A PRACTICE CHANGE INTERVENTION TO INCREASE THE PROVISION OF ANTENATAL CARE ADDRESSING ALCOHOL CONSUMPTION DURING PREGNANCY

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B Psyc (Hons I) (UNE)

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DECLARATIONS

Statement of Originality

I hereby certify that the work embodied in the thesis is my own work, conducted under normal supervision. The thesis contains no material which has been accepted, or is being examined, for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968 and any approved embargo.

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I hereby certify that this thesis is in the form of a series of papers. I have included as part of the thesis a written declaration from each co-author, endorsed in writing by the Faculty Assistant Dean (Research Training), attesting to my contribution to any jointly authored papers.

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Emma Doherty Date

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PUBLICATIONS INCLUDED AS PART OF THIS THESIS

The main body of this thesis consists of seven papers, all of which have been published. As these papers have been written as standalone publications there is overlap in content, particularly in the introduction and methods sections. The versions of the papers within this thesis document also reference appendices, which were not included in the versions that are published, but have been included here to further document study tools and resources.

Chapter 2

Doherty E, Wiggers J, Wolfenden L, Anderson A E, Crooks K, Tsang T W, Elliott E J, Dunlop A J, Attia J, Dray J, Tully B, Bennett N, Murray H, Azzopardi C and Kingsland M. Antenatal care for alcohol consumption during pregnancy: pregnant women's reported receipt of care and associated characteristics. BMC Pregnancy and Childbirth 2019; 19:299. https://doi.org/10.1186/s12884-019-2436-y

Chapter 3

Doherty E, Kingsland M, Wiggers J, Anderson A E, Elliott E J, Symonds I, Tully B, Dray J and Wolfenden L. Barriers to the implementation of clinical guidelines for maternal alcohol consumption in antenatal services: a survey using the theoretical domains framework. Health Promotion Journal of Australia 2019; 00:1-7. https ://doi.org/10.1002/hpja.258

Chapter 4

Doherty E, Kingsland M, Wolfenden L, Wiggers J, Dray J, Hollis J, Elliott E J, Daly J, Bailey K A, Attia J, Hunter M, Symonds I, Tully B, Tremain D and Hodder R K. Implementation strategies to improve preconception and antenatal care for tobacco smoking, alcohol

consumption and weight management: a systematic review protocol. Systematic Reviews 2019; 8:285. https://doi.org/10.1186/s13643-019-1193-3

Chapter 5

Doherty E, Kingsland M, Wiggers J, Wolfenden L, Hall A, McCrabb S, Tremain D, Hollis J, Licata M, Wynne O, Dilworth S, Daly J B, Tully B, Dray J, Bailey K A, Elliott E J and Hodder R K. The effectiveness of implementation strategies in improving preconception and antenatal preventive care: a systematic review. Implementation Science Communications 2022; 3:121. https://doi.org/10.1186/s43058-022-00368-1

Chapter 6

Kingsland M, Doherty E, Anderson A E, Crooks K, Tully B, Tremain D, Tsang T, Attia J, Wolfenden L, Dunlop A, Bennett N, Hunter M, Ward S, Reeves P, Symonds I, Rissel C, Azzopardi C, Searles A, Gillham K, Elliott E and Wiggers J. A practice change intervention to improve antenatal care addressing alcohol consumption by women during pregnancy: Research protocol for a randomised stepped-wedge cluster trial. Implementation Science 2018; 13:112. https://doi.org/10.1186/s13012-018-0806-x

Chapter 7

Doherty E, Kingsland M, Elliott E J, Tully B, Wolfenden L, Dunlop A, Symonds I, Attia J, Ward S, Hunter M, Azzopardi C, Rissel C, Gillham K, Tsang T W, Reeves P and Wiggers J. Practice change intervention to improve antenatal care addressing alcohol consumption during pregnancy: a randomised stepped-wedge controlled trial. BMC Pregnancy and Childbirth 2022; 22:345. https://doi.org/10.1186/s12884-022-04646-7

Chapter 8

Doherty E, Wiggers J, Wolfenden L, Tully B, Lecathelinais C, Attia J, Elliott E J, Dunlop A, Symonds I, Rissel C, Tsang T W and Kingsland M. Differential effectiveness of a practice change intervention to improve antenatal care addressing alcohol consumption during pregnancy: exploratory subgroup analyses within a randomised stepped-wedge trial. Midwifery 2023; 116:103528. https://doi.org/10.1016/j.midw.2022.103528

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OTHER PUBLICATIONS DURING CANDIDATURE

An additional 14 papers have been published, accepted for publication or are under peer-review. Eight of these papers directly relate to the work undertaken as part of this thesis and six contribute to the public health and behavioural sciences field in other topic areas.

Papers directly related to the work of this thesis

1. Reeves P, Szewczyk Z, Kingsland M, Doherty E, Elliott E J, Dunlop A, Searles A and Wiggers J. Protocol for an economic evaluation and budget impact assessment of a randomised, stepped-wedge controlled trial for practice change support to increase routine provision of antenatal care for maternal alcohol consumption. Implementation Science Communications 2020; 1:91. https://doi.org/10.1186/s43058-020-00079-5 [see Appendix 1].

2. Szewczyk Z, Reeves P, Kingsland M, Doherty E, Elliott E, Wolfenden L, Tsang T W, Dunlop A, Searles A and Wiggers J. Cost, cost-consequence and cost-effectiveness evaluation of a practice change intervention to increase routine provision of antenatal care addressing maternal alcohol consumption. Implementation Science 2022; 17:14. https://doi.org/10.1186/s13012-021-01180-6 [see Appendix 2].

3. Dray J, Licata M, Doherty E, Tully B, Williams B, Curtin S, White D, Lecathelinais C, Ward S, Hasson S, Elliott E J, Wiggers J and Kingsland M. Enhancing clinician participation in quality improvement training: implementation and impact of an evidence-based initiative to maximise antenatal clinician participation in training regarding women's alcohol consumption during pregnancy. BMC Health Services Research 2022; 22:402. https://doi.org/10.1186/s12913-022-07717-9 [see Appendix 3].

