol consumption was calculated by Jessors method. Heavy drinking: At least 5 or 6 drinks on some occasions and at least 45 drinks per month. Moderate drinking: A range of quantities varying from once a month to daily, but never meeting the criteria for heavy drinking. Rare drinking: not drinking at all or consuming alcohol less than once a month and never having 5 or 6 drinks on any one occasion. **Newborn outcomes:** Weight, length and head circumference Rosett 1983 **Evaluation of alcohol consumption:** Self-reported. Drinking histories included separate questions on the frequency, quantity and variability of the use of wine, beer and liquor. Responses were standardised so that a 'drink' represented the volume of a beverage containing 15mL of absolute alcohol. Those who abstained or decreased their alcohol consumption below the defined level for 'heavy' drinking before the third trimester were considered 'reduced' drinkers. Both publications The decision as to whether a patient had abstained, moderated or continued heavy drinking was based on the evaluation of the psychiatrist and the counsellor as well as on observations by the Prenatal Clinic staff. Since denial of drinking is common, when there were discrepancies between reported reduction in alcohol use and clinical observations suggesting continued heavy use, the patient was judged to have continued heavy drinking. All decisions about the changes in drinking patterns during pregnancy were made without knowledge of pregnancy outcome.
Data analyses & statistics	Rosett 1980 Not reported. Rosett 1983 Chi-squared tests were used to assess differences between women who sustained heavy drinking and those who reduced their drinking.
Study quality	Poor (A) No. In Rosett *et al* 1980, 85 women reported heavy drinking. 69 (81%) delivered a child and were included in the study analyses. In Rosett *et al* 1983 162 women reported heavy drinking, however 49 (30%) enrolled in the study. (B) No adjustments were made for potential confounders. (C) Yes. All enrolled women were followed until delivery and included in the analysis. (D) Possibly. Alcohol consumption was self-reported. The authors note that when there were discrepancies between self-reported consumption and observations of heavy drinking by clinic staff, it was assumed that women were heavy drinkers.

Results (within scope of review)	Rosett 1980 Proportion of women who abstained or had a significant reduction of alcohol consumption prior to their third trimester which was sustained throughout delivery • 36% (22% abstained totally, 7% had an occasional drink but never more than 2, 6% had 4 or more drinks on several occasions but did not consume more than 45 drinks a month). Women who did not change their alcohol consumption had more previous live births and had registered for care later in their pregnancies ($p<0.005$) when compared with women who reduced their alcohol consumption. Percentage of infants ≤ 10^{th} percentile for weight • Group who reduced alcohol consumption – 8% • Group who did not reduce alcohol consumption – 45% Percentage of infants ≤ 10^{th} percentile for length • Group who reduced alcohol consumption – 4% • Group who did not reduce alcohol consumption – 20% Percentage of infants ≤ 10^{th} percentile for head circumference • Group who reduced alcohol consumption – 4% • Group who did not reduce alcohol consumption – 27% Rosett 1983 Proportion of heavy drinkers who abstained or markedly reduced alcohol consumption before the third trimester • 67% (39% were abstinent and 28% reduced their consumption) Differences between women who reduced alcohol consumption and those who didn't • Younger ($p<0.05$) and nulliparous ($p<0.05$)
Authors conclusions	Rosett 1980 Alcohol ingestion in everyday life cannot be directly measured or monitored and usually varies greatly over time. Some women deny the extent of their drinking while others cannot remember. Data on reduction of drinking were obtained within the counselling relationship. It is recognised that women who wish to please may exaggerate their reports of moderation, however had this occurred, statistical relationship would have been weakened. The associations appear in spite of this possibility. Rosett 1983 Two thirds of the women who participated in three or more counselling sessions reduced their drinking. Frequency and quantity of alcohol did not predict therapeutic success. A three-phase classification of problem drinking was useful in designing treatment strategies: social problem drinking, symptom problem drinking and alcohol dependence (alcoholism). Since most of the women are young and in their early stages of alcohol abuse, they do not view themselves as alcoholics. They respond more readily to therapy integrated with routine care than to referrals to specialised alcohol centres.

Reviewers notes	Rosett 1980 It is unclear how many women met with the project psychiatrist as part of the intervention. Rosett 1983 There are a number of confounding factors, including the fact that women were referred to alcoholism counsellors and encouraged to join programs such as Alcoholics Anonymous. It is unclear how these programs may have influenced the results. The publication briefly describes 111 women who did not meet the inclusion criteria for the intervention (reasons included receiving care at another location, scheduling conflicts, the pregnancy was aborted and registration during the third trimester). Although the women were not enrolled in the study, the publications states that they were told that they had a better chance of having a healthy baby if they stopped drinking. A total of 13 women (11.7%) reported reduced drinking. It is unclear if this data was collected on all 111 women. The data was not included in the analysis and discussion and these women are not presented as a control group. Both publications It is unclear how many women in the cohort presented in Rosett *et al* 1980 are included in the cohort reported in Rosett *et al* 1983. As the women were recruited over a similar time period (1974-1977 and 1974-1979 from the same prenatal clinic) it is likely that there is a significant degree of overlap, however this is not discussed in either publication. Both publications discuss the potential problems associated with self-reported alcohol consumption. Both publications provide a detailed description of the intervention and the information given to the women. Neither study quantifies the reduction in alcohol consumption and it is therefore difficult to determine the clinical relevance of this outcome. Women who reduced their alcohol consumption and were no longer classified as heavy drinkers (>45 drinks per month) may still have been consuming significant amounts of alcohol.
Relevance to study question	These studies aim to evaluate the effect of a tertiary prevention strategy (counselling and prenatal care) on the rates of alcohol consumption during pregnancy.

ABBREVIATIONS:

THE QUALITY OF OTHER STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) HAS SELECTION BIAS BEEN MINIMISED?; (B) HAVE ADEQUATE ADJUSTMENTS BEEN MADE FOR RESIDUAL CONFOUNDING?; (C) WAS FOLLOW-UP FOR FINAL OUTCOMES ADEQUATE?; (D) HAS MEASUREMENT OR MISCLASSIFICATION BIAS BEEN MINIMISED?

Prenatal screening original studies

Citation	Sokol 1989
Level of evidence	Level III-2 (Diagnosis)
Country	United States
Research question/aims	To develop a brief questionnaire appropriate for detection of risk drinking
Study type/design	A study of test accuracy with an imperfect reference standard
Patient group	Consecutive African American women attending their first prenatal visit who reported any alcohol consumption in their lifetime N=971
Intervention	T-ACE CAGE MAST
Reference standard	Self-reported consumption of ≥1 ounces of absolute alcohol/day (determined by interview)
Outcome definitions and measurements	Alcohol consumption was self-reported. The screening tools were evaluated using the following measures: Sensitivity, specificity, PPV and efficiency. Heavy drinking was defined as ≥1 ounces of absolute alcohol/day. This was determined by obtaining a 1-week recall of average drinking around the time of conception. Screening also obtained a recent 2-week drinking history by beverage source. The interviewers were trained in eliciting alcohol history and consumption information.
Data analyses & statistics	The four CAGE questions (C=cut down, A=annoyed, G=guilt and E=eye opener) and the tolerance question were included in a stepwise linear discriminant analysis. A logistic regression was used to obtain fitted probabilities and odds ratios for risk-drinking for each of the four items, both as singular questions and in combination. Based on these results, the T-ACE tool was developed. The T-ACE, MAST and CAGE were evaluated using different cut-points and 'heavy drinking' as the reference standard.
Study quality	Fair (A) Yes. Patients were recruited consecutively. (B) Yes. All women completed all screening tests and the interview used to determine the reference standard. (C) No. The reference standard was imperfect as it was based on self-reported alcohol consumption. The same assessors evaluated the reference standard and the screening tools. (D) Not applicable. All evaluations were performed at the same time.

