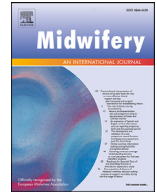




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Differential effectiveness of a practice change intervention to improve antenatal care addressing alcohol consumption during pregnancy: Exploratory subgroup analyses within a randomised stepped-wedge controlled trial

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ARTICLE INFO

Article history:

Received 28 April 2022

Revised 21 October 2022

Accepted 24 October 2022

Keywords:

Antenatal care
Alcohol
Pregnancy
Maternity
Implementation
Subgroup

ABSTRACT

Objective: A practice change intervention demonstrated improvements in the provision of antenatal care addressing alcohol consumption. The aim of this study was to explore whether the effectiveness of the intervention differed between subgroups of pregnant women and types and location of maternity services.

Design and Setting: Post-hoc exploratory subgroup analyses of the outcomes from a randomised stepped-wedge controlled trial conducted with all public maternity services within three sectors of a local health district in Australia.

Measurements: Two outcomes (receipt of alcohol assessment and complete care) measured at two visit types (initial and subsequent) were included in analyses. Logistic regression models explored interactions between pre-post differences and subgroups of women (age, Aboriginal origin, education level, disadvantage, gravidity and alcohol consumption in pregnancy) and services (geographic remoteness, service and provider type/s) that have been reported to be associated with variation in guideline implementation.

Findings: Surveys from 5694 women were included in the analyses. For the initial visit, no significant differential intervention effects between subgroups of women or type/location of services were found for either outcome. For subsequent visits, the intervention effect differed significantly only between Aboriginal origin subgroups (Aboriginal OR: 1.95; 95% CI: 0.99-3.85; non-Aboriginal OR: 5.34; 95% CI: 4.17-6.83; $p < 0.01$) and women's alcohol consumption in pregnancy subgroups (consumed alcohol OR: 1.28; 95% CI: 0.59-2.78; not consumed alcohol OR: 5.22; 95% CI: 4.11-6.65; $p < 0.001$) for assessment of alcohol consumption.

Key conclusions: These exploratory results suggest that the intervention may have had similar effects between different subgroups of women and types and location of services, with the exception of women who were non-Aboriginal and women who had not consumed alcohol, for whom the intervention was potentially more effective.

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Implications for practice: The practice change intervention could be implemented with different maternity service and provider types to effectively support improvements in antenatal care addressing alcohol consumption. These exploratory results provide further data for hypothesis generation regarding targeted areas for the testing of additional strategies that enable Aboriginal women to benefit equally from the intervention, and to ensure those women most in need of care, those consuming alcohol during pregnancy, have their care needs met.

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Introduction

Alcohol consumption during pregnancy can increase obstetric risk and adversely affect fetal development (Henderson et al., 2007; O'Leary et al., 2009; Patra et al., 2011). In recognition of such harms, many countries have released guidelines that recommend pregnant women do not consume alcohol (Butt, 2011; National Health and Medical Research Council, 2020; The Danish National Board of Health, 2010). Despite this, the prevalence of alcohol consumption during pregnancy remains high in a number of countries, including Ireland (60.4%), Denmark (45.8%), United Kingdom (41.3%) and Australia (35.6%) (Popova et al., 2017). There are many reasons why women consume alcohol in pregnancy, including: societal pressure; coping with adverse life experiences; alcohol dependence; cultural/traditional custom; lack of awareness of adverse effects on the fetus; and mixed messages from health professionals (Lyall et al., 2021; Popova et al., 2022).

Health services are a critical setting for addressing this risk as most women will access antenatal care (Australian Institute of Health and Welfare 2020) and interventions delivered by health professionals are effective in increasing alcohol abstinence during pregnancy (Ujhelyi Gomez et al., 2021). Antenatal care guidelines in Australia and elsewhere recommend all women receive, at their initial antenatal visit and throughout pregnancy: i) assessment of their alcohol consumption; ii) advice not to consume alcohol and explanation of the risks; and iii) referral to specialist support if required (Australian Government and Department of Health, 2020; World Health Organisation, 2014). However, these guideline recommendations are sub-optimally implemented in a number of countries including Australia (Doherty et al., 2019; Waller et al., 2016), United States (Arnold et al., 2013), Norway (Wangberg, 2015) and Denmark (Kesmodel and Kesmodel, 2011). For example, an Australian study found that less than one-third (27.9%) of pregnant women received guideline recommended care at their initial antenatal visit and 3.8% in subsequent visits (Doherty et al., 2019). Cross-sectional studies have also reported that such care is inconsistently provided, with characteristics of pregnant women (younger age, first pregnancy, lower education, not residing in an advantaged area, and of Aboriginal origin) and maternity services (rural based location and seeing a midwife or other provider, such as an Aboriginal Health Worker) associated with increased provision of care (Cheng et al., 2011; Davis et al., 2008; Doherty et al., 2019; Leroy-Creutz et al., 2015). This may be due to antenatal providers prioritising care for groups of women whom they assume are consuming alcohol or are less likely to be educated about the risks (Cheng et al., 2011; Doherty et al., 2019; Jones et al., 2011).

Two controlled trials to date have sought to improve the provision of antenatal care addressing alcohol consumption during pregnancy (Bazzo et al., 2015; Doherty et al., 2022). The first trial, conducted with four Italian public hospitals in 2013, found that action research and training significantly increased midwives' provision of guideline-consistent alcohol advice in a small sample (N=67) of pregnant women (intervention: 53% vs control: 20%; RR: 2.66; 95% CI: 1.27-5.56) (Bazzo et al., 2015). The second, undertaken by the

author team, was a trial of a multi-strategy practice change intervention conducted with all public maternity services within three sectors (one urban; two regional/rural) of a local health district in Australia. A seven-month intervention was delivered to all antenatal providers (medical, midwifery and Aboriginal Health Workers) to facilitate the routine provision of a recommended model of care to all women at three antenatal visits (initial, 27-28 weeks gestation and 35-36 weeks gestation) (Doherty et al., 2022). The intervention was found to be effective for all primary outcomes at all three time points, including: assessment of alcohol consumption (OR: 2.63; 95% CI: 2.26-3.05; $p < 0.001$); advice not to consume alcohol during pregnancy and of potential risks (OR: 2.07; 95% CI: 1.78-2.41; $p < 0.001$); complete care relative to alcohol risk level (advice and referral) (OR: 2.10; 95% CI: 1.80-2.44; $p < 0.001$); and all guideline elements relative to alcohol risk level (assessment, advice and referral) (OR: 2.32; 95% CI: 1.94-2.76; $p < 0.001$) (Doherty et al., 2022). Greater intervention effects were found for the 27-28 weeks and 35-36 weeks gestation antenatal visits compared with the initial antenatal visit (Doherty et al., 2022). The model of care was also reported to be acceptable to both Aboriginal (95.5%) and non-Aboriginal (98.8%) women (Doherty et al., 2022).

