CLINICAL PRACTICE GUIDELINE

ALCOHOL CONSUMPTION IN PREGNANCY

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Royal College of Physicians of Ireland
and
Health Service Executive

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Table of Contents
1. Revision History ................................................................. 3
2. Key Recommendations ....................................................... 3
3. Purpose and Scope ............................................................. 3
4. Background and Introduction .............................................. 4
5. Methodology ....................................................................... 5
6. Clinical Guidelines on Alcohol during Pregnancy .................. 6
7. Hospital Facilities ............................................................... 12
8. References .......................................................................... 13
9. Key Performance Indicators .................................................. 17
10. Implementation Strategy ...................................................... 18
11. Qualifying Statement .......................................................... 18
1. **Revision History**

<table>
<thead>
<tr>
<th>Version No.</th>
<th>Date</th>
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2. **Key Recommendations**

- There is uncertainty regarding what is a safe level of alcohol consumption in pregnancy. There is evidence that even low amounts of alcohol consumption during early pregnancy may increase the risk of miscarriage, therefore, while a cause and effect relationship cannot be established, pregnant women and women planning a pregnancy should be advised to avoid drinking alcohol in the first 12 weeks of pregnancy.

- Women should be advised that heavy drinking and “binge-drinking” during pregnancy (defined as more than 5 standard drinks or 7.5 UK units on a single occasion) may be harmful to the unborn baby and, in particular, are associated with the development of fetal alcohol syndrome (FAS).

- Although there is uncertainty regarding a safe level of alcohol consumption in pregnancy, at a low level there is no evidence of harm to the unborn baby, particularly after the first trimester. Indeed, there is evidence that low alcohol consumption in pregnancy is associated with better long-term outcomes. Women who choose to drink alcohol during pregnancy should be advised to drink no more than 1 to 2 units once or twice a week.

3. **Purpose and Scope**

The purpose of this guideline is to provide guidance for healthcare professionals on how to advise pregnant women and those considering pregnancy about the safety of alcohol consumption during pregnancy.

These guidelines are intended for healthcare professionals, particularly those in training, who are working in HSE-funded obstetric and gynaecological services. They are designed to guide clinical judgement but not replace it. In individual cases a healthcare professional may, after careful consideration, decide not to follow a guideline if it is deemed to be in the best interests of the woman.
4. Background and Introduction

Alcohol consumption during pregnancy is a topic that receives much public and professional attention with a large body of evidence in the literature about the potential effects on the developing embryo, fetus and child. It is generally accepted that both abusive and heavy drinking are associated with teratogenic effects, particularly intrauterine growth restriction, birth defects and neurodevelopmental problems (“Fetal Alcohol Syndrome”) (Riley et al 2011).

This is of growing importance given that alcohol consumption is prevalent among women of childbearing age and there is evidence that the proportion of women of childbearing age who drink heavily or binge-drink is increasing. In one study from Dublin, it was reported that 90% women consumed alcohol in the three months before pregnancy, with 65% drinking 0–5 units on average per week, 30% drinking 6–14 units per week and 5% drinking 15-20+ units per week. Over half of those who did consume alcohol reported at least one episode of binge drinking in the previous three months (Murphy et al 2013).

Additionally, data from the UK suggests that the proportion of women aged 16-44 years who drink more than 14 units per week has increased from 17% in 1992 to 33% in 2002, and the proportion of women who binge drink has increased concurrently (Henderson et al 2007, Rickards et al, 2004).

Given that 90% of women of childbearing age consume alcohol, and that at least half of all pregnancies are unplanned, it is inevitable that a proportion of fetuses are exposed to alcohol periconceptually and early in the first trimester. It is imperative, therefore, to have guidance for women and their caregivers about safety concerns associated with alcohol consumption in the antenatal period.

Most women who consume alcohol during pregnancy drink at low-moderate levels. It is important therefore to have clear, simple and evidence-based guidance about the safety or otherwise of alcohol on the developing fetus. Unfortunately, the literature that exists on alcohol and pregnancy is far from simple and often contradictory. There are a number of reasons for this.

