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**Evaluation of a Retrospective Diary for peri-conceptual and mid-pregnancy drinking in
Scotland: a cross-sectional study**

Running headline: Alcohol Retrospective Diaries in Pregnancy

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Conflict of Interests

The authors declare that they have no competing interests.

Abstract

Introduction. Heavy episodic ('binge') drinking among women in Scotland is commonplace; pre-pregnancy drinking is associated with continued antenatal drinking. Evidence for effectiveness of standardised antenatal alcohol assessment is lacking. Alcohol-exposed pregnancies may be missed. We assessed peri-conceptual and mid-pregnancy consumption using a week-long retrospective diary and standard alcohol questionnaires, and evaluated the agreement between these instruments.

Material and Methods. Cross-sectional study in two Scottish health board areas involving 510 women attending mid-pregnancy ultrasound scan clinics. Face-to-face administration of alcohol Retrospective Diary and AUDIT or AUDIT-C assessed weekly and daily alcohol consumption levels and patterns. Depression-Anxiety-Stress Scale (DASS-21) assessed maternal wellbeing. A sub-sample (n=30) provided hair for alcohol metabolite analysis. Pearson's correlation coefficient investigated associations between questionnaires and alcohol metabolite data.

Results. The response rate was 73.8%. The Retrospective Diary correlated moderately with AUDIT-C and AUDIT but elicited reports of significantly higher peri-conceptual consumption, (median unit consumption on 'drinking days' 6.8; range 0.4–63.8). Additional 'special occasions' consumption ranged from one to 125 units per week. Correlations between DASS-21 and Retrospective Diary were weak. Biomarker analysis identified three instances of hazardous peri-conceptual drinking.

Conclusions. Women reported higher consumption levels when completing the Retrospective Diary, especially regarding peri-conceptual 'binge' drinking. Routine clinical practice methods may not capture potentially harmful or irregular drinking patterns. Given the association between pre-pregnancy and antenatal drinking, and alcohol's known teratogenic effects, particularly in the first trimester, the Retrospective Diary may be a useful low-tech tool to gather information on alcohol intake patterns and levels.

Keywords: pregnancy; prenatal care; alcohol drinking; prenatal alcohol exposure; alcohol screening; biomarker; cross-sectional study

Abbreviations

AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	Alcohol Use Disorders Identification Test-C
DASS-21	Depression-Anxiety-Stress Scale-21
EtG	Ethyl Glucoronide
FAEE	Fatty Acid Ethyl Esters
HB	Health Board
RD	Retrospective Diary
SIMD	Scottish Index of Multiple Deprivation

• *Key Message*

Significant concerns exist about the identification of alcohol consumption peri-conceptually and during pregnancy.

A Retrospective Diary elicited much higher reports of alcohol consumption before and during pregnancy than standard tools. Formal validation is still required for use in pregnancy.

Introduction

In Scotland 40% of women aged 16-44 drink alcohol above recommended levels (1). Heavy episodic drinking is associated with unintended conception (2); while most abstain following pregnancy recognition (3), delayed recognition can hinder behaviour changes (4). Fetal alcohol syndrome and fetal alcohol spectrum disorder incur significant costs for the health service, social care, and educational and criminal justice systems (5). While proposed UK guidelines advocate abstinence in pregnancy (6) previous NICE (National Institute for Health and Care Excellence) guidelines qualified this: women who continue drinking should drink “no more than 1 to 2 UK units once or twice a week” (7); a UK unit corresponds to 7.9g or 10ml of ethanol (8). Drinking in pregnancy is a sensitive topic; detailed questioning may be difficult for midwives trying to establish a therapeutic relationship (9).

While only considered estimates (8), consumption rates during pregnancy vary from 8% in the USA (10) to 25-40% in the UK (11), and 63% in Dublin (12). Problems include recall, denial, social desirability bias, conflicting advice (13) and methodological difficulties. Focusing on overall levels may mask heavy episodic (‘binge’) drinking, an important teratogenic factor.

While self-report remains the preferred UK approach, a systematic review of instruments, including the Alcohol Use Disorders Identification Test (AUDIT) (14), its 3-item version AUDIT-C (15), and others (T-ACE, TWEAK, CAGE, NET) questioned their performance as stand-alone tools during pregnancy (16). Focusing on a cut-off score indicative of overall hazardous or harmful drinking rather than consumption levels and patterns may miss clinically significant non-dependent or irregular drinking. Biological marker testing is expensive (17).