There is increasing attention in the field of implementation science for an equity lens to be integrated into the design and conduct of practice change interventions so that they reach and effectively reduce health disparities among vulnerable groups (Brownson et al., 2021; Kerkhoff et al., 2022). It has also been recognised that limiting the reporting of trial outcomes to the overall effectiveness of practice change interventions does not answer the question for whom the intervention is effective? (Albrecht et al., 2013; Powell et al., 2019; Proctor et al., 2011) To address this, the standards of evidence for effective programs and policies developed by the Society for Prevention Research recommends that the effects of interventions be explored for subgroups within study samples as defined by sociodemographic and risk characteristics (Flay et al., 2005). In trials that have demonstrated overall effectiveness, such as the practice change intervention conducted by the author team (Doherty et al., 2022), it is possible that the intervention had a large effect for one subgroup and no or lesser effect for another (Flay et al., 2005). Exploring differences in intervention effects between subgroups provides context to trial outcomes and elicits useful information to guide further development and tailoring of the intervention to ensure equitable access to support and care.

Consistent with such recommendations, a number of implementation trials in healthcare settings have conducted subgroup analyses to explore differences in intervention effectiveness, including trials specific to maternity care (Hajek et al., 2001; Manfredi et al., 2011; Molina et al., 2020). For example, a secondary analysis of the BetterBirth trial that provided peer coaching to improve adherence to essential birthing care practices examined the effect of the intervention by two types of professional groups (nurses and auxiliary nurse midwives) and found no significant differences between groups in adherence at two months (64.1% vs 68.1%; $p = 0.76$) and 12 months (56.1% vs 49.2%; $p = 0.69$) after the commencement of coaching (Molina et al., 2020). Further, a trial in the United States that implemented clinical practice guidelines,

educational meetings and materials and outreach visits to improve the provision of smoking cessation care for pregnant women found significant differences in receipt of advice for women attending non-medical clinics versus medical-led clinics (OR: 2.08; 95% CI: 1.48–2.94 vs OR: 0.60; 95% CI: 0.38–0.96; $p < .001$). There were, however, no significant differences between clinic types in referral to smoking cessation counselling (Manfredi et al., 2011). A third trial conducted in the United Kingdom that also sought to improve smoking cessation care found similar rates of care provision between current smokers and ex-smokers (asked to blow into CO monitor: 95% vs 95%; given booklet to read: 100% vs 100%; explained that there would be a follow-up: 72% vs 75%) following the implementation of educational meetings, educational materials and reminders with midwives (Hajek et al., 2001).

It is unknown whether practice change interventions seeking to improve antenatal care addressing alcohol consumption during pregnancy are effective for all types of maternity services and groups of pregnant women as neither of the two studies conducted to date (Bazzo et al., 2015; Doherty et al., 2022) reported effect by subgroups. To address this gap, post-hoc subgroup analyses were conducted to explore the differential effectiveness of a multi-strategy practice change intervention in improving antenatal care addressing alcohol consumption during pregnancy between subgroups of pregnant women and maternity services.

Methods

Study design and setting

This study is a secondary exploratory subgroup analysis of the primary outcomes from a randomised stepped-wedge controlled trial (Kingsland et al., 2018). The research question was developed in partnership with maternity service partners who sought to contextualise the overall trial outcomes. The trial was conducted in all public maternity services in three geographically and administratively defined sectors (clusters) of a single Local Health District in Australia from July 2017 to May 2020. The maternity services provide antenatal care to 6,100 women annually (70% of births in the district) in one major city (Sector One: 4300 births per annum) and two regional/rural areas (Sectors Two and Three: 1200 and 600 births respectively) (Australian Institute of Health and Welfare 2020). The effect of the intervention was determined by comparing practice change outcomes between the pre-intervention and post-intervention periods for the three sectors combined, as previously reported (Doherty et al., 2022). The trial was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12617000882325). The study was conducted in accordance with the Declaration of Helsinki, relevant ethics institutions approvals (Hunter New England Local Health District: 16/11/16/4.07, 16/10/19/5.15; The University of Newcastle: H-2017-0032, H-2016-0422; and Aboriginal Health and Medical Research Council: 1236/16) and an Aboriginal Health Impact Statement that was endorsed by the Hunter New England Aboriginal Health Unit prior to study commencement.

Participant eligibility and recruitment

All 28 antenatal care teams within the public maternity services participated in the study, including: 13 hospital and community-based midwifery clinics; five hospital medical clinics; five Aboriginal Maternal Infant Health Services (AMIHS); three midwifery continuity of care group practices; one specialist service caring for women with complex pregnancies; and one specialist service caring for women with social vulnerabilities. Three hundred and twenty-nine antenatal care providers, including 233 midwifery staff, 82 medical staff and 14 Aboriginal Health Workers delivered

antenatal care across these teams during the intervention period and were eligible to receive the practice change support.

All women had the potential to receive the recommended model of care when attending their routine antenatal visit at three time points: initial visit; 27–28 weeks gestation visit; and 35–36 weeks gestation visit. To be eligible to participate in surveys for outcome data collection, women had to: be 18 years or older; be 12 to 37 weeks gestation; have a sufficient level of English to complete the survey; and be mentally and physically capable of completing the survey. Women were ineligible for the surveys if they had: been determined by clinical discretion to be ineligible; received the majority of their antenatal care through a private provider; already given birth; a negative pregnancy outcome; already selected to participate in the study in the past four weeks; or previously declined participation. Extracts from the maternity service's medical record and appointment systems were used to generate a weekly sample of women who were sent an information statement. Aboriginal and Torres Strait Islander women (the term Aboriginal will be used from this point) and/or women attending an AMIHS were first sent a text message offering survey completion by either telephone or online. Non-Aboriginal women were called to invite participation in the interview with online mode offered if the telephone interview was declined.