4. Tsang T W, Kingsland M, Doherty E, Anderson A E, Tully B, Crooks K, Symonds I, Tremain D, Dunlop A, Wiggers J and Elliott E J. Predictors of alcohol use during pregnancy in Australian women. Drug and Alcohol Review 2022; 41:171-181. https://doi.org/10.1111/dar.13330 [see Appendix 4].

5. Tsang T W, Kingsland M, Doherty E, Anderson A E, Tully B, Ward S, Wiggers J, Elliott E J. Written information and health professionals are the information sources about alcohol use in pregnancy most often used by pregnant women. Drug and Alcohol Review 2022; 1-11. https://doi.org/10.1111/dar.13512 [see Appendix 5].

6. Tsang T W, Kingsland M, Doherty E, Wiggers J, Attia J, Wolfenden L, Dunlop A, Tully B, Symonds I, Rissel C, Lecathelinais C, Elliott E J. Effectiveness of a practice change intervention in reducing alcohol consumption in pregnant women attending public maternity services. Substance Use: Treatment, Prevention and Policy 2022; 17:63. https://doi.org/10.1186/s13011-022-00490-2 [see Appendix 6].

7. Hall A, Doherty E, Nathan N, Wiggers J, Attia J, Tully B, Elliott E J, Oldmeadow C, Chiu S and Kingsland M. Longitudinal exploration of the rate, time-points and extent of change in care delivery following a successful antenatal care practice change intervention: A secondary analysis. [Under Review – BMC Health Services Research; see Appendix 7].

8. Doherty E, Wiggers J, Nathan N, Hall A, Wolfenden L, Tully B, Elliott E J, Attia J, Dunlop A, Symonds I, Tsang T W, Reeves P, McFadyen T, Wynne O and Kingsland M.

Iterative delivery of an implementation support package to increase and sustain the routine provision of antenatal care addressing alcohol consumption during pregnancy: study protocol for a stepped-wedge cluster trial. BMJ Open 2022; 12:e063486. https://doi.org/10.1136/bmjopen-2022-063486 [see Appendix 8].

Papers not directly related to the work of this thesis

1. Kingsland M, Barnes C, Doherty E, McCrabb S, Finch M, Cumpston M, Armstrong R, Tudor Car L, Doyle J and Wolfenden L. Identifying topics for future Cochrane Public Health Reviews. Journal of Public Health 2021; 1-4. https://doi.org/10.1093/pubmed/fdab287

2. Hollis J L, Doherty E, Dray J, Tremain D, Hunter M, Takats K, Williams C M, Murray H, Pennell C E, Tully B, Wiggers J, Daly J and Kingsland M. Are antenatal interventions effective in improving multiple health behaviours among pregnant women? A systematic review protocol. Systematic Reviews 2020; 9:204. https://doi.org/10.1186/s13643-020-01453-z

3. Bartlem K, Wolfenden L, Colyvasd K, Campbell L, Freund M, Doherty E, Slattery C, Tremain D, Bowman J and Wiggers J. The association between the receipt of primary care clinician provision of preventive care and short-term health behaviour change. Preventive Medicine 2019; 308-315. https://doi.org/10.1016/j.ypmed.2019.03.046

4. Hall A, Shoesmith A, Doherty E, McEvoy B, Mettert K, Lewis C, Wolfenden L, Yoong S, Kingsland M, Shelton R C, Wiltsey Stirman S, Imad N, Sutherland R, Nathan N. Evaluation of measures of sustainment and sustainability determinants for use in

community, public health and clinical settings: A systematic review. Implementation Science 2022; 17:81. https://doi.org/10.1186/s13012-022-01252-1

5. Reynolds R, Kingsland M, Daly J, Licata M, Tully B, Doherty E, Farragher E, Desmet C, Lecathelinais C, McKie J, Williams M, Wiggers J, Hollis J. Breastfeeding intentions, practices and reasons for cessation and associations with pregnancy, maternal and infant characteristics: a cross-sectional study. International Breastfeeding Journal 2023; 18:8. https://doi.org/10.1186/s13006-023-00545-5

6. Yoong S, Turon H, Wong C, Bayles L, Finch M, Barnes C, Doherty E, Wolfenden L. An audit of the dissemination plans and strategies included in food based international dietary guidelines. [Under Review – Public Health Nutrition].

CONFERENCE PRESENTATIONS GIVEN DURING CANDIDATURE

1. Doherty E, Kingsland M, Elliott E J, Tully B, Wolfenden L, Dunlop A, Symonds I, Attia J, Ward S, Hunter M, Azzopardi C, Rissel C, Gillham K, Tsang T W, Reeves P and Wiggers J. How can we improve antenatal care addressing alcohol consumption during pregnancy in public maternity services? The Fetal Alcohol Spectrum Disorder (FASD) Forum. Virtual Conference: May 2022. [Awarded best research presentation].

2. Doherty E, Kingsland M, Elliott E J, Tully B, Wolfenden L, Dunlop A, Symonds I, Attia J, Ward S, Hunter M, Azzopardi C, Rissel C, Gillham K, Tsang T W, Reeves P and Wiggers J. Australasian Society of Behavioural Health and Medicine. Virtual Conference: February 2022.

3. Doherty E, Kingsland M, Elliott E J, Tully B, Wolfenden L, Dunlop A, Symonds I, Attia J, Ward S, Hunter M, Azzopardi C, Rissel C, Gillham K, Tsang T W, Reeves P and Wiggers J. Practice change intervention to improve antenatal care for alcohol consumption: a randomised stepped-wedge controlled trial. Scientific Drug and Alcohol Conference (APSAD). Virtual Conference: November 2022.