Firstly, there are difficulties with data ascertainment. There will never be, for obvious reasons, a randomised control trial comparing outcomes in those women who abstain from alcohol consumption compared with those who drink low or moderate amounts and those who drink heavily. As a result, most studies rely on patient recall, which may be unreliable and bias outcomes.

Secondly, there are several factors that are thought to contribute to the degree to which the developing embryo is affected by prenatal alcohol consumption. It is not a simple dose-response relationship (Conover and Jones 2012). These factors include fetal genetic susceptibility, differences in the vulnerability of
different brain regions, timing of the embryological exposure and alterations in maternal metabolism (Maier and West 2001, Chiodo et al 2010).

Finally, there is concern that a publication bias may exist against those studies that conclude that there is minimal or no risk associated with maternal alcohol consumption during pregnancy (Conover 2012). Koren and Fernandes explored this hypothesis in 2010. They asked a panel of experts to review a study demonstrating adverse effects associated with maternal alcohol consumption and a second study finding no such problems. The 11 reviewers of the negative study (finding no adverse effects) tended to reject the paper more often when compared with the 11 reviewers of the positive paper (finding adverse effects). This tendency, if it translates into published literature, may lead to an overestimate of the risks associated with maternal drinking during pregnancy (Koren and Fernandes 2010).

Whilst there is an appealing simplicity for a recommendation for abstinence only, without sufficient evidence to support such a recommendation this advice may lead to undue anxiety or guilt in women who do consume alcohol during pregnancy and have an adverse outcome which may or may not be related. There is an onus, therefore, to present unbiased review of the existing literature to advise women and clinicians alike to make an informed choice about the decision to consume alcohol, or not, during the antenatal period.

5. Methodology

Medline, EMBASE and Cochrane Database of Systematic Reviews were searched using terms relating to alcohol and pregnancy, fetal alcohol syndrome and fetal alcohol spectrum disorder. Searches were limited to humans and restricted to the titles of English language articles published between 1970 and 2014. Relevant meta-analyses, systematic reviews, intervention and observational studies were reviewed.

Guidelines reviewed included:

6. Clinical Guidelines on Alcohol during Pregnancy

6.1 Identification of those at risk

In order to accumulate accurate data regarding the prevalence and outcomes associated with alcohol consumption during pregnancy all women should be questioned regarding their alcohol intake at their first antenatal appointment. A particular priority of antenatal screening should be to identify those who are at risk of heavy alcohol consumption during pregnancy and those with an alcohol addiction problem.

A number of risk factors for alcohol addiction have been identified (Chudley 2005). These include:

- Advanced maternal age
- Lower education level
- Smoking
- Lower socioeconomic status
- Paternal drinking
- Current drug use
- Poor nutrition
- Reduced access to antenatal care

A number of tools have been developed to assist with the accurate identification of those at risk. One such tool is the T-ACE, an adaptation of a traditional alcohol-screening test, the CAGE questionnaire, which was based on a 4-item scale including:

- Have you ever felt you should cut down on your drinking?
- Have people annoyed you by criticising your drinking?
- Have you ever felt bad or guilty about your drinking?
- Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (eye-opener)?

The T-ACE consists of the following 4 questions.

- Tolerance: "How many drinks does it take to make you feel high?" (More than 2 drinks = 2 points)
- Annoyed: "Have people annoyed you by criticising your drinking?" (Positive response = 1 point)
• Cut down: "Have you ever felt that you ought to cut down on your drinking?" (Positive response = 1 point)
• Eye opener: "Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover?" (Positive response = 1 point)

Any score of 2 total points or higher on the T-ACE survey indicates a positive screen for at-risk drinking (Sokol et al 1989). The T-ACE can identify 90% or more of potential risk drinkers (Chang et al 1998).

The identification of those at risk of heavy alcohol consumption during pregnancy or those with an alcohol addiction problem should lead to prompt referral to appropriate support services to reduce both fetal and maternal risk. The identification of those who consume low-moderate amounts of alcohol is also of importance for ongoing audit and analysis of outcomes.