Intervention

A guideline-consistent model of care (Australian Government and Department of Health, 2020; World Health Organisation, 2014) was developed for implementation by antenatal providers as part of routine antenatal care at the initial antenatal visit; 27–29 weeks gestation antenatal visit; and 35–37 weeks gestation antenatal visit. The elements of the recommended model of care were:

- i) assessment of alcohol consumption using the three item Alcohol Use Disorders Identification Test Consumption tool (AUDIT-C) (Babor T F, 2001);
- ii) brief advice that it is safest not to consume alcohol during pregnancy and explanation of the potential risks; and
- iii) offer of referral to the free, government-provided Get Healthy in Pregnancy telephone coaching service ((New South Wales Department of Health 2018) for women at Medium Risk (AUDIT-C score = 3–4) (Aboriginal women were also to be offered referral to counselling services provided by local Aboriginal Community Controlled Health Services (ACCHS)) or referral to the Drug and Alcohol service (provided by the health district) for women at High Risk (AUDIT-C score 5 +).

The seven-month practice change intervention to support the implementation of the recommended model of care into routine clinical practice consisted of the following evidence-based strategies: leadership/managerial supervision (Flodgren et al., 2011); local clinical practice guidelines (Rotter et al., 2010); electronic prompts and reminders (Shojania et al., 2014); local opinion leaders/champions (Flodgren et al., 2011; Welsh et al., 2015; Woo et al., 2017); educational meetings and materials (Forsetlund et al., 2009; Reeves et al., 2013); academic detailing (including audit and feedback) (Chaillet et al., 2006; Ivers et al., 2012; O'Brien et al., 2007); and monitoring and accountability for performance (Ivers et al., 2012). Intervention development was guided by the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) with implementation strategy selection targeting system and individual clinician level barriers elicited from formative surveys with antenatal providers in the participating services (Doherty et al., 2019; Kingsland et al., 2018).

A number of the evidence-based strategies were built into existing health district systems and were accessible by design to all antenatal providers. For example: reminders were built into the

electronic medical record system used by all maternity services at point of care; the local clinical practice guideline was made available through the district's policy and procedure online directory; performance measures were included on manager's quarterly accountability reports; and an online education module was made available through the district's online training platform. The content and delivery of strategies that were provided in-person were tailored to meet the needs of each of the different service locations, service types and provider types. For example, the educational meetings presented a context specific model of care that considered the usual ways of antenatal care delivery for each of the different service and provider types and included local referral processes for each of the locations. The delivery of these meetings was tailored to align with each services usual processes for training and supporting staff, including mandatory staff education days, junior doctor orientation days, team meetings, clinic staff handover huddles and one-on-one (Dray et al., 2022).

The service delivery needs of Aboriginal women were also considered and addressed by embedding elements of self-determined cultural inclusion into each of the practice change strategies. The cultural inclusion elements addressed overarching and localised key themes from formative focus groups with Aboriginal women who had attended a participating maternity service in the previous two years. For example: culturally appropriate referral pathways that were available in each service location for Aboriginal women were incorporated into the clinical practice guideline; educational meetings included prevalence data to address the stereotype that Aboriginal women are more likely to consume alcohol in pregnancy than non-Aboriginal women; case studies demonstrated culturally appropriate assessment and care provision in antenatal visits; audit and feedback data presented care provision rates for Aboriginal and non-Aboriginal women separately; and culturally appropriate educational resources for guiding discussions with Aboriginal women were provided.

Control period

Prior to the intervention, antenatal care addressing alcohol consumption during pregnancy was provided as per usual practice.

Data collection procedures

Data regarding receipt of care and demographic characteristics of women were collected through the outcome data collection telephone and online surveys. Additional demographic data and maternity service information were obtained from the district's medical record and appointment systems.

Measures

Receipt of antenatal care addressing alcohol consumption during pregnancy

All women were asked whether their antenatal care provider/s: assessed their alcohol consumption during the antenatal visit and, if so, whether this was consistent with the three AUDIT-C questions; advised them that it is safest not to consume alcohol during pregnancy; advised them of the potential risks; and offered a referral for further support. All responses were recorded as yes, no or don't know. Women were also asked about their alcohol consumption since pregnancy recognition using the AUDIT-C (Babor T F, 2001) to determine the elements of the model of care that were recommended for the woman's alcohol risk level.

Subgroups of pregnant women and maternity services

Data were collected for characteristics that have previously been reported to be associated with variations in the provision of

clinical guideline recommendations addressing alcohol consumption during pregnancy (Cheng et al., 2011; Davis et al., 2008; Doherty et al., 2019; Leroy-Creutz et al., 2015):

- Pregnant women subgroups. Women reported their age, Aboriginal origin, highest level of education completed, and whether this was their first pregnancy. The AUDIT-C (Babor T F, 2001) was used to determine whether the woman had consumed alcohol since pregnancy recognition. The woman's residential postal code was obtained from the electronic medical record to determine the woman's index of social disadvantage.
- Maternity service subgroups. The antenatal care team and postal code of the service (used to determine geographical remoteness of the service) was obtained from the electronic appointment system. The type of antenatal care providers seen in the antenatal visit was reported by women in the survey.

Power calculations

Based on the assumption of 80% power and an alpha level of 0.01, detectable differences in the absolute effectiveness of the intervention between pre- and post-intervention periods range from 8.6% to 31.0% for outcomes for the initial antenatal visit and 7.2% to 23.8% for outcomes for subsequent antenatal visits.

Statistical analysis

Statistical analyses were undertaken using SAS version 9.3 (SAS Institute Inc, 2011). Total AUDIT-C score was categorised into levels of risk (No Risk: AUDIT-C score 0; Low Risk: AUDIT-C score 1-2; Medium Risk: AUDIT-C score: 3-4; and High Risk: AUDIT-C score: 5+) (Health, 2017). Data collected for antenatal visits at 27-28 weeks gestation and 35-36 weeks gestation were collapsed into a 'subsequent visits' variable. Receipt of care questions were dichotomised (yes/no) with responses of 'don't know' coded as 'no'.