Results (within scope of review)	The strongest predictor of risk drinking was the tolerance item (OD 8.5). The guilt item did not significantly improve prediction of risk drinking (F to remove <1.00). Therefore the four items found to be predictive of risk drinking (T, A, C and E) were included in a new screening tool (the T-ACE). A logistic regression was used to develop a scoring system. As the tolerance item had significantly more predictive value (OR 8.5) than the other three items (OR from 1.8 to 3.5), a positive response to the T item was allocated 2 points, with a positive score to the other three items given one point. The screening tools were then compared to the reference standard in order to compare their performance and determine an appropriate cut-point for a positive T-ACE • T-ACE at a cut-point of ≥1, ≥2, ≥3 Predicted to be risk drinkers: 23, 13, 4 Sensitivity: 76, 69, 38 Specificity: 79, 89, 97 PPV: 14, 23, 40 • CAGE at a cut-point of ≥1, ≥2 Predicted to be risk drinkers:20, 9 Sensitivity: 59, 38 Specificity: 82, 92 PPV: 13, 18 • MAST at a cut-point of ≥1, ≥5 Predicted to be risk drinkers 26, 5 Sensitivity: 76, 36 Specificity: 76, 96 PPV: 13, 29
Authors conclusions	The current study demonstrates that in terms of brevity, the T-ACE is superior to both the MAST and CAGE in identifying risk-drinking behaviour. It achieves considerably higher sensitivity. The reason appears related to the inclusion of the tolerance item. Women who unconsciously or deliberately seek to minimise the extent of their drinking will be less apt to perceive the tolerance item as an indication of drinking and thus be more apt to answer the tolerance item honestly. Further studies are required to evaluate the predictive validity of the T-ACE. The results must be interpreted cautiously. All patients were African American and attended an inner-city clinic. This limits generalisablity. The use of ≥1 ounce of absolute alcohol per day is a conservative definition of high-risk drinking. The study does not evaluate drinking patterns.
Reviewers notes	This publication used an imperfect reference standard (self-reported alcohol consumption). However, it is still informative to compare different screening tools against the same imperfect reference standard. Comparisons should not be made between different publications. The authors selected a cut-point of ≥2 for the T-ACE a priori. They implied that this cut-point was the most appropriate after it was compared to the reference standard, however this was not explicitly stated. The authors do not discuss the limitations associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the T-ACE, MAST and CAGE. **This study provides results relevant to questions regarding prenatal screening.**

ABBREVIATIONS: OR=ODDS RATIO

THE QUALITY OF SCREENING STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WERE PATIENTS SELECTED CONSECUTIVELY?; (B) IS THE DECISION TO PERFORM THE REFERENCE STANDARD INDEPENDENT OF THE TEST RESULTS?; (C) WAS THERE A VALID REFERENCE STANDARD? ARE THE TEST AND REFERENCE STANDARD MEASURED INDEPENDENTLY ; (D) HAS CONFOUNDING BEEN AVOIDED? IF THE REFERENCE STANDARD IS A LATER EVENT THAT THE TEST AIMS TO PREDICT, IS ANY INTERVENTION DECISION BLIND TO THE RESULT?

Citation	Russell 1994
Level of evidence	Level III-2 (Diagnosis)
Country	United States
Research question/aims	To determine the efficacy of alcohol screening questionnaires
Study type/design	A study of test accuracy with an imperfect reference standard
Patient group	Consecutive pregnant African American women who reported any alcohol consumption in their lifetime N=4,743
Intervention	TWEAK T-ACE MAST CAGE NET
Reference standard	Self-reported consumption of ≥1 ounces of absolute alcohol/day (determined by Timeline Follow Back method)
Outcome definitions and measurements	Alcohol consumption was self-reported. The screening tools were evaluated using the following measures: Sensitivity, specificity, PPV, efficiency, follow-up rate, ROC curve The TWEAK, T-ACE and NET were not administered as separate screening tools. Subjects were asked the tolerance item from the T-ACE separately, all other items were embedded in the MAST or CAGE. All questions were administered by trained interviewers. Risk drinking was defined as ≥1 ounces of absolute alcohol/day.
Data analyses & statistics	The screening tools were evaluated using different cut-points and 'risk drinking' as the reference standard. ROCs for the screening questionnaires were investigated. The cut-point at which a ROC curves comes closest to the upper left corner of the graph indicates the point at which sensitivity is optimised with respect to specificity. All screening tools were evaluated using a cut-point of 1, 2 and 3.
Study quality	Fair (A) Yes. Patients were recruited consecutively. (B) Yes. All women completed all screening tests and the Timeline Follow Back method to determine the reference standard. (C) No. The reference standard was imperfect as it was based on self-reported alcohol consumption. The same assessors evaluated the reference standard and the screening tools. (D) Not applicable. All evaluations were performed at the same time.

Results (within scope of review)	The ROC curves of the five screening tools were similar. Sensitivity increased rapidly as cut-points decrease, with a relatively small decrease in specificity. The largest area under the ROC curve was for the TWEAK, although this was closely followed by the T-ACE and MAST. The NET and CAGE performed less well. The optimal combination of sensitivity and specificity was a cut-point of 2 for the TWEAK and T-ACE. • T-ACE at cut-point of ≥1, ≥2, ≥3 Sensitivity: 83, 70, 45 Specificity: 75, 85, 97 PPV:17, 22, 46 • TWEAK at cut-point of ≥1, ≥2, ≥3 Sensitivity: 87, 79, 59 Specificity: 72, 83, 94 PPV: 16, 22, 39 • MAST at cut-point of ≥1, ≥2, ≥3 Sensitivity: 80, 69, 61 Specificity: 75, 85, 92 PPV: 16, 21, 32 • CAGE at cut-point of ≥1, ≥2, ≥3 Sensitivity: 68, 49, 30 Specificity: 86, 87, 98 PPV: 23, 22, 52 • NET at cut-point of ≥1, ≥2, ≥3 Sensitivity: 71, 61, 24 Specificity: 86, 87, 99 PPV: 23, 22, 58
Authors conclusions	This study validated the utility of T-ACE in screening for risk drinking during pregnancy. The TWEAK compared favourably to the T-ACE across a range of potential cut-points. The importance of the tolerance item was confirmed by the fact that the T-ace performed almost as well as the TWEAK and substantially better than the CAGE. Although MAST performed reasonably well in the present study, the most compelling argument against using MAST is that it is too long and difficult to score. Dramatic differences in the performance of all the questionnaires were associated with changes in their cut-points, illustrating the need to consider cut-point, as well as the questionnaire, when selecting a screening method. The merits of self vs interviewer administered questionnaires are worth further research. A critical question is whether administering the TWEAK, T-ACE and NET independently would change results, rather than derive them from items embedded in the MAST and CAGE.
Reviewers notes	This publication used an imperfect reference standard (self-reported alcohol consumption). However, it is still informative to compare different screening tools against the same imperfect reference standard. Comparisons should not be made between different publications. The authors discuss the limitations associated with self-reported alcohol consumption. The authors discuss the potential confounding influence of using embedded items rather than administering each questionnaire separately.
Relevance to study question	This study aims to evaluate the T-ACE, TWEAK, MAST, NET and CAGE. **This study provides results relevant to questions regarding prenatal screening.**

ABBREVIATIONS:

THE QUALITY OF SCREENING STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WERE PATIENTS SELECTED CONSECUTIVELY?; (B) IS THE DECISION TO PERFORM THE REFERENCE STANDARD INDEPENDENT OF THE TEST RESULTS?; (C) WAS THERE A VALID REFERENCE STANDARD? ARE THE TEST AND REFERENCE STANDARD MEASURED INDEPENDENTLY ; (D) HAS CONFOUNDING BEEN AVOIDED? IF THE REFERENCE STANDARD IS A LATER EVENT THAT THE TEST AIMS TO PREDICT, IS ANY INTERVENTION DECISION BLIND TO THE RESULT?

