Practice change intervention to improve antenatal care addressing alcohol consumption during pregnancy: a randomised stepped-wedge controlled trial

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Abstract

Background: Clinical guideline recommendations for addressing alcohol consumption during pregnancy are sub-optimally implemented and limited evidence exists to inform practice improvements. The aim of this study was to estimate the effectiveness of a practice change intervention in improving the provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services.

Methods: A randomised stepped-wedge controlled trial was undertaken with all public maternity services in three sectors (one urban, two regional/rural) of a single local health district in New South Wales, Australia. All antenatal care providers were subject to a seven-month multi-strategy intervention to support the introduction of a recommended model of care. For 35 months (July 2017 – May 2020) outcome data were collected from randomly selected women post an initial, 27–28 weeks and 35–36 weeks gestation antenatal visit. Logistic regression models assessed intervention effectiveness.

Results: Five thousand six hundred ninety-four interviews/online questionnaires were completed by pregnant women. The intervention was effective in increasing women’s reported receipt of: 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 relevant to alcohol risk level (advice and referral) (OR: 2.10; 95% CI: 1.80–2.44; \(p<0.001\)) and all guideline elements relevant to alcohol risk level (assessment, advice and referral) (OR: 2.32; 95% CI: 1.94–2.76; \(p<0.001\)). Greater intervention effects were found at the 27–28 and 35–36 weeks gestation antenatal visit compared with the initial antenatal visit. No differences by sector were found. Almost all women (98.8%) reported that the model of care was acceptable.

Conclusions: The practice change intervention improved the provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services. Future research could explore the characteristics of pregnant women and maternity services associated with intervention effectiveness as well as the sustainment of care practices over time to inform the need for, and development of, further tailored practice change support.

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Background
Alcohol consumption during pregnancy is associated with adverse outcomes for the exposed child, including birth defects, developmental delays and Fetal Alcohol Spectrum Disorder [1–3]. It also contributes to pregnancy complications and poor obstetric outcomes, such as impaired placental blood flow, intrauterine growth restriction and stillbirth [4–6]. As there is no determined threshold for the safe consumption of alcohol during pregnancy, many countries have produced guidelines that recommend pregnant women do not consume alcohol [7]. Despite this, the global prevalence of alcohol consumption at any time during pregnancy has been estimated at 9.8% with notably higher rates of consumption reported in Ireland (60.4%), Denmark (45.8%), United Kingdom (41.3%) and Australia (35.6%) [8].

Systematic reviews support the effectiveness of psychosocial and brief interventions, including those delivered by health professionals, in increasing abstinence and reducing levels of alcohol consumption during pregnancy [9–11]. Consistent with such evidence, international [12] and Australian national [13] clinical guidelines recommend at the initial antenatal care visit and in subsequent visits throughout pregnancy all women receive: i) assessment of alcohol consumption using a validated tool; ii) brief advice that it is safest not to consume alcohol during pregnancy and an explanation of the potential risks associated with consumption; and iii) referral to specialist services for further support if required.

Despite the existence of such guidelines, provision of the recommended care elements is highly variable in public maternity services [14–18]. Whilst the majority of women report being asked about their alcohol consumption at some point during their pregnancy (51–97%) [14–17], less than half report being assessed using a validated tool (42%) [18]; advised about alcohol consumption (11–35%) [15, 17]; and referred to further support if required (10–50%) [14, 17]. Further, just over a quarter (28%) of pregnant women report receiving all guideline care elements (assessment, advice and referral) relevant to their alcohol risk level at the initial antenatal visit and 4% at subsequent antenatal visits [17]. The provision of such care has been reported to vary across maternity services, with larger and urban based services associated with lower levels of care provision [17, 19].

A variety of barriers may impede maternity services from implementing these guideline recommendations for addressing alcohol consumption during pregnancy as part of routine antenatal care. Such barriers have been reported at the individual level for both the health professionals delivering care (e.g. lack of knowledge and a perception that women may not find care acceptable) [18, 20, 21] and the managers responsible for the implementation of the clinical guideline in their antenatal service (e.g. stress) [20] as well as more broadly at the organisational level (e.g. lack of environmental systems and resources to prompt care) [20, 22]. Implementation strategies that have demonstrated effectiveness in increasing evidence-based practice in healthcare generally, and maternity services specifically, such as educational meetings [23, 24], local opinion leaders [25–27], audit and feedback [28–30] and electronic prompts [31], may overcome such barriers to care provision. However, given the variable results reported in systematic reviews on the effectiveness of such strategies for a variety of care practices (absolute improvement range: 0–20%) [23–32], it is recommended that strategy development be guided by an implementation framework and tailored to local context and barriers in order to maximise intervention effectiveness [33, 34]. Interventions that have been developed in this way have been shown to yield improvements in care provision in the range of 9 to 47% [35–37].

Only one controlled trial to date has assessed the effectiveness of implementation strategies in improving antenatal care addressing alcohol consumption. The 2013 trial conducted with Obstetrics and Gynaecology Units in four Italian public hospitals found that a significantly greater proportion of women who attended a hospital that was provided with training and action research support, received ‘correct’ advice from a midwife (53%), compared with women who received advice from a midwife at a control hospital (20%; RR: 2.66, 95% CI: 1.27–5.56) [38]. The trial, however, was non-randomised, did not report or adjust for baseline rates of care delivery and had a small sample size for the advice outcome (N = 67). To address this evidence gap, we conducted a study to examine the effectiveness of a multi-strategy practice change intervention in improving antenatal care addressing alcohol consumption during pregnancy.
Methods

Aim
The aim of this study was to estimate the effectiveness of a practice change intervention in increasing the provision of guideline recommended antenatal care (assessment, advice and referral) addressing alcohol consumption during pregnancy by public maternity services. The differential effect of the intervention on care provision by type of antenatal visit and sector, and pregnant women’s acceptability of the model of care implemented were also examined.

Study design and setting
A randomised stepped-wedge controlled trial was conducted in all public maternity services in three geographically and administratively defined sectors (clusters) of the Hunter New England Local Health District (HNELHD) in New South Wales, Australia. The three sectors were selected because they represented a mixture of areas and were of sufficient size. A seven-month practice change intervention was delivered sequentially in each of the sectors. Data were collected continuously across all sectors for 35 months (July 2017 to May 2020) with the primary outcomes determined by comparing practice change between baseline and follow-up periods for the three sectors combined (see Fig. 1). The maternity services provide antenatal care to 6100 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) [39].

The study was registered with the Australian and New Zealand Clinical Trials Registry (registration number: ACTRN12617000882325; registration date: 16/06/2017). Reporting of this study is in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement for stepped-wedge cluster randomised trials. We obtained ethics approval before we began the study (HNELHD: 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).

Study methods are further outlined in the published protocol [40].

Random allocation and blinding
An independent statistician randomly allocated the order of intervention delivery to the three participating sectors. Study personnel randomly selected women to participate in data collection and those involved in collecting outcome data were blind to intervention order. All randomisations were non-stratified and conducted using a computerised random-number generator. As the intervention changes practice, we could not blind antenatal providers to the intervention.

