Screening and alcohol brief interventions in antenatal care: a realistic evaluation

Lawrence Kweku Doi

Thesis submitted for the degree of Doctor of Philosophy

School of Nursing, Midwifery and Health

University of Stirling

2012

Declaration

I declare that this thesis is entirely my own work and has been submitted only for the degree of PhD in the University of Stirling.

Lawrence Kweku Doi

2012

Acknowledgements

I would like to use this unique opportunity to acknowledge the divine support of the almighty God for seeing me through this PhD journey.

I am extremely grateful to the school of Nursing, Midwifery and Health, University of Stirling for funding this PhD study. My sincere gratitude goes to my supervisors: Dr Ruth Jepson, Dr Helen Cheyne and Professor Sally Wyke. They have supported and encouraged me throughout the course of my PhD, providing me with invaluable advice and comments. Helen - special thanks go to you for your expert advice in the field and your useful links during the data collection phase of this study. Sally - thanks for steering me on the right path whenever I reached crossroads and needed expert opinion. Ruth - what else can I say, 'you have made all the difference between me being here and not being there'. I am eternally grateful!

I am thankful to the consultant midwife, Mrs Sandra Smith at St. John's hospital, Livingston and the three community midwifery team leaders in West Lothian – Mrs Yasmine Akyaempong, Ms Carol Blair and Ms Dianne McNally - who helped me tremendously during the planning and recruitment of participants for this study. I also wish to thank members of the Health Improvements Units, NHS Health Scotland especially Mr George Howie and Miss Sarah Currie for their useful insight into the screening and ABI initiative in Scotland, which further helped to shape my thoughts during the conceptualization of this study. Most importantly, this thesis would not have materialised without the participants who took part in this study. I thank you all for taking the time to share your experiences and opinions with me.

I would also like to give a special acknowledgment to my parents, Mary and Dominic (who does not need to be here to inspire) for being a great source of inspiration in all aspects of my life. Also, thanks to my brother, Ambrose for being a great pillar in the family. Most symbolically, I am indebted to my wife, Anita for her unwavering love, support and encouragements through the ups and downs of this PhD journey. Lastly, but never the least, thanks are also due to my kids, Jason and Zoe for being a great source of motivation in diverse ways.

Abstract

Background: Prenatal alcohol consumption is one of the leading preventable causes of birth defects, including fetal alcohol syndrome and learning disabilities. Although there is strong evidence of the benefits of screening and alcohol brief interventions (ABIs) in reducing hazardous and harmful drinking among the primary care population, evidence of its effectiveness with the antenatal care population is limited. Nevertheless, the Scottish Government is incorporating an alcohol screening and ABI programme as part of the routine antenatal care provided to women in a bid to protect the health and safety of the unborn child and improve subsequent health and developmental outcomes. This research therefore seeks to increase understanding of the factors that are likely to influence the effectiveness of this recently implemented programme. It also aims to explore the extent to which contemporary issues such as change in guidelines regarding alcohol consumption during pregnancy influences perceptions and attitudes, and the possible implications of these on the screening and ABI delivery.

Methods: The study described in this thesis employed a realistic evaluation methodology. Realistic evaluation is a theory-driven approach to investigating social programmes. It is concerned with hypothesising, testing and refining programme theories by exploring the interaction of contexts, mechanisms and outcomes. To identify the relevant screening and ABI programme theories, two separate systematic reviews, a critical review and four face-to-face interviews were undertaken with health policy implementers. The findings were used to construct context, mechanism and outcomes propositions. The propositions were then tested by conducting individual interviews with seventeen pregnant women and fifteen midwives, a further six midwifery team leaders were involved in a focus group discussion. A thematic approach using a hybrid of inductive and deductive coding and theme development informed the qualitative analysis.

Results: In the context of uncertainties regarding the threshold of drinking that causes fetal harm, pregnant women reported that screening assessment helped them to reflect on their drinking behaviour and facilitate behaviour change. For women who drank at hazardous and harmful levels before attending the booking appointment, screening and ABI may be helpful in terms of eliciting behaviour change. However, they may not be very beneficial in terms of reducing harm to the fetus as it has been found that drinking during the first trimester poses the most risk to the fetus.

Training and resources provided to midwives as part of the screening and ABI programme were found to be facilitating mechanisms that midwives indicated improved their skills and confidence. However, most of the midwives had not subsequently employed the motivational interviewing skills required for the ABI delivery, as many of the pregnant women reported that they reduced or abstained from alcohol consumption once pregnancy was confirmed. The outcome noted was that midwives confidence decreased leading to missed opportunities to appropriately deliver the ABI to eligible

women. The small numbers of women being identified for ABI meant midwives rarely delivered the ABI. This negatively influenced midwives attitudes as they then accorded ABI low priority in their workload. Other disenabling mechanisms noted to be hampering the implementation of the screening and ABI initiative included midwives contending with competing priorities at the booking appointments, and the lack of adequate rapport between midwives and pregnant women at the booking appointment to discuss alcohol issues appropriately, leading to women providing socially desirable responses to screening questions.

Conclusions: The findings of this study has generated greater explanations of the working of the screening and ABI programme in antenatal care setting and has provided transferable lessons that can be used by others intending to implement similar programmes in other settings.

Abbreviations

A&E	Accident and Emergency
ABI	Alcohol Brief Intervention
ABV	Alcohol by Volume
ADH	Alcohol Dehydrogenase
ADHD	Attention Deficit Hyperactive Disorders
ALDH	Aldehyde Dehydrogenase
ARBD	Alcohol-Related Birth Defects
ARND	Alcohol-Related Neurodeveoplmental Disorder
BMA	British Medical Association
CASP	Critical Appraisal Skills Programme
CBA	Controlled Before-and-After
CDC	Centre for Disease Control
CDSR	Cochrane Database of Systematic Reviews
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CMO	Context, Mechanism and Outcome
CRD	Centre for Reviews and Dissemination
DARE	Database of Abstracts of Reviews of Effectiveness
FAE	Fetal Alcohol Effect
FAS	Fetal Alcohol Syndrome
FASD	Fetal Alcohol Spectrum Disorder
FG	Focus Group
FRAMES	Feedback, Responsibility, Advice, Menu of options, Empathy, Self-efficacy
HR	Hazard Ratio
GGT	Gamma-glutamyl Transferase
GUS	Growing Up in Scotland
HEAT	Health Improvement, Efficiency, Access and Treatment
IFS	Infant Feeding Survey
IQ	Intelligence Quotient
ISD	Information Service Department
ITS	Interrupted Time Series
IUGR	Intrauterine Growth Restriction
KCND	Keeping Childbirth Natural and Dynamic
LCM	Local Consultant Midwife
MEOS	Microsomal Ethanol-Oxidizing Systems
MI	Motivational Interviewing
MW	Midwife
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence

NOFAS	National Organisation on Fetal Alcohol Syndrome
OR	Odds Ratio
PW	Pregnant Woman
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised Control Trial
SG	Scottish Government
SGA	Small for Gestational Age
SIGN	Scottish Intercollegiate Guidelines Network
SWHMR	Scottish Women-Held Maternity Records
T-ACE	Tolerance, Annoyed, Cut-down, Eye-opener
TWEAK	Tolerance, Worried, Eye-opener, Amnesia, (K) Cut-down
UK	United Kingdom
US	United States of America
WHO	World Health Organisation

Table of Contents

Table of Tables

Table of Figures

Table of Boxes

Table of Appendices

1. 0 Chapter One: introduction and background

1.1 Introduction

The thesis employs the principles of realistic evaluation (Pawson and Tilley, 1997) to examine the recently implemented screening and alcohol brief interventions (ABIs) in Scottish antenatal care setting. This first chapter outlines the overall aims, research questions and the rationale for the thesis. It also sets the background for the thesis. The study design and structure of the thesis are presented in the latter part of this chapter to aid navigation through the remaining chapters.

1.2 Aims of the study

The main aim of this thesis was to increase understanding of the factors that are likely to influence the effectiveness of the recently implemented screening and ABIs in Scottish antenatal care setting. A subsidiary aim was to explore from midwives' and pregnant women's perspectives, perceptions and attitudes to drinking alcohol during pregnancy. The aims were addressed by examining the following research questions:

1. What are the underlying mechanisms influencing the implementation of screening and ABI in antenatal care setting?

2. What are the contextual issues that are likely to enable or disenable the implementation of the screening and ABI initiative in antenatal care setting?

3. What are the expectations, intentions and perceived benefits of the screening and ABI initiative - for policy makers and those responsible for implementation?

4. In what dimensions would contemporary issues, for example recent change in guidelines regarding alcohol consumption during pregnancy, influence perceptions and attitudes to alcohol consumption during pregnancy?

5. What are the practical implications of the study findings for the long-term embedding of the screening and ABI initiative into routine antenatal care?

1.3 Rationale for study

Alcohol use among women remains a significant issue in Scotland. Figures from the Scottish Health Survey showed that in 2009 among the women who drank alcohol, a third exceeded recommended daily limits on their heaviest drinking day, with 17% drinking more than twice the recommended daily limit of two to three units (Scottish Government, 2011). As many women consume alcohol without knowing that they are pregnant (Chang et al., 2005), there is a likelihood of increased alcohol-exposed pregnancies in Scotland. Women generally tend to reduce or abstain from alcohol once pregnancy is confirmed (Suliaman et al., 1988; Plant, 1997; Raymond et al., 2009). Nevertheless, a substantial proportion of women (25%) in Scotland continue to drink whilst aware of their pregnancy (Ford, 2008). Alcohol consumption whilst pregnant is a threat to healthy pregnancy outcomes and is one of the leading preventable causes of birth defects, including fetal alcohol syndrome (FAS) and learning disabilities.

To protect the health and safety of the unborn child and subsequent health and developmental outcomes, screening and ABIs have recently been implemented across Scottish antenatal care setting. However, much of the existing randomised controlled trials of ABIs in antenatal care setting have originated from the US and research evidence of effectiveness of ABIs in this setting is limited. Moreover, there is currently dearth of work in this field regarding the effectiveness of ABIs in routine antenatal care.

In addition, the means by which change will be achieved (mechanisms) that may enhance effectiveness of an intervention under one setting (research settings) may not necessarily be transferable to a different setting (routine practice) (Pawson and Tilley, 1997). Even if they do, they might have differential impacts. For instance, ABI relies on an individual's motivation to change problem behaviour, but factors that may influence motivation may differ across settings or among population groups. Furthermore, while ABI may aim to reduce hazardous and harmful drinking levels to sensible levels (Moyer and Finney, 2005), for example among primary care populations, in antenatal care there are uncertainties regarding the drinking threshold at which fetal damage could occur (Stratton et al., 1996; Mukherjee et al., 2006). Therefore, the Scottish ABI initiative aimed for abstinence from alcohol during pregnancy rather than reduction of alcohol use. The promotion of abstinence, on the other hand, has been argued to discourage drinking behaviour change (Marlatt and Witkiewitz, 2002).

Midwives have been required to assume the responsibility of screening and delivering ABI to pregnant women. However, current knowledge of the factors that influence their involvement in this alcohol intervention activity is limited (Watson et al., 2010).

In addition, drinking patterns or cultures differ between societies (Rodriguez et al., 2009). Societal alcohol norms to some extent, determine how responsive populations are to discuss issues of drinking or to self-report their consumption levels (Chiaffarino et al., 2006). Societal alcohol norms could also influence the provision of alcohol information by midwives to the clients. The dimensions of these differences and their implications on screening and ABI in Scotland are unknown. In the midst of these complex and dynamic contextual issues, plans of policy implementers and the intended outcomes of the intervention could be affected. This thesis therefore utilizes a

methodological approach, which focuses on the impact of contextual issues on the mechanisms of the intervention to produce anticipated outcomes.

1.4 Alcohol consumption

Alcohol is a psychoactive (mind-altering) drug widely used in different societies. Consumption patterns usually differ between the genders. Traditionally, whereas it has been deemed 'unladylike' for women to indulge in heavy drinking, male heavy drinking is celebrated and seen to be an indication of masculinity (Jung, 2010: 314). Although, male drinkers typically out-number female drinkers, medically there have been concerns that women are at higher risk of developing alcohol-related health harms because of their physiological disposition (Shaw, 1980; Thom, 1994).

Women, like men, drink for many reasons. However, a variety of reasons have been suggested to explain the current increasing trend of women's drinking behaviour. For example, it has been argued that the upsurge in feminism in the 1960s pushed women's issues to the fore and changed their position in many societies (Thom, 1994; Jung, 2010). Women now have more freedom to consume alcohol and more opportunities are available for them to enjoy alcoholic drinks (Plant, 1997; Waterson, 2000; Stanerwick et al., 2007). In the current social milieu, women are now able to occupy territories traditionally reserved for male drinking activities without feeling stigmatised. For example, Brooks (2009) noted that in many societies, contemporary young women as compared to their forebears, now have greater freedom to consume alcohol and socialise in bars, pubs and clubs with little social resistance.

Rising alcohol consumption patterns among women have also been attributed to their changing gender roles. For instance, Jung (2010) indicated that the remarkable change

in women's role during the past century from housewives to career women has meant that women now are economically independent but also, have to cope with stressful dual roles. It has been suggested that the pressure this brings compels some women to resort to alcohol consumption (Jung, 2010).

Another area viewed as promoting women's drinking behaviour focuses on the changing trend of alcohol advertising. Advertisers now involve female celebrities to emphasize that alcohol consumption among women is associated with fashion, sexual attractiveness and success. Advertising strategies that target women in this way correlate with increased alcohol sales (Shaw, 1980).

1.5 Epidemiology of alcohol use in women and pregnant women

The prevalence of alcohol consumption and patterns of drinking are usually estimated through population-based surveys. In 2006, the World Health Organisation (WHO) estimated that 56% of adult women in the UK had consumed alcohol in the previous year (WHO, 2011). Recent findings from the Scottish Health Survey showed that in 2009 among the women who indicated that they drank alcohol, 33% drank above recommended daily limit of two to three units in the previous week (Scottish Government, 2011). Combined data for 2008 and 2009 showed that the average weekly alcohol consumption for women was 8.2 units. Of this, the most favoured alcoholic beverages were wine, which comprised of 4.2 units and then spirits, which constituted 2.3 units. Considering specific age groups, women between 16-24 years of age were found to be consuming the highest weekly units of alcohol at 12.1 units (Scottish Government, 2011). Regarding binge drinking, which for women is defined as consumption of six or more units on one occasion (see Box 2.1 for definitions of drinking levels), there appeared to be a slight decline in trend. In 2003, 19% of women

reported binge drinking as compared to 18% in 2008, and 17% in 2009 (Scottish Government, 2011).

Other useful indicators of the prevalence of alcohol consumption in any particular population are the health burdens of diseases or conditions associated with alcohol abuse. Examples of such indicators are alcohol-related mortality rates and alcohol-related harms. For instance, the trend in liver cirrhosis mortality rate from 1950 to 2002 showed that Scotland has had one of the steepest increased mortality rates of the disease in Western Europe (Leon and McCambridge, 2006). The report added that between 1987 and 2002 liver cirrhosis mortality rates in women increased by almost half in the UK, with Scotland recording the highest rise of 46% as compared to England and Wales that recorded 44% increase. These figures, although concerning, are lower than their male counterparts who recorded more than a double-fold increase of 104% within the same period. Alcohol-related mortality rates have also recorded similar patterns between men and women. For instance, alcohol-related mortality rate for females in 2009 was lower (14.4 per 100,000 population) than that of males (30.0 per 100,000 population) (Scottish Government, 2011). However, the proportion of women found to be using alcohol prior to an episode of deliberate self-harm (a risk factor for suicide), which required medical attention in 2006, was slightly higher for females (51%) than males (49%) (Doi, 2006).

Uncertainties surround the prevalence of alcohol consumption in pregnancy due to contested issues about drinking in pregnancy (see the next section on self-report for detailed account). However, across countries it appeared that the reported trend in the rate of alcohol consumption among pregnant women, aged 18-44 years, had not

changed significantly over the years. For example in US, the Centre for Disease Control (CDC) reported rates of alcohol consumption from 1991 to 2005 as ranged between 10.2% and 16.2% among 22,027 pregnant women involved in a population-based survey (CDC, 2009). This report added that among the pregnant women that consumed alcohol, the age group 34 to 44 years were most likely (17.7%) to report any alcohol use (CDC, 2009). Similarly, another US national survey on drug use and health reported that in 2006 and 2007, 11.6% of pregnant women, aged 15 to 44 self-reported to have consumed alcohol in the previous month. Among this group, the average alcohol consumption was reported to be 2.4 standard drinks on the days women drank (US Department of Health and Human Services, 2008). A recent population based survey in Canada estimated that 10.8% of women who had a singleton live birth from 2005 to 2006, consumed alcohol at some point during their pregnancy (Walker et al., 2011). In Europe, a large national survey in Denmark involving 86,752 women reported that 23.9% of pregnant women experienced at least one episode of binge drinking during the first six weeks of pregnancy (Strandberg-Larsen et al., 2008).

Across the UK, the Infant Feeding Survey (IFS) is the primary source of information about mothers drinking behaviour and provides data about prenatal alcohol consumption. Since its inception in 1975, the IFS has been conducted every five years. It is based on a representative sample of mothers selected from birth registers across the UK. The most current survey was conducted in 2010 with the final report expected in the summer of 2012. However, the 2005 survey involving 9,416 participants, found that 54% of mothers reported that they drank alcohol during pregnancy (Bolling et al., 2007). This rate however indicated a slight decline in prevalence from the previous survey in 2000 where 61% of the 9,500 women reported drinking in pregnancy

(Hamlyn et al., 2002). In Scotland, recent analysis of the Growing Up in Scotland (GUS)[1] dataset showed that 25% of pregnant women reported that they had consumed some level of alcohol during pregnancy (Ford, 2008).

1.6 Self-reporting of alcohol consumption

Estimation of prevalence of prenatal alcohol consumption relies mainly on self-report of past and current use because of unavailability of appropriate objective biological markers to detect drinking (Taylor, 1993; Alvik et al., 2006). Biological methods such as breath analyzer, urinalysis and blood test could only detect very recent drinking and may be unable to differentiate between a single or chronic use because of the rapid rate of alcohol metabolism (Littner and Bearer, 2007; Bhuvaneswar et al., 2007). Therefore, in practice the only appropriate way to ascertain drinking habits in pregnancy is by self-report.

1.6.1 Self-report of alcohol use: a contested issue

Self-reports of drinking behaviour are widely acknowledged to produce distorted results (Chang et al., 1998; Bhuvaneswar et al., 2007). One reason that could bias self-report is the inability of many people to estimate correctly the true strength of alcohol. In the UK, this is compounded by the difficulties in converting measures of different alcoholic beverages to standard units (MacAskill et al., 2008). One consequences of this is unintended underreporting of alcohol consumption (Jones et al., 2006; ISD, 2009). However, for many individuals, the extent to which self-reported patterns of alcohol consumption is distorted depend on how people rationalize their drinking behaviour (Jung, 2010). Among pregnant women, the negative social and cultural stigma attached

[1] GUS survey is a longitudinal study launched in 2005 by the Scottish Government to examines the characteristics and behaviour of 8,000 children in Scotland from birth to late adolescence (Scottish Government, 2008).

to prenatal drinking are known to yield underestimation of drinking levels (Bhuvaneswar et al., 2007). Therefore, self-reporting of alcohol use in pregnancy to health professionals could be particularly predisposed to underreporting bias, because of the perceived consequences of such information disclosure, for example fear of disapproval or even in extreme cases, fear of losing custody of the child.

There is an ongoing debate as to whether retrospective self-reports are more prone to underreporting bias than prospective or concurrent self-report. Proponents for the latter often cite that retrospective account is more prone to recall-bias. To augment their assertion, Feunekes et al. (1999) showed in a meta-analysis that prospective design of alcohol data collection yield better estimates than retrospective design. On the other hand, Alvik et al. (2006) compared these two methods of reporting in a Norwegian sample of pregnant women. The authors found that prospective self-report of alcohol consumption is rather more liable to underestimation of fetal alcohol exposure. Moreover, heavy drinkers were more likely to underreport current drinking but reported past drinking accurately. They argued that anxiety about possible risk to the fetus might sway women to reduce their reported quantity of consumptions when asked in order to avoid being blamed in future instances where the resulting infant has birth defects. Whether retrospective or prospective reporting, self-report of alcohol use is a subjective account and to some extent predisposed to inaccuracies.

1.6.2 Screening tools

A number of validated screening tools have been devised to enhance the identification and validity of self-report estimates of alcohol consumption in different population groups. Among pregnant women, screening tools that focus questions on alcohol-related problems rather than direct consumption levels have been shown to elicit high positive predictive values (Ernhart et al., 1988). T-ACE (Tolerance, Annoyed, Cut-

down, Eye-opener) and TWEAK (Tolerance, Worried, Eye-opener, Amnesia, (K) Cut-down) are the two most often recommended screening tools for use among pregnant women because they have high specificity[1] and sensitivity[2] to this population group (Chang et al., 1998; Flynn et al., 2003; Bhuvaneswar et al., 2007).

The T-ACE[3] consists of four questions but is positive with a score of two or more. Each of "A", "C" and "E" questions carry one point but when a pregnant woman reports that more than two standard drinks are required for her to feel "high" she gains two points on the "T" (Chang, 2001). The TWEAK[4] is used to detect risk drinking of twenty-eight grams or more of pure alcohol per day while pregnant. A score of two or more indicates a positive outcome for risk drinking in pregnancy. A woman scores two points each when she answers positive to "T" (thus intake of more than five standard drinks) and "W". Any positive response to the three other elements in the questionnaire yields a point each (Chang, 2001).

1.7 Alcohol measure

In UK, alcohol is measured in 'units' although other countries prefer to use 'standard drinks'. One unit of alcohol is equivalent to half a pint of standard beer (3.5% alcohol by volume (ABV) or a glass of wine (8% ABV) or a single measure of spirits (37.5% ABV) (Alcohol Focus Scotland, 2005). Units of alcohol are usually determined by

[1] Sensitivity of a screen is the probability that a woman who is a risk drinker test positive.

[2] Specificity of a screen is the probability that a woman who is not a risk drinker test negative.

[3] T – ACE [T – How many drinks does it take to make you feel high; A – Have people annoyed you by criticizing your drinking?; C - Have you ever felt you ought to 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?]

[4] TWEAK [T – How many drinks can you hold?; W – Have your close friends or relatives worried or complained about your drinking in the past year?; E – Do you sometimes take a drink in the morning when you get up?; A – Has a friend or family member ever told you about things you said or did while you were drinking that you could not remember?; K – Do you sometimes feel the need to cut down on your drinking?]

multiplying the quantity (volume) of a drink by its strength (% ABV) then dividing by 1000. For instance, wine at 13% ABV in a 125ml glass will have 1.6units. Whereas a unit of alcohol is equivalent to 8 grams or 10ml of absolute alcohol in the UK, this figure is smaller compared to that of other countries (see Table 1.1). Currently, there are no internationally agreed criteria for categorising alcohol (Duffour, 1999).

Table 1.1 Alcohol 'unit' and its equivalent in grams in some selected countries

Country	**Standard Drink/ Unit Size (in grams of ethanol) ie 1unit =**
United Kingdom	8
Netherlands	9.9
Australia, Hungary, Ireland, New Zealand, Poland, Spain	10
Finland	11
Denmark, France, Italy, South Africa	12
Canada	13.6
Portugal, USA	14
Japan	19.75

Source: International Centre for Alcohol Policies (2007)

1.8 Drinking in pregnancy: a brief historical perspective

For women, alcohol consumption has long been involved in the issue of sex and pregnancy. For instance, in the eighteenth and nineteenth centuries, it was known that women used alcohol to reduce vaginismus because of the assumption that it relaxes the vaginal musculature (Plant, 1997). Reports also highlight the use of large quantities of alcohol by women during that period to terminate unwanted pregnancies (Waterson, 2000).

Drinking during pregnancy has also long been connected with adverse fetal outcomes. For instance, in the Bible, an angel advised Samson's mother of an imminent conception but admonished her "not to drink wine, nor strong drink, and eat not any

unclean thing" (Dake, 2001: 473). In ancient Greece, there was legislation to forbid newly married couples from drinking alcohol on their wedding night in order to avoid conceiving deformed children (Plant, 1997). In 1720, it was noted that the removal of laws on distillation of alcohol caused increased availability of cheap wine in Britain (Taylor, 1993). The consequences of this on the fetus caused the College of Physicians to report to the British Parliament in 1726 of the "weak, feeble and distempered" characteristics observed in children whose mothers participated in those drinking episodes (Taylor, 1993: 122). In spite of these historic links between prenatal drinking and adverse fetal outcomes, it was not until 1968 that French researchers, Lemoine and colleagues demonstrated scientifically that alcohol use in pregnancy could produce infants with congenital anomalies (Stratton et al., 1996; Calhoun and Warren, 2007).

1.9 Effects of prenatal alcohol consumption on the fetus

A range of fetal outcomes have been associated with drinking during pregnancy. The current research evidence in relation to this is reviewed in more depth in chapter two. However, it is important to review briefly below one of the most serious teratogenic manifestation of *in-utero* alcohol exposure.

1.9.1 Fetal Alcohol Syndrome

Congenital anomalies in infants associated with prenatal alcohol consumption gained prominence with the identification and coining of the phrase 'Fetal Alcohol Syndrome' (FAS) by American researchers, Jones and his colleagues in 1973. Jones et al. (1973) examined eight cases of children born to mothers of different ethnic backgrounds who had abused alcohol during pregnancy. They found that these infants "have similar patterns of cranio-facial, limb and cardio-vascular defects associated with prenatal-onset growth deficiency and developmental delay" (Jones et al., 1973: 1267). Although, their research lacked the legitimacy to claim causality, because of the

possible role of confounders such as maternal smoking and other drug use, in the manifestation of the outcome, it nevertheless generated remarkable research activities in the field.

Currently, FAS is widely recognised as an incurable, lifelong condition that affects the central nervous system causing growth retardation and facial malformations (CDC, 2002). It is one of the most common causes of nonhereditary learning disability (Stratton et al., 1996). St. Clair (1991) outlined the criteria for FAS diagnosis. Firstly, noting that there is pre- or post birth growth retardation below the tenth percentile for infant age. Secondly, the central nervous system is involved, resulting in symptoms of developmental delay, or intellectual impairment. Finally, there is distinctive facial dysmorphology with at least two of the three signs of microcephaly, microphthalmia and/or shortened palpebral fissures, poorly developed philtrum, thin upper lip or flattening of the maxillary area of the upper lip. Figure 1.1 shows a patient with features of FAS.

It is estimated that FAS prevalence ranges from 0.5 to 3.0 per 1,000 live births in most populations across the globe (Stratton et al., 1996). The Centre for Disease Control estimated prevalence of FAS in the US to be 0.2-1.5 per 1,000 live births (CDC, 2005). In Australia depending on the population subgroup under consideration, rates have been shown to be 0.6-4.7 per 1,000 live births (Harris and Bucens, 2004). Very high rates of 46.4 per 1,000 live births have been reported in South Africa (May et al., 2000).

Figure 1.1 An FAS patient diagnosed at birth and photographed at ages 1, 8 and 18 years

Source: Reprinted with permission from the author, Professor Ann Streissguth (Streissguth, 2007)

The precise burden of FAS in Scotland, and in the UK, is unknown because there is no structured surveillance or recording systems to detect and estimate incidence and prevalence. However, in 2004 rates in Scotland and England were estimated to be 0.21 per 1,000 live births (Mental Health Foundation, 2009). While some of these figures are low in relative terms, the gravity of the condition and its personal and social consequences make it a significant public health concern. Moreover, it has been suggested that variations in case ascertainment are likely to result in misdiagnoses or misclassification of the condition (Little et al., 1990; Taylor, 1993; Stoler and Holmes, 1999) resulting in a hidden population suffering from the condition (Sokol et al., 2003).

1.9.2 Other fetal alcohol terminologies

Recently, a non-diagnostic umbrella term, fetal alcohol spectrum disorder (FASD) has been coined to encompass all disabilities (including FAS) arising from prenatal alcohol

exposure (NOFAS, 2004). Notwithstanding, the other terminologies are still in use. It is estimated that FASD prevalence is about four times higher than FAS (CDC, 2005).

In circumstances where there is evidence that a fetus might have been exposed *in-utero* and has some of signs of FAS but does not meet its full diagnostic criteria, the defect is described as fetal alcohol effect (FAE). Another fetal defect associated with prenatal alcohol consumption is Alcohol-Related Neurodeveoplmental Disorder (ARND). This is a diagnostic classification and it manifests in individuals who were prenatally exposed to alcohol and have central nervous system abnormalities but lack the facial characteristics of FAS or growth deficiency (Stratton et al., 1996). Also, prenatal alcohol exposed individuals who have physical defects such as malfunction of the heart, bone, kidney, vision or hearing system are said to be exhibiting Alcohol-Related Birth Defects (ARBD) (Stratton et al., 1996).

1.10 Mechanism of alcohol metabolism in the body

Metabolic activity of alcohol in a pregnant woman's body to some extent determines the level of exposure to the developing embryo or fetus. After alcohol is ingested, it is absorbed by the gastrointestinal tract. The rate of absorption is however, affected by timing, dosage, pattern of drinking and the nutritional status of an individual (Gemma et al., 2007). Removal of alcohol from the body is achieved by a combination of metabolism, excretion and evaporation. It is estimated that upon ingestion of alcohol, 85% is metabolized in the liver, with the other 15% removed from the body unchanged through the breath, urine and sweat (St. Clair, 1991). Alcohol has a rapid rate of metabolism in the liver, taking approximately an hour per unit in the average human adult (Littner and Bearer, 2007; Bhuvaneswar et al., 2007; Jung, 2010).

According to St. Clair (1991), two pathways are involved in metabolism of alcohol. These are the hydrogenase system, accounting for 80% of the breakdown of ethanol (chemical name for alcohol) and the microsomal ethanol-oxidizing systems (MEOSs). Microsomal enzymes through oxidation of alcohol carry out MEOS. The hydrogenase system employs two enzymes; alcohol dehydrogenase (ADH) and aldehyde dehydrogenase (ALDH) and their role is to breakdown the alcohol molecule and eliminates it from the body.

During the process, ADH first breaks down ethanol in the body into a toxic compound called acetaldehyde. Acetaldehyde exists in the body briefly before it is further broken down by ALDH to acetate (or it derivative, acetic acid) which is a less toxic compound. The body can use the acetic acid for energy (Rutherford, 2007), however the acetate could be broken down further into carbon dioxide and water, which are non-toxic products that can easily be utilized or eliminated by the body. It is important to note that if the rate of consumption exceeds the rate of the liver's capacity to metabolize ethanol, accumulation of alcohol occurs resulting in "intoxicating effects" (Jung, 2010: 116).

1.10.1 Factors affecting prenatal alcohol metabolism

The rate at which alcohol is metabolized determines blood alcohol concentrations (Shankar et al., 2007). Peak blood alcohol level (physiological condition) is widely acknowledged as the main determinant of alcohol teratogenicity[1] in humans (Abel and Hannigan, 1996). However, genetic variations in humans account for 50% of alcohol metabolism and may partly regulate peak blood alcohol levels (Gemma et al., 2007), emphasizing the differential effects of prenatal drinking on fetal outcomes.

[1] Teratogen is an agent that causes malformation of embryo.

1.10.1.1 Physiological factors

Alcohol is freely distributed in the body of a pregnant woman upon consumption. Transportation of alcohol from the mother to the fetus occurs through the placenta, and alcohol level in the mother is in equilibrium with that of the fetus (Shankar et al., 2007). The fetus is thus directly exposed to alcohol when the mother drinks. As compared to the mother, the fetus has less dehydrogenase to metabolize ethanol, as a result alcohol exposure is prolonged and the end-organ effects of alcohol in the fetus may be considerable (Bhuvaneswar et al., 2007).

Several mechanisms by which alcohol affect the fetus have been proposed (Smith, 1997; Shankar et al., 2007; Haggarty et al., 2008). These are mainly based on animal experimentations due to ethical challenges of investigating this in humans. Two pathways are thought to be involved and these could be described as direct and indirect.

The direct mechanism posits that the build up of alcohol in the body of the fetus increases target organ concentration, adversely affecting a specific subset of cells within the embryo. For instance, because the face, limbs, urogenital tract, and the central nervous system all use the same subset of genes to dictate growth and development, increased concentration of a toxicant (ethanol) would disrupt these tissues to some extent (Smith, 1997). It is likely that depending on the trimester of alcohol exposure and thus the organ under development at the time, defects could manifest in the infant as structural or functional (Aronson, 2002).

Indirect effects of prenatal alcohol consumption on the fetus occur when the presence of alcohol reduces the transportation of essential elements such as blood oxygen and fatty acids to the fetus through the placenta (Shankar et al., 2007; Haggarty et al., 2008). For example, the fetus does not have good storage facilities for fatty acids and therefore

relies on the mother for a continuous supply. Any interruption of this supply may have significant functional consequences for brain and retina development (Coletta et al., 2010). In a study to assess the impact of ethanol on fatty acid transport on the human placenta *ex-vivo*, Haggarty et al. (2008) found that after perfusion of the right proportion of the placenta with fatty acids, the presence of 2mg/ml of ethanol significantly reduced the rate of transfer of two important fatty acids (α-linolenic and docosahexaenoic acid). The results suggest that the presence of low concentration of ethanol in the placenta may deny the fetus the benefits of these nutrients for normal brain and retina development.

1.10.1.2 Genetic predisposition

Women tend to have a low body mass and smaller liver size compared to men and so metabolize alcohol more slowly. Moreover, when comparing pregnant women and non-pregnant women, alcohol metabolism is much more suppressed in pregnant women due to elevation of oestrogen levels (Gill, 2000). Oestrogen is a known ADH and ALDH inhibitor, which means, it decreases the rate of alcohol metabolism. In the early stages of pregnancy, the total amount of estrogens in the maternal serum increases by 10-100 times, and in mid to late pregnancy by 100-1000 times compared to that of non-pregnant woman (Niimi, 2008).

Another important genetic variation that accounts for the differential manifestation of teratogenic effects on fetus of maternal alcohol consumption is the variation in enzyme activities. Individual variations in ADH and ALDH enzymes activity means the conversion of alcohol to acetaldehyde or acetaldehyde to acetate occur more quickly in some individuals than in others. An individual who has slow rate of ALDH activity would therefore have elevated acetaldehyde in the body upon consumption of alcohol prolonging exposure to the toxic products. On the other hand, factors that promote

increased rate of metabolism and clearance of alcohol during pregnancy, such as quick activity rate of ALDH can significantly protect the fetus from developing fetal defects, for example, FASD (Shankar et al., 2007).

1.11 Policies and guidelines on alcohol use during pregnancy

Most countries have policies and guidelines that guide alcohol consumption during pregnancy. A number of countries like Canada, France, Netherlands, New Zealand, Spain, Australia and the US advise women to abstain from alcohol while pregnant. Others for example Ireland, Switzerland and the UK focus on encouraging women to avoid high levels of alcohol in pregnancy.

In the US, the Surgeon General states emphatically that women who are pregnant or wish to become pregnant should abstain from alcohol consumption (Office of the Surgeon General, 2005). The Australian Government also recommends, "for women who are pregnant or planning a pregnancy, the safest option is not to drink" (Department of Health and Ageing, 2009). In the UK, the Department of Health advises that "pregnant women should abstain from alcohol but if they wish to drink, this should be limited to not more than one or two units of alcohol once or twice a week" (Department of Health, 2007). This advice is similar to that issued by the Royal College of Obstetricians and Gynaecologists (RCOG) in 2006, which states that "women should avoid drinking excessive amount of alcohol when pregnant but there is no evidence that drinking one or two units once or twice a week is harmful" (RCOG, 2006). The National Institute of Health and Clinical Excellence (NICE) guidelines place emphasis on the importance of women avoiding alcohol in the first trimester. It states, "pregnant women and women planning pregnancy should be advised not to drink alcohol in the first three months of pregnancy because it is associated with adverse outcome and that

binge drinking is particularly harmful to the fetus. However, if they choose to drink they should be advised not to drink more than one or two units once or twice a week" (NICE, 2008). In Scotland, the NHS Health Scotland recommendation states that, "it is best to avoid alcohol completely during pregnancy, as any alcohol you drink while pregnant will reach your baby and may cause harm" (NHS Health Scotland, 2010a: 11). Overall, different countries have different advice regarding alcohol use in pregnancy, which could lead to confusion and uncertainty for women and midwives.

1.12 Policy context

In recent years, there has been keen interest at the health policy level to screen and deliver Alcohol Brief Interventions (ABIs) in a number of clinical settings. In 2003 the Scottish Intercollegiate Guidelines Network (SIGN 74) recommended that screening and ABIs should be delivered to harmful and hazardous drinkers in primary care settings and possibly, in A&E departments and antenatal care settings (SIGN, 2003). Recently, the British Medical Association (BMA) echoed the importance of utilizing the opportunistic nature of the intervention to deliver it to a variety of clinical populations (BMA, 2008). However, in practice, it was rarely offered to patients (Rome et al., 2008) in spite of alcohol-related burden in Scotland continuing to be among one of the highest in Western Europe (Leon and McCambridge, 2006).

These issues led the Scottish Government to establish new health improvement targets for NHS Health Boards. These targets, referred to as HEAT H4 (HEAT - Health Improvement, Efficiency, Access and Treatment) required NHS Health Boards in Scotland to screen and deliver a cumulative total of 149,449 ABIs from April 2008 to March 2011 in the three priority settings of primary care, A&E and antenatal care (McAuley, 2009). The targets were originally designed for a period of three years and

were intended to lay foundation for long-term embedding of screening and ABIs into routine practice across these settings.

1.13 Locating this research within the policy context

At the time of this study, discussions with key policy informants indicated that although the initiative was implemented in good time in primary care and then A&E, implementation in antenatal care settings was delayed because of organisational challenges. However, when the policy was finally implemented in late 2009, among the fourteen Health Boards in Scotland, only three (NHS Lothian, NHS Lanarkshire and NHS Tayside) were known to have fully implemented it. Therefore, it was considered appropriate to recruit participants for this study, from the NHS Lothian health board area, in particular as it has a diverse mix of rural and urban populations.

Midwives are expected to screen and deliver ABI to women in antenatal care in Scotland. They have been required to assume this task because traditionally within the UK, the midwives' role has been to provide care to all women through pregnancy, childbirth and in the postpartum period. Within the UK, almost all women will receive care from a midwife and this means they are considered to be ideally placed to deliver public health information or interventions. Reid (2011) described that the emergence of the NHS in 1948 revolutionised the maternity services by placing emphasis on hospitalisation and medicalisation of childbirth. However, in recent years, there has been a shift from the medicalised model of care towards more midwife-led and women centred care, as well as the introduction of policies, which have aimed to empower women to make informed decisions in their care. For example, a Scottish Government initiative, Keeping Childbirth Natural and Dynamic (KCND) aimed to maximise the

opportunities for normal birth available within maternity services (NHS Health Scotland, 2010b).

1.14 Alcohol Brief Interventions

Alcohol brief interventions are time-limited interventions, lasting for about 10-15 minutes that focus on assessment, advice and strategies to reduce alcohol consumption or change drinking behaviour. According to Chang et al. (2005) components of ABIs should include assessment, personalised feedback about drinking behaviour, goal setting, behaviour modification strategy and minimal follow-up reinforcement visits or ongoing support. The acronym FRAMES (Feedback, Responsibility, Advice, Menu of options, Empathy, Self-efficacy) has been coined to describe the model widely used to deliver ABIs. Alcohol brief interventions often target people with mild to moderate alcohol problems often described as hazardous[1] and harmful[2] drinkers with the aim of reducing their drinking to low levels. ABI however, has been shown to be ineffective for dependent drinkers, and this group may require specialist alcohol treatment services (Moyer and Finney, 2005).

Heather (2004) indicated that brief interventions for alcohol problems exist in two main forms of brief treatment and opportunistic alcohol brief interventions. He explained that brief treatment is offered in specialist treatment centres where alcohol users are actively seeking help for their problem. However, ABI is a public health approach to alcohol problems and is delivered in settings where people have attended for reasons other than alcohol problems but have been identified to be drinking excessively. Due to their

[1] Hazardous drinking refers to drinking consistently over recommended limits, but without alcohol related problems.

[2] Harmful drinking refers to consuming more than recommended limits, at higher levels than hazardous drinking. People drinking at this level exhibit clear evidence of alcohol-related problems but without this having resulted in their seeking treatment.

opportunistic nature, the tenet of brief intervention is motivation. In this regard, the individual may not have recognised that their drinking may be potentially harmful so they need to be motivated to modify their drinking habit. Motivational interviewing technique is therefore the approach often used to deliver ABI.

1.14.1 Motivational Interviewing

Motivational interviewing (MI) is defined as a directive and client-orientated counselling style that promotes intrinsic motivation to change by addressing ambivalence (Miller and Rollnick, 2002). Motivational interviewing is driven by the concept that logically, people have an innate ability to adapt and make appropriate changes to their behaviour. It is often argued that motivation to change is greatly enhanced if the client is equipped with abilities to change problem behaviour rather than being compelled to alter such behaviour (Rollnick and Allison, 2004). Therefore, the role of the counsellor in motivational interviewing is to unleash the potential for change that is embedded within the individual. This is achieved when a collaborative relationship develops between the client and the counsellor during the interviewing process (Woolard et al., 2011).

Miller and Rollnick (2002) identified four principles that underpin motivational interviewing. The first is to express empathy by using reflective listening to appreciate the client's perspective without being judgemental. Further to this, there is the need to develop discrepancy of client's beliefs and how they conflict with the current behaviour. Thirdly, there is the need to roll with resistance by showing understanding rather than being confrontational. Lastly, self-efficacy is supported by enhancing the client's desire to achieve change.

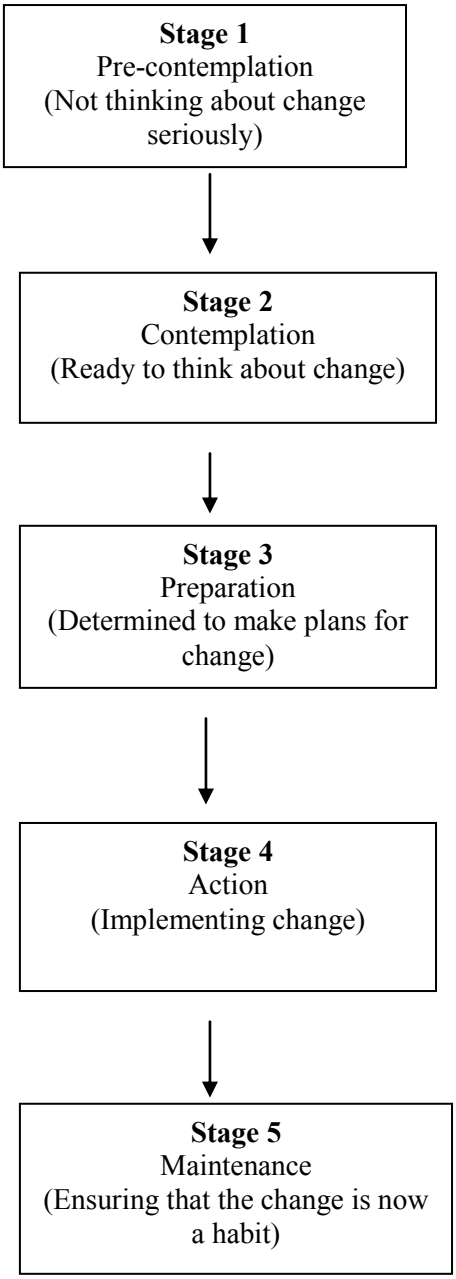
Treasure (2004) argued that although MI has its basis in clinical empiricism, several theoretical perspectives have been formulated to provide an academic framework. These he noted as trans-theoretical model of change and cognitive dissonance theory.

1.14.1.1 Trans-theoretical model of change

The trans-theoretical model is a behaviour change theory. It operates by identifying the stage of change of the individual and recognising why it is imperative to change certain behaviour as well as enhancing self-efficacy to ensure there is confidence to achieve it (Treasure, 2004). It also helps to identify different representations of stage of change that may help explain people's successes or failures as they attempt to change their problem behaviour (Jackson, 2006). The stages involved in the trans-theoretical model are illustrated in Figure 1.2.

The rationale that drives the use of this model in the development of motivational interviewing is that change is first assumed as the responsibility of the individual. In this regard, it could be postulated that the individual receiving ABI is assumed to be at an early stage of change. Therefore, the person providing the intervention explores and understands the individual's readiness to change and processes that could bring about change in drinking habits. They then translate the information into the perspective for the client emphasizing the benefits that would be derived from changing problem drinking. Utilizing this perspective, the client is provided with skills needed to change hazardous or harmful drinking behaviour.

Figure 1.2 Trans-theoretical model of change



Source: Treasure (2004)

1.14.1.2 Cognitive dissonance theory

Cognitive dissonance theory is a communication theory. Cognitive dissonance occurs when people hold conflicting beliefs simultaneously. Cognitive dissonance theory posits that people are motivated to reduce dissonance because it is psychologically uncomfortable to hold two contradictory beliefs (Elliot and Devine, 1994). To postulate this theory in relation to alcohol intervention, it could be asserted that people may hold particular representations about their drinking behaviour and may be biased to believe that their choices are correct, disregarding any contrary available evidence. The counsellor therefore helps the individual to reduce dissonance by placing emphasis on the destructiveness of that drinking problem behaviour, whilst eliciting their drive to change attitudes, beliefs and actions.

1.15 Key theories

1.15.1 Theories of health behaviour

Interests in understanding the factors that underpin the performance of health behaviours have increased in recent years. Several theories of health behaviour are described in the health and psychology literature. These theories help us to identify determinants of health behaviour, and in certain circumstances, they are used as a basis to design interventions to address problem behaviours (MRC, 2006). This study therefore reviews three of the most influential theories of health behaviour – the Health Belief Model (Rosenstock, 1996; Rosenstock, 1974), the Theory of Reasoned Action (Fishbein and Ajzen, 1975; Ajzen and Fishbein, 1980) and the Theory of Planned Behaviour (Ajzen, 1988) - to help increase our understanding of how and why people participate (or not) in risky drinking behaviour. Each of the theories of health behaviour are based on social cognition models, which fundamentally states that behaviour is best

understood in terms of people's perceptions of their social environment (Connor and Norman, 1995).

1.15.1.1 Health Belief Model

The Health Belief Model (HBM) postulates that the degree to which people perceive a threat to their health from a particular behaviour determines how motivated they are to prevent that behaviour (Rosenstock, 1996; Quah, 1985). According to Rosenstock (1966), the concept of the HBM assumes that an individual's readiness to take action concerning specific health behaviour depends on certain factors and not on the professional's view of the actual threat of that behaviour. These factors focus on two aspects of the individual's representation of health and health behaviour, which are threat or risk perception and behaviour evaluation (Sheeran and Abraham, 1995). Threat perception deals with perceived susceptibility to illness and perceived severity of the consequences of such illness. Behavioural evaluation concerns two sets of beliefs. One deals with perceived benefits of reducing susceptibility or efficacy of the recommended health behaviour and the other concerns the cost of or barriers to taking action. Relating these factors to prenatal alcohol consumption it suggests that in order for a woman to take action to avoid an alcohol exposed pregnancy, there is the need for her to (1) perceive that the fetus is susceptible or could be harmed by alcohol; (2) believe that the harm could be considerable (e.g. FAS); (3) believe that there are specific benefits in taking action (i.e. FAS could be prevented); and (4) the pregnant woman needs to perceive that there are no major barriers or cost involved in undertaking that action. Rosenstock (1966) argued that one additional variable, cues to action (which is often ignored) is necessary to complete the HBM. Cues to action triggers health behaviour change when the appropriate beliefs listed above are held. These 'cues' may include a range of triggers such as the individual's awareness that

someone else indulging in that behaviour has been negatively affected, a mass media campaign and the individual's perception of the severity of symptoms (Rosenstock 1966; Sheeran and Abraham, 1995).

1.15.1.2 Theory of Reasoned Action and the Theory of Planned Behaviour

The Theory of Reasoned Action (TRA) examines the relationship between attitude and behaviour. The TRA assumes that people are rational and make systematic decisions based on available information (Ajzen and Fishbein, 1980). There are two main concepts that underline TRA, these are the 'principles of compatibility' and the concept of 'behavioural intentions'. The principles of compatibility states that in order to predict specific behaviour directed to specific target action within a given context and time, specific attitudes that correspond to the specific target action, time and context should be examined (Ajzen, 1988). According to the TRA, behaviour is determined by 'behaviour intention' to enact the behaviour. However, two key factors underline 'behavioural intentions'. These are 'attitudinal factors' and 'social normative factors'. Attitudinal factors entail a person's belief about the perceived consequences of performing the behaviour and their evaluation of these consequences. Social normative factors or the subjective norm concerns the individual's perception of the social pressure on him or her to perform or not perform the behaviour.

The Theory of Planned Behaviour (TPB) is an extension of the Theory of Reasoned Action. The TPB asserts that not all behaviour may be under a person's volitional control. Ajzen (1991) suggested that an additional component, perceived behavioural control, is necessary to predict behaviour intentions. Perceived behavioural control is defined as the extent to which performance of a behaviour is easy or difficult. The addition of this component in the TPB suggests that people are more attracted to

perform behaviours that they have control over and are reluctant to perform behaviours over which they have no control (Connor and Sparks, 1995).

1.15.2 Theories of policy implementation

The implementation of screening and ABI in Scotland falls within the domain of theories of policy implementation. It is therefore important to introduce some of the main theories in this area briefly in this chapter and I will revisit the subject in chapter nine in relation to the screening and ABI implementation in Scotland. Policy implementation is defined as the process of turning policy, usually incorporated in a statute, into practice. However, there is often a gap between what was planned (policy expectations) and what actually occurs in practice (policy results) (Pawson and Tilley, 1997; deLeon and deLeon, 2002). Three main activities are involved in policy implementation. They are interpretation (translation of policy into administrative directives), organisation (establishment of administrative units and procedures necessary to execute the programme) and application (delivery of service). However, in terms of theoretical perspective, three main theories or themes are suggested to govern policy implementation - the 'top-down' approach, 'bottom-up' approach and the principal-agent theory (Schofield, 2001; deLeon and deLeon, 2002).

1.15.2.1 The top-down approach

The top-down theory suggests that policy makers are central actors in policy implementation; as such, they place emphasis on factors that can be manipulated at the central level (Matland, 1995). The top-down policy implementation offers a hierarchical model, which assumes a command and control orientation (Schofield, 2001; deLeon and deLeon, 2002). They believe that for policy implementation to have a positive impact the following steps are required: policy goals need to be clear and consistent, restrict the number of actors within the implementation process, limit the extent of

relevant change, and the responsibility for implementation needs to be placed in agencies sympathetic to the policy goal (Matland, 1995). One main criticism of the top-down policy implementation approach is that it is overly optimistic in its expectations, making its objectives highly unlikely to be met within a complex programme. This is because policy formulation often fails to take adequate account of the role of stakeholders described as street level bureaucrats (deLeon and deLeon, 2002) who have expertise and knowledge of the true problem that policy makers want to address (Matland, 1995; Schofield, 2001; deLeon and deLeon, 2002). This may result in policies that may not adequately meet the needs of street level bureaucrats.

1.15.2.2 Bottom-up approach

Bottom-up theory proposes that policy thrives best when the role of the street level bureaucrats involved in service delivery and target groups of implementation are taken into account (Matland, 1995; Schofield, 2001). In this sense, they believe that successful implementation of a policy is only possible when the actors fundamentally affected by a policy are actively involved in its planning and execution (deLeon and deLeon, 2002). The concept put forward by the 'bottom-uppers' is that because street level bureaucrats are actively involved, the complexities surrounding the implementation process could potentially be fully identified at the very onset of the planned change and addressed appropriately. For example, implementation costs associated with a new programme could be captured at the initial change before the addition of top level bureaucratic costs. However, this has the tendency of disproportionately allocating resources in the implementation process (deLeon and deLeon, 2002). Another weakness with the bottom-up approach is that in a democratic system, policy is made by elected representatives of the population therefore street level bureaucrats or local service deliverers do not have the same power legitimacy in

exercising policy control (Matland, 1995). As a result, the bottom up approach of policy implementation has the tendency to undermine bureaucratic accountability.

1.15.2.3 Principal-agent theory

Principal-agent theory suggests that there exists a relationship between those who define policy (principal) and those who implement it (agent) and this may include agreements that enable the principal to state what is provided and verify that it has been achieved (deLeon and deLeon, 2002). Often, there is conflict of interest in the relationship because the two parties have different interests (asymmetric information). This problem arises when the specific duties to be performed are in the best interest of the principal but not in the interest of the agent.

The relevance of these theories to the findings of this study will be explored in the Discussion chapter.

1.16 Study design

Following a review of the literature and the phase of implementation of the screening and ABI at the time of this study (the screening and ABI programme was already implemented within the NHS Scotland), a realistic evaluation methodology (see chapter four – methodology and methods - for details) was considered the most appropriate design for the study. Briefly, a realistic evaluation is a theory-driven approach to investigate social programmes. It offers a perspective that helps to assess the nature of a programme and how it works, whilst incorporating the contextual basis for explaining and understanding the programme (Pawson and Tilley, 1997). To put this into perspective, the focus of this study was not to examine whether the screening and ABI was working or not. It was rather to understand how contextual issues involved with consumption of alcohol in pregnancy coupled with the pre-existing circumstances

within maternity services could interact with the underlying mechanisms of screening and the ABI programme to influence the intended outcome of the initiative in Scottish antenatal care settings. Fundamental to this was the need to gather data from perspective of key 'actors' involved or affected by the implementation of screening and ABI. Given the fact that data collection for this study started about six months after the implementation of the ABI in antenatal care settings, it was considered premature to assess summative outcomes but possible to assess process outcomes. Consequently, more emphasis was placed on the context and mechanism components of the realistic evaluation framework. Carrying out the study at this stage and especially using realistic evaluation approach may offer an indication of how the programme has been integrated in antenatal care, highlights policy makers and implementers concerns, and identifies areas that will require special attention to ensure sustainability when it is fully embedded into routine antenatal care system.

1.17 Structure of Thesis

There are three main stages involved in the realistic evaluation framework and this informed the structure of the thesis (see Table 1.2). Briefly, the first stage concerns development of concepts or underlying assumptions about the interventions and how they are expected to operate. The underlying assumptions about how the programme is expected to work are called the programme theories. The programme theories are constructed as the plausible context, mechanism and outcome (CMO) configurations, which are then used to guide the remaining aspects of the evaluation (Pawson and Tilley, 1997; Pawson, 2006). The data for this stage was obtained from the literature and those involved in implementing the screening and ABI programme.

The second stage comprises of testing the programme theories identified in stage one based on CMO configurations using appropriate data from stakeholders who are expected to deliver the intervention in practice and clients who are expected to change behaviour because of the intervention.

The final stage involved interpretation of the analyses to assess whether the theory about how the screening and ABI work is supported or refuted and revisiting the theory to build an explanation of how the programme might work for whom and under what circumstances. Based on the explanation, suggestions are made to improve the programme theory.

In terms of the chronology of the chapters, the first chapter highlights the rationale for the study. It provides an overview of contextual basis within which this study was carried out and important issues necessary to understand the issue of prenatal alcohol consumption. It also introduces the methodology employed by the thesis.

Chapter two reviews the evidence to ascertain specific fetal outcomes associated with drinking in pregnancy. Based on the review, theories are proposed to be tested among pregnant women and midwives.

Chapter three is in two parts. The first part, reviews the evidence bearing on ABI in various health care settings. The second part specifically reviews available published intervention studies in depth to examine the utility of ABI in antenatal care settings. The chapter concludes by outlining the programme theories of how the screening and ABI is expected to work.

Table 1.2 Stages involved in the thesis

Stage	Sources of data and chapter	
Stage 1 – Development of propositions (programme theories). This includes generating ideas about which contextual factors are likely to be important, considering potential mechanisms and deciding on which outcomes should be the focus of inquiry	Two separate systematic reviews and a critical review (chapter two and three)	Qualitative in-depth interviews with four key policy informants (chapter five)
Stage 2 – Testing or exploring the propositions identified in stage 1. Exploring contextual issues to see how they relate with the mechanism to produce outcome	Qualitative interviews and a focus group with twenty one midwives, including community midwives, team leaders and a consultant midwife (chapter six)	Qualitative interviews with seventeen pregnant women (chapter seven)
Stage 3 – Refining and explaining the CMO propositions to assess whether the theories about how the programme works is supported or refuted and revisiting the initial concepts to build an explanation	Interpretation of the findings in stage 1 and 2 to generate explanation about what works, for whom, how and in what circumstances (chapter eight)	

Chapter four describes the qualitative methods used to generate primary data for this thesis. In the chapter, a number of theoretical and methodological points in relation to realistic evaluation are raised.

Chapter five is devoted to presentation of the findings from policy informants' (referred to as policy implementers in this study) about their expectations, intentions and perceived benefits of the screening and ABI initiatives. As the final chapter of stage one, the programme theories identified in this chapter are combined with the ones from

chapter two and three to formulate CMO propositions which are further explored among midwives and pregnant women.

Chapter six documents the findings from midwives viewpoints by testing and exploring the CMO propositions identified in the reviews together with the interviews of policy implementers.

Chapter seven presents the findings from pregnant women perspectives by exploring and testing the propositions formulated on the basis of chapter two, three and five.

Chapter eight forms the final stage of the realistic evaluation framework and involves refining and explaining the CMO propositions identified from the earlier chapters to generates understanding of how the screening and ABI might work for whom, how and under what antenatal care circumstances.

Chapter nine discusses the relevance of the findings to existing knowledge and concludes with implications of the study findings for the long-term embedding of the screening and ABI initiative into routine antenatal practice.

2. 0 Chapter Two: A systematic review of effects of prenatal alcohol consumption

2.1 Introduction

A review of the literature forms an integral part of the initial stage of realistic evaluation. In this chapter, a systematic review of observational studies that examined the effects of drinking in pregnancy on the fetus is presented. It begins by explaining and outlining the usefulness of systematic reviews. It continues by discussing the rationale for this review, followed by methods used. It appraises the included studies and presents findings based on levels and patterns of drinking and their related outcomes on the fetus or infants. It concludes by outlining the programme theories that emerged from the findings and would be employed in subsequent stages of the realistic evaluation framework.

2.2 Systematic reviews

Systematic reviews provide robust and comprehensive overviews of primary research findings within a specified topic area. Unlike the traditional and non-systematic approach of many literature reviews, systematic reviews use a scientific and transparent approach, intended to minimise bias and offer reproducibility (NICE, 2006; Petticrew and Roberts, 2006; Aveyard, 2010). This approach is achieved by following transparent, systematic and robust procedures. The main procedures involved are: identification of research questions and pre-defining selection criteria for studies; explicit, reproducible methodology; a systematic and exhaustive search to identify all relevant studies; an assessment of the validity of the findings of the included studies; and a systematic synthesis and a clear presentation of study findings (Higgins and Green, 2009; Aveyard, 2010). Primarily, systematic reviews are concerned with

answering questions about cause and effects relationships and the effectiveness of interventions (Petticrew and Roberts, 2006; Bowling, 2009). Whereas these questions may be the focus of most systematic reviews, a review can also answer questions about the prevalence of a disease or differential effectiveness of a programme by settings or population groups. Overall, systematic reviews are an essential step in translation of research evidence into evidence-based clinical practice and health care provision (Bowling, 2009). Often systematic reviews include meta-analysis when appropriate, which is a statistical synthesis that summarises results of two or more studies that address related questions in a similar way (Petticrew and Roberts, 2006; Smith and Dixon, 2009). Where there are significant differences between studies, a narrative synthesis is usually undertaken.

2.3 Rationale for the systematic review

The relationship between prenatal alcohol consumption and the risk of adverse outcomes on the fetus is a topical one. In 2007, Henderson and colleagues published two systematic reviews, which looked at this association within limited categories of drinking patterns (Henderson et al., 2007a; Henderson et al., 2007b). Their reviews examined observational studies conducted from 1970's up to July 2005. They found no consistent significant associations between low-moderate drinking and the birth outcomes considered. For binge drinking, the only consistent adverse finding related to neurodevelopmental outcomes. However, there has been a considerable upsurge in the number of studies published after their reviews, some involving large population based cohort studies (Aliyu et al., 2008; Kelly et al., 2009; 2010). In addition, the increasing prevalence of congenital anomalies generally attributed to prenatal alcohol and other substance misuse among contemporary populations, has spurred recent global interest

on the subject. The quest to provide conclusive evidence means more research continues to emerge in this field.

Recently, the publication of studies based on the UK Millennium Cohort Study indicated that drinking at low levels in pregnancy was related to better cognitive outcomes in infants compared to infants of mothers who abstained (Kelly et al., 2009; 2010). The findings of these studies generated nationwide debates as the authors were widely quoted by the media, with headlines, such as *"a tipple in pregnancy can help child later"* emerging in some news papers (METRO, 2008, 30th October). This extensive media coverage resulted in some sections of the population questioning whether recent clinical recommendations to abstain from alcohol during pregnancy were based on evidence.

Based on these concerns, it seemed important to update the evidence and incorporate all levels of alcohol exposure to ascertain the direction and dimension of recent observational research findings. Moreover, the relevance of regular updates in the field of adverse effects of prenatal alcohol consumption to health professionals is well recognised (Diekman et al., 2000). When examining the association between prenatal alcohol consumption and fetal outcomes, the timing of exposure has relevance (Abel and Hannigan, 1996; Shankar et al., 2007; O'Leary et al., 2010a). Therefore, the trimester of alcohol exposure and thus the fetal organ under development at the time, determines the extent of damage (Aronson, 2002).

The aim of this review was to systematically identify and appraise current evidence, published after the two reviews by Henderson and colleagues, on the effects of different levels of drinking and their specific corresponding fetal outcomes. A secondary aim was to examine the evidence pertaining to the association between timing of alcohol

exposure and a spectrum of fetal outcomes. Overall, the objective of this systematic review was to help develop realistic evaluation programme theories.

2.4 A critique of the Henderson and colleagues reviews

A critique of the two systematic reviews published by Henderson and colleagues (2007a; 2007b) was carried out to inform judgement about their robustness and assess their contribution to the field of effects of prenatal alcohol exposure. The NICE quality assessment tool facilitated this quality appraisal (see Table 3.1) (NICE, 2006). The authors stated that the two reviews originated from a piece of work, which they carried out for the UK Department of Health (Gray and Henderson, 2006). It is important to note that because of their common origin, they have similar or same methods.