Variables for two of the trial's four primary outcomes were created for analyses (assessment and complete care). Two other trial outcomes were not included in subgroup analyses as they were composites of the included outcomes and to limit the number of interactions explored. The two included outcomes were analysed for two visit types (initial or subsequent visit) due to the previously reported differential intervention effect between time points (Doherty et al., 2022).

Assessment of alcohol consumption: reported receipt of assessment consistent with the first AUDIT-C question (for women who reported in the survey an AUDIT-C score of 0) and reported receipt of assessment consistent with all three questions of the AUDIT-C (for women with AUDIT-C ≥ 1).

Complete care (brief advice and referral) relative to level of alcohol risk: reported receipt of advice that it is safest not to consume alcohol during pregnancy and of the potential risks associated (all women) and referral offered (for AUDIT-C ≥ 3).

Condensed response categories were created for the following subgroups of women: age ('18-<25 years' or '25-<35 years' or '35 years and older'), Aboriginal origin ('Aboriginal and/or Torres Strait Islander' or 'neither Aboriginal or Torres Strait Islander'), highest education level completed ('completed high school or less' or 'completed technical certificate or diploma' or 'completed university or college degree or higher'), consumed alcohol in pregnancy ('yes' or 'no'). Women's residential postal codes were used to determine socio-economic disadvantage using the Index of Relative Socio-Economic Disadvantage (Statistics, 2008) ('most disadvantaged' or 'least disadvantaged'). The type of antenatal care team attended was categorised into midwifery-led clinic/service (hospital and community-based midwifery clinics, midwifery group practice continuity of care and multidisciplinary care for women with social

vulnerabilities), medical clinic (specialist medical clinics and multi-disciplinary care for women with complex medical needs) and AMIHS. The postal codes of the antenatal care team were used to determine geographic remoteness using the Access/Remoteness Index (Department of Health and Aged Care 2001) of Australia ('major city' or 'regional or remote'). Types of antenatal care provider seen in the antenatal visit were grouped into 'midwife only', 'doctor only', 'midwife and doctor' and 'Aboriginal Health Worker'.

Descriptive statistics were used to describe characteristics of pregnant women and maternity services and care received by women. Logistic regression models were used to compare period terms (pre-intervention vs post-intervention) for the two outcomes (assessment and complete care) at each of initial and subsequent antenatal visits, by each of the six subgroups of women and three subgroups of maternity services (nine models per outcome). All models included an interaction term (period term x subgroup) to explore the differential intervention effects over time between subgroups. Within subgroup pre-post differences are presented, and described when the between group interaction was significant. All models were adjusted for health sector (fixed effect; clusters one, two, three) and time (fixed effect; month of antenatal visit) and the subsequent antenatal visit models were also adjusted for antenatal visit (fixed effect; 27-28 weeks gestation, 35-36 weeks gestation). Although the analyses were exploratory, an alpha level of 0.01 was used given the multiple comparisons performed. With a total of 36 models assessed, based on a Binomial Test, there would be a 30% probability of seeing one or more significant interaction tests due to chance alone. Therefore, any interactions resulting from this sub-group analysis that are significant must be interpreted with caution and only be used for the purpose of hypothesis generation. Due to the small sample sizes for AMIHS (type of antenatal care team) and Aboriginal Health Workers (type of antenatal provider), measures of intervention effectiveness are not displayed for these subgroup categories.

Results

Over the 35-month study period, 11384 women were selected to participate in the survey, 10116 (88.9%) women were deemed eligible on the day of attempted contact and 7571 (74.8%) of these women were contactable. Of the 7386 women who were deemed eligible on contact, 5909 (80.0%) consented to participate. A total 5694 surveys were completed by pregnant women, with 1845 completed for an initial antenatal visit and 3849 for a subsequent antenatal visit (Figure 1).

The majority of women who completed the survey did not identify as Aboriginal (95%), were aged 25 to 35 years old (64%) and were not in their first pregnancy (60%). Most pregnant women attended a midwifery led clinic/service (90%) for their initial antenatal visit and saw a midwife only (79%). At subsequent visits, the majority of pregnant women attended a medical clinic (52%) or midwifery led clinic/service (46%) and saw a midwife only (58%), both midwife and doctor (23%) or doctor only (17%). Nine percent of women reported consuming alcohol since pregnancy recognition (Table 1).

Demographic variables are missing data from between 1 and 9 participants.

Differential effectiveness of the practice change intervention at the initial antenatal visit

Overall, the practice change intervention was effective in increasing pregnant women's receipt of assessment of alcohol consumption (OR: 1.45; 95% CI: 1.17-1.79) and complete care (OR: 1.51; 95% CI: 1.23-1.86) at the initial antenatal visit (Table 2). There were no significant differential intervention effects over time between

any subgroups of pregnant women or maternity services and the outcomes of assessment and complete care at initial antenatal visits.

Differential effectiveness of the practice change intervention at subsequent antenatal visits

Overall, the practice change intervention was effective in increasing pregnant women's receipt of assessment of alcohol consumption (OR: 4.64; 95% CI: 3.71-5.80) and complete care (OR: 2.91; 95% CI: 2.33-3.62) at subsequent antenatal visits (Table 3). There were significant differential intervention effects over time between Aboriginal origin subgroups and assessment of alcohol consumption (interaction p-value <0.01). Significantly greater within group intervention effects were found for non-Aboriginal women (pre: 7.82% vs post: 26.64%; OR: 5.34; 95% CI: 4.17-6.83) than Aboriginal women (pre: 21.52% vs post: 31.30%; OR: 1.95; 95% CI: 0.99-3.85).

The intervention effect also differed significantly between women who consumed alcohol in pregnancy subgroups and assessment at subsequent antenatal visits (interaction p-value <0.001). Greater within group effects were found for women who reported that they had not consumed alcohol in pregnancy (pre: 8.70% vs post: 28.76%; OR: 5.22; 95% CI: 4.11-6.65) than those who reported that they had (pre: 8.15% vs post: 8.51%; OR: 1.28; 95% CI: 0.59-2.78).

There were no significant interactions between subgroups of maternity services and effectiveness of the intervention over time in improving assessment and complete care outcomes at subsequent antenatal visits.