6.2 Alcohol and the risk of miscarriage

There appears to be an increased risk of pregnancy loss in the first trimester in women who consume alcohol during this time, when compared to those who abstain (Henriksen et al 2004, Feodor Nilsson et al 2014). The evidence is strongest for those who drink heavily or binge drink in early pregnancy (Avalos et al 2014, Henriksen et al, 2004), though there is some evidence that even low-moderate alcohol intake increases the risk (Henderson et al 2007, Andersen et al 2012).

The best advice, therefore, is for women to abstain from drinking alcohol during the first trimester of pregnancy. It is important to remember, however, that many studies examining the relationship between early pregnancy loss and alcohol are subject to both confounding and ascertainment bias (Henderson et al 2007). Early pregnancy loss is a particularly common event, occurring in up to 25% of all clinical pregnancies. A cause and effect relationship with alcohol consumption cannot be established. Clinicians should be cautious not to apportion blame in women who miscarry who have consumed alcohol in the periconceptual period.

Women who are planning pregnancy who seek advice should be advised that there is an association between alcohol intake and miscarriage, so that reducing or abstaining from alcohol consumption in the periconceptual period is the best advice.

6.3 Alcohol and the risk of stillbirth
The association between low-moderate levels of alcohol consumption during pregnancy and the risk of stillbirth has been examined in a number of studies with conflicting results (Henderson et al 2007). A number of these studies suggested a protective effect with higher rates of stillbirth in women who did not drink at all. (Davis et al 1982, Marbury et al 1983, Little et al 1993).

There appears to be some evidence linking heavy or binge drinking during pregnancy and a higher risk of stillbirth (Strandberg-Larsen et al 2008). Data from the Danish National Birth Cohort of over 89,000 found that binge drinking three or more times during pregnancy was associated with an increased risk of stillbirth, with an adjusted hazard ratio of 1.56 (95% confidence interval 1.01-2.40).

### 6.4 Fetal alcohol syndrome

Fetal alcohol syndrome (FAS) was first described in the Lancet in 1973 (Jones and Smith 1973; Jones et al. 1973). It refers to the constellation of features associated with heavy maternal alcohol consumption during pregnancy. It is diagnosed when characteristic facial dysmorphology (short palpebral fissures, elongated mid-face, flattened maxilla), fetal growth restriction and central nervous system or neurodevelopmental abnormalities are present following antenatal alcohol exposure.

Worldwide estimates suggest that 0.97 per 1,000 live births are affected by FAS, representing a significant financial cost to healthcare services (Abel 1995, Klug and Burd 2003). One study from Dublin identified just 3 cases in 61,241 pregnancies, with one case in each of the low, moderate and heavy alcohol intake groups, an incidence the authors concluded was lower than expected (Murphy et al 2014).

The challenge with FAS prevention lies firstly, in the correct identification of those at risk and then with appropriate pregnancy interventions to prevent or reduce risk in those with alcohol dependence. There is a relative paucity of data in the literature regarding appropriate treatment specific to pregnant women who are identified as having an alcohol addiction problem.

A Cochrane review in 2008 did not identify sufficient evidence to evaluate the effectiveness of psychosocial interventions in pregnant women enrolled in alcohol treatment programmes, for either improving neonatal outcomes, maternal abstinence or treatment retention (Stade et al 2009). The review concluded that there is a need for high quality randomised controlled trials to determine the effectiveness of psychosocial interventions in pregnant women enrolled in alcohol treatment programmes. Similarly no data were available to determine the effectiveness of pharmacologic interventions in pregnant women enrolled in alcohol treatment programmes (Smith et al 2009).
Nonetheless, efforts should be made to identify those at risk and to ensure they engage with the appropriate medical, social and support services available to reduce fetal antenatal exposure. It is also important to identify those infants born with symptoms or signs of FAS promptly so that interventions may take place to reduce the ongoing risk to the mother’s own health, and to that of any subsequent offspring.