The authors had clearly defined questions for their reviews. For example, Henderson et al. (2007a) indicated that their objective was to assess whether drinking up to 84g of alcohol per week (seven standard drink/day) was associated with a greater risk of adverse pregnancy outcome compared with total abstinence. They stated clearly the criteria studies need to fulfil in order to be included or excluded. There is a more likelihood of selection bias in systematic reviews if only one reviewer determines whether studies are selected or not (Petticrew and Roberts, 2006). Both reviews achieved this requirement, as they indicated that two members of the research teams independently carried out this activity. However, only one author was involved in the quality assessment of studies. One disadvantage with this approach is that the probability of being biased in judging or scoring studies increases (Petticrew and Roberts, 2006). Moreover, the quality score was not adequately taken into account when undertaking the syntheses. Overall, the methods for retrieving papers for the reviews were appropriate and well described. For instance, the authors elaborated that

"electronic search was supplemented by reviewing bibliographies of review articles and discussing with experts in the field" (Henderson et al., 2007a: 1070).

The authors limited their reviews to "studies published in the English language in a peer-reviewed journal" (Henderson et al., 2007b: 243). Restricting review to studies published in a specific language, though pragmatic, may exclude research evidence published in other languages, especially in reviews where conclusions are made based on availability of very small number of studies. In this instance, it could be argued that as Henderson et al. (2007a) included only fourteen studies, availability of a number of studies with contradicting findings, for example in the French language may have impact on their conclusions. However, this may be unlikely because many non-English language journals also publish their abstracts in English. Therefore, it is possible that if the authors had discovered that this was the case they would have reconsidered their eligibility criteria.

The authors relied on articles published only in peer-reviewed journals. However, over reliance on peer-reviewed publications may miss important grey literature, which may contribute to the evidence base (Aveyard, 2010). In addition, there is also the issue of publication bias where studies with positive outcomes are more likely to be submitted and are more likely to be accepted for publication in peer-reviewed journals. Nevertheless, it is generally recognised that influential evidence in the health field are usually published in peer-reviewed journals. Regardless of the few methodological deficiencies highlighted, these two systematic reviews represent comprehensive syntheses of the evidence of effects of prenatal alcohol exposure on the fetus and developing infant.

2.5 Review questions

1. What levels of prenatal drinking are related to adverse birth outcomes?

2. When in pregnancy is alcohol consumption particularly harmful to the fetus?

2.6 Methods

2.6.1 Search strategy

A preliminary search was carried out in Medline using generic search terms for the target group, exposure and outcome (for example: 'women' 'infants', 'fetal effects') to identify a spectrum of relevant literature. Based on the titles of identified literature, key words were drafted in to design a search strategy (see Appendix 1). Using this strategy, a final literature search was carried out in Medline (1988 – September 2011) and Embase (1996 - September 2011). Relevant published articles in relation to prenatal alcohol exposure and fetal or infant outcomes were identified. A further search was carried out from my personal Reference Manager database of alcohol and pregnancy articles compiled through a weekly supply from the Scottish Addictions Study Group. This research group is based in Stirling University and one of its roles is to collect and compile a comprehensive electronic database of all articles published in known alcohol and drugs journals as well as from other sources (e.g. government websites). These are then distributed to all members weekly. In addition, bibliographies of relevant studies were also searched. Retrieved articles were de-duplicated, limited to English language, humans and from 2006 to September 2011. All results were downloaded into a single Reference Manager database.

2.6.2 Selection criteria

Studies were included if:

- they were published in a peer reviewed journal;

- were cohort, case-control or cross-sectional;
- they examined alcohol consumption in pregnancy;
- reported one or more of the following: spontaneous abortion, stillbirth, birth weight, impaired growth, preterm birth, malformation, birth defects, fetal alcohol spectrum disorders (FASD) including fetal alcohol syndrome (FAS), and neurodevelopment.

Studies were excluded if:

- alcohol consumption occurred outside pregnancy;
- data on alcohol exposure was not reported separately from other risk factors;
- conducted in a developing country.

2.6.3 Quality assessment

The aim of quality assessment of studies is to evaluate the appropriateness of the study design and methods and examine systematic errors (bias) within studies that may influence the validity of findings (Petticrew and Roberts, 2006). In observational studies, confounding factors could also influence validity. According to Bhopal (2002: 79), a confounder "is the error in the estimate of the measure of association between a specific risk factor and disease outcome, which arises when there are differences in the comparison populations other than the risk factor under study". Assessing the quality of included studies therefore, helps to identify which studies have a high or low risk of bias, which may affect the robustness of the findings.

Currently, there is no consensus in the use of quality checklists in systematic reviews of observational studies and many different tools are available to assess different methodological aspects (Mallen et al., 2006). Quality appraisal in this review was

facilitated by using a checklist for observational studies (see Table 2.1) published by the Critical Appraisal Skills Programme (CASP, 2004).

Table 2.1 Checklist for appraising included studies

No	Item	Answer		
1	Did the study address a clearly focused question?	Yes	No	Can't tell
2	Did the authors use an appropriate method to answer their questions?			
3	Were participants recruited in an acceptable way?			
4	Were the controls selected in an appropriate way?*			
5	Was the exposure accurately measured to minimise bias?			
6	Was the outcome accurately measured to minimise bias?			
7	Have the authors identified all the important confounding factors?			
8	Was the follow-up of subjects who completed enough?+			
9	What are the results of this study?			
10	How precise is the estimate of risk?*			
11	Do you believe in the results?			
12	Can the results be applied to the local population?			
13	Do the results of this study fit with other available evidence?			

*Applies to case control studies only
+ applies to cohort studies only

2.6.4 Categorisation of alcohol consumption and alcohol-related risks

Lack of universal definitions for alcohol levels mean that categories of alcohol levels vary between countries and studies (Duffour, 1999). However, efforts were made to maintain the definitions provided in individual studies, but to further enhance

comparability between studies, a common criteria (see Box 2.1) was adapted from Kelly et al. (2009).

Box 2.1 Definition of levels and pattern of drinking

Low : 1 – 2 units per week or per occasion

Moderate: 3 – 6 units per week or 3 – 5 units per occasion

Heavy: ≥7 units per week

Binge: ≥6 units per single occasion

Furthermore, to ascertain the level of risk associated with prenatal alcohol exposure and fetal outcomes reported by included studies, it was considered necessary to define risk categories (see Box 2.2). This was done in agreement with my supervisors.

Box 2.2 Category of risk for examining included studies

No risk: a protective effect or no association reported

Low risk: modest risk elevation or increased risk but difference not statistically significant

Risk: Statistically significant association

2.6.5 Study selection and data extraction

To enhance transparency and avoid anecdotal selection of studies in systematic reviews, it is recommended that two people independently assess and decide studies to be included (Aveyard, 2010). Based on the outlined inclusion criteria above, one of my supervisors (RJ) and I independently assessed and selected titles and abstract for inclusion. There were no differences in study selections.

Relevant data from individual studies were extracted into an electronic data extraction form (part presented under results section). The form contained two sections. One part contained details and findings of included studies and the other part contained items from the quality appraisal checklist above. One supervisor (RJ) independently reviewed about 5% of the extracted data from individual studies to check for accuracy and consistency.

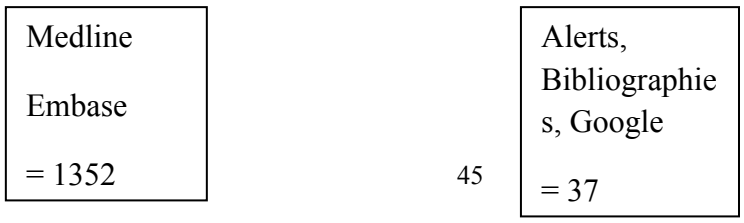
2.6.6 Analysis

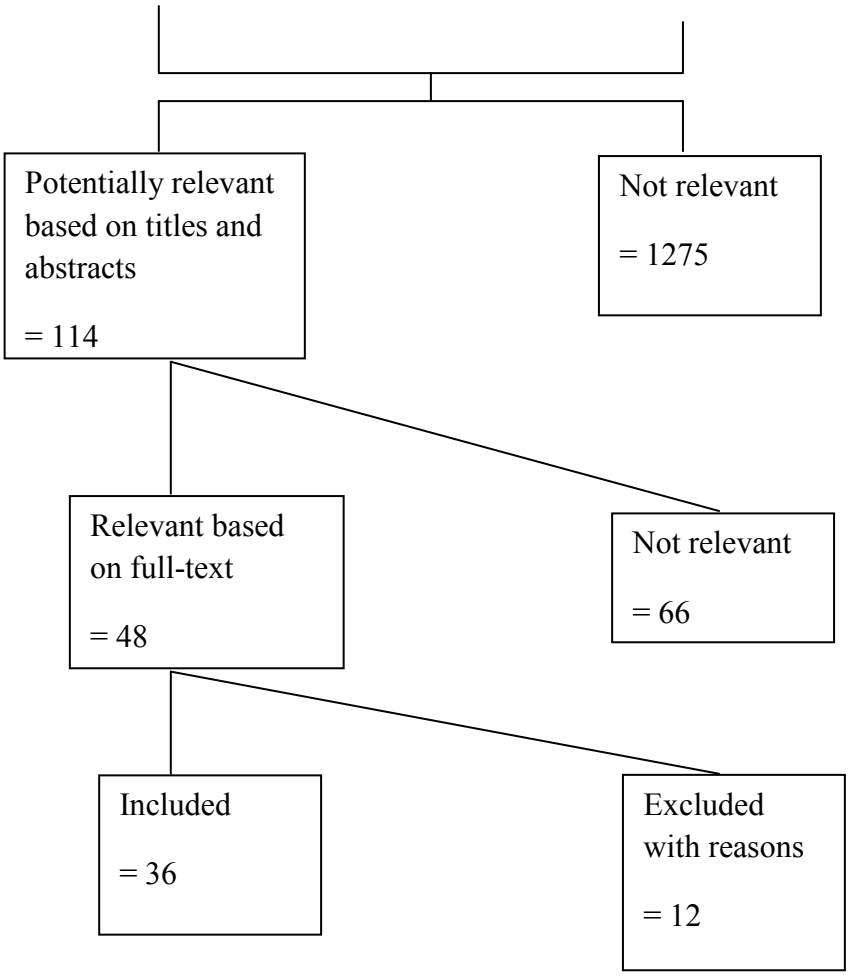
Narrative syntheses of the results are provided based on fetal outcomes to enhance explanatory account. A meta-analysis was not undertaken due to the heterogeneity in the methods and quality of different studies and the varied fetal outcomes considered. Petticrew and Roberts (2006) cautioned that conducting meta-analysis in the midst of heterogeneity is likely to produce similar effects sizes from conceptually dissimilar studies rendering the results spurious.

2.7 Results

Searches of the databases returned 1985 articles. However, after removing duplicates 1352 articles remained (Figure 2.1). A further search through my personal library resulted in 26 additional articles. Eleven articles were further obtained from the bibliographies of included text and searches in Google and Google scholar. Of the total 1389 articles considered, 36 met the inclusion criteria and were included in this review.

Figure 2.1 Flow chart of the literature search





2.7.1 Excluded studies

The reasons for excluding 12 articles after full text consideration varied among studies (Appendix 2). For instance, Romitti et al. (2007) considered drinking in the perinatal period (two months before pregnancy and two months after) and did not assess outcome separately for infants exposed to alcohol exclusively at each time period. Other articles only described the features of FASD children and did not examine causal relationships of prenatal alcohol exposure and FASD (Kodituwakku et al., 2006; Aragon et al., 2008).

2.7.2 Included studies

The majority of the 36 included studies were cohort studies (n =28; 78%). Only one was a cross sectional study and the rest were case-control studies (n =7; 19%). The quality of included studies were generally adequate with only three studies (Fryer et al., 2007; McGee et al., 2008; McGee et al., 2009) assessed to be of weak methodological quality (having significant methodological flaws which may have led to bias in the conclusions). The most common methodological deficiency among all the studies centred on accurate ascertainment of alcohol exposure (see Appendices 3, 4 and 5). The rapid rate of alcohol metabolism in the human body precluded the use of objective alcohol measures (e.g. biological markers) in included studies. Also, most studies did not use validated screening tools. The contest between the validity of prospectively and retrospectively collected prenatal alcohol consumption data was evident across studies, with most studies defending the appropriate use of either one or both. Some studies focused on evaluation of effects of several risk factors (including alcohol and others, for example caffeine consumption) on the fetus (Dew et al., 2007; Mongraw-Chaffin et al., 2008). The number of confounders, which were adjusted for varied across studies but cigarette smoking was the most common. Specific details, methods and findings of included studies are discussed below based on the outcomes considered.

2.7.3 Fetal Alcohol Spectrum Disorders (FASD)

Three studies evaluated fetal alcohol spectrum disorders including, fetal alcohol syndrome (FAS), fetal alcohol effects (FAE), and alcohol-related birth defects (ARBD) (Table 2.2). The study designs used were cohort (O'Leary et al., 2010b); case-control (Coyne et al., 2008); and cross-sectional (Landgren et al., 2010). The rare occurrence of these conditions means that the studies relied on small sample sizes to draw conclusions. For instance, Landgren et al. (2010) recruited only 71 participants and by

the nature of their study design had no reference group to assess differential alcohol exposure. In some instances, their assessment of prenatal alcohol use was determined from the account of foster parents. Moreover, no potential confounders were controlled for and this might render any relationship between alcohol consumption and FASD spurious. The sample used by Coyne et al. (2008) included a high proportion of indigenous Australians (65%) among which the prevalence of FAS has been shown to be high. This high-risk group used limits the generalizability of their findings. However, in order to avoid potential bias and enhance quality of data, researchers involved in retrieval of alcohol consumption data from mothers were blinded to infant's group status.

All the studies found consistent association between heavy levels of drinking and fetal outcomes (FASD). Coyne et al. (2008) found that mothers who drank heavily in pregnancy were at increased risk of having infants with FAS compared to controls (68.9% versus 17%, p = 0.000). O'Leary et al. (2010b) also reported that as compared to controls, drinking in the first trimester was associated with increased odds of ARBD (adjusted OR = 4.6; 95% CI, 1.4 – 14.3).

Table 2.2 Contextual details of included studies by level or pattern of drinking in relation to outcome (FASD)

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
a. Coyne b. 2008 c. Australia	a. Case-control (retrospective) b.115	Review of hospital records and follow-up interviews with mothers if there were incomplete data	FAS of children and adolescents aged 1 to 17 years	Hospital records	As compared to controls (17%) mothers of heavy drinkers had significant numbers of infants (68.9%) with FAS (p=0.000)	Low, moderate: no risk Heavy: risk
a. Landgren b. 2010 c. Sweden	a. Cross-sectional b. 71	Medical records, secondary reports from adoptive parent	FASD (FAS, FAE, ARND)	Medical examination, various scales	52% of infants identified with FASD. Of this FAS accounted for 30%; FAE, 14% and ARND for 9%	Low, moderate, heavy: risk
a. O'Leary b. 2010b c. Australia	a. Cohort b. 4,714	Post-partum postal questionnaire	Alcohol Related Birth Defects (ARBD)	Medical examination	Heavy prenatal alcohol use in the first trimester was associated with increased odds of ARBD as compared to controls (aOR = 4.6; 95% CI 1.4 – 14.3).	Low, moderate: no risk Heavy: high risk

Table 2.3 Contextual details of included studies by level or pattern of drinking in relation to outcome (spontaneous abortion and stillbirth)

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
a. Aliyu B. 2008 c. USA	a. Cohort (retrospective) b. 655,979	Postpartum interview	Early stillbirth	Missouri vital (birth) record system	Incidence of stillbirth found to be 5.3 per 1,000. Among mothers who experienced stillbirth, mothers who drank in pregnancy were 80% more likely to experience early stillbirth as compared to abstainers (aHR) = 1.8, 95% CI 1.3 – 3.0). Mothers who drank ≥5 were at increased risk to experience stillbirth as compared to abstainers (aHR = 1.7, 95% CI, 1.0-3.0)	Low, moderate: low risk Heavy: high risk
a. Strandberg-Larsen b. 2008 c. Denmark	a. Cohort (prospective) b. 89,201	Prenatal – computer assisted telephone interview	Spontaneous abortion (<22 weeks of fetal death) and Stillbirth (>22 weeks of fetal death)	Civil registry system and Danish Medical Birth Registry	Binge (frequency) drinking was not related to spontaneous abortion. Women had ≥3 binge episodes were significantly at risk of experiencing stillbirth as compared to non-binge drinkers (aHR = 1.56, 95%CI, 1.01 – 2.40)	<u>Spontaneous abortion</u> Binge: no risk <u>Stillbirth</u> Binge: risk

2.7.4 Spontaneous abortion and stillbirth

Two studies with low risk of bias considered the association between prenatal alcohol consumption and the risk of stillbirth or spontaneous abortion (Table 2.3). Both were very large cohort studies with one being prospective (Strandberg-Larsen et al., 2008) and the other retrospective (Aliyu et al., 2008). In one (Aliyu et al., 2008) information on alcohol exposure in pregnancy was collected after delivery and was not restricted to the trimester in which drinking occurred. The main outcome considered was early stillbirth. This was defined as *in-utero* fetal death occurring at <28 weeks gestation (Aliyu et al., 2008). Strandberg-Larsen et al. (2008: 603) defined stillbirth as "≥22 completed weeks of gestation" and spontaneous abortion as "<22 completed weeks of gestation". Both adjusted for potential confounding factors that are associated with stillbirth and spontaneous abortion including cigarette smoking and maternal age. However, adjusting for the number of previous spontaneous abortions may represent over-adjustment in Stranberg-Larsen et al. (2008) study, especially if the previous spontaneous abortions were related to alcohol.

Both found association between various levels or pattern of drinking and stillbirth. However, Strandberg-Larsen et al. (2008) observed that binge drinking was not related to spontaneous abortion and the trimester that drinking occurred had no significant influence on late spontaneous abortion. It is important to note that these studies were well conducted and had very large sample sizes, giving considerable confidence in these outcomes.

2.7.5 Growth, preterm birth and birth weight

Six studies reported on these outcomes (see Table 2.4) and all but two were case-control studies (Chiaffarino et al., 2006; Mariscal et al., 2006). Of the cohort studies, two were based on the same cohort (Jaddoe et al., 2007; Bakker et al., 2010). Bakker et

al. (2010) considered fetal growth characteristics or Intrauterine Growth Restriction (IUGR) across three time points in pregnancy. Jaddoe et al. (2007) considered SGA, preterm and birth weight as fetal outcomes. The terms IUGR and SGA are often used interchangeably, but the distinction between them is that IUGR describes fetal growth characteristics that deviate from genetically expected size whereas SGA is determined at birth and it is birth weight, which is below the 10^{th} percentile for gestational age (Ross, 2011). O'Leary et al. (2009b) reported on double outcomes of SGA and preterm birth. Dew et al. (2007) focused only on preterm birth, Chiaffarino et al. (2006) on SGA and Mariscal et al. (2006) reported on birth weight.

Dew et al. (2007) examined multi-risk factors in relation to the birth outcome and as such provided limited information on extent of alcohol exposure. In addition, they adjusted for only two confounders (cigarette smoking and illicit drug use). Mariscal et al. (2006) and O'Leary et al. (2009b) reported that low numbers of women found to be drinking at higher levels limited the analysis that they were able carryout.

Bakker et al. (2010) found that there was no association between low and moderate drinking on fetal growth characteristics. However, prenatal drinking was associated with fetal weight gain (difference = 0.61g/week, 95% CI 0.18 – 1.04) indicating that as compared to abstainers, mothers who continued drinking during pregnancy had bigger babies. There were consistent findings of no association of low levels of drinking with SGA. For higher levels of drinking, the risk was inconsistent with only one (Chiaffarino et al., 2006) of three studies reporting a strong association of three or more drinks in the first trimester with SGA (OR = 3.2, 95% CI 1.7-6.2). Low levels of drinking were not associated with low birth weight, there was an evidence of a dose-response effect. All the three studies evaluating the association of prenatal drinking and with preterm birth

found some form of association with drinking moderately or higher at some point in pregnancy. The risk pertaining to all outcomes under this category were more marked in women who drank in the first trimester.

Table 2.4 Contextual details of included studies by level or pattern of drinking in relation to outcome (growth, preterm birth and birth weight)

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
a. Bakker b. 2010 c. Netherlands	a. Cohort (prospective) b. 7,333	Prenatal postal questionnaire	Fetal growth characteristics (head and abdominal circumference, femur length, fetal weight)	Fetal ultrasound examination	No adverse effects on fetal growth. Mothers who continued to drink had protective effects on fetal weight (difference = 0.61g/week, 95% CI 0.18 – 1.04)	Low, moderate: No risk
a. Chiaffarino b. 2006 c. Italy	a. Case-control b. 2,521	Prenatal and ante partum interviews	SGA	Clinical measurement	No effects on fetus of women who drank 1 or 2 drinks/day. Women who drank ≥3 drinks/day at various stages in pregnancy had increased risk of SGA [1st trimester OR = 3.2 (95% CI 1.7-6.2); 2nd trimester 2.7 (95% CI 1.4-4.5); 3rd trimester 2.9 (95% CI 1.5-5.7)]	Low: no risk Moderate, heavy: risk
a. Dew b. 2007 c. USA	a. Cohort (retrospective) b. 83,685	Infant's birth certificate	Preterm births	Infant's birth certificate of birth that occurred	17.3% of infants born to women who were drinkers were preterm compared to 10.1% of non-drinkers and difference not significant. The simultaneous use	Low/moderate/heavy/binge: Low risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
					of all three exposures (alcohol, smoking and illicit drug use) considered was associated with a significant preterm birth (31.4%)	
a. Jaddoe b. 2007 c. Netherlands	a. Cohort (prospective) b. 7141	Prenatal postal questionnaire	Birth weight, SGA, preterm birth	Hospital records, fetal ultrasound examination	Main analysis: no associated between alcohol use in pregnancy and adverse birth outcomes. Sub-analysis: women who drank ≥1/day in early pregnancy had adverse birth outcomes [low birth weight (aOR = 4.81 (95% CI 1.10 -21.08), SGA (aOR = 1.45 (95% CI, 0.33- 6.44) and preterm birth (aOR = 2.51 (95% CI 0.92 – 6.81)]	<u>All birth outcomes considered</u> Low, moderate, heavy, binge : No risk
a. Mariscal b. 2006 c. Spain	a. Case-control b. 2,003	Ante-partum questionnaire	Low birth weight	Weighing scale	Drinking <6g/day had protective effects on birth weight (aOR = 0.64; 95% CI 0.46-0.88). Consumption of ≥12g/day was associated with increased risk but not significant after adjusting for confounders (aOR = 1.56; 95% CI, 091 – 2.69)	Low: no risk Moderate, heavy: low risk
a. O' Leary	a. Cohort	Post-partum postal	Fetal growth and	Proportion of	Low levels of drinking not	<u>SGA</u>

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
b. 2009b c. Australia	(prospective) b. 4,719	questionnaire	preterm birth	Optimal Birth weight, Midwives record system	associated with preterm birth. Risk associated with heavier levels of drinking. There was still risk for moderate and high levels drinkers who stopped before 2nd trimester as compared to abstainers (aOR = 1.73; 95%CI 1.01 – 3.14)	Low/moderate: No risk Heavy/binge: low risk <u>Preterm</u> Low: no risk Moderate/heavy/ binge: risk

2.7.6 Malformation: Cryptorchidism

Four studies reported on the relationship between alcohol consumption in pregnancy and Cryptorchidism (Table 2.5). Cryptorchidism manifests as undescended testis and may predict infertility. It can either be transient (spontaneous descent within three months period) or persistent (lasting for a longer duration and may require surgery). All but one of the studies that reported on this outcome was case-control (Mongraw-Chaffin et al., 2008). The small number of cases (84) however, limited the power of the study. Only one study reported on transient Cryptorchidism (Damgaard et al., 2007). All studies adjusted for a range of potential confounders but Damgaard et al. (2007) and Mongraw-Chaffin et al. (2008) did not adjust for maternal fertility treatment, which has been shown to be a strong predictor of Cryptorchidism (Jensen et al., 2007).

Only one study found risk of moderate level of drinking on Cryptorchidism (Damgaard et al., 2007). There were consistent findings regarding the association between binge drinking and the risk of Cryptorchidism. However, the association was modest. Stranberg-Larsen et al. (2009) found that binge drinking during gestational weeks 7 to 15 was particularly prone to Cryptorchidism (adjusted HR between 1.03 and 1.66). The modest strength of the association observed in these studies, may be attributed to the fact that the numbers of women drinking at this level in pregnancy are usually small, rendering studies limited in power to detect significant associations.

Table 2.5 Contextual details of included studies by level or pattern of drinking in relation to outcome (Malformation)

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
a. Damgaard b. 2007 c. Denmark and Finland	a. Cohort (prospective) b. 2,496	Prenatal - postal questionnaire and telephone interview	Cryptorchidism	Clinical examination at birth and 3 months	Women who drank ≥5 drinks/week were significantly at risk (OR = 3.10, 95% CI 1.05 – 9.10	Low: no risk Moderate: low risk Heavy: risk Binge: low risk
a. Jensen b. 2007 c. Denmark	a. Cohort (retrospective) b. 5,716	Prenatal - postal questionnaire	Cryptorchidism	Danish national patient register	No association observed for average weekly prenatal consumption and persistent cryptorchidism. For binge drinking there was association but was not significant (aRR = 1.4, 95% CI, 0.9 – 2.1)	Low, moderate, heavy: no risk Binge: low risk
a. Mongraw-Chaffin b. 2008 c. USA	a. Case-control (prospective) b. 280	Prenatal interview	Cryptorchidism (persistent) at 2 years of age	Medical examination	Prenatal alcohol consumption was not associated with cryptorchidism	Low, moderate, heavy: no risk
a. Strandberg-Larsen	a. Cohort (prospective) b. 41,268	Prenatal – computer assisted telephone	Cryptorchidism	Danish hospital discharge register, mothers self-report at 6 and 18 months	Maternal drinking was not associated with cryptorchidism. However, ≥3 binge episodes during weeks 7 to 15 were associated with	Low, moderate, heavy: no risk Binge: low risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
b. 2009 c. Denmark		interview			increased but non-significant risk	

2.7.7 Neurodevelopmental outcomes

Twenty-one studies considered neurodevelopmental fetal outcomes in relation to levels or pattern of drinking (Table 2.6). However, for comparability, I have sub-categorised these outcomes as cognitive (related to intellectual abilities or sensory functions) and behavioural (emphasizing mannerism). Of the total, six examined both outcomes, five evaluated only cognitive and 10 looked at behavioural outcomes.

2.7.7.1 Cognitive outcomes

In total, eleven studies evaluated this outcome. Sample sizes varied from as low as 51 (McGee et al., 2009) to as high as 12,495 (Kelly et al., 2009). Three were conducted in the UK (Kelly et al., 2009; 2010; Sayal et al., 2009). Two separate papers reported on the same large population based cohort with the infant cognitive outcomes assessed at age three and five years (Kelly et al., 2009; 2010). One study reported findings of two similar studies conducted in South Africa and USA (Dodge et al., 2009). A range of validated scales was used to assess cognitive abilities including the Wechsler Intelligence Scale for children. Whereas nine studies assessed cognitive outcomes in children less than 10 years of age, two studies considered outcomes in adolescents (Howell et al., 2006; O'Callaghan et al., 2007).

There were consistent findings of no risk of association among studies considering low levels in relation to various measures of cognition. Two studies reported a protective effect of this level of drinking (Kelly et al., 2009; 2010). All but one reported an increased risk of moderate and heavy drinking on cognitive outcomes (Kelly et al., 2010). The unexpected findings reported by Kelly et al. (2010) may partly be explained by the method used to assess alcohol exposure and attrition. First, women were asked about their alcohol consumption nine months after delivery and this retrospective assessment of alcohol use in pregnancy is particularly prone to recall bias. This could

indicate why women who either drank heavily or binge drank were grouped under a single category. Moreover, no validated screening tool was used. The findings pertaining to binge drinking were inconsistent, three studies reported an association and three observed no association. Concerning the particular stage in pregnancy, that drinking could be more harmful to cognition, two studies found an association of third trimester drinking with language delay (O'Leary et al., 2009a) and learning difficulties (O'Callaghan et al., 2007). On the other hand, Willford et al. (2006) found an association of first and second trimester drinking on cognitive ability among African-American children.

2.7.7.2 Behavioural outcomes

Sixteen studies examined this outcome and all but one was cohort studies (Fryer et al., 2007). Sample sizes ranged from a minimum of 69 (Fryer et al., 2007) to a maximum of 21,678 (Rodriguez et al., 2009). Age of assessment of behavioural outcome ranged from as early as two years (O'Leary et al., 2010c) to as late as 25 years (Barr et al., 2006). The dominant behaviours among the studies were attention or Attention Deficit Hyperactive Disorders (ADHD) and psychiatric disorders. Different validated tools were used to examine behaviours and this seemed to be influenced by the country in which the studies were conducted. Studies from the UK tended to use the Strengths and Difficulties Questionnaire whilst Australian studies were likely to employ the Child Behaviour Checklist Questionnaire. One study assessed the relationship between the prenatal alcohol use and the onset of adolescents alcohol use. However, they relied on adolescent (14 years of age) self-report (Alati et al., 2008). Considering the legal dimensions involved with underage drinking, it is likely that participants underreported drinking. Some studies relied on multi-informant measures (parents and teachers) in identification of problem behaviours (Sayal et al., 2007; Rodriguez et al., 2009)

whereas others relied on parent's report only (Kelly et al., 2010). However, Goodman et al. (2003) showed with the Strengths and Difficulties Questionnaire that multi-informant measures produce more reliable data than data from a single-informant.

There was consistent evidence of increased risk of heavy and binge prenatal alcohol consumption on behavioural outcomes among all studies (except Howell et al., 2006) that evaluated these exposures. Of the 11 studies that focused on moderate drinking, 82% reported an increased risk in relation to behavioural outcomes. For low levels, the findings were inconsistent with 55% of 11 studies reporting no association, and one study (Robinson et al., 2010) reported a protective effect (light drinking in first trimester versus abstainers, z = -0.12, (95% CI, -0.23, -0.01). However, in many western countries, it is widely known that light drinkers are likely to be from more economically advantaged backgrounds than abstainers (HM Government, 2007; Kelly et al., 2010) and as such, their children are likely to exhibit better behavioural patterns. Concerning the trimester in which drinking could have a profound effect on behaviour, five of the seven studies that evaluated this found that first trimester drinking is particularly prone to adverse behavioural outcomes.

Table 2.6 Contextual details of included studies by level or pattern of drinking in relation to outcome (neurodevelopmental)

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
a. Alati b. 2006 c. Australia	a. Cohort (prospective) b. 2,138	Prenatal and ante partum interview	Onset of alcohol disorders from adolescence to 21 years of age	Behaviour	Composite International Diagnostic Interview – computerised version	Prenatal alcohol use of ≥3 was associated with alcohol disorders. 1st trimester drinking significantly associated with early onset of alcohol disorders (aOR = 2.95; 95% CI 1.62 – 5.36) than 3rd trimester (aOR = 1.35; 95% CI 0.69 – 2.63)	Moderate, heavy: risk
a. Alati b. 2008 c. Australia	a. Cohort (prospective) b. 4,363	Prenatal and ante partum interview	Onset of adolescent (14 years) alcohol use	Behaviour	Adolescent self-report at 14 years of age	Mothers who drank ≥3 in pregnancy had adolescents at increased risk of reporting alcohol consumption of ≥3 at age of 14 years compared to mothers who abstained or drank <2	Low: low risk Moderate, heavy: risk
a. Barr b. 2006 c. USA	a. Cohort (prospective) b. 400	Prenatal interview	Various psychiatric disorder at age 25 years	Behaviour	Structured clinical interviews for DSM-IV (SCID) at 25 years of follow-up	The odds of experiencing six psychiatric disorders and traits were more than double	Binge: high risk
a. Dodge b. 2009	a. Cohort b. 543	Post partum and ante partum	Interhemispheric transfer of tactile	Cognition	Finger localisation test	Study 1: heavily exposed infants showed more transfer-related errors than controls. Study 2: Infants made	Moderate, heavy, binge: risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
c. South Africa (study 1) & USA (study 2)		interviews for South Africa and USA studies respectively	information			more errors if their mothers reported binge drinking during pregnancy as compared to if she drank regularly without binge drinking	
a. Fryer b. 2007 c. USA	a. Case-control b. 69	Caregiver report, maternal self report, medical/social/legal records	Psychiatric disorders of children with an average of about 12 years	Behaviour	Kiddie Schedule for Affective Disorders, Schizophrenia for School-Age Children –Present and Lifetime Version or Computerised Diagnostic Interview Schedule for Children-IV	Prenatal alcohol use was associated with most of the psychiatric characteristics studied. The effect was more marked when considering ADHD (case, 94.87% versus control, 30%; point estimate 0.65; 95% CI 0.46-.82)	Heavy: risk
a. Howell b. 2006	a. Cohort (prospective) b. 265	Prenatal alcohol report	Intellectual ability (IQ), Academic	Behaviour and cognition	Used several scales (e.g. Vineland Adaptive Behaviour Scales),	Alcohol exposed adolescents had significantly lower IQ at moderate and heavy levels as compared to	IQ Moderate, heavy: Risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
c. USA			achievements and school functioning in Adolescents		medical examination and school records	controls. There was no evidence of behaviour and conduct problems at school.	Behaviour Moderate, heavy: no risk
a. Jacobson b. 2011 c. USA	a. Cohort (prospective) b. 262	Ante partum interview	Number processing, ADHD	Behaviour and cognition	Wechsler Intelligence Scale for Children (3rd edition) and various neuropsychological tests	Prenatal alcohol exposure was associated with poorer number processing (mathematics achievements) rs = -0.12, p<0.05. Heavy prenatal alcohol exposed adolescents had 4 times prevalence of ADHD than mothers who abstained.	Number processing Moderate & heavy: risk ADHD Low: low risk Moderate: risk Heavy: high risk
a. Kelly b. 2009 c. UK	a. Cohort (prospective) b. 12,495	Post-partum interview	Behavioural problem and cognitive deficits in children at age 3 years	Behaviour and cognition	Strengths and Difficulties Questionnaire, British Ability Scale, Bracken School Readiness Assessment	Infants whose mothers drank 1-2 /week or per occasion were not at increased risk of relevant behavioural difficulties or cognitive deficits but children of heavy drinkers were.	Behaviour Low: no risk Moderate, heavy or binge: risk Cognitive Low: no risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
							Heavy or binge: risk
a. Kelly b. 2010 c. UK	a. Cohort (prospective) b. 11,513	Post-partum interview	Behavioural problem and cognitive deficits in children at age 5 years	Behaviour and cognition	Strengths and Difficulties Questionnaire, British Ability Scales	Children of low drinkers were not at increased risk of behavioural and cognitive deficit (rather had protective effects on cognition) for all variables considered.	<u>Behaviour</u> Low: no risk Moderate, heavy/binge: low risk <u>Cognitive</u> Low, moderate, heavy/binge: no risk
a. Larkby b. 2011 c. USA	a. Cohort (prospective) b. 592	Prenatal interview	Conduct disorder at age 16 years	Behaviour	Diagnostic Interview Schedule-IV	Prenatal alcohol use associated with significant conduct disorder. For mothers who drank ≥1 in the 1st trimester, 36% of their adolescents had conduct disorder as compared to 16% adolescents whose mothers did not drink in 1st trimester (Fisher's exact =14.7, $p = 0.002$). Third trimester drinking was not a risk factor for conduct disorder	Low, moderate and heavy: Risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
a. McGee b. 2008 c. USA	a. Case-control b. 147	Caregiver report, maternal self-report, medical/social/legal records	Concept formation	Cognition	Wisconsin Card Sorting Test and California Card Sorting Test	Impaired concept formation in children was associated with heavy consumption of alcohol during pregnancy	Heavy: risk
a. McGee b. 2009 c. USA	a. Case-control b. 51	Maternal self report, medical/social/legal records	Language performance	Cognition	Clinical Evaluation of Language Fundamentals-preschool version	Children exposed to alcohol had impaired receptive and expressive language abilities compared to controls (Mean 92.76 versus 106.27, effect size = 0.98)	Heavy: risk
a. O'Callaghan b. 2007 c. Australia	a. Cohort (prospective) b. 5,139	Prenatal and ante-partum interview	Attention, learning and intellectual ability at 14 years	Behaviour and cognition	Subscale of the Child Behaviour Checklist, Wide Range Achievement Test – Revised and Raven's Standard Progressive Matrices Test	Consumption of <1 glass/day in early or late pregnancy not associated with any adverse outcomes. Alcohol exposure of ≥1 glass/day in late pregnancy associated with increased prevalence of learning difficulties and was more marked in adolescents whose mother binge drank (Raven score <85, 1 SD)	<u>All outcomes</u> Low : no risk Moderate, Heavy: low risk Binge : risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
a. O'Leary b. 2009a c. Australia	a. Cohort (prospective) b. 1,739	Post-partum postal questionnaire	Delayed language development in 2-year-old infants	Cognition	Communication scale from the Ages & Stage questionnaire	Low levels of prenatal drinking not associated with language delay at any period as compared with controls. Increased risk observed for moderate-heavy and binge pattern of drinking in 3rd trimester.	Low: no risk Moderate/heavy/ binge: risk
a. O'Leary b. 2010c c. Australia	a. Cohort (prospective) b. 2,224	Post-partum postal questionnaire	Child behaviour at 2, 5 and 8 years	Behaviour	Child Behaviour Checklist questionnaire	Low level of prenatal drinking was not associated with infant's behaviour problems. Heavy drinking in the first trimester was associated with increased odds of internalised behaviour problems including anxiety/ depression, somatic complaints (aOR = 2.65; 95% CI 1.36 – 5.14). Moderate level of drinking also increased the odds of anxiety/ depression (aOR = 2.24; 95% CI 1.16 – 4.32)	Low: no risk Moderate/heavy/ binge: risk
a. Robinson b. 2010	a. Cohort (prospective) b. 2,370	Prenatal interview at 18 weeks and 34	Child behaviour at over 2, 5, 8, 10 and 14	Behaviour	Child Behaviour Checklist questionnaire	Light drinking in first trimester was associated with significant lower z-scores (low scores means better outcome) in infants across the 14	Low, Moderate: no risk Heavy: risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
c. Australia		weeks	years			years of follow-up as compared to abstainers (-0.12, 95% CI, -0.23, -0.01). Heavy drinking was associated with higher CBCL scores.	
a. Rodriguez b. 2009 c. Denmark and Finland	a. Cohort (prospective) b. 21,678	Prenatal questionnaire	ADHD of children between 7 and 15 years	Behaviour	Strengths and Difficulties Questionnaire	After adjusting for smoking and social adversity, prenatal alcohol consumption was not related increased risk of child's inattention or hyperactive symptoms	Low: No risk
a. Sayal b. 2007 c. UK	a. Cohort (prospective) b. 9,086	Prenatal postal questionnaire	Childhood mental health problem between ages 4 and 8 years	Behaviour	Strengths and Difficulties Questionnaire	First trimester drinking of <1 drink/week was associated with increased clinically significant mental health problems in girls at about 4 years (OR = 1.45; 95% CI, 1.01 -2.10). Association remained with time.	Low: Risk
a. Sayal b. 2009 c. UK	a. Cohort (prospective) b. 6,355	Prenatal interview	Childhood mental health problem between ages 4 and 8 years	Behaviour and cognition	Strengths and Difficulties Questionnaire and Wechsler Preschool and	Consumption of ≥4 drink/occasion was associated with childhood mental health problems (adjusted regression co-efficient = 0.46, *p*=0.002). Association was greater in	Childhood mental health Binge: risk IQ Binge: no risk

a. First author b. Year of pub c. Country	a. Type of study b. Sample size	Measure of alcohol exposure	Main outcome	Category of outcome	Measure of outcome	Main findings	Inference based on level or pattern of drinking reported
			and IQ at 4 years		Primary Scale of Intelligence	girls than in boys.	
a. Willford b. 2006 c. USA	a. Cohort (prospective) b. 638	Prenatal interview	IQ at 10 years	Cognition	Stanford-Binet Intelligence Test	African-American women but not Caucasian, who drank in their first and second trimester had infants who were at increased risk of experiencing cognitive problems.	Low: no risk Moderate, heavy: risk Binge: no risk
a. Zammit b. 2009 c. UK	a. Cohort (prospective) b. 6,356	Prenatal and post partum postal questionnaire	Psychotic symptoms at 12 years	Behaviour	Psychosis-like Symptoms Semi-structured Interview (PLIKS)	Maternal alcohol use in pregnancy was associated with suspected or definite PLIKS (aOR = 1.19, 95%CI, 0.97-1.45). First trimester but not third trimester, alcohol use was associated with increased risk of PLIKS.	Low, Moderate, heavy: risk

2.7.8 Summary of the evidence

Based on effect size, magnitude and number of studies, a summary of the evidence and types of fetal outcomes is presented in Table 2.7.

Table 2.7 A summary of the evidence of prenatal drinking and categories of fetal or infant outcomes

Drinking level or pattern	OUTCOME								
	FASD Including FAS	Spontaneous abortion	Stillbirth	IUGR/ SGA	Low birth weight	Preterm	Cryptorchidism	Neurodevelopmental	
								Cognition	Behaviour
Low	X	—	?	X	X	X	X	X	?
Moderate	X	—	?	?	?	?	X	✓	✓
Heavy	✓	—	✓	✓	✓	✓	?	✓	✓
Binge	—	X	✓	✓	?	✓	✓	?	✓

Key
✓ = evidence of risk
X = no evidence of risk
? = inconclusive evidence of risk
— = data unavailable to determine risk

2.8 Discussion

This review found no evidence of risk regarding the effects of low levels of prenatal drinking on fetal outcomes. There is some evidence pertaining to the effects of moderate drinking on neurodevelopmental outcomes and consistent evidence of risks in relation to higher levels of drinking (heavy and binge) on almost all fetal outcomes considered. The evidence was robust for nuerodevelopmental outcomes, mainly because it contributed over 50% of the total studies assessed in this review. The specific neurodevelopmental outcomes principally prone to alcohol teratogenicity were

attention, conduct problems and psychiatric disorders. The findings regarding the inconsistent effects of low and moderate prenatal consumption concur with the findings of Henderson et al. (2007b). However, this review found evidence of neurodevelopmental risk of prenatal moderate drinking. For binge drinking, there was a consensus between the findings of this review and the findings of Henderson et al. (2007a) of possible effects on neurodevelopmental outcomes. In addition this review found consistent evidence of effects of binge drinking for stillbirth, IUGR/SGA, preterm and cryptorchidism. The differences observed between the findings of this review and those of Henderson et al. (2007a; 2007b) may represent a new evidence of the effect of alcohol on these outcomes but I cannot preclude the possibility that the results may be due to differences in definitions of drinking categories used.

Drinking during the first trimester of pregnancy was found to be particularly harmful to the fetus. Many women will continue to drink into their first trimester while they are unaware of their pregnancy thus drinking at this stage may generally be higher as compared to the period when pregnancy is well recognised. With the fetus being more susceptible at this stage, the effects of alcohol could be profound (Whitty and Sokol, 1996; Niimi, 2008). It has also been noted that first trimester self-reports of drinking may be more reliable as women tend to accurately report their drinking behaviour during the period when pregnancy is unconfirmed (Chang et al., 1998). Therefore, it is possible that for studies that relied on retrospective account of pregnant women, the women might have admitted to first trimester drinking or reported them more accurately than second or third trimester alcohol intake.

The absence of evidence regarding binge drinking in some of the outcomes examined may not necessarily be evidence of no effect. Most women who continue to drink in pregnancy drink at low-moderate levels and only few binge drink (Plant, 1984; Hamlyn et al., 2002). Consequently, in this review most studies had few participants under this category resulting in studies which were unable to perform analysis for this drinking group (Mariscal et al., 2006) or lacking sufficient power to detect significant associations (O'Leary et al., 2009a). In addition, some studies determined alcohol exposure based on the average number of drinks per week (Aliyu et al., 2008; Rodriguez et al., 2009). This has the potential to mask the effects attributable to binge pattern of drinking on the outcome of interest because peak blood alcohol level is an important determinant of teratogenecity (Abel and Hannigan, 1996).

It could be argued that the number of pregnancies resulting in miscarriages, spontaneous abortions and stillbirth may possibly lead to underestimation of congenital anomalies associated with prenatal drinking. Often studies examining outcomes other than these outcomes, exclude women who experienced these conditions or possibly these women may be unwilling to participate in research immediately after losing a baby. Yet it could be likely that fetal exposure to alcohol may be involved in the miscarriage or spontaneous abortion and these numbers may be unaccounted for in subsequent analysis. This hypothesis could be supported by Abel's (1997) review that found a very high rate of spontaneous abortion among alcoholic women. In this current review, one study reported a 4.2% prevalence of spontaneous abortion and stillbirth among the sample of women studied yet, only about 1% reported binge drinking (Stranberg-Larsen et al., 2008). Taking into consideration the adverse outcome of their pregnancy, women may be likely to underreport alcohol levels to avoid blame.

Most accounts of alcohol exposure of included studies in this review were ascertained through self-report. However, whether the accounts were underestimated or overestimated depend on the country where the study was conducted because social norms may have an influence (Rodriguez et al., 2009). For instance, Chiaffarino et al. (2006) argued that in Italy, alcohol is socially accepted and there is generally dearth of clinical recommendations to abstain from alcohol during pregnancy. Therefore, women are likely to provide good self-report of alcohol use. This could imply that in countries like Scotland where recent guidelines strongly promote no alcohol use in pregnancy, women may underestimate their consumption when pregnant. Some studies tried to minimise reporting and recall bias by collecting alcohol exposure data prospectively (Jaddoe et al., 2007). It could be postulated that if systematic underreporting was common among these studies, then higher forms of drinking might have produced the adverse outcomes observed in this review.

Alcohol consumption measures differed across country and this reflected on how studies categorised alcohol levels or patterns. This could have an impact in terms of comparability of findings across studies and should be taken into account when interpreting the results of this review. One standard drink (unit) of alcohol is equivalent to 8g of pure alcohol in the UK, 10g in Australia and 12g in Denmark (International Centre for Alcohol Policies, 2007). There were varied definitions across studies in terms of defining alcohol categories. This was noticeable between and even within countries. For instance, Barr et al. (2006: 1062) (USA) defined binge as "5 or more drinks on at least one occasion". Dodge et al. (2009: 1629) (USA) and Sayal et al. (2009: 289) (UK) both defined it as "4 or more drinks per occasion". Lack of uniformity makes it difficult to determine the exact drinking threshold beyond which an effect could manifest.

2.8.1 Limitations of the review methodology and primary studies

The systematic approach utilized in this review ensured that the available published literature was searched and synthesised in a comprehensive and thorough manner. Because of this, expert opinion and 'grey' literature were not included, although it is recognised they can both provide valuable evidence.

Although this review employed a widely used CASP checklist to assess study quality, it is recognised that using a different checklist might have rated studies differently. Yet it is unlikely that the difference could have been considerable because there is some degree of commonality between quality appraisal checklists especially on key quality indicators. All the items in the CASP tool used for assessing the quality of observational studies have three answer options – yes, no and can't tell - with the exception of two items. The first asks - what are the results of the study? Then, it itemises the important aspects to consider as follows:

What are the bottom line results?

Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?

How strong is the association between exposed and outcome?

What is the absolute risk reduction?

The second question asks - how precise are the results? And prompts -

Look out for the size of confidence intervals.

For the purpose of this review, I made minor revisions to these two items on the CASP tool. I categorised studies into one of the three answer options above – yes, no and can't tell - depending on how well they satisfied the criteria in the further details section outline by that item. This facilitated the award of quality score to studies and aided comparison between studies.

All the items in the CASP tool used for assessing the quality of observational studies have three answer options – yes, no and can't tell - with the exception of two items. The first asks - what are the results of the study? Then, it itemises the important aspects to consider as follows:

What are the bottom line results?

Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?

How strong is the association between exposed and outcome?

What is the absolute risk reduction?

The second question asks - how precise are the results? And prompts -

Look out for the size of confidence intervals.

For the purpose of this review, I made minor revisions to these two items on the CASP tool. I categorised studies into one of the three answer options above – yes, no and can't tell - depending on how well they satisfied the criteria in the further details section outline by that item. This facilitated the award of quality score to studies and aided comparison between studies.

This review used a free text terms and not Medical Subject Headings (MeSH) search terms. Free text terms search has the advantage of picking up keywords entered by authors regardless of the context they have been used. It can generate a large number of papers, which many may not be completely relevant to the topic under investigation. MeSH searching is more precise and tends to retrieve papers, which are more relevant to the topic. MeSH searching has the advantage of picking up the majority of papers on a topic irrespective of the different keywords used by authors. A weakness of using MeSH searching is that as the index terms are added by hand, mistakes are sometimes

made, and there may be a time lag of up to three months before an article is indexed. As this review was concerned with including the most recent evidence of the effects of alcohol on the fetus, relying on a MeSH search would have missed the most recent research. Nevertheless, it is recognised that using free text terms may have missed a small proportion of relevant papers but this is unlikely as I also carried out a comprehensive search through bibliographies of included studies.

Limited number of studies reporting on certain outcomes, for example, with only two studies reporting outcomes on stillbirth and spontaneous abortion, it could be argued that the evidence for these outcomes may be weak as compared to neurodevelopmental outcomes, which were evaluated by 21 studies originating from different countries with varied study designs. Nevertheless, the two studies that reported on stillbirth and spontaneous abortion used very large sample sizes and these may well represent robust evidence in their own right. It is important to note that certainty of the findings in this review largely depended on the size and quality of study as well as the aggregate number of studies reporting on an outcome. Varied cut-off points across studies that were used to categorise alcohol consumption levels means it was impossible to convert drink measures into a standard one (example UK alcohol category system) to enhance uniformity.

2.8.2 Implications for research, policy and practice

In the face of such inconsistent findings relating to lower levels of drinking, it is not surprising that healthcare providers and women are still sceptical about specific fetal effects of prenatal drinking. More consistent reporting would be useful. Therefore, more research; monitoring specific adverse fetal outcomes of prenatal drinking, particular low-moderate drinking levels would be helpful to further advance the evidence base. Estimating daily average of alcohol use in pregnancy may be more useful than reporting

average per week. This may help avoid classifying drinking status erroneously but help ascertain direct outcomes attributable to specific patterns of consumption in pregnancy. It could be useful for international organisations, for example the WHO to champion international definitions or uniform measures of alcohol across the globe to enhance comparability and generalizability of alcohol consumption data across countries. This uniformity may also facilitate the quest to establish the exact threshold of prenatal drinking that fetal damage could occur.

2.9 Conclusion

The inconsistent findings relating to moderate level of drinking means the effects on the fetus of prenatal alcohol consumption at this level are still uncertain. For women who wish to drink while pregnant, current available information about levels of drinking and their specific corresponding risks to the fetus could be provided.

The absence of objective marker for prenatal alcohol exposure meant ascertainment of levels or patterns of consumption presented studies with challenges that translated as the main limitation among all included studies. Perhaps, this is typical of research conducted in the field of prenatal alcohol use. As Plant (1985: 50) admitted, "there is probably no such thing as the perfect study in the alcohol-related field because the alleged association between maternal drinking during pregnancy and fetal harm is particularly a difficult area to conduct research".

2.10 Key features

The following propositions resulted from this systematic review:

- The uncertainties regarding the effects of low and moderate levels of drinking in pregnancy may influence attitudes and drinking behaviour in pregnancy.

- The adverse effects of drinking in first trimester is profound as compared to second and third trimester drinking and may presents challenges to the timing of screening and ABI delivery.

- Midwives knowledge and understanding of risk could influence their attitudes and have an impact on the priority they accord to identification and delivery of ABI to pregnant women.

3. 0 Chapter Three - Alcohol brief interventions: evidence of effectiveness

3.1 Introduction

This chapter is divided into two parts. The first part is a systematic review of reviews of alcohol brief interventions (ABIs) across four different healthcare settings. It begins by outlining the main features of a systematic review of reviews and the rationale for this type of review within the context of this thesis. It also reports on the evidence of effectiveness of ABIs and discusses potential differences in the application of the interventions across healthcare settings of primary care, accident and emergency department (A&E), antenatal care settings and general hospital settings. Where necessary, rationales for the use of some procedures and tools or decisions made are provided. Finally, the results of the included reviews are presented, followed by discussions of the result and the implications for the current study.

The second part comprises of detailed discussions of ABI-specific primary studies within antenatal care settings. This part is especially necessary as it complements the systematic review of reviews and helps in the ascertainment of programme theories.

3.2 Part 1: The effectiveness of ABI to change drinking behaviour in health care settings: a systematic review of reviews

3.2.1 Rationale for synthesising evidence from systematic reviews

A review of reviews is a systematic review that includes only other reviews. It follows the same procedures of systematic review (see section 2.2). It provides an overview of the research evidence in a particular topic area by bringing together all systematic reviews (Jepson et al., 2010). According to the Centre for Reviews and Dissemination (CRD) York, a systematic review of reviews is essential when examining a broad research question with several other systematic reviews already available in the subject area (CRD, 2009).

There are several systematic reviews published to assess the effectiveness of ABIs in various healthcare settings. Yet with many such setting-specific systematic reviews available, they have not been compiled and evaluated in any systematic way to assess whether there are differences in how the intervention works across a range of healthcare settings and the potential factors that account for these differences. For instance, whereas it is known that the settings and population groups may influence the effectiveness of ABIs, (Emmen et al., 2004; Scottish Health Action on Alcohol Problems, 2008), the dimension of the influence and its implications are unclear. For example, circumstances that may compel patients' attendance of primary care facility may be completely different from those attending emergency departments. As a result, it is likely that how an ABI may influence drinking behaviour change among these two population groups may differ.

The aim of this systematic review of reviews was to systematically collate and synthesize review level-evidence to determine effectiveness and the strength of

evidence of ABI to change drinking behaviour in health care settings. Overall, the objective of this systematic review was to help develop realistic evaluation programme theories.

3.2.2 Research questions

1) What are the differences in effectiveness and the strength of the evidence of ABI delivered in healthcare settings of primary care, Accidents and Emergency, antenatal care and general hospital?

2) Does ABI differ in effectiveness across sub-sections of healthcare populations?

3) What are the main factors that could influence the effectiveness of ABI and how do they differ by healthcare settings?

4) If ABI is identified to be effective, how long does it sustain abstinence or reduction of alcohol use?

3.2.3 Methods

3.2.3.1 Search strategy for identification of reviews

Pragmatically, it is impossible to identify all available research on a topic to include in a review (Aveyard, 2010). Yet, for review to use a systematic approach, it is recommended that a comprehensive attempt must be made to include the most relevant studies (Petticrew and Roberts, 2006; Aveyard, 2010). Accordingly, in this review effort was made to locate all relevant reviews. A predefined search strategy was developed and a computerised literature search was undertaken using Ovid databases of Medline (1996-2011), Cochrane Database of Systematic Reviews (CDSR) (2005-2011), ACP Journal Club (1991-2011) Database of Abstracts of Reviews of Effectiveness (DARE), Embase (1996-2011) and psycINFO (1987-2011). DARE and CDSR databases were important for this review because they contain high quality reviews of

healthcare interventions. Searches were performed using free text terms. The search took into consideration the study design ('systematic review', 'meta-analysis' or evidence-based review), exposure (alcohol) and the intervention of interest (ABI) (see Appendix 6). The appropriate Boolean operators (OR, NOT and AND) were used to connect search terms. Further searches were also made in Google/Google search engine and by searching all reference lists of included studies and also, from my own bibliographic resources. The search results were downloaded into Reference Manager and de-duplicated.

3.2.3.2 Inclusion criteria

Retrieved reviews were considered if:

1) they were systematic review or meta-analysis;

2) evaluated the effectiveness of ABI or data on ABI was reported separately from other interventions;

3) conducted in healthcare settings or with healthcare population;

4) outcomes were related to change in drinking behaviour; prevention or reduction in alcohol consumption and; promotion of moderate drinking or abstinence;

5) were published between January 1999 and January 2011 – this time frame was chosen because it is likely that the evidence beyond this period are either out of date or high quality primary studies are likely to be included in recent reviews.

3.2.3.3 Exclusion criteria

Reviews were excluded if:

1) they considered only dependent drinkers;

2) they did not report alcohol misuse outcomes separately from other substance use disorders;

3) data or studies reviewed were reported in another review;

4) not published in the English language (only English language papers were included due to limited time and resources).

3.2.3.4 Review selection

A preliminary screening of all retrieved items was carried out in Reference Manager. Any review title that was outside the topic of interest was eliminated. It is recommended in systematic approach to review that at least two reviewers rather than one must independently assess studies for inclusion to eliminate the subjective decision to include or exclude studies (Aveyard, 2010). In this regard, one of my supervisors (Helen Cheyne (HC) and I independent scrutinised abstracts of the remaining papers and selected reviews that met the inclusion criteria. Any differences were resolved in consultation with a second supervisor (Ruth Jepson (RJ). This was often done by obtaining and reading the full text of the paper copy. However, if there were two or more reviews published in the same area or covered same primary studies, one with the highest quality score (see Table 3.1 for quality criteria checklist) or the most current were selected (see Appendix 7).

3.2.3.5 Quality assessments

The reviews were assessed for quality to determine the appropriateness of the design and methods and assess the validity and strength of the evidence. The rationale for assessing quality is to identify potential sources of bias that could affect the results of the included reviews. Assessments of bias therefore recognise and score reviews that

have transparent and replicable methodological and analytical procedures (Jepson et al., 2010). I independently assessed all reviews that met the inclusion criteria for quality and twenty percent (20%) checked by one of my supervisors (RJ). Any disparities were resolved through discussions. The published checklist (Table 3.1 and 3.2) for review originally developed by NICE (2006) and revised by Jepson et al. (2010) was adapted to guide the quality appraisal phase of this review. Judgement of level of evidence of each included review was based on indication of likelihood of bias (e.g. ++) and for the type of evidence it reviewed (e.g. 1). So for instance, a high quality systematic review of only RCTs will be assigned 1++.

3.2.3.6 Data extraction and analysis

An electronic data extraction form was designed, piloted with several relevant reviews, and was revised. I then extracted data from each included review onto this form. Two other supervisors (RJ and HC) independently reviewed about 10% of the extracted data from individual studies. Data extracted include study details, settings, main findings and quality criteria.

A narrative approach was taken to synthesis the findings of the included studies and no meta-analysis was conducted because it is deemed inappropriate for this type of review because of limited access to original data sources (Jepson et al., 2010). The results are provided based on health caresettings to enhance intra and inter comparability of findings among reviews, and particularly to facilitate explanatory accounts.

Table 3.1 Criteria used for appraising included reviews

	Answer	
Criteria	**Yes (1)**	**No (0)**
1. Was there a focused aim or research question?		
2. Explicit inclusion / exclusion criteria		

3. More than 1 assessor / selector		
4. Provide details of databases searched		
5. Lists years searched		
6. Followed up references in bibliographies		
7. Experts consulted for further sources		
8. Grey literature included / searched		
9. Specified search terms / strategy		
10. Not restricted to English language papers only		
11. Quality assessed		
12. Data supports conclusions		

Note:
++ a review must answer yes to at least 10 criteria indicated above
+ a review must answer yes to at least 7 criteria indicated above
- a review did not meet the 7 criteria necessary for + classification

Table 3.2 Type of evidence score of included reviews

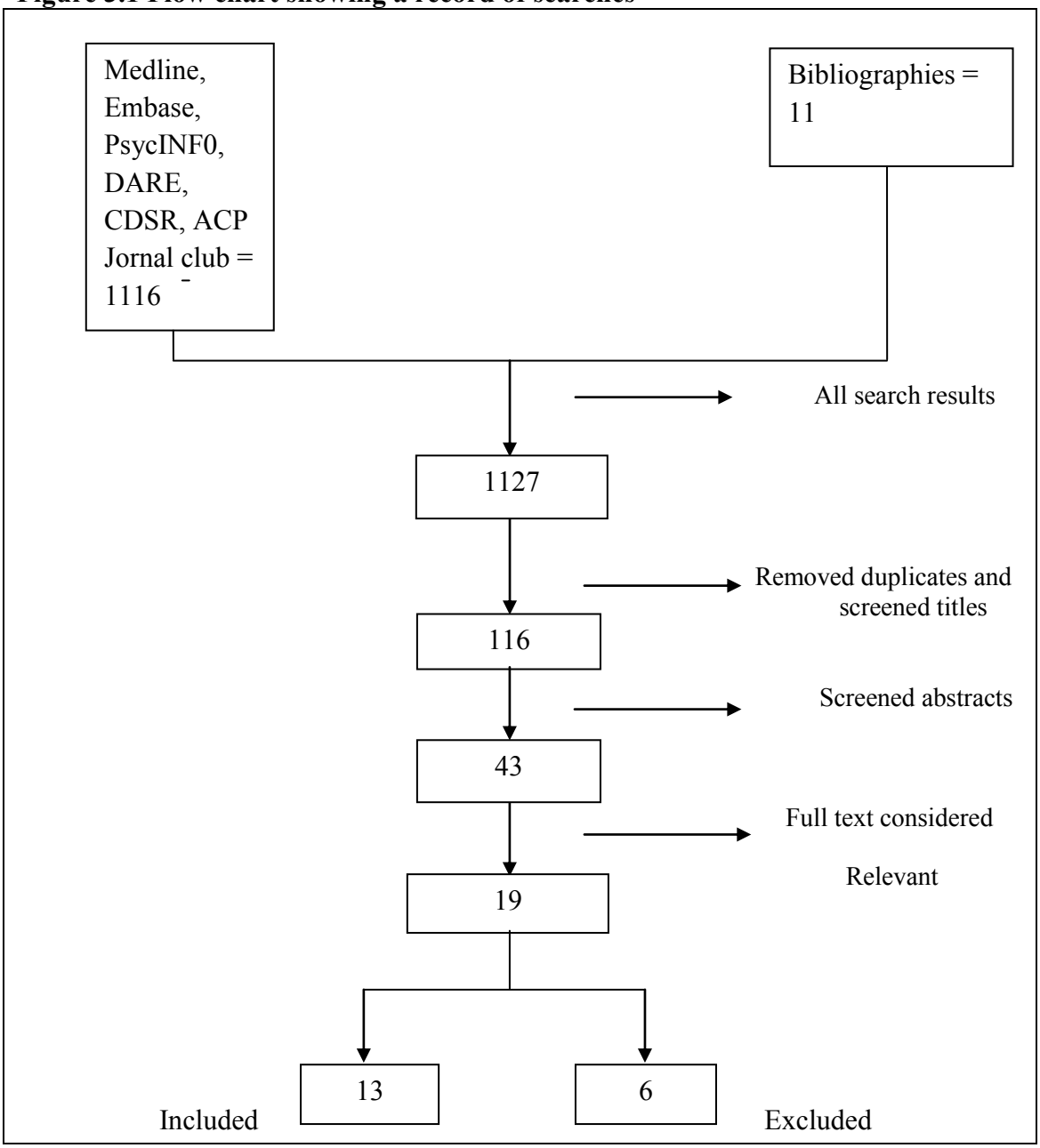
Classification	Type of evidence
1	Systematic reviews of RCTs
2	Systematic reviews of individual, non-RCTs, case–control studies, cohort studies, controlled before-and-after (CBA), interrupted time series (ITS), correlation studies
1&2	Systematic reviews of **both** RCTs and non-RCTs, case–control studies, cohort studies, controlled before-and-after (CBA), interrupted time series (ITS), correlation studies

3.2.4 Results

3.2.4.1 Results of the search

Searches of the databases and bibliographies resulted in 1127 reviews (Figure 3.1). After removing duplicates and screening of titles and abstracts, 43 articles were retained and reviewed in full. After full-text consideration, 13 studies were finally included in this review. A brief summary of these reviews is shown in Table 3.3.