Discussion

This is the first reported study to explore the differential effectiveness of a practice change intervention designed to improve antenatal care addressing alcohol consumption during pregnancy between subgroups of pregnant women and maternity services. Overall, the study found limited evidence of differential effectiveness of the intervention between subgroups of pregnant women and no evidence of differential effectiveness between types or location of maternity services. There were no significant differential effects of the intervention between any of the subgroups and either outcome at the initial antenatal visit. For assessment of alcohol consumption at subsequent antenatal visits, the intervention effect differed between Aboriginal origin subgroups, and women's alcohol consumption in pregnancy subgroups. These exploratory results suggest that the model of care that was implemented in public maternity services was appropriate for delivery to most groups of pregnant women and that the implementation strategies utilised to support care provision similarly addressed barriers that existed across different service types, locations and professional groups.

The practice change intervention may have produced differential effects in assessment at subsequent antenatal visits between Aboriginal and non-Aboriginal women, with greater increases found for the latter group who had lower reported prevalence pre-intervention (21.52% vs 7.82%). Non-Aboriginal women had more than 5-times the odds of receiving assessment post-intervention compared to pre-intervention (OR: 5.34; 95% CI: 4.17-6.83), whereas Aboriginal women's odds increased by almost double (OR: 1.95; 95% CI: 0.99-3.85). Some components of the practice change strategies may have contributed to a greater intervention effect for non-Aboriginal women compared to Aboriginal women. Care provision data supplied to antenatal providers and maternity managers as part of the audit and feedback and performance monitoring strategies included a breakdown by women's Aboriginal

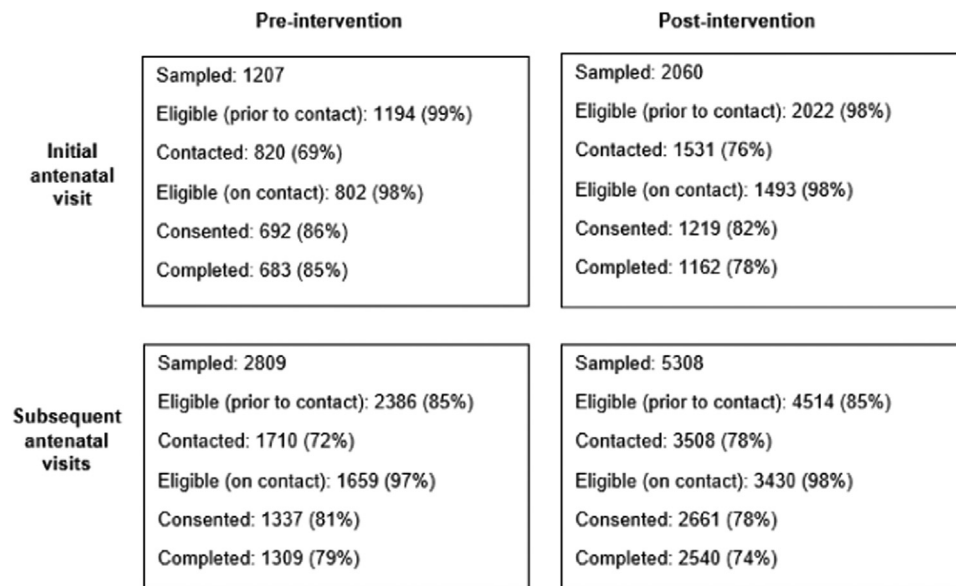


Fig. 1. Recruitment at pre- and post-intervention for initial and subsequent antenatal visits.

Table 1
Characteristics of pregnant women and maternity services at pre- and post-intervention.

Characteristics	Initial antenatal visit		Subsequent antenatal visits	
	Pre-intervention (N=683) n (%)	Post- intervention (N=1162) n (%)	Pre-intervention (N=1309) n (%)	Post-intervention (N=2540) n (%)
Age				
18 - <25 years	139 (20%)	200 (17%)	251 (19%)	368 (14%)
25 - < 35 years	433 (63%)	736 (63%)	844 (65%)	1622 (64%)
35 years +	111 (16%)	226 (19%)	213 (16%)	548 (22%)
Aboriginal origin	42 (6%)	67 (6%)	80 (6%)	115 (5%)
Highest education level completed				
Completed high school or less	211 (31%)	345 (30%)	379 (29%)	615 (24%)
Completed technical certificate or diploma	252 (37%)	400 (34%)	488 (37%)	899 (36%)
Completed university or college degree or higher	220 (32%)	417 (36%)	440 (34%)	1021 (40%)
Area index of disadvantage				
Most disadvantaged	427 (63%)	615 (53%)	826 (63%)	1298 (51%)
Least disadvantaged	256 (37%)	547 (47%)	483 (37%)	1241 (49%)
First pregnancy	271 (40%)	459 (40%)	547 (42%)	1016 (40%)
Consumed alcohol in pregnancy	51 (7%)	95 (8%)	135 (10%)	236 (9%)
Antenatal care team geographic remoteness				
Major city	400 (59%)	885 (76%)	749 (57%)	1941 (76%)
Regional and remote	283 (41%)	277 (24%)	560 (43%)	598 (24%)
Antenatal care team				
Midwifery led clinic/service	626 (92%)	1033 (89%)	581 (44%)	1190 (47%)
Medical clinic	51 (7%)	118 (10%)	708 (54%)	1302 (51%)
Aboriginal Maternal Infant Health Service	6 (1%)	11 (1%)	20 (2%)	39 (2%)
Provider/s in antenatal visit				
Midwife only	525 (78%)	926 (80%)	669 (51%)	1582 (62%)
Doctor only	27 (4%)	49 (4%)	281 (22%)	382 (15%)
Midwife and doctor	120 (18%)	174 (15%)	342 (26%)	555 (22%)
Aboriginal Health Worker	4 (1%)	8 (1%)	14 (1%)	18 (1%)

origin. This strategy demonstrated that, at pre-intervention, non-Aboriginal women were receiving assessment at lower rates than Aboriginal women and may have prompted antenatal providers to address this differential. Further, as previous studies have reported that antenatal providers selectively assess women based on assumptions of those most likely to be consuming alcohol in pregnancy, such as Aboriginal women (Browne and Fiske, 2001; Lyall et al., 2021; Niccols et al., 2010), the educational meetings directed antenatal providers to assess all women, irrespective of their characteristics. Continued research and practice to test and

identify strategies that are both effective and culturally appropriate is warranted to ensure that Aboriginal women benefit from any practice change intervention seeking to improve antenatal care addressing alcohol consumption during pregnancy. Of the 304 Aboriginal women who completed a survey, 76 were attending an AMIHS and 228 were attending a general antenatal team (midwifery or medical team). As Aboriginal women attending an AMIHS had higher reported rates of care than Aboriginal women as a group, the specific strategies used by AMIHS in providing culturally responsive services could be used to inform adaptations to

Table 2

Initial antenatal visit: Differential effectiveness of the practice change intervention by subgroups of pregnant women and maternity services.