Prospective diaries have been found to elicit higher reports of alcohol use in pregnancy than self-report questionnaires (18), and interviews offer the possibility of probing for more accurate information (19). However, capturing prospective peri-conceptual or early pregnancy data, while feasible, is logistically difficult. The well-established Retrospective Diary (RD) approach (20) - and the similar Time-Line Follow-Back (TLFB) (21) – offer an alternative approach but, to our knowledge, have not been used in pregnancy in the UK. While the TLFB is comprehensive, completing it takes some time. The RD, taking less time, may be more feasible in clinical practice. We therefore set out to evaluate RD use, comparing it with standard questionnaires in two Scottish health board (HB) areas. We assessed

agreement with maternal wellbeing measures and, in a sub-sample, with metabolite biomarkers. We specify how much pregnant women reported drinking before conception or before pregnancy confirmation (which we define as ‘peri-conceptual’) as well as during pregnancy.

Material and Methods

This cross-sectional study was in two Scottish HBs, which both include urban and rural areas: HB1 (NHS Fife) population 354 000; HB2 (NHS Ayrshire and Arran) population 368 000. Women attending their mid-pregnancy ultrasound scan (19-21 weeks gestation) were recruited from February-June 2015. All pregnant women aged sixteen or over were sent invitation letters one week in advance. Researchers obtained written consent after discussion in a private room before or immediately following the scan, whichever was convenient. Our limited exclusion criteria increased representativeness: only women under 16, or those deemed by clinic staff or researcher to be unable to understand the nature of the study, were ineligible. Women were not approached if an anomaly had been identified, or if they appeared visibly distressed. Participants received a £10 ‘thank you’ voucher.

In a face-to-face discussion, consenting women provided socio-demographic information (age, parity, gestation, and marital, occupational, educational, ethnic and smoking status); postcodes generated Scottish Index of Multiple Deprivation [SIMD] scores. Women completed the Depression-Anxiety-Stress Scale (DASS-21) (22) (seven questions for each of three negative emotional states) and the HB’s standard alcohol questionnaire. HB2 uses AUDIT, a ten-item questionnaire assessing consumption (frequency, amount, effects). In HB1 a modified three-question version is applied twice: AUDIT-C [A] for the previous thirty days; AUDIT-C [B] for pre-pregnancy. Completing the AUDIT / AUDIT-C took two minutes. Lastly, women completed two week-long RDs, which typically took five minutes: RD1 for the peri-conceptual period (“Before you were pregnant / before you knew you were pregnant”), RD2 for a recent mid-pregnancy week (supporting information file – RD). The RDs established firstly whether the woman drank at all (if not, the interview ended); if she did drink, when and with whom, and whether she had a ‘typical’ drinking pattern. Finally, she listed those drinks consumed on ‘drinking days’. Actual-size ‘flashcards’ were used to prompt recall and accuracy over drink sizes. From these responses daily and weekly alcohol unit totals were calculated.

We evaluated the RD against the locally-used screening tools. The researcher entered data for all drinking days in the specified timeframe.

For those who did not drink alcohol every week, RD data were adjusted to accommodate 'drinking weeks' frequency. When consumption above recommended pre-pregnancy guidelines was identified, the woman was offered details of local support services.

Once recruitment was nearing completion hair samples from thirty participants (HB1 n=11; HB2 n=19) were collected for biomarker assay; cost considerations restricted the sample size. We wanted to assess the feasibility of biomarker analysis in this population: this may offer a solution to the sensitive subject of recording consumption. While expensive, biomarkers provide an objective assessment of consumption over specified periods. These women received an extra £5 voucher. Women using peroxide or with short hair (less than 6 cm) were ineligible. Fatty Acid Ethyl Esters (FAEE) reflect consumption over the preceding six months (i.e. including pre-conception weeks for these women); Ethyl Glucuronide (EtG) reflects consumption over three months. We used Pragst et al.'s (17) thresholds indicative of excessive drinking: FAEE >0.5 ng/mg; EtG >30 pg/mg. Analysis was conducted by Randox Laboratories.