Participant eligibility and recruitment

Maternity services and providers
All maternity services within the three sectors received the practice change intervention. The types of services included: hospital and community-based midwifery clinics; hospital medical clinics; midwifery continuity of care group practices; Aboriginal Maternal and Infant Health Services (AMIHS); and specialist services caring for women with complex pregnancies or social vulnerabilities. All antenatal care providers in these services were eligible to receive the implementation strategies, including midwifery and medical staff and Aboriginal Health Workers (AHWs). Clinicians who were not the primary providers of antenatal care (e.g. social workers) were not targeted for the intervention.

Pregnant women
All women who attended a participating maternity service had the potential to receive the recommended model of care. During the 35-month study period, women were eligible to participate in study interviews/online questionnaires if they: attended an initial antenatal visit or 27–28 weeks gestation visit or 35–36 weeks gestation visit with a participating public maternity service in the preceding week; were 18 years or older; were 12 to 37 weeks gestation; had a sufficient level of English; and were mentally and physically capable of completing the interview/online questionnaire. Women were ineligible for data
collection if: receiving majority of antenatal care through a private provider; had already given birth; had a negative pregnancy outcome; were already selected to participate in the study in the past four weeks; or previously declined participation.

**Procedure for recruiting women for interviews/online questionnaires**

Extracts from the maternity service’s medical record and appointment systems were used to randomly generate a weekly sample of 105 eligible women across the three sectors (initial visit: 30 women; 27–29 weeks gestation visit: 30 women; 35–36 weeks gestation visit: 45 women). Sampled women were first mailed an information statement outlining the purpose of the study. One week later, non-Aboriginal women were called to invite participation in a telephone interview with online mode offered if the telephone interview was declined. Based on advice received regarding a culturally appropriate survey approach for Australia’s First Nations peoples, women identifying as Aboriginal and/or Torres Strait Islander (the term Aboriginal will be used from this point when referring to Aboriginal and/or Torres Strait Islander peoples or organisations) and/or women attending AMIHS were sent a text message offering either telephone interview or online modes. Women received up to 10 telephone contact attempts within a two-week period with the same time limit applied for completion of the online questionnaire.

**Intervention**

**Model of care addressing alcohol consumption during pregnancy**

A model of care consistent with systematic review evidence of effective interventions in reducing alcohol consumption during pregnancy [9–11] and international [12] and Australian national [13] clinical guideline recommendations was implemented. The model of care was delivered to women who attended an initial antenatal visit, a 27–29 weeks gestation visit and 35–37 weeks gestation visit. Women attend their initial antenatal visit with the public maternity service at a mean gestation of 19 weeks. The 27–29 and 35–37 weeks gestation visits were selected by maternity services as they are the only two subsequent visits that all women are scheduled to attend. The recommended model of care consisted of three key elements (see Fig. 2):

1) **Assess**: Assessment of all women’s alcohol consumption using the three item Alcohol Use Disorders Identification Test - Consumption (AUDIT-C) tool [41]. The total score was used to assign an alcohol risk of harm category: No Risk (score = 0); Low Risk (score: 1–2); Medium Risk (score: 3–4); and High Risk (score: 5+) [42].

2) **Advise**: Provision of two components of advice to all women: i) that it is safest not to consume alcohol during pregnancy; and, ii) explanation of the potential risks associated with alcohol consumption during pregnancy.

3) **Refer**: Offer of referral to the free government Get Healthy in Pregnancy telephone coaching service [43] to all women assessed as being at Medium Risk, with Aboriginal women also offered referral to counselling at Aboriginal Community Controlled Health Services. Offer of referral to all women at High Risk to the Drug and Alcohol service provided by the health district. Follow-up of women who had previously accepted a referral to an abovementioned service at the 27–29 and 35–37 weeks gestation visits.

![Fig. 2](Recommended model of care for addressing alcohol consumption at the initial antenatal visit, 27–29 weeks gestation visit and 35–37 weeks gestation visit)
Implementation strategies

The implementation strategies were developed through a staged process. First, antenatal provider and manager barriers to the implementation of the recommended model of care were explored using a quantitative online questionnaire based on the Theoretical Domains Framework (TDF) [44, 45]. The TDF consolidates constructs from 33 behaviour change theories and is one of the most commonly applied frameworks in implementation science as it incorporates constructs at both the individual (e.g. knowledge) and broader environmental context (e.g. resources) levels. It is used as a planning tool in intervention development to identify factors (i.e. barriers and enablers) influencing behaviour and subsequently guide selection of the most appropriate behaviour change techniques [44, 45]. Next, implementation strategies that incorporated TDF behaviour change techniques for the identified barriers were chosen based on a review of the literature and in consultation with experts in implementation science, clinical practice change, health service research and treatment of alcohol harms. The application of the selected implementation strategies in maternity services were then developed through consultations with key antenatal providers and managers in each sector. The content and delivery of strategies to the local context was also tailored to each sector’s usual processes. Lastly, cultural appropriateness was embedded into the implementation strategies through consultations with Aboriginal health staff, local community members and organisations, as well as focus groups with Aboriginal women who had recently attended a participating maternity service. Further detail on the development of the implementation strategies, including the findings of the antenatal provider and manager questionnaires, have been published elsewhere [20, 40]. All strategies other than the dedicated Clinical Midwife Educator (CME) as the local opinion leader and academic detailing were implemented with the potential and intention that they continue to be implemented post the seven-month intervention period due to their organisational and systems focus (see Table 1 for a description of the implementation strategies).

Control group

Before the intervention, each of the three sectors provided antenatal care addressing alcohol consumption during pregnancy as usual. Such care varied between maternity services as no local procedures were in place. The only guidance to provide care for alcohol consumption in antenatal visits prior to the intervention was a single non-validated question in the medical record at the initial antenatal visit.

Primary and secondary outcomes

The primary outcomes of the study are the proportion of pregnant women at the initial, 27–28 weeks gestation and 35–36 weeks gestation antenatal visits who report receipt of: i) assessment for alcohol consumption using the AUDIT-C; ii) brief advice related to alcohol consumption during pregnancy; iii) care relative to alcohol risk level (advice and referral); and iv) assessment for alcohol consumption using the AUDIT-C and care relative to alcohol risk level (advice and referral). Secondary outcomes reported in this paper are the effects of the intervention on antenatal visit and sector and pregnant women’s acceptability of the model of care.

Data collection procedures

Data were collected through women’s self-report interviews/online questionnaires as it is subject to less response bias than health-professional self-report of clinical adherence and can provide complete outcome data unlike medical records [46]. Questions used in the interviews/online questionnaires were developed based on previous studies conducted with pregnant women about their consumption of alcohol [47] and self-report of receipt of healthcare [16, 48]. Data regarding receipt of antenatal care addressing alcohol consumption and the demographics of women were collected through the interviews/online questionnaires. The telephone interviews were conducted by trained female interviewers who were independent from the maternity services and project team. The interview and questionnaire were reviewed for cultural appropriateness by Aboriginal women and pilot tested prior to the study commencing. Additional data regarding women’s demographics and service characteristics were obtained from the district’s medical record and appointment systems and project logs.