4. Doherty E, Kingsland M, Tully B, Elliott E J, Wolfenden L, Tsang T W, Dunlop A, Symonds I, Attia J, Azzopardi C, Hunter M, Ward S, Reeves P, Rissel C, Gillham K and Wiggers J. A practice change intervention to improve antenatal care addressing alcohol consumption by women during pregnancy. Australian Nursing and Midwifery Conference. Newcastle, Australia: May 2021.

5. Doherty E, Kingsland M, Tully B, Elliott E J, Wolfenden L, Tsang T W, Dunlop A, Symonds I, Attia J, Azzopardi C, Hunter M, Ward S, Reeves P, Rissel C, Gillham K and Wiggers J. A practice change intervention to improve antenatal care addressing alcohol consumption by women during pregnancy. Fetal Alcohol Spectrum Disorder Hub Seminar. Virtual Conference: March 2021. [Awarded people's choice].

6. Doherty E, Kingsland M, Anderson A E, Tully B, Dray J, Elliott E J and Wiggers J. Antenatal care for alcohol consumption: pregnant women's receipt and acceptability of care. Australian Nursing and Midwifery Conference. Newcastle, Australia: May 2019.

7. Doherty E, Anderson A E, Crooks K, Tully B, Tremain D, Tsang T W, Attia J, Wolfenden L, Dunlop A, Bennett N, Hunter M, Ward S, Reeves P, Symonds I, Rissel C, Azzopardi C, Searles A, Gillham K, Elliott E J, Wiggers J and Kingsland M. Antenatal care for alcohol consumption: a study of pregnant women's receipt and acceptability of care. Australasian Fetal Alcohol Spectrum Disorder Conference. Perth, Australia: November 2018.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

CHAPTER 8

LIST OF ABBREVIATIONS

ACCHS	Aboriginal Community Controlled Health Service
AD	Absolute Difference
ALSWH	Australian Longitudinal Study of Women's Health
AMIHS	Aboriginal Maternal Infant Health Service
AQUA	Asking QUestions about Alcohol in Pregnancy
AUDIT-C	Alcohol Use Disorders Identification Test – Consumption
BWS	Best Worst Scaling
CATI	Computer Assisted Telephone Interview
CBA	Controlled Before-After Study
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CME	Clinical Midwife Educator
DALY	Disability Adjusted Life Year
DCE	Discrete Choice Experiment
DSF	Dynamic Sustainability Framework
EPOC	Effective Practice of Care
ERIC	Expert Recommendations for Implementing Change
FAS	Fetal Alcohol Syndrome
FASD	Fetal Alcohol Spectrum Disorders
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HNELHD	Hunter New England Local Health District
ICC	Interclass correlation coefficient
IR	Interquartile Range
ITT	Intention to Treat
MD	Mean Difference
NOS	Newcastle Ottawa Scale
OR	Odds Ratio
OSIS	Overview of Synthesis and Included Studies

PDSA	Plan-Do-Study-Act
PRISMA	Preferred Reporting Items for Systematic Reviews
RCT	Randomised Controlled Trial
RR	Risk Ratio
SD	Standard Deviation
SMD	Standardised Mean Difference
TDF	Theoretical Domains Framework
WHO	World Health Organisation

TERMINOLOGY

The term Aboriginal is used within this thesis, in recognition that Aboriginal people are the original inhabitants of New South Wales, Australia (NSW Ministry of Health, Communicating Positively: A Guide to Appropriate Aboriginal Terminology, Guideline No. GL2019_008; 2019. NSW Ministry of Health: North Sydney).

SYNOPSIS

The consumption of alcohol during pregnancy impacts the development of the fetus and is associated with a range of harms for the exposed child that are evident throughout different life stages (pre- and neo-natal, childhood and adolescence, and adulthood). Despite international and national guidelines consistently recommending pregnant women to not consume alcohol, the prevalence of consumption remains high in a number of countries, including Australia. Brief and psychosocial focussed interventions delivered by health professionals are supported by systematic review evidence as effective strategies in reducing women's alcohol consumption during pregnancy.

The provision of such interventions as part of routine antenatal care is recommended as a priority harm-reduction strategy by international organisations and the Australian Government. Antenatal clinical guidelines recommend that all pregnant women have alcohol consumption addressed at initial and subsequent antenatal visits using an evidence-based model of care consisting of three key elements: assessment, advice and referral. Public maternity services are an important setting for the implementation of these guidelines in countries that have widespread publicly funded health care, such as Australia. Despite this opportunity, relatively little is known about the extent and consistency of recommended care provision in these services; pregnant women's acceptability of receiving such care; and antenatal care provider and maternity manager barriers to guideline implementation. There is also a lack of evidence regarding implementation strategies that may be effective in supporting providers deliver recommended antenatal care addressing preventable modifiable risk factors, including alcohol consumption.

To address these gaps, the broad aims of this thesis were to:

- Assess the prevalence and consistency of guideline recommended care addressing alcohol consumption during pregnancy (assessment, advice and referral) at initial and subsequent visits in public maternity services.
- Assess pregnant women's acceptability of receiving such care in their routine antenatal visits.
- Assess antenatal provider and manager barriers to implementing the guideline recommendations.
- Synthesise evidence regarding the effectiveness of implementation strategies in improving guideline recommended care addressing modifiable risk factors (tobacco smoking, weight gain and alcohol consumption) in settings providing pregnancy focussed care (antenatal and preconception).
- Evaluate the effectiveness of a multi-strategy practice change intervention in improving the provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services.

These aims were addressed through a series of studies undertaken within all public maternity services in three geographically and administratively defined sectors of a single local health district in New South Wales, Australia. These studies included: a cross-sectional prevalence of care survey with pregnant women attending public maternity services; a cross-sectional survey of antenatal clinicians and maternity managers based on the Theoretical Domains Framework assessing barriers to care provision; and a randomised stepped-wedge controlled trial testing the implementation of a theoretically, empirically and end-user informed multi-strategy practice change support package. The trial was evaluated through weekly cross-sectional surveys of pregnant women who had recently attended participating maternity services over a period of 35 months. In addition, a systematic review of controlled studies that have tested the

effect of implementation strategies in supporting health professionals provide pregnancy focused care addressing tobacco smoking, weight management and/or alcohol consumption was undertaken.