Citation	Russell 1996
Level of evidence	Level III-2 (Diagnosis)
Country	United States
Research question/aims	To investigate the efficacy of the TWEAK and T-ACE
Study type/design	A study of test accuracy with an imperfect reference standard
Patient group	Pregnant African American women who reported any alcohol consumption in their lifetime N=2,717 A separate cohort of pregnant African American women who reported any alcohol consumption in their lifetime of women received the T-ACE only N=1,420
Intervention	TWEAK T-ACE MAST CAGE
Reference standard	Self-reported consumption of ≥1 ounces of absolute alcohol/day (determined by Timeline Follow Back method)
Outcome definitions and measurements	Alcohol consumption was self-reported. The screening tools were evaluated using the following measures: Sensitivity, specificity, PPV, efficiency, ROC curve The TWEAK, T-ACE and NET were not administered as separate screening tools for the first 2,717 subjects. Subjects were asked the tolerance item from the T-ACE separately, all other items were embedded in the MAST or CAGE. All questionnaires were administered by trained interviewers. The second set of 1,420 subjects were administered the T-ACE alone. Risk drinking was defined as ≥1 ounces of absolute alcohol/day.
Data analyses & statistics	The screening tools were evaluated using different cut-points and 'risk drinking' as the reference standard. ROC curves were generated and the area under the curve calculated using the method of Hanley and McNeil.
Study quality	<u>Fair</u> (A) Possibly. The screening tools were administered to women on their first prenatal visit, however it was not clearly stated if recruitment was consecutive. (B) Yes. All women completed all screening tests and the interview used to determine the reference standard. (C) No. The reference standard was imperfect as it was based on self-reported alcohol consumption. The same assessors evaluated the reference standard and the screening tools. (D) Not applicable. All evaluations were performed at the same time.
Results (within scope of review)	All four instruments were effective in distinguishing risk drinkers from non-risk drinkers. The area under the curve was similar for the TWEAK and T-ACE, both of which were significantly larger than those for the MAST and NET. A cut-point of 2 was most appropriate for the T-ACE and TWEAK • TWEAK at cut-point of ≥1, ≥2, ≥3 Sensitivity: 92, 91, 67 Specificity: 67, 77, 92 PPV:17, 22, 39 • T-ACE at cut-point of ≥1, ≥2, ≥3 Sensitivity: 91, 88, 61 Specificity: 70, 79, 95 PPV: 18, 23, 47

	• MAST at cut-point of ≥1, ≥2, ≥3 Sensitivity: 80, 69, 61 Specificity: 73, 84, 91 PPV: 17, 23, 32 • CAGE at cut-point of ≥1, ≥2, ≥3 Sensitivity: 66, 46, 27 Specificity: 81, 93, 99 PPV: 20, 32, 56 There was no significance difference in the mean age, parity, gravidity, prepregnancy weight, and smoking in the two groups of subjects. However, alcohol consumption was significantly higher in the sample screened with T-ACE alone, 0.4 ± 1.3 oz of absolute alcohol per day compared with 0.2 ± 0.8 oz, and 9.1% of the population reporting risk drinking compared with 6.5%. • TACE alone Sensitivity: 67 Specificity: 86 PPV 33
Authors conclusions	The sensitivity of the T-ACE decreased when it was administered alone rather than as part of an interview that included the MAST and CAGE. Additional research is needed to determine whether the reduction of sensitivity in T-ACE when it is administered alone is reliable, whether the sensitivity of TWEAK is similarly reduced when it is administered alone, and, if so, how MAST and CAGE may condition patients' responses to the TWEAK and T-ACE screening items. One limitation to studies of this nature is that an objective measure of alcohol intake that could serve as a "gold standard" is lacking. Despite an intensive search for a reliable, valid biomedical marker, there is consensus that well designed self-report measures provide the best available method of determining alcohol intake. A number of procedures to enhance the validity of self-reported data were employed in the present study. Interviewers were trained to ask about alcohol use in a sensitive manner. It was emphasized to respondents that the time frame for questions on alcohol consumption was prior to pregnancy, to avoid any stigma attached to admitting large alcohol intakes during pregnancy.
Reviewers notes	This publication used an imperfect reference standard (self-reported alcohol consumption). However, it is still informative to compare different screening tools against the same imperfect reference standard. Comparisons should not be made between different publications. The authors do not adequately discuss the implications of the T-ACE alone group and the T-ACE embedded group having significantly different alcohol consumption at baseline. They do not clearly state which cut-point was used to assess the T-ACE alone, although it is presumably 2. The publication clearly discusses the importance of finding an optimal sensitivity and specificity, as well as the importance of selecting an appropriate cut-point. It also discusses the relationship between PPV and prevalence. The authors discuss the limitations associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the T-ACE, TWEAK, MAST and CAGE. **This study provides results relevant to questions regarding prenatal screening.**

ABBREVIATIONS:

THE QUALITY OF SCREENING STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WERE PATIENTS SELECTED CONSECUTIVELY?; (B) IS THE DECISION TO PERFORM THE REFERENCE STANDARD INDEPENDENT OF THE TEST RESULTS?; (C) WAS THERE A VALID REFERENCE STANDARD? ARE THE TEST AND REFERENCE STANDARD MEASURED INDEPENDENTLY ; (D) HAS CONFOUNDING BEEN AVOIDED? IF THE REFERENCE STANDARD IS A LATER EVENT THAT THE TEST AIMS TO PREDICT, IS ANY INTERVENTION DECISION BLIND TO THE RESULT?