6.5 Alcohol and fetal anomalies other than fetal alcohol spectrum disorder

A systematic review in 2007 assessed the association between low-moderate levels of alcohol consumption and the incidence of malformations, including fetal alcohol effects, in the baby (Henderson et al 2007). Six studies met criteria for inclusion in the systematic review, and of these only one reported a significant association between low-moderate levels of alcohol consumption and malformations. However, that study included white women only and was unadjusted for potential confounders.

In a study of over 4700 cases of alcohol consumption during pregnancy, it was concluded that the risk of birth defects was increased in infants exposed to alcohol in-utero (Martinez – Frias at al 2004). However, while the odds ratios (ORs) in this group were increased for eye anomalies, limb defects and oral clefts, all of the confidence intervals included unity. Similarly, a case control study from a Norwegian population found that women who reported any binge-drinking during pregnancy were more likely to have an infant with an oral cleft, with higher ORs in those who drank more frequently. Again, however, all the confidence intervals included 1.0 (DeRoo et al 2008).

A study from the United States found that women who reported alcohol consumption during the periconceptional period had an increased risk of delivering an infant with a conotruncal heart defect, however no association with oral clefts was found (Grewal et al 2008). A series of papers originating from the Danish National Birth Cohort examined the association between maternal alcohol consumption and congenital anomalies in the offspring, including cryptorchidism (Strandberg-Larsen et al 2009), cardiac septal defects (Strandberg-Larsen et al 2011) and autism (Eliasen et al 2010). None of these studies identified an increased risk.

It is reasonable to conclude that, to date, there is no consistent evidence of adverse effects across different studies with which to draw conclusions or make recommendations.
6.6 Alcohol and childhood behavioural and cognitive outcomes

As the constellation of anomalies that define FAS includes neurodevelopmental anomalies, much attention in the literature has been focused on a possible dose response relationship between alcohol and childhood behavioural and cognitive outcomes. It has been hypothesised that those who consume low-moderate amounts of alcohol during the antenatal period may be at risk of neurodevelopmental, cognitive or behavioural problems that are less severe than those associated with fetal alcohol spectrum. This hypothesis, however, has not been confirmed in the literature with conflicting results.

One study of over 2000 women in Western Australia did not find any association between low levels of alcohol and childhood behavioural problems (O’Leary et al 2010). These authors did identify an increased risk of internalising behaviours in offspring exposed to heavy alcohol use in the first trimester, and an increased risk of anxiety/depression in offspring exposed to both moderate (≤ 7 standard drinks / week) and higher levels of alcohol.

In contrast, the Western Australian Pregnancy Cohort (Raine) Study of 2900 pregnancies with 14 years of follow up identified a clinically meaningful reduction in total, internalising and externalising behavioural problems in those children exposed to light and moderate drinking in the first 3 months of pregnancy (Robinson et al, 2010).

A series of papers published in 2012 from Denmark in association with the Centers for Disease Control and Prevention (CDC), Atlanta, USA, all failed to demonstrate any association between low to moderate alcohol consumption during pregnancy and the child’s intelligence, attention or executive function at 5 years of age. Furthermore, only weak and no consistent associations between maternal binge drinking and executive functions were observed. (Skogerbø et al, 2013; Falgreem Eriksen et al, 2012; and Kesmodel et al, 2012).

A recent systematic review of the effect of moderate alcohol consumption during pregnancy on speech and language outcomes in children found that language was not impaired as a result of low to moderate alcohol consumption during pregnancy (O’Keefe et al, 2014).

Data from the prospective UK Millennium Cohort study have been used to assess the effects of light drinking during pregnancy and the risk of socio-emotional difficulties, behavioural problems and cognitive deficits and the findings at 3, 5 and 7 years of age reported (Kelly et al 2009, Kelly et al 2012, Kelly et al 2013). Interestingly, these authors identified a J-shaped relationship between mothers’ drinking during pregnancy and outcomes. Children born to light drinkers had more favourable (lower) behavioural difficulties test scores and also more favourable (higher) cognitive test scores compared with non-drinkers.
It is reasonable to reassure women who drink low-moderate amounts of alcohol during pregnancy that they are highly unlikely to cause behavioural, emotional or cognitive harm in their offspring.