Figure 3.1 Flow chart showing a record of searches



3.2.4.2 Excluded reviews

Following full text consideration, thirty articles were excluded with reasons (see Appendix 7 for references and specific reasons for exclusion). The common reasons for exclusion were:

1. Reporting on the same studies that have been covered by an included review.
2. Review not systematic review or meta-analysis.
3. A more recent or better quality review available.

3.2.4.3 Reviews included: details, settings and target populations

The included reviews considered both RCTs and non-RCTs of varying numbers. Moyers et al. (2002) covered the highest number of individual studies (56). Whilst Ballesteros et al. (2004b) included only seven studies in their meta-analysis.

Of the thirteen reviews included in this systematic review of reviews, two evaluated ABI in antenatal care settings (Stade et al., 2009; Gilinsky et al., 2010); four in primary care (Ballesteros et al., 2004a; Ballesteros et al., 2004b; Bertholet et al., 2005; Kaner et al., 2009); three in emergency department or A&E (D'Onofrio and Degutis, 2002; Havard et al., 2008; Nilsen et al., 2008) and the remaining four reviews in general hospital settings (Moyer et al., 2002; Emmen et al., 2004; Vasilaki et al., 2006; McQueen et al., 2009). Kaner et al. (2007) review was updated in 2009, and the most recent review was used. For the purpose of this study, all reviews that focused on healthcare populations but unclear or included settings of interest in addition to other non-healthcare settings were considered under general hospital settings. For instance, one study (Vasilaki et al., 2006)

although predominantly included studies that targeted health care population, yet included students. D'Onofrio and Degutis (2002) also noted that although their target population was primarily A&E patients, the limited number of studies available to them compelled them to expand their review to encompass data covering other population groups, including students and hospitalized adults.

The target populations for the included review were varied. Primarily, the reviews targeted healthcare populations drinking at hazardous or harmful levels. Reviews that focused mainly on ABI for dependent drinkers were excluded in this study. Because this group have more severe alcohol problems, they usually require specialist addiction treatment and do not qualify within the tenet of ABI as brief and opportunistic intervention (Heather, 2004). However, some included reviews (Moyer et al., 2002; Vasilaki et al., 2006; Gilinsky et al., 2010) considered studies with all types of participants regardless of their drinking status, including dependent drinkers. On the other hand, other reviews (Havard et al., 2008; Stade et al., 2009) specifically excluded studies that focused on dependent drinkers.

Table 3.3 Interventions to reduce alcohol use in different healthcare settings

a. First Author b. Year	No. of studies included	Type of review	Target population	Setting	Study objective	Main results	Conclusion	Quality rating
a. Stade b. 2009	4 (only 3 were ABI)	Systematic review	Pregnant women or women planning pregnancy (But included studies only had pregnant women)	Antenatal	Was to determine the effectiveness of psychological and educational interventions to reduce alcohol consumption during pregnancy	Results favoured abstinence of alcohol in pregnancy but there were no significant differences between groups.	(+) effect of psychological and educational (including ABI) interventions. Heterogeneity between studies limits ability to determine the type of intervention which would be most effective.	1++
a. Gilinsky b. 2010	8 (only three were ABI)	Systematic review	Pregnant women (drinking any amount of alcohol, including dependent drinkers)	Antenatal	Was to consider additional evidence by including RCTs and non-RCTs to determine whether pregnant women reduced alcohol consumption during pregnancy following interventions delivered during antenatal care.	There was some evidence from a small number of studies that single session face-to-face ABIs resulted in positive effects on the maintenance of alcohol abstinence during pregnancy. Women choosing abstinence as their drinking goals and heavier drinking women who participated with a partner were more likely to be abstinent at follow-up.	(+) effect but more intensive interventions may be required to encourage women who continue to drink during pregnancy to reduce their consumption.	1&2+

a. First Author b. Year	No. of studies included	Type of review	Target population	Setting	Study objective	Main results	Conclusion	Quality rating
a. Bertholet b. 2005	19	Systematic review with meta-analysis	Primary care but not seeking help for alcohol related problems	Primary care	Was to evaluate the evidence of efficacy of ABIs aimed at reducing long-term alcohol use and related harm.	8 studies reported a significant effect of intervention. The adjusted intention-to-treat analysis showed a mean pooled difference of −38 g of ethanol (95% CI −51 to −24g/wk) in favour of ABI. No difference between genders	(+) Effect of reducing alcohol consumption at 6 and 12 months.	1+
a. Ballesteros b. 2004a	13	Systematic review with meta-analysis	primary care patients	Primary care	Was to assess the efficacy of BIs as applied in primary care settings by using estimates for the decrease in the proportion of hazardous drinkers.	ABIs outperformed minimal interventions and usual care (random effects model OR = 1.55, 95%, CI 1.27–1.90; RD = 0.11, 95% CI 0.06–0.16; NNT = 10, 95%, CI 7–17). No clear evidence of a dose-effect relationship	(+) Effect though moderate	1+
a. Ballesteros b. 2004b	7	Systematic review with meta-analysis	primary care patients	Primary care	Was to update former evidence on differential gender effectiveness of ABIs for harmful alcohol consumption.	Standardized effect sizes for the reduction of alcohol consumption were similar in men (d = - 0.25; 95% CI - 0.34 to -0.17) and women (d = - 0.26; 95% CI - 0.38 to - 0.13). The odds ratios (OR) for the frequency of individuals who drank below harmful levels were also similar (four studies; OR for men = 2.32;	(+) Effect among genders and differences negligible	1-

a. First Author b. Year	No. of studies included	Type of review	Target population	Setting	Study objective	Main results	Conclusion	Quality rating
						95% CI 1.78–2.93; OR for women = 2.31; 95% CI 1.60–3.17).		
a. Kaner b. 2009	29	Systematic review with meta-analysis	Primary care patients	Primary care	Was to assess the effectiveness of ABI to reduce alcohol consumption. To assess whether outcomes differ between trials in research settings and those in routine clinical settings.	At follow-up of one year or longer, intervention group reduced alcohol intake than control group (mean difference: -38g/week, 95% CI -54 to -23. Sub-group analysis confirmed the benefit of ABI in men (mean difference: -57g/week, 95% CI -89 to -25, I2 = 56%), but not in women (mean difference: -10g/week, 95% CI -48 to 29. Little evidence of a greater reduction in alcohol intake with longer treatment exposure or among trials which were less clinically representative	(+) Effect and was clear in men, but not in women. The lack of evidence of any difference in outcomes between efficacy and effectiveness trials (suggests that the current literature is relevant to routine primary care.)	1++
a. Nilsen b. 2008	14	Systematic review	Injury patients	A&E department	Was to review findings concerning the effectiveness of providing ABI in these settings and to explore factors contributing to its effectiveness	Overall, there was a general trend of reduced alcohol intake, particularly among ABI patients than control patients. Interventions that are more intensive tended to yield results that are more favourable.	(+) Effect but to some extent inconclusive	1&2+

a. First Author b. Year	No. of studies included	Type of review	Target population	Setting	Study objective	Main results	Conclusion	Quality rating
a. Havard b. 2008	13	Systematic review with meta-analysis	A&E Patients	A&E department	Was to critique the methodological adequacy of studies and to conduct a meta-analysis to examine the extent to which interventions (ABIs) in this setting are effective in reducing alcohol consumption and related harm.	Meta-analyses revealed that interventions did not significantly reduce subsequent alcohol consumption, but were associated with approximately half the odds of experiencing an alcohol-related injury (OR = 0.59, 95% CI 0.42–0.84).	Inconclusive evidence of ABI to reduce subsequent alcohol intake but (+) Effect in reducing subsequent alcohol-related injuries.	1&2+
a. D'Onofrio b. 2002	39	Systematic review	Diverse including inpatient, outpatient, and college settings,	A&E department	Was to systematically review the medical literature in order to determine the strength of the recommendation for screening and ABI for alcohol-related problems in the emergency department setting	A positive effect of the intervention was demonstrated in 32 studies.	(+) Effect	1&2+

a. First Author b. Year	No. of studies included	Type of review	Target population	Setting	Study objective	Main results	Conclusion	Quality rating
a. Moyer b. 2002	56	Systematic review with meta-analysis	Treatment seeking and non-treatment seeking	Unclear	Was to compare ABIs with both control conditions and extended treatment, and by summarizing effects across different categories of drinking related outcomes at multiple follow-up points	For studies comparing ABI to a control group in non-treatment seeking population, small to medium aggregate effect sizes in favour of ABIs emerged across different follow-up points. At >3–6 months, the effect for ABIs compared to control conditions was significantly larger when individuals with more severe alcohol problems were excluded. For studies comparing ABI with extended treatment in treatment seeking samples, the effect sizes were largely not significantly different from zero.	(+) effect of ABI in non-treatment-seeking samples.	1&2-
a. Emmen b. 2004	8	Systematic review	Problem drinkers in general hospital (opportunistic identification)	General hospital (hospital or specialist outpatient clinic)	Was to determine the effectiveness of opportunistic brief interventions for problem drinking	Only one study, with a relatively intensive intervention and a short follow up period, showed a significantly large reduction in alcohol consumption in the intervention group.	Inconclusive evidence	1&2++

a. First Author b. Year	No. of studies included	Type of review	Target population	Setting	Study objective	Main results	Conclusion	Quality rating
a. Vasilaki b. 2006	15	Meta-analysis	Students and different patient groups	Mixed (College, out-patient, A& E and general hospital settings)	(1) Was to examine whether or not motivational interviewing (MI) as ABI is more efficacious than no intervention in reducing alcohol consumption; (2) was to examine whether or not MI is as efficacious as other interventions.	Among the 9 studies that compared ABI with no treatment, the aggregate effect size was 0.18 (95% C.I. 0.07 - 0.29), but was greater 0.60 (95% C.I. 0.36 - 0.83) when, in a post-hoc analysis, the follow-up period was three months or less. Its efficacy also increased when dependent drinkers were excluded. Another 9 studies compared ABI with another treatment (aggregate effect size = 0.43(95% CI. 0.17 - 0.70), indicating that ABI is more efficacious that other interventions.	(+) Effect; about 87 minutes of MI as ABI reduces hazardous drinking in the short term	1&2+
a. McQueen B. 2009	11	Systematic review with meta-analysis	Hospital in-patients	General hospital ward	Was to determine whether ABIs reduce alcohol consumption and improve outcomes for heavy alcohol users	As compared to a control group, participants who received ABI, significantly reduced their alcohol intake per week (SMD -0.18; 95% CI -0.33 to -0.03). However, at 6 months follow-up there was no statistically significant difference between the control and intervention group (p=0.27).	Inconclusive evidence, though it appears that alcohol consumption could be reduced at one year follow up	1++

3.2.4.4 Methodological quality of included studies

Most of the reviews included in this study were of high quality with low risk of bias. From the 13 articles reviewed, four (31%) met NICE (2006) criterion for excellent methodology. Seven reviews (54%) also achieved good methodological quality. Only two studies (Moyer et al., 2002; Ballesteros et al., 2004b) were judged to have weak methodological quality (-). The common methodological deficiencies were lack of grey literature inclusion and reporting only English language studies.

Overall, the level of evidence of the reviews could be described as moderate. For 38% (1++ or 1&2++) of the reviews, the level or strength of the evidence was high. Also, 46% (1+ or 1&2+) could be deemed as well conducted so had good level of evidence.

3.2.4.5 Antenatal care

Two reviews (Stade et al., 2009; Gilinsky et al., 2010) evaluated the effectiveness of a range of interventions, including ABI, a self-help manual, supportive counselling and high feedback ultrasound aimed at reducing alcohol use in pregnancy. Neither review conducted meta-analysis, citing substantial dissimilarities in the interventions and outcome measures between included studies as the reason. They (Stade et al., 2009; Gilinsky et al., 2010) also expressed concern about the methodological deficiencies of included studies. Stade et al. (2009) showed that there was moderate evidence that psychological and educational interventions (ABI inclusive) have positive effects of reducing alcohol use in pregnancy. Although, Stade et al. (2009) provided no clear definitions of ABI neither did they provide findings specifically for ABI. Yet implicitly, it could be inferred that most of the interventions described were ABIs.

Gilinsky et al. (2010) on the other hand, were clear that there was some positive evidence of effect of single session face-to-face ABI to maintain abstinence during pregnancy. They also showed that ABI had positive effects for women who preferred

abstinence as their drinking goal and women participating with a partner. However, Gilinsky et al. (2010) concluded that for women who continue to drink in pregnancy, intensive interventions maybe more appropriate.

3.2.4.6 Primary care

Ballesteros et al. (2004a; 2004b), Bertholet et al. (2005) and Kaner et al. (2009) evaluated the effectiveness of ABI to reduce drinking levels among primary care patients. All four reviews carried out meta-analyses. Overall, there was evidence that ABI was effective in changing drinking habits among primary care patients. At follow-up of one year or longer, a high quality review (Kaner et al., 2009) found that the ABI group reduced their consumption more than the control group (mean difference: -38 grams/week, 95% CI -54 to -23).

There was inconclusive evidence as to whether the effectiveness of ABI was sensitive to gender. Kaner et al. (2009) showed that ABI had more significant impact of reducing alcohol intake in men (mean difference: -57 grams/week, 95% CI -89 to -25, I2 = 56%), than women (mean difference: -10 grams/week, 95% CI -48 to 29, I2 = 45%). However, Ballesteros et al. (2004b) and Bertholet et al. (2005) found no evidence of differential impact of ABI between the genders. There was no clear evidence of dose-response relationship between the intervention modalities (degree of intensity of ABI and type of provider) and drinking outcomes. A single review (Kaner et al., 2009) showed that ABI is equally effective under research settings (efficacy) as in clinical settings (effectiveness).

3.2.4.7 Accident and emergency (A&E)

Among the three reviews that evaluated effectiveness of ABI in A&E settings (D'Onofrio and Degutis, 2002; Havard, et al., 2008; Nilsen et al., 2008), there seemed to be inconclusive evidence regarding its effectiveness to reduce drinking outcomes.

Nilsen et al. (2008) reported that 11 of the 14 included studies in their review reported significant effects of the intervention on at least one of the outcomes considered, including alcohol intake, alcohol related negative consequences and injury frequency. D'Onofrio and Degutis (2002) also showed that 90% of their included studies reported that ABI was effective in reducing alcohol intake, although the authors acknowledged that A&E specific studies were limited in number in their review.

The only meta-analysis included under A&E category (Havard et al., 2008) found that ABI was not effective in reducing participant's subsequent (12 months follow-up period) alcohol consumption, although it was effective in reducing alcohol-related injuries (odd ratio = 0.59, 95% CI, 0.42 - 0.84). It is important to note that, the authors considered a number of interventions broadly as ABI. These include counselling (some incorporating motivational interviewing techniques) and non-counselling intervention (computer-based interventions). Generally, the reviews indicated that considering the circumstances of A&E patients, it is likely that direct observation of participants drinking behaviour could stimulate behaviour change, which may translate in positive effects (Hawthorne effects) in both control and intervention groups.

3.2.4.8 General hospital settings

Moyer et al. (2002); Emmen et al. (2004); Vasilaki et al. (2004); and McQueen et al. (2009) evaluated the effectiveness of ABIs to reduce alcohol consumption among different populations mainly presenting to general hospital settings. Overall, there was evidence of a small effect for ABIs in reducing alcohol intake, although the evidence was derived from heterogeneous population groups. For instance, among in-patients heavy drinkers, McQueen et al. (2010) showed that compared to a control group, ABIs reduced, though not significant, the amount of alcohol consumed per week by 69 grams at 6 months follow up. However, at one year of follow-up, the standard mean difference

of alcohol consumption showed that the intervention group significantly reduced their consumption more than the control group (SMD -0.18; 95% CI, -0.33 to -0.03). Emmen et al. (2010) also found that among the eight studies considered for their review, only one study reported a significant effect of ABIs to reduce alcohol intake. They explained that for that study, the intervention was relatively intensive and the follow-up period was short. In addition, the treatment was biased to favour the intervention group.

There was some evidence that ABI was effective in both treatment seeking and non-treatment seeking populations (Moyer et al., 2002; Vasilaki et al., 2006). Moyer et al. (2002) found that when considering hazardous and harmful drinkers alone, in non-treatment seeking patients, ABI was effective in significantly reducing drinking related outcomes as compared to a control group at more than three months follow-up. However, when ABI was compared to the extended treatment in treatment seeking population, the effect sizes were found not to be significantly different from zero. Similarly, Vasilaki et al. (2006: 328), showed in their meta-analysis that "the aggregate effect size of ABI was 0.18 (95% C.I. 0.07 - 0.29), but was greater 0.60 (95% C.I. 0.36 - 0.83) when, in a post-hoc analysis, the follow-up period was three months or less". They indicated that the efficacy of the intervention increased when dependent drinkers were excluded, in treatment seeking samples. Moyer et al. (2002) also reported no differential gender benefit of ABI.

3.2.5 Discussions of findings

3.2.5.1 Summary of main findings

This systematic review of reviews evaluated the effectiveness of ABIs on alcohol consumption across different healthcare settings and features likely to affect their outcome. Thirteen reviews were included.

The primary outcome measure was change in alcohol consumption. This review showed that there was consistent evidence that ABIs were effective in primary care settings. All the four reviews in the primary care category found positive effects of ABIs on alcohol consumption. The numbers of primary studies included in individual reviews were also many, strengthening the evidence.

There was some evidence that ABIs were effective in general hospital and in antenatal care settings. The evidence from antenatal care settings, although positive, relied on a very limited number of primary studies, rendering the evidence tentative concerning its robustness. The effectiveness of ABIs among antenatal care population was also strongly linked to fidelity to certain conditions for example; involvement of a partner, or the ABI ensuring that abstinence was maintained for women who planned to abstain.

The evidence in A&E was inconclusive in terms of reducing drinking outcomes but was rather effective in reducing subsequent alcohol related injuries. In general hospital settings, ABI benefited both patients seeking treatment (especially low alcohol dependent) and those not seeking treatment for alcohol problems.

3.2.5.2 Gender

The result on the effectiveness of ABI on gender was interesting. In primary care settings, of the three reviews that reported data on gender (Ballesteros et al., 2004b; Bertholet et al., 2005; Kaner et al., 2009), only one high quality review (Kaner et al., 2009) found a differential effectiveness of ABI in favour of men. Men, generally drink at high levels as compared to women (Shaw, 1980; Thom, 1994); therefore, it is likely that any reduction in drinking among males could be more marked as compared to women. It has been reported that as compared to women, men are likely to delay seeking medical attention for health-related conditions (Adamson et al., 2003).

Therefore, it is possible that those that presented to their general practitioners' had considerable medical related problems. So, to prevent long-term risk factors, assistance to reduce alcohol intake would be more welcomed and could explain the considerable impact ABI had on their drinking behaviour.

3.2.5.3 Duration of effectiveness

The evidence that ABI could reduce alcohol intake at one year among primary care and general hospital in-patients populations (Kaner et al., 2009; McQueen et al., 2009) is an important one. Although this points to the view that regular reinforcement could be needed to sustain a long-term drinking behaviour change in certain patients. The period up to which ABI could exert its influence on drink reduction or abstinence among antenatal care populations was unclear. But if this was a possibility among antenatal care populations, then it would mean that considering the nine months window of fetal development, delivering ABI to pregnant women early in the first trimester could reduce drinking to non-hazardous levels or possibly abstinence, reducing *in-utero* fetal exposure. Women who would like to go back to drinking could then do so after delivery. This could particularly appeal to women who plan not to breast feed. However, for those who would like to, booster ABI could be offered at breast-feeding clinics. As alcohol intake during breast-feeding also has adverse outcomes for infants as it may be associated with reduced lactation, infant sleep disorder, and adverse impact on infant's motor development and influence early learning about alcohol (Mennella, 2001).

3.2.5.4 Assessment or screening

In this review, it was clear that assessment alone reduced alcohol intake among 'no treatment' control groups. This is encouraging for practices that wish to implement universal alcohol screening for ABI. Since most people deny or report lower alcohol

consumption in the presence of health practitioners, offering screening alone may produce positive outcomes, resulting in improved health. There was however, an interesting observation from one of the A&E reviews. McQueen et al. (2009) observed that at six months of follow-up there was no difference at the level of reduction of alcohol consumption between control and ABI groups. However, the difference was significant at 12 months in favour of the ABI group. It is likely that the screening might have caused the control group to also reduce their drinking levels for the short-term. However, at the long-term the ABI might have sustained drinking behaviour change among the intervention group.

3.2.5.5 Study design and ABI definitions

About 62% of the reviews conducted meta-analysis albeit based on few selected studies out of the overall number of studies. For instance, of the nineteen studies that were considered for Betholet et al. (2005) review, only ten were included in their meta-analysis. None of the two reviews, conducted with antenatal population carried out meta-analysis. The majority of the reviews cited significant heterogeneity[1] between studies as the reason for not conducting meta-analysis.

Besides, the definition of the term ABI was found to be problematic. Nilsen (2008: 198) argued that although most studies label their interventions as "brief interventions", there was significant differences in study protocols as to what actually constitute the term "brief interventions" (ABI). In this review, it was observed that some reviews considered multitudes of interventions, like computer-based approaches, educational leaflets and self-help manuals simply as ABI. Implicitly, there were differences in terms of types, duration and intensity of the interventions. Often 10 - 15 minutes with a

[1]Heterogeneity describes a variety of approaches, comparison groups and outcomes in studies

patient is described as ABI and anything over may be categorised as extended ABI. There are also single session and multi-session ABIs. Heather (1995) argued that the effectiveness of ABIs should be linked to the type of investigations and with the populations used. The wide variety of interventions broadly categorised as ABI masks the actual impact of drinking reduction that could be associated with specific ABI strategy, limiting generalization.

3.2.5.6 Robustness

The variation in the number of primary studies included in the different reviews need to be considered when interpreting the results of this review. The numerous numbers of RCTs and non-RCTs conducted with primary care populations means that reviewers were able to limit their review to only include the 'gold standard' studies, enhancing the subsequent evidence based. However, for some other settings, for example in antenatal care settings, in terms of ABI, only two RCTs and one cluster randomised trial were included in the two included reviews. Looking at these two scenarios it would be logical to conclude that conclusions drawn from primary care based reviews are likely to be more robust than the antenatal care based reviews where the primary evidence base is sparse.

3.2.5.7 Potential limitations

One limitation of systematic review of reviews is its inability to offer depth account in specific areas (Jepson et al., 2010). However, it could be argued that under this circumstance, it offered an insight into the different ways in which ABIs had been employed to elicit drinking behaviour change across a range of healthcare settings, thus offering comparability. However, to compensate for lack of adequate details of the intervention components within the reviews, ABI-specific primary studies in antenatal care settings had been thoroughly reviewed in the second part of this chapter.

This review relied on papers that have reviewed primary studies. As such, based on the reviews, I was limited by interventions that the authors had considered as ABI. For some of them it was clear that definition of ABI was lowered to include interventions that may not generally be considered ABI. For example, Emmen et al. (2004) considered audio-visual presentations as ABI but because they have broadly categorised them together with other interventions as ABI it had to be included in this review.

The nature of this review meant it was impossible to combine data to provide pooled estimates. This would have been particularly useful to provide summary effect sizes for settings, facilitating the comparison of effectiveness of ABI across settings. The process also minimises potential reviewer bias (Petticrew and Roberts, 2006). Nevertheless, this would have been problematic considering the fact that none of the reviews from antenatal care setting conducted meta-analysis, because of substantial heterogeneity that existed among primary studies. Besides, this review made explicit all reviews that provided such summary measures and offered them appropriate recognition.

3.2.5.8 Implication for research, this thesis and practice

In the primary care settings, ABI has been evaluated extensively. However, looking at the paucity of RCTs that evaluate effectiveness of ABI in antenatal care settings and considering the fact that the ones available are all US based, the generalizability of ABI study findings to UK antenatal care populations is unclear. More so, healthcare systems and drinking guidelines differ across countries. There is therefore an urgent need for research in antenatal care settings to evaluate ABI effectiveness from other countries and possibly further evaluate the findings that inclusion of a partner enhances the effectiveness of the intervention. The observation that screening alone reduces alcohol consumption in control groups is encouraging. This is because in healthcare settings

where often time for consultation is limited, universal screening, to some extent, could be relied upon to produce positive drinking behaviour change.

The programme theories that can be deduced from this review are outlined at the end of this chapter.

3.2.6 Conclusion

Ten of thirteen systematic reviews and meta-analysis found evidence to support the use of ABI to reduce alcohol consumption among a range of health care populations. Although the robustness of the evidence varies across settings, there is evidence that ABI is more effective than no intervention to reduce alcohol consumption. Whereas in settings, for example primary care, extended delivery of ABI has no added benefits, in antenatal care setting, booster components may be required for hazardous and harmful drinkers to reduce alcohol consumption.

3.3 Part 2: Critical review of primary studies of ABI amongst antenatal populations

3.3.1 Background

The two systematic reviews in the antenatal setting indicated the effectiveness of ABI in reducing alcohol consumption, and possibly, alcohol related fetal effects (Stade et al., 2009; Gilinsky et al., 2010). However, both reviews examined a spectrum of interventions (including high feedback ultrasound techniques and self-help manual strategy) that have been employed to reduce alcohol use in pregnancy and did not provide depth account of ABI specific studies. Moreover, both raised concerns about the poor methodological qualities generally found among included studies. As the purpose of this stage of the thesis is to formulate programme theories of how the ABI might work in Scottish antenatal care, it was germane to thoroughly review the empirical intervention studies found by the two systematic reviews. The focus of this

part of the thesis was to include published studies that had specifically evaluated ABI effectiveness to change drinking habits among antenatal populations. Aside from searching the bibliographies of the above named reviews, an additional search was carried out specifically in Medline and Google to check for any new studies, but no studies were found. The rationale for this part of the thesis was to examine factors likely to influence the effectiveness of the intervention, taking into account the internal validity within each study.

Four intervention studies were retrieved that have examined ABI in pregnant women (Chang et al., 1999; 2000; 2005; O'Connor and Whaley, 2007). All were from the US. Chang et al. (2000) only provided additional information on an aspect of an included study (Chang et al., 1999) and therefore both references were considered as one study. The first study (Chang et al., 1999) provided the main data for this review but the second study (Chang et al., 2000) also provided supplementary data to this review where necessary. Overall, two RCTs and one cluster-randomised trial were included in this critical review. Table 3.4 provides details of the studies.

Table 3.4 RCTs of alcohol brief interventions in antenatal settings

a. First author b. Date of publication c. Country	a. Population b. Settings	Objectives	Person delivering intervention	Intervention details	Main findings	Vital quality criteria
a. Chang b. 1999 c. USA	a. pregnant women. b. obstetric practice	Examined the impact of ABI on antepartum alcohol consumption	Researcher	Intervention group: - -Received comprehensive assessment -Assessment lasted for over 2 hours - Single session ABI lasted for about 45 minute -A take-home manual given to each participant - participants informed about US current recommendation of abstinence from alcohol during pregnancy - A follow-up interview conducted at about 2 months after delivery -Financial incentives given at assessment and follow-up Control group: - -A 2-hour comprehensive assessment only -Financial incentives given at assessment and follow-up	-Both groups reduced alcohol intake although the difference was not significant -Irrespective of study groups, the risk of antepartum drinking increased to about 3-fold among participants who drank in pregnancy before the study assessment -Among the 143 participants who were abstinent before the study assessment, the ABI group maintained higher rate of abstinence at follow-up (86% versus 72%, p = 0.04)	**Design** RCT **Sample size** 250 **Power Calculation** Not reported **Blinding** Yes **Concealment of allocation** Unknown **Method of randomisation** Computer assignment **Attrition** Low
a. Chang b. 2005 c. USA	Pregnant women at risk of prenatal alcohol use	Evaluated the effectiveness of ABI to	Researcher or Nurse practitioner	Intervention group:- -Received a comprehensive diagnostic interview - Involvement of a partner chosen by the woman	-Both the intervention group and control group reduced their alcohol consumption. - ABI group significantly reduced their alcohol intake during	**Design** RCT **Sample size** 304 **Power**

a. First author b. Date of publication c. Country	a. Population b. Settings	Objectives	Person delivering intervention	Intervention details	Main findings	Vital quality criteria
	and a support partner	reduce prenatal alcohol use when a chosen partner is included		-Partners assessment of participant alcohol use done separately -Women received a 25-minute single-session ABI - intervention consisted of a knowledge assessment and feedback; goal setting; behaviour modification strategy; and a summary for participants - Financial incentives given to participants, including support partners at assessment and follow-up -Control group:- -Received diagnostic interview only - Financial incentives given to participants at assessment and follow-up	pregnancy, especially for women who drank more at the beginning of the study (regression co-efficient, b= -0.163, standard error (b)=0.063, $p<.01$). -Among women who drank heavily, the impact of ABI was significantly enhanced when the woman's support partner was involved (b=-0932, (b)=0.468, $p<0.05$).	**Calculation** Yes **Blinding** Yes **Concealment of allocation** Unknown **Method of randomisation** Computer assignment **Attrition** Low
a. O'Conner b. 2007 c. USA	a. Women drinking during pregnancy b. community settings	Assessed the effectiveness of ABI in helping low-income minority women achieve abstinence	Trained nutritionist	Intervention group:- -Received comprehensive assessment of alcohol use -Received a standardized workbook-driven ABI, that included education and feedback, cognitive-behavioural procedures, goal setting, and contracting Control group:-	-Compared with the control group, ABI group were 5-times more likely to be abstinent by the third trimester [OR = 5.39; 95% CI 1.59-18.25] - ABI did not have a significant effect or interaction with gestational age -A statistically and clinically	**Design** Cluster RCT **Sample size** 255 **Power Calculation** No **Blinding** No

a. First author b. Date of publication c. Country	a. Population b. Settings	Objectives	Person delivering intervention	Intervention details	Main findings	Vital quality criteria
		from alcohol during pregnancy		- Received a comprehensive assessment of alcohol use -Advised to stop drinking during pregnancy. - No financial incentive mentioned	significant condition and initial level interaction ($F_{1, 194}$=3.59, P < 0.06) favoured the ABI group on infant birth weight -Infant birth length also yielded a statistically significant interaction between conditions and initial consumption level, $F_{1, 194}$= 4.48, P < 0.03. -There was low rate of fetal death in the treatment group (0.9%) as compared to the control group (2.9%).	**Concealment of allocation** Not possible **Method of randomisation** centres randomised into the treatment and control groups **Attrition** high

3.3.2 Main study findings

Chang et al. (1999) conducted an RCT with 250 pregnant women who have used alcohol during either pregnancy or at least six months prior to pregnancy. After a comprehensive assessment of the control group, and an assessment plus ABI for the intervention group, they found that both groups had reduced their consumption at follow-up of two months after delivery and the differences between the groups were not significant. This result implies that the ABI provided no additional benefit than the assessment only approach. In a further study by same authors (Chang et al., 2000) but focusing on the 123 women that constituted the intervention arm of the previous study (Chang et al., 1999), the authors examined the significance of drinking goal setting on the drinking behaviour of pregnant women. They found that women who identified abstinence as their ante-partum drinking goal were more likely to be abstaining from alcohol at the time of study enrolment. Also, current drinkers who identified abstinence as their goal, reduced subsequent prenatal alcohol consumption. Furthermore, current drinkers who named FAS as a reason to abstain decreased their subsequent alcohol use.

Chang et al. (2005) found that ABI was effective in reducing alcohol consumption in pregnancy, particularly among women who consumed more at study enrolment. The study demonstrated the importance of involving a woman's support partner in ABI. The partner was any other supportive adult who was aware of her health habits and had been chosen by the woman. The factors that were found to increase the risk of prenatal drinking included amount of alcohol use in pregnancy before study enrolment, level of education, number of years of regular use of alcohol and decreased ability to manage temptation to drink in social situations. For heavy-drinking women, the ABI was more effective when a partner participated.

O'Connor and Whaley (2007) examined the effectiveness of ABI among pregnant women from low-income communities. Their design was a cluster-randomised trial, where twelve centres were randomised to six each of ABI and control groups. The intervention was a multi-session ABI approach. At the third trimester of follow-up, they showed that pregnant women who received ABI reduced their consumption level by up to five times less than the control group, although the control group also reduced their alcohol intake. Infants whose mothers received ABI also had favourable neonatal outcomes.

3.3.3 Assessment of risk of bias in trial design

Methodological robustness is essential to minimise biased results in RCTs (Schulz et al., 2010). Critical review of how the risk of bias was accounted for by the individual studies is discussed below. The critique was facilitated by the CONSORT statements for reporting individual and parallel group RCTs (Schulz et al., 2010) and cluster randomised trials (Campbell et al., 2004).

3.3.3.1 Assessment and recruitment

All the studies reported that assessment only reduced alcohol consumption in the control groups. It seemed they all provided thorough assessment for the control group. In the RCT by O'Connor and Whaley (2007), the participants in the control group received a comprehensive assessment of alcohol use and were advised to stop drinking during pregnancy. The monthly repetition of assessment or ABI to women found to be still drinking seemed ethical but might have introduced assessment effects and a possible performance bias into the study as unequal treatments were given to segments within groups (Adjetunmobi, 2002; Schulz et al., 2010). This was instituted in both groups. However, regular advice to the members of the control group found to be still drinking though ethical was likely to reduce the magnitude of the effect size.

Subsequently, it was no surprise when the result at follow-up showed that both groups substantially reduced their drinking levels even though it was more marked in the intervention group than in the control group. Hawthorne effects could also be employed to explain the reduction of alcohol use by the control group. Because the realisation that someone's drinking habit is being monitored could be likely to induce behavioural changes to conform to acceptable norms although participants had not directly received the active intervention. This could be profound particularly regarding prenatal alcohol consumption. Similarly, Chang et al. (1999) provided a 2-hour long alcohol assessment to the control group, including the use of several screening tools. Chang et al. (2005) used T-ACE screening tool to identify participants into their study. Screening or assessment procedures to the control group under these circumstances was necessary to confirm drinking levels but had the potential to mask the full effects of an intervention by exerting an intervention effect and prompting participants to reconsider their risky health behaviour.

3.3.3.2 Randomization

O'Connor and Whaley (2007) conducted a cluster randomised trial aimed to prevent potential contamination between participants and present a balanced randomization. One weakness with this design is that randomization of centres rather than individuals may result in non-comparable groups at baseline (Anderson et al., 2004). Albeit they did mention that, all participants were of low-income backgrounds. Randomisation was however, conducted after individuals within groups consented to participate in the study, reducing the risk of post-randomisation selection bias. In addition, O'Connor and Whaley (2007) used the centres as units of randomization and the intervention was targeted at the cluster level, so it was appropriate that outcomes were calculated at the cluster level (Campbell et al., 2004; van de Vijver et al., 2008). All the studies (Chang

et al., 1999; 2005; O'Connor and Whaley, 2007) reported a balanced number of participants randomized into intervention and control groups and comparability of groups at baseline with respect to the variables of interest. This ensured that no group had undue advantage and confounding factors had equal chance of occurring in each group (Adjetunmobi, 2002).

3.3.3.3 Concealment of allocation

Concealment of allocation to groups was not possible in O'Connor and Whaley's (2007) trial because it was cluster RCT. Yet, how Chang et al. (1999; 2005) concealed participants' allocation into groups was unclear. Nevertheless, it is worth noting that inadequate allocation concealment could cause selection bias by influencing participants' assignment to study groups by investigators.

3.3.3.4 Blinding

Only Chang et al. (1999) indicated that research assistants who conducted the follow-up interview were blind to the result of the initial assessment. O'Connor and Whaley (2007) did not report of any blinding of outcome assessors. The inclusion of a support partner in the intervention arm of Chang et al. (2005) study meant it was practically impossible to blind outcome assessors. However, to minimise bias they reported that structured tools were used to collect data and they used different research assistants for diagnostic and follow-up interviews. Lack of adequate blinding might have introduced observer bias.

3.3.3.5 Staff administering intervention

All the trials used dedicated project staff to deliver the intervention. O'Connor and Whaley (2007) used trained nutritionist to administer the intervention to participants. The ABI approach was integrated into existing practices of the nutritional care. To enhance the quality of the measurement, nutritionists were required to attain 100%

reliability before administering all the components of the intervention to study participants. O'Connor and Whaley (2007) used audiotapes during the delivery of the interventions, which acted as a staff training resource. However, this approach had the tendency to promote socially desirable answers because participants may have felt vulnerable because their account of alcohol consumption during pregnancy was being recorded. Hence, Chang et al. (1999; 2005) realised the potential flaw with the approach and avoided it in their trials.

3.3.3.6 Methods for detecting drinking levels

All studies reviewed (Chang et al., 1999; 2005; O'Connor and Whaley, 2007) relied on retrospective self-report of alcohol use. This is prone to recall bias and participants may have distorted their drinking levels. Objective measures such as biological markers are problematic in detecting prenatal alcohol use (see section 1.6). As such, participants are often required to give a retrospective account of their drinking habit.

3.3.3.7 Attrition and follow-up

Chang et al. (2005) reported a very low attrition of 5% although they did not report on the differences in the rate attributed to intervention and control group. Nevertheless, that could not have had a substantial impact on the results considering the high follow-up rate. Similarly, Chang et al. (1999) reported an excellent follow-up rate of 99%. The high rate of follow-up in both studies could be attributed to the provision of financial incentives to study participants. Chang et al. (1999) gave $50 for participating in the assessment and $75 for follow-up. Participants in Chang et al. (2005) study received $50 for assessment and $100 for follow up. At assessment, it was likely that participants might have overestimated their drinking level as they might have felt that negative results could indicate ineligibility. Similarly, at follow-up since participants were aware of the rationale of the study, the incentives might have incited the provision of desirable

answers to the investigators. However, it is unclear which direction the effects would be overestimated. The attrition reported by O'Connor and Whaley (2007) was high in both groups (24.6%, control; 27.6% brief intervention). However, for those lost to follow-up their treatment conditions of alcohol risk or consumption level was not significantly different from those who remained. However, Edwards and Rollnick (1997) showed that among primary care population participating in ABI study, those who remain in studies are most susceptible to the intervention. If this, to some extent, could be extrapolated to antenatal populations, it means the effect of O'Connor and Whaley (2007) intervention could possibly be overestimated. On the other hand, it is possible that the reduced sample size resulting from attrition affected the power of the study, thereby reducing the magnitude of the effect size, particularly its being cluster randomised design. Nevertheless, no intention-to-treat analysis was performed to compensate for the lost to follow-up.

3.3.3.8 Power and Outcome

O'Connor and Whaley (2007) did not report on how sample size was determined in their trial although the sample size of 255 at assessment seemed adequate for detecting potential outcome differences between groups. However, an increased number of participants would have been more appropriate considering the cluster randomised trials design they employed, especially when Chang et al. (1999) and Chang et al. (2005) used 250 and 304 participants respectively in their individual RCTs. As compared to individually or parallel group RCT, cluster randomised trials require increased sample size in order to obtain equivalent statistical power (Campbell et al., 2004).

3.3.4 Summary

The findings imply that screening or assessment only may be enough to reduce drinking in some pregnant women. For the majority of women who drink in pregnancy, extended

or multi-session ABIs and inclusion of a booster component, such as involvement of a partner may be necessary to enhance ABI effectiveness. Involvement of dedicated project staff may also be a necessary requirement to help pregnant women reduce alcohol consumption. However, this may prove to be a challenge in practice where resources are limited.

The methodological qualities in Chang et al. (1999; 2005) could be described as adequate although the provision of substantial financial incentives to participants had slight potential to bias the results of the studies. The methodological quality of O'Connor and Whaley (2007) was inadequate, and the high attrition meant caution should be exercised in interpreting their findings.

3.4 Key features

The following propositions resulted from the reviews:

- Screening only has the capacity to reduce alcohol consumption to some extent.
- Trained, support and dedicated personnel are essential for effective screening and ABI delivery.
- Pregnant women who drink at high levels are likely to change behaviour when a booster component, such as inclusion of a partner, allowing adequate time for delivery or employing multi-session approach.

4. 0 Chapter Four: Methodological discussions and methods

4.1 Introduction

This study employs realistic evaluation research methodology and the current chapter discusses in depth the approach taken. The rationale for the chosen design and methods are discussed, and the procedures involved with recruitment and primary data collection are presented. Interconnected with data collection is the issue of ethics, and this is discussed in some detail. A reflection of how the fieldwork proceeded is also outlined. The chapter concludes with the methods and procedures used for analysing the qualitative data generated by the study.

4.2 Research paradigms and methodology

One of the features of research is to identify the methodological approaches that inform it (Groenewald, 2004). It is necessary therefore, to give a brief overview of the methodological issues involved in undertaking this study and their philosophical basis. Prior to this, it is important to define the term 'methodology', which is often confused or interchanged with the term 'methods'.

Appleton (2009: 20) gave an explicit definition of both terms:

*"**Methodology** is the rationale and philosophy underpinning the study design and its execution, including the researcher's ontological or epistemological perspective and **method**, is a specific data collection and analysis technique, such as systematic reviews, surveys or focus groups".*

This, therefore, implies that methodology underpins the choice of research methods for collecting data. Yet, methodological issues rest on the researcher's theoretical

perspective of ontology (the nature of existence) and epistemology (what is it possible to know about the world and how can it be known) (Corbin and Strauss, 2008). Patton (2002) indicated that theoretical positions should not be the main drivers for research. However, Green and Thorogood (2009) argued that employing theoretical perspective in research enhances the transparency or reliability of research findings by informing the research questions asked, and how the researcher intends answering them.

In relation to ontology, Snape and Spencer (2003: 11) identified three distinctive categories based on the assumption of social reality and, its construction. First, materialism, which acknowledges that there is a real world yet "only material features, such as economic relations or physical features of that world" constitute reality. The second is idealism, and it assumes that "reality is only knowable through the human mind and through socially constructed meanings". Realism is the third branch of ontology and positions itself within epistemological poles of positivism and relativism (Rycroft-Malone et al., 2010). It presumes that there is an external reality, which exists, independent of our beliefs and understanding, and that events, and experiences are triggered by underlying mechanisms and structures, which may be described (Bhaskar, 1975). Its distinctive feature is that it places emphasis on generative causal explanations and uses such explanatory strategies to further scientific knowledge (Pawson and Tilley, 1997). A variant of realism, critical realism, forms the theoretical basis of realistic evaluation (Wilson and McCormack, 2006; Marchal et al., 2010) and is discussed below.

4.2.1 Critical Realism

Byng et al. (2005) noted that critical realism is often attributed to the works of Bhaskar and colleagues. It is a philosophical approach that combines realist ontological and

relativist epistemological perspectives (Isaac, 1990 quoted in McEvoy and Richards, 2003). Critical realists concur with the interpretivists' view of causation in relation to the cause and effect explanation to social phenomena. They consider that variables that reflect facts are conceptual interpretations and the correlation between variables should be regarded as descriptions rather than explanations of causal relations in themselves (Cruickshank, 2003). They also agree with positivists that the social world is observable and exists independently of our representation of it (Cruickshank, 2003; Denzin and Lincoln, 2005). In addition, they agree with the post-positivist view that scientific observations are fallible since the scientists operating within that conceptual framework influence them (McEvoy and Richards, 2003).

However, critical realists oppose positivists on the basis that, critical realists suggest that social phenomena are meaningful and should be constructed socially, therefore they cannot be subjected to measurements. Critical realists also believe that the role of the researcher is to contribute to the construction of a narrative rather than aiming to discover the truth (Cruickshank, 2003). Overall, they posit that reality consists of strata and that scientific enquiry should be concerned with analysis of the mechanisms, processes, and structures that account for the patterns observed rather than emphasizing on statement of regularity (Denzin and Lincoln, 2005).

McEvoy and Richards (2003) outlined four distinctive features of critical realism. The first, and perhaps most important, is that critical realists' focus of scientific enquiry is to obtain knowledge about mechanism of causation based on generative principles or mechanisms (Byng et al., 2005). Generative mechanisms are the structures, powers and relations that offer explanation to how things work, discovering if they have been activated and under what condition, yet they are non-observable and are only

recognised through their effects (McEvoy and Richards, 2003; Wilson and McCormack, 2006). Secondly, critical realists assert that it is necessary to recognise the multi-layers of reality through which various mechanisms of causation operate, including the influence of environment and social behaviour. Thirdly, they acknowledge the interdependence between social structures and human agency. Social structures provide the resources for individuals to operate, yet under certain circumstances, individuals are able to manipulate the social structures in which they operate (McEvoy and Richards, 2003). Finally, critical realists offer a critique of prevailing social order and are not necessarily committed to a specific theory.

4.2.2 Realistic evaluation

Realistic evaluation is a theory-driven approach to evaluation of social programmes, developed by Pawson and Tilley (1997) in response to recent interest in understanding how interventions or social programmes work rather than emphasizing on whether they work or not (McEvoy and Richards, 2003; Pawson, 2006). Pawson and Tilley (1997) asserted that weaknesses in the previous experimental format of evaluation necessitated the introduction of a realistic approach to evaluation. The weaknesses included the 'Martinson problem', which refers to the tendency of experimental evaluations to produce conflicting results, and the 'black box problem' which describes the overemphasizing of programme outcomes rather than interrogating, what 'mechanisms' are acting to produce which 'outcomes' and within what 'context' (Pawson and Tilley, 1997: 30; Gill and Turbin, 1999). These weaknesses resulted in a situation where much of the emphasis on causation focussed on cause-and-effect relationships. Pawson and Tilley (1997) argued that programmes are often introduced within complex social systems, which are in constant transformation, therefore evaluation needs to take account of the settings within which it is implemented. Wilson and McCormack (2006)

explicitly explained that mechanisms of causation always occur within a particular context and it is important to understand their relationship. The tenet of realistic evaluation therefore, is to understand what makes a programme work, for whom, how and under what circumstances. Alternatively, it describes, what mechanisms (ideas and opportunities) cause which outcome patterns (whether a programme works or not) and in which context (social and cultural conditions). This is often denoted as context (C) and mechanism (M) and Outcome (O) configuration or CMO configuration and it is represented as:

Context + Mechanism = Outcome

4.2.2.1 Context

Context is described as the pre-existing conditions within which a programme or public health intervention is implemented (Marchal et al., 2010). Because these conditions are pre-existing they are significant because they may facilitate or impede the intended mechanism of change of the embedded intervention. In other words, context dictates how a programme operates. Therefore, whether an intervention works or not is largely, dependent on the contextual factors. However, context does not just imply locality. Pawson (2006) identified four areas of contextual factors that may influence the implementation of an intervention. They are the capabilities of key actors; the interpersonal relationships that develop in the locality within which the intervention is implemented (e.g. lines of communication in the organisation); the institutional settings (culture, rules, routines); and wider contexts (national policies, guidelines, social rules).

4.2.2.2 Mechanism

Mechanism is the main arm of the CMO framework on which realistic evaluation revolves (Pawson and Tilley, 1997; Pawson, 2002). Mechanism explains what aspects of the system enable it to produce change (Pawson, 2006). They are therefore the

drivers or factors of the intervention that influence change or bring about an effect. Pawson and Tilley (1997) defined it as the process by which participants interpret and act upon the intervention components. Wand et al. (2010) further described that mechanisms refers to the reasons, decisions and choices people make when confronted with an intervention. Overall, Pawson and Tilley (1997) identified the three main features of a programme mechanism. First, it should reflect the concept that the programme is embedded within layers of social reality. Thus, it should take account of the point that it is through the conjunction of social structure and human agency within a complex social system to effects change. Secondly, "it (the mechanism) is expected to take the form of a proposition which will take account of how both macro and micro processes constitute the programme" (Pawson and Tilley, 1997: 66). Finally, it should be able to "demonstrate how programme outputs follow from stakeholders' choices (reasoning) and their capacity (resources) to put these into practice" (Pawson and Tilley, 1997: 66).

4.2.2.3 Outcomes patterns

Outcome patterns are the intended and unintended consequences of a programme emerging from the interaction between context and mechanism. Outcome patterns are varied and it is necessary that that programmes should be tested against a range of output and outcome measures including implementation variation, temporal outcome variations, and personal attribute outcome variations (Pawson and Tilley, 1997).

4.2.3 Strategies and methods of realistic evaluation

Realistic evaluation may employ quantitative or qualitative methods, but the choice of method is dependent on the hypothesis being tested and the availability of data (Pawson and Tilley, 1997). Yet, Maluka et al. (2011) noted that it has a predisposition towards qualitative methods. In this study, qualitative methods were utilized. As noted in

chapter one, considering the stage of the implementation of screening and ABIs in antenatal care settings, it was considered important for this study to focus on process rather than summative outcomes. If a quantitative research strategy had been employed, it would have been used to measure aspects such as 'perception', 'attitudes', 'intentions' and 'expectations', this would have been unlikely to cover the depth and richness required to explore fully participants' views and understanding of the issues relating to the research questions outlined in this study. Quantitative study methods would assume that concepts such as perception and attitude for enquiring about the social world are static rather than a process (Snape and Spencer, 2003). Moreover, a quantitative study method would attempt to code the social world based on predetermined operational variables, which would narrow the parameters of the subject and destroy valuable data (Marshall and Rossman, 2011).

Pawson and Tilley (1997) identified three stages of realistic evaluation enquiry. The first stage is the identification of the programme theory or consideration of a plausible CMO configuration. This involves the generation of concepts or ideas of contextual factors that are likely to influence the intervention or programme, identification of potential mechanisms and deciding on which programme outcome patterns should be considered (Byng et al., 2005). This stage may be informed by data sources such as literature review, policy document review as well as interviews with stakeholders and practitioners.

The next stage focuses on gathering appropriate data to interrogate the hypothesis formed in stage one. Based on the findings of the previous stage, some key individuals or institutions may be considered as important sources of data for this stage. The likely

source of the data may include administrative records, interviews, focus groups and surveys.

The final stage involves the assessment and interpretation of the analyses, determining whether theories about how the programme works are refuted or supported. The results are then used to revise the programme theories or initial CMO configurations and to build an explanation of the programme. Pawson and Tilley (1997) however, made an important observation that although realistic evaluation seeks to offer explanations based on the CMO propositions, it is often impossible to attend to all the elements in the proposition and there may be more elaboration of the findings on some particular sub-sets than others. Nevertheless, they explained that the findings of realistic evaluation should always identify the configuration of features needed to sustain a programme.

Several limitations of the realistic evaluation methodology have been noted in research practice. First and perhaps most importantly is that although the principles are clear in the text, the lack of adequate procedures regarding how its methodological enquiry should progress in practice presents a challenge regarding the operationalisation of the approach (Rycroft-Malone et al., 2010). Another limitation noted by Tolson et al. (2007) concerns the evaluation of an evolving programme. In this regard, they suggested that realistic evaluation does not provide adequate guidance about the appropriate time to construct a full CMO configuration. Gill and Turbin (1999) also indicated that while it is relatively easy to propose a plausible CMO configuration, obtaining relevant data for all three elements is difficult. Finally, and possibly the most common challenge that has been highlighted in several projects that have applied the

approach entails the difficulty involved in clearly distinguishing and defining 'context' and 'mechanism' (Gill and Turbin, 1999; Rycroft-Malone et al., 2010).

4.3 Setting the scene

NHS care in Scotland is provided through 14 regional health boards, which plan and deliver health services within their geographical jurisdiction, with overall policy directed by the Scottish Government Health Directorates (Cheyne et al., 2011). Participants for this study were recruited from one Scottish health board, NHS Lothian. The population of Scotland was estimated to be 5,254,800 in 2011 and with an estimated coverage of 848,727 individuals, NHS Lothian serves the second largest population group in Scotland (General Register Office for Scotland, 2012b).

Birth rate in Scotland in 2011 was 11.1 per 1,000 population, however this compares to NHS Lothian birth rate of 9.8 births per 1,000 population (General Register Office for Scotland, 2012b). Thus, NHS Lothian birth rate was slightly below the national birth rate. Overall, figures shows that between 2002 and 2010, the birth rate in Scotland increased by 4.3% (Scottish Government, 2011c).

Maternity care is a universal service provided to all women. There are only two maternity units in NHS Lothian, the Simpson Centre for Reproductive Health, based in the Royal Infirmary Edinburgh and St John's Hospital at Howden in Livingston. The Head of Midwifery provides professional and managerial leadership, supported by midwifery managers. There are also the supervisors of midwives. They have no managerial role but professional guidance and statutory regulatory roles, which are govern by the Nursing and Midwifery Council (Nursing and Midwifery Council, 2004). They provide guidance and support the practice of midwives in the area of safe practice and ensuring that they deliver a high standard of care. Within NHS Lothian, community

based midwives provide the majority of care to women during the antenatal and post-natal periods, involving the women's General Practitioner or Obstetrician as appropriate based on the woman's needs and local care pathways (NHS Lothian, 2011). These midwives are organised in eight geographically based community midwifery teams.

Midwifery care has traditionally had a public health role, recent Scottish Government policy has increased the public health focus of maternity care with the aim of encouraging midwives to assume a greater public health role in order to improve health and social wellbeing for all women and reduce health inequalities (Midwifery 2020 Programme, 2010a; Scottish Government, 2011b). This means that the community midwives' role has now become even more significant and demanding. Community midwives now have to deal with an increase in birth rate; facilitating some women's choice for homebirth; early postnatal discharge of women from hospital; increased awareness of child protection issues; women who have complex health and social care needs; women who are misusing alcohol and drugs; and the increase in numbers of migrant women who require the use of interpreter for antenatal appointments (Midwifery 2020 Programme, 2010a). Delivering these services often requires that more focus are placed on supporting the women and their families (Midwifery 2020 Programme, 2010a). However, Deery (2005) has argued that in spite of midwives being encouraged to provide supportive relationships to clients, they are not always adequately prepared for the supportive nature of their role. There have also been concerns that the organisational culture within the NHS may act as a barrier for midwives to realise their support needs (Kirkham and Stapleton, 2000). It is therefore imperative to highlight that it is in the midst of some of these issues and the increasing midwifery workloads that the screening and ABI programme was implemented.

4.4 Choice of study methods

As noted in the description of the realistic evaluation framework in chapter one, primary data sources for this study were generated through three participant groups - key policy implementers, pregnant women and midwives.

4.4.1 Primary data collection

In accordance with qualitative research methods, this study gathered primary data through in-depth interviews (semi-structured individual interviews) and a focus group (with midwives).

4.4.1.1 In-depth interviews

In-depth interviews are field tools that generate narratives on specific research topics (Miller and Crabtree, 1999). In-depth interviews are useful when researching sensitive and complex behaviours (Coombes et al., 2009). As such, this method was well suited for this study because the issue of drinking in pregnancy can be described as both sensitive and complex. Moreover, in-depth interviews offer the opportunity to generate rich qualitative data (Arthur and Nazroo, 2003).

In-depth interviews can be either unstructured or semi-structured interviews. In this study, semi-structured interviews rather than unstructured interviews were employed because with the semi-structured interview the researcher has a broad set of questions to explore by probing the interviewee to discover and expatiate upon relevant issues. In addition, the use of semi-structured interviews ensured that relevant issues were covered consistently across all participants within a group whilst also offering a degree of flexibility to discover participant-specific salient narratives (Arthur and Nazroo, 2003). It could be argued that even in the most unstructured interviews, interviewers still have key topics or themes that they aim to be explored during the interview (Arthur and Nazroo, 2003; Legard et al., 2003).

4.4.1.2 Focus groups

Focus groups are a qualitative research technique, which involve interaction and discussions between members of a group who are brought together for a particular purpose. Focus groups are socially oriented and assume that participants' attitudes and

beliefs are socially constructed during the interaction (Marshall and Rossman, 2011). Compared to other qualitative methods of data collection, focus groups have several advantages. Firstly, they use group dynamics to stimulate discussions (Bowling, 2009). As Foster-Turner (2009: 11) attested: "the purpose of a focus group is to encourage interaction among group members to promote self-disclosure in order to learn more about how they think and feel, and their attitudes and opinions". In this way participants have the opportunity to listen to each other's views and by that process, they construct their own ideas. More so, as the discussion progresses, participants' responses may become more focussed and refined, and this may move the discussion into greater depth (Finch and Lewis, 2003).

Another advantage of focus groups is that, through the process of group discussions the interviewer, due to limited interaction with participants, may have less influence on their opinions about the topic (Finch and Lewis, 2003). Finally, Foster-Turner (2009) acknowledged the importance of focus groups in evaluation research in the sense that they may be useful in monitoring the progress of service or policy change from different stakeholders' perspectives.

However, focus groups have their own challenges. The first is the power dynamics associated with a group setting. Power dynamics refer to the potential for over-domination of the group by one or two members of the group. To overcome this, Marshall and Rossman (2011) suggested that the interviewer must be conscious of this risk and facilitate the group well. Secondly, the issue of time is very important in focus group interviews. Time can be easily lost when participants discuss issues that are irrelevant to the topic. In addition, bringing individuals together for a focus group can be a difficult task, especially when the group is not pre-existing. Finally, analysis of the

data generated by focus groups could be problematic especially when context is required to be incorporated to understand participants' views (Marshall and Rossman, 2011).

4.5 Participants' selection

Quantitative and qualitative research methods have different approaches to sampling. Quantitative research is concerned with probability sampling with the goal of producing statistically representative samples, whilst qualitative research uses non-probability sampling intended to select participants who have particular features to facilitate depth exploration and understanding of the research theme (Ritchie et al., 2003). This study utilized mainly purposive sampling as well as a snowballing technique, which are forms of non-probability sampling techniques to select participants. Purposive sampling involves strategically sampling study participants with a 'purpose' to represent key criteria identified by the research. The main reasons for gathering information from 'specific' individuals in research are: to gather information efficiently; to obtain information usually unavailable to the researcher; and to gain particular understanding or interpretation of a subject (Gilchrist and Williams, 1999). Snowball sampling involves the researcher asking the initial participants to identify and approach other members within the target group who could take part in the research (Bowling, 2009).

In order to discover a range of views to further generate the programme theories, to test them and also to answer the research questions, it was deemed appropriate to include participants to reflect the three levels of the screening and ABI implementation in the antenatal care setting:

a) policy implementers – those involved in overseeing the planning and implementation of the programme.

b) midwives – those who delivered the service. The role of midwives in the implementation process is an important one. This is because realistic evaluation assumes that they are in a position where they translate programme theories into practice in order to effect behaviour change in clients.

c) pregnant women – those who received the service.

4.5.1 Selection criteria: policy implementers

During the conceptualisation and development of the research proposal, we (my supervisors and I) had a series of discussions with those with key roles in development and/or implementation of the screening and ABI strategy in Scotland. During that period, those involved with the programme in antenatal care settings were identified and noted as potential participants for the study, because their opinions are considered important to realistic evaluation as they help to formulate programme theories (Pawson and Tilley, 1997).

4.5.2 Selection criteria: midwives

At the time of data collection, almost all midwives in NHS Lothian had been trained in alcohol screening and delivery of ABI. Therefore, all midwives involved in alcohol screening and delivery of ABI were considered for inclusion. This study aimed to selectively sample midwives with a range of roles including community midwives and their team leaders and consultant midwives.

4.5.3 Selection criteria: pregnant women

Antenatal care is provided to all pregnant women in Scotland. In this study, the following inclusion criteria were used. Pregnant women who:

1. were above 18 years
2. had used alcohol either before or during pregnancy
3. were screened for alcohol use or offered advice or ABI

4. were competent to consent and participate in the study

The main criteria for exclusion were women who had been identified as alcohol dependent or receiving treatment for alcohol use. This group were considered to have more severe alcohol problems that required specialist addiction treatments. Moreover, screening and ABI has been shown to be ineffective for this group of alcohol consumers (Heather, 2004). In addition, it was considered likely that these women may have had more extreme views than the others or that their views might be influenced significantly by their contact with specialist alcohol treatment services.

4.6 Recruitment of participants

The following sections describe how the three groups of participants were recruited for the study.

4.6.1 Policy implementers

Two key policy implementers of screening and ABI in antenatal care setting who were identified during the early stages of the thesis were invited to participate in the research. They were initially contacted by email and provided with the study information sheet (Appendix 8) and a summary of the research protocol (Appendix 9). A snowball technique was used to recruit two more participants into this category. All participants approached responded in the affirmative by email.

4.6.2 Midwives

First, I wrote to the Head of Midwifery in NHS Lothian to seek her support and permission to undertake this research. Once this was granted, the local consultant midwife (LCM) in West Lothian was identified as the contact person with whom I liaised with in all matters concerning recruitment of midwives (and pregnant women). The rationale for initiating recruiting through the LCM rather than the Head of Midwifery was that, in Scotland the consultant midwive role generally has no direct line managerial responsibilities. This implies that the possibility of participants feeling coerced to participate in the study was minimised.

To publicise the study and encourage midwives to participate, I attended one of their monthly team meetings and had an opportunity to talk with midwives about the study. Afterwards, all midwives present were given information packs. In addition, about eighty additional information packs were also distributed to the midwifery team leaders to be given to midwives who were unavailable for the meeting. The information packs contained an invitation letter (see Appendix 10 for an example), information sheet (Appendix 11), an expression of interest form (see Appendix 12 for example) and a stamped self-addressed envelope. The main reason for giving midwives the information packs regardless of whether they were present at the meeting or not was to ensure that all potential participants received accurate and consistent information about the study to allow them to make informed decisions and not feel that they were rushed to agree to participate. Nevertheless, one midwife indicated her interest by completing and giving back her form to me on that day. Midwives were given an option to participate in either one-to-one interviews or focus groups.

4.6.3 Pregnant women

Recruitment of pregnant women was facilitated by their maternity care provider. Plans to recruit pregnant women were discussed with the LCM. In order to facilitate the recruitment process, it was considered appropriate to involve the three midwifery team leaders in West Lothian. Two separate sets of information packs were designed. One was for women who had received ABI and the other was for women who were screened for alcohol use but had not been offered ABI.