The work encompassed in this thesis has contributed to advancing research and practice in a number of ways. Firstly, this thesis reported that public maternity services do not routinely provide the recommended care elements (assess, advise, refer) for addressing alcohol consumption during pregnancy, with particularly low levels found at later antenatal visits. Care was also found to be inconsistently provided, with characteristics of pregnant women (older age, not a first pregnancy, higher education, residing in an advantaged area, non-Aboriginal origin) and maternity services (urban located) associated with decreased odds of care receipt. Despite sub-optimal care, pregnant women reported high acceptability for receipt of all recommended care elements in antenatal visits. A number of barriers were reported by antenatal clinicians as impeding their delivery of such care, including absence of supporting resources, lack of expectation from others that alcohol will be addressed and low confidence in providing each of the recommended care elements. The main barriers reported by maternity managers included stress and complexities in managing clinical practice change.

The systematic review concluded that implementation strategies probably increase elements of antenatal care related to tobacco smoking and weight management. The ability to draw a stronger conclusion of the effect of such strategies on the provision of guideline recommended care addressing alcohol consumption was constrained by the absence of randomised controlled studies, lack of reported outcomes regarding assessment and referral, and very-low-certainty in the evidence for advice outcomes.

The multi-strategy practice change intervention tested in the randomised stepped-wedge controlled trial was developed using theory and empirical evidence, and strategy content and delivery informed by end-users and Aboriginal partners. The intervention was found to be effective in improving all elements of guideline recommended care both overall, and at initial and subsequent antenatal visits. The intervention resulted in similar effects between subgroups of women and types and location of maternity services, with the exception of non-Aboriginal women and women who had not consumed alcohol in pregnancy, for whom the intervention was more effective in increasing assessment of alcohol consumption at subsequent antenatal visits.

The thesis identified two key issues to be further explored in order to advance research and practice in this area: a need to further increase the proportion of women who receive guideline-recommended antenatal care addressing alcohol consumption during pregnancy through the testing of iterative improvement approaches; and a need to sustain care provision after the withdrawal of active implementation support.

CHAPTER 1

Introduction: The harms of alcohol consumption during pregnancy and strategies to support the implementation of guideline recommended antenatal care in public maternity services

This chapter involves four sections. Section 1 first outlines the evidence related to the harms and burden of alcohol consumption at the population level and specific to pregnancy. It then presents an overview of guideline recommendations to reduce alcohol-related harm during pregnancy and the estimated global and Australian prevalence of pregnant women meeting such recommendations. The section concludes with an overview of effective interventions for the reduction of alcohol-related harm during pregnancy. Section 2 outlines international and Australian national strategies and clinical guidelines that support alcohol consumption during pregnancy being addressed as part of routine antenatal care and highlights public maternity services as an important setting for these to be implemented. It then presents an overview of the evidence regarding the current provision and consistency of guideline recommend care in public maternity services, pregnant women's acceptability of such care, and antenatal provider's barriers to guideline implementation. Section 3 introduces implementation science as a field that can guide the development and evaluation of strategies to improve guideline implementation. It then provides an overview of the evidence regarding the effectiveness of such strategies in clinical care generally and for addressing modifiable risk factors in maternity services specifically. The three sections highlight the need for studies to be conducted to address the identified evidence gaps. The chapter concludes with Section 4, which outlines the thesis aims and structure.

SECTION 1: ALCOHOL-RELATED HARM AND BURDEN, INCLUDING DURING PREGNANCY, AND EVIDENCE OF EFFECTIVE INTERVENTION TO REDUCE HARM DURING PREGNANCY

1.1 Alcohol-related harm and burden at a population level

Alcohol causes harm through multiple mechanisms of effect, including: i) intoxication (immediate effects of alcohol on the central nervous system causing temporary impairment of physical coordination, perception, cognition and behaviour); ii) toxicity (toxic effects of alcohol as a carcinogen, hepatotoxic and poison on the organs and tissues of the person consuming alcohol and as a teratogen on the development of the embryo/fetus exposed to alcohol in utero); and iii) dependence (effects of alcohol as an addictive substance causing neuro-adaption of the dopamine pathway through repeat exposure) [1].

Each of these mechanisms of effect can cause direct and indirect harms to the person consuming alcohol, other people and broader society [1]. The most prevalent harms resulting from the mechanism of intoxication include: intentional injuries (e.g. self-harm and interpersonal violence) and unintentional injuries (e.g. poisoning, falls, traffic accidents, workplace accidents and drownings). The most prevalent harms resulting from the mechanism of toxicity include: gastrointestinal diseases (e.g. liver cirrhosis and pancreatitis); cancers (e.g. oral, oesophageal, liver colorectal and breast); cardiovascular diseases (e.g. haemorrhagic stroke and hypotensive heart disease); infectious diseases (e.g. tuberculosis); and a range of adverse conditions and secondary disabilities resulting from prenatal alcohol exposure (e.g. Fetal Alcohol Spectrum Disorder (FASD)). The most prevalent harms resulting from the mechanism of dependence are neuropsychiatric conditions (e.g. alcohol use disorders) [1]. Harms resulting from alcohol also extend to people other than the consumer of alcohol (e.g. interpersonal violence), and to the broader society, including direct costs to sectors such as healthcare, emergency services, criminal justice and social welfare and the indirect costs of premature morbidity and mortality, lost productivity and social exclusion [1-4].