Ethical Approval was granted in July 2014 by the East of Scotland Research Ethics Committee 1 (ref. 14/ES/0023).

Statistical analyses

Based on the latest available birth rate (58 590) and 95% confidence, a total sample of 456 was estimated to detect a 5% proportion drinking more than 14 units a week peri-conceptually (the recommended limit for non-pregnant women). The biomarker assay's recruitment quota was thirty women.

Total daily and weekly alcohol unit consumption was estimated using Excel (Microsoft Office 2013). Using both paper copies and electronic files meant missing data were rare; any instances were confirmed at monthly review meetings. Data were then exported to SPSS version 22 for full analysis.

Histograms of all continuous variables were produced to examine their distributions, in particular skewness, and to identify any extreme observations. There was no indication of

any outlying data points and all values complied with the exclusion criteria. Normality of distribution of continuous data was assessed by visual inspection, coefficient of skewness and application of the Shapiro-Wilks test. Between-group comparisons of continuous measures were made using *t* tests for plausibly normal data (e.g. age) and the Mann-Whitney U for skewed data (e.g. total alcohol unit consumption). χ^2 was used to examine between-group differences in categorical variables, including ethnicity, smoking group and excessive alcohol consumption. Agreement between RD and standard questionnaires was estimated using Kappa. Pearson's correlation coefficient explored agreement between RD, AUDIT / AUDIT-C, DASS-21 and alcohol metabolite data.

Age was plausibly normally distributed. Gestation, booking gestation, cigarette consumption, DASS-21 and its component scores, AUDIT and AUDIT-C, and the numbers of alcohol units consumed peri-conceptually and during pregnancy, were positively skewed. SIMD was plausibly uniformly distributed.

Results

We recruited 510 women (HB1 n=274; HB2 n=236; response rate 73.8%). Fifteen potentially eligible women were not approached: 12 because they had received bad news at the scan, two whom the researcher knew personally, and one whom the midwife felt had insufficient English language skills to understand the nature of the study. Reasons for declining participation included “don’t drink” (n=4); “too busy” (n=6); “feeling unwell” (n=1); “working nightshift” (n=1). We exceeded our target in order to reach our hair samples quota: approximately one in five of those asked agreed to provide a hair sample. When compared with a random sample of women attending that clinic, study participants were found to be similar regarding age, deprivation score and ethnicity, but were more likely to be primiparous and (in HB1) to be smokers (Table 1).

Identification of peri-conceptual drinking

For women who drank (470/510), RD-assessed consumption ranged from 0.4-63.8 units daily (median 6.8), and from 0.4-94.5 units weekly (median 8.0). The RD identified 19.6% (100/510) drinking over 14 units a week peri-conceptually, although not always every week. Fifty-five (10.8%) did so weekly; fifteen (2.9%) drank over 14 units a week every 1.5-2 weeks; fifteen did so up to every fourth week, with ‘non-drinking weeks’ in between.

When compared with responses to the AUDIT / AUDIT-C question “How many units of alcohol did you drink on a day when you were drinking?” the RD assessment of mean daily alcohol consumption on ‘drinking days’ was significantly higher (Table 2). For example, the fifth data column shows that, when completing the RD, 66 women in HB1 said they drank 10+ units on a drinking day. Just previously, when completing the AUDIT-C, only 42 cited this amount; 17 reported 7-9 units, and seven reported 5-6 units. Table 2 excludes the 40 teetotal women.

Significantly more women reported peri-conceptual ‘binge’ drinking (six or more units on one occasion) when completing the RD compared with AUDIT / AUDIT-C - HB1: 53.3% (146/274) vs. 11.7% (32/274) [$\chi^2=108.64$, $df=1$, $p<0.001$]; HB2 50.8% (120/236) vs. 21.2% (50/236) [$\chi^2=45.05$, $df=1$, $p<0.001$].

In HB2, 56 women volunteered that on birthdays, anniversaries, and holidays they drank over and above their usual consumption, so the researchers re-applied the RD1. Additional unit consumption ranged from 1-44 daily and from 1-125 weekly.