Citation	Chang 1998
Level of evidence	Level III-2 (Diagnosis)
Country	United States
Research question/aims	To test the effectiveness of the T-ACE
Study type/design	A study of test accuracy with an imperfect reference standard
Patient group	Consecutive pregnant women attending prenatal care N=350 (250 T-ACE positive and 100 T-ACE negative)
Intervention	T-ACE (with two variations: scoring positive to the tolerance item using >2 drinks, or ≥2 drinks) SMAST AUDIT Medical record
Reference standard	DSM-III-R More than two drinks per drinking day (as determined by Timeline Follow Back, AUDIT and response to a health and habits survey) Self-reported consumption of ≥1 ounces of absolute alcohol/day (determined by Timeline Follow Back method).
Outcome definitions and measurements	Alcohol consumption was self-reported. The screening tools were evaluated using the following measures: Sensitivity, specificity, ROC curve Risk drinking was defined as ≥1 ounces of absolute alcohol/day. The T-ACE was considered positive in women scored ≥2.
Data analyses & statistics	Women initiating prenatal care were asked to complete a health and habits survey while waiting for their first appointment. The survey contained the T-ACE, as well as questions about other health habits, such as smoking and diet. The screening tools were evaluated using different cut-points and 'risk drinking', DSM-III-R diagnosis and more than two drinks per drinking day as the reference standards Each subject's computerized and paper medical records were retrieved by two research assistants using a review form. Information about the subject's obstetric history, medical history, and obstetric staff assessment of alcohol and drug use was collected. Inter-observer reliability was assessed by having each research assistant masked to review 40 medical records reviewed by the other. Simple descriptive statistics comparing T-ACE– positive and –negative subjects were calculated. Results are reported as means or percentages. Chi-squared and Wilcoxon rank-sum tests were used to assess differences between subjects. Sensitivity and specificity were calculated for each instrument. ROC curve analysis was used to compare the performance of the alcohol screening tests, the T-ACE, AUDIT and SMAST.
Study quality	Poor (A) Partially. Patients were recruited consecutively, however a consecutive sample of 250 T-ACE positive and 100 T-ACE negative subjects were included in the final cohort. (B) Yes. All women completed all screening tests and the interview used to determine the reference standard. (C) No. The reference standard was imperfect as it was based on self-reported alcohol consumption. The same assessors evaluated the reference standard and the screening tools. (D) Not applicable. All evaluations were performed at the same time.

Results (within scope of review)	The AUDIT performed significantly better than either the T-ACE or the SMAST as a predictor of lifetime alcohol diagnoses based on ROC analysis. The AUDIT also performed significantly better than the T-ACE or the SMAST as a predictor of current drinking. The difference between the predictive abilities of the T-ACE and the SMAST for risk drinking was not statistically significant . • T-ACE with a positive tolerance item at >2 using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 87, 92, 89 Specificity: 37, 37, 38 • T-ACE with a positive tolerance item at ≥2 using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 60, 74, 60 Specificity: 66, 71, 67 • AUDIT with a cut point of ≥11 using DSM-III-R and current alcohol consumption as the reference standard Sensitivity: 7, 3 Specificity: 99, 98 • AUDIT with a cut point of ≥10 using DSM-III-R and current alcohol consumption as the reference standard Sensitivity: 11, 7 Specificity: 99, 97 • AUDIT with a cut point ≥8 using DSM-III-R and current alcohol consumption as the reference standard Sensitivity: 27, 15 Specificity: 97, 94 • SMAST using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 15, 11, 8 Specificity: 98, 96, 94 • Medical record using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 16, 7, 20 Specificity: 94, 90, 96 Even though 96% of subjects were asked by obstetric staff about alcohol consumption, only 33 (9%) women were noted as using alcohol at any time.
Authors conclusions	The T-ACE, with tolerance of two drinks or more, was the most sensitive screen for detecting lifetime alcohol diagnoses (88%), risk drinking (92%), and current drinking (89%), but it was also the least specific. The T-ACE outperformed medical staff assessment of alcohol consumption, even though nearly all women (96%) were asked about drinking when they enrolled in prenatal care. Comparison of the predictive ability of the T-ACE, AUDIT and SMAST using ROC curve analysis reveals that the AUDIT has the best overall accuracy in predicting DSM-III-R lifetime alcohol diagnoses and current drinking, when cut-points are not considered. However, the superior performance of the AUDIT Test must be balanced against the requirements of its administration (asking ten core clinical questions, with responses scored from 0 to 4 and then summing results to achieve a total score ranging from 0 to 40) and, more importantly, the necessity of establishing an appropriate cut-point for the prenatal patient. Current cut-points resulted in unacceptable sensitivity for all three types of drinking in this study.
Reviewers notes	This publication used an imperfect reference standard (self-reported alcohol consumption). However, it is still informative to compare different screening tools against the same imperfect reference standard. Comparisons should not be made between different publications. The authors discuss the limitations of selecting 250 T-ACE positive and 100 T-ACE negative women. The authors discuss the limitations associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the T-ACE, SMAST, AUDIT and medical records. **This study provides results relevant to questions regarding prenatal screening.**

ABBREVIATIONS: ROC=RECEIVED OPERATOR CURVE

THE QUALITY OF SCREENING STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WERE PATIENTS SELECTED CONSECUTIVELY?; (B) IS THE DECISION TO PERFORM THE REFERENCE STANDARD INDEPENDENT OF THE TEST RESULTS?; (C) WAS THERE A VALID REFERENCE STANDARD? ARE THE TEST AND REFERENCE STANDARD MEASURED INDEPENDENTLY ; (D) HAS CONFOUNDING BEEN AVOIDED? IF THE REFERENCE STANDARD IS A LATER EVENT THAT THE TEST AIMS TO PREDICT, IS ANY INTERVENTION DECISION BLIND TO THE RESULT?

Citation	Chang 1999a
Level of evidence	Level III-2 (Diagnosis)
Country	United States
Research question/aims	To determine the accuracy of screening instruments with clinical predictors for identify prenatal alcohol use
Study type/design	A study of test accuracy with an imperfect reference standard
Patient group	Pregnant women attending prenatal care N=350 (250 T-ACE positive and 100 T-ACE negative)
Intervention	T-ACE AUDIT SMAST Clinical predictors T-ACE plus clinical predictors AUDIT plus clinical predictors
Reference standard	Current alcohol consumption (as determined by Timeline Follow Back, AUDIT and response to a health and habits survey)
Outcome definitions and measurements	Alcohol consumption was self-reported. The screening tools were evaluated using the following measures: Sensitivity, specificity, ROC curve Current alcohol consumption was defined as any alcohol consumed while pregnant up to the time of study enrolment. Clinical predictors were defined as 1) alcohol craving in the past week 2) routine obstetric care, 3) over 30 years and 4) early recognition of pregnancy.
Data analyses & statistics	Women initiating prenatal care were asked to complete a health and habits survey while waiting for their first appointment. The survey contained the T-ACE, as well as questions about other health habits, such as smoking and diet. Group means were compared using the Wilcoxon rank-sum test. The independent variable of interest was current alcohol consumption. Three linear logistic regression models were created and assessed in terms of their ability to predict the criterion standard. They were: Model 1, the screening instrument alone (i.e., T-ACE, AUDIT, SMAST); Model 2, select clinical covariates alone; and Model 3, the screening instrument plus the clinical covariates. Selection of clinical covariates for Models 2 and 3 was based on the results of preliminary bivariate analyses. The log likelihood for Model 3, the screening instrument plus the clinical covariates, was compared with the nested screening instrument-only model using the likelihood ratio test. All models were evaluated for clinically plausible interactions among the main effects and for goodness-of-.t using the Hosmer- Lemeshow test. ROC analysis was used to compare the predictive accuracy of each screening instrument alone (Model 1) and with the clinical covariates (Model 3). For each model, relative predictive ability with standard errors (SE) was computed. Areas under the ROC curve for the models were then compared using the nonparametric method of Hanley and McNeil and provided for the correlations required for comparison of ROC curves derived from the same cases. Each model of the screening instrument plus clinical covariates was then validated using the statistical technique known as the bootstrap. In this study, 1,000 replicate samples of 350 subjects were selected using sampling with replacement as a first step in verifying reproducibility of the areas under the ROC curve. Each subject's computerised and paper medical records were retrieved by two research assistants using a review form. Information about the subject's obstetric history, medical history, and obstetric staff assessment of alcohol and drug use was collected. Inter-observer reliability was assessed by having each research assistant masked to review 40 medical records reviewed by the other.