The burden attributable to such alcohol-related harms has remained stable internationally, but increased in Australia, over the past decade [1, 5]. Alcohol is the fourth highest risk factor contributing to the burden of disease globally [1, 6]. In 2016, alcohol was responsible for 5.3% of total mortality (three million deaths) and 5.1% of the total burden of disease and injury (132.6 million Disability Adjusted Life Years (DALYs)) [1]. In Australia, alcohol is the fifth highest risk factor contributing to the burden of disease and the top risk factor for people aged 15 to 44 years [5]. In 2018, alcohol misuse was responsible for 4.1% of total mortality (6,512 deaths) and 4.5% of the total burden of disease and injury (222,108 DALYs). The proportion of the total burden attributable to alcohol in 2018 in Australia was: 100% of FASD; 100% of alcohol use disorders; 14.9% of injuries; 11.1% of mental health conditions; 7.2% of gastrointestinal diseases; 4.9% of cancers; 4.0% of cardiovascular diseases; 3.2% of infections; and 1.6% of neurological conditions [5].

International studies have estimated the economic burden attributable to the harmful use of alcohol to be between 0.45% and 5.44% of a country's gross domestic product [7]. In Australia, the costs of alcohol-related harm for the person consuming alcohol in 2010 was $14.4 billion [8]. Of this burden, the highest costs were associated with lost productivity ($6.0 billion), traffic accidents ($3.7 billion), criminal justice system costs ($3.0 billion) and health care system costs ($1.7 billion) [8]. It is further estimated that harms experienced by other people result in an additional cost to Australian society of $6.8 billion annually [3].

The World Health Organisation (WHO) and Australian Government have identified a number of priority population groups for reducing the risk of alcohol-related harm, including those who: are in the youngest and oldest age groups; are socio-economically disadvantaged; are of

Aboriginal and/or Torres Strait Islander origin; have a mental or physical health condition; have a family history of alcohol dependence; and women who are pregnant [1, 9].

1.2 Alcohol-related harm during pregnancy

Alcohol is a teratogen that freely crosses the placenta of a pregnant woman to the embryo/fetus [10-12]. As the embryo (period of development up until the end of the eighth week of gestation) and fetus (period of development from nine weeks gestation to birth) have limited ability to metabolise alcohol, concentrations similar to that of the mother are reached and, as a result, normal embryo and fetal development can be disrupted [13]. The potential for harm is present throughout the whole of pregnancy [14] and exposure during certain developmental periods can result in permanent structural and/or functional defects to the brain and other organs [15]. Systematic reviews of longitudinal and case-control studies examining the outcomes of alcohol consumption at varying timings, quantities and frequencies during pregnancy show a range of harms to the pregnancy and exposed child at different life stages (pre- and neo-natal, childhood and adolescence, and adulthood) [16]. In some instances, evidence of such harms can lead to a clinical diagnosis of FASD for the exposed child [17, 18].

1.2.1 Pre- and neo-natal outcomes

1.2.1.1 Placental function, miscarriage, preterm birth, low birth weight

Systematic reviews have shown that alcohol consumption during pregnancy increases the risk of placental abruption (Odds Ratio (OR): 1.48; 95% Confidence Interval (CI): 1.37, 1.60) and a reduction in placental weight of 51 grams (95% CI: −82.8, −19.3) [19]. Reviews have also found that any alcohol consumption in pregnancy is associated with a greater risk of miscarriage (OR: 1.19; 95% CI: 1.12, 1.28) [20] and low levels of alcohol consumption (<= 32 grams (3.2 standard drinks) per week) are associated with an increased risk of being small for

gestational age (OR: 1.08; 95% CI: 1.02, 1.14) and preterm birth (OR: 1.10; 95% CI: 0.95, 1.28) compared to no alcohol exposure controls [21].

A dose-response meta-analysis found that compared to abstinence, the risk of low birth weight is apparent from 24 grams (2.4 standard drinks) of alcohol per day (Risk Ratio (RR): 1.23; 95% CI: 1.10, 1.36) and linearly associated up to 120 grams (12.0 standard drinks; RR: 7.48; 95% CI: 4.46, 12.55). The risk of small-for-gestational-age is significant for alcohol consumption from 24 grams (2.4 standard drinks) per day (RR: 1.17; 95% CI: 1.03, 1.32) and linearly associated up to 84 grams (8.4 standard drinks) per day (RR: 2.02; 95% CI: 1.47, 2.77). The risk of preterm birth has been found to be significant for alcohol consumption from 36 grams (3.6 standard drinks) per day (RR: 1.23; 95% CI: 1.05, 1.44) and linearly associated up to 84 grams (8.4 standard drinks) per day (RR: 1.96; 95% CI: 1.41, 2.73) [22].

1.2.1.2 Congenital anomalies

A review of prenatal alcohol exposure on embryo/fetal structural development identified a number of body systems and organs directly impacted, including: the central nervous system, heart, kidneys, liver, gastrointestinal tract, endocrine system, eyes, arms and legs, palate, teeth, external genitals and ears [23]. Reviews have shown that any prenatal alcohol exposure is associated with a significant decline in protein synthesis or enzyme activity of the liver (Hedges's $g = -1.149 \pm 0.108$; 95 % CI −1.361 to −0.938) [24]. High levels of consumption (>24 grams (2.4 standard drinks) of alcohol per day) and 'binge drinking' (>48 grams (4.8 standard drinks) of alcohol on one occasion) have also been found to be associated with congenital heart defects (heavy drinking OR: 3.76; 95% CI: 1.00, 14.10; binge drinking OR: 2.49; 95% CI: 1.04, 5.97) and moderate drinking (<24 grams (2.4 standard drinks) of alcohol

per day) with conotruncal heart defects (OR: 1.35; 95% CI: 1.05, 1.75) and d-Transposition of the Great Arteries (OR: 1.86; 95% CI: 1.09, 3.20) [25].