A set of information packs containing an invitation letter (Appendix 10), information sheet about the study (Appendix 13), and an expression of interest form (Appendix 12) with a stamped self-addressed envelope, were given to all three team leaders to be distributed to their team members. The selection criteria for pregnant women was attached to each information pack as a guide for midwives. Subsequently, midwives identified pregnant women who matched the inclusion criteria and passed on the

information pack to them. Potential participants were asked to return the completed expression of interest form to me if they were interested in taking part in the research. Individuals were then contacted directly to arrange a mutually convenient date, time and venue for the interview. A day before the meeting, participants were contacted by telephone to confirm arrangements.

Originally, it was thought that to achieve each response would require four information packs to be given to pregnant women. Therefore, to obtain a sample of 15-20 women, 90 information packs were equally ditributed to the three midwifery team leaders. However, after a very poor response rate (four pregnant women over a two month period) 150 more information packs were added. Later, 250 more packs were added to recruit specifically women who were offered ABI, as we anticipated that this group may be difficult to reach (see section 9.5 on research governance issues that might had affected recruitment of participants).

4.7 Incentives

The contribution participants in research provide cannot be overestimated and incentives are often given to them to express the researcher's appreciation (Patton, 2002). All participants who participated in the study with the exception of policy implementers were offered £20 pounds of high street store vouchers of their choice after the interview or focus group. This was to compensate participants for their time and effort in attending the interviews or focus group. This was especially important for pregnant women because interviews were carried out in either a hospital or a health centre and it was appropriate to compensate participant's out-of-pocket expenses incurred by travelling to attend interviews.

The use of incentives in healthcare research is often debated and proponents against it claim that it may introduce bias to the participants' responses (Green and Thorogood, 2009). However, it could also be argued that incentives may encourage 'hard to reach' groups to participate in research who may not have done so otherwise in the absence of

such incentives. In addition, due to the sensitivity of the subject, we anticipated that some pregnant women might not wish to talk about the issue, especially if they drank before they knew they were pregnant. Therefore, using incentives probably helped to access this group of participants. Thus, incentives not only aimed to enhance the response rate, but also aimed to support recruitment of a broad range of participants who provided diverse perspectives for the study.

4.8 The topic guide

A topic guide is a list of topics and subtopics of issues identified to be relevant to the research (Patton, 2002; Green and Thorogood, 2009). The topic guide helped to ensure that all participants were offered comparable opportunities to express their views on questions predetermined to be relevant to the study. Although topic guides were used they were not considered to be 'fixed structures'. Participants were therefore not always asked questions in the same order or way across interviews. To enhance the flow of the interview and focus groups, topics were pursued as they emerged in participants' responses.

The questions were designed based on ideas or concepts gained from reading the literature, reflected on substantive issues on the subject matter, and discussions with other researchers, and were deemed relevant to achieve the study's aims. Although, literature and theories may inform the design of topic guides, yet Arthur and Nazroo (2003) cautioned against over reliance on their use because of their tendency to undermine the 'exploratory' principles of qualitative enquiry. Fundamentally, the topic guides for all participants were tailored to either generate programme theories or interrogate the various programme theories already identified (see Appendices 14, 15 and 16 for topic guides for the various participant groups).

4.8.1 Piloting the topic guide

Preparation is a necessity so that the topic guide is able to facilitate generation of useful data, and is an integral aspect of research (Green and Thorogood, 2009; Silverman, 2010). Therefore, the topic guide for pregnant women was piloted prior to the main data collection for this study. A convenience sample of five women, including two pregnant women agreed to participate in the pilot study. They were recruited from my local church for a focus group. Although, the focus group interview was digitally recorded and transcribed, the transcripts were neither coded nor analysed. This was because the purpose of the focus group was to test the topic guide and to further practice the technique of running a focus group rather than generate study data.

The pilot however, highlighted various issues that were addressed and enhanced upon in subsequent data collection. First, at the initial stages participants answered directly to me as is usually done in one to one interview, rather than discussing issues among themselves. It was apparent that even though participants knew each other well, there was initial anxiety. This was partially due to lack of adequate time for participants to interact with each other or 'break the ice' because of time limitations. The focus group started about 30 minutes behind schedule because participants were late. In the subsequent interview, demographic information was extracted from the topic guide, and drafted as standalone paperwork (see Appendix17). The intention was, through the process of providing factual information about themselves, participants would relax and provide an opportunity for the me to know more about the them (such as whether they have other children or not or whether they have a job or not).

From this initial focus group, I realised that placing knowledge questions at the top of the topic guide list was inappropriate and may be a reason why participants were uncomfortable answering questions at the initial stages. In this regard, knowledge

questions like, ‘which trimester do you think drinking could be more harmful to the fetus?’ were removed from the top list of the topic guide and were discussed later on as the interview progressed and participants were more relaxed.

Another observation from the pilot related to double part questions. It was realised that participants often answered the part of the question they were most comfortable with and ignored other parts. For instance, ‘do you think help should be available in antenatal care for women who drink and what sort of help do you think will be useful’, was either framed in two ways or prompts were used to explore further details based on answers participants provided in the principal interview.

It was apparent from the interview transcript that several opportunities were missed to use probes or prompts to elicit further details from participants. As a result, the topic guide was revised to trigger the use of more probes and prompts where necessary.

The final issue that was highlighted from the pilot was handling intermittent ‘silence’. Whenever this happened, I felt uncomfortable and quickly tried to continue with the next question when apparently participants had not fully explored the topic under discussion. This led to my asking participants leading questions. This observation was noted and I improved upon it in the subsequent interviews.

4.9 Ethical issues

4.9.1 Sensitive topic /potential risk to participants

Research in health care commonly involves sensitive topics and is often associated with potential social and psychological harm (Boulton, 2009). It is important to acknowledge that drinking alcohol in pregnancy may be a sensitive issue. However, in this study I was interested in speaking to women about their views and perceptions of issues about alcohol consumption in pregnancy rather than providing women with potential fear-

causing information. I adopted a non-judgemental and neutral approach to ensure that participants were relaxed, comfortable and above all, spoke freely. It was initially decided that, if a participant became distressed and decided to discontinue participation in the interview or focus group, any information already obtained from such a participant would be removed from the study and destroyed. Fortunately, there was no such experience. Yet, "interviews are interventions because they affect people" (Patton 2002: 405). Therefore, an information sheet containing contact details of a midwife and local alcohol support services (West Lothian Drug and Alcohol Services, and West Lothian Alcohol and Drug Action Team) were available for participants who may have exhibited signs of distress or who wanted further information. However, only one pregnant woman requested such advice from me. She was asked to speak to the contact midwife who was available in a nearby office at the end of the interview, and was given an information sheet for further support. She however, declined to speak to the midwife and jokingly said, 'I will look it up on the internet'. I followed her up with a phone call the next day but she reassured me that everything was all right; therefore, no further action was taken.

In order to safeguard against any potential risk to participants or to me (as a male researcher), all interviews with women were conducted in a designated room within NHS premises.

4.9.2 Informed consent

Written informed consent was sought from all participants before commencing each interview or focus group (see Appendix 18 for an example of the consent form used).

4.9.3 Confidentiality and anonymity

In order to comply with the Data Protection Act 1998 (The National Archives, 1998), confidentiality was maintained at all times throughout the study. However, in relation to

data from policy implementers, the information sheet indicated that their organisations would be mentioned in the report but their names would not (see Appendix 8 for information sheet). This was because it was recognised that there was a possibility that their colleagues could identify them, as they constituted a small pool of experts in the area.

At the beginning of the interview or focus group, participants were reassured that their contribution would remain confidential. Audio−recordings of each participant were assigned a unique identification number in the interview transcript. Moreover, I did all the transcribing and no third party had access to the data other than my supervisors.

Data generated within the study was stored securely. Participants' names as provided on the consent forms and demographic data were stored securely in a locked cabinet within an office in the University of Stirling. All information, including memos and field notes, was entered into a database on a computer in the University of Stirling. After the study, data will be securely stored and kept in accordance with the University of Stirling regulation – which is that data is kept for 10 years then securely destroyed.

4.9.4 Ethical constraints

I encountered a number of ethical challenges, which impacted on the research process. Firstly, the original application to NHS research ethics committee on 27th November 2009, outlined that the study would utilize focus groups and individual interviews as a means of data collection for midwives and pregnant women. However, the ethics committee refused to grant me approval and insisted that only focus groups should be used. Subsequently, a second application was made incorporating the changes they requested. This was approved. However, within a month of delivering 240 information packs to midwives which they were requested to pass to pregnant women to inform

them of the study, no responses were received. Upon further discussions with midwives, they explained that some of the pregnant women who were informed about the study expressed considerable interest in taking part but raised doubt about being involved in discussing the issue in a group context, whilst others were concerned about the time commitment involved in taking part in a focus group.

From the 100 information packs distributed to midwives, five midwives expressed interest of taking part but it proved impossible to convene a date for a focus group that was suitable for more than any two of them. This was understandable because by their nature of work, community midwives are geographically dispersed and their work patterns differ.

Consequently, on the 4th May 2010, I used these reasons as a basis to apply for a protocol amendment and requested that the ethics committee grant me the permission to conduct individual interviews with both midwives and pregnant women. This application was granted.

It is important to highlight that NHS ethics committees usually have set dates for meetings to discuss applications, which are usually some weeks apart. This means that several weeks elapse between the time an application is made and the time that an outcome is received. Considering the time constraint associated with full-time doctoral study, the events above had a substantial toll on my data collection period.

Another issue that possibly interfered with recruitment was the venue for conducting the interviews. In the original ethics application, I indicated that interviews would take place at a venue convenient to participants. However, the ethics committee insisted that all interviews should be conducted in a designated room within an NHS premises in

order to safeguard against any potential risk to participants or to me as a researcher. The basis of this request was not made clear but I felt it was possibly on gender lines, namely a male researcher interviewing pregnant women. However, as a result the very limited choice of venues available probably contributed to the low response rate this study experienced.

Finally, regarding the recruitment of pregnant women who had received ABI, I planned to recruit these women retrospectively by requesting a list of all women who have received ABI in NHS Lothian and inviting a sample of them to take part. This decision was made following discussions with relevant staff who indicated that it was possible to generate this list. This strategy received ethics approval but unfortunately NHS Lothian maternity services management did not approve the strategy and they insisted that women should be recruited prospectively through their midwives. However, the prospective recruitment strategy they required proved extremely difficult as none of the pregnant women in this category expressed an interest in participating. An alternative would have been to try and recruit from other health boards but there was no guarantee that this would have been more successful. Moreover, establishing new clinical contacts and recruiting from other health boards would have meant investing more time and resources, which were deemed not viable within the constraint of this doctoral study.

Finally, for ethical reasons, this study required midwives to make the initial approach to pregnant women about the study. This prevented a direct contact between study participants and me. This was considered appropriate as midwives gave the information packs to only the women who satisfied the inclusion criteria. However, it was impossible to know whether midwives distributed all the packs or not. Nevertheless, anecdotal feedback indicated that they proactively distributed them.

4.9.5 Ethical approval

The study received ethical approval from the School of Nursing, Midwifery & Health (University of Stirling) Ethics Committee. All research within the school is required to receive approval from the School Ethics Committee. Participants involved in this study (with the exception of the pilot) were Scottish Government staff and NHS staff or patients. Therefore, approvals were also sought from the NHS Research Ethics Committee and NHS Lothian Research and Development office. All NHS research governance approvals for the study were granted between January 2010 and June 2010 (see Appendices 19, 20, 21 and 22).

4.10 Data collection: fieldwork

Data collection for all groups of participants involved in the study is discussed below. Data was collected by means of interviews or a focus group. Interviews and the focus group lasted between 30 minutes and 70 minutes. Both interviews and focus group were recorded with participant consent using a digital Olympus audio recorder. Audio recording of interviews and focus groups is considered necessary because it reduces the risk of loss of valuable data (Coombes et al., 2009). All participants signed consent forms prior to commencing the interview and completed a short demographic questionnaire - for pregnant women (see Appendix 17). Participants were assured of confidentiality and were informed of the fact that they could stop the interview at anytime if they no longer wished to participate.

4.10.1 Interviews with policy implementers

Interviews were conducted with two NHS Health Scotland and two Scottish Government staff who were key members of the implementation of screening and ABI programme in various health care settings across Scotland (see chapter five for policy implementers characteristics). On their request, the Scottish Government staff were

interviewed together. The realistic evaluation framework used in this study acknowledges that higher authorities (policy-makers) institute programmes; however, their output depends on the co-operation of practitioners and participants. Often there are disparities between the vision of those who instigate and those who implement programmes (Pawson and Tilley, 1997). Therefore, questions to stakeholders explored their expectations, concerns and perceived benefits of the newly implemented ABI delivery. The rationale for the implementation was also explored (Appendix 14).

4.10.2 One-to-one interviews with midwives

When conducting interviews with different categories of participants (in this case pregnant women and midwives), it is usually common to have core questions that have relevance to both groups in addition to group specific questions (Foster-Turner, 2009). Accordingly, some aspects of the interviews with midwives were designed to parallel those of pregnant women in order to facilitate comparison of data across groups. Fundamentally, the interviews were tailored to explore the programme theories. More emphasis was placed on interrogating outcome patterns in midwives because their role at this early stage of the implementation process was deemed vital to achieve the long-term programme's objective. The following topic areas (see Appendix 16) were part of questions that formed the basis of enquiry: opinion of alcohol use in pregnancy; how they deliver the ABI; opinion concerning the appropriate timing to deliver the intervention; views about how the ABI was introduced; availability of support; attitudes towards guidelines or policies about issues relating to alcohol use in pregnancy and general views on implementation issues that were raised by the policy implementers.

4.10.3 Focus group with midwives

Midwives who participated in this study were largely community midwives. This was because in their role they were likely to screen and deliver ABI to women. The nature

of their work meant they were usually based in different geographical areas and it was difficult to bring them together for a focus group. As a result, a pre-existing group of midwifery team leaders who met regularly for meetings was targeted and one focus group was conducted with them. Krueger (1994) argued that the advantage of involving a homogeneous group in a focus group is to help generate rich data since participants are comfortable with each other and are able to engage fully in discussions. It was anticipated that since team leaders have managerial or supervisory responsibilities; their perspectives on the screening and ABI implementation issues would be different from other midwives.

The topic guide used for the focus group was similar to the one used in the one-to-one interviews with midwives but it was anticipated that to fully explore issues, it was important that questions focussed on screening and ABI initiatives (Appendix 16). The focus group setting offered opportunity for midwives to discuss ABI delivery, emphasizing how they collaborated, and challenged or shared meanings about important issues as they emerged in the discussions (Stewart et al., 2007). The focus group was carried out with assistance from a fellow researcher.

4.10.4 One-to-one interviews with pregnant women

Initial questions in the topic guide (Appendix 15) were structured in a relatively generic manner. Questions were chosen which were easy to talk about, and elicited spontaneous thoughts among participants (Finch and Lewis, 2003). The opening question for pregnant women was ‘were you given any information about alcohol by your midwife since becoming pregnant’? They were then prompted to describe what happened. Based on the answers that ensued, their responses were probed further. Gradually more sensitive and more challenging questions were asked as the interview progressed. The main topic areas covered included, attitudes to alcohol use in pregnancy; perception of

risk of drinking during pregnancy; opinions about information about alcohol given to pregnant women; recent alcohol discussions with midwives; and knowledge and understanding of issues of alcohol use in pregnancy and harm of the fetus. After each interview, I reflected on how the interview proceeded in my field notes. Often, new relevant ideas raised by participants were noted and explored in subsequent interviews.

4.11 Data preparation

Qualitative studies generate large amounts of data usually in textual or audio format. In this study, I transcribed verbatim all data generated from participants using Microsoft Word processor. The intensive nature of transcribing audio files meant that I repeatedly listened to all the recordings allowing me to immerse myself in the data enhancing thorough familiarisation with the raw data. Transcripts were then checked, edited and imported into NVivo software package. NVivo is a computer assisted qualitative analysis software package for managing data, facilitating analysis and helping with interpretation of data (Richards, 2009).

4.12 Data analysis

There are several approaches for analysing qualitative data. However, currently there are no specific outlines for analysing qualitative data in realistic evaluation (Tolson et al., 2005). This study adopted a thematic approach that utilized a hybrid process of inductive and deductive coding and theme development (Fereday and Muir-Cochrane, 2006). As such, it combined the data-driven inductive approach of Boyatiz (1998) and the deductive a priori code template of Crabtree and Miller (1999). The rationale for using this approach was that it allowed the context, mechanism and outcomes components of realistic evaluation to be integral to the deductive analytical process in addition to facilitating themes to emerge from the data through the inductive coding approach.

Fereday and Muir-Cochrane (2006) outlined six main stages involved in the use of the deductive and inductive approach of thematic analysis. Firstly, there is the need to develop a code manual. Secondly, there should be opportunity to test for the codes reliability. Thirdly, you identify initial themes emerging from the data. Using the code manual, codes are then applied to the documents whilst you note emerging codes. Following this, codes are connected into themes. The final stage is to corroborate the themes through the process of confirming findings. Based on these stages, the processes utilized by this thesis are described below under two sub-topics of coding and themes. It is important to note that because of the large amount of qualitative data generated by this study and to ensure transparency in the analysis, data from the three groups of participants (policy implementers, midwives and pregnant women) were analysed separately.

4.12.1 Coding

Coding group materials by topic and this procedure facilitates new insight into the data (Richards, 2009). In this study, based on the CMO elements and the research questions, a provisional coding manual[1] was developed. However, in order not to be too restrictive and to lose the richness of the data by using the exact CMO elements as codes, their descriptive features were used. For example, when considering codes for contextual issues, representations of context such as interpersonal relationships, institutional (clinical) settings and wider context (Pawson, 2006), were used. Boyatiz (1998) asserted that for a code to be credible, it must capture the qualitative richness of the phenomenon.

[1] A series of codes generated in a study.

Using NVivo, coding occurred by selecting the appropriate segments of text and coding them appropriately. NVivo describes these codes as 'free nodes' (Richards, 2009). For example, in the case of pregnant women's interview data, thirty-six free nodes were generated. New codes were devised when new ideas emerged from the data. When a new code was identified, previous transcripts were re-read to determine if the new codes were applicable to the texts. Thus, the coding manual was continually revised throughout the coding process. After this process, the coding manual was re-evaluated removing duplicates and refining substantive codes. A final coding framework was then produced.

The reliability of coding is greatly enhanced if two or more analysts independently code a qualitative transcript rather than relying on the judgement of a single analyst (Stewart et al., 2007). With this in mind, I invited two supervisors (RJ and HC) to independently code about 5% of the entire transcripts. Generally, inter-coder agreements were high and the minor disagreements were resolved through discussions.

4.12.2 Theme development

Boyatiz (1998: 4) defined a theme as "a pattern found in the information that at the minimum describes and organizes the possible observations and at maximum interprets aspects of the phenomenon". Through the connection of similar free nodes, themes were discovered. Agreements and disagreements in opinions between segments of the data were illuminating at this stage. Critical at this stage was the need to ensure that themes were representative of the original data (Fereday and Muir-Cochrane, 2006). Consequently, transcripts were re-read ensuring that themes had appropriately captured their phenomena. The analysis then advanced to the interpretative phase. Text search, querying and model functions available in NVivo were used to facilitate the analytical

process. With the emergence of patterns of meaning, similarities and differences within units of the data were interrogated.

4.13 Reflections on the researcher's position within the data collection

Mason (2002) asserted that in qualitative inquiry, the role of the researcher within the data generation is active and reflexive and it is imperative that this is examined. Firstly, it could be argued that being a male researcher interviewing women had an influence on data generated. Although, it was unclear whether this encouraged participants to share their 'world' with me or not. However, before the beginning of each interview, I usually identified ways to establish rapport. Frequently, I did this by raising issues relating to caring for babies or little children. If the participants already had children, we talked briefly about them and I was able to get opportunity to say, I also have a little boy. This, not only generated participants' interest but it helped them relax before the interview. Some of the participants, especially the pregnant women appreciated my presence as an interviewer and spoke openly about their experiences and the dilemmas they were negotiating in their lives. For instance, after completing one of the interviews, one pregnant woman commented, "it was nice talking about some of these issues openly with you".

The issue of English not being my first language is worth mentioning. It likely that questions, especially those not formulated in the topic guide, might have been asked by me in a slightly different way from the way a native speaker might have spoken. To minimise this, I made conscious efforts to think through prompts and probes carefully and framed them in simplified manner.

The appearance of the researcher to research participants is another important factor to be considered in qualitative research. I was aware of this and dressed smartly for all interviews.

5. 0 Chapter Five: Policy implementers' results

5.1 Introduction

The rationale for this stage of the study was to involve individuals who would articulate policy viewpoints about the screening and ABI programme in Scotland and specifically in antenatal care settings. These interviews were intended to complement findings from the literature reviews (chapters two and three) to help formulate the programme theories as postulated by the realistic evaluation framework. The chapter begins by outlining characteristics of participants and themes that emerged from the data. This is followed by presentation of the findings. When necessary relevant literature is drawn upon to support the discussions. As the last chapter in the stage one of the thesis structure, the chapter brings together the programme theories identified in chapters two and three, as well as those identified from the policy implementers in this chapter, to construct plausible CMO configurations that would be explored further in subsequent chapters.

5.2 Participants' characteristics

Four individuals from Scottish Government and NHS Health Scotland whose role is to develop and/or implement policy (hereafter may be referred to as policy participants) were involved in this stage of the study. The minimum duration of the interviews was 41 minutes and the maximum was 56 minutes. Participants' details are given in the Table 5.1 below.

Table 5.1 Details of policy participants

Code	Organisation	Role
SG1	Scottish Government (SG)	Overseeing national ABI implementation by working with Health Boards to achieve HEAT targets and also to look at long term role of embedding ABI into the mainstream care within the three settings outlined in the HEAT target
SG2	Scottish Government	Support SG1 in their role and also working with the national ABI support team –which provides leadership to the Health Boards for delivery of ABI HEAT targets. Co-ordinate activities of antenatal ABI sub-groups
HS1	NHS Health Scotland (HS)	Involved in strategic implementation and operational activities of ABI across Health Boards including developing training resources
HS2	NHS Health Scotland	Involved in strategic implementation and operational activities of ABI across Health Boards including developing training resources

5.3 Themes

Themes were developed using a hybrid approach of deductive and inductive coding. However, when codes were merged into major themes, single inductive codes for example timing of ABI delivery in antenatal were merged into an overarching theme of clinical settings. As a result, all the five major themes identified could broadly be described as being derived deductively (see Table 5.2).

Table 5.2 Development of themes

Theme	Sub-theme	Coding approach
Policy drivers and training	• Policies • Training and support	Deductive
Clinical settings	• Antenatal care • Timing of ABI delivery • Interpersonal relationships	Deductive
Policy implementers perspectives of the attitudes of women and midwives	• Midwives' attitudes • Pregnant women's attitudes	Deductive
Perceived benefits of ABI		Deductive
Barriers and challenges		Deductive

5.4 Policy drivers and training

This theme describes what policy participants considered as the main policy drivers for implementing screening and ABI in antenatal care settings and views on perceived factors likely to enhance the delivery of the intervention.

5.4.1 Policy drivers

All policy participants unreservedly acknowledged that the HEAT target was the single most important drive for the implementation of ABI in antenatal care settings. Participant HS1 recognised this and noted the contribution of other factors.

> *Well, in terms of policy, the HEAT target is obviously the main driver for ABI programme. Of course not just antenatal, but primary care and A&E as well. So to my knowledge there isn't any other mandatory policy drivers for introducing ABI. The other kind of main policy drivers in this area are about, kind of a more general policy driver is about health improvement and reducing health inequalities (HS1).*

Participant HS2 cited the commitment of the Chief Medical Officer of Scotland to curb the surge of alcohol related health burden in Scotland as a reason.

> *I think the other one will be a long-standing interest at the Chief Medical Officer level in Scotland related to FAS or FASD. So, at the Chief Medical Officer level there have been concerns about that, which is translated into the need for the health service within the context of antenatal work to do more to ensure that women have accurate, up to date information and they are aware of what the potential consequences might be of drinking during pregnancy (HS2).*

Whereas SG2 indicated that recent changes in antenatal care policy meant it was logical for ABI to be implemented at the time.

> *Also, KCND, which is Keeping Childbirth Natural and Dynamic, had a huge impact in the way antenatal services were delivered, making sure that rather than going to the GP, ensuring that pregnant women in the initial stages are directed to the midwife in the first instance. So, I think definitely that is a policy driver, more from I think how antenatal care is delivered which then has an impact on things such as ABIs being delivered in that setting. So, this is sort of the wider context (SG2).*

This emphasis on KCND suggests that the midwives rather than GPs are better placed to deliver ABI to pregnant women. Previously, women had to attend their GP to confirm pregnancy before being referred to a midwife thus prolonging the time before the booking appointment[1]. One of the aims of the KCND initiative was that midwives would be the first point of healthcare contact for women. It was anticipated that this would allow midwives to undertake the initial pregnancy risk assessment, including addressing the issue of alcohol use in pregnancy at an earlier stage.

HS1 said that, although the evidence base for implementation of ABI in antenatal care is not strong as compared to primary care and A&E, directives from clinical guidelines

[1] The first appointment pregnant women have with midwives during which detailed assessment and medical history are recorded.

have stressed the need for its implementation in the antenatal care setting.

> *Antenatal care, there is very little (evidence). There have only been a handful of controlled studies done, not just in the UK but across the world. So the evidence base is limited but it was in the SIGN guidelines as a recommended area for doing it in and recently it has been included in the NICE public health guidelines as a recommended area along with a host of other areas where the evidence base is limited. So, I think there's evidence for doing it in this settings out with primary care. Thus antenatal and A&E has generated more kind of plausible theory about this is an obvious area where alcohol misuse should be targeted and ABI as an evidence based intervention that works elsewhere, so the plausible theory is that the strength of its effectiveness elsewhere would transfer I suppose to antenatal settings to some degree to make a difference. (HS1).*

The above extract implies that, whereas HS1 was convinced of ABI's effectiveness in primary care, its use in the antenatal care setting, to some extent, was deemed to be based on theoretical assumptions but not on robust evidence.

The Scottish Government sets health targets for NHS Health Boards in Scotland. In the abstracts below, the national ABI policy lead (SG1) explained the essence of the HEAT targets and what was expected from Health Boards regarding ABI delivery:

> *The board as a whole had one number (of ABIs) that they had to deliver. Whether they deliver all in primary care or all in antenatal, it was totally up to them as to how that split worked and how it was managed. Yes, you know, it may not be the best you know based on the quality outcome and things like that but what it did do was to raise the priority and raise the pressure within Boards to make sure that these services and professions got the focus they needed to actually embed this going forward (SG1).*

Whereas targets may be performance indicators as highlighted by SG1 above, they also have the potential to compromise quality when practitioners are focussed on trying to reach set targets. For instance, since Health Boards are only obliged to report on the number of ABIs delivered, it is possible that less emphasis would be placed on other aspect of the ABI components. For example, putting in place appropriate mechanisms

to measure outcomes on the number of women who reduced their alcohol intake or providing adequate follow up support.

Another important issue that participants acknowledged had facilitated the ABI policy initiative was the current media focus on issues of prenatal drinking.

> *I think slowly but surely, you are seeing much more communication in the media about alcohol exposed pregnancies, which you didn't see before. Things like FAS is becoming much more commonly talked about among clinical and health staff and again women are aware of the impact of alcohol exposed pregnancies so I think these things all help cheer us on (HS1).*

By the above assertion, HS1 believed that media input had helped in terms of publicity and relaxing the previous societal view of regarding alcohol intake in pregnancy as a taboo subject (Plant, 1997).

5.4.2 Training and support

It was noted that nearly all midwives, especially community midwives who provide antenatal care to women have been trained on screening and delivery of ABI in Scotland. All policy participants considered training of midwives as milestone for the ABI programme. Training and support had always been an important issue in ABI implementation in various settings (Johnson et al., 2010). ABI training has the potential to overcome practitioner barriers like inadequate knowledge and skills (Mengel et al., 2006). Overall, policy participants agreed that the ABI initiative had provided a pool of trainers with the aim of assisting midwives to improve their confidence and understanding of the ABI protocol; ensuring consistency of delivery; and that it provided them with materials to undertake the screening and referral process.

Participants highlighted that the training programme for the ABI implementation was initiated by NHS Health Scotland and the extracts below articulated what they felt to be

its importance.

> *So certainly, the training programme for screening and ABI kind of trained midwives to improve on their (motivational) interviewing skills and to use screening tools appropriately; when you probe and when not to probe and kind of act on cues to have it in an non-invasive, informal conversation to glean information in that way. And obviously when we get to the ABI, we use the principles of FRAMES[1] as well and of course the other resources we produced. We produced a specific professional pack for antenatal staff for ABI which is kind of a one stop shop which discusses the evidence base, the screening tools, it has got clip sheets in it, it has got prompt cards and that should help not just the staff but the women who receives the ABI because it can be used interactively in terms of rolling it out appropriately (HS1).*

HS1 identified FRAMES as the protocol used in antenatal care. The use of a specific protocol could help midwives to follow specific framework in ABI delivery especially as it was found in the previous review (chapter three) that definitions and components of what constituted ABI varied between studies.

Interwoven with training is the issue of confidence. Policy participants felt that training of midwives was likely to promote confidence, ensuring that they were able to openly discuss alcohol issues with pregnant women. Improved confidence means with time midwives will spend less time in screening and delivering ABI, enhancing the integration of the programme into routine care. All policy participants shared this idea. The extract below elucidates this.

> *So it (screening and ABI) should be able to be delivered within that 5-10 minutes window for consultation effectively. But that depends on the training and the confidence of the midwife or practitioner to deliver that. The higher the confidence the easier it fits into the conversation, possible the quicker. Certainly some anecdotal feedback is, the more you do, the quicker you get at it. Because you get more comfortable doing it so you don't kind of necessarily follow it step by step (SG1).*

[1] One of the approaches for delivering ABI. The acronym FRAMES stands for Feedback, Responsibility, Advice, Menu of options, Empathy, Self-efficacy.

This quote suggested that, whereas regular delivery may enhance the delivery procedure, delivering on ad-hoc basis could have the negative effect of reducing confidence and time efficiency.

To help midwives to identify the appropriate women for ABI, the ABI initiative introduced the use of screening tools. Policy participants reported that training also promoted the appropriate use of these tools. They revealed that TWEAK and T-ACE are the screening tools currently recommended and used in Scottish antenatal care settings, replacing the previous 'yes' or 'no' style of questioning women about alcohol consumption. Among prenatal population, these two screening tools are associated with high sensitivity and specificity (Russell et al., 1994). Policy participants were of the view that, as compared to the previous questions, these tools have the potential to produce robust and reliable data.

> *So where there have been benefit is the use of validated screening tool. So screening tool are obviously set up to kind of navigate the way round or counteract people trying to kind of, I suppose, people trying to underestimate or overestimate their alcohol consumption (HS1).*

HS1 reported that in order to ensure that all who require an ABI are identified, screening in antenatal care setting has been extended to include pre-pregnancy risk drinking.

> *However, if she says prior to becoming pregnant she drank at levels that could be deemed hazardous or harmful, then there is an argument that you could do ABI based on pre-pregnancy drinking. Whether that goes against the ethos of what ABI should be – opportunistic based on current drinking is where the evidence base lies – is a different argument I suppose and I suppose may impact on effectiveness of the outcome you are looking at (HS1).*

Although, the screening tools are only validated for prenatal drinking, it has been shown that pre-pregnancy drinking is a strong predictor of risk drinking during

pregnancy (Russell et al., 1994; Chang et al., 2006). As a result, by screening for alcohol intake from these two perspectives ensures that there is a high probability of identifying women abusing alcohol and reduce the risk of losing pregnant women who may otherwise screen positive for ABI. In addition, finding out what women drank before pregnancy may offer midwives the context where they can slot-in alcohol advice independent of the client's current non-drinking status.

5.5 Clinical settings

This theme was identified deductively. From the realistic framework, it was anticipated that the culture, rules and routines within antenatal care may be different in comparison to other settings, like primary care in which screening and ABIs are well established. I therefore explored from policy perspective the extent to which these factors had been considered in the implementation approach.

5.5.1 Antenatal care

All policy participants were of the view that midwives' varied opinions and attitudes towards alcohol use may have implications for screening and the delivery of ABI (see section 6.4 for midwives attitudes). However, they all commended midwives for their enthusiastic approach to the ABI initiative. Generally, they were of the opinion that midwives felt it was part of their role to help women in various aspects of their health during pregnancy, including controlling their alcohol use.

> *So, they (midwives) saw it as being consistent with their practice, sort of the kind of thing you expect midwives to be discussing. They saw it, you know within the context of the SWHMR (Scottish Women-Held Maternity Records) notes and that kind of approach being quite consistent to be integrated and embedded within that (HS2).*

However, later HS2 expressed an alternate view from the comments above when asked to give an opinion of the suitability of screening and ABI in antenatal care:

> *I think there is a definite sort of ambivalence within midwifery about whether it is the best, you know an appropriate setting for alcohol screening and intervention given the range of other things they will say are equally, if not higher in terms of importance, yeah. They do certainly report that they feel that they are putting in an awful lot of effort at a time they can use to discuss other things (HS2).*

This view was probably based on initial feedback from midwives following delivering ABI in practice. Therefore, it could be inferred that not all midwives were totally convinced about the usefulness of screening and ABI in antenatal care. It could be argued that, midwives attitudes would had been different if the number of women who needed the ABI could account for the resources invested. HS2 by making reference to 'given the range of other things that are equally important' indicates that as compared to other issues that need to be discussed at the booking, screening and ABI seemed less of a priority for midwives. This suggests that given the amount of information midwives have to provide to women at the booking, the quality of screening and fidelity to delivery of the ABI may be compromised. There is also the possibility that pregnant women may struggle to comprehend the considerable amount of information provided to them within a short space of time, which may have consequences on how well they are able to utilize the skills gained from ABI to effect positive drinking behaviour change.

5.5.2 Timing of ABI delivery

The time to intervene on alcohol use in pregnancy is important to consider because the period that alcohol is consumed in pregnancy is directly related to type and extent of adverse fetal outcomes (Ornoy and Ergaz, 2010). Policy participants were particularly apprehensive about the timing of delivery of ABI, and were concerned about the fact

that women may have drunk alcohol during pregnancy by the time they come for their first booking appointment.

> *...this is it, it is where doing ABI in antenatal stage is too late because traditionally the majority of women would have seen their GP or their midwife at 12 weeks, generally in their first appointment and at that point if they have been drinking hazardously or harmfully or even more extremely than that, then the damage to the unborn baby is more likely to be done by then, in the early stages. So the effect of ABI at that point is probably fairly redundant (HS1).*

HS1 assertion above suggested that ABI might not be beneficial for the unborn child of a woman who drank at higher levels in her first trimester since drinking in the first trimester could be associated with increased fetal risk and this view is supported by the review in chapter two.

Participants suggested that the opportunities pregnancy present was one of the reasons for targeting antenatal care settings. This is because the prenatal period presents a window of opportunity where women are assumed to be motivated to change negative health behaviours (Nilsen, 2009).

> *Why the focus has been on antenatal is purely because there is a captive audience there and all women regardless of their normal engagement with health services, generally well engage with the health service when they are pregnant at some stage so that would seem to be an opportunity to tackle them at that point (HS1).*

> *...and it is a time that women might actually be motivated to change, it is also a time where, women if they have been drinking prior to becoming pregnant and haven't planned to become pregnant might be a bit concern about a potential harm that might have been done to the baby in that early stage of pregnancy (HS2).*

Interestingly, policy participants acknowledged the possibility of ABI being delivered in pre-pregnancy services like family planning clinics where it is more likely to have greater impact than in antenatal care settings.

The alternative will be to do ABI at a family planning clinic or somewhere else whether women's clinic or a GP surgery, where a woman is indicating she is going to try for a baby; or when she is going to go off the contraceptive pill; or something at that stage where obviously you can make a much bigger and more in terms of preventing the drinking becoming hazardous or harmful; or at a point where it is going to affect the conception of the baby (HS1).

I actually think maybe getting some of that information to women at the time when they are not pregnant is equally important and actually after pregnancy as well (HS2).

Opportunistically, the prenatal period seemed to be a good time to elicit health behaviour change, yet policy participants also acknowledged that active behaviour change strategies would have greater merits if they could be done pre-pregnancy and could be further enhanced during pregnancy.

5.5.3 Interpersonal relationships

Policy participants thought that the reason why midwives rather than GPs were asked to screen and deliver the ABI was as a result of policy change as well as an opportunity for midwives to establish good social relationships with women at early stage in their pregnancy.

There is a new policy for maternity called keeping childbirth natural and dynamic and the ethos of that policy is to make pregnant women's first point of contact always the midwife. So naturally, it makes sense to ask midwives to do the ABI. The midwives themselves are also able to kind of build up a rapport with women over time with a relationship (HS1).

The screening and ABI, are meant to be carried out at the booking appointment. Policy participants suggested that both midwives and pregnant women are keen to protect the good social relationship that exists within antenatal care settings. In this regard, HS1 was of the view that, generally women are often unwilling to disclose their exact drinking levels at early stage of the relationship with their midwives. Participant SG2 also highlighted that midwives are equally careful to sustain good relationships with

their clients.

> *...women are reluctant to divulge information. They might get looked upon negatively by their midwife especially at the first appointment. So particularly alcohol consumption with all the negative associations that are with alcohol consumption in pregnancy, women are reluctant to divulge that to the midwife for fear of kind of a breakdown of that relationship (HS1).*

> *In terms of relationship, they (midwives) are very cautious about not ruining that relationship. Because, it takes a while to build up rapport with individual women and I remember being referred to it as 'the straw that could break the camel's back'. If they bring that in, obviously since it is a sensitive matter as you said, so it is raising it at the right time and going about it in appropriate way...(SG2)*

HS1's reference to the fact that women 'might get looked upon negatively' reflects the ingrained societal norm of disapproval of women drinking in pregnancy. If women know that they may be seen by, the same midwife throughout their pregnancy and possibly beyond, they might prefer to maintain the relationship with their midwives, and intentionally or inadvertently provide socially desirable answers to health screening questionnaires (see section 7.10.1 for pregnant women's account). Midwives are also having to negotiate this sensitive relationship, trying to build up trust and establish rapport. They have to balance supporting women they have just met, usually for the first time and deal with problem behaviours without destroying the relationship they plan to have with them (see section 6.8.2 for midwives findings).

HS2 articulated that sensitive issues are better discussed in well established relationships and this attribute may be absent during the booking appointment.

> *These are sensitive issues and one might argue that they are best discussed when a practitioner has an opportunity to develop a bit of trust and a relationship with a patient. And if that screening and potentially ABI delivery is done at the very first you know booking appointment, well you haven't had that opportunity to build that kind of trust and relationship. Different from a*

doctor/GP-patient relationship where even if you visit your GP, you know reasonably frequently, you still kind of know them and they know you. It might be different from midwife and pregnant woman relationship, I think (HS2).

HS2 acknowledged the potential difference in relationships that occurs in primary care and antenatal care (potential differences between health care settings discussed in chapter three). This relationships difference suggests that there may be underlying differences in how ABI operate within these two settings. This is because the principles of ABI, and for that matter motivational interviewing strategy, rely strongly on established rapport between a practitioner and a client and the supposed bond that develops in antenatal care has the potential to enhance its delivery and subsequent follow-up. Yet, it is unclear where the direction of influence would be when ABI is delivered at the booking appointment when the relationship is fairly new and undeveloped.

5.6 Policy implementers' perspectives of the attitudes of women and midwives

This theme was informed by the research question. It was anticipated that the attitudes of key players (midwives and pregnant women) in the implementation process would be crucial to whether the intervention achieved its intended outcome or not. Midwives are in a position to translate the intervention's theory into practice. Therefore, a positive attitude towards no alcohol consumption in pregnancy could result in actively implementing the screening and ABI strategy according to protocol. Conversely, a negative attitude that there is not enough evidence of the harm caused by drinking alcohol in pregnancy could result in under utilization of the screening and intervention. Pregnant women's positive or negative attitudes to drinking in pregnancy, to some

extent could determine their motivation to change drinking behaviour and acceptance of screening and ABI. Therefore, I explored from policy participants' perspective their assumptions of midwives and pregnant women's attitudes that they believe would impact upon the screening and ABI initiative.

5.6.1 Attitudes of midwives

Some policy participants reiterated that midwives attitudes, either positive or negative, were crucial to the success of the implementation of screening and ABI delivery to pregnant women. Below SG2 highlighted some of the possible implications of midwives varied opinions on their attitudes to the sort of information their might provide to women.

> *There is a very wide view of what midwives themselves consider to be acceptable. Some think it should be zero tolerance, you don't drink anything, others think having one to two units a week once or twice a week, which is still within the guidelines, is acceptable... Depending on what their own view is, they might find that difficult to hide. You know, they might say, one or two isn't harmful, don't worry. I know what is like. So they might sympathise with them or they might be quite harsh with their opinions (SG2).*

It is important to note that pregnant women who inconsistently drink one or two units of alcohol per week are unlikely to screen positive using the T-ACE and TWEAK screening tools. However, the ABI initiative in Scotland is encouraging women to set abstinence goals.

Policy implementers acknowledged that some midwives' negative attitudes towards discussing alcohol consumption with women may purely be down to ethical reasons, especially when dealing with a woman who may have already drunk alcohol in pregnancy.

> *...traditionally, maybe not much now, there has been a barrier for midwives themselves to feel confident about asking about alcohol consumption for a*

reason as I said, for almost we don't want to open up Pandora's Box about how much she is drinking and if actually more then it's affecting the baby (HS1).

HS1's reference to the fact that midwives would like to avoid opening up the 'Pandora's Box' might suggest midwives unwillingness to confront issues that they felt they have no time and adequate skills to appropriately address.

Participants also indicated that midwives negative attitudes might be reflections of midwives' own drinking behaviour, as a results they might be unwilling to discuss alcohol consumption with pregnant women (see section 6.4.1 for midwives' account).

Midwives, like other health professionals are just reluctant to ask about alcohol consumption because their own alcohol consumption can be hazardous or harmful and they find that as a barrier to asking their clients about alcohol consumption (HS1).

Policy participants expressed concern that some midwives tend to undervalue the detrimental effects of alcohol and as a result, it is not accorded much emphasis in relation to other risky health behaviours in pregnancy.

The other kind of main issue is that midwives up until now haven't seen alcohol as potentially as big a priority as something like smoking or I don't know, physical activity or diet. We will argue alcohol is just as important as those are. I mean certainly it's important as smoking and it should be viewed as high priority. I mean FAS is kind of a fairly new kind of emerging condition which is only kind of recently been recognised in the medical field. The figures coming out from that, we don't have a full grasp of the prevalence of FAS but we are talking about 1 in a 1,000 babies being affected by some sort of FASD and that is probably underestimate. So that shows the potential impact that alcohol consumption in pregnancy is having (HS1).

5.6.2 Pregnant women's attitudes

Policy implementers acknowledged that the current guidelines present mixed messages to women.

The way in which the message has evolved to date, is kind of potentially confusing to women. Because whilst it says, 'ideally no alcohol during pregnancy' and then it slightly fudges the issue about saying, 'however if you do choose to drink, you know, no more than one or two units once or twice a week' (HS2).

This confusion is likely to have implications on women's drinking behaviour and eventually influence their attitudes to alcohol interventions (see section 7.9.2 for pregnant women's account of the implications of mixed messages). It is possible that the flexibility in the guidelines will prompt women to be more relaxed about their drinking behaviour or it may tend to influence their information seeking behaviour (see section 7.7.2 for pregnant women's alcohol information seeking behaviour).

I think the research from women will tend to support that they feel that provided the topic is discussed in an appropriate and sensitive manner, they are quite happy to have that discussions and actually surprise when practitioners doesn't ask that kind of stuff (HS2).

However, both SG participants had contrary views about that:

We talked about the cultural challenges that people in Scotland don't like talking about how much they drink. Which goes across all settings but I think it is more so within antenatal because maybe women know that they shouldn't be drinking therefore, they are not going to really face up and say, 'yes I had two glasses of wine last night' or whatever it is (SG1).

But then there might be people that might not be honest or they are not being as open with the units that they are drinking in weeks...(SG2).

SG1 and SG2 realised that the negative connotations associated with drinking in pregnancy coupled with discussion of their personal drinking habits with a health professional present a challenge for some women to adequately discuss alcohol consumption with their midwives (see section 7.10.1 for pregnant women's drinking information disclosure).

5.7 Perceived benefits of ABI programme / Policy expectation

From the research question, I was interested in understanding policy implementers' expectations (short, intermediate and long-term impacts) of the screening and ABI initiative in antenatal care settings. Therefore, this theme was explored deductively. Participants outline a number of benefits for both women and the unborn baby.

> *A lot of time women don't realise that they are pregnant until you know they are two or three months in, but I think any reduction in alcohol at that point reduces the risk, the risk maybe had happen but any reduction will be of benefit to both the mum and the baby but also for future pregnancies as well. About educating the mum that if you are thinking of getting pregnant again, then you know maybe you should cut down on your alcohol or stop drinking altogether and thus just a general awareness raising (SG1).*

> *...I mean obviously they may have been damage done up to 3 months but well some of the damage can be reversed, additional damage can be prevented and severity of that damage can be, I suppose, reduced if women change their drinking as a result of ABI at 6, 8 or 10 weeks whenever it is done. So there are benefits for that. After that if, they see a change on the impact ABI has had, then I suppose there are potentials for those changes to remain with the women post-natally (HS1).*

In primary care, the efficiency of ABI is known to last for about to 12 months (Kaner et al., 2009). If this is transferable to antenatal care, then pregnant women who received ABI were likely to sustain their reduction or abstinence from during the course of their pregnancy and early stages of motherhood. Although SG1 suggestion that the effects of ABI could be sustained for the next pregnancy, are not currently substantiated by evidence, but this is a plausible hypothesis. Screening and ABI might increase pregnant women's awareness of the effects of drinking in their next pregnancy but it is unclear if this would translate into a significant positive drinking behaviour change.

Undoubtedly, the prevention of alcohol-exposed pregnancies remained a major issue on the agenda of the ABI programme. Below HS1 made explicit the main rationale for its implementation.

> *We feel that it does merit the time purely because it is such a major issue. And I think you have seen in a lot of the literature that FASD are the leading cause of developmental disabilities in the developed world. I mean that is not an insignificant statement, it is a major statement and the only way to prevent FASD is to prevent alcohol exposed pregnancies and ABIs is a way to prevent alcohol exposed pregnancies. So we see it as very important (HS1).*

It could be argued that preventing alcohol-exposed pregnancy would have been better tackled at pre-conception care especially when it is likely that women might have drunk early in pregnancy before their first contact with the midwives (see section 7.7.1. for pregnant women's drinking behaviour at the time of pregnancy recognition).

5.8 Barriers and Challenges

The goal of the ABI initiative was to embed the intervention into an already established antenatal care system. In common with any innovative programme, there are bound to be challenges that need to be identified and overcome to ensure implementation success. Particularly, in antenatal settings, it is widely known that challenges led to a delay in the implementation of the intervention as compared to the other two settings of primary care and A&E. The SG national lead for ABI delivery in Scotland explained:

> *...and a lot of Boards as SG2 indicated, it was later on, it was maybe into year 2 or some were a wee bit late, into year 3 of the target before they started looking at antenatal just purely because of the challenges we have talked about. They looked at the delivery in primary care and A&E first and then to antenatal third (SG1).*

Further to this, I explored from policy implementers point of view, the challenges they had already identified from the initial implementation process or the barriers they

envisaged may influence successful embedding of screening and ABI delivery into routine antenatal care. The biggest challenge they indicated was the time allocated for midwives to deliver the intervention. Others include midwives and pregnant women's attitudes to alcohol in pregnancy, and issues associated with the screening tools currently being used and cultural issues.

All participants identified time for midwives to screen and deliver ABI as the biggest challenge. Below are the abstracts of participants when asked:

> *I: Considering the limited evidence base of ABI in antenatal, what do you think are the main challenges for implementing this intervention in antenatal settings?*
>
> *HS2: Well I think the main challenges are undoubtedly, time. Whereas we say screening and ABI shouldn't be a very lengthy process, it still require some time to be allocated to it. So alcohol is competing with a range of other things for that valuable time.*
>
> *HS1: There is also a bit more practical issues about time at the booking appointment. As I said there is a whole host of issues that midwives are going through with women, like smoking, like diet, like physical activity, like general health behaviour, about the changes women go through about being pregnant and with all the different other appointment they have got to keep. So alcohol is competing with a lot of different other issues. So the time to address appropriately and get good information is again limited.*

Since screening and ABI were competing with other equally important issues at the booking appointment, time was connected with the notion of how midwives assign significance to the issue of drinking in pregnancy. At present, policy implementers felt midwives were slightly underestimating the implications of alcohol use in pregnancy. Participants argued that alcohol should be given the priority it deserves by midwives, by according it with the same urgency given to other important issues that need to be discussed at the booking appointment.

I think a bigger issue is whether compared to the range of other things that have to be addressed, you know whether alcohol is of sufficient priority to merit the use of valuable time (HS2).

The issue of time is very crucial to the delivery of the intervention. Because if time is limited, it means midwives may not be willing to delve into details of a woman's drinking behaviour in case it leads to other things they are unprepared for as HS1 highlighted:

It is quite conceivable that you could carry out screening and ABI in 5-10 minutes and do it appropriately and effectively and that has been shown in other settings. I suppose where additional time comes in is when you open up a kind of major issue. For example, a woman who have been drinking quite a lot and then a lot of it shift then to discuss about things that will impact on the baby that they may not be happy about (HS1).

All policy participants indicated that the number of women screening positive to hazardous and harmful alcohol consumption was low. These low numbers may prove to be a challenge to service in terms of numbers actually benefitting from the intervention.

The feedback from antenatal is that, they just couldn't get, that what we've got anyway, is that they are screening everybody and they are not getting anybody saying that they are drinking. So that was the feedback that we received (SG2).

In terms of women's self-reporting of what level they are drinking at during pregnancy, very few screen positive using a tool like TWEAK or T-ACE. So what the Boards are saying is, we are screening large numbers of women but actually very few are actually screening positive. So for them there is kind of real issue there in terms of the balance of where you might argue that the benefit to the few women that need the intervention might be great. There is a big effort that has to go in order to reach and benefit those few women. So they see it as kind of disproportionate effort (HS2).

The low numbers of women who may benefit from ABI may have implications for the delivery of the ABI, as midwives will rarely get the opportunity to practice what they learnt from the training.

However, they all agreed that the low numbers were expected for the reason:

> *The majority of women probably don't drink, I mean there are high percentage of women who drink during pregnancy but the majority of women don't drink and those who do drink, drink infrequently (HS1).*

HS1 expressed subtle scepticism regarding the legitimacy of ABI in antenatal care settings, probably in acknowledgement of the low numbers of pregnant women who have received ABI to date. The good evidence base of ABI in other healthcare settings had been cited earlier by HS1 as a rationale for introducing it in antenatal care settings. It was hoped that its successful implementation would help add on to it budding evidence base.

> *There is not a lot of evidence in there (antenatal) at the moment, so that was part of it as well, was to look at try and build the evidence...(SG1).*

> *...but has been much more slower process because we don't have that evidence based there to refer to (HS1).*

Nevertheless, HS1 identified differences between the drinking habits of pregnant women and other health care populations that may account for the potential differences in the effectiveness of ABI among these groups.

> *The difficult with midwives doing it is, ABI is obviously targeted at women drinking hazardously and harmfully. The majority of women probably don't drink... so ABI is not technically appropriate for a woman in pregnancy (HS1).*

Another barrier was to do with the origin of the screening tools that are currently being used in antenatal care. All policy participants were in agreements that the wording was not ideal and the language sounded a bit alien to the Scottish culture. They were however, of the view that midwives could tailor the questions to women's understanding.

> *If you take for instance TWEAK, because of its American origin and the way in which it kind of evolved, if you take that first question in TWEAK, "how many drinks does it take to make you feel high?" That terminology is not the kind of terminology that practitioners in Scotland will use and feel comfortable with using. So what we are trying to do here is to kind of contextualise it and say, well look, this is what it is trying to say and you could describe this to women in a slightly different way (HS2).*

In this regard, for midwives to identify women drinking at hazardous and harmful levels correctly, their interpretation of the screening tools may be essential.

SG1 pointed out that the general acceptance of alcohol use in Scotland posed difficulty with introducing screening and ABI in Scotland health care system because it challenges societal norms.

> *There is always a cultural challenge, which is really general in whatever setting you are going to be in. Wherever you are raising questions around alcohol, you are completely challenging Scottish culture at the moment where alcohol fit into life in general, not for everybody but there is kind of culture there. So, that is always gonna be a challenge (SG1).*

Chiaffarino et al. (2006) indicated that acceptance of alcohol in a society removes stigmatisation and promotes open discussions about women's drinking habits. SG1 suggested that to some extent, ABI is challenging Scottish-drinking norms. However, it can also be argued that if alcohol is widely accepted in the society, then pregnant women could easily discuss their consumption with their midwives, enhancing identification of women for the ABI. Conversely, if guidelines and people criticize women for drinking in pregnancy, the opposite scenario may prevail.

5.9 Key features

The following programme theories (propositions) resulted from this chapter:

- The HEAT targets and KCND initiative may offer midwives regular opportunity to assess women drinking levels.

- Policies like KCND may facilitate early identification of alcohol use and intervention.
- Antenatal period is a good opportunity to screen and deliver ABI because women are already motivated to change drinking behaviour
- Training and supports have the potential to negate barriers and promote ABI delivery.
- Training and support may increase midwives knowledge about prenatal alcohol issues.
- Training and support raised the priority of the screening and ABI programme; may assist midwives to improve their confidence and understanding of alcohol issues; it may ensure fidelity to screening and ABI delivery; and provide them with the relevant materials to undertake the screening and referral process.
- The level of priority accorded to ABI by midwives may be essential for its delivery in the midst of other competing issues.
- The amount of information to be provided to women at the booking may compromise the quality of screening and ABI delivery.
- Screening has been extended to also identify pre-pregnancy hazardous and harmful drinking to ensuring that all women who are at risk of drinking in pregnancy are covered.
- Delivery of ABI in antenatal care settings may be late regarding the health and safety of the fetus but there could be other benefits such as, subsequent reduction of maternal alcohol use.

- Midwives and pregnant women's attitudes to drinking in pregnancy could determine the extent of acceptability of screening and the ABI in antenatal care settings.

- Low number of ABI deliveries means midwives confidence and motivational interviewing skills may reduce and this may influence quality of delivery over time.

- Strong relationships that develop in antenatal care settings between midwives and pregnant women may enhance ABI delivery.

- The continued relationship that midwives have with pregnant women in antenatal care may inadvertently cause pregnant women to provide socially desirable responses to alcohol screening.

- The mandate given to midwives to interpret validated screening tools for women understanding may have unexpected consequences.

5.10 Plausible context, mechanism and outcome configurations

The central theme of realistic evaluation is to build theories and test them. The initial set of programme theories are propositions which span contexts, mechanisms and outcomes and they describe and drive the remaining aspects of the evaluation (Pawson and Tilley, 1997; Wand et al., 2011). Based on this principle, and considering that this section forms the final part of stage one of the realistic evaluation framework for the thesis, the programme theories outlined in this chapter together with the ones in chapter two and three were used to construct a plausible CMOs that informed subsequent data

collection. Table 5.3 shows the possible context, mechanism and outcome configurations.

Table 5.3 Proposed CMO configurations

Context	Mechanism	Outcome
Proposed CMO configuration one Uncertainties abound regarding the evidence of effects of moderate levels of drinking on the fetus	**M1:** Midwives and pregnant women attitudes towards risk of drinking in pregnancy may be important for screening and ABI delivery. **M2:** Training and support may enhance midwives understanding of risk. **M3:** Through the initiative, midwives have regular opportunity to assess women drinking levels. **M4:** Regular discussions with women about prenatal drinking may help raise awareness and offer midwives opportunity to address issues of uncertainties bothering women.	**O1:** The positive attitudes may promote screening and ABI delivery and negative attitudes may have the opposite effect. **O2:** There could be improved understanding of risk of prenatal drinking for midwives and women. **O3**: There could be Improved ability to impart alcohol assessment knowledge to women **O4:** There is increased possibility that relevant information and advice offered to women.
Proposed CMO configuration two Antenatal period is a good opportunity to screen and deliver ABI because there is a captive audience and most women are motivated to change drinking behaviour.	**M1:** The good relationships that develop in antenatal care settings between midwives and pregnant women may influence ABI delivery. **M2:** Screening only may reduce alcohol consumption to some extent.	**O1:** Women may increase or decrease reported levels of drinking **O2:** Women are likely to abstain or reduce. **O3:** Misidentification of women could be a possibility. **O4:** Inclusion of a booster

Context	Mechanism	Outcome
	M3: The mandate given to midwives to interpret validated screening tools for women understanding may have unexpected consequences. **M3:** Booster component such as inclusion of a partner, allowing adequate time for delivery or employing multi-session approach may be essential to alter the behaviour of women drinking hazardously or harmfully in pregnancy.	component may help such category of women reduce alcohol consumption
Proposed CMO configuration three The adverse effects of drinking in first trimester is profound as compared to second and third trimester drinking and may present challenges to the timing of screening and ABI delivery.	**M1:** Policies like KCND may facilitate early identification of alcohol use and intervention. **M2:** Screening has been extended to also identify pre-pregnancy hazardous and harmful drinking. **M3:** Screening and ABI to be delivered in the midst of other competing issues. **M4:** Undeveloped relationship at the booking appointment may affect screening and delivery of ABI.	**O1:** Risk to the fetus may be reduced and it could change subsequent maternal drinking behaviour. **O2:** It may ensure that all women who are at risk of hazardous or harmful drinking are covered. **O3:** The amount of information to be provided to women at the booking may compromise the quality of screening and ABI delivery. **O4:** Women may provide socially desirable response to screening.
Proposed CMO configuration four Training, support and dedicated personnel are	**M1:** Training may equip midwives with knowledge of risks of prenatal drinking	**O1:** May improve understanding of risk and positive change in attitudes

Context	Mechanism	Outcome
essential for effective screening and ABI delivery.	**M2:** Training and support may build capacity and ensure fidelity to ABI delivery **M3:** Training and support valuable in raising awareness among midwives about the need to intervene **M4:** Additional resources like the ABI professional pack provided to midwives could be valuable when utilized appropriately **M5:** Training and support may facilitate integration of the programme in antenatal care and encourage midwives to accept the initiative as part of their role	**O2a:** May improve skills and increase confidence to screen and deliver ABI **O2b:** Increased ability to assess units of various alcoholic beverages **O3:** May raised priority of screening and ABI programme **O4:** Boast morale and facilitate screening and ABI delivery **O5:** Greater involvements in alcohol intervention activities
Proposed CMO configuration five Few women consume alcohol in pregnancy	**M1**: Midwives likely delivering ABI to few women.	**O1**: The skills midwives gained from training could be redundant as such their confidence may plummet **O2**: ABI priority disregarded therefore the few women who drink hazardously or harmfully may not benefit from midwives' ABI delivery skills

6. 0 Chapter Six: Midwives' results

6.1 Introduction

This chapter is the beginning of stage two of the realistic evaluation framework employed by this thesis. It aims to explore and test the theories identified in chapters 2, 3 and 5 from midwives' perspective. The following sections outline the characteristics of the midwives and the themes that emerged from the data. At the introduction of each theme, the background and overall findings under that particular theme are usually given followed by presentation of the results. Where necessary the literature is drawn upon in relation to the discussions. The chapter concludes by outlining the key findings.

6.2 Participants' characteristics

One hundred information packs were distributed to midwives across the Lothian Health Board area and twenty-one midwives participated in this part of the study resulting in a response rate of 21%. Fifteen midwives participated in a one-to-one interview and six participated in a focus group.

6.2.1 Individual interviews

A consultant midwife, two team leaders and twelve community midwives participated in a one-to-one interview. Table 6.1 provides details of participants. The duration of the interviews ranged from 36 to 71 minutes.

Table 6.1 Characteristics of midwives involved in one-to-one interviews

Pseudonym	Position
Sheila	Team leader
Pat	Community midwife
Sophie	Community midwife
Cynthia	Community midwife
Fiona	Community midwife
Katy	Community midwife
Belinda	Team leader
Silvia	Community midwife
Esther	Community midwife
Lorna	Community midwife
Annabel	Community midwife
Julie	Community midwife
Hilary	Community midwife
Yvonne	Community midwife
Rachel	Consultant midwife

6.2.2 Focus group

Six team leaders participated in a focus group (FG). The FG discussions mainly focused on issues related to the screening and ABI programme in antenatal care settings (see section 4.9.4 rationale for the focus group) and it lasted an hour. Table 6.2 provides details of midwives involved in the focus group.

Table 6.2 Characteristics of focus group participants

Pseudonym	Position
Lynne	Team leader
Anna	Team leader
Vic	Team leader
Rhoda	Team leader
Eugenia	Team leader
Gloria	Team leader

6.3 Themes

Seven major themes were identified. All themes were identified deductively (see Table 6.3) based on the research questions and previous chapters. Whereas the one-to-one interviews provided data for all seven themes, the focus group spanned only four themes (see section 4.9.4 for detail). Although themes are presented individually in the sections below, implicitly they overlap. Individual interview data and focus group data are presented together where appropriate.

Table 6.3 Themes identified in the midwives data

Theme	Sub theme	Coding approach	Data source
Attitudes to drinking	• Personal drinking habits • Risk to the fetus	Deductive	One-to-one interview
Midwives' perceptions of pregnant women's drinking behaviour		Deductive	One-to-one interview
Midwives' assessment of risk		Deductive	One-to-one interview
Screening and ABI delivery	• Identification • ABI in practice • Missed opportunities • Advice	Deductive	One-to-one interview Focus group
Clinical settings	• Midwives' role • Relationship and booking appointments	Deductive	One-to-one interview Focus group
Benefits of ABI	• Benefits for women • Benefits for midwives	Deductive	One-to-one interview Focus group
Challenges		Deductive	One-to-one interview Focus group

6.4 Attitudes to drinking

It was hypothesized in chapter two that the uncertainties about the effects of low-moderate levels of drinking on the fetus could have a subtle influence on midwives attitudes to prenatal alcohol consumption. It is germane to note that attitudes of midwives toward alcohol consumption in pregnancy may directly or inadvertently influence their decisions about the help and advice they offer women or their approach to ABI delivery. It may also determine the level of priority they accord to the issue of drinking in pregnancy in the midst of other competing issues.