Study quality	Poor (A) Partially. Patients who returned the questionnaire were recruited consecutively, however a consecutive sample of 250 T-ACE positive and 100 T-ACE negative subjects were included in the final cohort. (B) Yes. All women completed all screening tests and the interview used to determine the reference standard. (C) No. The reference standard was imperfect as it was based on self-reported alcohol consumption. The same assessors evaluated the reference standard and the screening tools. (D) Not applicable. All evaluations were performed at the same time.
Results (within scope of review)	The T-ACE and AUDIT alone correctly identified 65 and 70 percent of current prenatal drinkers. The SMAST performed only slightly better than random chance prediction and it was not included in the subsequent model development. Area under the ROC curve • T-ACE: 0.647 • AUDIT: 0.708 • SMAST: 0.518 • Clinical predictors: 0.688 • T-ACE plus clinical predictors: 0.747 • AUDIT plus clinical predictors: 0.752
Authors conclusions	The predictive ability of the screening instruments was enhanced by the addition of clinical covariates. However, only the T-ACE was significantly enhanced. The predictive accuracy of screening instruments for current, antenatal alcohol consumption can be enhanced by the addition of common clinical variables. The T-ACE in particular can be significantly improved when the patient's age, alcohol craving in the past week, and specific obstetric data (routine care and early recognition of pregnancy) are incorporated into screening (p=0.001). The predictive accuracy of the AUDIT, a ten item screening instrument, was not improved with additional clinical information. Notably, only 20% of the 120 pregnant women with current alcohol consumption were documented in the obstetric record as having used any alcohol. This rate is in spite of the questioning of 96% of the subjects by their obstetric providers about alcohol use. Thus, improvement in the identification of prenatal alcohol use is possible.
Reviewers notes	This publication used an imperfect reference standard (self-reported alcohol consumption). However, it is still informative to compare different screening tools against the same imperfect reference standard. Comparisons should not be made between different publications. The authors discuss the limitations of selecting 250 T-ACE positive and 100 T-ACE negative women. The authors do not discuss the limitations associated with self-reported alcohol consumption.
Relevance to study question	This study aims to evaluate the T-ACE, SMAST, AUDIT and clinical predictors. **This study provides results relevant to questions regarding prenatal screening.**

ABBREVIATIONS:

THE QUALITY OF SCREENING STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WERE PATIENTS SELECTED CONSECUTIVELY?; (B) IS THE DECISION TO PERFORM THE REFERENCE STANDARD INDEPENDENT OF THE TEST RESULTS?; (C) WAS THERE A VALID REFERENCE STANDARD? ARE THE TEST AND REFERENCE STANDARD MEASURED INDEPENDENTLY ; (D) HAS CONFOUNDING BEEN AVOIDED? IF THE REFERENCE STANDARD IS A LATER EVENT THAT THE TEST AIMS TO PREDICT, IS ANY INTERVENTION DECISION BLIND TO THE RESULT?

Citation	Chang 1999b
Level of evidence	Level III-2 (Diagnosis)
Country	United States
Research question/aims	To determine efficiency of the TWEAK
Study type/design	A study of test accuracy with an imperfect reference standard
Patient group	Consecutive pregnant women attending prenatal care N=135
Intervention	TWEAK (T1: The first tolerance item was positive if the subject answered two or more) TWEAK (T1: The first tolerance item was positive if the subject answered more than two) TWEAK (T2: The second tolerance item was positive if the subject answered more than 5) Medical records
Reference standard	DSM-III-R alcohol diagnosis More than two drinks per drinking day (as determined by Timeline Follow Back, AUDIT and response to a health and habits survey) Current alcohol consumption (as determined by Timeline Follow Back, AUDIT and response to a health and habits survey)
Outcome definitions and measurements	Alcohol consumption was self-reported. The screening tools were evaluated using the following measures: Sensitivity, specificity, ROC curve The first tolerance item was “how many drinks does it take before you begin to feel the first effects of alcohol? The second tolerance item was ‘how many drinks does it take before the alcohol makes you feel asleep or pass out? Or, if you never drink till you pass out, what is the largest number of drinks you have had?” Risk drinking was defined as more than two drinks per day. Each subject’s computerized and paper medical records were retrieved by two research assistants using a review form. Information about the subject’s obstetric history, medical history, and obstetric staff assessment of alcohol and drug use was collected. Inter-observer reliability was assessed by having each research assistant masked to review 40 medical records reviewed by the other.
Data analyses & statistics	Women initiating prenatal care were asked to complete a health and habits survey while waiting for their first appointment. The survey contained the T-ACE, as well as questions about other health habits, such as smoking and diet. Chi-squared and Wilcoxon rank-sum tests were used to assess differences between subjects. ROC analysis was used to assess the predictive ability of all versions of the TWEAK.
Study quality	Fair (A) Yes. Patients were recruited consecutively. (B) Yes. All women completed all screening tests and the interview used to determine the reference standard. (C) No. The reference standard was imperfect as it was based on self-reported alcohol consumption. The same assessors evaluated the reference standard and the screening tools. (D) Not applicable. All evaluations were performed at the same time.

Results (within scope of review)	• TWEAK (T1≥2) using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 84, 92, 88 Specificity: 25, 30, 56 Predictive ability: 0.653, 0.678, 0.645 • TWEAK (T1>2) using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 59, 71, 55 Specificity: 78, 81, 70 Predictive ability:0.712, 0.787, 0.644 • TWEAK (T2>5) using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 57, 68, 57 Specificity: 71, 74, 66 Predictive ability:0.677, 0.734, 0.644 • Medical records using DSM-III-R, risk drinking and current alcohol consumption as the reference standard Sensitivity: 16, 8, 22 Specificity: 95, 88, 97
Authors conclusions	The T1≥2 version of the TWEAK was the most sensitive but the least specific. The medical record was the least sensitive, but most specific report of alcohol use. The T1>2 version of the TWEAK had the greatest predictive ability for both lifetime DSM-III-R alcohol diagnoses and risk drinking. All three versions of the TWEAK had comparable predictive ability for current alcohol consumption. The T1>2 version of the TWEAK had the best overall predictive ability on the basis of ROC analysis. The sensitivity of the TWEAK can be increased using the T1 question with a cut point set at two drinks, with decreased specificity and some loss of predictive ability. For screening purposes, increased sensitivity may be desirable.
Reviewers notes	This publication used an imperfect reference standard (self-reported alcohol consumption). However, it is still informative to compare different screening tools against the same imperfect reference standard. Comparisons should not be made between different publications. The authors do not discuss the limitations associated with self-reported alcohol consumption. The majority of subjects (96%) had an alcohol assessment documented in their medical records, however only 7% of women with lifetime alcohol diagnoses, 3% of risk drinkers and 8% of current drinkers were correctly identified. This highlights the lack of accurate and effective alcohol assessments currently being performed by clinicians.
Relevance to study question	This study aims to evaluate the TWEAK and medical records. **This study provides results relevant to questions regarding prenatal screening.**

ABBREVIATIONS:

THE QUALITY OF SCREENING STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WERE PATIENTS SELECTED CONSECUTIVELY?; (B) IS THE DECISION TO PERFORM THE REFERENCE STANDARD INDEPENDENT OF THE TEST RESULTS?; (C) WAS THERE A VALID REFERENCE STANDARD? ARE THE TEST AND REFERENCE STANDARD MEASURED INDEPENDENTLY ; (D) HAS CONFOUNDING BEEN AVOIDED? IF THE REFERENCE STANDARD IS A LATER EVENT THAT THE TEST AIMS TO PREDICT, IS ANY INTERVENTION DECISION BLIND TO THE RESULT?