The central nervous system/brain is the most impacted system during pregnancy as alcohol exposure has the potential to disrupt development throughout the whole of pregnancy, whereas other organ development is susceptible to harm at specific times in pregnancy. The central nervous system/brain is susceptible to major defects in structure from prenatal alcohol exposure during the period of conception up to 20 weeks gestation and major functional defects and minor structural defects from 20 weeks gestation to birth [15]. The structural damage from prenatal alcohol exposure is evident in magnetic resonance imaging studies that have shown reduced brain volume and malformations of the corpus callosum in children exposed to alcohol in utero [23].

1.2.2 Childhood and adolescence outcomes

1.2.2.1 Developmental delay and behavioural problems

The neurodevelopmental impairments from prenatal alcohol exposure can lead to substantial comorbid conditions and secondary disabilities in childhood and adolescence [26]. Systematic reviews have found a significant association between moderate to heavy prenatal alcohol exposure and primary school aged children's gross motor performance (OR: 2.9; 95% CI: 2.1, 4.0), including deficits in balance, coordination and ball skills [27], as well as complex fine motor skills, such as visual motor integration [28]. Reviews have also found moderate prenatal alcohol exposure to be associated with adverse behaviours in children aged six months to five years (Cohen's d*:* −0.15; 95% CI: −0.28, −0.03) [29] and low to moderate exposure with a trend towards child behavioural attention problems (OR: 1.21; 95% CI: 0.46, 3.32) [30] compared to abstinence controls. Pooled results from studies examining behaviour in children exposed to

high levels of alcohol consumption have also demonstrated higher total (Mean Differences (MD): 12.1; 95% CI: 7.7, 16.5), internalising (MD: 6.3; 95% CI: 3.1, 9.5) and externalising (MD: 12.5; 95% CI: 7.9, 17.0) problem scores compared to children not prenatally exposed to alcohol [31].

1.2.2.2 Cognitive abilities and educational achievement

Systematic reviews have shown significant associations between any prenatal binge-drinking exposure and cognition for children aged six months to 14 years (Cohen's d: −0.13; 95% CI: −0.21, −0.05) [29]. Reviews have also found any prenatal alcohol exposure to be significantly associated with negative impacts on shifting attention (Cohen's d: -0.61; 95% CI: -0.94, -0.29) and a trend for heavy exposure on encoding attention (Cohen's d: -0.79; 95% CI: -1.59, 0.00) [30] in children aged six to 18 years. Prenatal alcohol exposure at more than 1.4 standard drinks per day has been associated with deficits in working memory and executive function, especially numeracy tasks, at 7.5 years of age [32, 33]. In children aged 10 years, alcohol consumption of three or more standard drinks per week during pregnancy has been associated with verbal and nonverbal learning and memory scores [34] and less than one standard drink per day in the first and second trimesters with poorer school performance [35] compared to abstinent controls.

1.2.2.3 Social interactions and problems with the law

Systematic reviews have found high levels of prenatal alcohol exposure to be associated with conduct disorder problems (OR: 2.11; 95% CI: 1.42, 3.15) [36] and school-aged children having higher levels of rule breaking behaviour, delinquency, aggressive behaviour, social problems and social incompetence compared to no exposure controls [31]. Longitudinal studies have also found an association between prenatal alcohol exposure and substance abuse [37, 38], mental health disorders [39, 40] and inappropriate sexual behaviours [41] in adolescence.

1.2.3 Adulthood outcomes

Longitudinal studies have reported that deficits in motor function and issues arising from impaired fetal growth have been shown to extend into adulthood [42]. Studies exploring the secondary disabilities experienced by adults who were exposed to alcohol in utero have reported wide ranging effects, including poorer physical and mental health [43], lower rates of employment obtainment and maintenance [44], higher rates of contact with law enforcement [45] and challenges with living independently [46].

1.2.4 Clinical diagnosis of alcohol-related harm during pregnancy

As described above, the teratogenic effects of alcohol on the development of the embryo/fetus brain and other organs can lead to a range of adverse outcomes. FASD is the umbrella term for the spectrum of adverse effects that can be seen in infants, children and adults that were exposed to alcohol during pregnancy. Fetal Alcohol Syndrome (FAS) was first described in the literature in 1968 to describe children with facial anomalies, poor prenatal and/or postnatal growth and neurodevelopmental issues as a result of known high alcohol exposure in utero [47]. By 2000 it was recognised that neurodevelopmental outcomes may be present in the absence of physical anomalies and the umbrella term FASD was coined to encompass broader diagnostic categories [48]. The Australian Guide to the Diagnosis of FASD stipulates that a clinical diagnosis requires evidence of prenatal alcohol exposure and severe impairment in three or more domains of central nervous system structure (e.g. structural brain damage) or function (e.g. motor skills, cognition, language, attention, social skills) [17].

The manifestations of FASD are multifaceted, with a 2016 review finding 428 conditions, spanning 18 of the 22 International Classification of Diseases chapters (ICD-10), co-occurring

with a diagnosis of FASD [26]. The most prevalent conditions occurred within the congenital malformations, deformities and chromosomal abnormalities (43%) and mental and behavioural disorders (18%) chapters. Comorbid conditions, including language, auditory, visual, developmental, cognitive, mental and behavioural problems were also found to be highly prevalent in individuals with FASD (range: 50% to 91%) [26].

1.3 Prevalence of alcohol-related harm during pregnancy

The literature examining the prevalence of alcohol-related harm during pregnancy has mainly focussed on FASD. The estimated global prevalence of FASD is 7.7 per 1000 people. The prevalence estimates by WHO region are: European Region (19.8 per 1000); Region of the Americas (8.8 per 1000); African Region (7.8 per 1000); Western Pacific Region (6.7 per 1000); Southeast Asia Region (1.4 per 1000); and Eastern Mediterranean Region (0.1 per 1000) [26]. FASD prevalence estimates are higher in a number of sub-populations, including children in care (312.4 per 1000), correctional systems (146.7 per 1000) and special education (84.2 per 1000) [49]. There is currently no Australian national alcohol-related harm or FASD prevalence data [50]; however a 2012 report of available state and territory medical record data estimated that 2% of all babies born in Australian would meet FASD diagnostic criteria [51]. Prevalence rates for FASD have been reported for specific populations in Australia, including the juvenile justice system (363.3 per 1000) [52] and remote Aboriginal communities in Western Australia (194 per 1000) [53].