Measures

Receipt of antenatal care addressing alcohol consumption during pregnancy

Women were asked whether their antenatal care providers assessed their alcohol consumption during the antenatal visit and, if so, whether this was through questions consistent with the AUDIT-C tool (were you asked: how often you currently consume alcohol; number of standard drinks on a typical drinking day; and occasions of consuming 5 or more standard drinks?) (yes, no, don’t know). All women were asked whether they were: advised that it is safest not to consume alcohol during pregnancy; advised of the potential risks of consuming alcohol during pregnancy; and offered a referral for further support. Women who were completing an interview/online questionnaire for a 27–28
or 35–36 weeks gestation visit were also asked if they had accepted a referral for alcohol consumption in a previous antenatal visit and, if so, whether progress of the referral was followed-up.

**Acceptability of the model of care addressing alcohol consumption during pregnancy**

During the intervention follow-up period, women's acceptability of alcohol consumption being addressed as part of routine antenatal care was assessed using a 5-point Likert scale (possible responses: strongly agree, agree, unsure, disagree, strongly disagree). Women reported their acceptability overall and for each care element received in the antenatal visit, including: being asked about alcohol consumption, being advised that it is safest not to consume alcohol during pregnancy and being advised about the potential risks of alcohol consumption.

**Demographics of pregnant women**

Women reported in the interview/online questionnaire their: age, Aboriginal origin, education, employment, marital status and gravidity. Information on woman's postcode and allocated model of antenatal care were collected from the medical record and appointment systems. All women were asked to report their alcohol consumption using the AUDIT-C tool [41].

**Sample size and power calculations**

Data for estimating the intra-class correlation co-efficient (ICC) could not be derived from previous cluster randomised trials. Given that the outcomes within clusters were not expected to be highly correlated and the magnitude of outcomes between clusters different, an ICC of 0.01 was selected. Based on this, it was predicted that 200 completed interviews/online questionnaires per month would provide 80% power to detect an absolute increase in care provision of 15% (based on a conservative estimate).
estimate of 50% care provision at baseline) in at least one of the four primary outcomes at a 1.25% significance threshold (Bonferroni adjusted for the four primary outcomes). Eighty percent power was chosen as there were only three sectors (clusters) that were assessed as suitable for the trial.

**Statistical analysis**
Statistical analyses were undertaken using SAS version 9.3 [49]. Condensed response categories were created for pregnant women’s demographics. We grouped total AUDIT-C scores according to national guidelines [42]. Women's reported acceptability of each of the care elements was dichotomised into ‘acceptable’ (strongly agree and agree) and ‘not acceptable’ (strongly disagree, disagree and unsure). Aboriginal women’s acceptability of the model of care was also examined separately given the embedding of cultural inclusion into the practice change intervention.

Response options to the receipt of care questions were dichotomised (yes/no) with responses of ‘don’t know’ coded as ‘no’. The following primary outcome variables were created:

- **Assessment of alcohol consumption**: reported receipt of a question consistent with the first AUDIT-C question (for women who reported in the interview/online questionnaire an AUDIT-C score of 0) and reported receipt of all three questions consistent with the AUDIT-C (for women with AUDIT-C ≥ 1).
- **Brief advice related to alcohol consumption during pregnancy**: reported receipt of advice that it is safest not to consume alcohol during pregnancy and of the potential risks associated with alcohol consumption during pregnancy (all women).
- **Complete care (brief advice and referral)**: relative to level of alcohol risk: reported receipt of complete advice (all women) and referral offered or followed-up (for AUDIT-C ≥ 3).
- **Assessment of alcohol consumption using the AUDIT-C and complete care**: (brief advice and referral) relative to level of alcohol risk: reported assessment via AUDIT-C (all women) and complete advice (all women) and referral offered or followed-up (for AUDIT-C ≥ 3).

Descriptive statistics were used to describe women’s demographics and reported receipt and acceptability of the model of care. To assess the change in receipt of care from baseline to follow-up, logistic regression models were used. For each outcome, the model included a period term (fixed effect; baseline - follow-up difference) and was adjusted for sector (fixed effect; clusters one, two and three), antenatal visit (fixed effect; initial visit, 27–28 weeks gestation, 35–36 weeks gestation) and time (fixed effect; month of antenatal visit). To explore the intervention effect over time within and between antenatal visit types an interaction term (period term x antenatal visit) was included in the above models, with the between group analysis combining subsequent antenatal visits (27–28 weeks and 35–36 weeks gestation visits) for comparison with the initial antenatal visit. We also explored the intervention effect over time within and between sectors by including an interaction term (period term x sector) into the above models. We summarise the effects of the intervention by Odds Ratios (ORs) with their 95% Confidence Intervals (CIs) and significance levels.

**Deviation from protocol [40]**
The practice change intervention was delivered at seven monthly intervals instead of the planned six months resulting in data being collected for 35 months instead of 34 months. The number of women sampled per week was increased from 72 to 105 in order to meet the required number of interviews/online questionnaires to power the study. More women were sampled at 35–36 weeks gestation (45 per week, compared with 30 per week for other visits) to account for the larger number of women at this time point who became ineligible between sampling and data collection as they had given birth. Formal meetings with management were held bi-monthly instead of monthly with informal communication occurring between meetings to enable quicker feedback on the implementation of the intervention. Ninety-eight percent of antenatal providers received training during the intervention period instead of the planned 100%.

**Results**

**Maternity services and providers**
All 28 antenatal care teams in the three sectors participated in the study: 13 hospital and community-based midwifery clinics; five hospital medical clinics; five AMIHS; three midwifery continuity of care 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 (233 midwifery; 82 medical; and 14 AHWs) delivered antenatal care during the intervention period in the three sectors.

**Pregnant women**
Of 11,384 women who were selected to participate in data collection, 10,116 (88.9%) were deemed eligible and of these, 7,571 (74.8%) were contacted within the two-week contact period. Of the 7,386 women who were
eligible on contact, 5909 (80.0%) consented to participate and 5694 (77.1%) completed an interview/online questionnaire (see Fig. 3). Most participants were not Aboriginal (94.7%), had completed at least a technical certificate or diploma (72.6%) and were employed (70.9%) (see Table 2).

Receipt of antenatal care addressing alcohol consumption during pregnancy
As shown in Table 3, the odds of women reporting receipt of an assessment consistent with the AUDIT-C (baseline: 28.4% vs follow-up: 40.6%; OR: 2.63; 95% CI: 2.26–3.05) and receipt of complete brief advice (baseline: 18.7% vs follow-up: 26.7%; OR: 2.07; 95% CI: 1.78–2.41) was significantly greater at follow-up for the three sectors combined. Significant intervention effects were also found for receipt of complete care (advice and referral) (baseline: 18.5% vs follow-up: 26.6%; OR: 2.10; 95% CI: 1.80–2.44) and receipt of all guideline care elements (assessment and complete care) (baseline: 12.6% vs follow-up: 19.4%; OR: 2.32; 95% CI: 1.94–2.76).