Citation	Dawson 2001
Level of evidence	Level III-2 (Diagnosis)
Country	United States
Research question/aims	To determine the accuracy of the TWEAK and nine alternative screening tools at evaluating high-risk and moderate-risk drinking during pregnancy
Study type/design	A study of test accuracy with an imperfect reference standard
Patient group	Pregnant women who reported any alcohol consumption in their lifetime N=404
Intervention	TWEAK TWEAK + HIGH4 TWEAK + KEPTFROM TWEAK + INJURE TWEAK + ALCTRT TWEAK + PARTNER TWEAK + SMOKER TWEAK + ASSIST TWEAK + UNWANTED TWEAK + ASSALT
Reference standard	Low-risk (no alcohol consumption during pregnancy) Moderate-risk (consumed some alcohol, but an average daily consumption of ≤1 drink and drank 3 or more drinks less than once a month) High-risk (average daily consumption of >1 drink or drank 3+ drinks once a month or more). (all determined by interview)
Outcome definitions and measurements	Alcohol consumption was self-reported. The screening tools were evaluated using the following measures: Sensitivity, specificity, false positives Subjects were asked about their alcohol consumption during the 3 months before they were sure they were pregnant and since they were sure they were pregnant. For both periods they were asked overall frequency of drinking, usual number of drinks, typical drink size, largest number of drinks, and frequency of consuming the largest quantity for beer, wine, coolers, and liquor. In addition, they were asked how frequently they drank 3+ drinks of all types of alcohol combined. The standard TWEAK items was calculated with the tolerance item (can hold 5+ drinks) and worry item contributing 2 points each and the other elements contributing 1 point each, summing to a possible 7 points. The T-ACE item on number of drinks to get high was included but was scored positive at a level of 4+ drinks rather than the more usual 2+ or 3+ drinks. The additional items were: HIGH4: how many drinks does it take for you to feel high? (positive if 4+) KEPTFROM: has alcohol kept you from doing something you had to do? INJURE: have you injured yourself or something else as a result of drinking? ALCTRT: have you ever been treated for alcohol problems? PARTNER: do you have a partner with alcohol problems? SMOKER: are you a current smoker? ASSIST: have you been the recipient of public assistance? UNWANTED: have you had an unwanted pregnancy? ASSALT: have you been injured in a fight or assault in the past year?

	The following definitions were used: Low-risk was defined as no drinking at all (N=284). Moderate-risk was defined as some drinking but average daily ethanol intake of >1 drink and drank 3+ drinks less than once a month (N=85). High-risk was defined as an average daily ethanol intake of >1 drink or drank 3+ drinks once a month or more often (N=34).
Data analyses & statistics	Women were interviewed while waiting to be seen by a physician, by using an audio, computer-assisted self-interview that was programmed onto a laptop computer. Respondents completed the interview anonymously by listening to an audio version of the questionnaire at the same time as the questions appeared on the laptop computer screen. Alternative TWEAK screening tools were developed by evaluating the ability of risk indicators to predict both any (i.e., high- or moderate-) risk drinking and high-risk drinking during pregnancy. ORs were estimated to indicate the excess odds of risk drinking among women with positive responses to the risk indicators. Risk indicators were included if they met any of the following criteria: 1. OR of ≥3.0 in predicting any risk drinking during pregnancy 2. OR of ≥2.0 in predicting any risk and correlation of <0.30 with TWEAK 3. OR of ≥5.0 in predicting high-risk drinking during pregnancy 4. OR of ≥4.0 in predicting high-risk and correlation of <0.30 with TWEAK Each risk indicator that satisfied any of these four criteria was combined with the TWEAK. One point was added to the TWEAK score if the additional risk indicator was positive; two points were added if it exhibited an exceptionally high association with risk drinking—an OR of ≥5.0 for any risk drinking or ≥8.0 for high-risk drinking. The resulting range of scores for the alternative screeners was from 0 to 8 in most cases and from 0 to 9 in the remainder. Three scoring alternatives were evaluated: Cut-point option 1: 0 (low-risk), 1 (moderate-risk), 2+ (high-risk) Cut-point option 2: 0–1 (low-risk), 2 (moderate-risk), 3+ (high-risk) Cut-point option 3: 0 (low-risk), 1–2 (moderate-risk), 3+ (high-risk)
Study quality	<u>Poor</u> (A) No. Patients were not recruited consecutively. The 404 included subjects were drawn from a sample of 507 women who presented for a prenatal visit. The publication did not state how these 404 subjects were selected. (B) Yes. All women completed all screening tests and the interview used to determine the reference standard. (C) No. The reference standard was imperfect as it was based on self-reported alcohol consumption. The same assessors evaluated the reference standard and the screening tools. (D) Not applicable. All evaluations were performed at the same time.

Results (within scope of review)	The sensitivity for the TWEAK and nine alternative screeners was evaluated for high-risk, moderate-risk and any risk. The specificity was calculated for high-risk and any risk. The false positive rate for moderate-risk subjects was also evaluated. All of these evaluations were calculated for the 10 screening tools. Please refer to the original publication for these values. The TWEAK demonstrated a sensitivity of 70.6% in predicting high-risk drinking during pregnancy when we used the standard cutoff of 2+ points for high-risk drinking. It was less sensitive when a score of 1+ points to predict any risk drinking (65.6%) or moderate-risk drinking (57.6%). Specificity for the TWEAK was 73.2% with respect to high-risk drinking and 63.7% with respect to any risk drinking. Of the false positives for any risk drinking, 40.2% were estimated as being at moderate as opposed to high-risk. Relative to the basic TWEAK, alternative screeners based on the first scoring option (0, 1, and 2+ points) generally showed an increase in sensitivity at the cost of reduced specificity, but few of the differences were statistically significant. Adding ASSIST or UNWANTED significantly increased the sensitivity for moderate-risk drinking to 71.8% and 74.1%, respectively. The addition of SMOKER significantly decreased specificity for high-risk drinking (59.3%), and SMOKER, ASSIST, and UNWANTED all reduced the specificity of the TWEAK in predicting any risk drinking (52.7%, 50.2%, and 48.4%). Use of the second scoring option (0–1, 2, 3+) resulted in significant increases in specificity at the cost of consistent but nonsignificant reductions in sensitivity. This held true for high-risk, moderate-risk, and any risk drinking across eight of the nine alternative screening instruments. The use of the third scoring option (0, 1–2, 3+) tended to have the same effect, but only the parameters for high-risk drinking were affected. The third scoring option also significantly increased the proportion of false positives classified as moderate-risk, a benefit in terms of reducing the cost of false positives.
Authors conclusions	The one alternative screening instrument that showed promise for improvement over the basic TWEAK was the TWEAK + SMOKER screener when the second scoring option was used (2+ points for any risk, 3+ points for high-risk). It appeared to increase both specificity and sensitivity for high-risk drinking, although neither of these differences was statistically significant. This was accomplished without any apparent adverse effect on the sensitivity and specificity for any risk or moderate-risk drinking. Using the second scoring option for the TWEAK + SMOKER, an additional 23.7% of lifetime drinkers would be included into the target group for moderate intervention and 7.2% into the target group for intensive intervention; however, 3.7% of lifetime drinkers would be assigned to a lower level of intervention (moderate as opposed to intensive) than if the TWEAK and original TWEAK scoring schemes were used to identify high-risk drinking only. These figures are somewhat lower than in prior studies. The difference is probably influenced by this study's definition of high-risk drinking, which used a somewhat more conservative threshold than many prior studies and which also defined risk drinking in terms of episodic heavy drinking. The consumption of 3+ drinks once a month, sufficient for classification into the high-risk category in this study, may not be highly correlated with alcohol problem indicators that are by their nature more representative of sustained heavy drinking or alcohol dependence than of social drinking or alcohol abuse. In this study we did not find any indicators that significantly improved the TWEAK as a screener for high-risk drinking during pregnancy. A TWEAK score of 1 point is recommended for identifying moderate-risk women, with 2+ points continuing to represent the threshold for high-risk drinking.
Reviewers notes	This publication used an imperfect reference standard (self-reported alcohol consumption). However, it is still informative to compare different screening tools against the same imperfect reference standard. Comparisons should not be made between different publications. The authors discuss the limitations associated with self-reported alcohol consumption. The addition of a smoking item to the standard TWEAK increased sensitivity and specificity for high-risk drinking using an alternative scoring system (although the increase was not significant). The authors discuss the limitations of this study, including its small, nonrepresentative sample and the comparison of multiple screening tools rather than testing specific hypotheses related to any specific screener.
Relevance to study question	This study aims to evaluate the TWEAK and nine variations of the TWEAK. **This study provides results relevant to questions regarding prenatal screening.**