1.4 Burden of alcohol-related harm during pregnancy

As above, the majority of literature examining the burden resulting from alcohol-related harm during pregnancy has focussed on FASD. The burden of FASD is broad and affects not only the individual, but other people (e.g. family unit) and societal systems, including health,

education, employment, social services, law enforcement and criminal justice [54]. A 2018 systematic review that reported on the economic impact of FASD in four countries (United States of America, Canada, Sweden and New Zealand) found that the mean annual cost to support a child with FASD was $22,810 USD and for adults $24,308 USD [55]. A 2013 cost of illness study conducted in Canada found that the highest contributors to the overall cost of FASD were productivity losses due to premature morbidity and mortality (41%; $532 million to $1.2 billion CAD), criminal justice system costs (29%; $378.3 million CAD) and healthcare costs (10%; $128.5 to $226.3 million CAD) [56]. The economic costs of alcohol-related harm during pregnancy more broadly, and for FASD specifically, have not been modelled in Australia, but are estimated to be proportionally just as high as that for Canada [55]. It has been suggested that preventing one case of FASD incurs only 3% of the costs it requires to provide the necessary support services to an individual living with FASD [55].

1.5 Guideline recommendations to reduce alcohol-related harm during pregnancy

Given the harms associated with alcohol consumption during pregnancy, international guidelines produced by WHO recommend that pregnant women do not consume alcohol [57]. A consistent recommendation to this effect is also reflected in national level guidelines of 56 countries [58], including those in high income countries: Canada [59]; United States of America [60]; United Kingdom [61]; France [62, 63]; Denmark [64]; and Australia [9]. The Australian Guidelines to Reduce Health Risks from Drinking Alcohol in 2009 recommended ‘for women who are pregnant or planning a pregnancy, not drinking is the safest option [65].’ The guidelines were reviewed and subsequently updated in 2020 with a stronger recommendation ‘to prevent harm from alcohol to their unborn child, women who are pregnant or planning a pregnancy should not drink alcohol [9].’

1.6 Prevalence of alcohol consumption during pregnancy

Despite international and national guidelines recommending pregnant women do not consume alcohol, the global prevalence of alcohol consumption at any time during pregnancy was estimated at 9.8% in a 2017 systematic review that incorporated all countries that had national prevalence data available [26]. The estimated prevalence rates of alcohol consumption during pregnancy by WHO region are: the European Region (25.2%); Region of the Americas (11.2%); African Region (10.0%); Western Pacific Region (8.6%); South-East Asia Region (1.8%); and Eastern-Mediterranean Region (0.2%) [26]. It was further estimated that a small proportion of women consume alcohol at high levels during pregnancy (defined as four or more standard drinks on a single occasion), with WHO region estimates of 3.1% for the African Region; 2.8% for the Region of the Americas; 2.7% for the European Region and 1.8% for the Western Pacific Region [26].

In Australia, cross-sectional surveys and cohort studies have reported a prevalence rate of alcohol consumption at any time during pregnancy between 55% and 82% [66-75]. The largest national cross-sectional population survey, last conducted in 2019, found that 55% of women who had been pregnant in the previous 12 months consumed alcohol while pregnant before awareness of their pregnancy [73]. The reported rate of alcohol consumption reduced to 15% after pregnancy recognition. Of those who consumed alcohol after pregnancy recognition, 10% reported consuming alcohol at a frequency of at least two to four times a month and 4% consumed at least three to four standard drinks per typical drinking occasion [73].

The largest pregnancy cohort studies conducted in Australia within the last decade that have examined alcohol consumption during pregnancy are the Triple B Pregnancy Cohort Study [74] and The Asking QUestions about Alcohol in pregnancy (AQUA) Cohort Study [69]. The

Triple B Pregnancy Cohort Study (N=1534) recruited women from public antenatal clinics in two states of Australia (New South Wales and Western Australia) between 2008 and 2013. The study found that 62% of women reported consuming alcohol before awareness of their pregnancy and 37% after recognition [74]. Alcohol consumption at least weekly was reported by 7% of women after pregnancy recognition in the first trimester, 10% in the second trimester and 12% in the third trimester [74]. The average quantity of alcohol consumed on a typical drinking day was 1.5 standard drinks in all trimesters. Occasions of 'binge drinking' (>4 standard drinks) were reported by 9% of women after pregnancy recognition in the first trimester, 4% in the second trimester and 3% in the third trimester [74]. The AQUA study (N=1570), which recruited women from Victorian public antenatal clinics between 2011 and 2012, reported that 59% of women consumed alcohol at some stage during pregnancy [69]. Twenty seven percent of women consumed alcohol in the first trimester only, 27% consumed alcohol in the first trimester as well as the second and/or third trimesters, 5% consumed alcohol in the second and/or third trimester only or reported an irregular pattern of consumption that could not be classified [69].

In a sub-sample of 1614 women participating in the Australian Longitudinal Study of Women's Health (ALSWH) who had been pregnant between 2000 and 2009 and consumed alcohol prior to their pregnancy, 82% reported consumption at some stage during pregnancy [75]. Almost half of women surveyed (47%) indicated they consumed alcohol at least weekly and just under one-quarter (23%) usually consumed three or more standard drinks on a typical occasion. In a further analysis of 1577 women from the ALSWH who reported risky drinking patterns prior to pregnancy (weekly consumption and/or binge drinking) almost half (46%) reported that they continued these risky patterns during pregnancy, 40% reduced alcohol consumption and only 14% completely abstained from alcohol in pregnancy [70].