Receipt of antenatal care addressing alcohol consumption during pregnancy by type of antenatal visit
As shown in Table 3, there were significant differences in intervention effectiveness between the initial antenatal visit and the 27–28 and 35–36 week gestation antenatal visits for all outcomes. The intervention effect for receipt of all guideline elements was greater for visits at 27–28 weeks gestation (OR: 3.43; 95% CI: 2.33–5.05) and 35–36 weeks gestation (OR: 4.88; 95% CI: 3.10–7.66) compared with the initial visit (OR: 1.64; 95% CI: 1.32–2.04). Despite the greater intervention effect, the proportion of women reporting receipt of all guideline elements relative to reported alcohol risk level at follow-up was lower for visits at 27–28 weeks gestation (13.3%) and 35–36 weeks gestation (12.5%) than at the initial visit (33.8%).

Receipt of antenatal care addressing alcohol consumption during pregnancy by sector
As shown in Table 4, all outcomes were significant within each sector other than advice on potential risks in Sector Three. There were no significant differences in intervention effectiveness between the three sectors for any outcome.

Acceptability of the model of care addressing alcohol consumption during pregnancy
Of the 715 women who received at least one element of care in the follow-up period, 707 (98.8%) reported that the care received addressing alcohol consumption during pregnancy was acceptable. Ninety-nine percent of women who reported being asked about their alcohol consumption (586/589), being advised that it is safest not to consume alcohol during pregnancy (508/511) and being advised about the potential risks (376/378) reported that receipt of these individual care elements was acceptable. For Aboriginal women, reported acceptability was 95.5% (42/44) for the overall model of care, 100% (33/33) for being asked about their alcohol consumption, 96.9% (31/32) for being advised that it is safest not to consume alcohol during pregnancy and 100% (27/27) for being advised about the potential risks.

Discussion
This is the first randomised controlled study internationally to estimate the effectiveness of a practice change intervention in improving the implementation of guideline recommended antenatal care addressing alcohol consumption during pregnancy. The intervention was effective in increasing the proportion of women who received an assessment of their alcohol consumption via a validated tool and care relevant to their alcohol risk level. Greater intervention effects were found for antenatal visits at 27–28 and 35–36 weeks gestation than at the initial antenatal visit for all primary outcomes. There were no differential intervention effects between the three sectors. Almost all women, including Aboriginal women, agreed that the model of care was acceptable.

The study findings support the limited evidence available regarding the effectiveness of implementation strategies in improving guideline recommended care addressing alcohol consumption during pregnancy. Like the Italian study [52], which based intervention on action research and training in Obstetrics and Gynaecology Units, we observed a positive effect of advice about consuming alcohol during pregnancy. The effect sizes of these two studies are not comparable as the Italian study reported receipt of ‘correct’ advice in a small sample of pregnant women who received information from their midwife, whereas our study reported on increases in receipt of advice in a large, random sample of women attending an antenatal visit. The effect sizes in our study are larger than the pooled effects of 32 studies included in a 2015 Cochrane review of tailored implementation interventions addressing determinants of health care practices in various clinical settings (OR: 1.56; 95% CI: 1.27–1.93) [52]. When comparing the effects of this intervention with those of the three individual studies in the review that explicitly reported use of an implementation framework or model [35–37], we found similar results. This suggests that the positive outcomes of the intervention may be attributable to the multi-strategy approach that was tailored to antenatal provider’s barriers and guided by the TDF. To understand the mechanisms by
Sectors assessed for suitability and selected (n=3)

Sectors randomised (n=3; 100%)

- Sector 1
  - Period 1
    - Intervention
      - (n=14 antenatal teams; 100% of teams eligible and participated)
      - Sampled: 2433
        - Eligible (prior to contact): 2185 (89.8%) Contacted: 1637 (74.9%)
        - Eligible (on contact): 1885 (96.8%)
        - Consented: 1329 (83.8%)
        - Completed: 1309 (82.6%)

- Sector 2
  - Period 2
    - Intervention
      - (n=10 antenatal teams; 100% of teams eligible and participated)
      - Sampled: 356
        - Eligible (prior to contact): 314 (88.2%)
        - Contacted: 191 (60.8%)
        - Eligible (on contact): 188 (98.4%)
        - Consented: 141 (75.0%)
        - Completed: 137 (72.9%)

- Sector 3
  - Period 3
    - Intervention
      - (n=4 antenatal teams; 100% of teams eligible and participated)
      - Sampled: 260
        - Eligible (prior to contact): 232 (89.2%)
        - Contacted: 142 (61.2%)
        - Eligible (on contact): 137 (96.5%)
        - Consented: 119 (86.9%)
        - Completed: 116 (84.7%)

  - Period 4
    - Sampled: 2189
      - Eligible (prior to contact): 1939 (88.6%)
      - Contacted: 1504 (77.6%)
      - Eligible (on contact): 1471 (97.8%)
      - Consented: 1155 (78.5%)
      - Completed: 1106 (75.2%)

  - Period 5
    - Sampled: 1659
      - Eligible (prior to contact): 1460 (88.0%)
      - Contacted: 1196 (81.8%)
      - Eligible (on contact): 1162 (97.2%)
      - Consented: 941 (81.0%)
      - Completed: 900 (77.5%)

    - Sampled: 427
      - Eligible (prior to contact): 369 (86.4%)
      - Contacted: 257 (89.6%)
      - Eligible (on contact): 255 (99.2%)
      - Consented: 199 (78.0%)
      - Completed: 187 (73.3%)

    - Sampled: 304
      - Eligible (prior to contact): 265 (87.2%)
      - Contacted: 195 (73.6%)
      - Eligible (on contact): 193 (99.0%)
      - Consented: 148 (75.6%)
      - Completed: 139 (72.0%)

Reasons for exclusion. Eligible (prior to contact):
- given birth or had a negative pregnancy outcome (n=1221);
- declined participation via toll free number (n=47).
- Contacted: no contact (n=1297);
- initial contact without being able to confirm eligibility (n=1250).
  Eligible (on contact): non-English speaking (n=144); did not recall seeing service n=22; not mentally or physically able to complete the survey (n=19).

Mode of survey completion. Telephone (n=5602); Online (n=92).

Fig. 3 CONSORT Flowchart
which implementation strategies affected study outcomes, process outcomes like antenatal providers’ exposure to, and perceived appropriateness of, the strategies need to be examined [33, 53]. Fewer than 20% of women at intervention follow-up received all elements of recommended assessment and care relevant to their alcohol risk level, which indicates that some elements may be harder for antenatal providers to implement into routine practice than others. The element of care least reported by pregnant women post-intervention was advice on the potential risks associated with alcohol consumption in pregnancy. Barriers such as a perception that women who have not disclosed alcohol consumption during pregnancy do not require an explanation of the risks [54], may persist for antenatal providers. Future research could assess the barriers specific to this care element to determine whether additional implementation strategies are required to support its provision. Additionally, an exploration of intervention effectiveness based on whether women reported consuming alcohol during pregnancy would further contextualise study outcomes and inform whether the tailoring of implementation strategies is required for clinicians seeing different groups of women [55]. The tailoring of strategies could potentially target the intervention to support the needs of different groups of pregnant women and facilitate efficiencies in providing alcohol assessment and care in time limited antenatal visits.