	Assessment (AUDIT-C)				Complete care (advice safest not to consume, explanation of potential risks and referral offer if required)				
	Pre-intervention n (%)	Post-intervention n (%)	Within group OR (95% CI)	Between group Interaction p-value	Pre-intervention n (%)	Post-intervention n (%)	Within group OR (95% CI)	Between group Interaction p-value	
All women	451 (66.13%)	821 (70.71%)	1.45 (1.17; 1.79)	0.06	243 (35.63%)	477 (41.09%)	1.51 (1.23; 1.86)	0.08	
Age									
18-<25	96 (69.57%)	127 (63.50%)	0.85 (0.52; 1.36)			74 (53.62%)	109 (54.50%)		1.22 (0.78; 1.91)
25-<35	284 (65.59%)	534 (72.65%)	1.61 (1.23; 2.12)		135 (31.18%)	302 (41.09%)	1.87 (1.43; 2.45)		
35+	71 (63.96%)	160 (70.80%)	1.53 (0.93; 2.50)		34 (30.63%)	66 (29.20%)	1.08 (0.65; 1.80)		
Aboriginal origin				0.18				0.16	
Yes	31 (75.61%)	45 (68.18%)	0.78 (0.32; 1.91)		23 (56.10%)	31 (46.97%)	0.89 (0.40; 1.99)		
No	420 (65.52%)	775 (70.84%)	1.45 (1.16; 1.83)		220 (34.32%)	446 (40.77%)	1.61 (1.29; 2.01)		
Education level				0.79				0.73	
Completed high school certificate or less	143 (68.10%)	242 (70.35%)	1.28 (0.87; 1.88)		96 (45.71%)	176 (51.16%)	1.56 (1.08; 2.23)		
Completed technical certificate or diploma	172 (68.25%)	294 (73.50%)	1.45 (1.01; 2.07)		90 (35.71%)	179 (44.75%)	1.74 (1.24; 2.44)		
Completed university or college degree or higher	136 (61.82%)	285 (68.35%)	1.52 (1.07; 2.17)		57 (25.91%)	122 (29.26%)	1.42 (0.97; 2.08)		
Area index of disadvantage				0.63				0.46	
Most disadvantaged	290 (68.08%)	447 (72.80%)	1.48 (1.10; 1.99)		161 (37.79%)	272 (44.30%)	1.65 (1.25; 2.18)		
Least disadvantaged	161 (62.89%)	374 (68.37%)	1.33 (0.97; 1.84)		82 (32.03%)	205 (37.48%)	1.41 (1.02; 1.95)		
First pregnancy				0.60				0.25	
Yes	178 (65.68%)	317 (69.06%)	1.32 (0.94; 1.84)		117 (43.17%)	212 (46.19%)	1.35 (0.98; 1.86)		
No	273 (66.42%)	504 (71.79%)	1.48 (1.12; 1.95)		126 (30.66%)	265 (37.75%)	1.71 (1.30; 2.26)		
Consumed alcohol in pregnancy				0.41				0.22	
Yes	12 (23.53%)	21 (22.34%)	1.04 (0.46; 2.37)		11 (21.57%)	34 (36.17%)	2.51 (1.12; 5.60)		
No	439 (69.57%)	800 (74.98%)	1.48 (1.17; 1.89)		232 (36.77%)	443 (41.52%)	1.49 (1.19; 1.86)		
Antenatal care team geographic remoteness				0.70				0.24	
Regional or rural	171 (73.39%)	129 (78.66%)	1.29 (0.79; 2.12)		98 (42.06%)	97 (59.15%)	1.92 (1.26; 2.95)		
Major city	280 (62.36%)	692 (69.41%)	1.44 (1.12; 1.84)		145 (32.29%)	380 (38.11%)	1.44 (1.12; 1.84)		
Antenatal care team				0.81				0.25	
Midwifery led clinic/service	416 (66.56%)	743 (71.93%)	1.46 (1.15; 1.84)		226 (36.16%)	425 (41.14%)	1.52 (1.21; 1.90)		
Medical clinic	30 (58.82%)	70 (59.32%)	1.21 (0.61; 2.40)		11 (21.57%)	46 (38.98%)	3.00 (1.37; 6.57)		
Aboriginal Maternal Infant Health Service	5 (83.33%)	8 (80.00%)	-		6 (100.00%)	6 (60.00%)	-		
Provider/s in antenatal visit				0.74				0.15	
Midwife only	358 (68.19%)	670 (72.35%)	1.39 (1.08; 1.79)		194 (36.95%)	395 (42.66%)	1.55 (1.22; 1.97)		
Doctor only	13 (48.15%)	24 (48.98%)	1.10 (0.42; 2.88)		11 (40.74%)	12 (24.49%)	0.49 (0.18; 1.39)		
Midwife and doctor	72 (60.00%)	120 (68.97%)	1.67 (1.01; 2.76)		34 (28.33%)	64 (36.78%)	1.90 (1.13; 3.19)		
Aboriginal Health Worker	3 (75.00%)	4 (57.14%)	-		2 (50.00%)	3 (42.86%)	-		

Table 3
Subsequent antenatal visits: Differential effectiveness of the practice change intervention by subgroups of pregnant women and maternity services.