6.4.1 Personal drinking habits

Policy implementers interviewed for this study indicated that midwives own drinking behaviour could influence their attitudes to alcohol intervention activities (see section 5.6.1). During the interview, midwives sometimes spoke about their own alcohol use to emphasis a point or convey an opinion and this was used to understand the kind of advice they gave to women.

Midwives who reported that they did not drink alcohol had negative views about drinking in pregnancy. Sheila expressed one such view:

> *Nothing affects my views on drinking, I know what I feel about drinking, I don't agree with it, even in the healthy 'unpregnant' person (Sheila).*

Some of the midwives felt that, compared to a woman's life span, pregnancy is of negligible duration. As such, they believed that giving up on alcohol for that brief period should not be too difficult for women. This view was not only limited to the midwives who said they did not drink themselves. Some of the midwives who indicated that they did drink also shared similar sentiments as reflected in Belinda's extracts.

> *...that is why in planning a pregnancy abstinence from alcohol is the best. Because again it is just such a short period of time. I am not saying to women to*

cut alcohol as a lifestyle choice forever, but when you think of what they are doing and what they are growing; the health of the nation and the health of the baby, it just a little thing to do, it could be just a little thing to do with a proper education (Belinda).

For Belinda, the fact that an individual drinks does not necessarily mean they should risk drinking in pregnancy. Her assertion implies that the benefits to the fetus of abstaining from alcohol should be a priority over personal preferences for drinking.

Some of the midwives who reported that they used alcohol showed scepticism regarding the current push for abstinence in pregnancy. Lorna for instance, questioned the rationale behind Scotland's current recommendation of abstinence from alcohol when pregnant (NHS Health Scotland, 2010a).

Certainly as a midwife I will probably join in and say, "how come women in France drink and they don't suffer from alcohol and here in Britain they are giving mixed messages to women saying don't drink alcohol at all because it might have an effect" (Lorna).

However, it was noted that regardless of what midwives own drinking habits were there was no clear distinction as to whether they advised abstinence or not.

If somebody says to me, "I am going to a wedding today, can I have a wee champagne?" I will say, "sure have a few sips of champagne, why not?" That is not drinking; you know that is like joining in with the celebration. But they should be drinking lots of water, if they are having wine, they can dilute it or something but I won't be saying to them absolutely not (Lorna, said she drinks).

If a pregnant woman said to me, "I am going to a wedding at the weekend and I want to have a glass of champagne". I will say, "have a glass of champagne. Have it with food. Even a small glass of champagne is not going to do any harm". Because I know what binge drinking is about (Julie, said she does not drink).

The above references to 'a wedding' are indications of some midwives acceptance towards occasional drinking, especially for a celebration. A survey in Denmark also found that 69% of midwives deemed some alcohol intake in pregnancy as acceptable

(Kesmodel and Kesmodel, 2011). Some guidelines in the UK are also more accommodating towards occasional alcohol consumption of one or two units per week (Department of Health, 2007; NICE, 2008).

6.4.2 Risk to the fetus

Midwives attitudes to drinking in pregnancy were also influenced by their perception of risk to the fetus.

> *I am aware of fetal alcohol syndrome and the problems it can come with drinking in pregnancy, so my point of view is no alcohol in pregnancy (Pat).*

Throughout the interviews, it was apparent that the uncertainties regarding the threshold at which alcohol could harm the baby encouraged many of the midwives to take cautious stance towards abstinence from alcohol during pregnancy.

> *I think I have always taken the view that it will be better to not drink at all than be unsure about what amount is safe, then it will be better not to drink at all than to risk taking too much that way (Fiona).*

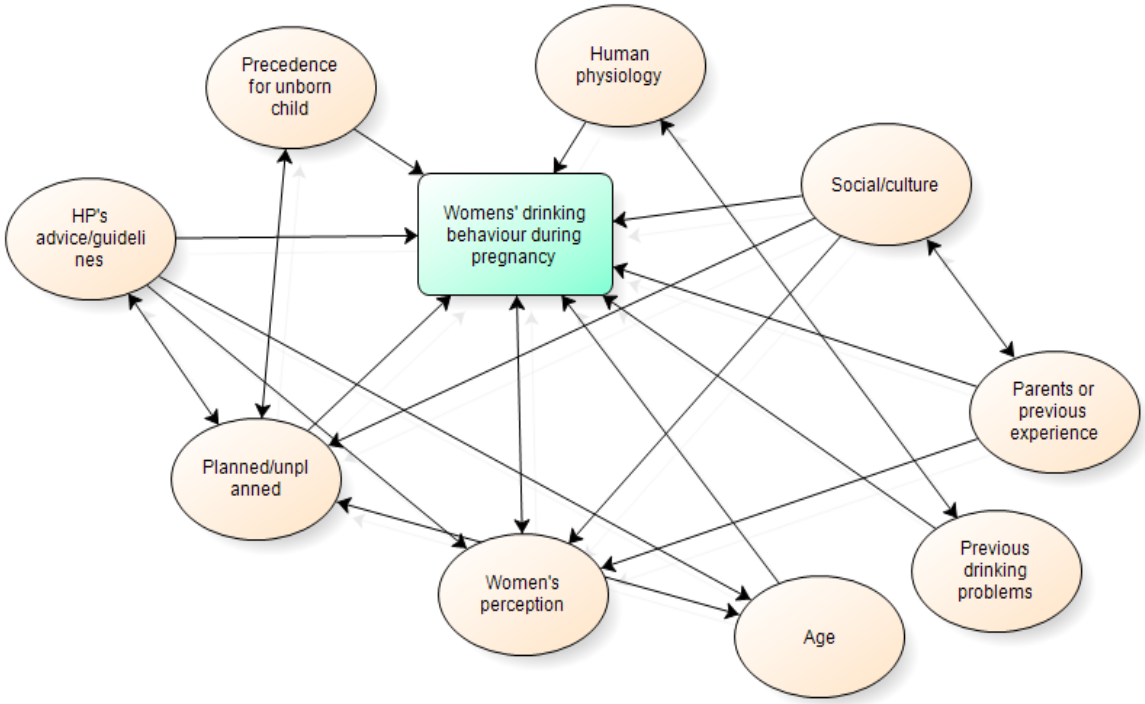
Thus, some participants believed that abstinence from alcohol in pregnancy is the best in the midst of uncertainties because it is safer to be over cautious rather than risk the health of an unborn child.

6.5 Midwives' perceptions of pregnant women's drinking behaviour

Midwives reported on their observation of women's drinking pattern during pregnancy and identified specific factors that influence those behaviours. Midwives perceived that prenatal alcohol consumption was influenced by a variety of factors. Whereas some of these factors may promote sustained drinking in pregnancy, many were inhibitory, with participants emphasizing that most women discontinue alcohol use after pregnancy

confirmation for different reasons. The factors reported include physiological changes that occur in the body during pregnancy; pre-pregnancy drinking problem, planned or unplanned pregnancy status, women's personal views, cultural, social and most importantly precedence for the health of the unborn child. Figure 6.1 illustrates factors identified by midwives and the inter-relationships between them. It was common for participants to either report that most of the women they cared for drank at the time of conception and during early stages of pregnancy, or periods when pregnancy was unconfirmed (see section 7.7.1 for pregnant women's accounts). With this assertion, almost all midwives were of the view that pre-conception prevention strategies would be more beneficial for the health of the fetus than interventions delivered in antenatal.

Figure 6.1 Midwives report of factors that influence women drinking during pregnancy and their interrelations



All midwives said that the majority of the women they see report that they do not consume alcohol whilst pregnant and are often baffled when they are questioned about alcohol. Most expressed the view that alcohol seemed less of a problem among pregnant women as compared to smoking and the use of other drugs.

> *Sometimes I feel that women think you are a bit crazy because you are even asking them if they drink in pregnancy. You know it is almost like they expect you to know that or they will say, 'well I am pregnant, of course I don't drink'. You know some women it is just automatic, you are pregnant, and you don't drink (Pat).*
>
> *Certainly, alcohol is not a big problem that I see with my women. That's not to say that there's isn't women drinking but certainly when we talk about it, when we ask I don't have women saying to me that they are drinking in pregnancy. There are plenty women that will tell me they are smoking and I have women that will tell me they are taking drugs (Sophie).*

They perceived that most women are aware of the current guidelines of no alcohol drinking in pregnancy and as a result, they have taken the initiative to avoid alcohol using in pregnancy before they even make contact with them.

> *I think by the time most of them have come to us most of them say I don't drink now. So they already know that drinking in pregnancy is not recommended (Lorna).*
>
> *I think most women have already decided what they are going to do. So I think by the time they see me, I am confirming what they think themselves. So I think most women decide not to drink (Annabel).*

All midwives identified the health of the baby as being the primary factor in women's decision whether to drink or not in pregnancy. Throughout the interviews, participants were quick to add that most women were motivated to cease drinking; at least from the point pregnancy was confirmed.

> *I think the concern is the baby for the vast majority of them. You know, one of their big questions always through the pregnancy: 'will baby be ok?' They kind of want this 100% perfection at the end of it. And they want to do anything they*

can to achieve that goal and I think certainly, alcohol is seen as a big issue. So the main driver is not to harm the baby (Silvia).

Silvia's assertion echoed the one by Belinda below but she added that for some women, the choice occurs naturally often dictated by the tendency of the body's physiology to react to alcohol when pregnant.

In the early stages, women will go of alcohol through nausea and vomiting but not by choice. Often if it's been a conscious choice for the woman to reduce it herself, then it will be for the baby's health more than their own health (Belinda).

Fiona's view was different. She believed that the emotional imbalances associated with pregnancy might rather facilitate drinking, especially for problem drinkers.

It is a very hard time for women. Women can become depressed and if they have had a problem with drink before that might be quite a starter to drink again in pregnancy (Fiona).

Another factor that participants identified to influence drinking behaviour in pregnancy was culture or social perspective. Below Yvonne, noted that cultural norms may have strong connotations and may sometimes prevail over clinical recommendations.

It depends, I looked after a woman, she is from France, she had not changed her diet at all, and she had carried on drinking in her pregnancy because that is what she would do in her country (Yvonne).

Yvonne's observation was that although this woman is now based in Scotland, she had retained values from her native country that have not been altered by current recommendations in Scotland. Chiaffarino et al. (2006) argued that people from countries with liberal outlook on alcohol use in pregnancy, are likely to report their true level of alcohol use in pregnancy.

It was commonly reported by the midwives that women that planned their pregnancy were more likely not to drink in pregnancy (this concurs with pregnant women's findings in section 7.7.1). For some women, planning pregnancy could mean that an attempt has been made to explore ways to have healthy pregnancy. It could possibly involve contacts with family planning clinics regarding advice on discontinuing contraceptive use or help with conception. In some cases, it may entail contacts with fertility clinics as Sheila illustrated below.

> *The women I see in my area are all well read. They are mature women; most of my clients are over the age of 30. A lot of them have gone on through the infertility treatment. So you have got a high level of people who are looking for a healthy baby and will have researched it all and would have been given all the information if they go through the IVF programme they have been told there that alcohol use is out of the window (Sheila).*

Under these circumstances because there have been considerable efforts towards the pregnancy at pre-conception, maximum care is usually exercised, including forgoing negative health habits to ensure healthy pregnancy outcomes.

There were mixed beliefs about the influence of previous pregnancies on women's drinking habits. For example, Katy argued that women with no children are bound to drink more than women who have other children. Financial and time commitments connected with childcare are therefore likely to discourage drinking. She perceived that those with children were less likely to drink.

> *The ones that have got children already, the majority of them tend not to drink as much because they have got other children and it will mean getting a baby sitter to look after the children. There is very few of them that I have come across that have been drinking with children (Katy).*

A small number of midwives indicated that women might continue to drink, especially if they observed no abnormality in their previous children although they had drunk

during those pregnancies. A couple of the participants noted that some women relied on the experiences of other family members or friends who drank during pregnancy but had positive outcome as the rationale for continued drinking in pregnancy.

6.6 Midwives' assessment of risk: timing and pattern of drinking

It was hypothesized in chapter two that midwives knowledge and understanding of risk could have an impact on the urgency and priority they accord to identification and delivery of ABI to women. Generally, participants showed good understanding of the effects of alcohol on the fetus. It was common knowledge among all participants that heavy sustained drinking causes FAS. Most of the views expressed by participants were in line with evidence but there were few who had views that were more congruent with their personal experiences of drinking. A few other midwives were sceptical about the effects of alcohol on the fetus because they felt that, although they had worked as midwives for so long and had seen women abusing alcohol, they observed no anomalies in children born to those mothers.

Aside awareness of FAS, several participants were able to identify several adverse fetal outcomes associated with drinking in pregnancy.

> *Well we know that it can cause various things in early pregnancy between brain damage, low birth weight, miscarriage and it just harms your baby. It is like smoking, it is still a drug (Cynthia).*

There were varied views relating to low-moderate levels of drinking. Whereas some were unsure of the effects of low-moderate level of drinking, others thought this level of drinking posed no risk to the fetus.

> *...if somebody, even somebody who is quite advanced in their pregnancy, then goes and have a drink for whatever reason, I mean they will feel lousy, but I don't think the baby will be harmed by that (Annabel).*

> *...you know towards the end of a pregnancy if they go to a wedding or a birthday party maybe one drink wouldn't be harmful but certainly no more (Sophie).*

By the assertion above, Annabel related her assumption of risk-free drinking to two factors. First, her reference to 'a drink' presumably implied low level drinking and secondly the term 'advanced' in her description could mean drinking during late pregnancy.

Alcohol interaction with diet was noted to be relevant in the relationship between alcohol and fetal defects.

> *Excessive alcohol is always going to be damaging to the woman and the baby. But whether or not if you have a glass of wine with your dinner two or three nights a week if that is going to affect the baby or not, I will probably debate. Probably, say that it wouldn't have any effect on that baby (Julie).*

By the above extract, Julie recognised the relevance of nutrition to modulate the effects of alcohol. Nutrition certainly alters alcohol metabolism. Using an animal model, Shanker et al. (2007) observed that rate of metabolism was greatly reduced in under-nourished pregnant rats as compared to adequately fed ones. This indicates that lack of adequate nutrition during periods of alcohol consumption increased tissue concentration of ethanol extrapolating that the fetus may be exposed to the toxic effects of alcohol in the absence of adequate diet.

To better understand midwives knowledge of effects of prenatal alcohol use, I explored their views on the trimester they considered drinking in pregnancy could be most dangerous to the fetus. It was clear that majority considered drinking in the first trimester to be more risky for the fetus, which is congruent with the evidence found in chapter two.

> *It is the whole pregnancy but probably at the time when most women are drinking anyway. And it is the time that they don't realise that they are pregnant, when the central nervous system are being formed. Certainly, within the first three months, I think and that will have a big impact on the fetus (Belinda).*

On the other hand, Annabel expressed the viewpoint that sustained pattern of drinking throughout pregnancy could cause fetal defects but drinking in the first trimester seemed to carry very low risk. She perceived that most women drink unknowingly of the presence of an embryo in the early stages in pregnancy and by her opinion; the number of children harmed in this way is very low and does not reflect the number of occurrence of the habit. As such, this difference could mean it is the first trimesters, which poses the least risk.

> *I don't know if we really know what the effects of alcohol are on the developing fetus. I am not too sure about that. I think it is more to do with continuing drinking through pregnancy. I mean if you drank alcohol without knowing that you have conceived or in early times of conception, it doesn't seem to affect (the baby). I would have said that it doesn't affect (the baby) because so many people have done it, you know (Annabel).*

By the statement above, Annabel presumed that the effects of alcohol on the fetus are manifested only by physical deformities and this was also highlighted by Lorna's comments below.

> *You know there is not enough evidence (of the effects of alcohol on the fetus) although that book (Ready, Steady, Baby!) says there is evidence. You know, all my career I haven't seen a lot of evidence and I don't think I come from a good area. We have more people who are dependent on all sort of things and we don't actually see children who have got, like FAS. So it does take a little bit to actually convince our public that there is a problem (Lorna).*

Lorna then supplemented her arguments with an example of a patient she cared for in the past. She reported that although the woman drank heavily during her pregnancy, she later had a healthy child. She said of the child:

... I still see that young girl growing up and she is beautiful and she is fine and all, and I think ok. I would expect that child to have an abnormality, you know obviously poor development but she is a beautiful child, she is very normal and all that (Lorna).

By this description, it seemed Lorna had some doubt about whether alcohol really has significant adverse impact on children. Nevertheless, it is important to understand that the effects of alcohol on the fetus are dependent on both genetic and environmental factors so there could be differential effects among individuals.

6.7 Screening and delivery of ABI

Midwives usually screen and identify women for ABI at the booking appointment (first appointment with a pregnant woman). Women who say they are drinking or indicated that they drank pre-pregnancy are further assessed with T-ACE or TWEAK screening tools (see section 1.6.2) to determine pregnancy risk drinking. Pregnant women who screen positive may then be offered ABI.

6.7.1 Identification

Midwives felt that identifying alcohol use in pregnancy is a difficult task especially for non-problem drinkers because objective markers may be unavailable. One midwife explained that in the case of other drug abuse, patients' case notes might reveal that they are or have been on prescribed drugs to help treat, for instance illicit drug use.

I think with substance misuse it's a bit more clear because women are often in a service already where they are getting the methadone or whatever prescribed, alcohol is different but they are not getting prescribed that so it's easier for most women to conceal it so it is pretty unusual for us to have women admitting to drinking to excess (Eugenia, FG).

The current validated screening tools (see section 1.6.2 for details of T-ACE and TWEAK screening tools) replaced a previous non-validated one and are intended to aid

in the identification of more women eligible for ABI. Interestingly, some midwives perceived that that there had not been much difference in terms of numbers identified to be drinking.

> *And one that was going to tell you was always going to tell you anyway and I don't think we are disclosing any more or finding out about any more alcohol use than we ever did (Lynn, FG).*

Other few participants supported this claim. Yet, Anna's extract below showed that there have certainly been improvements in the quality of identification.

> *Of people who don't think they've got a problem and once you start adding it up there's a fair bit there but then they don't hide it because they didn't think it was a problem, you get more out of them than you would of before when you just wrote down social drinking, no problem (Anna, FG).*

To enhance identification midwives asserted that additional resources provided by NHS Health Scotland have been helpful.

> *Because of the confusion with units we have cup measures and we have slide rules that we got from the alcohol brief intervention team so that we can show them that a vodka, wicked or whatever is one and half units and not just one units. Sometimes that just enough for them to think, 'oh my goodness I didn't think it is so many units etcetera' (Belinda).*

Several midwives claimed that the wording of the screening tool seemed a bit difficult for some women to understand and answer, and difficult for midwives to record too (see section 5.8 for policy participants views on screening tools).

> *I have also found that the questions we ask are very difficult to answer because we ask how many alcohol do you drink in a week and you know you will get women saying, 'well I only really have a drink if I went out and I only really go out twice a month'. Do you know what I mean? So questions are hard to answer, hard to tick the boxes really (Julie).*
>
> *...difficulty in understanding what the wording means and being able to explain that to women (Rachel).*

Here, Rachel revealed that she found it difficult to understand the tools too. Midwives understanding of the tool are important because they might have to interpret them to women. Therefore, any wrong interpretation may mislead women. If women reportedly found it difficult to comprehend the tools then, it is likely that they may be misclassified. Misclassification could also occur when midwives have to convert descriptive information into numerical values when recording the screening response. The implications of this on the quality of data being collected are apparent.

Interestingly, some midwives indicated that most of their clients reported that they do not drink so they do not fully utilize the tools.

> *There is a screening tool but most of my women say I am not drinking so I don't ever have to resort to that which is quite nice in this area (Sheila).*

Participants explained that after the screening questions, there is a prompt that helps to assess whether an ABI is required. The prompt also enhances the subsequent follow-ups.

> *And then there is a question, is the intervention required? and we tick that so if she has been previously drinking more than fourteen units a day or if she is currently drinking, and then as you were saying at each antenatal check beyond that there is a prompt you know, so you can follow that up (Vic, FG).*
>
> *When we ask them, you go back three-four weeks later or at certain point in the pregnancy to ask about the alcohol intake as well and you know, follow up anything that might arise or whatever (Rhoda, FG).*

6.7.2 Views and understanding of ABI delivery

Midwives had different opinions about the ABI initiative and it appeared that many were not convinced of its usefulness. It was apparent some midwives were uncertain of the rationale of ABI and the expectations of what they were required to do.

The HEAT target is more to train all the midwives and have the questions asked and once we have ask the questions sometimes it is not followed through, I mean we could ask all the questions or is it just for them to get the statistics or is it for us to do something about it. I am not sure why (Sheila, team leader).

Following on from Sheila's response, I asked:

I: But you told me that you have received training in ABI, so is it not within your capacity to do the ABI?
Sheila: We will follow them through, we will probably refer them to their GP who will then refer them on to the appropriate counsellors or you know if they felt there is the need to get help to stop and that what it is about. It's to recognise if there are people who need the help.

In the focus group, team leaders had conflicting ideas about the ABI as well. Below one team leader gave a description of her opinion about ABI.

The term 'brief intervention' is a complicated term you think it is some kind of physical thing to do where really it's really just sort of delivering the bit about the preventative care you know on your alcohol. To me it is, the alcohol consumption is unsafe and this is the recommendations, that is to me what a brief intervention is and if it is unsafe then we are going to refer on that's part of it (Gloria, FG).

To this statement, one member of the group added that they could not remember the protocol involved in delivering the ABI. Her colleague chipped in jokingly, *"well, you just give them a bit of advice and a leaflet and pat them on the head"*.

Several midwives felt that the main aim of the ABI was just to raise awareness of alcohol. Although this may be part of the components of the FRAMES model of ABI currently in use in the antenatal care, there are other elements too, such as assessing readiness to change, goal setting, involving adequate behaviour modification strategy and enhancing self-efficacy.

I think it is good to raise awareness about alcohol and that all we are doing, we are not doing any particular ABI in trying to cure them or anything that is not

my job. I am here to educate them to be responsible parents and realise that it is not a good thing to do in pregnancy and just to raise awareness of alcohol consumption. To let them know, because people don't know what a unit is and what, how much is seen as excessive. So we raise that part and they can work out for themselves that all midwives are to do is to raise awareness (Sheila).

Sheila's reference to the phrase, '(*not) trying cure them or anything'* may infer that she did not understand the effectiveness of ABI in reducing alcohol intake or promote abstinence in harmful and hazardous drinkers.

Some midwives could not see ABI as adequate on its own and felt women need to be referred on to a specialist for further care. Below is an example from one of the interviews to elucidate this assertion:

I: Do you think it is your role as a midwife to carryout ABI?

Katy: I think it is our role to give them advice and to be able to advice them about alcohol and say we can direct them in a way to somebody who could help them to be able to offer help and say well this is what we need to do, we can contact such and such a person and these people know more information because we can't know everything. If we try to do everything, I think we will get traumatised doing it.

Midwives could refer clients to other health professionals and below one team leader clarified the position about referral pathways.

We do occasionally refer (to other specialist), if there was somebody with a (alcohol) problem (Lynn, FG).

6.7.3 ABI in practice

Few midwives reported that they have offered ABI to women.

I completed my training in February, so six months now and out of those, I have probably given only about five ABIs (Belinda).

I think I have only got one woman at the moment who was a younger woman and was very honest when she came along and told me her levels and they were

very high. And so subsequently we had discussions (ABI) and now she says she is not drinking anything at all now (Julie).

It was common for midwives to report that they had not carried out ABI since the inception of the programme. Similar statements like, *"Fortunately, I have never had anybody since we started it, that needed the help"* by Sheila was echoed by several participants throughout the interviews.

In the focus group when the question came up about the number of ABIs they have delivered since its inception, participants were quick to answer:

Absolutely very few (Lynn, FG).

Another added:

Very very few (Vic, FG).

6.7.4 Missed opportunities

It was clear that under some circumstances, midwives may have missed opportunities to deliver the intervention.

...if I was concerned about anybody then I will certainly be finding out more about you know the ABI, The whole alcohol intervention, alcohol screen is very new to us as midwives. If one of my pregnant ladies was drinking then I will certainly be a lot more involved in that, will be a lot more knowledgeable about the alcohol intervention. I haven't had the situation; it has never arisen here for me other than the young girl who said 40 units (Pat).

Pat's illustration here depicted that she was unsure what to do if a woman required an ABI. However, the situation with the 'young girl' was an opportunity to deliver an ABI. She revealed earlier on in the interview that the young girl told her that she drank 40 units just before pregnancy, which was about three times over the recommended weekly allowance for non-pregnant women. Although she was clearly eligible for ABI, Pat had

not taken the opportunity to deliver the intervention.

Another midwife indicated that she has not had the opportunity to deliver ABI, yet she revealed that one of her clients reportedly drank 21 units per week in pregnancy. When I asked why that woman was not offered ABI she replied:

> *That particular girl had said she will look at what she was drinking and she is going to be coming back to see me so that is ongoing (Esther).*

Similarly, Cynthia also had an opportunity but did not offer any ABI, though she had already booked her client.

> *I haven't come across any problems so far but as I say there is only one girl who has just booked with me and I don't know she has admitted to having about eight units every two weeks (Cynthia).*

6.7.5 Advice

Advice about alcohol is one of the components of the FRAMES model of ABI. Most of the midwives were clear about the current advice to women concerning alcohol use in pregnancy. In the focus group, all the team leaders knew the current advice and the source of the advice.

> *Well the advice in pregnancy is that they should decide not to drink at all, all the literature that we give them says that, I know there is other stuff out there now days that's saying that it might be quite good for you to have a wee drink but the advice that we are giving, which is NHS Scotland advice, which is not to drink at all in pregnancy (Anna, FG).*

In the individual interviews, there were disparities among midwives concerning the current advice for pregnant women. Whereas most were aware of the current advice, some although, aware that the information and resources (Ready Steady Baby) had been updated, they thought the previous advice was still in use.

The ready steady baby book has been revamp so it kind of new you know. They've changed it all. I think in the ready steady baby book, there is an area that says it is ok to have one alcoholic drink (Pat).

I will say between 1 to 3units, the recommended weekly allowance, that will be to me, low level. If they exceed that, I will say that is when they need ABI (Sheila, team leader).

6.8 Clinical settings

As with any new intervention, organisational structures within the antenatal care settings are likely to influence screening and ABI delivery. From the interviews and the focus group, it was clear that a variety of factors could have significant impact on the effectiveness of the intervention within antenatal settings.

6.8.1 Midwife's role

Most participants agreed that tackling alcohol use in pregnancy is one of their public health roles and that alcohol use in pregnancy is a worthwhile enquiry to make and intervene. However, Katy felt they were compelled to do it because it is a government initiative.

Well we don't have any choice. We got to get on with it because it is one of the so called HEAT targets for the government so we've got to do it. So we have to do it. You might think someone else's must do it but we've got to do it. I mean we have no choice (Katy).

Nevertheless, for those who indicated that it was part of their role, some were of the opinion that the service has been added to their already huge workload.

I think it just part of a bigger package of care that we are now offering than we ever offered in the past and I suppose we have had ABI training... so the role is constantly growing whereas the midwife capacity probably isn't growing in time with that. But I think midwives see health promotion and public health as part of their role (Rachel, consultant midwife).

Here, it is important to bring into perspective that before the introduction of screening

and ABI, midwives were still asking about alcohol, but it was a couple of questions with 'yes' or 'no' answer options.

> *(Before the initiative) we probably asked them, were they drinking? Now we are asking them; what is your pattern of drinking, how many units do you drink in a week, how many units do you drink in a day, how many units were you drinking before you got pregnant. Whereas before we didn't actually (do that). That has only been this year in fact with the Scottish Government's directive (Lorna).*

Yet some felt that it was sort of 'information transition' which means once evidence emerges in an area, which is relevant to patient's care, it is appropriate that the information is passed on to them to improve their care.

> *I don't think alcohol was that much terribly mentioned previously, but neither were drugs or smoking. As the years have gone on, we are much more attentive with information, with health education. I think we know a lot more ourselves and we are more researched based so we can actually pass information on now to clients to help them, and with ABI to have a different lifestyle (Hilary).*

6.8.2 Relationships and booking appointments

Midwives believed that strategically they are well positioned to deliver health information or ABI and that the type of services they provide meant women are more likely to respond to them in terms of delivering health behaviour interventions (see section 7.10.1 for pregnant women's findings on this issue).

> *Midwives have good profile, we look after women we are suppose to have lots of knowledge, we are going to help them through their birth of their baby and give them advice in their first few weeks afterwards. We have got a profile that women hopefully take note of (Lorna).*

Some midwives perceived that their position as an authority figure could have negative consequences by encouraging women to underestimate their consumption levels.

> *Because I think that women you know if they are coming along and they are pregnant you know sometimes I think they find that, you know this is the midwife*

I have to do my best for my baby so they try and underestimate everything in a sense. Not everybody but I think there are a few people who might do that (Julie).

However, midwives generally highlighted that they were careful in handling alcohol use in pregnancy in order not to alienate their clients.

I mean somebody sitting in front of you and you don't want them feel that they can't come and see you again or whatever (Annabel).

Most midwives felt that screening and delivery of ABI at the booking appointment was not appropriate because of the potential implications it has on midwife-pregnant woman relationship, yet they recognised that under current circumstances for antenatal care it was the best option.

The other thing that makes it difficult is that at booking you have only just met the person. So, you are already asking a lot of personal questions. You probably haven't ever met her before and then you are required to you know take action whether it will be for ABI or gender based violence. It is very difficult, yes but I don't know when the good time will be, you know. Because by the time if you have met her for three or four times, she is already, well on in her pregnancy. And that is the longest appointment that you have so that is the most time you have with somebody (Rachel).

Here Rachel, felt that first appointment was unlikely to yield the best outcome for alcohol identification and intervention because it is the first time of meeting pregnant woman as such there could be problems with trust in divulging sensitive issues. Yet she recognised the challenges of offering it at times outwith the booking appointment.

A few midwives were of the view that the build up of rapport over time promotes confidence that may enhance discussion of alcohol issues with women.

Obviously it a bit sensitive talking about anything like that but it need to be discussed and you will know that the more you are able to build up a relationship with women that you are able to discuss these things (Fiona).

Fiona's description here was echoed by Lorna, who likened the issue of trying to identify at booking pregnant woman who have been drinking to that of a domestic violence victim.

> *I am just going back to (the issue of) domestic violence, if I was to ask a woman, are you violated against? Are you free to go home? Have you ever suffered violence at home? Do you think she is going to tell me when she does not even know me at booking? (Lorna)*

Fiona and Lorna's expressions above affirmed the difficulty of discussing sensitive issue with someone who is not an acquaintance. Alcohol use in pregnancy is certainly a sensitive issue for many pregnant women and midwives to discuss in the context of antenatal care.

Some midwives perceived that women may not be in a good frame of mind at their booking appointment and this may affect their receptiveness to an ABI.

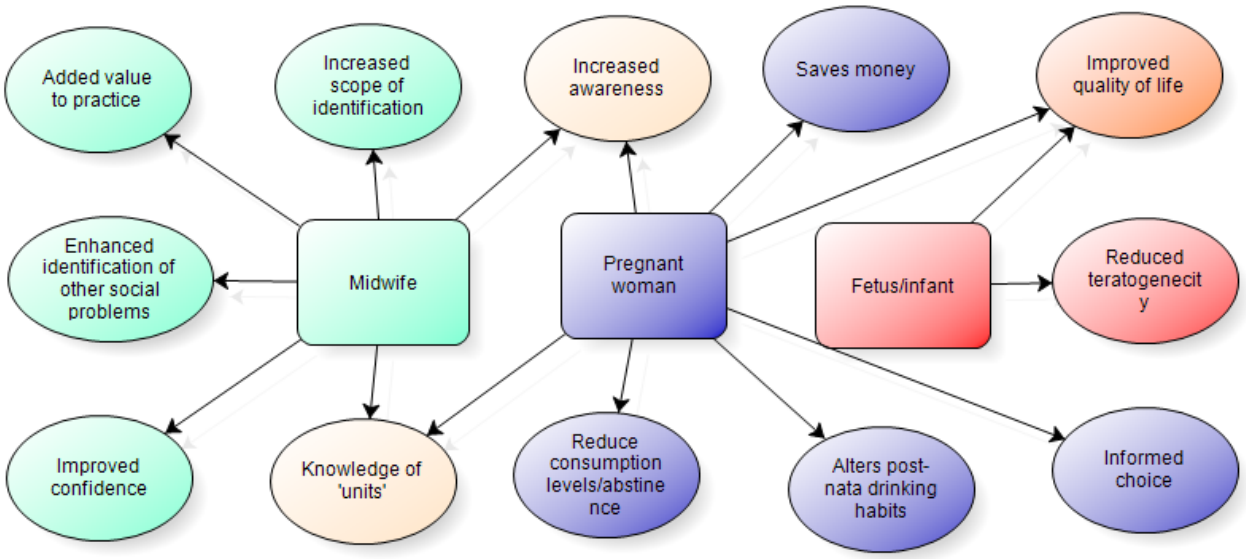
> *I think it is difficult to do it at the booking visit, as I said, because you have just met somebody. It is not a situation that is easy because the woman already feels probably nervous about coming to the appointment, nervous about meeting somebody new, you haven't built up a relationship I suppose and it is easier to do anything if you have built up a relationship with somebody (Rachel).*

As noted in chapter one, ABI utilizes motivational interviewing approach to alter drinking behaviour, as such under these circumstances, a midwife's skilfulness in using the technique would be relevant in making the woman feel comfortable at the booking appointment and in generating interest and eventually motivating her to change her drinking behaviour.

6.9 Benefits of screening and ABI

Midwives recalled that the ABI programme had several positive sides, for not only women and their unborn child but for the value it has added to their practice. Figure 6.2 highlights the main benefits highlighted by midwives.

Figure 6.2 Summary of midwives' perceived benefits of ABI in antenatal care.



6.9.1 Benefits for women and fetus

Midwives overall outlook was that screening and ABI created awareness about alcohol use in pregnancy and its place in antenatal care was good because pregnancy is a stage where women are motivated to change negative health behaviours.

> *There's not many other opportunities that women are told you shouldn't be drinking you know it's not, I think pregnancy is one of the times that women are more than happy to stop drinking, most women are more than happy to stop so it probably is a good time to do brief intervention (Sophie).*

However, there were differences in views as to the benefits to women who might have already used alcohol. A minority of participants felt that for those women the burden on the fetus could be reduced.

> *...hopefully we are preventing any further damage to the baby (Cynthia).*

For most midwives, ABI in antenatal care was a bit late and may not necessarily be of benefit to the current pregnancy but may benefit subsequent pregnancies and future lifestyle. One participant felt that providing the ABI especially to those women, who drank excessively pre-pregnancy, might help equip women with information that could encourage them to have healthy drinking pattern once they have had the baby.

> *The good thing for me is that a lot of the girls here, are binge drinkers, and we are giving them that information. Hopefully, once they've got a baby they are not going to go back to that binge drinking way of life (Julie).*

By this, Julie believed that awareness may translate into behaviour change. Sophie gave an interesting reason why the increased in knowledge might translate into drinking behaviour change for pregnant women.

> *At the moment, we are trying to discourage them from drinking in pregnancy. You are asking about their drinking habits beforehand which hopefully when they've not had alcohol for nine months, it's easier to go back to a safe limit of alcohol than going back to your old habits because you've abstained from alcohol for nine months (Sophie).*

Julie also highlighted the post-pregnancy benefits of ABI to the child:

> *If she can stop alcohol and smoking and drugs and have a good diet and do all the positive stuff. And when the baby is born, hopefully he will be born into a smoke free home with parents who don't drink excessively. It is going to give that child a much better chance, plus the cost of all of that. Financially, the woman can't afford because quite often we are talking about a single mother, they don't have a partner (Julie).*

According to Julie, drinking is an expensive habit, and especially so for the non-affluent

woman, as she described, therefore any reduction or abstinence would mean more money would be available to support both mother and baby.

Some participants believed the ABI helps pregnant women reflect on their level of drinking and re-evaluate the impact of their habit.

> *I think a lot of the intervention I give is to actually let people realise that they are binge drinkers and they don't realise that (Sophie).*

The midwives felt that this was often achieved by improving women's ability to determine units in their drinks thereby enhancing informed decision about how much absolute alcohol is in a drink for those who opt to continue drinking. Below Pat gave an example of the essence of discussing units of alcohol with women.

> *...I asked her exactly how much she was drinking, she was to give me a typical week before she was pregnant and explained what a unit was and she told me that it was 40 units a week. So if nothing else, it made her aware of what is a safe limit for young girls, non-pregnant and really how far over that she was going on a weekly basis (Pat).*

As Pat explained, going through units of alcohol consumption with pregnant women may not only equip them with knowledge to determine the units of alcohol in their drinks, but it may also offer them the opportunity to reassess their drinking pattern and determine whether it is within or over sensible limits.

6.9.2 Benefits for midwives

Midwives were of the view that the initiative has broadened their scope of practice and that they are able to find opportunities to advice women who may otherwise report that they are not drinking in pregnancy. They revealed that previously they just asked a single question to find out whether a woman drank or not and often did not know how to respond appropriately to the answers given. They reported that with the ABI

initiative there is the opportunity to advise women about drinking within recommended levels beyond pregnancy irrespective of client's current drinking status.

> *I would say and this is personal I can't speak for my team. But the only thing I would say that's changed is that I now talk to women about when they go back to drinking afterwards. Because the majority will say I was drinking, I don't drink now. So the only thing that has changed is I will talk about when you go back to drinking again, what you are saying that you drank before it's you know more than you should be (drinking) (Anna, FG).*
>
> *Whereas now, you know even if they are saying I don't drink I will quite often will say that is great, that is probably the best thing to do because we don't know what the effects of alcohol are on your baby. So there is raised awareness certainly, so there is a bit more information coming there than before, so for that it is a good thing (Lorna).*

In the focus group, some members agreed with that and one midwife clarified that this was possible because the screening tool include questions about pre-pregnancy drinking behaviour.

Midwives also welcomed the opportunities inherent within the ABI approach of asking about partner's drinking habits. They felt that it offered a perspective to explore other issues beyond alcohol. Lorna recalled:

> *Remember it is not just about the women, it is about the man as well, we ask about the men's drinking habit. We don't do ABI (for partners) but we are able to ask and consider and think you know, is there a problem. Because from a social point of view as well, two parents who drink, then it becomes an issue from a child protection point of view (Lorna).*

It was common for midwives to assert that, for them the initiative had generated more awareness about prenatal alcohol use and the training had equipped them with the ability to convert different types of alcoholic beverages into standard alcohol units.

> *It was a shock to me I suppose our own drinking habits are actually excessive. I know how to drink now (Lorna).*

I can count units of alcohol now; we can count most types of alcohol now (Rhoda, FG).

Few midwives reported that their family members and people around them had also benefited from their newly acquired knowledge of determining units in drinks.

...we all went to Napier (University) to have this ABI training and all of us community midwives were all shocked when they pour a glass of wine. In fact my husband that night was going to watch a football match with his friends and had two bottles of beer and when we worked it out that was something like 3.5 units and he was driving back, and he was quite surprised. So it is not just my pregnant clients but it is also my family and people round about me that I am trying to make more aware (Julie).

All midwives reported that the training improved their confidence to deliver the ABI and most important gave them the enthusiasm to discuss alcohol use in pregnancy more freely with women.

I think having done the course though, it makes you more confident to be able to ask them that. It is not just a case of oh well have you had a drink, why, you know (Cynthia).

Some added that the screening tool on their TRAK maternity[1] system has added valuable dimension to their practice, for example in terms of improved confidence, as there is a proof to show women rationale for enquiring about alcohol.

It probably makes me feel more comfortably actually in asking them about their drinking. Because there is, you know a system there that shows them (Sophie).

Some participants viewed the data being generated by the initiative as one that would be useful in future because it could help improve the quality of information provided to pregnant women.

I don't think the message from the government was very clear for women. I don't think it was making things clear for women in pregnancy, you know as far

[1] TRAK maternity is a new electronic maternity information system for streamlining maternity records.

as knowing exactly how much they could drink or not. And I believe that ABIs now will hopefully help to rectify that, because we are now collecting data from women before pregnancy and in pregnancy. So hopefully, that will go to correcting that advice that is issued by governing bodies, will be better and accurate (Julie).

It could also be seen that not only would the data improve quality of future recommendations but also midwives are also now in a position where they can convey consistent information to women.

6.10 Challenges

With the perceived challenges of the screening and ABI initiative in antenatal care settings outlined in the policy implementers' interview data, I asked midwives to identify the main challenges that the implementation of the programme had posed to their practice or some of the difficulties they had identified since its inception. A variety of challenges were identified. Workload pressure and time constraint were deemed significant barriers. Others saw alcohol problems as of low priority especially in the midst of other competing priorities. A pregnant women's capacity to assimilate the vast amount of information provided at the booking appointment and the social intricacies surrounding the issue of drinking in pregnancy were also stated as a challenge.

Midwives perceived their position as 'easy targets' where higher authorities were always demanding that they add on new responsibilities to their role. They emphasized that the ABI initiative had been added to their already overstretched midwifery services.

...because we are at that point of contact and women will engage; with kind of sexual health, chlamydia and everything. It seems, you know, oh midwives can do that it will only take them a few minutes, you don't kind of realise that we've got this 'dual perfect' we are in the middle of this and everyone is demanding of something and there is a limit, unfortunately to how much we can do (Silvia).

In some practices, the booking appointment had been allocated an hour and half but most participants indicated that they had an hour in which to carry out the booking appointment. Finding time at the booking appointment to deliver screening and ABI was seen as the single most important challenge.

> *Time constraint is almost always a big issue because if ABI is required, it is not just a simple case of she no longer drinks alcohol and we are happy with the plan so no intervention is required. If intervention is required that could eat into your time or the rest of the care for that booking appointment (Belinda, team leader).*

I then asked Belinda whether she thought time constraints would be a barrier to offering ABI. She responded:

> *It could if that particular lady has had other issues that needed to be addressed, at that moment in time I will not do a brief intervention, I will bring her back to another appointment and do it there. I will always follow it up (Belinda, team leader).*

Although Belinda indicated that she would carry out the ABI in future, another team leader, Sheila felt a brief advice and referral would be her best option.

> *I mainly advice and point them in the right direction for information further to that. There is limited time and resources we can only do the wee quick questions (screening) and just advice, you know this is the recommended, this is what you should be doing, this is what is acceptable (Sheila, team leader).*

Time to convert different types of alcoholic beverages into standard units was also seen as a problem and participants in the focus group agreed with that. Some gave examples of scenarios of how burdensome this could be.

> *Asking people in terms of units per week is quite difficult because first of all you've got to work out what the units are and whether it's a big glass of wine, small glass of wine, strong wine, weak wine, it's a real nightmare and then just work it out per week rather (Vic, FG).*

I have a panic attack every time somebody says a bottle of wine; I go oh how many units is that (Lynn, FG).

Interestingly, one participant pointed out that because most of her clients do not consume alcohol, the time constraint for screening and ABI was not an issue for her.

When they are actually coming to us antenatally for their appointments, it is just a quick question we are just asking them if they are drinking alcohol. I would say 99.9% of my women would say no and I don't do any more about it (Sophie).

There was a divided opinion on the priority accorded to the alcohol at the booking. Whereas many were of the view that alcohol is equally important to screened for compared to other risk factors associated with fetal effects, a few thought otherwise. Many competing issues that were required to be discussed at that first appointment meant that, some midwives regarded drinking as of low priority. For example according to Lorna, the evidence of its effects on the fetus has not yet been fully validated relative to other risk factors.

It is not possible to ask all the questions, alcohol use is just one of them. We've got to do domestic violence, alcohol use, smoking, you know and all the stuff. If somebody says I smoke then we have to give them all the literature, the DVD, arrange for referrals. So you can imagine, it (alcohol) is only one of the aspects and sadly it is not the most important one because there is not a lot of evidence there that we have a lot of children who have FAS (Lorna).

Some participants were worried that the sheer amount of information provided at the booking may adversely influence pregnant women's capacity to assimilate relevant information, especially when a behaviour change intervention is involved.

I guess the other thing is that, not only are we pushed for time, but the amount of information that women can take on board. You know if you are thinking that you have got another twenty areas of information to give women you know, you wonder well can they take all that in (Julie).

Cynthia was of the view that because drinking in pregnancy is unacceptable in the Scottish culture, this discouraged women from disclosing their true consumption levels.

> *People know that it is not good and therefore don't always tell you the truth because they know that maybe you disapprove or it will make them feel guilty if they knew that they are honest and told you (Cynthia).*

A few midwives were sceptical about the benefits of ABI for the unborn child of women who drank before their first appointment.

> *I don't think it has benefits probably, you know, not for the women who didn't know, it was unplanned pregnancy, they haven't changed their lifestyle prior to conceiving so I don't think it makes a difference to the fetus (Rachel).*

Rachel felt that for this group of women, their fetus had already been exposed to alcohol so delivering ABI to such group of women may not be beneficial to the fetus. Women in this category may present a challenge to the ABI initiative in antenatal care settings.

6.11 Key features

The main features from the midwives data are:

- Midwives underlying views against drinking in pregnancy reflected on the advice they are likely to provide to women.
- ABI may not be particularly beneficial to the current pregnancy as a considerable number of women drank in early stages in pregnancy before contact with their midwives.
- Midwives had good understanding of fetal risk of prenatal drinking but a few were sceptical about actual effects on the fetus because they felt the prevalence of the habit did not reflect episodes of harm in infants.

- High demands on midwives' time and role meant that screening and delivery of ABI are negatively affected at the booking appointment.

- Screening and ABI thrives on established relationships. Effective identification and delivery of ABI was compromised at the booking appointments as the woman and the midwives are strangers to each other.

- Difficulties in understanding screening tools exerted more time demands on midwives and this likely resulted in misidentification.

- Training and resources improved midwives' confidence.

- Midwives felt screening and ABI was part of their role however, they were demoralised because only few had delivered the intervention.

- Midwives underutilisation of the full ABI protocol limited its utility and fidelity.

- Low numbers of ABI deliveries negatively affected midwives skills and confidence.

7. 0 Chapter Seven: Pregnant women results

7.1 Introduction

This chapter aims to explore and test the theories identified in chapters two, three and five from the perspective of pregnant women (see section 4.2.3 for strategies and methods of realistic evaluation). In addition, it presents depth accounts of the secondary aim of the thesis, which is to explore perceptions and attitudes to alcohol use in pregnancy. At the introduction of each theme, the background and overall findings under that particular theme are usually given followed by presentation and discussions of the results. Where necessary the literature is drawn upon in relation to the discussions. At the end of this chapter, the main findings for the pregnant women are outlined.

7.2 Participant characteristics

Following the distribution of 490 information packs to recruit pregnant women for this study, 17 women subsequently participated in one-to-one semi-structured interviews. This represents a response rate of 3.5% (see section 9.5 for details about recruitment challenges). Interviews lasted between 30 minutes and an hour. Participants' ages ranged from 21 to 41 years (median age 31 years). The minimum gestation at the time of interview was 17 weeks and the maximum was 39 weeks (median 31 weeks). Twelve of the women had no children, three had one child, one had two children and the remaining woman had three children. Twelve of them were married and all but one had jobs. In their current pregnancy, thirteen had drunk alcohol and only four had totally abstained. Table 7.1 outlines the pseudonyms, demographics and current drinking status

of pregnant women involved in this study. All women had either been screened for or advised about their current alcohol use by their midwives. However, none could recall whether they received an ABI.

Table 7.1 Pregnant women's characteristics

Pseudonym	Age (years)	Duration of pregnancy (weeks)	No. of Children	Marital Status	Employment Status	Current drinking status
Rose	31	17	1	Y	Y	Drank whilst unaware of pregnancy but stopped upon confirmation
Linda	30	36	3	Y	Y	Drank whilst unaware of pregnancy but stopped upon confirmation
Anita	25	27	0	N	Y	Drank whilst unaware of pregnancy but stopped upon confirmation
Gina	25	35	0	N	Y	Drank whilst unaware of pregnancy but stopped upon confirmation
Deborah	21	31	0	N	Y	Drank whilst unaware of pregnancy but stopped upon confirmation
Adel	28	37	0	Y	Y	Drank on a special occasion with knowledge about pregnancy
Evelyn	29	39	0	Y	Y	Stopped drinking before pregnancy
Lucy	37	39	0	Y	Y	Drank whilst unaware of pregnancy but stopped upon confirmation
Sarah	39	25	0	Y	Y	Still drinking at low level
Ruby	36	38	0	Y	Y	Drank on a special occasion with knowledge about pregnancy
Olivia	30	20	0	Y	N	Still drinking at low level
Jessica	31	35	2	Y	Y	Still drinking at low level
Jane	41	33	0	N	Y	Drank whilst unaware of pregnancy but stopped upon confirmation
Daisy	38	27	1	N	Y	Stopped drinking before pregnancy
Abigail	32	31	1	Y	Y	Stopped drinking before pregnancy
Mary	28	28	0	Y	Y	Still drinking at low level
Madison	32	27	0	Y	Y	Stopped drinking before pregnancy

Key
Y = Yes
N= No

7.3 Themes

Employing the Fereday and Muir-Cochrane (2006) hybrid approach of deductive and inductive coding and theme development, seven themes were identified (see Table 7.2). Five originated from both the research questions and the realistic evaluation framework (deductive) and two were data-driven (inductive). Although themes are presented individually, it is recognised that there are overlaps between them.

Before or after each quotation I have included a pseudonym of participants and where appropriate, I have added relevant details of their age, duration of pregnancy and their drinking status to support the arguments. If the question I asked had been included, I used 'I' to represent myself as the 'Interviewer'.

Table 7.2 The themes

Theme	Sub-theme	Coding approach
Attitudes and views about drinking in pregnancy	• Preference for the unborn baby's health • Influence of attitudes on behaviour • Feelings about drinking whilst unaware of pregnancy	Deductive
External influences	• Partners' drinking behaviour • Social circumstances that discourage drinking • Circumstances that promote drinking	Inductive
Previous pregnancies and experiences of other women	• Previous pregnancies • Experiences of family and friends	Inductive
Planned and unplanned pregnancies	• Drinking behaviour at the time of pregnancy recognition • Planning: information seeking behaviour	Deductive
Assessment of risk	• Risk perception • Short-term effects on fetus • Understanding of risk • Trimester of risk	Deductive
Awareness of policies, guidelines and debate	• Awareness and knowledge of current recommendations • Sources of confusion • Suggestions on ways to advise women	Deductive
Clinical settings	• Drinking information disclosure • Follow-up expectations • Preference for support • Reaction to objective alcohol screening	Deductive

7.4 Attitudes and views about drinking in pregnancy

This theme was informed by the research questions and findings from policy implementers' interviews. It was anticipated that pregnant women's attitudes to drinking would be influenced by a variety of factors including the current debate about the effects of low levels of drinking on the unborn child, women's personal experiences and most importantly their direct contacts with their midwives through screening for alcohol use. Recent introduction of ABIs in antenatal care means all women attending their booking appointments are now screened for alcohol use either before pregnancy or during pregnancy. Assessment only for alcohol use without an intervention is known to reduce alcohol intake (see critical review, section 3.3.3.1 for detail). In this study, it was envisaged that because participants had drunk pre-pregnancy or during pregnancy, they were more likely than non-drinkers, to be sensitive to the screening, which may directly or inadvertently influence their attitudes to alcohol intake in pregnancy.

All participants said they considered the health of the fetus as a priority in their alcohol intake decision making. Although participants generally did not criticize low levels of drinking in pregnancy, this was not identified as the deciding factor as to whether they drank or not in pregnancy. Women had varied reasons for drinking in pregnancy and their views spanned both positive and negative aspects of drinking in pregnancy. Many of the women in this study drank whilst unaware of their pregnancy and among this group, most of them viewed their action as unacceptable and were worried.

7.4.1 Preference for the unborn baby's health

The decision to put the health of the unborn baby first was pre-eminent, irrespective of participants' drinking status. This had an overarching influence on women's attitudes, and subsequently affected their drinking behaviour. This was evident for Mary who was a current drinker and Abigail who had abstained from alcohol in her current pregnancy.

I still think during pregnancy you've got to do everything that you possibly can to look after yourself and your child so cutting down on alcohol will be my priority, if not cutting out completely (Mary, still drinking at low levels).

I think the fact that why do something that could harm a baby, you know something that you have a choice over then I don't understand why you will make the choice to do it (Abigail, stopped drinking before pregnancy).

Women generally expressed sentiments against high levels of drinking in pregnancy, probably because of the increased risk it poses to the baby, but were more accepting towards low levels. Both current drinkers and those no longer drinking equally shared this notion.

...like a small amount of drink probably wouldn't be harmful when you are pregnant but I definitely wouldn't accept or think that it was acceptable for anybody else to have high volumes of alcohol when they were pregnant (Rose, drank whilst unaware of pregnancy but stopped upon confirmation).

I could understand binge drinking or whatever (as unacceptable) but if people don't drink too much I don't see it being a problem (Jessica, still drinking at low level).

7.4.2 Influence of attitudes on behaviour

Participants who were no longer drinking described the positive aspects of not drinking in pregnancy. They argued that abstaining from alcohol seemed reassuring compared to having to deal with the uncertainties of drinking in pregnancy.

I just personal think it just easier not to drink at all and there is no ambiguity so it better just to say I am not doing it. That way you are fine, you don't need to worry about it (Abigail, stopped drinking before pregnancy).

Others were of the view that money spent on alcohol could be saved, in addition to not worrying about unnecessary hangovers.

...it's even cheaper because you don't have to buy anything. You just have to buy juice unlike in the past you would buy juice and maybe just one bottle (Madison, stopped drinking before pregnancy).

> *I am a bit jealous (when I see my colleagues drinking) but then I just think it is only nine months (laughter). But I don't get the hangovers the next day so the next day I don't regret it (Gina, drank whilst unaware of pregnancy but stopped upon confirmation).*

Mary's view was different. She identified some positive aspects of drinking.

> *...it is not causing any harm to the baby and it is not causing any harm to me and in some cases, it might actually increase my wellbeing because having a glass for social reasons you know might make me more relaxed and quicker to settle (Mary, still drinking at low level).*

By outlining some positive attributes of drinking and asserting the harmlessness of her drinking behaviour, Mary could be seen as justifying her drinking behaviour. It has been shown with smoking that people often use such strategies to avoid self-blame or blame from others (Heikkinen et al., 2010).

Gina stopped drinking in pregnancy because she preferred to drink large quantities of alcohol during her drinking sessions, so although she had no strong feelings against drinking at minimal levels, this kind of drinking was not appealing to her.

> *For me there is no risk but as I said before just I don't see the point of just having one drink, you might as well have none. Where there seem people may just have a glass of wine with a meal, and if there is no risk and they can stop themselves drinking any more then, I don't see any harm (Gina, 25, drank whilst unaware of pregnancy but stopped upon confirmation).*

The capacity to resist drinking beyond low levels was therefore imperative for Gina and she recognised that she did not possess that attribute.

7.4.3 Feelings about drinking whilst unaware of pregnancy

Many of the participants who drank early in pregnancy unaware of their pregnancy status seemed to be remorseful of their behaviour and were quite anxious about the unknown consequences. The extracts below from Adel and Linda illustrate their

feelings:

> *Oh yeah, I was worried (that I drank), not much worried but you see when I think about it does make me feel sick about it. It's awful! (Adel, 28).*

> *When I came for my scan, I was told that I was three months pregnant and I felt so guilty for drinking because obviously I had a lot to drink (Linda, 30).*

It was clear from the above statements that participants were carrying out their normal lifestyle pre-pregnancy and would not have drunk if they had known they were pregnant. Yet, because they were unaware of the presence of the pregnancy, it was possible that they had consumed high levels of alcohol.

7.5 External influences on decision-making

This theme evolved inductively. Participants recalled the circumstances that influenced their decision whether to drink or not in pregnancy.

7.5.1 Partners' drinking behaviour

Married women or women with partners commonly reported that their husband or partners' drinking behaviour had an effect on their personal drinking behaviour. Below Olivia highlighted the drinking partnership with her husband.

> *My husband and I don't go out a lot. If it was a party or some sort of special event, we have a glass of wine or a beer but other than that, alcohol isn't a staple in our diet so I didn't miss it and he actually stopped drinking since I have been pregnant (Olivia).*

Olivia felt that her decision not to drink in pregnancy has had an influence on her husband's drinking habit not to drink.

Jane had a different assertion. She assumed that because her husband drinks heavily during drinking episodes, it was necessary that she remained sober to take care of him during periods of insobriety.

When we were trying to have a baby, I basically didn't drink, hardly at all because my husband is a heavy drinker so that kind of put me off drinking anyway. If he is drinking, I tend not to drink because one of us got to be sober (Jane).

When Jane was asked to explain further, she added:

I think when you kind of see how somebody can lose control or you know becomes forgetful, you are actually seeing every day the effects of alcohol on somebody. So even though you know, you are only drinking once in a while even in that one occasion when I have got a bit drank, you know - 'Am I like him?' ; 'Am I forgetting things'; 'Am I doing silly things'; 'Am I you know tripping over'; 'Am I falling downstairs' - so definitely that is the main emphasis for me. Because I still drink with friends but I never drink if my partner is drinking (Jane).

Many of the participants revealed that their partners were not keen for them to be drinking in pregnancy.

Actually, my husband's attitude for now is that he can drink for two. So it means I just take the car and I drive him, so it's fine (laughter) (Mary).

Interestingly, among all the women who discussed a partner's drinking behaviour, only Abigail reported that her husband proactively encouraged her to drink.

He obviously drinks and he was like "oh you can have one or two glasses and it will not do you any harm" (Abigail).

7.5.2 Social circumstances that discourage drinking

It was apparent that religion and culture had a role in some of the women's decisions to stop drinking in pregnancy. Below, Madison highlighted that her current Christian faith had an important impact on her decision not to drink in pregnancy.

So the fact that we are now Christians plus the fact that we were planning a baby, all made me really decide to stop drinking... I mean where I come from back in Africa, people don't drink much... (Madison).

Bowie et al. (2006) showed that among black populations in the US, regular Church

attendance was associated with fewer alcohol problems.

Olivia also commented on the influence of culture on her drinking behaviour.

> *I think being from the United States...you know, we have friends here that we hang round with, we visit but I think I grew up in a culture where at least the people around me didn't drink during pregnancy (Olivia).*

It was common among participants who had cars that driving was used as a proxy to avoid peer pressure to drink in social situations as well as acting as a disincentive for the women themselves.

> *I think you will probably have a sip of whatever someone else was drinking but usually if you are pregnant then you are the designated driver during the entire pregnancy. So everybody else go out, have a good time and drinks and party but you are the one that doesn't. You are the one that drive everybody home, and make sure they need to go anywhere they need to go safely (Olivia).*

Evelyn however revealed that people's attitudes towards seeing pregnant women in places, such as pubs and bars, are powerful enough to discourage drinking in pregnancy:

> *I was in the pub last night with my husband, obviously, I am heavily pregnant, and you do get the funny look even though I wasn't drinking (Evelyn, 29 weeks pregnant).*

For Daisy, the responsibilities associated with adulthood and taking care of a child were enough to discourage her from drinking.

> *I suppose I am older and my lifestyle is very different and before I got pregnant the last time I lived in London, I went out a lot and probably drank quite a lot. So it had a big impact on my life stopping drinking for that pregnancy. I mean I didn't drink much when I was pregnant and I certainly drank differently. I will drink things like spirit or shandy something with a little bit of alcohol but it was largely watered down to soft drink it was largely about social thing though because I was still going out with friends who were drinking. This time round I have got a small child, I work, I never go out so I just don't feel the need to drink to be honest (Daisy, 38).*

7.5.3 Circumstances that promote drinking

Women described various circumstances in which it seemed appealing to drink in pregnancy. The common circumstances women gave that promote drinking in pregnancy were 'missing drinking' and special events (e.g. wedding, holidays). Rose apparently missed drinking and recalled the circumstances that could persuade her to drink in pregnancy:

> *When I was pregnant with my first baby I think I did really want, it wasn't so much of a craving but for the froth of beer I really wanted...if it was like the way it was before and I really, really wanted it maybe I would have it or if it was a special occasion or something maybe I will have it. But I think if my midwife did say, "you know you can have this and you can have that", then I think yeah, then maybe if it was a wedding or something, I think you would have something (Rose, drank whilst unaware but stopped upon confirmation).*

Special life events and occasions were also seen to promote drinking:

> *And then just the other week it was my wedding anniversary and there was a bottle of champagne so I had a small glass of champagne and enjoyed it (Sarah, still drinking at low levels).*

> *I did drink quite a lot in the first two weeks just because we were on holiday - you know we were going to see shows (Adel, drank heavily whilst unaware of pregnancy).*

Other conditions, such as having a meal with a drink seemed appealing for Jessica:

> *For instance, I know this weekend we are going for a meal - me and my husband. We are getting rid of the kids for the weekend so I know when we go out I would have a couple of wine with a meal (Jessica).*

From these accounts, it could be viewed that women's decision to drink in pregnancy were influenced by different circumstances. It was apparent that although some of the women drank on special occasions whilst aware that they were pregnant but they restricted the amount they drank.

7.6 Previous pregnancies and experiences of other women

This was a deductive theme. Participants who had drunk alcohol during the early stages of their pregnancy found it reassuring to compare their drinking behaviour with their own previous experiences or that of friends and family members who had similar experiences with positive outcome.

7.6.1 Previous pregnancies

Participants who drank alcohol but had previous healthy babies were of the view that they could carry on with their previous drinking habits because they felt there was no proof to indicate otherwise:

> *Because obviously, if there had been something wrong it will play in the back of your mind that I had a few drinks, it could be something that I had done or whatever... (Jessica, 2 children, still drinking at low levels).*

Daisy's account was different. Although, she drank through her first pregnancy she decided not to consume alcohol in her current pregnancy.

> *I haven't drank anything in this pregnancy but in my last pregnancy I had an occasional drink because I assumed that it was safe to do so. That was 5 years ago and the official advice then was that occasional drink, 1 or 2 drinks kind of every couple of weeks will be fine and safe (Daisy, 38, one child).*

Although, Daisy revealed that her first child was perfectly healthy, she experienced difficulties with subsequent pregnancies. Moreover, when she considered her age, she felt compelled to alter her drinking behaviour as she explained below:

> *I suppose because I am older, because it has taken me a long time to get pregnant and I have had miscarriages in the intervening period so I am a lot more cautious in every aspect and in every way in approaching this pregnancy. I was very relaxed in my last pregnancy. It was a very easy pregnancy. This time it has taken a long time to get pregnant. It's been a very difficult pregnancy and*

I just wanted to do everything, do the safest possible just to make sure that everything is ok (Daisy, 38, one child).

Alcohol interaction with maternal age has consequences for the fetus. For instance, Chiodo et al. (2010) showed that infants born to older mothers who were involved in binge drinking during their pregnancies had significant adverse neurobehavioral outcomes especially on attention.