Greater intervention effects were found for outcomes at the 27–28 and 35–36 weeks gestation antenatal visits, which had low reported rates of care prior to the intervention. These outcomes demonstrate an important shift for maternity services because, although clinical guidelines recommend that alcohol consumption be addressed throughout the antenatal period, behavioural risk screening has previously been confined to the initial antenatal visit and not re-addressed unless a risk was identified [54, 56]. In the context of limited care at these later antenatal visits, the intervention supported practice change by providing a schedule for care and the supporting systems

| Demographic variables | Baseline (N = 1992) | Follow-up (N = 3702) | Total (N = 5694) |
|-----------------------|--------------------|----------------------|-----------------|
| Age                   | n (%)              | n (%)                | n (%)           |
| Mean (SD)             | 29.3 (5.3)         | 30.2 (5.2)           | 29.9 (5.2)      |
| Aboriginal, or Torres Strait Islander, or both | 122 (6.1%) | 182 (4.9%) | 304 (5.3%) |
| Highest education level completed |                  |                      |                 |
| Completed high school or less | 590 (29.6%) | 960 (25.9%) | 1550 (27.2%) |
| Completed technical certificate or diploma | 740 (37.1%) | 1299 (35.1%) | 2039 (35.8%) |
| Completed university or college degree or higher | 660 (33.1%) | 1438 (38.8%) | 2098 (36.8%) |
| Employment status     |                    |                      |                 |
| Employed full time    | 647 (32.5%)        | 1417 (38.3%)         | 2064 (36.2%)    |
| Employed part time or casual | 685 (34.4%) | 1293 (34.9%) | 1978 (34.7%) |
| Home duties           | 348 (17.5%)        | 506 (13.7%)          | 854 (15.0%)     |
| Student               | 60 (3.0%)          | 77 (2.1%)            | 137 (2.4%)      |
| Not employed          | 251 (12.6%)        | 407 (11.0%)          | 658 (11.6%)     |
| Marital status        |                    |                      |                 |
| Married or defacto relationship | 1711 (85.9%) | 3289 (88.8%) | 5000 (87.8%) |
| Geographic remoteness |                    |                      |                 |
| Major city            | 1149 (57.7%)       | 2826 (76.3%)         | 3975 (69.8%)    |
| Regional and rural    | 843 (42.3%)        | 875 (23.6%)          | 1718 (30.2%)    |
| Area index of disadvantage |          |                      |                 |
| Most disadvantaged    | 1253 (62.9%)       | 1913 (51.7%)         | 3166 (55.6%)    |
| Least disadvantaged   | 739 (37.1%)        | 1788 (48.3%)         | 2527 (44.4%)    |
| First Pregnancy       | 818 (41.1%)        | 1476 (39.9%)         | 2294 (40.3%)    |
| Allocated model of antenatal care |        |                      |                 |
| Low risk              | 1233 (61.9%)       | 2273 (61.4%)         | 3506 (61.6%)    |
| High risk             | 759 (38.1%)        | 1420 (38.4%)         | 2179 (38.3%)    |

Access/Remoteness Index of Australia [50] was used for categorising Geographic remoteness and Index of Relative Socio-Economic Disadvantage (IRSD) [51] for Area index of disadvantage

Demographic variables are missing data from between 1 and 9 participants.
| Model of care element | Initial antenatal visit | 27–28 weeks gestation visit |
|----------------------|-------------------------|----------------------------|
|                      | Baseline: N = 682        | Baseline: N = 670          |
|                      | Follow-up: N = 1161      | Follow-up: N = 1139        |
|                      | n                       | n                          |
| Assessment of alcohol consumption (via AUDIT-C) | 451 (66.1%) | 821 (70.7%) | 1.45 (1.17; 1.79) | 0.37 (0.28; 0.48) | 0.001 | 0.001 |
| Complete brief advice (safest not to consume and potential risks) | 245 (35.9%) | 478 (41.2%) | 1.50 (1.22; 1.84) | 0.001 | 0.001 |
| Advice safest not to consume | 447 (65.9%) | 853 (73.4%) | 1.77 (1.43; 2.19) | 0.001 | 0.001 |
| Advice on potential risks | 268 (39.3%) | 508 (43.7%) | 1.43 (1.17; 1.75) | 0.001 | 0.001 |
| Complete care relative to level of alcohol risk (complete brief advice and referral) | 243 (35.8%) | 477 (41.1%) | 1.51 (1.23; 1.88) | 0.001 | 0.001 |
| Assessment of alcohol consumption (via AUDIT-C) and complete care relative to level of alcohol risk | 192 (28.2%) | 392 (33.8%) | 1.64 (1.32; 2.04) | 0.001 | 0.001 |
Table 3 (Continued)

| Model of care element | 35–36 weeks gestation visit | Total | Between group differences |
|-----------------------|-----------------------------|-------|---------------------------|
|                       | Baseline N = 637            | Follow-up N = 1398 | OR (95% CI) | p-value | Baseline N = 1989 | Follow-up N = 3698 | OR (95% CI) | p-value | Initial vs subsequent antenatal visits OR (95% CI) | p-value |
| Assessment of alcohol consumption (via AUDIT-C) | n | % | n | % | 5.39 (3.87; 7.50) | < 0.001 | n | % | n | % | 2.63 (2.26; 3.05) | < 0.001 |
| Complete brief advice (safest not to consume and potential risks) | 45 | 7.1% | 263 | 18.8% | 3.72 (2.66; 5.22) | < 0.001 | 371 | 18.7% | 986 | 26.7% | 2.07 (1.78; 2.41) | < 0.001 |
| Advice safest not to consume | 87 | 13.7% | 465 | 33.3% | 3.88 (2.99; 5.03) | < 0.001 | 666 | 33.5% | 1742 | 47.1% | 2.62 (2.28; 3.01) | < 0.001 |
| Advice on potential risks | 121 | 19.0% | 393 | 28.1% | 2.01 (1.59; 2.55) | < 0.001 | 539 | 27.1% | 1249 | 33.8% | 1.70 (1.49; 1.95) | < 0.001 |
| Complete care relative to level of alcohol risk (complete brief advice and referral) | 43 | 6.8% | 263 | 18.8% | 3.92 (2.78; 5.53) | < 0.001 | 367 | 18.5% | 984 | 26.6% | 2.10 (1.80; 2.44) | < 0.001 |
| Assessment of alcohol consumption (via AUDIT-C) and complete care relative to level of alcohol risk | 23 | 3.6% | 175 | 12.5% | 4.88 (3.10; 7.66) | < 0.001 | 251 | 12.6% | 718 | 19.4% | 2.32 (1.94; 2.76) | < 0.001 |