Identification of drinking since pregnancy recognition

Of the 92 women (18.0%) whose RD2 responses indicated pregnancy drinking, 55 (59.7%) said this was just once or twice. However, 14 (2.7%) still drank weekly, and another ten (1.9%) did so fortnightly or monthly. 'Drinking days' intake ranged from 0.4-14.0 units (median 1.5); weekly intake ranged from 0.4-24.0 units (median 1.5). Overall identification of reported drinking by RD and AUDIT-C in HB1 was not significantly different: 41/274 (14.9%) and 36/274 (13.1%) respectively ($\chi^2=0.377$; $p=0.54$).

Excess consumption during pregnancy

The AUDIT-C identified four women who had drunk more than two units on a single occasion (the advised upper limit (7)) in the previous month; the RD identified ten ($\chi^2 =2.63$ [df=1]; $p=0.104$) (range 0.5-4.2 units). The same comparison could not be made in HB2: AUDIT covers the previous year, but does not ask specifically for drinking during pregnancy. However, the RD identified 18/236 (7.6%) women who reported drinking more than two units on a single occasion (range 2.3-14 units).

Correlation of RD weekly unit estimates and other measures

Retrospective Diary estimates of weekly peri-conceptual consumption correlated moderately with AUDIT total scores in HB1 ($r=0.65$) and with AUDIT-C [B] scores in HB2 ($r=0.64$). Correlations with DASS-21 (sub-scale and total scores) were weakly positive. Correlations between RD weekly estimates and hair metabolites were weak (EtG) and low-moderate (FAEE). Values of r between RD estimates of pregnancy consumption and all other measures were less than 0.36 (Table 3).

Excess consumption estimated by alcohol metabolites

Hair samples were obtained from 30 women. In nine cases FAEE analysis could not be performed due to insufficient sample; this was also true of one EtG analysis. Three of the 21 analyses indicated 'hazardous' peri-conceptual consumption (FAEE >50 ng/mg). Two of these three women recorded heavy episodic consumption in the RD; none did so when completing the AUDIT. Correlations with the RD were low-to-moderate. All EtG assay results were well below the 30 pg/mg threshold for hazardous drinking (17).

Discussion

The 7-day RD in this two-site cross-sectional study showed moderate-to-strong correlation with standard questionnaires. However, higher consumption levels were recorded when completing the RD, notably regarding peri-conceptual ‘binge’ drinking. While we cannot say whether our findings apply elsewhere, or whether repeated measures would confirm our analysis, this benefit of RDs over other consumption estimates has already been noted over some time (23). However, retrospective assessments can lead to over-reporting (24). Prospective diary-keeping may provide greater accuracy (18) but longitudinal use involves considerable participant commitment (25). Assessing contemporaneous peri-conceptual consumption poses logistical difficulties: women would need to be recruited before they became pregnant, with those becoming pregnant followed up for the early weeks of gestation. The RD, while subject to recall bias, can be used with those for whom the pregnancy is already established, which may increase the likelihood of participation. A combined retrospective and prospective approach may offer the most feasible means of recruiting and following women up.

Establishing those days of the week on which alcohol is ever drunk, then confirming the type and number of drinks consumed, appears to be more effective than asking women how many units they usually consume. One participant commented that this approach “makes you think about the drink”, which may mitigate recall bias, and reflects the TLFB approach (21). The RD, being slightly quicker to complete than the TLFB, would potentially be more easily incorporated into clinical practice (20). Anonymising the data may have encouraged greater honesty than would occur in clinical practice. While the AUDIT form has small (5mm-20mm) ‘thumbnail’ images of five common drinks, our use of actual size ‘flash cards’ of all popular drinks may have prompted more accurate recognition of actual consumption.

Given the known harmful effects of bingeing (even when not exceeding weekly limits) and the association between pre-pregnancy and pregnancy drinking (26), accurate reporting of patterns is essential. However, concerns have been raised about identification of levels and patterns by existing tools. Social desirability bias and stigma may cause under-reporting (13). Questionnaires using thresholds for brief interventions may not accurately identify problem drinkers and an alcohol-exposed pregnancy. Drinking in pregnancy is an international phenomenon, and we believe the essential lesson from this study – that the RD elicited many more reports of heavy consumption - to be instructive. RDs have been used internationally in various populations, and our 73.8% response rate suggests good acceptability. Our aim was

not formally to validate the RD for pregnant women, but to evaluate its use against standard tools.