Furthermore, some participants who have had a previous negative experience said they took cautious approach. Evelyn revealed the reason behind her decision not to drink in her current pregnancy.

We lost a baby last July. I think about eleven weeks but I had cut back on my drinking when I was trying to get pregnant the first time and obviously we lost the baby and I just thought of not drinking at all this time when I was trying to conceive (Evelyn, 39 weeks pregnant, stopped drinking before pregnancy).

Here, Evelyn felt that alcohol was probably part of the reason why she lost her first baby. As such, she presumed that to avoid the previous experience, she needed to do something different. Therefore, she decided to abstain from alcohol in her current pregnancy.

7.6.2 Experiences of family and friends

Participants who drank in pregnancy often justified their behaviour by referring to the perceived lack of adverse outcome on someone else's child. Adel, for instance used her neighbour's experience as a basis for drinking in pregnancy.

Like I am saying I was going by other people's influences, the fact that my neighbour was drinking - she had three children, and that make me think it can't be that dangerous (Adel).

Sarah also used the fact that her mother drank in pregnancy but had healthy children as a reason for drinking in pregnancy.

I know for example, from my parent, my mother drank through her pregnancy and she smoked through pregnancy as well and I would like to infer from her that her generation was doing the same. So it is very difficult for us to understand. Actually, we know that it has happened before and we think that we have turned out relatively normal (Sarah).

Witnessing bad experiences of others were enough to dissuade some women from drinking in pregnancy:

One of the reasons why I have really stayed clear of alcohol is because my uncle's girlfriend. I was a little girl when she was pregnant but they were heavily involved in drugs and alcohol and even during her pregnancy she was and they have never had their son tested but yet he has all the signs and symptoms of fetal alcohol syndrome. That was so sad to me growing up because he did not have any say in it, you know it is not like he could have prevented his mum from drinking whiles she was pregnant. So for that reason in itself I knew I wouldn't drink or do that to my child during pregnancy (Olivia).

Similarly, Lucy echoed this sentiment when I asked her the question:

I: What would you say was the main reason that made you stop drinking?

Lucy: I think that fact that my sister's friend, her wee boy had that problem and I don't know whether it was due to the drinking or not. But I think that had a bigger impact...

Many of the participants recognised that individual differences need to be recognised when comparing the effects of prenatal alcohol consumption on fetus.

Maybe, everyone is different in the way they drink alcohol anyway so she normally drinks a couple of glasses every night when she is not pregnant. So she naturally drinks a lot of wine. I guess in general I am not really a big drinker anyway so if I was to drink how she drinks her wine I will be really drunk (Adel).

Genetic variations have been shown to play an important role in differential manifestation of adverse fetal outcomes resulting from maternal alcohol use (Shankar et al., 2007).

7.7 Planned and unplanned pregnancies

7.7.1 Drinking behaviour at the time of pregnancy recognition

Planned or unplanned pregnancies influences the timing of drinking behaviour in pregnancy. The timing that drinking occurred in pregnancy is an important determinant of the type and extent of fetal defects. Although drinking throughout pregnancy has an impact on the fetus, for instance on the central nervous system (Ornoy and Ergaz, 2010). Yet, drinking in the first trimester is particularly noted to be of considerable risk (Sayal, 2007; Henderson et al., 2007a; Robinson et al., 2010). Seven of the women in this study indicated that they drank without the knowledge of their pregnancy, probably during their first trimester. This was particularly common among women who did not plan their pregnancies as can be seen in Deborah's account.

> *It wasn't a planned pregnancy and it took a bit longer so I think I was probably about six or seven weeks pregnant before I realised but as soon as I knew I stopped drinking (Deborah, 21, unplanned).*

However, Mary however planned her pregnancy but continued drinking:

> *Well, I suppose when I was trying to conceive I hadn't cut alcohol completely but I wouldn't have more than one or two drinks in a week. I am not a heavy drinker anyway but I hadn't cut alcohol out completely (Mary, 28, still drinking at low level).*

Sarah also continued drinking even though she planned her pregnancy. She gave an interesting reason why she decided not to stop drinking before pregnancy.

> *I was still drinking before I realised that (I was pregnant) but I as I said, it was not a great deal but I was kind of conscious that I might have been (pregnant) but I didn't stop. It was kind of one of these funny things but I didn't sort of place all my bets on it and I was trying to carry on life normally as I would have done if I am not pregnant (laughter) (Sarah, 39, first pregnancy, still drinking at low level).*

Sarah had previously struggled to get pregnant and decided not to stop drinking in order to avoid any added pressure of focusing only on trying to conceive.

7.7.2 Planning: information seeking behaviour

Participants were of the opinion that the information about the effects or advice about alcohol should be readily available for women. They preferred to have received information about alcohol from health professionals before pregnancy. They expressed sentiments against the practice of receiving the information when they were already way into their pregnancy.

> *May be you should get the information before you get pregnant so that you know that you avoid it before and during pregnancy. What is the point of drinking when you are two months pregnant before you receive the information from your midwife. You've already done the harm so the earlier you get it the better (Madison).*

However, for some women who planned their pregnancies, their information seeking behaviour was different. They had the opportunity of receiving information about alcohol prior to pregnancy.

> *At the beginning or even if you are planning because most people plan to have children. Like when I was going through the IVF the specialist said, "you should stop drinking" (Lucy, drank whilst unaware of pregnancy but stopped upon confirmation).*

> *Well, I was in the family clinic in Edinburgh and I had kind of a guideline sheet for you know like advice for getting pregnant or something like that, I can't remember the name of it exactly but it kind of had guidelines and things to cut down and things to do, recommendations on exercise and things. So I already had that information but I think I was quite proactive whereas I don't know of everybody. And in situations where it will be unplanned pregnancy it will be difficult (Mary, still drinking at low levels).*

Lucy and Mary, although both actively received information about alcohol from health professionals or health facilities before pregnancy, but it was unclear how this impacted on their drinking behaviour as they both used alcohol in their current pregnancies.

7.8 Assessment of risk

Alcohol consumption whilst pregnant could be deemed as risk taking behaviour, especially because of the risk to not only the woman, but also to the fetus. In this study, it was considered important to explore how women perceive the risk of drinking to their fetus since this is likely to have an influence on their behaviour (Sjöberg, 1998). Knowledge and understanding of harmful effects of drinking can also enhance the motivation to change problem behaviour (Vasilaki et al., 2006).

In this study, participants' considerations of risk were affected by different factors including current drinking status. However, it was not clear whether having other children had an impact on women's understanding of risk. Participants, although aware of the risk of drinking but few were not sure what the exact risks were.

7.8.1 Risk Perception

When comparing the risk of drinking in pregnancy, participants underestimated the risk of their drinking behaviour. For example, Olivia was quick to criticise a friend's drinking habit whilst she described her own drinking as "sips".

> *I think it was risky for her to do that but it just didn't catch up with her. But I am sure there are some women that drink throughout their pregnancy and they have perfectly healthy babies but I never want to take that chance. I mean I will say a couple of weeks ago I was out with my friends and my husband had a beer and I took two sips of it. And that will be about all that I will consume (Olivia).*

Chang et al. (2000) argued that understatement of alcohol intake is common among study participants under research conditions. Olivia comments presumed that she associated the risk of drinking to the unborn baby to higher categories of drinking.

On the other hand, some of the women were concerned about the negative prospects on the mother of drinking heavily whilst pregnant. They recognised that heavy drinking does not only potentially harm the unborn child but there is also the risk of physical harm to the mother. The extract below from Jane illustrates this.

> *I think when you binge drink, there is more risk of falling. You know, even if it is not the alcohol that is affecting the fetus and the baby's growth, you are at risk of actually harming yourself (Jane).*

7.8.2 Short term effects on the fetus

The immediate adverse effects of alcohol on the fetus were enough to dissuade some women from drinking in pregnancy. For some pregnant women in this study, though unsure of how alcohol affects the fetus, yet did not want to take chances, and had plausible reasons why alcohol could not be good for the fetus. Rose was particularly eloquent of the possible direct effects of alcohol in the body of a pregnant woman:

> *Yeah you can drink and have a baby and your baby can come out ok but who knows how that baby is feeling when you are drank. You baby could be drunk and feeling ill and feeling horrible. Yeah it's like hearing your baby is ill, it is feeling the heat, it is feeling sick. Obviously you don't want your baby to be feeling that, so why would you want your baby to be feeling that because you were having a drink (Rose).*

Ruby, also had this to say:

> *I know from what I have read that it takes the fetus two times more for the alcohol to be release from the fetus than it does from your own system. I know how it feels like when you've had too many to drink and the thought of doing that to your baby… (Ruby).*

Ruby indicated she would not prefer her unborn child to go through what she experiences when she had drunk heavily. So for that reason, heavy drinking was not an option for her.

7.8.3 Understanding of risk

Some of the women in this study were aware of the effects of alcohol on the fetus. For instance, Ruby was aware of the myriad of outcomes associated with drinking in pregnancy as depicted in the following statement:

> *Obviously they can cause that kind of smaller baby in birth, and kind of detrimental effects, physically and mentally particularly, is it hand and facial and on hand and heart and the central nervous system can be affected (Ruby, drank on special occasions).*

On the other hand, few of the women imagined that because alcohol has teratogenic properties, it is likely to cause harm; and they lacked knowledge of specific harms to the fetus. Neither were they aware of levels of drinking that cause harm to the fetus. In this regard, most took a precautionary approach by refraining from alcohol consumption prior to pregnancy. Madison, put this explicitly as *'prevention is better than cure',* which is reflected below.

> *I really don't know the effects of alcohol on the baby in the womb. I don't know actually what it causes...I don't know how much quantity you have to take to affect the child. I don't know how much or how less so I just feel it's better to avoid it in general whiles pregnant to minimise the risk of your child having any defects (Madison, stopped drinking before pregnancy, no children).*

Interestingly, participants were quick to associate deformities or disabilities observed in other children with maternal drinking behaviour during pregnancy, although they had no clinical justification. It is possible that the growing debates concerning what constitute clinical features of FAS (Little et al., 1990; Taylor, 1993; Stoler and Holmes, 1999) undoubtedly have generated awareness even in non-clinicians. Some participants

in this study to some extent knew the features of FAS. Some even recognised it as a lifelong condition and extreme adverse outcome of prenatal drinking.

> *...all that pops up in my head is the fetal alcohol syndrome, 'cause that can be disfiguring as well as other problems. And its incurable they can't treat it so once that's been caused, would I say you can't undo it. Things like Asthma, respiratory problems and any other problems that can happen before the baby is born, they can be kind of treated moderately and they pick up but if you baby is born with fetal alcohol syndrome, there's nothing you can do about it. You just got to get on with it (Anita).*

Further, there were indications that the effects of smoking in pregnancy is much more publicised than drinking in pregnancy. Women seemed to be more aware of the health risk of smoking than alcohol. Adel was quick to compare her knowledge of the effects of smoking in pregnancy with that of alcohol.

> *I don't think I've ever been told the effects of what the alcohol could have on the baby. Obviously I know about smoking that if you smoked you are likely to have a smaller baby but I don't think I've ever been told about the effects of alcohol (Adel).*

Anita said she would rather look for more information on smoking in pregnancy than drinking because she presumed that she had the capacity to control her drinking behaviour.

> *I think because I was a smoker I wasn't a big drinker so I focussed more on the smoking than the drinking. Because the smoking to me was an addiction, while the drinking I could take or leave it. So I did more research as such on that (Anita).*

7.8.4 Trimester of risk

The trimester that the unborn child is exposed to alcohol is important. The first trimester has been shown to be especially dangerous because that is the period where the initial cell divisions and the other vital organs are formed (Smith, 1997). Based on

this, I explored women's knowledge about this. It was clear that many participants were aware of harmful effects associated with first trimester drinking. For instance, for Olivia, drinking in the first trimester would be risky and a good cause to be concerned:

> *I will be nervous to drink in the first trimester because your risk of miscarriage is high (Olivia).*

For Evelyn, although she did not drink in pregnancy, but she believed that if she was tempted to drink she would rather drink late in pregnancy rather than early in pregnancy. It seemed that women in this study especially those who were not current drinkers were quick to criticize drinking in the first trimester, yet they condoned drinking late in pregnancy. The extract below from Evelyn emphasized this point.

> *If you are going to drink, I think it will be more safe after the first trimester. That's when you are setting all the blue print down for your baby, isn't it? It is the most important time for defects and things. If I have to have a drink I think I will do it later on in pregnancy as oppose to earlier on but I still wouldn't (Evelyn, stopped before pregnancy).*

Interestingly, this view was in contrast to Olivia's who drank quite a lot in the first trimester. She commented that drinking later on in pregnancy is more critical than in the first trimester.

> *I guess I probably felt that since I was so early in the pregnancy and the baby wasn't developing at a faster rate it wasn't a big of a deal. Like now, if I will have too many drinks you know, one night or a couple of days a week I will definitely bring it up with my midwife because it is something to be concern about. But I just feel like the first trimester is early on, development-wise for the baby you don't have to worry as much (Olivia, still drinking at low levels).*

Olivia felt that the rate of fetal development was slow in the first trimester as compared to the late trimesters. As such, any effects of alcohol on the fetus were likely to be significant at periods of rapid fetal developments.

7.9 Awareness of policies, guidelines and debates

In UK, the national advice by NICE (2008) and RCOG (2006) to pregnant women is not to drink alcohol but if a woman chooses to drink, she should limit it to one to two units once or twice a week. However, in an attempt to present a uniform and clear message to women, NHS Health Scotland is now promoting the no alcohol use in pregnancy message. This is the advice in the Ready Steady Baby[1] book (NHS Health Scotland, 2010a), and that is the advice midwives are encouraged to provide to women during ABI delivery. Since all participants in this study had all allegedly been screened for ABI, or received advice about alcohol, I therefore explored this theme to check if participants were aware of these changes.

7.9.1 Awareness and knowledge of current recommendation

It was clear that most of the women who were expecting their first babies were aware of the current recommendation but it was not clear whether knowledge of current recommendation translated into compliance. Many of the women indicated that their midwives advised them not to drink in pregnancy. From the extract below, it could be observed that Lucy's midwife advised her not to drink during pregnancy and she stopped drinking once pregnancy was confirmed.

> *She (midwife) basically said that alcohol shouldn't be drank during pregnancy (Lucy, 38, first pregnancy, drank whilst unaware of pregnancy but stopped upon confirmation).*

On the other hand, Mary said that she knew of the recommendation of no alcohol in pregnancy, but she continued to drink in her pregnancy.

> *I do know that it is recommended throughout your pregnancy you abstain from alcohol, you know that is the medical guidelines (Mary, 28, first pregnancy, still drinking at low levels).*

[1] A resource book for pregnant women in Scotland.

A recent longitudinal study has however shown that among women in Southampton young women were less likely to comply with public health guidelines (Crozier et al., 2009).

Some pregnant women were unaware of the current recommended guidelines. Olivia originated from the US and she did not know of their recommendations either.

> *I don't know any guidelines (Olivia, 30, first pregnancy, still drinking at low level).*

However, it seemed women who had previously been pregnant were rather more aware of previous guidelines as can be seen in Abigail's account.

> *I: Can you tell me the current recommendations about drinking in pregnancy?*
>
> *Abigail: I think it is one to two units a week (32, one child, stopped drinking before pregnancy).*

Interestingly, Daisy thought the advice had changed from no alcohol use in pregnancy to acceptance of low levels of alcohol in pregnancy.

> *As I say the last time I read... and there was a media coverage quite recently that said, it kind of moved away from the position that nothing, no alcohol should be consumed to occasional, very light drinking is ok (Daisy,38, one child, stopped drinking before pregnancy).*

It was apparent that women were either aware of current or previous recommendation, yet many were still confused about the official guidelines.

7.9.2 Sources of confusion

Women had mixed perceptions about the use of 'unit' as measuring tool in alcohol guidelines. Whiles most were quite comfortable with it others found difficulties.

> *Oh no I have absolutely no clue in units. Sometimes you just see an advert in the telly and you say to your self is that how many units? (Jessica).*

It could be suggested that changes in guidelines were sources of confusion for women.

> *However, I think there was round about the time I was pregnant with my first child, there was something that came up in the news saying that it was acceptable to drink. It was ok to have however many units whilst pregnant. And then I think since then it came out saying you shouldn't have any. So I can't tell you how many units are acceptable in pregnancy (Rose).*

It was apparent that although most of the women had been advised not to drink alcohol in pregnancy by their midwives, the message seemed to have been adulterated by information in the media. Often women made references to reports and articles they have read or heard in the media that presented conflicting information and were sources of confusion.

> *I think that the advice is extremely confusing because obviously, there is a lot of media coverage about the issue and about what is a safe and acceptable amount of alcohol to consume during pregnancy and the actual advice is really confusing. One moment you hear not to have anything and the next minute you hear occasional unit of alcohol is safe. So it is very confusing (Daisy).*

In the extract below, Jane revealed that when she was attending the interview she heard from the radio about a new research that had been published that emphasized that low levels of drinking posed no risk to the fetus.

> *I heard in the news today that there have been a new thing out saying, you know a couple of drinks doesn't affect the fetus at all, so it's quite an interesting research so it will be quite interesting to find out more about that (Jane).*

When Jane was asked what would be the implications for what she heard in the news, she responded:

> *I think I will probably not be quite so strict about the drinking. I don't think I'll go to having the report said, 'I could have one to two drinks, so I'm gonna have one to two drinks'. I think it will just be a case of if there is an occasion I will like to have kind of proper toast. At a wedding or something like that, I will probably say yeah, I will have a small drink and certainly not have the guilty*

feelings... (Jane, 41, drank whilst unaware of pregnancy but stopped upon confirmation).

The change in the official guidelines was also seen as a source of confusion. However, for Daisy, the change in guidelines had positive influence on her drinking behaviour:

I haven't drank anything in this pregnancy, but in my last pregnancy I had an occasional drink because I assumed that it was safe to do so. That was 5 years ago and the official advice then was that occasional drink, 1 or 2 drinks kind of every couple of weeks will be fine and safe (Daisy).

The above account by Daisy could mean that greater awareness of official guidelines may be important to reduce the confusion regarding what is acceptable to drink in pregnancy.

7.9.3 Suggestions on ways to advise women

Participants were asked to offer ideas about ways to help women abstain from alcohol or to make the advice of alcohol use in pregnancy more useful for them (aside from the usual advice from their midwives). Women highlighted that although they were aware that drinking in pregnancy was not good but they did not know the exact consequences associated with specific levels of drinking or pattern.

Probably I would want to know more about what could be wrong with the babies or whatever, if you drink well even a minimum amount of alcohol. Because I will just take that most babies that have got something wrong with them due to alcohol, maybe their mothers drank quite a lot throughout their pregnancy. But then I could be wrong because I have never seen anything to say that if you have a few drinks this could happen or whatever (Jessica).

Some participants expressed the view that visual proofs of the effects of drinking on infants would be helpful, especially using circumstances that people in similar positions could relate to themselves.

I also think it helps for people to be able to relate to others. Like let say that there was a woman who pretty much drank heavily through her pregnancy and

unfortunately her child was born with FAS or something along those lines. You know, to have some form of a workshop where those women could go to if they think they are drinking too much during their pregnancy and then see firsthand what damage they could possibly do to their child, it will be really impactful to women (Olivia).

Women also wanted the advice in pregnancy to be consistent:

I think it will just be helpful if they came out with a recommendation and stuck with it and there was consensus across the board rather than having conflicting nature of advice, which I think, is difficult. So you know, part of me feels that it is simpler just to have zero tolerance and say actually when you are pregnant don't drink and then there is no ambiguity about it whereas at the minute it is quite ambiguous (Abigail).

7.10 Clinical settings

Midwives are supposed to carry out screening and ABI during booking appointments. Based on the accounts of policy implementer in sections 5.5 and 5.8, I explored women's views to identify factors that may facilitate or act as barriers to the intended outcome of reduction of alcohol use or abstinence. Therefore, this theme was explored deductively.

7.10.1 Drinking information disclosure

It was evident from the participant's responses that social relationship with a midwife and 'timing' of discussion of alcohol issues were the two most important factors that influence the kind of drinking information women provide at the antenatal appointments.

Participants were in agreement that a good social relationship with a midwife is important in order to divulge sensitive information for example, alcohol consumption in pregnancy.

I'm really happy with my midwife that I see over just at the health centre over there. She is very friendly and she makes you relaxed so you tell her the truth. Which yea, it is good 'cause it means that you go in and you don't feel like God she's gonna ask me if I've… and I'm gonna get a row here. You know, you can tell her and she'll be fine. I think if I drank too much, in her eyes, I would get a disapproving look but it would be the end. She wouldn't fall out with me and the next time I went (Anita).

It was clear that women respected the social relationship they had with their midwives and were prepared to listen to their advice (see section 5.5 for policy implementers' opinions and 6.8.2 for midwives' account on this issue).

I have got quite a good relationship with my midwife and just go by what she says because obviously she knows better than I do so (Lucy).

The stronger the relationship the more likely women felt they could confide in the midwife. This was evident in the fact that women who had seen a particular midwife over a number of pregnancies felt they developed strong rapport with them over time as a result they could trust them to handle sensitive information in a professional manner.

Yea, I think my current midwife was my midwife with the previous pregnancy so I know her from there. I don't find her judgemental in anyway and I just think that she will be there to support you know, if she found out that I drink a lot or something. I think she will be trying to support me to make the right choices but without making me feel that, I was a terrible person you know (Abigail, one child).

This was contrary to Jane's view. She confessed that because it was her first pregnancy and she was not familiar with the midwife, she refrained from providing details about her drinking habits.

...It's like the midwife, you've never met the midwife, you've come for the first time you have no idea of the type of person they are, they have no idea about you so you are not going to give out a lot of information (Jane, first pregnancy).

However, some of the women indicated that they felt that honesty was important and

they had no problems informing their midwife about their true level of consumption if they were worried about it.

> *I am a pretty honest person so I will have no problem you know telling my midwife from the get go how much I was drinking. I mean I do think it helps when you develop more relationship with someone to be honest but I usually have no problems being honest from the get go about things (Olivia, first pregnancy).*

Interestingly, some of the women said they would only disclose their true level of consumption to their midwives if an anomaly was discovered through conducting other tests. Linda disclosed that she did not discuss her concerns with her midwife for the fear of being rebuked or being told that the baby had been harmed.

> *I thought if I had said to her that look, it turns round that when I became pregnant I had a lot to drink, I was maybe worried that she will say oh well there could be something wrong so just kept my fears to myself. Like I said, I came back for my twenty weeks scan and they had a detailed wee thing on it, I just thought I will wait and see if they say, there is something wrong with it then I will pipe up that I have been drinking (laughter) but thankfully everything was alright. So I kept it to myself (Linda).*

Madison also felt that if the harm was already done then health professionals could not do much to reverse that. However, she later indicated that she would inform them if further tests were able to detect any aberrations.

> *I won't really discuss it with anybody because there is nothing they can do about it I've already drank you know, so I'll just talk about it with my husband… but if during my scans they check and they detect anything wrong and then they might be able to tell me because they will ask me anyway during my consultations with them (Madison).*

However, young women in this study did not consider drinking in pregnancy as a priority in the midst of other competing priorities. For Jane, though she was clearly

concerned about the amount of alcohol she drank whilst pregnant, she did not discuss it with her midwife but secretly sought reassurance from other means.

> *At the time that I had the concern, my concerns were overridden by the twin thing, so all my questions were about the twins. I really don't think my one binge drinking would have done (any harm), and all the scans have shown that the babies are growing fine and you know everything is going as they should do so that kind of confirms that everything is ok (Jane).*

The participants were also asked how they would respond if their midwives advise that, they change their drinking habit. It was clear that the circumstances surrounding a pregnancy had an influence on how women received and used information about alcohol. The more desperate a woman was for a child, the more likely they heeded to midwife's advice.

> *I have been trying for a baby for so long that I would have done anything that anybody said that almost you know sounds sensible, I will have done (laughter). You know if she told me at that point to cut my working hours back or change my job or do something, I would have considered doing it. If it had been ten years ago then it might have been slightly different (Jane, 41, first pregnancy).*

In Jane's statements above, it could be observed that age was the underlying reason why she would feel obliged to respond to the advice of the midwife.

7.10.2 Follow-up expectations

Some women observed that the follow-up pathway on alcohol intervention in pregnancy was not adequate. They highlighted that after the booking appointment there were no further enquiries about it.

> *She (midwife) only discussed it (alcohol) at the beginning when I first met her and she never really said anything after that. So, it is not as if it has been drummed into you not to drink through your pregnancy or anything (Lucy, drank whilst unaware of pregnancy but stopped upon confirmation).*

This assertion was not peculiar to participants who stopped drinking, because Adel who

continued drinking on a special occasions throughout her pregnancy echoed it and even informed the midwife about it at the booking appointment but that was the end of the story.

> *I did say in the beginning that I drink, probably about eight to ten units a week but they never asked me again. She (midwife) never checked to find out whether you have given up or you are meant to give up (Adel).*

When asked how she would feel if the midwife had asked about alcohol on every appointment, she responded:

> *I would have taken it more seriously I think and I don't think I would have drunk at all. It will then seem much more important… I think obviously if it will cause a damage and it was serious enough then they will ask you in every appointment, then I wouldn't really have touched any at all (Adel).*

7.10.3 Preference for support

Many of the women involved in this study were not drinking at a threshold that required ABI. This means most were unaware of the availability of such support. Participants were asked to indicate their preference for a health professional from whom they would like to receive help from in a scenario in which they required help to deal with their drinking. They were also asked to give a rationale for their choice. Of the fifteen pregnant women that responded to this question, eight opted for the midwife with the remainder indicating that they would prefer either a GP or an alcohol specialist. Participants were in agreements that the invaluable bond they were able to build with their midwife throughout the pregnancy period would help them heed to their advice:

> *I suppose with the midwife the beauty of that is that you start to develop a relationship with the midwife which maybe means then that they can kind of help with the sort of more social aspect of it whereas if you are referred to a specialist it becomes 'medicalised'. It is about the medical impact whereas in fact, it might be more psychological or you know those sorts of social pressures that are causing the dependency or the heavy drinking (Abigail).*

On the other hand, some participants indicated that referral to another health professional or a drug or alcohol specialist for help might be more beneficial because they were considered more knowledgeable in their field. As such, and they were likely to command greater attention. Below Olivia compared this to her recent experience of a referral by her midwife to a physiotherapy session.

> *In that physiotherapy workshop, there was a midwife at the very beginning and she just kind of talked to the group and asked how far along everyone was. It wasn't different than my midwife's appointment you know and when the physiotherapist came she said, ok this is the physiotherapist and she has new information that I haven't heard from my midwife. So I was much more attentive and paid attention to what she had to say because I haven't heard her before and I felt that she was definitely a specialist and she knows what she was talking about (Olivia).*

Jane however believed that helping women reduce or abstain from alcohol should be a joint thing:

> *I think you certainly believe a lot of what the other health professional says about the alcohol because you will feel that they are specialist in the alcohol hence they know, they are experienced but then you also have to bear in mind that the midwife is maybe seeing the effects of the alcohol on the, you know, babies (Jane).*

Some participants indicated that the degree of severity of a drinking problem should reflect whom you see. A mild drinking problem was designated to the midwife and a specialist was preferred for a more severe drinking problem and this concur with the literature.

> *I suppose it will be probably be a little bit of both. Initial help from the midwife and then if it was so severe that you needed an outside support then, yes to be referred on (Ruby).*

From the literature, more severe drinking problems (alcohol dependents) usually require specialist alcohol treatments services rather than ABI (Heather, 2004). However, a

recent study has shown that when delivered by dedicated alcohol nurses, ABI was able to reduce alcohol use among dependent drinkers not seeking treatments in an acute hospital setting (Cobain et al., 2011).

7.10.4 Reaction to objective alcohol screening

Women were asked to respond to how they will react in circumstances where they would be asked to provide blood samples to check if their unborn baby was at risk of FAS or any other alcohol related harm. Although, using biological markers have been shown to be unrealistic in antenatal populations (Bhuvaneswar et al., 2007), it has been indicated that for drinkers combining ABI with feedback on blood alcohol test (for example, Gamma-glutamyl Transferase (GGT) levels) could be an effective way to reduce alcohol levels (Nilsen, 2009).

Many of the participants had no problem allowing their blood to be taken only if it was part of routine checks.

> *I think if it's kind of targeted at you, you'll feel God they're trying to catch me out. But if it's just general, well we're just doing this just a random blood test you know, just to check everything is ok, then you'd be like, go take what you want (Anita).*

Anita's comments indicated that objective alcohol measure could be more acceptable if it was done as part of the routine antenatal checks.

Ruby, however, thought in her circumstance of continuing to drink in pregnancy that would have offered her reassurance.

> *In my situation I would have been completely wanting that to happen because they will then be up and doing any checks to see if there was any danger to the baby (Ruby, still drinking but on special occasions).*

Few of the women expressed resentment over the idea. To them it would represent mistrust from their midwives if their reported consumption level or pattern were

unaccepted. This kind of sentiments was common among participants who were no longer drinking in pregnancy.

> *I will feel like they don't believe me. Again there will be this whole thing as to why you are not believing me and I will feel like I was a child that was getting told off by the parents you know this is what you are going to do, make sure you are not cheating. I'd feel like they don't trust me (Deborah, drank whilst unaware of pregnancy but stopped upon confirmation).*

> *I will probably feel quite offended because I will think I must look like a drinker. But I suppose people who have got alcohol problem might be a way of keeping them off the drink. They might think if I am getting tested it might give them will power... (Evelyn, stopped before pregnancy).*

On a positive side, Evelyn asserted that the strategy might encourage some women to abstain from drinking in pregnancy.

7.11 Key features

The main features that emerged from the data were:

- The health of the baby was found to be the main reason women said they abstained or reduced alcohol consumption in pregnancy.

- Pregnant women, though aware that alcohol could be harmful to the fetus, were unsure of the specific risks.

- Some women generally did not consider drinking low levels to be harmful yet this perception was not found to influence their decision whether to drink or not in pregnancy.

- One common reason why women said they drank in pregnancy was that they were unaware they had conceived.

- Women who drank early in their pregnancy without knowledge of their pregnancy expressed concern about the health and safety of the fetus, yet some did not discuss such concerns with their midwives.

- A good rapport with a midwife was viewed as necessary to enhance sensitive information disclosure.

- In instances where women drank, they found it reassuring to relate their previous experiences or that of friends who indulged in similar habits but with no negative fetal outcomes.

- Some women who planned their pregnancies and were given information about the risk of drinking in pregnancy were not found to be abstinent at the time of conception.

- Knowledge of current NHS Scotland recommendation of no alcohol use in pregnancy did not translate into following that recommendation.

- The media was seen by many women as a source of propagating conflicting alcohol use in pregnancy messages.

- Some women indicated that they were not adequately followed-up even though they indicated at the booking appointment that they were drinking.

8. 0 Chapter Eight: Interrogating the context, mechanism and outcome configurations

8.1 Introduction

This chapter forms the third stage of the realistic evaluation framework of the thesis. It uses the results from stage two (midwives and pregnant women findings) to revise the initial CMO propositions identified in stage one (see Table 5.3). As noted earlier, realistic evaluation begins with a set of programme theories or propositions and concludes with more refined propositions that could be subjected to future testing (Wand et al., 2011). These refined propositions describe and explain how a programme might work for whom and how, in a particular setting in order to generate transferable lessons that may be used by others who intend to implement similar programme (Pawson and Tilley, 1997; Wand et al., 2007).

8.2 The Context, mechanism and outcome (CMO) configurations

8.2.1 First set of CMO configurations

The context for the first set of CMO configurations was that there are uncertainties regarding the risks of lower levels of drinking. The uncertainties could pose challenges to screening and alcohol intervention activities in antenatal care settings. Table 8.1 shows the refined propositions.

Table 8.1 Refined CMO configurations one

Context	Mechanism	Outcome
Uncertainties abound regarding the evidence of effects of moderate levels of drinking on the fetus	**Midwives** **M1:** Midwives had greater understanding of risk after undergoing training so provided relevant alcohol advice to women **M2:** Through screening, midwives used the opportunity to teach women how to assess their alcohol intake and calculate units of alcohol	**Midwives** **O1a:** Midwives understanding of risk of drinking in pregnancy improved **O1b:** Midwives appreciated the need to intervene and this promoted positive change in attitudes **O2:** Improved capacity to impart alcohol assessment knowledge to women and through which women could make informed alcohol consumption decisions
	Pregnant women **M1:** Through screening, there was regular opportunity for midwives to raise awareness about alcohol and address issues of uncertainties bothering women **M2:** Screening and ABI initiative offered women opportunity to learn current alcohol guidelines from their midwives	**Pregnant women** **O1**: Increased awareness of the risks of drinking in pregnancy **M2:** Increased awareness of alcohol guidelines promoted compliance which resulted in abstinence or reduction in alcohol use

It was clear from the analysis that both midwives and pregnant women showed a good understanding of risks of drinking in pregnancy. However, especially with the pregnant women, some were not aware of specific risks associated with prenatal drinking neither were they aware of the levels or patterns of drinking that harm to the fetus could occur.

It was encouraging that some women valued and heeded the alcohol advice provided to them by their midwives (see section 7.10.1). Also, once some women were aware of alcohol guidelines they complied. The mechanism that midwives provided relevant advice to women because of the training they received may not work in situations where midwives are not providing women with the current NHS Scotland recommendation of no alcohol intake during pregnancy, especially if they feel their drinking is not problematic. It may also not work in instances where some midwives assume that occasional consumption is acceptable as was reflected in the analysis where midwives felt it was probably all right to have occasional drinks during special events. However, in the context, that drinking below moderate levels poses low risk to the fetus and women preferred to continue drinking in pregnancy, the mechanism that screening offers midwives opportunity to teach women about calculating the units of alcohol in alcoholic beverages would be useful. This mechanism will work for such group of women because they might have gained skills to correctly estimate their units of alcohol consumption. However, it was evident that in the midst of uncertainties regarding risk, some pregnant women took a precautionary approach and abstained in the interest of the health of their unborn child.

The mechanism that the initiative offered midwives opportunity to raise awareness about alcohol and address issues of uncertainties bothering women might work if midwives could reiterate more to women about some of the specific fetal effects of drinking and the seriousness of some of the conditions. This is because women indicated in section 7.9.3 that this information would be relevant for them, and could therefore encourage more women to abstain and perhaps think about their drinking behaviour in subsequent pregnancies.

8.2.2 Second set of CMO configurations

The context for the second set of CMO configurations was that the antenatal period is a good opportunity to screen and deliver ABI because there is a captive audience and most women are motivated to change their drinking behaviour (see Table 8.2).

Table 8.2 Refined CMO configurations two

Context	Mechanism	Outcome
Antenatal period is a good opportunity to screen and deliver ABI because there is a captive audience and most women are motivated to change drinking behaviour	**Midwives** **M1:** Undeveloped relationship at the booking appointment affected screening and delivery of ABI. **M2:** Antenatal screening tools difficult for women to understand and answer correctly and difficult for midwives to record responses **M3:** There was little indication that midwives used booster components such as extending ABI delivery or inclusion of a partner, as such fidelity to the modalities of the appropriate ABI delivery in antenatal setting was largely absent	**Midwives** **O1:** Women more likely provided socially desirable response to screening. **O2:** Misclassification of women likely and decrease in quality of data collected **O3:** Midwives unlikely to alter behaviour change for women drinking hazardously or harmfully
	Pregnant women **M1:** Pregnant women respected and valued the good and continued relationship they had with their midwives **M2:** Midwives were seen as an authority figure and this intimidated women **M3:** Screening reduced alcohol	**Pregnant women** **O1:** Increased adherence to midwives' advice **O2:** Women limited the amount of drinking information they disclosed and likely affected screening results.

Context	Mechanism	Outcome
	consumption to some extent.	**O3:** Women reduced or abstained after assessment

Motivational interviewing, the technique for delivery ABI thrives on well-developed relationships (Rollnick and Allison, 2004; Woolard et al., 2011). It was evident from the pregnant women's findings that a good relationship with a midwife was necessary for them to adequately disclose sensitive alcohol information (see section 7.10.1). Midwives also recognised that carrying out alcohol intervention activities at the first appointment was difficult for them because of the new and undeveloped relationship at that appointment (see section 6.8.2). This mechanism worked for women who were able to establish good rapport with their midwives and trusted them enough to report their true level of consumption. The mechanism that women respected the good relationship with their midwives also reflected in the fact that women adhered to their advice. However, as the findings from pregnant women showed in section 7.10.1, some women felt intimidated at the first antenatal appointment and refrained from disclosing their true drinking levels. This category of women was unlikely to screen positive and could not benefit from the ABI. Another example in section 7.10.1 was the situation where some pregnant women although expressed concern that they were worried about the health and safety of their unborn baby, because they drank excessively during the beginning of their pregnancy yet did not raise such concerns with their midwives.

In the context that women are motivated to change their drinking behaviour during pregnancy or when planning a pregnancy, as was evident in the pregnant women's results - because some women even felt very worried about unknowingly drinking in

pregnancy. For these categories of women, screening only by their midwives positively changed their drinking behaviour.

From Table 5.3, the proposed mechanism was that a booster component for example extended ABI may be required to change drinking behaviour among women drinking hazardously or harmfully in pregnancy. However, it was evident from midwives findings (see section 6.7.2), which was confirmed by the pregnant women that most of the midwives utilized only the advice element within the FRAMES model. There was no evidence that midwives explored pregnant women's motivations or barriers to change, or readiness to change. With pregnant women, in the context that most are motivated to change drinking behaviour, women who still drink hazardously or harmfully may lack the impetus to address their problem behaviour themselves and may require enhanced motivation to change drinking behaviour. However, with time limited at the booking, midwives may not fully use their motivational interviewing technique effectively to intervene for this group of women. Instead, they might resort to referral for women drinking at these levels. Furthermore, some pregnant women expressed a desire for midwives to be more involved in alcohol intervention follow-up activities than what is already available (see section 7.10.2). Pregnant women, who felt this way, used this as indication that drinking in pregnancy was not risky. A possible outcome is that midwives who do not adequately monitor women's progress are unlikely to help such women drinking at these high levels to change drinking habits.

8.2.3 Third set of CMO configurations

The context for the third set of CMO configurations was that the adverse effects to the fetus of drinking in the first trimester is profound as compared to the second and third trimester drinking and may present challenges to the timing of screening and ABI delivery in antenatal care (see Table 8.3).

Table 8.3 Refined CMO configurations three

Context	Mechanism	Outcome
The adverse effects to the fetus of maternal drinking in the first trimester is profound as compared to the second and third trimester drinking and may present challenges to the timing of screening and ABI delivery.	**Midwives** **M1:** Screening and ABI delivered in the midst of other competing issues.	**Midwives** **O1:** The large amount of information provided to women at the booking compromised the quality of screening and ABI delivery.
	Pregnant women **M1:** Policies like KCND facilitated early identification of alcohol use and offered opportunity for intervention. **M2:** Screening extended to also identify pre-pregnancy hazardous and harmful drinking.	**Pregnant women** **O1:** Risk to the fetus reduced and subsequent maternal drinking behaviour also reduced. **O2:** This ensured that all risk drinking in pregnancy are detected.

It was evident from the midwives findings that screening and ABI were competing with other equally important issues at the booking appointment (see section 6.10). So, for women who might have significant other problems aside drinking for example, domestic abuse issues, screening and ABI may be disregarded or given less priority. Also, in the midst of competing priorities, as some midwives generally perceived that alcohol consumption had not been a problem among their clients, opportunities to deliver the intervention were missed as was seen in the pregnant women's (see section

7.10.2) and midwives (see section 6.7.4) findings.

It was clear from the policy implementers' and midwives' results that currently midwives are screening women for alcohol use earlier because of the KCND initiative, yet it was evident that substantial numbers of women in this study drank early in the first trimester before pregnancy was confirmed (see Table 7.1). This mechanism might not work for women, in terms of reducing harm to the fetus, in circumstances where large quantities of alcohol had already been consumed prior to the booking appointment. This is because of the greater risk associated with first trimester drinking. However, for these women it might work, in terms of drinking behaviour change, by generating increased awareness about alcohol, including risk drinking in pregnancy and could be beneficial for altering drinking behaviour for the remainder of the pregnancy and possibly for future pregnancies. As the pregnant women data showed in section 7.9.1, improved awareness may not necessarily promote abstinence but could help to reduce consumption levels or patterns. It was not clear from the data whether women, who otherwise drank, but had not yet, had any alcohol in the first few weeks of pregnancy drank later in pregnancy. For this group of women, early screening could sustain abstinence for the remaining duration of their pregnancy and therefore improve the health of the women.

It was clear from the policy implementers' findings that the coverage of screening and ABI have been extended to include pre-pregnancy drinking because drinking before pregnancy is a risk factor for prenatal risk drinking (Day et al., 1993; Russell et al., 1994; Chang et al., 2006). Women who screen positive based on pre-pregnancy drinking could benefit from the programme because screening and ABI may reduce risk drinking in pregnancy.

Table 8.2 showed the mechanism that the screening tool was reported to be complicated by midwives and it is also shown in the mechanism in Table 8.3 that it is being delivered in the midst of competing priorities at the booking appointment. In the circumstance where midwives may feel that it is taking more time to screen clients, the quality of delivery (and therefore effectiveness) may be compromised. The more time spent to screen women could probably be a reason why some midwives preferred to refer women identified to be drinking at high levels to other health professionals as was seen in section 6.7.2. Such sign postings and referral might be an attempt to avoid lengthy conversations. However, it is worthy to note that the screening and ABI programme was introduce in antenatal care settings in order to offer midwives an opportunity to fully intervene in risk drinking behaviour during pregnancy.

8.2.4 Fourth set of CMO configurations

The context for the fourth set of CMO configurations was that training, support and dedicated personnel are essential for effective screening and ABI delivery as indicated in Table 8.4.

Table 8.4 Refined CMO configurations four

Context	Mechanism	Outcome
Training, support and dedicated personnel are essential for effective screening and ABI delivery.	**Midwives** **M1:** Training equipped midwives with more knowledge about risks of prenatal drinking **M2:** Built capacity and ensured there was a scope to enhance fidelity to ABI delivery **M3:** Additional resources	**Midwives** **O1:** Improved understanding of risks and this translated in positive change in attitudes **O2a:** Improved skills and increased confidence to screen and deliver ABI **O2b:** Increased ability to

Context	Mechanism	Outcome
	provided for midwives indicated as very useful **M4:** Generated awareness among midwives about the need to intervene **M5:** Training and support facilitated midwives acceptance of screening and ABI as part of their role	assess units of various alcoholic beverages **O2c:** Further training required to ensure fidelity to ABI delivery **O3:** Raised awareness and priority of screening and ABI programme **O4:** Boasted morale and facilitated screening and ABI delivery **O5:** Generated greater involvements in alcohol intervention activities

The training and support equipped midwives with more knowledge and understanding of the risks of drinking in pregnancy and thereby improving their skills and confidence to screen and deliver ABI to women. Some midwives also gained positive attitudes towards alcohol from the training programme. Positive change in midwives attitudes towards alcohol intervention activities might have direct benefits for their clients. Training also built midwives capacity and ensured that there was a scope to promote fidelity to ABI delivery. It was evident that midwives improved their understanding of unit conversion tremendously and they had an ABI professional pack, which they indicated was useful as a teaching resource to women. With increased capacity and availability of resources, midwives felt confident that they could adequately do ABI. However, there was not enough evidence of their fidelity to ABI delivery (see next section for details).

Training and support generated awareness among midwives about the need to intervene in alcohol consumption during pregnancy and facilitated midwives acceptance of screening and ABI as part of their role. Training also helped to raise the priority of the screening and ABI initiative and boosted midwives morale. In the context that dedicated personnel are essential for screening and ABI delivery, the outlined mechanisms above might work because training and support negated considerable numbers of practitioners' barriers - for example lack of adequate confidence and skills - that prevent them from involvements in alcohol intervention activities (Lock et al., 2002; Tsai et al., 2010).

8.2.5 Fifth set of CMO configurations

The context for the fifth set of CMO configurations was that few women participate in risk drinking behaviour when they know they are pregnancy (see Table 8.5).

Table 8.5 Refined CMO configurations five

Context	Mechanism	Outcome

Context	Mechanism	Outcome
Few women participate in risk drinking behaviour when they know they are pregnancy	**Midwives and pregnant women** **M1**: ABI is delivered to very few women in antenatal care	**Midwives and pregnant women** **O1a**: The skills midwives gained from training were rarely put into practice and as such confidence and fidelity was reduced **O1b**: ABI no longer a priority for midwives therefore the few women who drink at risky levels were unlikely to benefit as the ABI was not delivered effectively

It was clear in the pregnant women findings that few women drank in pregnancy once they were aware they were pregnant therefore few women are likely to be involved in risk drinking in pregnancy. This was confirmed in the midwives findings in section 6.7.3. As was shown in the CMO configuration four, training promoted midwives confidence. Therefore, if midwives rarely delivered the intervention, their confidence may reduce and may feel inadequate to competently deliver the ABI. This was confirmed in the midwives findings where some midwives felt that their role within the screening and ABI initiative was to refer hazardous and harmful drinkers to other health professionals (see section 6.7.2). The mechanism in Table 8.5 might work in circumstances where midwives regularly deliver ABI to women. It might also work in situations where regular training is provided to midwives to refresh and sustain their ABI delivery skills in motivational interviewing.

In addition, in the context that few women screened positive for ABI in pregnancy, there is tendency that some midwives might have lowered the priority and the urgency to intervene for the few women who might have drunk hazardously and harmfully as was seen in section 6.7.4. Midwives who felt this way, although still screened women but may not adequately deliver the intervention as compared to situation where they felt there was a real cause for concern. Under these mechanisms, ABI might not work for the few women who may drink at hazardous and harmful levels.

8.3 Summary

This chapter pooled together the findings of the thesis based on realistic evaluation perspective. It highlighted how the screening and ABI programme is currently working in antenatal settings illuminating areas where lessons can be learned to further enhance the programme. The main findings of this chapter began with the assertion that in the context of uncertainties regarding the threshold of drinking that causes fetal harm, assessment of pregnant women to ascertain their alcohol use was found to help women reflect on their drinking behaviour and facilitate behaviour change. However, in the context that women drank at hazardous and harmful levels before attending the booking appointment, screening and ABI may be helpful in terms of eliciting behaviour change but may not be very beneficial in terms of reducing harm to the fetus as it was found that drinking during the first trimester poses the most risk to the fetus. Training and resources provided to midwives as part of the screening and ABI programme were found to be facilitating mechanisms that midwives indicated that improved their skills and confidence. However, it was found that most of the midwives had not employed the motivational interviewing skills required for ABI delivery, because many of the pregnant women indicated that they reduced or abstained from alcohol once pregnancy was confirmed. The outcome noted was that midwives confidence decreased leading to

missed opportunities to appropriately deliver the intervention to eligible women. In addition, it was found that the small numbers of women being identified for ABI meant midwives rarely delivered the ABI. This negatively influenced midwives attitudes as they accorded ABI with low priority. Other disenabling mechanisms noted to be hampering the implementation of the screening and ABI initiative included midwives contending with competing priorities at the booking appointments, and the lack of adequate rapport between midwives and pregnant women at the booking appointment to discuss alcohol issues appropriately, leading to women proving socially desirable responses to screening questions.

9. 0 Chapter Nine: Discussions and conclusions

9.1 Introduction

This chapter discusses the findings of the thesis. The chapter also places the thesis in perspective by discussing the critical meaning and relevance of the study findings. The implications of the findings for research, policy and midwifery practice are then presented. Finally, as the last chapter of this thesis, it documents the overall conclusions of the thesis.

9.3.1 Attitudes and drinking behaviour

Attitudes and beliefs towards alcohol consumption in pregnancy could determine whether people drink in pregnancy or not. Findings from the pregnant women's data showed that their attitudes to drinking were influenced by the view that the unborn baby might be harmed. Interestingly, some women who identified the health of the baby as the reason to change drinking behaviour chose to reduce their consumption levels rather than completely abstain. This finding concurred with a qualitative study which found that women's priority to protect the health and safety of their unborn child did not necessarily result in them opting for abstinence but may have resulted in them reducing the amount of alcohol consumed (Raymond et al., 2009). Many health professionals and researchers believe that abstinence is the safest option especially in the absence of robust evidence regarding the exact threshold at which alcohol consumption could harm the fetus (Stratton et al., 1996; Mukherjee et al., 2006). In this study, it was clear that this uncertainty compelled some women to stop drinking in pregnancy as they expressed the notion that 'prevention is better than cure'.

Midwives attitudes to prenatal alcohol consumption may play a significant role in the

extent of their involvement in alcohol intervention activities. This study found that midwives personal use of alcohol influenced their attitudes to drinking in pregnancy and to some extent determined the kind of advice they gave to pregnant women. Whilst abstainers completely condemned the behaviour, there were conflicting opinions from those who drank. Among this group, while some felt it was necessary for pregnant women to abstain, others thought women could drink occasionally or reduce their consumption levels. A study exploring nurses attitudes towards ABI in primary care in the north-east of England, found that nurses who were hesitant about the ABI related activities were the ones who used alcohol themselves (Lock et al., 2002). It appears that health professionals' personal drinking status may play a subtle role in alcohol intervention activities. However, considering the underlying differences among service user groups that present to antenatal care and primary care, the primary healthcare nurses' negative attitudes may be understandable. More particularly current research findings also support low-moderate drinking among primary care populations. It has been shown that drinking at this level lowers the risk of coronary artery disease and ischemic stroke in men over 40 years old and women during the menopause (Britton and McKee, 2000). Nevertheless, in antenatal care, the health of the mother and fetus are directly involved, so positive change in attitudes may be essential to further promote alcohol intervention activities.

The wellbeing of the fetus was clearly one of the reasons why some midwives who were 'drinkers', felt that it was important for pregnant women to abstain to reduce alcohol exposed pregnancies. As anticipated midwives who were themselves drinkers and who had relaxed opinions about drinking in pregnancy were the ones who indicated that they would advise women to take low amount of alcohol on special occasions. Although, this is in line with the current NICE guidelines (NICE, 2008), the ABI

programme and the current NHS Health Scotland recommendation promote abstinence (NHS Health Scotland, 2010a). Reassuringly, a study from Denmark has shown that a change in official guidelines facilitated positive change in attitudes, beliefs and knowledge about prenatal alcohol consumption (Kesmodel and Kesmodel, 2011). With change acknowledged as a process (Treasure, 2004), it is likely that there could be further improvements in midwives attitudes to drinking issues during pregnancy in Scotland.

9.3.2 Knowledge about risk

Enhancing midwives knowledge about the risk of drinking in pregnancy will enable them to further understand the need to screen and deliver ABI in antenatal care settings. It will also encourage pregnant women to appreciate the benefits to be gained from reduction or abstention from alcohol. In this study, all the women understood that drinking in pregnancy could pose some degree of risk to either the fetus or themselves. However, few of the women were aware of the spectrum of fetal health risks associated with prenatal drinking. However, the majority knew about FAS. Peadon et al. (2010) also found that among the 1,103 Australian women aged 18 to 45 years involved in a national survey, FAS was the most common fetal health outcome participants were familiar with in terms of risks of prenatal alcohol consumption. In addition, only 67.5% of women in their survey agreed that they were aware of any effects of prenatal drinking on the fetus (Peadon et al., 2010). In this current study, almost all the women were aware of at least one form of effects of alcohol on the fetus or subsequent health and developmental outcomes that could result from this. The differences in knowledge could possibly reflect differences in study methods and study participants. While this study utilized a face-to-face interview method, Peadon et al. (2010) study used computer assisted telephone interviews. It is possible that the women prepared more for

a face-to-face interview than computer survey. In addition, pregnant women as compared to non-pregnant women were likely to be attentive to issues of pregnancy and childbirth. As such, pregnant women in the current study might have taken special interest in such issues, thereby reflecting their increased knowledge base.

Midwives showed good understanding of risk of prenatal drinking on the fetus. Many were able to name correctly the various fetal outcomes associated with drinking in pregnancy especially for heavy sustained drinking. However, there were varied views regarding the risk of low-moderate consumption.

As expected, many of the women and midwives perceived that drinking in the first trimester is particularly risky for the fetus. This is supported by the evidence (Whitty and Sokol, 1996; Sayal et al., 2007). Unfortunately, many of the pregnant women in this study used alcohol during the first trimester whilst unaware that they had conceived and in some instances, it was clear that the women had drunk excessively. However, in the context of stigmatisation of prenatal drinking, some of the women did not report their true drinking levels to their midwives although they subsequently reduced their consumption. This is in line with existing literature which reports that women tend to reduce their consumption once pregnancy is known (Strandberg-Larsen et al., 2008; Chang et al., 2008).

9.3.3 Alcohol dialogue between midwives and pregnant women

One important finding was that some midwives did not adequately follow-up women who indicated at the booking appointment that they had consumed alcohol. Fundamentally, this could be an indication of the limited time available in the antenatal care in which midwives are often required to address competing priorities. However, it could also be possible that once midwives became aware that the women had already

drunk in pregnancy, they avoided discussing the issue, particularly as the topic becomes more sensitive. It has been shown in primary care in Norway that General Practitioners felt uncomfortable discussing alcohol use with patients because of its emotive nature (Nygaard and Aasland, 2011). The capacity to deal with negative case reaction has also been reported to discourage health professionals from initiating alcohol intervention activities (Lock et al., 2002). In this study, it was possible that midwives felt focusing on drinking could bring up the issue of potential fetal harm which might cause anxiety and distress to women. Alternatively, it might have been an attempt to avoid putting any strain on the pregnant woman-midwife good relationship, which both midwives and pregnant women saw as a priority.

During pregnancy, women are screened for different behavioural risk factors that may impact on healthy pregnancy outcomes. Some women understood that the most risky behaviours attracted the most attention from midwives. The midwives' findings showed that midwives felt alcohol consumption was not an issue in the majority of cases. Other behaviours, for example smoking was seen as more problematic than drinking alcohol. However, the more attention given to smoking could have negative implications for detecting alcohol problems. This is consistent with a US study where Chang et al. (2008) observing patient – provider communication about substance misuse, found that health professionals fixation with smoking meant that opportunities to offer alcohol interventions to pregnant women were missed. It is possible that already established smoking cessation strategies in antenatal care settings (Oliver et al., 2001; Lumley et al., 2004) might have made midwives more comfortable and knowledgeable about the risks of smoking (which are very well established) and possibly more comfortable to carryout intervention activities. Alternatively, women may have already accepted anti-smoking advice as part of routine practice. This may have eroded any barriers to

discussing it with midwives. These could be reassuring for the screening and ABI programme as they suggest that with the passage of time familiarity may facilitate delivery.

9.3.4 Screening

It was clear from the findings that the midwives screened women for both pre-pregnancy and pregnancy drinking. Although the current T-ACE and TWEAK have validity for prenatal drinking (Chang, 2001; Flynn et al., 2003), it has been noted that women who drank pre-pregnancy are more likely to participate in risk drinking during pregnancy (Day et al., 1993). The significance of this approach is that women, who may feel prompted to deny drinking in pregnancy due to stigmatisation, may find it more comfortable to report pre-pregnancy hazardous or harmful drinking. This group may also screen positive and gain benefits from the ABI programme. From a midwivery perspective, Nilsen et al. (2011) indicated that in a Swedish ABI implementation programme a strategy to use the AUDIT tool to ask pregnant women about their alcohol use in the year preceding their pregnancy, had considerable support from midwives as these midwives felt that avoiding direct consumption questions in pregnancy was more appealing.

9.3.5 Confidence to screen and deliver ABI

Lack of training for health professionals has been identified as a as a major barrier in many screening and ABI implementation activities (Lock et al., 2002; Johnson et al., 2010; Tsai et al., 2010). Training is known to improve skills and boost practitioner's confidence and therefore facilitates screening and ABI delivery. However, this may not always be the case. Research has shown that even after training some General Practitioners did not adequately deliver ABI (Kaner et al., 1999). In the current study, although midwives generally felt confident about their skills to screen and deliver ABI,

their account of models used for delivery showed that fidelity to ABI delivery was compromised.

Alcohol issues could be a particularly emotive topic, yet most midwives did not indicate signs of discomfort in raising the issue. It is likely that the training and resources provided for midwives by NHS Health Scotland made a great difference. Another area that helped with midwives confidence was the integration of the screening on the TRAK maternity (electronic maternity recording system). As the system had been built into the antenatal records, midwives who had little confidence in discussing alcohol issues could use the opportunity to inform pregnant women that, alcohol screening was part of the routine questions asked. Building alcohol questions into routine recoding systems had been noted as a good way of facilitating alcohol intervention activities (Nygaard and Aasland, 2011).

9.3.6 Relating findings to policy implementation theories

Matland (1995) suggested that among the different implementation approaches, none could be described as best implementation strategy but the appropriate strategy depends on the contingencies surrounding the policy issue being implemented and how best the implementation can address them. Plans for tackling hazardous and harmful alcohol consumption and alcohol related harms at the population level had been a priority for the Scottish Government for some time now (Scottish Government, 2009). However, with screening and ABI assuming the status of HEAT targets in 2008, I believed there was the need to facilitate the implementation process in order to support achievement of policy results. From the findings of this study, I could presume that midwives were not adequately involved in discussing how best they could incorporate the initiative into their current practice. This is because although midwives believed that involvement in public health intervention activities is integral to their role, they expressed the opinion

that the initiative had been imposed on them by policy makers, without due consideration of their existing workloads. This assertion was echoed in policy implementers' findings, where they acknowledged that initial problems and complexities within the antenatal care settings delayed implementation. The Scottish Government is very much focussed on central implementation of this sort of policy. With these findings in mind, I believe the screening and ABI implementation in antenatal care settings have been carried out as a top-down approach (Schofield, 2001; deLeon and deLeon, 2002). I feel the initiative would have fared even better if the views of midwives, especially concerning their current practice, had been integrated in the policy formulation and implementation, as would be the case in bottom-up policy implementation. deLeon and deLeon (2002) argued that practitioners would be more committed to change when policy implementation adopts a bottom-up approach which is more participatory and democratic, reflecting communal interest. The bottom-up theory also suggests that implementation consists of interaction between policy and settings (Matland, 1995). Therefore, if a bottom-up approach had been taken it would have given midwives more freedom to adapt the screening and ABI programme to the antenatal care context, given them more opportunities to make allowance for local difficulties and conditions. However, it is also possible that it would have led to patchy implementation and inequitable services across and between health boards.

It is recognised that not all policy initiatives can be implemented by the bottom up approach. In some instances, the top-down model seems more appropriate than a bottom-up approach, for example, regarding policies that concern national security. However, for a behaviour change intervention, like ABI, especially as it relies on motivational interviewing technique, the manner in which practitioners fully

accommodate interventions in their role and deliver them is deemed very essential and a bottom- up approach may have worked better.

In terms of the activities involved with policy implementation – interpretation, organisation and application - it could be argued that most of the factors that were identified to inhibit the implementation were attributed to routine administering of the intervention ('application'). However, 'organisation' has been a significant driver of the initiative. With screening and ABI being a HEAT target, NHS Health Scotland has played an important role of providing leadership and supporting (e.g. developing and co-ordinating training and instituting ABI delivery support teams) NHS boards to achieve targets. It is commendable that between April 2008 and March 2011, the national ABI HEAT target of 149,449 ABIs delivered were achieved by all three priority settings of primary care, A&E and antenatal care, prompting the Scottish Government to extend the target for 2011-2012 by an additional 61,081 (Scottish Government, 2011b). These figures are encouraging and reemphasise the Scottish Government's commitment to embedding the screening and ABI programme into routine practice. However, they represent performance targets and may not be commensurate in terms of quality of delivery and actual drinking behaviour change achieved.

The findings of this study also highlight the principal-agent problem of policy implementation. It could be seen from the policy implementers' findings that they felt the burden of fetal harm is increasing and there was a need by midwives to give a higher priority to screening and delivering of ABIs during antenatal care. However, midwives who participated in this study expressed the opinion that majority of their

clients do not drink at risky levels, and because of that, they felt the ABI was not a priority in the context of antenatal workloads.

9.4 Strength of the research

This study has several strengths. Firstly, to my knowledge, it is the first study to employ a realistic evaluation methodology to examine the implementation of screening and ABI in an antenatal care setting. The systematic approach of teasing out a meaningful CMO configuration generated greater insight into the implementation process whilst facilitating understanding of the how the screening and ABI worked in routine practice.

There have been arguments about whether there was a need for a new (realistic) evaluation approach aside from the traditional experimental and quasi-experimental approaches (Bennett, 1996). However, Pawson and Tilley (1997) making their case for an alternative evaluation design made important assertions, which have proved useful and relevant for this study. One of their arguments relate to the logic behind the cause and effect relationship in investigating social interventions. In an experimental or quasi-experimental design, the impact of intervention is determined by applying a treatment to one group (intervention) and not to the other group (control). In addition, with experimental designs, for example RCT, participants are randomly allocated to ensure that both intervention and control groups are well matched to eliminate other potential explanatory variables. For quasi-experimental methods, groups are manually matched based on specified qualities with the aim of eliminating any variables that may account for observed differences other than the intervention. With these procedural steps in place, any change observed between the groups assumes evidence of cause and effect. This, Pawson and Tilley (1997) referred to as successionist model of causation.

Pawson and Tilley (1997) argued that when dealing with social reality, it is difficult for the successionist model to thrive because it is practically impossible to control all explanatory variables. Further, a successionist model does not provide us with sufficient details of the events or circumstances that brought about change. They argued that social interventions work only where participants choose to co-operate and this co-operation depends on a complex interplay between motivation, circumstances and attitude. Realistic evaluation, therefore gives these issues their proper place in evaluation, providing us with knowledge of internal features of how the intervention caused change. Employing realistic evaluation in this study therefore helped to take into account the complexities of implementing the screening and ABI programme in a real world setting whilst increasing our understanding of how the screening and ABI worked or might work better to reduce alcohol consumption in pregnancy.

The context within which an intervention is implemented is increasingly being recognised as crucial in determining programmes' effectiveness. Therefore, the realistic evaluation design offered a perspective to focus on the context within which the programme was implemented. Realistic evaluation depicts that understanding of the general contextual issues are imperative to propose relevant mechanisms (Gill and Turbin, 1999). As a result, by conducting two systematic reviews and a critical review, the realistic evaluation design offered me the opportunity to gain in-depth understanding of research evidence pertaining to the effects of prenatal drinking on the fetus and efficacy of ABI to reduce drinking levels as a strong basis to postulate appropriate mechanisms of causation. Moreover, the interview with policy implementers further helped to identify specific contextual issues relevant to Scottish antenatal settings.