	Assessment (AUDIT-C)				Complete care (advice safest not to consume, explanation of potential risks and referral offer if required)			
	Pre-intervention n (%)	Post-intervention n (%)	Within group OR (95% CI)	Between group Interaction p-value	Pre-intervention n (%)	Post-intervention n (%)	Within group OR (95% CI)	Between group Interaction p-value
All women	113 (8.65%)	682 (26.88%)	4.64 (3.71; 5.80)		124 (9.49%)	507 (19.98%)	2.91 (2.33; 3.62)	
Age				0.17				0.06
18-<25	31 (12.40%)	113 (30.71%)	3.79 (2.42; 5.93)		48 (19.20%)	111 (30.16%)	2.10 (1.41; 3.13)	
25-<35	64 (7.58%)	443 (27.35%)	5.77 (4.30; 7.74)		62 (7.35%)	316 (19.51%)	3.76 (2.79; 5.09)	
35+	18 (8.45%)	125 (22.81%)	3.78 (2.22; 6.43)		14 (6.57%)	79 (14.42%)	2.80 (1.54; 5.09)	
Aboriginal origin				<0.01				0.04
Yes	17 (21.52%)	36 (31.30%)	1.95 (0.99; 3.85)		20 (25.32%)	35 (30.43%)	1.55 (0.80; 3.00)	
No	96 (7.82%)	645 (26.64%)	5.34 (4.17; 6.83)		104 (8.47%)	471 (19.45%)	3.19 (2.50; 4.06)	
Education level				0.08				0.82
Completed high school certificate or less	46 (12.17%)	174 (28.29%)	3.54 (2.45; 5.11)		57 (15.08%)	180 (29.27%)	2.82 (2.00; 3.98)	
Completed technical certificate or diploma	41 (8.40%)	242 (26.95%)	5.00 (3.46; 7.22)		43 (8.81%)	184 (20.49%)	3.20 (2.22; 4.61)	
Completed university or college degree or higher	26 (5.91%)	263 (25.78%)	6.59 (4.29; 10.13)		24 (5.45%)	141 (13.82%)	3.28 (2.08; 5.18)	
Area index of disadvantage				0.33				0.54
Most disadvantaged	82 (9.94%)	358 (27.62%)	4.43 (3.33; 5.89)		90 (10.91%)	285 (21.99%)	2.78 (2.10; 3.67)	
Least disadvantaged	31 (6.43%)	324 (26.13%)	5.62 (3.80; 8.30)		34 (7.05%)	222 (17.90%)	3.21 (2.19; 4.71)	
First pregnancy				0.44				0.86
Yes	46 (8.42%)	287 (28.28%)	5.34 (3.78; 7.56)		64 (11.72%)	239 (23.55%)	2.91 (2.13; 3.98)	
No	67 (8.80%)	395 (25.97%)	4.51 (3.37; 6.03)		60 (7.88%)	267 (17.55%)	3.02 (2.22; 4.11)	
Consumed alcohol in pregnancy				<0.001				0.30
Yes	11 (8.15%)	20 (8.51%)	1.28 (0.59; 2.78)		10 (7.41%)	50 (21.28%)	4.18 (2.02; 8.63)	
No	102 (8.70%)	662 (28.76%)	5.22 (4.11; 6.65)		114 (9.73%)	457 (19.85%)	2.82 (2.22; 3.57)	
Antenatal care team geographic remoteness				0.41				0.78
Regional or rural	47 (10.49%)	117 (32.87%)	5.52 (3.67; 8.32)		53 (11.83%)	95 (26.69%)	3.03 (2.04; 4.51)	
Major city	66 (7.68%)	563 (25.85%)	4.50 (3.42; 5.93)		71 (8.27%)	409 (18.78%)	2.83 (2.15; 3.72)	
Antenatal care team				0.19				0.89
Midwifery led clinic/service	49 (8.45%)	357 (30.00%)	5.99 (4.28; 8.40)		57 (9.83%)	238 (20.00%)	2.85 (2.06; 3.95)	
Medical led clinic	60 (8.49%)	303 (23.31%)	4.02 (2.96; 5.46)		60 (8.49%)	244 (18.77%)	3.05 (2.23; 4.16)	
Aboriginal Maternal Infant Health Service	4 (20.00%)	17 (43.59%)	-		7 (35.00%)	20 (51.28%)	-	
Provider/s in antenatal visit				0.62				0.66
Midwife only	63 (9.42%)	462 (29.24%)	4.91 (3.65; 6.60)		77 (11.51%)	342 (21.65%)	2.58 (1.95; 3.42)	
Doctor only	18 (6.41%)	60 (15.71%)	3.36 (1.92; 5.89)		14 (4.98%)	45 (11.78%)	3.15 (1.68; 5.91)	
Midwife and doctor	30 (8.77%)	150 (27.03%)	5.00 (3.23; 7.74)		30 (8.77%)	111 (20.00%)	3.32 (2.13; 5.17)	
Aboriginal Health Worker	2 (14.29%)	9 (50.00%)	-		2 (14.29%)	8 (44.44%)	-	

the care provided to Aboriginal women for alcohol consumption in general medical and midwifery clinics. Further, given that the prevalence of assessment and care for both groups of women remain low post-intervention, additional strategies could be tested to determine whether further equitable increases in care provision can be achieved.

The exploratory results also suggested a differential intervention effect for assessment of alcohol consumption at subsequent antenatal visits by women's alcohol consumption in pregnancy status. Improvements in assessment were found for women who reported that they had not consumed alcohol in pregnancy (OR: 5.22; 95 CI: 4.11-6.65), whereas no improvements were found for women who had (OR: 1.28; 95% CI: 0.59-2.78). This is in contrast to a previous study in maternity services that found no differences in the effectiveness of a practice change intervention in improving assessment of smoking status between current smokers and ex-smokers (Hajek et al., 2001) suggesting possible differences in intervention effect on provider behaviour by different risk factors or due to differences in the practice change strategies. Modifications were made to electronic medical records in this study to include alerts on women's files when alcohol consumption during pregnancy was identified at the initial visit. It is possible that antenatal providers were using these alerts from the initial visit to identify alcohol risk at subsequent antenatal visits rather than repeating the AUDIT-C assessment at each subsequent visit. Receipt of complete care (21.28%) was higher than assessment (8.51%) following the intervention for women consuming alcohol. This may indicate that antenatal providers prefer to have a general conversation with women about their alcohol consumption instead of asking the assessment questions again verbatim (Scholin and Fitzgerald, 2019) or see greater benefit in reinforcing previous advice and referrals, than in re-assessing risk as found in a study of obstetrician's views about provision of tobacco smoking care (Coleman-Cowger et al., 2014). However, assessment of alcohol consumption at each subsequent visit is a critical element of the model of care as a woman's level of risk may change between antenatal visits as demonstrated by the increasing prevalence of alcohol consumption in pregnancy found in the Australian Triple B cohort study (first trimester: 19%; second: 29%; and third: 30% (Hutchinson et al., 2018)). Mitigating such changes in alcohol consumption behaviours requires the delivery of different advice and support at different points of time (Australian Department of Health, 2017). Future research could assess the different methods being used by antenatal providers to identify alcohol consumption risk over time and explore barriers to reassessing alcohol consumption using a validated tool at subsequent visits for women who previously reported consuming alcohol. Such information could inform tailored adaptations to the practice change intervention to facilitate improvements in the provision of this element of care for women consuming alcohol throughout pregnancy. Tailored adaptations that could be tested include training antenatal providers to ask assessment questions in a conversational manner, such as Healthy Conversation Skills (Hollis et al., 2021), and assessing risk prior to the appointment using electronic applications, which is reported by pregnant women as a preferred method over face-to-face questioning (Muggli E et al., 2015) and shown to be an effective solution for other health risks and in other settings (Ngo et al., 2020).