ABBREVIATIONS:

THE QUALITY OF SCREENING STUDIES WAS ASSESSED USING THE FOLLOWING QUESTIONS: (A) WERE PATIENTS SELECTED CONSECUTIVELY?; (B) IS THE DECISION TO PERFORM THE REFERENCE STANDARD INDEPENDENT OF THE TEST RESULTS?; (C) WAS THERE A VALID REFERENCE STANDARD? ARE THE TEST AND REFERENCE STANDARD MEASURED INDEPENDENTLY ; (D) HAS CONFOUNDING BEEN AVOIDED? IF THE REFERENCE STANDARD IS A LATER EVENT THAT THE TEST AIMS TO PREDICT, IS ANY INTERVENTION DECISION BLIND TO THE RESULT?

Management systematic reviews

Citation	Premji 2007
Level of evidence	Level I (Intervention)
Research question/aims	To identify research based interventions for children and youth with FASD
Study type/design	Systematic review
Search strategy	The search included 40 peer-reviewed databases, 23 grey literature databases and the grey literature via internet search engines. The search included databases addressing nursing and medicine as well as education, language and linguistics, physical education, sociology, social work, interdisciplinary, law, northern studies, Canadian studies, disability and rehabilitation, and women's studies (this included MEDLINE and EMBASE). The search was limited to articles published after 1973 as this was the year that the term FAS was developed. The searches were not limited to type of study and included foreign language documents. Search terms were developed after consultation with a group of stakeholders. They were not listed in the publication.
Type of included studies	Randomised controlled trials or quasi experimental studies
Type of intervention	Any FASD a programme, in its broadest sense. Includes early intervention, interventions, strategies, education, medication, etc. The intervention must have targeted an individual with FASD, their caregiver, or their family. The programme did not need to be strictly for an FASD affected individual.
Outcome	All outcomes as defined by the publications were included.
Quality rating	Fair (A) Yes. Clinical question was clearly defined. (B) Yes. The search was extensive and the search strategy was clearly detailed. (C) Yes. The inclusion criteria was appropriate and clearly defined. (D) Partial. A quality assessment was performed, but the results were not included in the publication. (E) Yes. The studies were adequately summarised. (F) Adequate. Data was not pooled due to the difference in study design. (G) Adequate, heterogeneity between the studies was narratively discussed.
Data analyses & statistics	Narrative synthesis including tables of study characteristics and results. The results were not meta-analysed due to the heterogeneity of the identified publications.
Description of included studies	Riley 2003: Study type: Pretest-posttest controlled intervention Population: Primary school children with FAS. Intervention: 5 children attending the intervention school. Cognitive Control Therapy (not described). Two trained therapists administered the Cognitive Control Therapy programme, which consisted of 1-h therapy sessions each week. The duration was 10 months. Control: 5 children attending the control school received no intervention. Outcomes: Neuropsychological tests or intelligence quotient. Teacher rated behaviour scores. Oesterheld 1998: Study type: Randomised, double blind cross over. The duration was 5 days for 3 consecutive weeks. Subjects received no treatment for the 2 days between treatment trials. Population: Naive American children between 5-12 years with FAS, or partial FAS and ADHD. Intervention: 3 daily doses (7:30 AM ,11 AM, and 2 PM) of Methylphenidate (Ritalin) 0.6 mg/kg per dose. Control: Placebo and vitamin C Outcomes: Conners Parent Rating Scale – 48, Conners Teacher Rating Scale – 39, and Barkley Side-Effects Questionnaire completed by teacher and caregiver.

	Snyder 1997: Study type: Quasi experimental, modified placebo controlled, cross-over design. The duration was 3 days. There was a one-day washout period before commencing the study and a 3-day washout prior to cross over. Subjects returned to their regular medication during the 3-day washout. Population: Children between 6-16 years with FAS and ADHD who were taking psychostimulant medications. Intervention: Dosages individualized with each child receiving the previously prescribed dosage by his/her paediatrician. Methylphenidate (Ritalin), pemoline (Cylert) and dextroamphetamine (Dexedrine). Control: Placebo Outcomes: Vigilance task to assess attention, a short form of the Underlining Test to assess impulsivity, and Abbreviated Symptom Questionnaire – Parents to assess hyperactivity.
Results (within scope of review)	Riley 2003: There were no significant differences on neuropsychological tests or intelligence tests after implementation of a Cognitive Control Therapy programme. However, teachers anecdotally reported behavioural improvements following the intervention. Qualitative improvements with a trend towards functionality for children in the intervention group were noted in the therapists, teachers and school reports. Oesterheld 1998: There were significant reductions in hyperactivity, as measured by behavioural checklists, Conners Parent Rating Scale–48 and Conners Teacher Rating Scale–39, were seen when children were administered methylphenidate versus either placebo or vitamin C. No significant differences were found on measures of attention. Snyder 1997: There were significant reductions in hyperactivity when subjects were taking pscyhostimulant medication versus placebo. There was no significant effect of medication on measures of attention (Vigilance Task) or impulsivity (short form of the Underlining Test).
Authors conclusions	Although the intent was to assess the strength of the effect of interventions by undertaking a meta-analysis, this could not be accomplished as the included studies examined different interventions or outcomes. The efficacy of any reviewed interventions for children and youth with a FASD is not scientifically substantiated. This review is severely limited by the lack of scientific rigour of the three studies included and no conclusions can be drawn with regards to effective interventions for children and youth from birth to 18 years who are affected by a FASD. Understandably, there is a dire need to conduct rigorous intervention research in this area. These results indicate that information currently available on the effectiveness of interventions targeted at individuals with a FASD is non-specific, unsystematic, and has not been scrutinized in a scientific manner.
Reviewers notes	The extensive systematic review was identified three publications evaluating management strategies in individuals with FASD. It is difficult to draw conclusions from the publications did to the small sample size (ranging from N=4 to N=12). The publication did not give a specific quality rating, but noted that the systematic review was severely limited by the lack of scientific rigour of the three studies identified. It is therefore difficult to draw conclusions from this varied body of evidence.
Relevance to study question	This study aims to systematically review the evidence relating to FASD management strategies. **This study provides results relevant to questions regarding management.**