The diversity within participant groups ensured that a variety of different experiences was captured. For instance, in the pregnant women category, 12% of the participants were from ethnic minority groups. Moreover, women with different categories of drinking habits were involved, enriching participants' perspectives. In the midwives' group, community midwives, team leaders and a consultant midwife formed a good mix of participants.

Furthermore, the systematic review approach adopted by this thesis ensured that almost all available literature in the topic area that satisfied the inclusion criteria had the chance to be included in an unbiased manner. Synthesising and grading the evidence provided useful insight into the evidence base in the field, allowing me to place more emphasis on high quality evidence. More useful was the broader approach I used to examine screening and ABI across different health care settings. This enabled me to gain greater understanding of the potential differences in screening and ABI delivery across different health care settings.

Finally, analysing the qualitative data using a hybrid approach of inductive and deductive coding and theme development ensured that the data was fully explored without the limitations of more theoretically bounded methods such as interpretative phenomenological analysis (Braun and Clarke, 2006). The use of a codebook served as a record of evidence that provided the study with credibility (Fereday and Muir-Cochrane, 2006). In addition, there were only minor inter-rater differences in coding, which were resolved through discussion when I invited my supervisors to independently code a random sample of the qualitative data. This verification process further enhanced the rigour and reliability of the analysis. Finally, triangulation allowed comparison between the findings from the various participant groups and the

review evidence promoting rigour of the analysis (Tolson et al., 2005; Maluka et al., 2011).

9.5 Limitations

This study, like most other research projects has limitations and these should be taken into consideration when interpreting the findings. The study relied extensively on proceedings elsewhere (policy developments in the screening and ABI initiative), which were outwith my sphere to influence. On several occasions, it was clear that policy and academic timescales varied. For instance, at the start of my work on the thesis (later part of 2008) discussions with policy stakeholders indicated that since the HEAT H4 targets was instituted in April 2008, all three settings (primary care, A&E and antenatal care) were almost about to implement the screening and ABI initiative. Primary care and A&E introduced the programme as part of their routine practice shortly thereafter, yet it was not until the end of 2009 when few Health Boards started implementing it in antenatal care. Therefore, at the time of data collection, only a few women had been offered the ABI.

Moreover, operating within ethical constraints, it proved to be impossible to sample from the small number of pregnant women who had been offered ABI, given the time and resource constraints for a doctoral study. This limited further interrogation of the outcome component within the CMO configurations with respect to the pregnant women population group. Gill and Turbin (1999) experienced similar challenges in their study, emphasizing that when time and resources are limited it is difficult to collect adequate data for all the three elements within the CMO configuration.

In this study, an attempt was made to recruit women for the ABI category to examine their experiences of receiving the ABI and the influence the ABI has had on their

drinking behaviour. A plan was drawn to recruit retrospectively by writing to all those who had been offered the ABI within NHS Lothian at the time. However, NHS Lothian maternity services management did not approve this plan and they insisted that women should be recruited prospectively through their midwives. Ultimately, of the 250 extra information packs (240 had been distributed) that were sent out to midwives to recruit prospective women who had been given ABI, no replies were received even though there was a £20 incentives for women attached. It is important to note that during the recruitment period, regular emails and telephone calls were made to midwifery team leaders to encourage them to recruit women for the ABI arm of the study. These correspondences also asked them to remind their team to distribute the information packs to women who had been offered the ABI. However, it was possible that the few women who had been offered ABI did not wish to participate in an alcohol research study. Therefore, this study relied on the accounts of women who drank alcohol either pre-pregnancy or during pregnancy and who had been screened and/or given advice about alcohol use. Nevertheless, as the screening and ABI programme was in its early stages, it could be argued that the accounts of these women provided useful illuminating areas that need to be considered to enhance successful embedding of the programme into routine antenatal care beyond the HEAT targets.

Realistic evaluation proposes that identification of programme theories should precede testing and refining these theories. In this study, attempts were made to extensively outline programme theories through conducting reviews and supplementing them by conducting individual interviews with policy participants. However, during the process of testing the theories with midwives and pregnant women, new concepts were identified which were not initially formulated as programme theories. This often necessitated the need to revisit the initial analysis in stage one to accommodate this

'new' concepts into the initial theories. This means that the process of identifying, testing and refining programme theories was not entirely a linear process as depicted in Table 1.2 but some were carried out in an iterative fashion. Although, this proved time consuming and complex initially, it nevertheless offered depth to the analysis.

Using realistic evaluation, this study has produced knowledge of how screening and ABIs worked in antenatal care settings. However, it did not fully address the issue of whether screening and ABIs actually reduced drinking in pregnancy. Given the tendency of women to reduce or abstain from alcohol during pregnancy, it was difficult to determine fully the contributions of the various intervention components that potentially caused drinking behaviour change. It is recognised that in this regards, an experimental approach, using randomisation or matching could have eliminated other potential explanatory variables in order to assess outcomes solely attributable to the intervention. Possibly, conducting a realistic evaluation alongside an outcomes focused evaluation would be optimal but was outwith the potential of this thesis.

During the process of developing and refining the CMO configuration, it was often clear that an alternate CMO could be generated. However, this challenge was not unique to this study. Others who have employed realistic evaluation methodology have also encountered such difficulties (Byng et al., 2005; Tolson et al., 2005). However, Rycroft-Malone at al. (2010) indicated that the philosophical basis of realistic evaluation, realism make provision for more than one mechanism to operate concurrently. Therefore, it was important that the final CMO configurations outlined in this thesis were informed by the research questions.

The face-to-face method of data collection is appropriate for gaining insight into newly implemented projects, but it is open to social desirability and acquiescence bias.

Acquiescence bias is described as a participant's inclination to respond positively to questions without adequate evaluation of their content. It is possible that considering the emotive nature of alcohol consumption in pregnancy, women responded to questions to portray themselves as good mothers. Midwives, with the implicit knowledge that their practice was being examined were likely to respond to questions in ways that suggested that they are adherent to recommendations. Also, considering the approach of recruiting participants, it was likely that midwives who felt knowledgeable about screening and ABI and women who felt confident that they had something to contribute decided to participate in the study. It is likely that pregnant women and midwives who did not participate may have had different views.

Due to the sensitivity involved with drinking behaviour during pregnancy, individual interviews with women were deemed the most appropriate method for data collection. With midwives, both individual interviews and focus groups were conducted. It was anticipated that individual interviews might offer participants the privacy to share with me issues they may not otherwise discuss in a group settings, especially as the programme was a policy initiative. However, it was also recognised that group settings may offer opportunities for midwives to develop ideas in the course of discussion and to challenge other's opinions and in so doing move the discussions into dimensions which individual interviews may be unable to attain. I was keen to carry out more focus groups but unfortunately, challenges with recruitment (see Chapter 4 – ethical constraints) meant changes were made and I was compelled to conduct only one focus group with a pre-existing group (supervisors of midwives who meet monthly). Concerning the analysis, because only one focus group was carried out, I felt it was inappropriate to analyse the data separately from the individual interview data. As a result, the two sets of data were analysed together, retaining the individual quotes

within the focus group whilst highlighting areas of agreement and disagreement between participants' opinions.

The focus group used pre-existing group. Pre-existing groups may have their own established power relations (Purdam, 2010). However, in this study this pre-existing familiarity possibly served to facilitate discussion and diffuse tension between group members.

This study was conducted in only one Health Board in Scotland and represented the views of a relatively small number of participants. The findings of the study are therefore not generalizable to other Health Boards especially as policy participants in this study indicated that different areas might be using different screening and ABI models. However, generalizability was not the rationale for the study. Nevertheless, the insight this study has offered provides a valuable contribution to the knowledge base about screening and ABI implementation in routine antenatal care settings.

9.6 Overall recommendations of the study

9.6.1 Policy

Midwives were positive about the support available for the screening and ABI programme. However, in order to ensure sustainability beyond the achievements of the HEAT targets, ongoing support and input from the ABI delivery support teams and alcohol and drugs partnerships may be essential to maintain or improve the level of priority given to alcohol intervention activities in antenatal care.

Many of the pregnant women who had stopped drinking at the time of the interview had already consumed alcohol early in pregnancy. In order, to prevent or reduce alcohol-exposed pregnancies in Scotland, pre-pregnancy preventative measures may be more beneficial to reduce this risk. Alcohol interventions instituted at the family planning

clinics that target women planning to conceive may be highly useful in this respect. Also, as many people use alcohol before sexual activity (Royal College of Physicians, 2011); alcohol intervention programmes could be combined with sexual health programmes to maximise impact.

Globally, it could be useful for international organisations, for example the WHO to champion international definitions or uniform measures of alcohol across countries to enhance comparability and generalizability of alcohol consumption data. This uniformity may also facilitate the quest to establish specific threshold that alcohol causes damage to the fetus.

9.6.2 Practice

Many of the midwives involved in this study had rarely delivered ABI. The relatively small number of women requiring the ABI was reflected in the fact that some midwives were no longer confident in their ability to deliver ABI competently should the need arise. Regular refresher courses either annually or biennially may therefore be necessary for maintaining midwives competency to deliver ABI.

Alcohol brief intervention does not just mean giving advice about drinking. It has structure and requires the use of motivational interviewing. The practice of motivational interviewing requires a high level of skills and extensive training (Raistrick et al., 2006). Effective practical assessment tools that can measure the integrity of practitioners' motivational interviewing behaviour, for example, the Motivational Interview Treatment Integrity code could be a useful tool to assess and improve midwives motivational interviewing practice (Forsberg et al., 2008). Competency in motivational interviewing could also be useful to deliver other behaviour change interventions for example, smoking cessation programmes.

Successful behaviour change strategy using the trans-theatrical model of change (theoretical basis of ABI) would have more impacts if each individual's readiness to change problem behaviour were assessed (Raistrick et al., 2006). There are several Readiness to Change Questionnaires developed from the Stages of Change model and these could be used to assist midwives in assigning women to the appropriate stage of change. This would help tailor ABI to suit a woman's need as she moves through the various stages of change.

Some midwives were unclear of the care pathways should a pregnant woman screen positive for risk drinking. Clearly, midwives would require further guidelines to help them determine when ABI is appropriate and when women could be referred to specialist alcohol treatment services.

Most of the women in the study were motivated to reduce or abstain from alcohol when pregnancy was recognised. Therefore, for women who continue to drink at risky levels, extended brief intervention (lasting over 30 minutes) would be more appropriate to build pregnant women's confidence to change drinking behaviour (Chang et al., 1999).

It was clear that most midwives had good knowledge about the possible risks to the fetus of prenatal drinking. However, some did not know the wide range of possible outcomes that could result from prenatal drinking. Also, most pregnant women, although they suspected that prenatal drinking could be harmful to the fetus, were unsure of specific risks involved. Knowledge of risks (for example, FAS) is known to induce drinking behaviour change in pregnancy Chang et al., 2000). Considering this, future training could focus on improving midwives' knowledge of fetal alcohol risks. The tool developed in chapter two of this thesis could be a useful resource (see Table 2.7).

Considering that limited follow-up information on behavioural outcomes was being collected after the delivering of screening and ABI, there is a clear need, possibly on the TRAK system, to prompt midwives to regularly follow-up on women who received the intervention. This tool could be useful in terms of boosting midwives morale by providing them with firsthand evidence of the impact screening and ABI could have on drinking behaviour.

As trust-based relationships are essential to effective screening and ABI delivery, delivering them at the first antenatal appointment when they are likely to make the most impact, may be particularly challenging. In this situation, midwives may ask women to come back for a later appointment where a full ABI could be given. Nevertheless, increased expertise in motivational interviewing may however facilitate its delivery at the first antenatal appointment.

9.6.3 Research

In the face of such inconsistent findings relating to risks at lower levels of drinking, it is not surprising that healthcare providers and women remain sceptical about specific fetal effects of prenatal drinking. More consistent reporting would be useful. Therefore, more research; monitoring specific adverse fetal outcomes of prenatal drinking, particular at low-moderate drinking levels would be helpful to further advance the evidence base.

Further research that examines the effects of daily average alcohol consumption in pregnancy may be more useful than research that report average per week or month. Because animal experimentation suggests that peak blood level is most important in prenatal alcohol effects (Haggarty et al., 2008). This may help strengthen the evidence base of the effects of binge drinking on the fetus and may thereby enhance prenatal drinking guidelines.

The CASP quality assessment tool used for assessing quality of studies used in chapter two was developed for studies utilising observational design. However, in the field of prenatal alcohol exposure, the quality of studies may depend on whether alcohol consumption data were collected retrospectively, concurrently or prospectively. when information of alcohol consumption was taken or when alcohol consumption occurred. Therefore, it will be useful for future research to design quality appraisal tools that are specific for this field.

In the primary care settings, ABI has been evaluated extensively. However, there is paucity of RCTs that have evaluated the effectiveness of ABI in antenatal care settings. Those that are available have all been conducted in the US. This means that the generalizability of ABI study findings to UK antenatal care populations is unclear. Moreover, healthcare systems and drinking guidelines differ across countries. There is therefore an urgent need for more research in antenatal care settings, particularly in the UK to evaluate ABI effectiveness.

There is also the need for more research to evaluate the long term effects of NHS delivered ABI for women. Further research is also required to validate the emerging evidence that inclusion of a support partner in antenatal care settings enhances the effectiveness of the intervention (Chang et al., 2005).

Policy implementers indicated that the screening tools currently being employed in Scottish antenatal care were all developed in the US and some of the terminologies may be unfamiliar to practitioners in Scotland. Midwives also expressed difficulties in using

the tools to elicit useful information from women in the midst of time constraints. With these concerns, it seems reasonable to suggest that future research efforts could focus on developing screening tools that would be relevant to the UK context.

For further enhancement of evaluation studies, it would be useful for future research to consider conducting realistic evaluation alongside outcome-focused evaluation (e.g. RCT).

9.7 My personal perspective

I initially embarked on this research with a positivist perspective of conducting an experimental study (RCT or quasi-experimentation) as my background was in the natural sciences and I was also trained in public health and epidemiology for my master's degree. However, as I began reading about the realistic evaluation methodology and discussing with policy stakeholders about the stage of implementation of the screening and ABI programme in antenatal care in Scotland, I realised that an experimental study design utilizing quantitative methods might not be appropriate in this context. Therefore, I felt it was an opportunity to broaden my scope, learn, and employ other research methods skills. I therefore embarked on an extensive training in qualitative research methods techniques (both data collection and analysis methods) to improve on the fundamentals I gained whilst doing my master's degree at the University of Edinburgh. In addition, at the beginning of this research, I knew very little about the importance of involving policy stakeholders in research and the relevance of positioning research within theoretical perspectives.

Through this PhD, I think I have developed well as a researcher by using techniques such as interviewing and focus groups to collect data and valuing the unique perspective they provide in implementation and evaluation research. I have also gained

greater understanding about the relevance of using a theoretical approach in research, especially as this could provide a framework for evaluating the internal validity of research findings. Another useful lesson I have learnt through this PhD is about the importance of involving policy stakeholders in research. This could facilitate knowledge transfer and offer the findings and the recommendations of the research a better chance of being utilized. Most importantly, I have also realised that research does not always go according to proposed plans. Other external factors such as research governance could influence the direction or timescale of the research. Nevertheless, I feel this PhD has substantially increased my research horizon and has equipped me with relevant research skills that will further promote my future research endeavours.

9.8 Overall conclusions

This study has provided a significant contribution to a very limited evidence base in the field of screening and alcohol brief interventions in antenatal care settings. Alcohol consumption among women is of particular interest due to its connection with alcohol-exposed pregnancies. Alcohol brief interventions have gained much recognition in primary care, yet its effectiveness among antenatal care populations is still evolving. Antenatal populations form a unique group because of the direct involvement of the fetus. In order to ensure that the screening and ABI programme is adequately tailored to pregnant women and that the women are benefitting appropriately from the programme in Scotland, there was the need to understand the factors that could influence the effectiveness of the newly implemented screening and ABI programme and their implications in antenatal care. A methodological approach that delineated context, mechanism and outcome of the intervention was deemed to be appropriately suited for

this research. The refined propositions identified by this study generated greater explanations of the working of the initiative in antenatal care setting and provide transferrable lessons that can be used by others intending to implement similar programmes elsewhere.

This study has shown the important public health role the midwife has in influencing drinking behaviours of pregnant women. The significance of training midwives in the screening and ABI implementation process is very important. Training increased midwives capacity in diverse ways but most importantly, it increased their knowledge base and boosted their confidence. However, because most pregnant women were motivated to reduce their consumption or abstain completely from alcohol, most midwives have rarely had the opportunity to put into practice skills gained from the training. This had negative implications on effective identification of women and delivery of the intervention. In some instances, opportunities to deliver the intervention were missed. In order, to ensure that segments of antenatal populations who require the ABI benefit, refresher courses for midwives may be essential particularly in area of enhancing their motivational interviewing skills.

Many women had already drunk alcohol before their first appointment with the midwife. This may had resulted in midwives feeling that focusing on alcohol issues in subsequent visits may cause anxiety to women and could explain why midwives did not follow-up these women adequately. Lack of adequate time at the booking appointment was found to be a major barrier and had a greater bearing on fidelity and the quality of screening and ABI delivery.

Additionally, because most of the pregnant women were already motivated to reduce their consumption or abstain, it likely that assessment only or a brief advice to such

women caused them to reconsider their drinking habits. Also, because pregnant women valued their unique relationship with their midwives, midwives screening and delivery ABI is likely to elicit positive drinking behaviour change.

Finally, screening of alcohol use in antenatal care settings required that women collaborated with midwives to assess their units of alcohol consumption. The process could be particularly educative because it may increase pregnant women knowledge base and women who decide to still drink in pregnancy can make informed decision by sticking to not more than two units of alcohol per week.

References

ABEL, E.L. and HANNIGAN, J.H., 1996. Risk factor and pathogenesis. In: S. HANS-LUDWIG and S. HANS-CHRISTOPH, eds, *Alcohol, pregnancy and the developing child.* Cambridge: University Press, pp. 63-75.

ABEL, E.L., 1997. Maternal alcohol consumption and spontaneous abortion. *Alcohol and Alcoholism*, **32**(3), pp. 211-219.

ADAMSON, J., BEN-SHLOMO, Y., CHATURVEDI, N., and DONOVAN, J., 2003. Ethnicity, socio-economic position and gender - do they affect reported health-care seeking behaviour? *Social Science and Medicine,* **57**(5), pp. 895-904.

ADJETUNMOBI, O., 2002. *Making sense of critical appraisal.* London: Hodder Arnold.

AJZEN, I., 1988. *Attitudes, personality and behaviour*. Milton-Keynes: Open University Press.

AJZEN, I., 1991. The theory of planned behaviour. *Organizational Behaviour and Human Decision Processes*, **50**, pp. 179-211.

AJZEN, I. and FISHBEIN, M., 1980. *Understanding attitudes and predicting social behaviour.* Englewood Cliffs, NJ: Prentice-Hall.

AKVARDAR, Y. and UCKU, R., 2010. How are alcohol related problems prevented? Brief intervention approach in the treatment of alcohol use disorders. *Anatolian Journal of Psychiatry,* **11**(1), pp. 51-59.

ALATI, R., AL MAMUN, A., WILLIAMS, G.M., O'CALLAGHAN, M., NAJMAN, J.M., and BOR, W., 2006. In utero alcohol exposure and prediction of alcohol disorders in early adulthood: a birth cohort study. *Archives of General Psychiatry,* **63**(9), pp. 1009-1016.

ALATI, R., CLAVARINO, A., NAJMAN, J.M., O'CALLAGHAN, M., BOR, W., MAMUN, A.A., and WILLIAMS, G.M., 2008. The developmental origin of adolescent alcohol use: findings from the Mater University Study of Pregnancy and its outcomes. *Drug & Alcohol Dependence,* **98**(1-2), pp. 136-143.

ALCOHOL FOCUS SCOTLAND, 2005 – last updated, Alcohol and the body: healthy living. Glasgow, Alcohol Focus Scotland, Alcohol Focus Scotland, [Online]. Available: www.alcohol-focus-scotland.org.uk/26-alcohol-and-healthy-living [22/10/2008].

ALIYU, M.H., WILSON, R.E., ZOOROB, R., CHAKRABARTY, S., ALIO, A.P., KIRBY, R.S., and SALIHU, H.M., 2008. Alcohol consumption during pregnancy and the risk of early stillbirth among singletons. *Alcohol,* **42**(5), pp. 369-374.

ALVIK, A., HALDORSEN, T., GROHOLT, B., and LINDERMANN, R., 2006. Alcohol consumption before and during pregnancy comparing concurrent and

retrospective reports. *Alcoholism: Clinical and Experimental Research,* **30**(3), pp. 510-515.

ANDERSON, P., LAURANT, M., KANER, E., WENSING, M., and GROL, R., 2004. Engaging General Practitioners in the Management of Hazardous and Harmful Alcohol Consumption: Results of a Meta-Analysis. *Journal of Studies on Alcohol*, **65**(2), pp. 191-199.

APPLETON, J.V., 2009. Starting a new research project. In: J. NEALE, ed, *Research methods for health and social care*. Basingstoke: Palgrave Macmillan, pp. 16-29.

ARAGON, A.S., CORIALE, G., FIORENTINO, D., KALBERG, W.O., BUCKLEY, D., GOSSAGE, J.P., CECCANTI, M., MITCHELL, E.R., and MAY, P.A., 2008. Neuropsychological characteristics of Italian children with fetal alcohol spectrum disorders. *Alcoholism: Clinical & Experimental Research*, **29**(11), pp. 1909-1919.

ARONSON, J., 2002 – last updated, Alcohol-related birth defects and international adoption, [Online]. Available: http://www.russianadoption.org/fas.htm [11/01/2009].

ARTHUR, S. and NAZROO, J., 2003. Designing fieldwork strategies and materials. In: J. RITCHIE and J. LEWIS, eds, *Qualitative research practice: a guide for social science students and researchers*. London: Sage, pp. 109-137.

ASHENDEN, R., SILAGY, C., and WELLER, D., 1997. A systematic review of the effectiveness of promoting lifestyle change in general practice. *Family Practice*, **14**(2), pp. 160-175.

AVEYARD, H., 2010. *Doing a literature review in health and social care: a literature review - a practical guide.* 2nd edn. Berkshire: Open University Press.

BAKKER, R., PLUIMGRAAFF, L.E., STEEGERS, E.A., RAAT, H., TIEMEIER, H., HOFMAN, A., and JADDOE, V.W., 2010. Associations of light and moderate maternal alcohol consumption with fetal growth characteristics in different periods of pregnancy: the Generation R Study. *International Journal of Epidemiology,* **39**(3), pp. 777-789.

BALLESTEROS, J., ARINO, J., GONZALEZ-PINTO, A., and QUEREJETAD, I., 2003. Effectiveness of medical advice for reducing excessive alcohol consumption. Meta-analysis of Spanish studies in primary care. *Gaceta sanitaria*, **17**(2), pp. 116-122.

BALLESTEROS, J., DUFFY, J.C., QUEREJETA, I., ARINO, J., and GONZALEZ-PINTO, A., 2004a. Efficacy of Brief Interventions for Hazardous Drinkers in Primary Care: Systematic Review and Meta-Analyses. *Alcoholism: Clinical and Experimental Research,* **28**(4), pp. 608-618.

BALLESTEROS, J., GONZALEZ-PINTO, A., QUEREJETA, I., and ARINO, J., 2004b. Brief interventions for hazardous drinkers delivered in primary care are equally effective in men and women. *Addiction*, **99**(1), pp. 103-108.

BARR, H.M., BOOKSTEIN, F.L., O'MALLEY, K.D., CONNOR, P.D., HUGGINS, J.E., and STREISSGUTH, A.P., 2006. Binge drinking during pregnancy as a predictor

of psychiatric disorders on the Structured Clinical Interview for DSM-IV in young adult offspring. *American Journal of Psychiatry,* **163**(6), pp. 1061-1065.

BEICH, A., THORSEN, T., and ROLLNICK, S., 2003. Screening in brief intervention trials targeting excessive drinkers in general practice: Systematic review and meta-analysis. *British Medical Journal*, **327**(7414), pp. 536-540.

BEICH, A., THORSEN, T., ROLLNICK, S., PATTON, R., and RUKSTALIS, M., 2004. Excessive drinkers may benefit from brief interventions, but screening in general practice for case finding is not efficient. *Evidence-Based Healthcare*, **8**(1), pp. 10-11.

BENNETT, T., 1996. What is new in evaluation research? A note on the Pawson and Tilley article. *British Journal of Criminology*, **36**(4), pp. 567-578.

BERTHOLET, N., DAEPPEN, J.-B., WIETLISBACH, V., FLEMING, M., and BURNAND, B., 2005. Reduction of alcohol consumption by brief alcohol intervention in primary care: Systematic review and meta-analysis. *Archives of Internal Medicine*, **165**(9), pp. 986-995.

BHASKAR, R., 1975. *A realistic theory of Science.* Leeds: Leeds Books.

BHOPAL, R., 2002. *Concepts of epidemiology: an integrated introduction to the ideas, theories, principles and methods of epidemiology.* Oxford: Oxford University Press.

BHUVANESWAR, C.G., CHANG, G., EPSTEIN, L.A., and STERN, T.A., 2007. Alcohol use during pregnancy: prevalence and impact. *Primary Care Companion Journal of Clinical Psychiatry,* **9**(6), pp. 455-460.

BMA, 2008 – last updated, Alcohol misuse: tackling the UK epidemic, [Online]. Available: www.bma.org.uk/health_promotion_ethics/alcohol/tacklingalcoholmisuse.jsp [20/04/2010].

BOEKELOO, B.O. and GRIFFIN, M.A., 2007. Review of clinical trials testing the effectiveness of physician approaches to improving alcohol education and counselling in adolescent outpatients. *Current Pediatric Reviews*, **3**(1), pp. 93-101.

BOLLING, K., GRANT, C., HAMLYN, B., and THORNTON, A., 2007. Infant feeding survey: 2005, [Online]. Available: http://www.ic.nhs.uk/webfiles/publications/ifs06/2005%20Infant%20Feeding%20Survey%20%28final%20version%29.pdf [30/01/2011].

BOULTON, M., 2009. Research ethics. In: J. NEALE, ed. *Research methods for health and social care*. Basingstoke: Palgrave Macmillan, pp. 31-45.

BOWIE, J.V., ENSMINGER, M.E., and ROBERTSON, J.A., 2006. Alcohol-use problems in young black adults: Effects of religiosity, social resources, and mental health. *Journal of Studies on Alcohol*, **67**(1), pp. 44-53.

BOWLING, A., 2009. *Research methods in health: investigating health and health services.* 3rd edn. Berkshire: Open University Press.

BOYATIZ, R., 1998. *Transforming qualitative information: thematic analysis and code development.* Thousand Oaks, CA: Sage.

BRAUN, V. and CLARKE, V., 2006. Using thematic analysis in psychology. *Qualitative Research in Psychology*, **3**(2), pp. 77-101.

BRITTON, A. and MCKEE, M., 2000. The relationship between alcohol and cardiovascular disease in Eastern Europe: explaining the paradox. *Journal of Epidemiology and Community Health,* **54,** pp. 328-332.

BROOKS, O., 2009. *Negotiating power, resistance and control: Young women safety in bars, pubs and clubs.* Stirling: University of Stirling.

BURKE, B. A. 2004. *Motivational interviewing: A meta-analysis of controlled clinical trials*. The Science and Engineering: Dissertation Abstract International.

BURKE, B.L., ARKOWITZ, H., and MENCHOLA, M., 2003. The efficacy of motivational interviewing: A meta-analysis of controlled clinical trials. *Journal of Consulting and Clinical Psychology*, **71**(5), pp. 843-861.

BYNG, R., NORMAN, I., and REDFERN, S., 2005. Using realistic evaluation to evaluate a practice-level intervention to Improve primary healthcare for patients with long-term mental illness. *Evaluation,* **11**(1), pp. 69-93.

CALHOUN, F. and WARREN, K., 2007. Fetal alcohol syndrome: historical perspective. *Neuroscience and Biobehavioral Reviews*, **31**(2), pp. 168-172.

CAMPBELL, M.K., ELBOURNE, D.R., and ALTMAN, D.G., 2004. CONSORT statement: extension to cluster randomised trials. *British Medical Journal,* **328,** pp. 702-708.

CASP, 2004 - last updated, Making sense of evidence [Online]. Available: http://www.sph.nhs.uk/sph-files/casp-appraisal-tools/cohort%2012%20questions.pdf/view [10/08/2011].

CAYLEY, J., 2009. Effectiveness of brief alcohol interventions in primary care. *American Family Physician*, **79**(5), pp. 370-373.

CDC, 2002. Defining the national agenda for Fetal Alcohol Syndrome. *Morbidity and Mortality Weekly Report,* **51**(14), pp. 9-12.

CDC, 2005 – last updated, Fetal Alcohol Spectrum Disorders. [Online] Available: http://www.cdc.gov/ncbddd/factsheets/FAS.pdf [30/10/2008].

CDC, 2009. Alcohol use among pregnant women and non pregnant women of child bearing age - United States, 1991 - 2005. *Morbidity and Mortality Weekly Report,* **58**(19), pp. 529-532.

CHANG, G., 2001. Alcohol-screening instruments for pregnant women. *Alcohol Research and Health,* **25**(3), pp. 204-209.

CHANG, G., MCNAMARA, T.K., ORAV, J.E., and WILKINS-HAUG, L., 2006. Alcohol use by pregnant women: partners, knowledge, and other predictors. *Journal of Studies on Alcohol,* **67**, pp. 245-251.

CHANG, G., GOETZ, M.A., WILKINS-HAUG, L., and BERMAN, S., 2000. A brief intervention for prenatal alcohol use: An in-depth look. *Journal of Substance Abuse Treatment,* **18**(4), pp. 364-369.

CHANG, G., MCNMARA, T.K., ORAV, J.E., KOBY, D., LAVINGE, A., LUDMAN, B., VINCINTORIO, N.A., and WILKINS-HAUG, L., 2005. Brief intervention for prenatal alcohol use: A randomised trial. *Obstetrics & Gynecology,* **105**(5 Pt 1), pp. 991-998.

CHANG, G., WILKINS-HAUG, L., BERMAN, S., and GOETZ, M.A., 1999. Brief intervention for alcohol use in pregnancy: a randomized trial. *Addiction,* **94**(10), pp. 1499-1508.

CHANG, G., WILKINS-HAUG, L., BERMAN, S., GOETZ, M.A., BEHR, H., and HILEY, A., 1998. Alcohol use and pregnancy: improving identification. *Obstetrics & Gynecology,* **91**(6), pp. 892-898.

CHANG, J.C., DADO, D., FRANKEL, R.M., RODRIGUEZ, K.L., ZICKMUND, S., LING, B.S., and ARNOLD, R.M., 2008. When pregnant patients disclose substance use: missed opportunities for behavioural change counselling. *Patient Education and Counseling,* **72**(2008), pp. 394-401.

CHIAFFARINO, F., PARAZZINI, F., CHATENOUD, L., RICCI, E., SANDRETTI, F., CIPRIANI, S., CASERTA, D., and FEDELE, L., 2006. Alcohol drinking and risk of small for gestational age birth. *European Journal of Clinical Nutrition,* **60**(9), pp. 1062-1066.

CHIODO, L.M., DA COSTA, D.E., HANNIGAN, J.H., COVINGTON, C.Y., SOKOL, R.J., JANISSE, J., GREENWALD, M., AGER, J., and DELANEY-BLACK, V., 2010. The impact of maternal age on the effects of prenatal alcohol exposure on attention. *Alcoholism: Clinical & Experimental Research,* **34**(10), pp. 1813-1821.

COBAIN, K., OWENS, L., KOLAMUNNAGE-DONA, R., FITZGERALD, R., GILMORE, I., and PIRMOHAMEND, M., 2011. Brief intervention in dependent drinkers: a comparative prospective analysis in two hospitals. *Alcohol and Alcoholism,* **46**(4), pp. 434-440.

COLETTA, J.M., BELL, S.J., and ROMAN, A.S., 2010. Omega-3 fatty acids and pregnancy. *Review in Obstetrics and Gynecology*, **3**(4), pp. 163-171.

CONNER, M. and NORMAN, P., 1995. The role of social cognition in Health behaviours. In: M. CONNER and P. NORMAN, eds. *Predicting health behaviour*. Buckingham: The Open University Press.

CONNOR, M. and SPARKS, P., 1995. The theory of planned behaviour and health behaviours. In: M. CONNER and P. NORMAN, eds. *Predicting health behaviour*. Buckingham: The Open University Press.

COOMBES, L., ALLEN, D., HUMPHREY, D., and NEALE, J., 2009. In-depth interviews. In: J. NEALE, ed. *Research methods for health and social care*. Basingstoke: Palgrave Macmillan, pp. 197-210.

CORBIN, J. and STRAUSS, A., 2008. *Basics of qualitative research.* 3rd edn. California: Sage.

COYNE, K.L., DE COSTA, C.M., HEAZLEWOOD, R.J., and NEWMAN, H.C., 2008. Pregnancy characteristics of women giving birth to children with fetal alcohol syndrome in Far North Queensland. *Australian & New Zealand Journal of Obstetrics & Gynaecology.*, **48**(3), pp. 240-247.

CRABTREE, B. and MILLER, W., 1999. A template approach to text analysis: developing and using codebooks. In: B. CRABTREE and W. MILLER, eds, *Doing qualitative research*. Newbury Park, CA: Sage, pp. 163-177.

CRD, 2009 – last updated, Systematic Reviews: CRD's guidelines for undertaking systematic review in health care [Online]. Available: http://www.york.ac.uk/inst/crd/SysRev/!SSL!/WebHelp/SysRev3.htm [1/12/2010].

CROZIER, S.R., ROBINSON, S.M., BORLAND, S.E., GODFREY, K.M., COOPER, C., INSKIP, H.M., and SWS STUDY GROUP, 2009. Do women change their health behaviours in pregnancy? Findings from the Southampton Women's Survey. *Paediatric and Perinatal Epidemiology*, **23**(5), pp. 446-453.

CRUICKSHANK, J., 2003. Introduction. In: J. CRUICKSHANK, ed. *Critical realism: the difference it makes*. New York: Routledge, pp. 1-14.

CUIJPERS, P., RIPER, H., and LEMMERS, L., 2004. The effects on mortality of brief interventions for problem drinking: A meta-analysis. *Addiction*, **99**(7), pp. 839-845.

D'ONOFRIO, G. and DEGUTIS, L.C., 2002. Preventive care in the emergency department: Screening and brief intervention for alcohol problems in the emergency department: A systematic review. *Academic Emergency Medicine*, **9**(6), pp. 627-638.

DAKE, F.J., 2001. Judges. In: Anon. *Dakes annotated reference Bible*. Georgia: Dake Publishing, pp. 449-492.

DAMGAARD, I.N., JENSEN, T.K., PETERSEN, J.H., SKAKKEBAEK, N.E., TOPPARI, J., and MAIN, K.M., 2007. Cryptorchidism and maternal alcohol consumption during pregnancy. *Environmental Health Perspectives*, **115**(2), pp. 272-277.

DAY, N.L., COTTREAU, C.M., and RICHARDSON, G.A., 1993. The epidemiology of alcohol, marijuana, and cocaine use among women of childbearing age and pregnant women. *Clinical obstetrics and gynecology*, **36**(2), pp. 232-245.

DEERY, R., 2005. An action-research study exploring midwives' support needs and the effects of group clinical supervision. *Midwifery*, **21**(2), pp. 161-176.

DELEON, P., and DELEON, L., 2002.What ever happened to policy implementation? An alternative approach. *Journal of Public Administration Research and Theory: J-PART*, **12**(4), pp. 467–492.

DENZIN, N.K. and LINCOLN, Y., 2005. Introduction: the discipline and practice of qualitative research. In: N. K. DENZIN and Y. LINCOLN, eds. *The sage handbook of qualitative research*. 3rd edn. California: Sage.

DEPARTMENT OF HEALTH, 2007, *The pregnancy handbook.* London: Department of Health.

DEPARTMENT OF HEALTH AND AGEING, 2009 – last updated, If you are pregnant...the safest option is not to drink alcohol, [Online] Available: http://www.health.gov.au/internet/alcohol/publishing.nsf/Content/83B8C7EC9E890F23CA25767300752E39/$File/pregnant.pdf [27/08/2011].

DEW, P.C., GUILLORY, V.J., OKAH, F.A., CAI, J., and HOFF, G.L., 2007. The effect of health compromising behaviors on preterm births. *Maternal & Child Health Journal,* **11**(3), pp. 227-233.

DIEKMAN, S.T., FLOYD, R.L., DECOUFLE, P., SCHULKIN, J., EBRAHIM, S.H., and SOKOL, R.J., 2000. A survey of obstetrician-gynecologists on their patients' alcohol use during pregnancy. *Obstetrics & Gynecology,* **95**(5 pt 1), pp. 756-763.

DODGE, N.C., JACOBSON, J.L., MOLTENO, C.D., MEINTJES, E.M., BANGALORE, S., DIWADKAR, V., HOYME, E.H., ROBINSON, L.K., KHAOLE, N., AVISON, M.J., and JACOBSON, S.W., 2009. Prenatal alcohol exposure and interhemispheric transfer of tactile information: Detroit and Cape Town findings. *Alcoholism: Clinical & Experimental Research,* **33**(9), pp. 1628-37.

DOI, L., 2006. *Descriptive study of patterns of deliberate self-harm in Lothian, Scotland*. Edinburgh: University of Edinburgh.

DUFFOUR, M.C., 1999. What is moderate drinking: defining 'drinks' and drinking levels. *Alcohol Research and Health,* **23**(1), pp. 1-14.

DUNN, C., DEROO, L., and RIVARA, F.P., 2001. The use of brief interventions adapted from motivational interviewing across behavioral domains: A systematic review. *Addiction*, **96**(12), pp. 1725-1742.

EDWARDS, A.G. and ROLLNICK, S., 1997. Outcome studies of brief alcohol intervention in general practice: the problem of lost subjects. *Addiction*, **92**(12), pp. 1699-1704.

ELLIOT, A.J. and DEVINE, P.G., 1994. On the motivational nature of cognitive dissonance: dissonance as a psychological discomfort. *Journal of Personality and Social Psychology,* **67**(3), pp. 382-394.

EMMEN, M.J., SCHIPPERS, G.M., BLEIJENBERG, G., and WOLLERSHEIM, H., 2004. Effectiveness of opportunistic brief interventions for problem drinking in a general hospital setting: Systematic review. *British Medical Journal*, **328**(7435), pp. 318-320.

ERNHART, C.B., MORROW-TLUCAK, M., SOKOL, R.J., and MARTIER, S., 1988. Underreporting of Alcohol Use in Pregnancy. *Alcoholism: Clinical and Experimental Research,* **12**(4), pp. 506-511.

FEREDAY, J. and MUIR-COCHRANE, E., 2006. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. *International Journal of Qualitative Methods,* **5**(1), pp. 1-11.

FEUNEKES, G.I.J., VAN'T VEER, P., VAN STAVAREN, W.A., and KOK, F.J., 1999. Alcohol intake assessment: the sober fact. *American Journal of Epidemiology,* **150**(1), pp. 105-112.

FINCH, H. and LEWIS, J., 2003. Focus groups. In: J. RITCHIE and J. LEWIS, eds. *Qualitative research Practice: a guide for social science students and researchers*. London: Sage, pp. 170-198.

FISHBEIN, M. and AJZEN, I. 1975. *Belief, attitude, intention and behaviour: an introduction to theory and research*. MA: Addison-Wesley.

FLANIGAN, E.Y., AROS, S., BUENO, M.F., CONLEY, M., TROENDLE, J.F., CASSORLA, F., and MILLS, J.L., 2008. Eye malformations in children with heavy alcohol exposure in utero. *Journal of Pediatrics,* **153**(3), pp. 391-5.

FLYNN, H.A., MARCUS, S.M., BARRY, K.L., and BLOW, F.C., 2003. Rates and correlates of alcohol use among pregnant women in obstetrics clinics. *Alcoholism: Clinical and Experimental Research,* **27**(1), pp. 81-87.

FORD, C., 2008. *Understanding of the use of alcohol in pregnancy amongst women in Scotland: first year update.* Edinburgh: Scottish Government.

FORSBERG, L., BERMAN, A.H., KALLMEN, H., HERMANSSON, U., and HELGASON, A.R. (2008) A test of the validity of the motivational interviewing treatment integrity code. *Cognitive Behaviour Therapy*, **37** (3), pp. 183-191.

FOSTER-TURNER, J., 2009. Focus groups. In: J. NEALE, ed. *Research methods for health and social care*. Basingstoke: Palgrave Macmillan, pp. 211-224.

FRYER, S.L., MCGEE, C.L., MATT, G.E., RILEY, E.P., and MATTSON, S.N., 2007. Evaluation of psycopathological conditions in children with heavy prenatal alcohol exposure. *Pediatrics,* **119** (3), pp. 733-741.

GEMMA, S., VICHI, S., and TESTA, I.E., 2007. Metabolic and genetic factors contributing to alcohol induced effects and fetal alcohol syndrome. *Neuroscience and Biobehavioral Reviews,* **31,** pp. 221-229.

GENERAL REGISTER OFFICE FOR SCOTLAND, 2012a – Last updated, Mid-year population estimates, [Online]. Available: http://www.gro-scotland.gov.uk/statistics/theme/population/estimates/mid-year/index.html [21/08/2012].

GENERAL REGISTER OFFICE FOR SCOTLAND, 2012b – Last updated, Births: variation within Scotland, [Online]. Available: http://www.gro-scotland.gov.uk/files2/stats/high-level-summary/j11198/j1119812.htm [21/08/2012].

GILCHRIST, V.J. and WILLIAMS, R.L., 1999. Key informant interviews. In: B. F. CRABTREE and W. L. MILLER, eds. *Doing qualitative research*. 2nd edn. Thousand Oaks, CA: Sage, pp. 71-88.

GILINSKY, A., SWANSON, V., and POWER, K., 2010. Interventions delivered during antenatal care to reduce alcohol consumption during pregnancy: A systematic review. *Addiction Research and Theory* [Online]. pp. 1-16.

GILL, J., 2000. The effects of moderate alcohol consumption on female hormone levels and reproductive function. *Alcohol and Alcoholism*, **35**(5), pp. 417-432.

GILL, M. and TURBIN, V., 1999. Evaluating "realistic evaluation": evidence from a study of CCTV. *Crime Prevention Studies,* **10,** pp. 179-199.

GOODMAN, R., FORD, T., SIMMONS, H., GATWARD, R., and MELTZER, H., 2003. Using the strength and difficult questionnaire (SDQ) to screen for child psychiatric disorders in a community sample. *International Review of Psychiatry,* **15**(1-2), pp. 166-172.

GRAY, R., and HENDERSON, J., 2006. *Review of the fetal effects of prenatal alcohol exposure*. London: Department of Health.

GREEN, J., and THOROGOOD, N., 2009. *Qualitative methods for health research.* 2nd edn. London: Sage.

GREWAL, J., CARMICHAEL, S.L., MA, C., LAMMER, E.J., and SHAW, G.M., 2008. Maternal periconceptional smoking and alcohol consumption and risk for select congenital anomalies. *Birth Defects Research,* **82**(7), pp. 519-26.

GROENEWALD, T., 2004. A phenomenological research design illustrated. *International Journal for qualitative methodology*, **3**(1), pp. 43-55.

HAGGARTY, P., ABROMOVICH, DR., and PAGE, K., 2008. The effects of maternal smoking and ethanol on fatty acid transport by the human placenta. *British Journal of Nutrition,* **87,** pp. 247-252.

HAMLYN, B., BROOKER, S., OLEINKOVA, K., and WAND, S., 2002. *Infant feeding survey: 2000.* London: Department of Health.

HARRIS, K.R. and BUCENS, I.K., 2004. Prevalence of fetal alcohol syndrome in the top end of the Northern Territory. *Journal of Padiatrics and Child Health,* **39**(7), pp. 528-533.

HAVARD, A., SHAKESHAFT, A., and SANSON-FISHER, R., 2008. Systematic review and meta-analyses of strategies targeting alcohol problems in emergency departments: Interventions reduce alcohol-related injuries. *Addiction*, **103**(3), pp. 368-376.

HEATHER, N., 1995. Interpreting the evidence on brief intervention for excessive drinkers: the need for caution. *Alcohol and Alcoholism,* **30,** pp. 287-296.

HEATHER, N., 2004. Brief interventions. In: N. HEATHER and T. STOCKWELL, eds. *The essential handbook for treatment and prevention of alcohol problems*. Chichester: John Wiley & Sons, pp. 117-138.

HEIKKINEN, H., PATJA, K., and JALLINOJA, P., 2010. Smokers' accounts on the health risks of smoking: Why is smoking not dangerous for me? *Social Science and Medicine,* **71**(2010), pp. 877-883.

HENDERSON, J., KESMODEL, U., and GRAY, R., 2007a. Systematic review of the effects of prenatal binge-drinking. *Journal of Epidemiology & Community Health,* **61,** pp. 1069-1073.

HENDERSON, J., GRAY, R., and BROCKLEHURST, P., 2007b. Systematic review of the effect of low-moderate prenatal alcohol exposure on pregnancy outcome. *BJOG: An International Journal of Obstetrics & Gynaecology,* **114,** pp. 243-252.

HIGGINS, J.P.T. and GREEN, S., 2009. Cochrane handbook for systematic reviews of interventions, [Online]. Available: http://www.cochrane-handbook.org/ [30/01/2011].

HM GOVERNMENT, 2007. *Safe. Sensible. Social. The next steps in national alcohol strategy.* London: Department of Health.

HOWELL, K.K., LYNCH, M.E., PLATZMAN, K.A., SMITH, G.H., and COLES, C.D., 2006. Prenatal alcohol exposure and ability, academic achievement, and school functioning in adolescence: a longitudinal follow-up. *Journal of Pediatric Psychology,* **31**(1), pp. 116-26.

HYMAN, Z., 2006. Brief interventions for high-risk drinkers. *Journal of Clinical Nursing*, **15**(11), pp. 1383-1396.

INTERNATIONAL CENTRE FOR ALCOHOL POLICIES, 2007 – last updated, Standard alcohol units worldwide, [Online]. Available: http://www.icap.org/PolicyIssues/DrinkingGuidelines/StandardUnitsTable/tabid/253/Default.aspx [31/11/2008].

ISAAC, C., 1990. Realism and reality: some realistic reconsiderations. *Theory of Social Behaviour,* **20,** pp. 1-31.

ISD, 2009 – last updated, Alcohol statistics: Scotland, [Online]. Available: http://www.alcoholinformation.isdscotland.org/alcohol_misuse/files/alcohol_stats_bul_09.pdf [8/08/2009].

JACKSON, D.J., BATISTE, E., and RENDALL-MKOSI, K., 2007. Effect of smoking and alcohol use during pregnancy on the occurrence of low birthweight in a farming region in South Africa. *Paediatric and Perinatal Epidemiology,* **21**(5), 432-440.

JACKSON, P., 2006. The transtheoretical model. In: C. FELTHAM and I. HORTON, eds, *The SAGE handbook of counselling and psychotherapy*. 2nd edn. London: Sage, pp. 342-346.

JACOBSON, J.L., DODGE, N.C., BURDEN, M.J., KLORMAN, R., and JACOBSON, S.W., 2011. Number Processing in Adolescents With Prenatal Alcohol Exposure and ADHD: Differences in the Neurobehavioral Phenotype. *Alcoholism: Clinical and Experimental Research*, **35** (3), pp. 431-442.

JADDOE, V.W., BAKKER, R., HOFMAN, A., MACKENBACH, J.P., MOLL, H.A., STEEGERS, E.A., and WITTEMAN, J.C., 2007. Moderate alcohol consumption during pregnancy and the risk of low birth weight and preterm birth. The generation R study. *Annals of Epidemiology,* **17**(10), pp. 834-840.

JENKINS, R.J., MCALANEY, J., and MCCAMBRIDGE, J., 2009. Change over time in alcohol consumption in control groups in brief intervention studies: systematic review and meta-regression study. *Drug and Alcohol Dependence*, **100**(1-2), pp. 107-114.

JENSEN, M.S., BONDE, J.P., and OLSEN, J., 2007. Prenatal alcohol exposure and cryptorchidism. *International Journal of Paediatrics*, **96**(11), pp. 1681-1685.

JEPSON, R.G., HARRIS, F.M., PLATT, S., and TANNAHILL, C., 2010. The effectiveness of interventions to change six health behaviours: a review of reviews. *BMC Public Health*, **10**(538), pp. 1-16.

JOHNSON, M., JACKSON, R., GUILLAUME, P., MEIER, P., and GOYDER, E., 2010. Barries and facilitators to implementing screening and brief intervention for alcohol misuse: a systematic review of qualitative evidence. *Journal of Public Health,* **33**(3) pp. 412-421.

JONES, K., CHAMBERS, C., HILL, L., HULL, A., and RILEY, E., 2006. Alcohol use in pregnancy: inadequate recommendation for an increasing problem. *British Journal of Obstetrics and Gynaecology,* **113,** pp. 967-968.

JONES, K.L., SMITH, D.W., ULLELAND, C.N., and STREISSGUTH, A.P., 1973. Patterns of malformation in offspring of chronic alcoholic mothers. *The Lancet*, **301** (7815), pp. 1267-1271.

JUNG, J., 2010. *Alcohol, other drugs and behaviour.* 2nd edn. Thousand Oaks, California: Sage.

KANER, E.F.S., BEYER, F., DICKINSON, H.O., PIENAAR, E., CAMPBELL, F., SCHLESINGER, C., HEATHER, N., SAUNDERS, J., and BURNAND, B., 2007. Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database of Systematic Reviews,* **2**, Article no.: CD004148, pp. 1-90.

KANER, E.F.S., DICKINSON, H.O., BEYER, F.R., CAMPBELL, F., SCHLESINGER, C., HEATHER, N., SAUNDERS, J.B., BURNAND, B., and PIENAAR, E.D., 2009. Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database of Systematic Reviews,* **4**, Article no.: CD004148, pp. 1-90.

KANER, E.F.S., LOCK, C.A., MCAVOY, B.R., HEATHER, N., and GILVARRY, E., 1999. A RCT of three training and support strategies to encourage implementation of screening and brief alcohol intervention by general practitioners. *British Journal of General Practice,* **49**(446), pp. 699-703.

KELLY, Y., SACKER, A., GRAY, R., KELLY, J., WOLKE, D., and QUIGLEY, M.A., 2009. Light drinking in pregnancy, a risk for behavioural problems and cognitive deficits at 3 years of age? *International Journal of Epidemiology,* **38**(1), pp. 129-40.

KELLY, Y.J., SACKER, A., GRAY, R., KELLY, J., WOLKE, D., HEAD, J., and QUIGLEY, M.A., 2010. Light drinking during pregnancy: still no increased risk for socioemotional difficulties or cogntive deficits at 5 years of age? *Journal of Epidemiology & Community Health,* [Online]. Article no:.10.1136/jech.2009.103002 pp. 1-8.

KESMODEL, U.S. and KESMODEL, P.S., 2011. Alcohol in pregnancy: attitudes, knowledge and information practice among midwives in Denmark 200 to 2009. *Alcoholism: Clinical and Experimental Research,* **35**(12), pp. 1-5.

KESMODEL, U.S., UNDERBJERG, M., KILBURN, T.R., BAKKETEIG, L., MORTENSEN, E.L., LANDRO, N.I., SCHENDEL, D., BERTRAND, J., GROVE, J., EBRAHIM, S., and THORSEN, P., 2010. Lifestyle during pregnancy: neurodevelopmental effects at 5 years of age. The design and implementation of a prospective follow-up study. *Scandinavian Journal of Public Health,* **38**(2), pp. 208-219.

KIRKHAM, M., and STAPLETON, H. 2000. Midwives' support needs as childbirth changes. *Journal of Advanced Nursing,* **32**(2), pp. 465-472.

KODITUWAKKU, P., CORIALE, G., FIORENTINO, D., ARAGÓN, A.S., KALBERG, W.O., BUCKLEY, D., GOSSAGE, J.P., CECCANTI, M., and MAY, P.A., 2006. Neurobehavioral Characteristics of Children with Fetal Alcohol Spectrum Disorders in Communities from Italy: Preliminary Results. *Alcoholism: Clinical & Experimental Research,* **30**(9), pp. 1551-1561.

KRUEGER, R.A., 1994. *Focus groups: a practical guide for applied research.* 2nd edn. London: Sage.

LANDGREN, M., SVENSSON, L., STROMLAND, K., and ANDERSSON, G.M., 2010. Prenatal alcohol exposure and neurodevelopmental disorders in children adopted from eastern Europe. *Pediatrics,* **125**(5), pp. e1178-1185.

LARKBY, C.A., GOLDSCHMIDT, L., HANUSA, B.H., and DAY, N.L., 2011. Prenatal alcohol exposure is associated with conduct disorder in adolescence: findings from a birth cohort. *Journal of the American Academy of Child & Adolescent Psychiatry*, **50**(3), pp. 262-271.

LEGARD, R., KEEGAN, J., and WARD, K., 2003. In-depth interviews. In: J. RITCHIE and J. LEWIS, eds. *Qualitative research practice: a guide for social science students and researchers*. London: Sage, pp. 138-169.

LEON, D.A. and MCCAMBRIDGE, J., 2006. Liver cirrhosis mortality rates in Britain from 1950 to 2002: an analysis of routine data. *The Lancet,* **367**(9504), pp. 52-56.

LEONARDSON, G.R., LOUDENBURG, R., and STUCK, J., 2007. Factors predictive of alcohol use during pregnancy in three rural states. *Behavioral and Brain Functions,* **3**(8), pp. 1-6.

LITTLE, B.B., SNELL, L.M., ROSENFELD, C.L., GILSTRAP, L.C., and GANT, N.F., 1990. Failure to recognise fetal alcohol syndrome in newborn infants. *American Journal of Diseases of Children,* **144**(10), pp. 1142-1146.

LITTNER, Y. and BEARER, C.F., 2007. Detection of alcohol consumption during pregnancy-Current and future biomarkers. *Neuroscience and Biobehavioral Reviews*, **31**(2), pp. 261-269.

LOCK, C.A., 2004. Screening and brief alcohol interventions: What, why, who, where and when? A review of the literature. *Journal of Substance Use*, **9**(2), pp. 91-101.

LOCK, C.A., KANER, E., LAMONT, S., and BOND, S., 2002. A qualitative study of nurses' attitudes and practices regarding brief alcohol intervention in primary health care. *Journal of Advanced Nursing*, **39**(4), pp. 333-342.

LUI, S., TERPLAN, M., and SMITH, E.J., 2008. Psychosocial interventions for women enrolled in alcohol treatment during pregnancy. *Cochrane Database of Systematic Reviews*, **3**, Article No. CD006753, pp. 1-16.

LUMLEY, J., OLIVER, S.S., CHAMBERLAIN, C., and OAKLEY, L., 2004. Interventions for promoting smoking cessation during pregnancy. *Cochrane Database of Systematic Reviews,* **4,** Article no. CD001055, pp. 1-164.

MACASKILL, S., EADIE, D., GORDON, R., and HEIM, D., 2008. *Drinking in Scotland: qualitative insights into influences, attitudes and behaviours*. Edinburgh: NHS Health Scotland.

MALLEN, C., PEAT, J., and CROFT, P., 2006. Quality assessment of observational studies is not common place in systematic reviews. *Journal of clinical Epidemiology,* **59**(8), pp. 765-769.

MALUKA, S., KAMUZORA, P., SANSEBASTIAN, M., BYSKOV, J., NDAWI, B., OLSEN, O.E., and HURTIG, A., 2011. Implementing accountability for reasonableness framework at district level in Tanzania: a realistic evaluation. *Implementation science,* **6**(11), pp. 1-15.

MARCHAL, B., VAN BELL, S., KEGELS, G., HOEREE, T., VAN OLMEN, J., DIELEMAN, M., GERRETSEN, B., KANE, S., and ZWANIKKEN, P., 2010 – last updated, Theory driven inquiry for health systems research [Online]. Available: http://www.itg.be/internet/ds/tde/doc/TD%20inquiry%20Web%20text%20Download%20110214.pdf [10/10/2011].

MARISCAL, M., PALMA, S., LLORCA, J., PEREZ-IGLESIAS, R., PARDO-CRESPO, R., and DELGADO-RODRIGUEZ, M., 2006. Pattern of alcohol consumption during pregnancy and risk for low birth weight. *Annals of Epidemiology,* **16**(6), pp. 432-438.

MARLATT, G.A. and WITKIEWITZ, K., 2002. Harm reduction approach to alcohol use: health promotion, prevention and treatment. *Addictive Behaviour,* **27**, pp. 867-886.

MARSHALL, C. and ROSSMAN, G.B., 2011. *Designing qualitative research.* 4th edn. London: Sage.

MASON, J., 2002. *Qualitative researching.* 2nd edn. London: Sage.

MATLAND, R.E., 1995. Synthesizing the Implementation Literature: The Ambiguity-Conflict Model of Policy Implementation. *Journal of Public Administration Research and Theory: J-PART*, **5**(2), pp. 145-174.

MAY, P.A., BROOKE, L., GOSSAGE, J.P., CROXFORD, J., ADNAMS, C., KENNETH, J.L., ROBINSON, L., and VILJEON, D., 2000. Epidemiology of fetal alcohol syndrome in a South Africa Community in the Western Cape Province. *American Journal of Public Health,* **90**(12), pp. 1905-1912.

MAY, P.A., GOSSAGE, J.P., MARAIS, A.S., HENDRICKS, L.S., SNELL, C.L., TABACHNICK, B.G., STELLAVATO, C., BUCKLEY, D.G., BROOKE, L.E., and VILJOEN, D.L., 2008. Maternal risk factors for fetal alcohol syndrome and partial fetal alcohol syndrome in South Africa: a third study. *Alcoholism: Clinical & Experimental Research*, **32**(5), pp. 738-753.

McAULEY, A., 2009. *Alcohol consumption among pregnant women and brief interventions in the antenatal setting*. Edinburgh: Scottish Government.

McCAMBRIDGE, J. and JENKINS, R.J., 2008. Do brief interventions which target alcohol consumption also reduce cigarette smoking?. Systematic review and meta-analysis. *Drug and Alcohol Dependence*, **96**(3), pp. 263-270.

McEVOY, P. and RICHARDS, D., 2003. Critical realism: a way forward for evaluation research in nursing? *Journal of Advance Nursing,* **43**(4), pp. 411-420.

McGEE, C.L., BJORKQUIST, O.A., RILEY, E.P., and MATTSON, S.N., 2009. Impaired language performance in young children with heavy prenatal alcohol exposure. *Neurotoxicology & Teratology,* **31**(2), pp. 71-75.

McGEE, C.L., SCHONFELD, A.M., ROEBUCK-SPENCER, T.M., RILEY, E.P., and MATTSON, S.N., 2008. Children with heavy prenatal alcohol exposure demonstrate deficits on multiple measures of concept formation. *Alcoholism: Clinical & Experimental Research,* **32**(8), pp. 1388-1397.

McQUEEN, J., HOWE, T.E., ALLAN, L., and MAINS, D., 2009. Brief interventions for heavy alcohol users admitted to general hospital wards. *Cochrane Database of Systematic Reviews*, **3**. Article no. CD005191, pp.1- 47.

MENEGAUX, F., RIPERT, M., HEMON, D., and CLAVEL, J., 2007. Maternal alcohol and coffee drinking, parental smoking and childhood leukaemia: A French population-based case-control study. *Paediatric and Perinatal Epidemiology,* **21**(4), pp. 293-299.

MENGEL, M.B., SEARIGHT, R., and COOK, K., 2006. Preventing alcohol-exposed pregnancies. *Journal of the American Board of Family Medicine,* **19,** pp. 494-505.

MENNELLA, J., 2001. Alcohol's effects on lactation. *Alcohol Research and Health,* **25**(3), pp. 230-234.

MENTAL HEALTH FOUNDATION, 2009 – last updated, Fetal alcohol spectrum disorder [Online]. Available: http://www.learningdisabilities.org.uk/information/syndromes-and-conditions/fetal-alcohol-spectrum-disorder/ [6/09/2009].

METRO, 30 October 2008. *A tipple in pregnancy can help child later.* [Newspaper].

MIDWIFERY 2020 PROGRAMME, 2010a, - last updated, Midwifery 2020: delivery expectation, [Online]. Available: http://midwifery2020.org.uk/documents/M2020Deliveringexpectations-FullReport2.pdf [20/08/2012].

MIDWIFERY 2020 PROGRAMME, 2010b – last updated, Workforce and workload work stream, [Online]. Available: http://www.midwifery2020.org/documents/2020/Workforce_Workload.pdf [20/08/2012].

MILLER, W.L. and CRABTREE, B.F., 1999. Depth interviewing. In: B. F. CRABTREE and W. L. MILLER, eds. *Doing qualitative research*. 2nd edn. Thousand Oaks, CA: Sage, pp. 89-108.

MILLER, W.R. and ROLLNICK, S., 2002. *Motivational interviewing: preparing people for change.* New York: Guilford Press.

MODESTO-LOWE, V. and BOORNAZIAN, A., 2000. Screening and brief intervention in the management of early problem drinkers: Integration into healthcare settings. *Disease Management and Health Outcomes*, **8**(3), pp. 129-137.

MONGRAW-CHAFFIN, M.L., COHN, B.A., COHEN, R.D., and CHRISTIANSON, R.E., 2008. Maternal smoking, alcohol consumption and caffeine consumption during pregnancy in relation to a son's risk of persistent cryptorchidism: a prospective study in the child health and development studies cohort, 1957-1967. *American Journal of Epidemiology,* **167**(3), pp. 257-261.

MORTENSEN, T.L. and TONNESEN, H., 2004. Systematic alcohol intervention in hospital. *Ugeskrift for Laeger*, **166**(38), pp. 3284-3289.

MOYER, A. and FINNEY, J.W., 2005. Brief interventions for alcohol problems: factors that facilitate implementation. *Alcohol Research and Health,* **28**(1), pp. 44-50.

MOYER, A., FINNEY, J.W., SWEARINGEN, C.E., and VERGUN, P., 2002. Brief interventions for alcohol problems: A meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. *Addiction*, **97**(3), pp. 279-292.

MRC, 2006. *Developing and evaluating complex interventions: new guidance*. London: Medical Research Council.

MUKHERJEE, R.A.S., HOLLINS, S., and TURK, J., 2006. Fetal alcohol spectrum disorder: an overview. *Journal of the Royal Society of Medicine*, **99**(6), pp. 298-302.

NH-ZARR, T.B., GOSS, C.W., HEITMAN, E., ROBERTS, I.G., and DIGUISEPPI, C., 2009. Interventions for preventing injuries in problem drinkers. *Cochrane Database of Systematic Reviews*, **3**, Article no. CD001857, pp. 1-33.