6.7 Alcohol and other perinatal outcomes

Data from over 5000 pregnancies in the Screening for Pregnancy Endpoints (SCOPE) study did not find any association between alcohol consumption before 15 weeks of gestation and small for gestational age, reduced birthweight, pre-eclampsia or spontaneous preterm birth (McCarthy et al 2013). Similarly data from a Dublin cohort of pregnant women reported similar perinatal outcomes for non-drinkers, women who abstained from alcohol in the first trimester, and women who drank in the first and third trimesters of pregnancy (Murphy et al 2014).

A systematic review in 2007 did not identify consistent evidence for adverse perinatal outcome associated with low-moderate alcohol consumption during pregnancy. Indeed, a mildly protective effect for a number of outcomes (stillbirth, fetal growth restriction, decreased birthweight) was found (Henderson et al 2007). Caution should be taken with interpretation of such results. One possible explanation is the “healthy drinker effect”, where women with a poor obstetric history are more likely to abstain in a subsequent pregnancy. Secondly, as many studies are relying on retrospective patient recall, women with healthy outcomes may be less likely to under-report alcohol consumption during that pregnancy.

6.8 Binge drinking and pregnancy

Binge drinking is an important topic for women’s health, as well as for the fetus and child, particularly given the increasing rates among women of childbearing age (Henderson et al 2007). Binge drinking is often associated with unprotected sexual intercourse, potentially leading to unplanned pregnancies with inadvertent fetal exposure to alcohol by virtue of continued binge drinking up to the time that the pregnancy is recognised.

Women inadvertently exposed to a single binge episode of alcohol early in pregnancy before pregnancy recognition can be reassured that the risks of adverse effects in their baby are likely low.

The most conclusive evidence linking binge drinking during pregnancy with adverse pregnancy outcome, is in relation to the development of the FAS. It has been consistently shown that women who consume 7-14 alcoholic drinks per week throughout pregnancy have an increased risk of growth defects, characteristic facial features, and behavioural and neurocognitive abnormalities in their offspring (U.S. Department of Health and Human Services, 2005).
The evidence for any association between binge drinking during pregnancy and other adverse pregnancy outcomes is, again, inconclusive. A systematic review on the topic published in 2007 found no convincing evidence of adverse effects of prenatal binge drinking, except possibly on neurodevelopmental outcomes (Henderson et al 2007). A second systematic review published in 2012 similarly found that neurobehavioral effects are the most commonly reported adverse outcomes following binge drinking in pregnancy, though the data, particularly in relation to malformations, were inconsistent (Conover et al 2012). The issue of escalating binge-drinking behaviours, particularly in young women, however, is a public health concern, and an important topic for both clinicians and policy-makers.

7 Hospital Facilities

All women should be questioned regarding alcohol consumption at their first antenatal visit. The hospital should ensure that this can take place in a discrete area with privacy. The information should be recorded clearly yet discretely.
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9. **Key Performance Indicators**

- The proportion of women questioned regarding alcohol intake at the first antenatal consultation.
- The proportion of women advised by a healthcare professional regarding alcohol consumption during the antenatal period.
- The proportion of women with risk factors for alcohol addiction identified in the antenatal period.
- The proportion of women with an alcohol addiction problem appropriately identified in the antenatal period.
- The hospital and national incidence of fetal alcohol syndrome (FAS).
10. Implementation Strategy

- Implementation through HSE National Women and Infants Programme (NWIP).
- Distribution of guideline to all members of the Institute and to all maternity units.
- Distribution to other interested parties and professional bodies.

11. Qualifying Statement

These guidelines have been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. Clinical material offered in this guideline does not replace or remove clinical judgement or the professional care and duty necessary for each pregnant woman. Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise.

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible for:

- Discussing care with women in an environment that is appropriate and which enables respectful confidential discussion.
- Advising women of their choices and ensure informed consent is obtained.
- Meeting all legislative requirements and maintaining standards of professional conduct.
- Applying standard precautions and additional precautions, as necessary, when delivering care.
- Documenting all care in accordance with local and mandatory requirements.