ABBREVIATIONS: ADHD=ATTENTION DEFICIT HYPERACTIVITY DISORDER

THE QUALITY OF SYSTEMATIC REVIEWS WERE ASSESSED USING THE FOLLOWING QUESTIONS: (A) WAS A CLINICAL QUESTION CLEARLY DEFINED?; (B) WAS AN ADEQUATE SEARCH STRATEGY USED?; (C) WERE THE INCLUSION CRITERIA APPROPRIATE AND APPLIED IN AN UNBIASED WAY?; (D) WAS A QUALITY ASSESSMENT OF INCLUDED STUDIES UNDERTAKEN?; (E) WERE THE CHARACTERISTICS AND RESULTS OF THE INDIVIDUAL STUDIES APPROPRIATELY SUMMARISED? ; (F) WERE THE METHODS FOR POOLING THE DATA APPROPRIATE? AND (G) WERE SOURCES OF HETEROGENEITY EXPLORED?

Appendix E: Brief Summary of Other Screening Studies

A literature search was conducted in order to identify literature which evaluated an alcohol screening tool in pregnant women. Twelve publications were of poor quality with poorly reported outcomes. These publications were fully appraised as part of the review, however their poor design and quality meant they were of little clinical importance. They have been discussed on page 123, and described in more detail below.

Aros 2006

Pregnant women were interviewed to determine the average daily alcohol consumption. The authors selected ten items and evaluated their ability to correctly identify women who consumed an average of >48g alcohol/day. The items which identified the highest proportion of risk drinkers were 'become tipsy when drinking', 'tipsy when drinking during pregnant' and 'poor relationships'. The authors suggest that these questions could be incorporated into interviews designed to identify risk drinkers. However, these items also incorrectly identified a large proportion of non-risk drinkers (82% of non risk drinkers reported becoming tipsy when drinking). The authors do not discuss the implications of this low specificity.

Bad Heart Bull 1999

A self administered questionnaire was specifically designed for use in Native Indians (a very high-risk population). The questionnaire contained elements of the T-ACE as well as quantity and frequency questions. Compared to an extensive interview and review of the patients' medical records, the questionnaire had a sensitivity of 77% and a specificity of 93%. The authors consider this a useful tool for use in the Native Indian population.

Burd 2006

Maternal risk factors of mothers with FASD children identified through a FASD registry were compared with the maternal risk factors of mothers with children without FASD. Seven items were strongly correlated with a FASD or FAS diagnosis (graduated from high school, unmarried, being in treatment, smoking more than half a packet of cigarettes per day, having four or more children, prenatal alcohol use and having a child in foster care or adopted). An assessment of alcohol exposure was also included in a questionnaire, which had a sensitivity of 87%, a specificity of 78% and an accuracy of 82%. The authors noted that this seven item tool had acceptable performance characteristics.

Chasnoff 2001

Structured interviews were used to collect data on the use of drugs and alcohol during pregnancy. Regression analysis was used to determine the items which best predicted drug and alcohol use. The authors identified three questions: 'Have you ever drunk alcohol?', 'How much alcohol did you drink in the month before pregnancy?' and 'How many cigarettes did you smoke in the month before pregnancy?'. Low-risk women would be classified as those who reported never having used alcohol, average risk would be women a) who had used alcohol in the past, b) who had not smoked ≥3 cigarettes in the month before pregnancy, and c) who had not drunk alcohol in the month before pregnancy. High-risk women would be defined as those a) who have

used alcohol in the past and either b) who have smoked ≥3 cigarettes in the month before pregnancy or c) who have drunk alcohol in the month before pregnancy.

Chasnoff 2007

The 4P's plus is a substance abuse screening tool which asks: 'did your Parents have a problem with alcohol or drugs?', 'does your Partner have a problem with alcohol or drugs?', 'have you ever drunk alcohol' (Past) and 'how many cigarettes and alcohol did you drink in the month before you knew you were 'how many cigarettes and alcohol did you drink in the month before you knew you were Pregnant). Subjects were asked about their consumption of alcohol and range of illicit substances in an interview. The 4P's plus had a sensitivity 87%, specificity of 76%, positive predictive value of 36% and negative predictive value of 97%. It can not be used to detect alcohol consumption alone.

Clark 1999

Two screening tools, a short and long questionnaire, were compared. The short screening approach involved asking subjects to answer yes or no to three questions: 'smoking/drinking', 'drug use' and 'drug addiction/alcoholism' during pregnancy. The longer screening tool included more detailed questions about frequency of cigarette, alcohol and illicit drug use during pregnancy. Compared with the old approach, the new screening protocol increased reporting of smoking/alcohol use from 21% to 72% and reporting of alcoholism/drug abuse from 0% to 6%. The authors do not report alcohol use alone.

Goransson 2005

Pregnant women completed the AUDIT and recalled their alcohol consumption using the Timeline Follow Back method. A comparison group of pregnant women received standard care, which involved midwives asking direct questions about alcohol consumption and recording the results in the medical records. The AUDIT and Timeline Follow Back method identified 17% of women as risk drinkers. In contrast, no women were identified after reviewing their medical records.

Kesmodel and Olsen 2001

Four methods of evaluating alcohol consumption were compared. Pregnant women were asked about their current weekly alcohol intake and their alcohol intake in the week prior to the interview. They were also asked to complete a questionnaire with a single question on their current alcohol intake and keep a two week diary. The mean difference in reported alcohol consumption between the four methods was close to zero. Using an interview to assess current alcohol intake, completing the questionnaire and maintaining a diary were equally as effective. Asking about alcohol intake in the week prior to the interview seemed to be ineffective as three times as many subjects reported abstinence using this method when compared to the other three methods.

Lapham 1991

The authors developed a computer based program which identified high-risk behaviour and provided an educational program. Subjects rated the computer program favourably. Pregnant women were more likely to report alcohol use using a computer program when compared with a paper questionnaire (19% vs 6%).

Midanik 1998

Two modifications to the CAGE were evaluated: an alcohol CAGE which used the same questions but asked women to consider the year before they knew they were pregnant as the timeframe, and a drug CAGE which asked similar questions about drug use. The alcohol CAGE had a sensitivity of 73% and a specificity of 92%. The area under the ROC was 0.82. The authors state that the alcohol CAGE could be used as a screening tool in the prenatal setting.

Waterson and Murray-Lyon 1998

Pregnant women completed quantity/frequency questions, the CAGE and the BMAST. The most effective method of estimating alcohol intake was asking simple quantity/frequency questions and a question about bingeing. The CAGE was more reliable than the BMAST, although the authors concluded that these screening tools were unreliable in populations with a low level of risk drinking.

Waterson and Murray-Lyon 1999

Pregnant women completed quantity/frequency questions, the CAGE and some author defined items (including questions on binge drinking). The CAGE identified 33% of subjects who drank more than 280g of alcohol/week, 20% of those who consumed more than 100g of alcohol/week and 18% of binge drinkers. The authors concluded that the CAGE questions were unreliable and unnecessary in the clinical setting.