OR Odds Ratio, 95% CI 95% Confidence Interval; Intervention effects adjusted for sector, antenatal visit and time (month of antenatal visit); Missing 7 participants who did not provide all data for receipt of care measures
Table 4  Receipt of antenatal care addressing alcohol consumption during pregnancy by sector

| Model of care element | Sector 1 (urban) | Sector 2 (regional/rural) | Between group differences |
|-----------------------|------------------|--------------------------|--------------------------|
|                       | Baseline N=1308  | Follow-up N=3175         | Baseline N=302           | Follow-up N=385          | p-value |
|                       | n       | %    | n       | %     | OR (95% CI) | n       | %    | n       | %     | OR (95% CI) | p-value |
| Assessment of alcohol consumption (via AUDIT-C) | 346 | 26.5% | 1255 | 39.9% | 2.55 (2.15; 3.03) | <0.001 | 87 | 28.8% | 182 | 47.3% | 3.28 (2.27; 4.73) | <0.001 |
| Complete brief advice (safest not to consume and potential risks) | 219 | 16.7% | 791 | 24.9% | 1.97 (1.65; 2.35) | <0.001 | 65 | 21.5% | 151 | 39.2% | 2.78 (1.94; 3.97) | <0.001 |
| Advice safest not to consume | 408 | 31.2% | 1447 | 45.6% | 2.55 (2.18; 2.99) | <0.001 | 115 | 38.1% | 219 | 56.9% | 2.87 (2.04; 4.03) | <0.001 |
| Advice on potential risks | 325 | 24.9% | 1014 | 31.9% | 1.62 (1.39; 1.89) | <0.001 | 92 | 30.5% | 182 | 47.3% | 2.29 (1.65; 3.16) | <0.001 |
| Complete care relative to level of alcohol risk (complete brief advice and referral) | 216 | 16.5% | 789 | 24.9% | 2.00 (1.67; 2.39) | <0.001 | 65 | 21.5% | 151 | 39.2% | 2.78 (1.95; 3.98) | <0.001 |
| Assessment of alcohol consumption (via AUDIT-C) and complete care relative to level of alcohol risk | 144 | 11.0% | 562 | 17.7% | 2.13 (1.73; 2.62) | <0.001 | 46 | 15.2% | 119 | 30.9% | 3.13 (2.09; 4.67) | <0.001 |

| Model of care element | Sector 3 (regional/rural) | p-value |
|-----------------------|--------------------------|---------|
|                       | Baseline N=379          | Follow-up N=138 | OR (95% CI) | p-value |
|                       | n       | %    | n       | %     | OR (95% CI) | Sector 1 vs Sector 2 p-value | Sector 1 vs Sector 3 p-value |
| Assessment of alcohol consumption (via AUDIT-C) | 131 | 34.6% | 66 | 47.8% | 2.31 (1.46; 3.65) | <0.001 | 0.40 |
| Complete brief advice (safest not to consume and potential risks) | 87 | 23.0% | 44 | 31.9% | 1.79 (1.14; 2.82) | 0.012 | 0.19 |
| Advice safest not to consume | 143 | 37.7% | 76 | 55.1% | 2.73 (1.76; 4.22) | <0.001 | 0.81 |
| Advice on potential risks | 122 | 32.2% | 53 | 38.4% | 1.50 (0.59; 2.27) | 0.059 | 0.14 |
| Complete care relative to level of alcohol risk (complete brief advice and referral) | 86 | 22.7% | 44 | 31.9% | 1.82 (1.16; 2.87) | 0.010 | 0.21 |
| Assessment of alcohol consumption (via AUDIT-C) and complete care relative to level of alcohol risk | 61 | 16.1% | 37 | 26.8% | 2.33 (1.42; 3.83) | <0.001 | 0.25 |

OR Odds Ratio, 95% CI 95% Confidence Interval; Intervention effects adjusted for sector, type of antenatal visit and time (month of antenatal visit); Missing 7 participants who did not provide all data for receipt of care measures.
and resources. However, it also introduced a new task to these visits, which required time as well as new skills for some antenatal providers who may have not usually been the primary providers of this care. Further research that examines whether the practice change intervention was effective for all types of maternity services and antenatal providers at these visits is warranted to inform effective guideline implementation in public maternity services [55].

Despite the positive intervention effect, the proportion of women receiving guideline recommended care post-intervention remains less than optimal. The incremental cost effectiveness ratio of the practice change intervention has been estimated at $32,570 (95% CI: $32,566 - $36,340) per percent increase in women reporting receipt of the full guideline recommended model of care [57]. Often the results from implementation efficacy trials conducted in real-world settings are considered modest for the investment made [58]. It is increasingly recognised that ongoing, purposeful adaptations to implementation interventions may be required to maximise initial investments and optimise potential impacts [58]. Similar concepts are implicit in continuous quality improvement approaches often used in healthcare settings to enhance processes, safety and patient outcomes [59]. Such an approach could be applied with the public maternity services that participated in this trial to examine whether adapted strategies that are less comprehensive and less costly could further enhance the impacts of this trial.

It is also important to assess whether the organisational and system focussed strategies used in the intervention sustain improvements in care provision. In a 2015 systematic review of health professional's adherence to clinical practice guidelines in medical care, only seven of 18 trials were found to have sustained practices one or more years after active implementation support ceased [60]. It is possible that common barriers to sustaining practice improvements in health service settings, including high staff turnover and workload pressures, may influence the ongoing provision of antenatal care addressing alcohol consumption in the participating maternity services [61]. If it is found that improvements have not been sustained, additional evidence-based sustainability strategies, such as continued training opportunities and systematic adaptations to the intervention to continually increase fit with service context, may be required to facilitate ongoing care provision [62].

The study findings should be interpreted in light of a number of strengths and limitations. First, the study design provided a number of pragmatic and scientific advantages, including receipt of the intervention by all maternity services and recruitment of like services that could act as their own control. The large sample size and length of data collection were additional strengths. Co-production by research team, maternity services and Aboriginal community was a strength as it engendered a novel intervention relevant to needs of the services and the women. A potential limitation of the study was that several outcome measures required women to recall specific information from the antenatal visit; however, we sought to minimise recall bias by conducting interviews/online questionnaires within four weeks of visits. A quantitative approach was used to assess women's acceptability of the model of care, which may have limited women's ability to fully express their views on the care that they received. Future research could seek to contextualise acceptability further by incorporating qualitative research approaches. The study was conducted within one local health district in Australia and thus, the extent to which the results can be generalised is unknown. However, as the model of care was based on evidence and clinical guidelines, the practice change intervention was developed to address barriers that are consistent with the literature, and study outcomes were not significantly different between urban and regional/rural sectors, there is potential that the intervention could be applied in other jurisdictions and achieve similar outcomes.

**Conclusion**

The multi-strategy practice change intervention was effective in improving the implementation of guideline recommended care addressing alcohol consumption during pregnancy. Future research could explore the characteristics associated with improved care to inform whether further tailoring of the implementation strategies is required for different groups of pregnant women or maternity services. Additionally, an assessment of the study outcomes over time would determine whether care has been sustained and inform the need for additional sustainability strategies. Alcohol consumption in pregnancy is common and harmful and these results have important implications for public maternity services seeking to achieve positive outcomes for pregnant women and their babies.

**Abbreviations**

AHW: Aboriginal Health Worker; AMIHS: Aboriginal and Maternal Infant Health Services; AUDIT-C: Alcohol Use Disorders Identification Test – Consumption; CI: Confidence Interval; CME: Clinical Midwife Educator; HNELHD: Hunter New England Local Health District; NSW: New South Wales; OR: Odds Ratio; RR: Risk Ratio; TDF: Theoretical Domains Framework.