There were no significant differences in intervention effectiveness between maternity service types and locations and receipt of care outcomes at both the initial and subsequent antenatal visits. This suggests that the implementation strategies similarly reached all professional groups and were similarly effective in supporting care provision across different types of maternity services, including medical clinics, midwifery led services and AMIHS, and by location (rural/regional and urban). This result is similar to the Bet-

ter Birth trial that found no significant differences between professional subgroups and adherence to essential birth practices after peer coaching (Molina et al., 2020). It is also consistent with one of the outcomes from the multi-strategy implementation study conducted in the United States that found no differences between medical and non-medical led clinics in referrals to smoking cessation support services following an intervention involving clinical practice guidelines, educational meetings and materials and outreach visits (Manfredi et al., 2011). The observed similar effectiveness of the practice change intervention between the different types and locations of maternity services may reflect the implementation strategies selected to address both system and individual clinician barriers being elicited from a representative sample of antenatal providers. The systems level strategies, were evidence-based and designed to be equally accessible to all services and providers. Further, clinician level strategies were tailored to fit with the usual processes of each specific service location, service type and profession type to enhance accessibility. Systematic review evidence supports the overall effectiveness of such tailored intervention approaches in improving healthcare practices (Baker et al., 2015), however, prior to this study limited empirical evidence existed as to whether such interventions produce similar effects for all groups of services and patients involved. Further replication studies that use such a tailored approach to strategy development and delivery are required to determine whether they result in equal benefits for all maternity services and providers.

This study should be interpreted in light of a number of strengths and limitations. The subgroup analyses were not pre-specified, but were based on existing literature regarding characteristics of maternity services and women associated with variations in implementation of guideline-recommended care for addressing alcohol consumption during pregnancy. Due to the high number of models assessed caution needs to be applied when interpreting the results of these subgroup analyses. Any interactions that were found to be significant may be due simply to the multiple comparisons that were performed. These exploratory results should only be used for the purpose of hypothesis generation and not as the basis for changing practice. While the large sample size of the trial allowed for most subgroup analyses, a number of subgroups were too small to report on measures of intervention effectiveness and some observed trends may have reached statistical significance if sufficiently powered. Nonetheless, the findings of this exploratory study provide useful data for hypothesis generation of targeted areas for the testing of additional strategies to ensure equitable impact of practice change interventions.

Conclusion

This exploratory study found no evidence of differential intervention effects between types and locations of maternity services and limited evidence of differential effects between subgroups of pregnant women for assessment of alcohol consumption following a multi-strategy practice change intervention. There was evidence suggesting a differential intervention effect for assessment by Aboriginal origin and women's alcohol consumption in pregnancy subgroups at subsequent antenatal visits. Given the critical importance of improving care equitably for all groups of women, particularly those who are vulnerable or at greatest risk, more research is needed to identify implementation strategies that address not only existing deficits in antenatal care, but ensure that all groups benefit equally from any intervention to improve care. Whilst the results of subgroup analyses are exploratory and further replication studies are needed, this suggests tailored adaptations to the intervention may be beneficial to support increases in antenatal care addressing alcohol consumption during pregnancy.

Ethical Approval

The study was conducted in accordance with the Declaration of Helsinki and the relevant human ethics institutions approvals, including the Hunter New England Human Research Ethics Committee (16/11/16/4.07; 16/10/19/5.15), the Aboriginal Health and Medical Research Council (1236/16) and the University of Newcastle Human Research Ethics Committee (H-2017-0032; H-2016-0422). All women participating in data collection were fully informed of the purpose and procedures of the study and gave their informed consent prior to participation. All women were assured about the confidentiality of the information provided.

Funding Sources

This study was funded by a National Health and Medical Research Council (NHMRC) Partnership Project grant (APP1113032). The NHMRC did not have any role in the design of the study; in the collection, analysis and interpretation of the data; in the writing of the manuscript; or the decision to submit the manuscript for publication. As part of the NHMRC Partnership Grant funding arrangement, the following partner organisations also contributed funds: Hunter New England Local Health District Clinical Services Nursing and Midwifery, the Foundation for Alcohol Research and Education, and the NSW Health Office of Preventive Health.

Clinical Trial Registry and Registration number

Australian and New Zealand Clinical Trials Registry (Registration number: ACTRN12617000882325; Registration date: 16/06/2017) <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=372985&isReview=true>

Declaration of Competing Interest

Authors ED, JW, LW, BT, CL and MK received salary support from Hunter New England Clinical Services Nursing and Midwifery, which contributed funding to the project. Author CR received salary support from the NSW Office of Preventive Health, which contributed funding to the project. All other authors declare that they have no competing interests.

Acknowledgements

The authors thank the women and antenatal providers who participated in the study; Aboriginal women and organisations for their cultural advice; the project team, including Milly Licata and Julia Dray, for their contributions to the implementation of the study; the Clinical Midwife Educators in each of the sectors, Brendon Williams, Sophie Curtin and Debra White; and the Maternal Alcohol Cultural Review Group consisting of representatives from Aboriginal community members, Aboriginal Community Control Health Organisations and Aboriginal Health Service Staff for their review of the final manuscript.

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