While completing the RD takes longer than standard tools, a form which prompts recall may assist unconfident practitioners. Tackling lack of confidence has no single simple solution (27). Face-to-face administration has resource implications but the opportunity to discuss consumption patterns and levels may increase accuracy (19). The Scottish Government, which has prioritised alcohol brief interventions in pregnancy, estimates that 17% of women exceed weekly limits (1). Our finding that 19.6% said they did this peri-conceptually indicates that many are not optimising pre-conceptual health (8). We believe the RD captures consumption patterns and levels which other tools miss, although formal validation in pregnancy is still required. A future trial could test the RD against the ‘gold standard’ TLFB and standard tools.

The AUDIT and AUDIT-C forms do not provide weekly totals for comparison, and their categories (1-2 units; 3-4 units, etc.) also do not allow for direct comparison with official recommendations (e.g. ‘no more than 2-3 units’ on a single occasion). While consumption levels dropped sharply following pregnancy recognition (cf. (3)), a minority continued drinking. Payne et al claim that since many women delay motherhood, pregnancy only occurs once alcohol consumption patterns are well established, making it harder to cut down or stop (28).

Unintended pregnancy (estimated at 34-38% in Western and Northern Europe) is an additional consideration. Pre-pregnancy drinking patterns may persist if pregnancy recognition is delayed. Despite alcohol’s link with psychosocial ill health being well attested (29), the RD correlated weakly with DASS-21 – possibly due to questionnaire timing. Having just seen their baby’s image on a screen, some women may have under-reported poor psychological wellbeing. If the woman appeared upset, or an anomaly had been identified, she was not approached.

Our detection rate of 18.0% drinking alcohol since pregnancy recognition is lower than other UK and mainland Europe estimates (11, 30). Twenty-eight women admitted exceeding the recommended single-occasion limit of two units (five reported drinking more than six units), and eleven (2.2%) said they exceeded the four-unit weekly limit (7). To advise abstinence in pregnancy, but then – as NICE did at the time (7) – to suggest an apparently safe level may have created uncertainty.

We can conclude little from a low-moderate association between biomarker and RD data. Biomarker-identified ‘hazardous drinkers’ were identified by the RD as drinkers but not as the heaviest drinkers; they were not identified as heavy episodic drinkers by AUDIT. EtG results indicated that half the small sub-sample tested had drunk alcohol in the preceding three months. The proportion drinking in pregnancy may be higher than detected by questionnaires alone.

The Scottish HB areas in this cross-sectional study are not ethnically diverse. Primiparous women and, in HB1, smokers were more likely to be recruited. While very few women were ineligible, selection bias may still have occurred. Those declining rarely explained why, but, given the study’s purpose, some heavy drinkers may have felt disinclined to participate - as has been found in other studies - but the extent of this is not known.

Women who consciously under-reported consumption may have been disinclined to provide a hair sample – also a potential selection bias. Our planned biomarker analysis was limited, and failing to obtain sufficient samples in all cases precluded a full analysis.

The RD takes longer to complete than AUDIT / AUDIT-C, although less time than the TLFB. Recall bias may have been an issue. We did not ask about the timing of pregnancy recognition to distinguish pre- and post-conceptual drinking.

Many ‘drinking weeks’ were not ‘typical’, leading to additional analysis to account for their frequency. Obtaining the data from ‘extra’ drinking on special occasions entailed re-applying the RD form. So as not to affect the completion of AUDIT / AUDIT-C these were always completed before the RD, leading to a possible order effect.

Conclusions

Assessing pre-pregnancy as well as pregnancy drinking is important. Logistically, a retrospective approach is more feasible. However, screening using recommended thresholds for brief interventions may not identify alcohol-exposed pregnancies. Patterns of pregnancy drinking are irregular and are poorly captured by existing instruments. The RD correlated moderately with standard questionnaires, but obtained higher reports of consumption levels, including significantly higher estimates of peri-conceptual binge drinking; some of this occurred without exceeding recommended weekly limits. Recognising heavy drinking is an important step in the identification of those requiring specific interventions. Given the link between heavy pre-pregnancy drinking and continuing pregnancy drinking, RDs appear to offer significant benefits. Their ease of use make them amenable to adoption in clinical practice.

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