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Authors’ contributions
Authors JW and MK led the overall development of the research study and ED led the development of the manuscript. BT led the cultural governance for the study and coordinated the cultural review group. EJE, AD, TWT and SW provided the rationale and expertise on alcohol consumption during pregnancy and CA and MH on the maternity services setting. ED, BT, AD, MH, CA, IS, CR and KG contributed to the development of the model of care and implementation support strategies. ED, BT and PR contributed to the development of data collection methods. LW and JA provided overall guidance for the study design and data analysis. All authors read and approved the final manuscript. JW, MK and ED act as guarantors, accept full responsibility for the work, had full access to the data, and controlled the final decision to publish. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the manuscript for publication. As part of the NHMRC Partnership Grant (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.

Declarations
Ethics approval and consent to participate
As this study involved human participants, the conduct of the research was performed in accordance with the Declaration of Helsinki. The study was approved and conducted in accordance with the relevant ethics institutions, including the Hunter New England Human Research Ethics Committee (16/11/16/4.07; 16/10/19/5.13); the Aboriginal Health and Medical Research Council (12/6/16) 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.

Consent for publication
Not applicable.

Competing interests
Authors ED, MK, BT, LW, MH, CA, KG and JW received salary support from Hunter New England Clinical Services Nursing and Midwifery, which contributed funding to the project. Author SW received salary support from the NSW Office of Preventive Health, which contributed funding to the project. Author SW received salary support from the Foundation for Alcohol Research and Education, which contributed funding to the project. All other authors declare that they have no competing interests.

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References
1. Henderson J, Gray R, Brocklehurst P. Systematic review of effects of low-moderate prenatal alcohol exposure on pregnancy outcome. BJOG. 2007;114(3):243–52.
2. Patel J, Bakker R, Irving H, Jaddoe VWV, Malini S, Rehm J. Dose-response relationship between alcohol consumption before and during pregnancy and the risks of low birthweight, preterm birth and small for gestational age (SGA)-a systematic review and meta-analyses. BJOG. 2011;118(12):1411–21.
3. Flak AL, Su S, Bertrand J, Denny CH, Kesmodel US, Cogswell ME. The association of mild, moderate, and binge prenatal alcohol exposure and child neuropsychological outcomes: a meta-analysis. Alcohol Clin Exp Res. 2014;38(1):214–26.
4. O’Leary C, Jacoby P, DAurotine H, Bartu A, Bower C. Heavy prenatal alcohol exposure and increased risk of stillbirth. BJOG. 2012;119(8):945–52.
5. Sundermann AC, Zhao S, Young CL, Lam L, Jones SH, Velez Edwars DR, et al. Alcohol use in pregnancy and miscarriage: a systematic review and Meta-analysis. Alcohol Clin Exp Res. 2015;39(8):1606–16.
6. Gundogan F, Elwood G, Longato L, Tong M, Feijoo A, Carlson RI, et al. Impaired placation in fetal alcohol syndrome. Placenta. 2008;29(2):148–57.
7. National Health and Medical Research Council. Australian guidelines to reduce Health risks from drinking alcohol. Canberra: Commonwealth of Australia; 2020.
8. Popova S, Lange S, Probst C, Gmel G, Rehm J. Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis. Lancet Glob Health. 2017;5(3):e290–e9.
9. Stade BC, Bailey C, Dzendolaets D, Sgro M, Dowswell T, Bennett D. Psychological and/or educational interventions for reducing alcohol consumption in pregnant women and women planning pregnancy. Cochrane Database Syst Rev. 2009;2:CD004228-CD.
10. Nilsen P. Brief alcohol intervention to prevent drinking during pregnancy: an overview of research findings. Curr Opin Obstet Gynecol. 2009;21:496–500.
11. Ujhelyi Gomez K, Goodwin L, Jackson L, Jones A, Chisholm A, Rose AK. Are psychosocial interventions effective in reducing alcohol consumption during pregnancy and motherhood? A systematic review and meta-analysis. Addiction. 2021;116:1638–63.
12. World Health Organisation. Guidelines for the identification and management of substance use and substance use disorders in pregnancy. Geneva: WHO; 2014.
13. Department of Health. Clinical practice guidelines: pregnancy care - 2019 Edition. Canberra: Australian Government Department of Health; 2019.
14. Waller A, Bryant J, Cameron E, Galal M, Quay J, Sanson-Fisher R. Women’s perceptions of antenatal care: are we following guideline recommended care? BMC Pregnancy Childbirth. 2016;16(1):191.
15. Kesmodel US, Kesmodel PS. Alcohol in pregnancy: attitudes, knowledge, and information practice among midwives in Denmark 2000 to 2009. Alcohol Clin Exp Res. 2011;35(12):2226–30.
16. Health Q. Queensland Health maternity outpatient clinic patient experience survey 2015. Brisbane: Queensland Government, 2016.
17. Doherty E, Wiggers J, Wolfenden L, Anderson AE, Crooks K, Tsang TW, et al. Antenatal care for alcohol consumption during pregnancy: pregnant women’s reported receipt of care and associated characteristics. BMC Pregnancy Childbirth. 2019;19(1):299.
18. Wangberg SC. Norwegian midwives’ use of screening for and brief interventions on alcohol use in pregnancy: Sex Reprod Healthc. 2015;6(3):186–90.
19. Davis PM, Carr TL, La CB. Needs assessment and current practice of alcohol risk assessment of pregnant women and women of childbearing age by primary health care professionals. Can J Clin Pharmacol. 2008;15(2):e214–22.

20. Doherty E, Kingsland M, Wiggers J, Anderson AE, Elliott EJ, Symonds L, et al. Barriers to the implementation of clinical guidelines for maternal alcohol consumption in antenatal services: a survey using the theoretical domains framework. Health Promot J Austr. 2019;00:1–7.

21. Crawford-Williams F, Steen M, Esterman A, Fielder A, Mikocka-Walus A. “If you can have one glass of wine now and then, why are you denying that to a woman with no evidence”: knowledge and practices of health professionals concerning alcohol consumption during pregnancy. Women Birth. 2015;28(4):329–35.

22. Oni HT, Buutjens M, Bandthorn J, Davis D, Abdel-Latif M, Islam MM. Barriers and facilitators in antenatal settings to screening and referral of pregnant women who use alcohol or other drugs: a qualitative study of midwives’ experience. Midwifery. 2020;81:102595.

23. Reeves S, Perrier L, Goldman J, Zwarenstein M. Interprofessional education: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2013;2013(3):CD002213.

24. Forsetlund L, Bjorndal A, Rashidian A, Jamtvedt G, O’Brien MA, Wolf F, et al. Continuing education meetings and workshops: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2009;2009(9):CD003030.

25. Flodgren G, O’Brien MA, Parmelli E, Grimshaw JM. Local opinion leaders: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2019;6(6):CD000125.

26. Woo K, Millivorg M, Dowling D. Characteristics of quality improvement champions in nursing homes: a systematic review with implications for evidence-based practice. Worldviews Evid-Based Nurs. 2017;14(6):440–6.

27. Welsh SM, Sherriff A, Flodgren G. The champion for improved delivery of care to older people in long-term care settings: effects on professional practice, quality of care and resident outcomes. Cochrane Database Syst Rev. 2015;2015(11):CD011956.