NHS HEALTH SCOTLAND., 2010a. *Ready Steady Baby! your complete guide to pregnancy, birth and parenthood.* Edinburgh: NHS Health Scotland.

NHS HEALTH SCOTLAND, 2010b. *The Keeping Childbirth Natural and Dynamic (KCND) programme,* [Online]. Available: http://www.maternal-and-early-years.org.uk/the-keeping-childbirth-natural-and-dynamic-kcnd-programme [22/11/2011].

NHS LOTHIAN, 2011 – last updated, Maternity services, [Online]. Available: http://www.nhslothian.scot.nhs.uk/Community/MidlothianCHP/Services/Pages/MaternityServices.aspx [20/08/2012].

NICE., 2006. *Methods for the development of NICE public health guidance*. London: National Institute of Health and Clinical Excellence.

NICE, 2008 last updated, Antenatal care: NICE guideline, [Online]. Available: http://www.nice.org.uk/nicemedia/pdf/CG062NICEguideline.pdf [10/04/2009].

NIIMI, Y., 2008 - last updated, Drinking during pregnancy and fetal alcohol syndrome, [Online]. Available: http://www.childresearch.net/RESOURCE/RESEARCH/2008/NIIMI.HTM [7/01/2009].

NILSEN, P., 2009. Brief alcohol intervention to prevent drinking during pregnancy: an overview of research findings. *Current Opinion in Obstetrics and Gynecology,* **21,** pp. 496-500.

NILSEN, P., AALTO, M., BENDTSEN, P., and SEPPA, K., 2006. Effectiveness of strategies to implement brief alcohol intervention in primary healthcare: A systematic review. *Scandinavian Journal of Primary Health Care*, **24**(1), pp. 5-15.

NILSEN, P., BAIRD, J., MELLO, M.J., NIRENBERG, T., WOOLARD, R., BENDTSEN, P., and LONGABAUGH, R., 2008. A systematic review of emergency care brief alcohol interventions for injury patients. *Journal of Substance Abuse Treatment*, **35**(2), pp. 184-201.

NILSEN, P., WHALIN, S., and HEATHER, N., 2011. Implementing brief interventions in health care: lessons learnt from the Swedish risk-drinking project. *International Journal of Environmental Research and Public Health,* **8**, pp. 3609-3627.

NOFAS, 2004. FASD terminology summit, [Online]. Available: http://www.nofas.org/advocate/terminology.aspx [11/04/2009].

NURSING AND MIDWIFERY COUNCIL, 2004. *Midwives rules and standards*. London: Nursing and Midwifery Council.

NYGAARD, P. and AASLAND, O.G., 2011. Barriers to Implementing Screening and Brief Interventions in General Practice: Findings from a Qualitative Study in Norway. *Alcohol and Alcoholism*, **46**(1), pp. 52-60.

O'CALLAGHAN, F.V., O'CALLAGHAN, M., NAJMAN, J.M., WILLIAMS, G.M., and BOR, W., 2007. Prenatal alcohol exposure and attention, learning and intellectual ability at 14 years: a prospective longitudinal study. *Early Human Development,* **83**(2), pp. 115-123.

O'CONNOR, M.J. and WHALEY, S.E., 2007. Brief intervention of alcohol use by pregnant women. *American Journal of Public Health,* **97**(2), pp. 252-258.

O'LEARY, C., ZUBRICK, S.R., TAYLOR, C.L., DIXON, G., and BOWER, C., 2009a. Prenatal alcohol exposure and language delay in 2-year-old children: The importance of dose and timing on risk. *Pediatrics,* **123**(2), pp. 547-554.

O'LEARY, C.M., BOWER, C., ZUBRICK, S.R., GEELHOED, E., KURINCZUK, J.J., and NASSAR, N., 2010a. A new method of prenatal alcohol classification accounting for dose, pattern, and timing of exposure: improving our ability to examine fetal effects from low to moderate exposure. *Journal of Epidemiology & Community Health,* **64**(11), pp. 956-962.

O'LEARY, C.M., NASSAR, N., KURINCZUK, J.J., and BOWER, C., 2009b. The effect of maternal alcohol consumption on fetal growth and preterm birth. *BJOG: An International Journal of Obstetrics & Gynaecology,* **116**(3), pp. 390-400.

O'LEARY, C.M., NASSAR, N., KURINCZUK, J.J., DE KLERK, N., GEELHOED, E., ELLIOTT, E.J., and BOWER, C., 2010b. Prenatal alcohol exposure and risk of birth defects. *Pediatrics*, **126**(4), pp. 843-850.

O'LEARY, C.M., NASSAR, N., ZUBRICK, S.R., KURINCZUK, J.J., STANLEY, F., and BOWER, C., 2010c. Evidence of a complex association between dose, pattern and timing of prenatal alcohol exposure and child behaviour problems. *Addiction,* **105**(1), pp. 74-86.

OFFICE OF THE SURGEON GENERAL, 2005 – updated, Press release: US Surgeon General releases advisory on alcohol use in pregnancy, [Online]. Available: http://www.surgeongeneral.gov/pressreleases/sg02222005.html [12/01/2009].

OLIVER, S., OAKLEY, L., LUMLEY, J., and WATERS, E., 2001. Smoking cessation programme in pregnancy: systematically addressing development, women's concerns and effectiveness. *Health Education Journal,* **60**(4), pp. 362-370.

ORNOY, A. and ERGAZ, Z., 2010. Alcohol abuse in pregnant women: effects on the fetus and newborn, mode of action and maternal treatment. *International Journal of Environmental Research and Public Health,* **7**(2), pp. 364-379.

PATTON, M.Q., 2002. *Qualitative research and evaluation methods.* 3rd edn. Thousand Oaks, CA: Sage.

PAWSON, R., 2006. *Evidence-based policy: a realistic perspective.* London: Sage.

PAWSON, R. and TILLEY, N., 1997. *Realistic evaluation.* London: Sage.

PAWSON, R., 2002. Evidence-based Policy: The Promise of `Realist Synthesis'. *Evaluation*, **8**(3), pp. 340-358.

PEADON, E., PAYNE, J., HENLEY, N., D'ANTOINE, H., BARTU, A., O'LEARY, C., BOWER, C., and ELLIOTT, E.J., 2010. Women's knowledge and attitudes regarding alcohol consumption in pregnancy: a national survey. *BMC Public Health,* **10** (510), pp. 1-8.

PETTICREW, M. and ROBERTS, H., 2006. *Systematic reviews in the social sciences: a practical guide.* Malden, MA: Blackwell Publishing.

PLANT, M., 1984. Drinking amongst pregnant women: some initial results from a prospective study. *Alcohol and Alcoholism,* **19**(2), pp. 153-157.

PLANT, M., 1985. *Women, drinking and pregnancy.* London: Tavistock.

PLANT, M., 1997. *Women and Alcohol: contemporary and historical perspectives.* London: Free Association Book.

POIKOLAINEN, K., 1999. Effectiveness of brief interventions to reduce alcohol intake in primary health care populations: a meta-analysis. *Preventive Medicine*, **28**(5), pp. 503-509.

POIKOLAINEN, K., 2002. A nice try that fails: The Swedish council on technology assessment in health care (SBU) evaluation of the effect of treatment of alcohol and drugs problems: The epidemiologist's view. *Alcohol and Alcoholism*, **37**(5), pp. 416-418.

PURDAM, K., 2010. *Conducting focus groups: a brief overview.* Manchester: Centre for Census and Survey Research.

QUAH, S.R. 1985. The health belief model and preventive health behaviour in Singapore. *Social Science and Medicine,* **21**(3), pp. 351-363.

RAISTRICK, D., HEATHER, N. and GODFREY, C., 2006. *Review of the effectiveness of treatment for alcohol problems*. London: Department of Health.

RAYMOND, N., BEER, C., GLAZEBROOK, C., and SAYAL, K., 2009. Pregnant women attitudes towards alcohol consumption. *BMC Public Health,* **9**(175), pp. 1-8.

RCOG, 2006. Alcohol and pregnancy: information for you, [Online]. Available: http://www.rcog.org.uk/resources/public/pdf/alcohol_pregnancy_1206.pdf [10/04/2009].

REID, L., 2011. An evolving NHS: midwifery, [Online]. Available: http://www.60yearsofnhsscotland.co.uk/history/an-evolving-nhs/nursing/midwifery.html [22/11/2011].

RICHARDS, L., 2009. *Handling qualitative data.* 2nd edn. London: Sage.

RITCHIE, J., LEWIS, J., and ELAM, G., 2003. Designing and selecting samples. In: J. RITCHIE and J. LEWIS, eds, *Qualitative research practice: a guide for social science students and researchers.* London: Sage, pp. 77-108.

ROBINSON, M., ODDY, W.H., MCLEAN, N.J., JACOBY, P., PENNELL, C.E., DE KLERK, N.H., ZUBRICK, S.R., STANLEY, F.J., and NEWNHAM, J.P., 2010. Low-moderate prenatal alcohol exposure and risk to child behavioural development: a prospective cohort study. *BJOG: An International Journal of Obstetrics & Gynaecology,* **117**(9), pp. 1139-1150.

RODRIGUEZ, A., OLSEN, J., KOTIMAA, A.J., KAAKINEN, M., MOILANEN, I., HENRIKSEN, T.B., LINNET, K.M., MIETTUNEN, J., OBEL, C., TAANILA, A., EBELING, H., and JARVELIN, M.R., 2009. Is prenatal alcohol exposure related to inattention and hyperactivity symptoms in children? Disentangling the effects of social adversity. *Journal of Child Psychology & Psychiatry & Allied Disciplines,* **50**(9), pp. 1073-83.

ROLLNICK, S. and ALLISON, J., 2004. Motivational interviewing. In: N. HEATHER and T. STOCKWELL, eds. *The essential handbook of treatment and prevention of alcohol problems*. Chichester: Wiley & Sons, pp. 105-115.

ROME, A., BOYLE, K., and GOODALL, J., 2008. Review of the implementation of the SIGN 74 Guideline of the management of harmful drinking and alcohol dependence

in primary care and the Health Technology Assessment on the prevention of relapse in alcohol dependence. Edinburgh: NHS Health Scotland.

ROMITTI, P.A., SUN, L., HONEIN, M.A., REEFHUIS, J., CORREA, A., and RASMUSSEN, S.A., 2007. Maternal periconceptional alcohol consumption and risk of orofacial clefts. *American Journal of Epidemiology,* **166**(7), pp. 775-785.

ROSENSTOCK, I.M., 1966. Why people use health services. *The Milbank Memorial Quarterly,* **44**(3 pt 2), pp. 94-124.

ROSENSTOCK, I.M., 1974. The health belief model and preventative health behaviour. *Health Education Monographs*, 2, pp. 354-386.

ROSS, M.G., 2011 – last updated, Fetal growth restriction, [Online]. Available: http://emedicine.medscape.com/article/261226-overview [4/10/2011].

ROYAL COLLEGE OF PHYSICIANS., 2011. *Alcohol and sex: a cocktail for poor sexual health. Report of the alcohol and sexual health working party.* London: Royal College of Physicians.

RUSSELL, M., MARTIER, S.S., SOKOL, R.J., MUDAR, P., BOTTOMS, S., JACOBSON, S., and JACOBSON, J., 1994. Screening for pregnancy risk-drinking. *Alcoholism: Clinical & Experimental Research,* **18**(5), pp. 1156-1161.

RUTHERFORD, D., 2007 – last updated, Alcohol metabolism, [Online]. Available: http://www.netdoctor.co.uk/focus/nutrition/facts/lifestylemanagement/alcohol.htm [08/01/2010].

RYCROFT-MALONE, J., FONTENLA, M., BICK, D., and SEERS, K., 2010. Realistic evaluation: the case of protocol-based care. *Implementation science,* **5**(38), pp. 1-14.

SALASPURO, M., 2003. Intervention against hazardous alcohol consumption--secondary prevention of alcohol problems. In: M. BERGLUND, S. THELANDER, and E. JONSSON, eds. *Treating alcohol and drug abuse: an evidence-based review*. Weinheim: Wiley-VCH, pp. 1-41.

SAUNDERS, J.B., KYPRI, K., WALTERS, S.T., LAFORGE, R.G., and LARIMER, M.E., 2004. Approaches to Brief Intervention for Hazardous Drinking in Young People. *Alcoholism: Clinical and Experimental Research*, **28**(2), pp. 322-329.

SAYAL, K., 2007. Alcohol consumption in pregnancy as a risk factor for later mental health problems. *Evidence-Based Mental Health,* **10,** pp. 98-100.

SAYAL, K., HERON, J., GOLDING, J., ALATI, R., SMITH, G.D., GRAY, R., and EMOND, A., 2009. Binge pattern of alcohol consumption during pregnancy and childhood mental health outcomes: longitudinal population-based study. *Pediatrics,* **123**(2), pp. e289-296.

SAYAL, K., HERON, J., GOLDING, J., and EMOND, A., 2007. Prenatal alcohol exposure and gender differences in childhood mental health problems: a longitudinal population-based study. *Pediatrics,* **119**(2), pp. e426-434.

SCHOFIELD, J., 2001. Time for a revival? Public policy implementation: a review of the literature and agenda for future research. *International Journal of Management Reviews*, **3**(2), pp. 245-263.

SCHORLING, J., 2007. Review: Brief interventions including information sessions, motivational interviews, and cognitive bahavioural therapy reduce excessive alcohol consumption in primary care: Commentary. *Evidence-Based Medicine*, **12**(6), pp.179.

SCHULZ, K.F., ALTMAN, D.G., and MOHER, D., 2010. CONSORT 2010 statement: update guidelines for reporting parallel group randomised trials. *Annals of Internal Medicine,* **152**(11), pp. 1-8.

SCOTTISH GOVERNMENT, 2008. *Growing Up in Scotland: year 2 - results from the second year of a study following the lives of Scotland's children.* Edinburgh: Scottish Government.

SCOTTISH GOVERNMENT, 2009. *Changing Scotland's Relationship with Alcohol: A Framework for Action*, Scottish Government: Edinburgh.

SCOTTISH GOVERNMENT, 2011. *The Scottish Health Survey 2010: Volume 1, main report.* Edinburgh: Scottish Government.

SCOTTISH HEALTH ACTION ON ALCOHOL PROBLEMS, 2008. Screening and brief interventions for risky and harmful drinking, [Online]. Available: http://www.shaap.org.uk/UserFiles/File/Screening%20and%20brief%20interventions.pdf [30/01/2011].

SHANKAR, K., RONIS, M.J.J., and BADGER, T.M., 2007. Effects of pregnancy and nutritional status on alcohol metabolism. *Alcohol Research and Health,* **30**(1), pp. 55-59.

SHAW, S., 1980. The causes of increasing drinking problems among women. In: Camberwell Council on Alcoholism, ed, *Women & alcohol*. New York: Tavistock, pp. 1-40.

SIGN., 2003. Management of Harmful Drinking and Alcohol Dependence in Primary: SIGN 74. Edinburgh: Scottish Intercollegiate Guidance Network.

SILVERMAN, D., 2010. *Doing qualitative research.* 3rd edn. London: Sage.

SJÖBERG, L., 1998. Risk perception of alcohol consumption. *Alcoholism: Clinical and Experimental Research,* **22**(7), pp. 277S-284S.

SMITH, L. and DIXON, L., 2009. Systematic Reviews. In: J. NEALE, ed, *Research methods for health and social care*. Basingstoke: Palgrave Macmillan, pp. 63-77.

SMITH, S.M., 1997. Alcohol-induced cell death in the embryo. *Alcohol, Health and Research World,* **21**(4), pp. 287-297.

SNAPE, D. and SPENCER, L., 2003. The foundations of qualitative research. In: J. RITCHIE and L. LEWIS, eds, *Qualitative research practice: a guide for social science students and researchers*. Los Angeles: Sage, pp. 1-23.

SOKOL, R.J., DELANEY-BLACK, V., and NORDSTROM, B., 2003. Fetal Alcohol Spectrum Disorder. *JAMA: The Journal of the American Medical Association*, **290**(22), pp. 2996-2999.

ST.CLAIR, H.R., 1991. *Recognising alcoholism and its effects.* Basel: Karger.

STADE, B.C., BAILEY, C., DZENDOLETAS, D., SGRO, M., DOWSWELL, T., and BENNETT, D., 2009. Psychological and/or educational interventions for reducing alcohol consumption in pregnant women and women planning pregnancy. *Cochrane Database of Systematic Reviews,* **2**, Article no. CD004228, pp. 1-27.

STANERWICK, K., DAVIES, C., TUCKER, L., and SHERON, N., 2007. Binge drinking, sexual behaviour and sexually transmitted infections in the UK. *International Journal of STD & AIDS,* **18**, pp. 810-813.

STAROSELSKY, A., FANTUS, E., SUSSMAN, R., SANDOR, P., KOREN, G., and NULMAN, I., 2009. Both parental psychopathology and prenatal maternal alcohol dependency can predict the behavioral phenotype in children. *Paediatric Drugs,* **11**(1), pp. 22-25.

STEWART, D.W., SHAMDASANI, P.N., and ROOK, D.W., 2007. *Focus group: theory and practice.* 2nd edn. Thousand Oaks, CA: Sage.

STOLER, J.M. and HOLMES, L.B., 1999. Under recognition of prenatal alcohol effects in infants of known alcohol abusing women. *The Journal of Pediatrics,* **135**(4), pp. 430-436.

STRANDBERG-LARSEN, K., JENSEN, M.S., RAMLAU-HANSEN, C.H., GRONBAEK, M., and OLSEN, J., 2009. Alcohol binge drinking during pregnancy and cryptorchidism. *Human Reproduction,* **24**(12), pp. 3211-3219.

STRANDBERG-LARSEN, K., NIELSEN, N.R., GRONBAEK, M., ANDERSEN, P.K., OLSEN, J., and ANDERSEN, A.M., 2008. Binge drinking in pregnancy and risk of fetal death. *Obstetrics & Gynecology,* **111**(3), pp. 602-609.

STRATTON, K., HOWE, C., and BATTAGLIA, F., 1996. *Fetal Alcohol Syndrome: diagnosis, epidemiology, prevention and treatment.* Washington, DC: National Academy Press.

STREISSGUTH, A., 2007. Offspring effects of prenatal alcohol exposure from birth to 25 years: The Seattle prospective longitudinal study. *Journal of Clinical Psychology in Medical Settings,* **14**(2), pp. 81-101.

SULIAMAN, N.D., FLOREY, D.C.V., TAYLOR, D.J., and OGSTON, S.A., 1988. Alcohol consumption in Dundee primigravidas and its effects on the outcome of. *British Medical Journal,* **296,** pp. 1500-1503.

SUSS, H.M., 1995. The effectiveness of the treatment for alcoholics: Results of a metaanalysis. *Psychologische Rundschau*, **46**(4), pp. 248-266.

TAIT, R.J. and HULSE, G.K., 2003. A systematic review of the effectiveness of brief interventions with substance using adolescents by type of drug. *Drug and Alcohol Review*, **22**(3), pp. 337-346.

TAYLOR, D.J., 1993. Pregnancy alcohol consumption. *Fetal and Maternal Medicine Review,* **5**, pp. 121-135.

THE NATIONAL ARCHIVES, 1998 – last updated. The Data Protection Act 1998, [Online]. Available: www.legislation.gov.uk/ukpga/1998/29/contents [10/09/2011].

THOM, B., 1994. Women and alcohol: the emergence of a risk group. In: M. MCDONALD, ed, *Gender, drinks and drugs*. Oxford: Berg, pp. 33-54.

TOLSON, D., MCINTOSH, J., LOFTUS, L., and CORMIE, P., 2005. Developing a managed clinical network in palliative care: a realistic evaluation. *International Journal for Nursing Studies,* **44**(2007), pp. 183-195.

TREASURE, J., 2004. Motivational interviewing. *Advances in Psychiatric Treatment,* **10,** pp. 331-337.

TSAI, Y., TSAI, M., LIN, Y., WENG, C., CHEN, C., and CHEN, M., 2010. Facilitators and barriers to intervening for problem alcohol use. *Journal of Advanced Nursing*, **66**(7), pp. 1459-1468.

US DEPARTMENT OF HEALTH AND HUMAN SERVICES, 2008 – last updated, NSDUH report: alcohol use among pregnant women and recent mothers: 2002 to 2007. Available: www.oas.samhsa.gov [28/10/2009].

VAN DE VIJVER, F.J.R., VAN HEMERT, D.A., and POORTINGA, Y.H., 2008. Conceptual models of multilevel models. In: F. J. R. VAN DE VIJVER, D. A. VAN HEMERT, and Y. H. POORTINGA, eds, *Multilevel analysis of individuals and cultures*. New York: Lawrence Erlbaum Associates, pp. 3-26.

VASILAKI, E.I., HOSIER, S.G., and COX, W.M., 2006. The efficacy of motivational interviewing as a brief intervention for excessive drinking: A meta-analytic review. *Alcohol and Alcoholism*, **41**(3), pp. 328-335.

WALKER, M.J., AL-SAHAB, B., ISLAM, F., and TALAMIM, H., 2011. The epidemiology of alcohol ultilization during pregnancy: an analysis of the Canadian maternity experience survey (MES). *BMC: Pregnancy and Childbirth,* **11**(52), pp. 1-9.

WAND, T., WHITE, K., and PATCHING, J., 2010. Applying a realist(ic) framework to the evaluation of a new model of emergency department based mental health nursing practice. *Nursing Inquiry,* **17**(3), pp. 231-239.

WAND, T., WHITE, K., and PATCHING, J., 2011. Realistic evaluation of an emergency department-based mental health nurse practitioner outpatient service in Australia. *Nursing & Health Sciences*, **13**(2), pp. 199-206.

WATERSON, J., 2000. *Women and alcohol in social context.* Basingstoke: Palgrave.

WATSON, H., MUNRO, A., WILSON, M., KERR, S.M., and GODWIN, J., 2010. *The involvement of nurses and midwives in screening and brief interventions for hazardous and harmful use of alcohol and other psychoactive substances.* Geneva: World Health Organisation.

WHITTY, J.E. and SOKOL, R.J., 1996. Alcohol teratogenicity in humans. In: S. HANS-LUDWIG and S. HANS-CHRISTOPH, eds, *Alcohol, pregnancy and the developing child*. Cambridge: University Press, pp. 3-13.

WHO, 2011 - last updated, Patterns of consumption, alcohol consumers, [Online]. Available: http://apps.who.int/ghodata/?vid=93000 [20/11/2011].

WILK, A.I., JENSEN, N.M., and HAVIGHURST, T.C., 1997. Meta-analysis of randomized control trials addressing brief interventions in heavy alcohol drinkers. *Journal of General Internal Medicine*, **12**(5), pp. 274-283.

WILLFORD, J., LEECH, S., and DAY, N., 2006. Moderate prenatal alcohol exposure and cognitive status of children at age 10. *Alcoholism: Clinical & Experimental Research,* **30**(6), pp. 1051-1059.

WILSON, V. and MCCORMACK, B., 2006. Critical realism as emancipatory action: the case for realistic evaluation in practice development. *Nursing Philosophy,* **7**, pp. 45-57.

WOOLARD, R., CHERPITEL, C.J., and THOMPSON, K., 2011. Brief intervention for emergency department patients with alcohol misuse: implications for practice. *Alcohol Treatment Quarterly,* **29**, pp. 146-157.

ZAMMIT, S., THOMAS, K., THOMPSON, A., HORWOOD, J., MENEZES, P., GUNNELL, D., HOLLIS, C., WOLKE, D., LEWIS, G., and HARRISON, G., 2009. Maternal tobacco, cannabis and alcohol use during pregnancy and risk of adolescent psychotic symptoms in offspring. *British Journal of Psychiatry*, **195**(4), pp. 294-300.

Appendices

Appendix 1. Search strategy for retrieving studies from Medline and Embase (fetal effects of drinking)

Step	Search statement	number retrieved
1	case control	(233577)
2	(case adj2 control$)	(239363)
3	(prospective adj3 stud$)	(595396)
4	(retrospective adj3 stud$)	(650904)
5	observation$ stud$	(73336)
6	Cohort	(436273)
7	(cohort adj stud$)	(215209)
8	systematic review$	(87515)
9	meta-analysis	(114901)
10	6 or 3 or 7 or 9 or 2 or 8 or 1 or 4 or 5	(1859892)
11	(Pregnan$ adj women	(87848)
12	prenatal	(201744)
13	neonat$	(298769)
14	infant$	(1208889)
15	child$	(2555106)
16	maternal	(306942)
17	pregnan$	(982107)
18	alcohol$	(478020)
19	binge	(11553)
20	booze	(59)
21	drink$	(186414)
22	(alcohol$ adj consumption$)	(74257)
23	alcohol$ intake	(15469)
24	(low adj moderate)	(3013)
25	(heav$ adj2 drink$)	(9798)
26	(high$ adj2 drink$)	(5221)
27	25 or 21 or 26 or 20 or 22 or 18 or 24 or 19 or 23	(587875)
28	fetal alcohol syndrome	(5946)
29	foetal alcohol syndrome	(117)
30	FAS	(47464)
31	fetal alcohol effect$	(316)
32	foetal alcohol effect$	(13)
33	FAE	(994)
34	Fetal alcohol spectrum disorder$	(1134)
35	foetal alcohol spectrum disorder$	(32)
36	FASD	(799)
37	Alcohol related neurodevelopment$	(145)
38	ARND	(90)
39	(infant$ adj2 development$)	(8806)
40	Behaviour$	(271980)
41	stillbirth$	(13280)
42	low birth weight	(46079)
43	(birth adj weight)	(101283)
44	spontaneous abortion$	(21637)
45	miscarri$	(14015)
46	disorder$	(2002016)
47	abnormalit$	(537769)
48	(gestation$ adj age)	(138831)
49	preterm$	(67581)
50	neonat$ death	(4289)
51	pregnan$ outcome$	(57537)
52	35 or 33 or 32 or 42 or 30 or 44 or 29 or 28 or 39 or 36 or 40 or 41 or 38 or 34 or 45 or 37 or 43 or 31 or 46 or 47 or 48 or 49 or 50 or 51	(2949444)
53	11 or 12 or 13 or 14 or 15 or 16 or 17	(3956538)
54	10 and 27 and 52 and 53	(4735)
55	limit 54 to english language	(4419)

```
56 limit 55 to yr="2006 -Current"                    (2101)
57 limit 56 to humans                                (1985)
58 remove duplicates from 57                         (1352)
```

Appendix 2. Reasons for excluding studies for systematic review of effects of alcohol

Study details **1st author and Year**	**Reason**
Aragon, 2008	Outcome focused on description of the characteristics of children with FASD and not establishing cause and effect relationship
Flanigan, 2008	Study conducted and focused in developing country
Grewal, 2008	Exposure of alcohol not exclusive to prenatal period
Jackson, 2007	Study conducted and focused in developing country
Kesmodel, 2010	Not observational study (implementation research issues)
Kodituwakku , 2006	Outcome focused on describing the characteristics of children with FASD and not establishing cause and effect relationship
May, 2008	Study conducted and focused in developing country
Menegaux, 2007	Not outcome of interest
Romitti, 2007	Exposure of alcohol not exclusive to prenatal period
Sayal, 2007	Literature review and not a observational study
Staroselsky, 2009	No measure of alcohol exposure provided
Streissguth, 2007	Review of papers published on Seattle Prospective Longitudinal Study

Appendix 3. Main quality criteria for cohort studies

Study details - 1st author and year	Quality criteria							Bias category (based on n = ✓)
	appropriate way of recruitment	Accurate exposure measure	Accurate outcome measure	List of all confounders	Was follow up enough	Believe in result	General izability	Risk of bias 0 -2 = high 3–5 = moderate 6 - 7 = low
Alati, 2006	✓	~	~	✓	✓	✓	✓	Moderate
Alati, 2008	✓	~	~	✓	✓	✓	✓	Moderate
Aliyu, 2008	✓	~	✓	✓	✓	✓	✓	Low
Bakker, 2010	✓	~	✓	✓	✓	✓	~	Moderate
Barr, 2006	✓	~	✓	✓	✓	✓	X	moderate
Damgaard, 2007	✓	~	✓	✓	✓	✓	~	Moderate
Dew, 2007	✓	X	✓	X	✓	✓	X	Moderate
Dodge, 2009	✓	~	✓	✓	~	✓	~	Moderate
Howell, 2006	✓	~	~	✓	✓	~	X	Moderate
Jacobson, 2011	✓	~	✓	✓	✓	✓	X	Moderate
Jaddoe, 2007	✓	~	✓	✓	✓	✓	~	Moderate
Jensen, 2007	✓	~	~	✓	✓	✓	~	Moderate
Kelly, 2009	✓	~	~	✓	✓	✓	✓	Moderate
Kelly, 2010	✓	~	~	✓	✓	✓	✓	Moderate
Larkby, 2011	✓	~	~	~	✓	✓	✓	Moderate
O'Callaghan, 2007	✓	~	✓	~	✓	✓	✓	Moderate
O'Leary, 2009a	✓	~	~	✓	✓	~	✓	Moderate
O'Leary, 2009b	✓	~	✓	✓	✓	✓	✓	Low
O'Leary, 2010a	✓	~	~	✓	✓	✓	✓	Moderate
O'Leary, 2010b	✓	~	~	✓	✓	✓	✓	Moderate
Robinson, 2010	✓	~	~	✓	✓	✓	✓	Moderate
Rodriguez, 2009	✓	~	✓	✓	✓	✓	✓	Low
Sayal, 2007	✓	~	✓	✓	✓	✓	✓	Low
Sayal, 2009	✓	~	✓	✓	✓	✓	✓	Low
Strandberg-Larsen, 2008	✓	~	✓	✓	✓	✓	✓	Low
Strandberg-Larsen , 2009	✓	~	✓	✓	✓	✓	✓	Low
Willford, 2006	✓	~	~	✓	✓	~	X	Moderate
Zammit, 2009	✓	~	~	✓	✓	~	X	Moderate

Appendix 4. Main quality criteria for case control studies

	Quality criteria						Bias category (based on n = ✓)
Study details	**Appropriate way of recruitment (cases)**	**Appropriate way of recruitment (controls)**	**Accurate exposure measure**	**List of all confounders**	**Do you believe the results**	**Generalizability**	**Risk of bias 0 -2 = high 3–4=moderate 5 - 6 = low**
Chiaffarino, 2006	✓	~	~	✓	✓	✓	Moderate
Coyne, 2008	✓	✓	~	✓	✓	X	Moderate
Fryer, 2007	✓	~	X	X	~	~	High
Mariscal, 2006	✓	✓	~	✓	✓	✓	Low
McGee, 2008	✓	~	X	X	~	~	High
McGee, 2009	✓	~	X	X	~	~	High
Mongraw-Chaffin, 2008	✓	✓	~	✓	~	✓	Moderate

Appendix 5. Main quality criteria for cross-sectional study

Study details	**Quality criteria**							**Bias category (based on n = ✓)**
1st author and year	**appropriate way of recruitment**	**Accurate exposure measure**	**Accurate outcome measure**	**List of all confounders**	**Was follow up enough**	**Believe in result**	**Generalizability**	**Risk of bias** **0 -2 = high** **3–5 = moderate** **6 - 7 = low**
Landgren, 2010	✓	X	✓	X	X	X	X	High

Key
✓ = Yes
X = No
~ = Unsure

Appendix 6. Search strategy for ABI reviews

1 (drink* or drank or drunk or consump$ or intake) (724009)

2 (low or moderate or (low adj3 moderate) or high or binge). (5010980)

3 (harmful or hazardous). (76841)

4 2 or 3 (5065088)

5 Alcohol Drinking/ (45800)

6 Alcoholic Intoxication/ or binge drinking (13144)

7 5 or 6 (55519)

8 alcohol. (389649)

9 booze. (71)

10 (wine or spirit* or beer) (71835)

11 8 or 9 or 10 (452462)

12 1 and 11 (153646)

13 4 and 11 (129890)

14 7 or 12 or 13 (235273)

15 Behavior Therapy/ (40648)

16 (motivation$ or brief or psychosocial or education$ or behavio$) (2958767)

17 (intervention$ or counsel$ or interview$ or therapy). (3606580)

18 16 and 17 (690267)

19 (MI or ABI or BI or BAI)(92213)

20 15 or 18 or 19 (778493)

21 14 and 20 (29237)

22 (Brief interventions for hazardous drinkers delivered in primary care are equally effective in men and women) (4)

23 21 and 22 (4)

24 (meta-analysis or (systematic adj review) or (synthesis adj2 stud*) or Cochrane or evidence synthesis)(201136)

25 23 and 24 (1116)

26 remove duplicates from 25 (958)

Appendix 7. Reasons for excluding studies from the systematic review of reviews

Study details (1st author and date)	Reason
Akvardar, 2010	Review not in English language
Anderson, 2004	Review focused on change in GP practices regarding screening and advice for alcohol misusing patients
Ashenden, 1997	Reported on data that have been covered by included review
Ballesteros, 2003	Reported on data that have been covered by included review
Beich, 2003	Reported on data that have been covered by included review
Beich, 2004	Reported on data that have been covered by included review
Boekeloo, 2007	Reported on data that have been covered by included review
Burke, 2003	Reported on data that have been covered by included review
Burke, 2004	Not peer-reviewed publication
Cayley, 2009	Not a systematic review
Cuijpers, 2004	Outcome data focused on mortality
Dunn, 2001	Reported on data that have been covered by included review
Edwards, 1997	Date of publication outwith specified range for inclusion
Hyman, 2006	Review focused on the role of the nurse in the delivery of ABI
Jenkins, 2009	Focused on the control groups in ABI studies
Lock, 2004	Not a systematic review

Study details (1st author and date)	**Reason**
Lui, 2008	Review focused on dependent drinkers
McCambridge, 2008	Review focused on secondary impact of cigarette smoking
Modesto-Lowe, 2000	Not a systematic review
Mortensen, 2004	Unable to retrieve article
Nh-Zarr, 2009	Outcome data focused on injury (suicide) prevention
Nilsen, 2006	Focused on ABI implementation strategies rather than its effectiveness
Poikolainen, 1999	Reported on data that have been covered by included review
Poikolainen, 2002	Not a systematic review
Salaspuro, 2003	Not peer-reviewed publication
Saunders, 2004	Not a systematic review
Schorling, 2007	Commentary - not a systematic review
Suss, 1995	Review not in English language
Tait, 2003	Not setting of interest
Wilk, 1997	Date of publication outwith specified range for inclusion

Appendix 8. Policy implementers' information sheet

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Tel: 01786 466112

Participant Information Sheet

Title: The Alcohol Brief Intervention (ABI) – developing an understanding of how it works in antenatal setting.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully.

What is the purpose of the study?

The recent Scottish Government publication, Changing Scotland's Relationship with Alcohol: A Framework for Action (2009) showed the need to tackle hazardous and harmful use of alcohol amongst the Scottish populace. To attain this, HEAT 4 targets have been set by the Scottish Government for NHS Health Boards to deliver ABI in three priority settings of primary care, A&E departments and antenatal settings. However, the uniqueness of antenatal population coupled with the complexities and uncertainties surrounding the issue of drinking in pregnancy may make the delivery and implementation of ABI in this setting a challenge.

The aim of the study is to explore the factors that may influence the implementation and effectiveness of Alcohol Brief Intervention in antenatal setting.

By interviewing key stakeholders, we hope to gain insights to understand to what extent national policies impact on organisation policies and to develop understanding of the expectations, intentions and perceived benefits of the recently implemented ABI delivery.

This research is part of Mr. Lawrence Doi's PhD research study.

What does participating in the project involve?

We would like you to take part in a 30 minute telephone or face to face interview. Questions posed in the interview will focus on the implementation of ABI in antenatal setting.

How will the interviews be recorded?

We will audio record the interviews, which will then be transcribed for analysis. Interview transcripts will be anonymised and will be identified by a code number, not by name, so that what you say will remain anonymous. The tapes will be destroyed after the completion of the project. Interview transcripts will be stored securely for seven years in line with research protocols.

Can I be sure that all information will be kept confidential?

Yes. Everything that is said and any information about individuals will remain strictly confidential. Although the name of your organisation may be mentioned in the report, your name will not. Although it is possible within a small pool of experts that participate, you may be recognised by colleagues, but we will nevertheless report views thematically so that they cannot be attributed to a single participant.

Can I withdraw from the study?

Yes. You may withdraw from the study at any time and without giving a reason. Individuals within any organisation may decide to participate, or not, in the interviews with no detriment to their employment.

What will happen to the results of the research study?

The results of the study will be submitted as thesis for an award of PhD. The findings will also be published in academic journals. In all cases confidentiality will be maintained. We will send each participant a summary of our findings at the end of the study.

If I decide to take part, how will my consent be recorded?

For a face to face interview, we will require that you complete a consent form before the interview begins. For a telephone interview, a consent form will be attached with the information sheet. You can complete it and send it to me or you could read over this prior to the interview. If you are happy with this then we will record your verbal consent at the beginning of the interview. We will ask for individual consent from each participant.

Who is organising and funding the research?

Lawrence Kweku Doi is organising this study. He is being supervised by Dr Ruth Jepson, Dr Helen Cheyne and Prof Sally Wyke of the Department of Nursing and Midwifery at the University of Stirling. The University of Stirling is funding this research.

Does the study have ethical approval?

This study has been approved by the Department Research Ethics Committee, University of Stirling and NHS West of Scotland Research Ethics Committee 2.

Thank you for taking the time to read this information.

For more information about the study, please contact one of the researchers below:	
Mr Lawrence Doi Department of Nursing and Midwifery University of Stirling Stirling FK9 4LA Tel: 01786 466112 Email: l.k.doi@stir.ac.uk	Dr Ruth Jepson Department of Nursing and Midwifery University of Stirling Stirling FK9 4LA Tel: 01786 466402 Email: ruth.jepson@stir.ac.uk

If you would like to speak to someone who knows about this research but is an independent advisor, please contact:

Professor William Lauder
Department of Nursing and Midwifery
University of Stirling
Stirling FK9 4LA
Tel: 01786 466345 Fax: 0178466344
Email: william.lauder@stir.ac.uk

Appendix 9. A summary of research proposal for policy implementers

UNIVERSITY OF STIRLING

DEPARTMENT OF NURSING AND MIDWIFERY

(Version 2.0, 20/05/2010)

The alcohol brief intervention – developing an understanding of how it works in the antenatal setting

Researcher: Lawrence Kweku Doi

Prenatal alcohol use is a threat to healthy pregnancy outcomes and is one of the leading preventable causes of birth defects, including foetal alcohol syndrome and learning disabilities. The recent Scottish Government publication, Changing Scotland's Relationship with Alcohol: A Framework for Action (2009) showed the need to tackle hazardous and harmful use of alcohol amongst the Scottish populace. Indeed, to reduce alcohol consumption and alcohol related harm in pregnancy, Alcohol Brief Interventions (ABI) have been recently implemented in antenatal care across Scotland, most specifically through delivery on the HEAT 4 target. This PhD research is aiming to explore factors that influence the implementation of ABI in the antenatal setting and to develop understanding of how it modifies the drinking behaviour of pregnant women.

The research questions to be answered are:

What are the expectations, intentions and perceived benefits of the recently implemented ABI delivery - for policy makers, those responsible for implementation and pregnant women?

What are the experiences and attitudes of pregnant women towards receiving an ABI?

In what ways (if any) do ABIs influence reported drinking behaviour change amongst pregnant women?

The study will be undertaken using qualitative methods and will be driven by the principles of realistic evaluation. Realistic evaluation is a theory-driven approach to investigate social programmes. It offers a perspective that helps to assess the nature of a programme and how it works, whilst incorporating the contextual basis for explaining and understanding the programme. The research will utilize one to one semi-structured and telephone interviews with pregnant women, and those with key strategic and operational policy overview. The findings will provide useful learning about the implementation process and will further help improve the delivery of ABIs in the antenatal setting.

Appendix 10. Letter for participants (pregnant women)

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Postgraduate research student
Dept. of nursing and midwifery
University of Stirling
Stirling
FK9 4LA
Tel: 01786 466112
Email: l.k.doi@stir.ac.uk

Dear Participant,

Title of project: The Alcohol Brief Intervention – developing an understanding of how it works in antenatal setting.

You are invited to participate in a research study. You have been invited because we understand that you have been offered some form of advice and/or help on alcohol drinking during pregnancy by a health professional. We would like to know more about the advice and help you received, and how you feel it helped you (or not).

Before you agree to take part, it is important for you to understand why the research is being done, and what it will involve. Please take some time to read the information in the enclosed Participant Information Sheet. Please, feel free to talk to others about this study if you wish.

If you want more information, or have any queries about any of the points, please contact me on the telephone numbers above. If you would like further information about this study from my academic supervisor, feel free to contact Dr Ruth Jepson on 01786 466402. Independent people you could contact concerning this study are Ms Sandra Smith at St. John's Hospital (01506 523000) and Professor William Lauder (01786 466345).

Please complete the enclosed expression of interest form, if you are interested and you would like to take part in this study. The completed form should be sent to the researcher in the enclosed pre-paid envelope.

Thank you for taking the time to consider taking part in this research.

Yours sincerely,

Lawrence Doi

Appendix 11. Information sheet for midwives

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Title: Prenatal alcohol consumption - a qualitative study exploring pregnant women and midwives knowledge, perceptions and attitudes.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully.

What is the purpose of the study?

The aim of this study is to explore the extent to which the controversies and guidelines surrounding the effects of alcohol consumption in pregnancy influence drinking behaviour in pregnancy, and the provision of information or advice by midwives.

Recently drinking alcohol during pregnancy has received much attention, especially in the media. Currently women are being provided with a wide range of (sometimes conflicting) advice or information regarding this issue. This may make it difficult for some women to decide whether drinking in pregnancy is safe or not. Midwives may also find it difficult to know how to advise women as to what are the safe levels of alcohol consumption as well as how to respond to women's concerns and empower them to make informed decisions. As a midwife we are keen to find out your views on this matter.

This research is part of Mr. Lawrence Doi's PhD research study.

Why have I been chosen?

There will be a total of about 40 people taking part in this study. About 25 will be pregnant women and 15 will be midwives. You have been chosen because you are a Midwife who may have to either advise women or provide them with information about alcohol consumption during pregnancy.

Do I have to take part?

Your participation in the study would be greatly appreciated, however it is completely up to you whether to take part or not. If you do decide to take part you will be asked to sign a consent form. You will still be free to withdraw at any point in time without giving a reason.

What will taking part in the study involve?

This study will involve participation in a focus group (a group discussion with about four other Midwives). If you express interest in taking part, you will receive a telephone call from the researcher (Lawrence Doi) to arrange a date, time and venue for the focus group. The focus group will take place in a private room within the NHS premises at a time convenient to participants.

Will I be paid for participating?

You will be provided with a £20 high street store voucher as a compensation for your time and effort in attending the focus group.

What do I have to do?

If you are interested in taking part in the study, please complete, and return the enclosed expression of interest form. Once your form has been received, you will be contacted by telephone to arrange a date, time and venue for the focus group.

The focus group may last up to 1 hour 45 minutes and will be audio recorded. Your permission will be sought prior to recording. Only questions relevant to the research will be asked. The audio tape will be typed out but any information that will be able to identify individuals, for example participants name will be removed.

What are the potential benefits of taking part?

There might be no direct benefit for you but information from this study may help to improve the quality of alcohol information provided to pregnant women in the future.

Will I be able to be identified from the results?

No. All information collected about you will remain strictly confidential. Nothing in the report will be able to identify you. Only the researcher and research supervisors will have access to the data collected. All recordings will be stored securely and will be destroyed after this study.

What will happen to the results of the research study?

The results of the study will be submitted as thesis for an award of PhD. The findings will also be published in academic journals. In all cases confidentiality will be maintained. You may receive a short summary of the findings if you wish.

Who is organising and funding the research?

Lawrence Kweku Doi is organising this study. He is being supervised by Dr Ruth Jepson, Dr Helen Cheyne and Prof Sally Wyke of the Department of Nursing and Midwifery at the University of Stirling. The University of Stirling is funding this research.

Does the study have ethical approval?

This study has been approved by the Department Research Ethics Committee, University of Stirling and NHS West of Scotland Research Ethics Committee 2.

Thank you for taking the time to read this information.

For more information about the study, please contact one of the researchers below:

Lawrence Kweku Doi
Department of Nursing and Midwifery
University of Stirling
Stirling FK9 4LA
Email: l.k.doi@stir.ac.uk

Or

Dr Ruth Jepson
Department of Nursing and Midwifery
University of Stirling
Stirling FK9 4LA
Email: ruth.jepson@stir.ac.uk

If you would like to speak to a Midwife who knows about this research but is an independent adviser to this study, please contact:

Ms Sandra Smith
Maternity Services
St John's Hospital at Howden
Howden Road West
Livingston
West Lothian EH54 6PP

Appendix 12. Pregnant women's expression of interest form

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Title: The Alcohol Brief Intervention – developing an understanding of how it works in antenatal setting.

If you are interested in taking part in the above study, please complete this form and return it to the researcher (Lawrence Doi) in the pre-paid envelope provided. Expressing an interest does not imply that you are obliged to take part in the study if you later change your mind. Thank you.

Name…….

Telephone/Mobile……

Email (if possible)……..……..

Participant's signature……

Date……

Appendix 13. Pregnant women information sheet

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Tel: 01786 466112

Title: The Alcohol Brief Intervention – developing an understanding of how it works in antenatal setting.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully.

What is the purpose of the study?

The aim of this study is to explore the experiences of pregnant women of the help and/or advice they have received on how to reduce alcohol drinking during pregnancy. Drinking alcohol during pregnancy has received much attention, especially in the media. Recently, the NHS has decided to try to help women who drink to reduce the amount of alcohol they consume when they are pregnant. They call this 'alcohol brief intervention'. We are interested in hearing about your experiences of receiving this alcohol brief intervention because it will give us a good idea of how and why it is working (or not) and what else need to be done to improve it. This research is part of Mr. Lawrence Doi's PhD study.

Why have I been chosen?

There will be about 20 people taking part in this study. About 10-15 will be pregnant women - like you - who have received the alcohol brief intervention. You have been chosen because you are currently pregnant and you or your health professional have indicated that you have been offered alcohol brief intervention at some point during this pregnancy.

Do I have to take part?

Your participation in the study would be appreciated very much, however it is completely up to you whether to take part or not. If you do decide to take part you will be asked to sign a consent form, however you will still be free to withdraw at any point without giving a reason. Your decision to take part or to withdraw at any time during the study will <u>not</u> affect the care or support you receive now or in the future.

What will taking part in the study involve?

The study will involve taking part in an interview that will be conducted by the researcher (Lawrence Doi). If you express interest in taking part, you will receive a telephone call from the researcher to arrange a date, time and venue for the interview. A fellow researcher will be present during the interview. The interview will take place in a room within an NHS premises near you. Or if you prefer, you can have a telephone interview, whereby Lawrence will ring you at home at a time that is convenient to you.

Will I be paid for participating?

You will be provided with a £20 high street store voucher as a compensation for your time and effort in taking part in the interview.

What do I have to do?

If you are interested in taking part in this study, please complete and return the enclosed expression of interest form. Once your form has been received, you will be contacted by telephone to arrange a date, time and venue for the interview.

The interview may last up to an hour and it will be recorded with your consent. Only questions that will be of interest to this study will be asked. After the interview, the recordings will be typed out but anything that will identify you, for example, your name will be removed.

What are the possible disadvantages or risks of taking part?

Talking about drinking alcohol during pregnancy may be a sensitive issue. But the interview will focus on the information you have received from a health professional, your views and experiences of alcohol brief intervention. The interviewer (Lawrence Doi) will not be judging you in any way about the decision you have made about alcohol drinking. However, if you feel that taking part in the interview is distressing, you can decide to stop the interview at any time and withdraw from the study without giving a reason. If you wish to have further information at the end of the interview, Lawrence will be able to send you a list of useful contacts and websites.

What are the potential benefits of taking part?

Taking part in this study may be of no direct benefit for you but the information we gather may help to improve the quality of the delivery of alcohol brief interventions in future.

Will I be able to be identified from the results?

No. All information collected about you will remain strictly confidential. Nothing in the reporting will be able to identify you. Any information which might identify you will be removed from the report. Only the PhD supervisors from the Stirling University and the researcher will have access to the data from this study. All recordings will be securely stored and will be destroyed after this study.

What will happen to the results of the research study?

The results of the study will be submitted as a report for an award of PhD. The findings will also be published in academic journals. I will send you a short summary of the findings if you wish.

Who is organising and funding the research?

Lawrence Kweku Doi is organising this study. Dr Ruth Jepson, Dr Helen Cheyne and Prof Sally Wyke of the Department of Nursing and Midwifery at the University of Stirling are supervising him. The University of Stirling is funding this research.

Does the study have ethical approval?

The Department Research Ethics Committee, University of Stirling and NHS West of Scotland Research Ethics Committee 2 have approved this study.

For more information about the study, please contact one of the researchers below:

Lawrence Kweku Doi Department of Nursing and Midwifery University of Stirling Stirling FK9 4LA Tel: 01786 466112 Email: l.k.doi@stir.ac.uk	Dr Ruth Jepson Department of Nursing and Midwifery University of Stirling Stirling FK9 4LA Tel: 01786 466402 Email: ruth.jepson@stir.ac.uk

If you would like to speak to someone who knows about this research but is an independent advisor, please contact:

Professor William Lauder
Department of Nursing and Midwifery
University of Stirling
Stirling FK9 4LA
Tel: 01786 466345 Fax: 0178466344
Email: william.lauder@stir.ac.uk

If you would like to speak to a Midwife who knows about this research but is an independent advisor to this study, please contact:

Ms Sandra Smith
Maternity Services
St John's Hospital at Howden
Howden Road West
Livingston
West Lothian EH54 6PP

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET

Appendix 14. Topic guide for policy implementers

What other policy drivers, apart from H4, are there for implementing ABIs in antenatal settings?

Do you think prenatal period is the best time to deliver ABI to women and if so, at what point in the pregnancy?

Which group of health professionals are currently delivering ABIs to pregnant women? How do you think they have responded to being asked to deliver ABIs?

Do you think that midwives are best placed to deliver ABIs to women?

How long are midwives expected to screen and deliver ABI? When are they supposed to do this? Do you think that midwives are better placed to deliver ABI to women?

Do you think midwives delivering ABI at the booking appointment is the best approach?

What do you think are the main challenges that midwives may face in identifying and delivering ABI to women?

What is being done to ensure that ABI is adapted appropriately to antenatal population group?

What factors do you think might affect the uptake and delivery of ABI in the antenatal setting?

Considering many women don't realise that they are pregnant and continue to drink in the first trimester, what benefits will the ABI give to these women?

Do you think prenatal period is the best time to deliver ABI to women and if so, at what point in the pregnancy?

Considering that the evidence of effectiveness of ABI is limited in antenatal setting, what do you think are the challenges to implementing and delivering ABI in the antenatal setting?

What are the measures that have been put in place to facilitate ABI delivery in antenatal setting?

Are you collecting any data on uptake rates, completion rates and effectiveness of the interventions? Do you think they have informed the training needs of midwives in anyway?

What types of training and support are they currently receiving in order to deliver ABIs?

Are there any measures in place to monitor whether midwives are identifying and delivering ABIs to women who qualify?

Can you tell me the follow-up and referral strategy put in place for midwives to follow?

Do you think ABI is currently being delivered in a standardised way across all health boards and according to its original aims/objectives?

Do you think that booking appointment is the best time to discuss this issue?

What are your views on the alcohol screening tools currently in use on the TRAK maternity record system?

Appendix 15. Topic guide for pregnant women

A series of questions will drive the discussions forward. Outlined below is the interview guide that will be used. This will be interwoven with probes and prompts.

Were you given any information about alcohol by your midwife since becoming pregnant? Could you describe what happened?

What do you know about drinking alcohol in pregnancy?

Can you tell me from your point of view what you think about drinking alcohol during pregnancy?

What do you think the current recommendations are about drinking alcohol in pregnancy?

What do you think of these recommendations?

What do you think about other information given to pregnant women about alcohol consumption?

What do others around you say about it?

Whom did you discuss drinking alcohol in pregnancy with?

Do you think this information has affected the way you view alcohol consumption since you became pregnant?

What reasons (if any) have influenced you drinking?

What do you think binge drinking, high level of drinking, and low level of drinking is?

What would you consider as safe level of drinking in pregnancy?

Are you aware of any consequences of drinking in pregnancy on the unborn child?

Do you feel that your midwife made you more aware of the effects of drinking for the unborn baby?

What message do you think should be given to pregnant women who drink at high levels?

What message should be given to pregnant women who drink at low levels?

What do you think about encouraging pregnant women who are low drinkers to abstain altogether?

What do you understand about how alcohol is measured?

Did your midwife discuss alcohol measuring with you?

What do you think about the ‘unit system’ in measuring alcohol?

What sort of information do you think will be most appropriate or relevant to you?

Where would you like to receive information about alcohol?

When would you like to receive such information?

What do you think midwives think about women drinking alcohol during pregnancy?

Did you midwife ever discuss alcohol with you?

If **yes**, what happened?

If **no**, how would you have felt if she had?

At what stage in pregnancy would you feel comfortable to talk freely with your midwife about alcohol consumption?

How would you feel if your midwife suggested that you should change your drinking pattern and offered you help to do so?

Would you ever bring up the subject with your midwife or another health professional if you were worried about the way you drink?

Do you think that help should be available in the antenatal clinic for women who drink in pregnancy?

If yes, what sort of help do you think would be useful.

Appendix 16. Topic guide for pregnant women

One-to-one interviews

Can you tell me from your personal point of view what you think about drinking during pregnancy?

What clinical guidelines or recommendations about alcohol use in pregnancy do you currently know?

What do you think about them?

What information or advice is given to pregnant women about alcohol consumption?

What do you think about this information?

Do you think the content is appropriate to pregnant women?

Where do you think women primarily get their information about drinking during pregnancy?

Thinking about the women you see, what do you think are their views and understanding of alcohol drinking during pregnancy?

What do you think are the reasons why women reduce/abstain from alcohol when they are pregnant?

Do you think recent debates about the uncertainties of the effect of drinking on the fetus have affected your personal views on the issue?

How do you think pregnant women perceive these debates?

Has these uncertainties influence the way you advice pregnant women?

At what level of drinking do you think pregnant women should be advised about alcohol consumption?

What do you think about encouraging pregnant women who are low drinkers to abstain altogether?

What sort of information you think will be most appropriately target pregnant women who drink alcohol?

What do you think will encourage pregnant women to abstain from alcohol?

When do you think is the best time to provide advice to women at child bearing age?

How often do you discuss alcohol drinking with women?

How do you feel about discussing alcohol with women, especially those you think may drink too much?

Do you ever assess how much a woman drinks?

If yes, how do you do this and how do you feel about discussing their drinking.

How do pregnant women who drink alcohol react when you bring up the issue of alcohol?

Can you tell me your personal experiences in dealing with pregnant women on this issue?

What do you know about ABIs?

Have you received the training in screening and delivery of ABI? Prompt them to tell you what they thought.

Have you ever given an ABI to a woman?

If yes, tell me what normally happens or what issues you have encountered

If no, have you ever advised a women or given other help?

How did the women respond?

What do you think about giving ABIs in the antenatal setting? What are the barriers and facilitators?

Do you think your colleagues feel the same way as you?

Focus group

Could you tell me your role within the screening and ABI implementation process?

What are your opinions on how women report their alcohol intake to you?

Could you tell me what happens if a woman who has been drinking comes for an appointment?

How are you able to identify women who require ABI?

Can you tell me you views on the screening tools you are currently using to detect alcohol consumption in pregnancy?

How does the screening and ABI work within the booking appointment?

How long does it take on average to do a screening and to if necessary, offer an ABI?

What kind of pathway or protocol do you actually follow or what advice you are giving to women?

Do you have any idea about the number of ABIs you have delivered since it was implemented?

Have you noticed any change in the drinking habits of the women you screen or give ABI to?

What happens to the information you collect from women?

What kind of feedback are you expecting from the information you collect?

What arrangements are in place to refer women on if you need to?

What kind of support have you had as part of this initiative? Prompt for them to tell you more about it.

What has training or support added to your practice in terms of this initiative?

What would you say are the benefits of the screening and ABI to your practice?

What have been the challenges of implementing screening and ABI in antenatal care settings?

Do you think it will change practice in the longer term when the HEAT target finishes?

Appendix 17. Pregnant women's demographics

UNIVERSITY OF STIRLING

DEPARTMENT OF NURSING AND MIDWIFERY

Name:

Age:

Duration of pregnancy (in weeks):

Number of children:

Marital status: Yes ☐ No ☐

Employment Status: Yes ☐ No ☐

Appendix 18. Midwives consent form

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Tel: 01786 466112

CONSENT FORM – Midwives

Name of Researcher: Lawrence Doi *Please initial box*

1. I confirm that I have read and understand the information sheet dated 20/08/10 (version 1.4) for the above study. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that information collected during the study may be looked at by the research and supervisors, only where it is relevant to my taking part in this research. I give permission for these individuals to have access to the information I provide. ☐

4. I understand that the study will involve me taking part in a face to face interview or telephone interview. ☐

5. I understand that the face to face interview or telephone interview will be audio-recorded and destroyed at the end of the study. I understand that I will not be identifiable in the final report or publications. ☐

6. I agree to take part in this study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 19. NHS Research ethics approval letter (1)

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 3
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Mr Lawrence K. Doi
Student
University of Stirling
Department of Nursing and Midwifery
Stirling FK9 4LA

Date 11 Mar. 10
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Mr Doi

Study Title: **Prenatal alcohol consumption - a qualitative study exploring pregnant women and midwives knowledge, perceptions and attitudes.**
REC reference number: **10/S0709/7**
Protocol number: **1.2**

Thank you for your letter of 04 March 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter	-	15 January 2010
REC application	-	15 January 2010
Protocol	1.2	15 January 2010
Investigator CV	-	15 January 2010
Summary/Synopsis	1.2	15 January 2010
Disclosure Scotland - Mr L K Doi	-	18 January 2010
Copy of Unfavourable Opinion letter from WoSRES 2	-	21 December 2009
Letter from Dr R Jepson	-	10 January 2010
Approval for study letter from University of Stirling	-	11 November 2009
Letter of invitation to participant	1.2	15 January 2010
Evidence of insurance or indemnity	-	25 November 2009
Letter from Sponsor	-	25 November 2009
Dr R Jepson's CV	-	
Letter from University of Stirling - confirmation of registration as a PhD Candidate	-	12 October 2009
Participant Consent Form: Pregnant Women	1.2	15 October 2009
Participant Consent Form: Midwives	1.2	15 October 2009
Interview Schedules/Topic Guides	1.2	15 January 2010
Participant Information Sheet: Midwives	Version 1.3	04 March 2010
Participant Information Sheet: Pregnant Women	Version 1.3	04 March 2010
Response to Request for Further Information		04 March 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/S0709/7	**Please quote this number on all correspondence**

Good Luck with your study.

Yours sincerely

Liz Jamieson
Joint Committee Co-ordinator
On behalf of Dr Alex Crighton, Vice Chair

Enclosures: "After ethical review – guidance for researchers"
Copy to: Professor William Lauder

Appendix 20. NHS R&D approval letter (1)

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

DEN/JB/approval

04 March 2010

Mr Lawrence K Doi
Department of Nursing and Midwifery
University of Stirling
Stirling
FK9 4LA

NHS Lothian
Research & Development
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@luht.scot.nhs.uk

Director:
Professor David E Newby

Dear Mr Doi,

Lothian R&D Project No: **2009/P/GP/18**

Title of Research: Parental alcohol consumption - a qualitative study exploring pregnant women and midwives knowledge, perceptions and attitudes.

MREC No: 10/S0709/07 **LREC No:** N/A

CTA No: N/A **Eudract:** N/A

PIS: Version 1.2 dated 15 January 2010 **Consent:** Version 1.2 dated 15 January 2010

Protocol No: Version 1.2 dated 15 January 2010

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Following a REC final favourable opinion, final copies of all study documentation (with revised version numbers) should be sent, with the REC letter of favourable opinion, to the R&D office.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

Professor David E Newby
R&D Director

enc Research Governance Certificate ☑ (to be signed and returned)

Appendix 21. NHS Research ethics approval letter (2)

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 2
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Mr Lawrence K. Doi
Student
Department of Nursing and Midwifery
University of Stirling
Stirling
FK9 4LA

Date 17 Jun. 10
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Mr Doi

Study Title: **The alcohol brief intervention - developing an understanding of how it works in antenatal setting**

REC reference number: **10/S0709/34**
Protocol number:

The Research Ethics Committee reviewed the above application at the meeting held on 15 June 2010. Thank you for attending to discuss the study.

Ethical opinion

The Committee reviewed the study and agreed that there were no major ethical issues.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		28 May 2010
REC application		20 May 2010
Protocol	Version 2	20 April 2010
Investigator CV		
Participant Information Sheet: Pregnant Women	Version 2	20 April 2010
Participant Information Sheet: Stakeholders	Version 2	20 April 2010
Participant Consent Form: Pregnant Women	Version 2	20 April 2010
Participant Consent Form: Stakeholder	Version 2	20 April 2010
Letter of invitation to participant	Version 2	20 April 2010
Evidence of insurance or indemnity		25 May 2010
Letter from Sponsor		25 May 2010
Summary/Synopsis	Version 2	20 May 2010
Interview Schedules/Topic Guides	Version 2	20 April 2010
Expression of Interest Form	Version 2	20 April 2010
CV - Dr Ruth Jepson		
Report on PhD Panel Review		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/S0709/34	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Liz Jamieson

Liz Jamieson
Joint Committee Co-ordinator
On behalf of Dr Alex Crighton, Vice Chair

Enclosures:	List of names and professions of members who were present at the meeting "After ethical review – guidance for researchers"
Copy to:	Professor William Lauder

Appendix 22. NHS R&D approval letter (2)

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

CPP/ MJ/approval

1/07/2010

Mr Lawrence K Doi
Department of Nursing and Midwifery
University of Stirling
Stirling
FK9 4LA

NHS Lothian
Research & Development
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@luht.scot.nhs.uk

Director:
Professor David E Newby

Dear Mr Doi,

Lothian R&D Project No: **2010/R/RM/08**

Title of Research: The alcohol brief intervention - developing an understanding of how it works in antenatal setting

REC No: 10/S1001/33

CTA No: N/A

Eudract: N/A

PIS: v2, 20 April 2010

Consent: v2, 20 April 2010

Protocol No: v2, 20 April 2010

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Following a REC final favourable opinion, final copies of all study documentation (with revised version numbers) should be sent, with the REC letter of favourable opinion, to the R&D office.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

C Phillips

Dr Christine P Phillips
Deputy R&D Director

enc Research Governance Certificate ☐ (to be signed and returned)