28. Challett N, Dubre E, Dugas M, Audibert F, Tourigny C, Fraser WD, et al. Evidence-based strategies for implementing guidelines in obstetrics: a systematic review. Obstet Gynecol. 2006;108(5):1234–45.

29. Ivers N, Jamtvedt G, Flottorp S. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2012;6:CD000259.

30. O’Brien MA, Rogers S, Jamtvedt G, Osman AD, Ogdaard-Jensen J, Kristoffersen DT. Educational outreach visits: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2007;2007(4):CD004049.

31. Shojania KG, Jennings A, Mayhew A, Ramsay CR, Eccles MP, Grimshaw J. The effects of on-screen, point of care computer reminders on processes and outcomes of care. Cochrane Database Syst Rev. 2014;2014(3):CD001096.

32. Rotter T, Kinsman L, James EL, Machotta A, Gothe H, Willis J, et al. Clinical pathways: effects on professional practice, patient outcomes, length of stay and hospital costs. Cochrane Database Syst Rev. 2010;10(3):CD006632.

33. Wollfenden L, Foy R, Presseau J, Grimshaw JM, Ivers NM, Powell BJ, et al. Designing and undertaking randomised implementation trials: guide for researchers. BMJ. 2021;372:m2712.

34. Powell BJ, Fernandez ME, Williams NJ, Aarons GA, Beidas RS, Lewis CC, et al. Enhancing the impact of implementation strategies in healthcare: a research agenda. Front Public Health. 2019;7:3.

35. Beeckman D, Clays E, Van Hecke A, Vandenput N, Schoonhoven L, Verhaeghe S. A multi-faceted tailored strategy to implement an electronic clinical decision support system for pressure ulcer prevention in nursing homes: a two-armed randomized controlled trial. Int J Nurs Stud. 2013;50(4):475–86.

36. Cheater F, Baker R, Reddish S, Spiers N, Walio A, Gilles C, et al. Cluster randomized controlled trial of the effectiveness of audit and feedback and educational outreach on improving nursing practice and patient outcomes. Med Care. 2006;44(6):542–51.

37. Looijmans-van den Akker I, van Delden JM, Verheij TJM, van der Sande MAB, van Essen GA, Riphagen-Dalhuisen J, et al. Effects of a multi-faceted program to increase influenza vaccine uptake among health care workers in nursing homes: a cluster randomised controlled trial. Vaccine. 2010;28(31):5086–92.

38. Bazo S, Battaglia G, Riscio P, Moino G, Marini F, Bottarel M, et al. Evaluation of a multilevel and integrated program to raise awareness of the harmful effects of prenatal alcohol exposure in a local community. Alcohol Alcohol. 2015;50(6):708–15.

39. Australian Institute of Health and Welfare. Australia’s mothers and babies 2018: in brief. Canberra: AIHW; 2020.

40. Kingsland M, Doherty E, Anderson AE, Cooks K, Tully B, Tremain D, et al. A practice change intervention to improve antenatal care addressing alcohol consumption by women during pregnancy: research protocol for a randomised stepped-wedge cluster trial. Implement Sci. 2018;13(1):112.

41. Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG. AUDIT. The alcohol use disorders identification test: guidelines for use in primary care. Geneva: World Health Organisation; 2001.

42. Foundation for Alcohol Research and Education. Information for health professionals on assessing alcohol consumption in pregnancy using AUDIT-C. Canberra: Australian Department of Health; 2018. [Available from: http://www.alcohol.gov.au/internet/alcohol/publishing.nsf/Content/wwtk-audit-c]. Accessed 30 Oct 2020.

43. New South Wales Health. New South Wales Get Healthy in Pregnancy. Sydney: New South Wales Health, 2018. [Available from: https://www.gethealthynsw.com.au/program/get-healthy-in-pregnancy/]. Accessed 22 Dec 2020.

44. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. Qual Saf Health Care. 2005;14(1):26–33.

45. Cane J, O’Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci. 2012;7:37.

46. Hrisos S, Eccles MP, Francis JJ, Dickinson HO, Beyer F, et al. Are there valid proxy measures of clinical behaviour? A systematic review. Implement Sci. 2009;4:37.

47. Australian Institute of Health and Welfare. National Drug Strategy Households Survey detailed report 2016. Drug statistics series no 31. Cat. no. PHE 214. Canberra: AIHW; 2017.

48. Wiggers J, McElwee K, Freund M, Campbell L, Bowman J, Wye P, et al. Increasing the provision of preventive care by community health-care services: a stepped wedge implementation trial. Implement Sci. 2017;12(1):105.

49. SAS Institute. Base SAS 9.3 Procedures Guide. 2nd ed. Cary: SAS Institute Inc; 2011.

50. Department of Health and Aged Care. Measuring remoteness: accessibility/remoteness index of Australia (ARIA). Canberra: Commonwealth of Australia; 2001.

51. Australian Bureau of Statistics. SEIFA: socio-economic indexes for areas. Canberra: Commonwealth of Australia; 2008.

52. Baker R, Cammoso-Stefanovic J, Gilles C, Shaw EJ, Cheater F, Flottorp S, et al. Tailored interventions to address determinants of practice. Cochrane Database Syst Rev. 2015;2015(4):CD005470.

53. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Admin Pol Ment Health. 2011;38(2):65–76.

54. Jones SC, Tella J, Shorten A, Johnson K. Midwives and pregnant women talk about alcohol: what advice do we give and what do they receive? Midwifery. 2011;27(4):489–96.

55. Flay BR, Biglan A, Boruch RF, Castro FG, Gottfredson D, Kellam S, et al. Standards of evidence: criteria for efficacy, effectiveness and dissemination. Prev Sci. 2005;6(3):151–75.

56. McCourt C. Supporting choice and control? Communication and interaction between midwives and women at the antenatal booking visit. Soc Sci Med. 2006;62(6):1307–18.

57. Szewczyk Z, Reeves P, Kingsland M, Doherty E, Elliott E, Wollfenden L, et al. Cost, cost-consequence and cost-effectiveness evaluation of a practice change intervention to increase routine provision of antenatal care addressing maternal alcohol consumption. Implement Sci. 2022;17(1):14.

58. Wollfenden L, Bolsewicz K, Grady A, McCrab S, Kingsland M, Wiggers J, et al. Optimisation: defining and exploring a concept to enhance the impact of public health initiatives. Health Res Policy Syst. 2019;17(1):108.
59. Lynn J, Baily MA, Bottrell M, Jennings B, Levine RJ, Davidoff F, et al. The ethics of using quality improvement methods in health care. Ann Intern Med. 2007;146(9):666–73.

60. Ament SM, de Groot JJ, Maessen JM, Dirksen CD, van der Weijden T, Kleinjnen J. Sustainability of professionals’ adherence to clinical practice guidelines in medical care: a systematic review. BMJ Open. 2015;5(12):e008073.

61. Cowie J, Nicoll A, Dimova ED, Campbell P, Duncan EA. The barriers and facilitators influencing the sustainability of hospital-based interventions: a systematic review. BMC Health Serv Res. 2020;20(1):588.

62. Hailemariam M, Bustos T, Montgomery B, Barajas R, Evans LB, Drahota A. Evidence-based intervention sustainability strategies: a systematic review. Implement Sci. 2019;14(1):57

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