1.7 Evidence of effective intervention to reduce alcohol-related harm during pregnancy

A number of systematic reviews have examined the effectiveness of strategies to increase alcohol abstinence or reduce the amount of alcohol consumed during pregnancy [76-81]. A 2015 review of the effectiveness of community-wide public health interventions delivered through media campaigns (television, radio, newspapers, posters and social media), text messages and warnings on alcohol beverage containers found that in six of the seven included studies women's knowledge of the harms of alcohol consumption during pregnancy significantly improved [81]. Of four studies that reported consumption outcomes, only one found significant decreases in reported alcohol consumption (OR: 2.8; $p<0.001$) [82], but only for women who recalled being exposed to all three types of messages included in the intervention (warnings on alcohol beverage containers, warning poster in restaurants/bars and media advertisements).

A systematic review conducted in 2020 synthesised the evidence-base regarding the effectiveness of interventions delivered in any setting in preventing alcohol-exposed pregnancies [76]. Of 18 studies that included consumption outcomes, three examined the effect of public health educational strategies delivered in community and healthcare settings (none significant), three counselling-based strategies delivered in healthcare settings (none significant) and twelve brief interventions delivered in healthcare settings (four of these studies reported significant results). The four brief intervention studies that reported an effect were all conducted in antenatal care settings. Two tested longer duration single sessions [83, 84] and two tested shorter duration sessions delivered over multiple visits [85, 86]. Single session interventions of 25 minutes duration (regression co-efficient, b: -0.163; standard error: 0.063; $p<0.01$ [83]) and 60 minutes duration (t-statistic: 3.46; degrees of freedom: 33; $p<0.01$ [84])

were found to significantly reduce alcohol consumption among women drinking at high-risk levels in pregnancy. Four short brief intervention sessions delivered throughout pregnancy significantly decreased women's self-reported AUDIT scores compared to written information alone (F-statistic: 9.54; p=0.002) [85]. Assessment and monthly advice (10 to 15-minutes) for women who had consumed any alcohol in the first trimester resulted in women being five times more likely to be abstinent at the end of the third trimester compared to women who received assessment alone (OR: 5.39; 95% CI: 1.59, 18.25) [86].

A further systematic review conducted in 2020 examined the effectiveness of psychosocial interventions, including brief intervention, motivational interviewing and cognitive behavioural therapy in changing women's alcohol consumption behaviours during pregnancy [77]. Studies were included if the psychosocial intervention was delivered in a healthcare setting (usually as part of antenatal care in public maternity services, obstetrics practices and midwifery practices) or by a health professional as part of in-home care. Six of 20 identified studies were able to be pooled for meta-analysis, which found that the odds of achieving abstinence were 2.31 times higher in the intervention group compared to a control condition of usual care or no intervention (OR: 2.31; 95% CI: 1.61, 3.32; p<0.001) [77]. Content analyses of the factors impacting intervention effectiveness suggested that psychosocial interventions delivered over multiple visits may be more effective than a single session of longer duration, particularly for women consuming alcohol at lower levels in pregnancy [77].

SECTION 2: ANTENATAL CARE ADDRESSING ALCOHOL CONSUMPTION DURING PREGNANCY

2.1 Health services providing antenatal care identified as a priority setting for the reduction of alcohol-related harm in pregnancy

In line with the evidence described above, health services providing antenatal care have been identified as a priority setting to reduce alcohol-related harms during pregnancy by international organisations and the Australian government. The WHO Global Strategy to Reduce the Harmful Use of Alcohol published in 2010 [87] stipulated that policy and interventions should be implemented to support the identification and management of harmful drinking among pregnant women in healthcare settings.

The Australian National Alcohol Strategy, which provides a national framework for the prevention and minimisation of alcohol-related harms among individuals, families and communities, identified four priority areas of focus for the period 2019 to 2028 [88]. One of these priority areas *supporting individuals to obtain help and systems to respond*, includes recommendations for reducing the harms resulting from alcohol consumption during pregnancy. The strategy recommends that a settings-based approach to the identification, screening, assessment, brief intervention and referral of women be implemented in healthcare services, with maternity services providing antenatal care identified as a priority setting. Similarly, the Australian National FASD Strategic Action Plan (2018 to 2028) developed by the Australian Government recommends that as part of routine antenatal care all women receive universal screening and advice on the potential harms of alcohol consumption during pregnancy. The plan further recommends that medical, nursing and midwifery staff be provided with the necessary training and supports to be able to implement such practices [89]. The importance of implementation support is also reflected in the Australian National Alcohol Strategy [88], which recommends training and resources, such as those developed as part of

the national *Women Want to Know* initiative [90], be provided to maternity staff to support antenatal care addressing alcohol consumption become part of standard practice.

2.2 Antenatal clinical guideline recommendations

In line with the priorities identified in the strategies described above, international [57] and Australian national-level [91] antenatal clinical guidelines recommend that alcohol consumption be addressed with all pregnant women as part of routine antenatal care. The WHO Guidelines for the Identification and Management of Substance Use and Substance Use Disorders in Pregnancy recommend antenatal providers discuss alcohol consumption with all pregnant women as early in the pregnancy as possible and at every antenatal visit [57]. The Clinical Practice Guidelines for Pregnancy Care produced by the Australian Government Department of Health recommend that care be provided for alcohol consumption at the first antenatal visit and throughout pregnancy [91]. Such recommendations are endorsed by professional bodies internationally [92, 93]; and within Australia, including the Royal Australian and New Zealand College of Obstetricians and Gynaecologists [94] and the Australian College of Midwives [95].

Consistent with systematic review evidence and evidence suggesting the feasibility of addressing alcohol consumption within an antenatal visit [96], international and Australian clinical guidelines recommend that a brief model of care is delivered at multiple visits [57, 91]. As described above, brief interventions of shorter duration delivered at multiple time-points are potentially more effective than single longer duration interventions in reducing alcohol consumption for pregnant women, especially those consuming at low risk levels [76, 77]. The international and Australian clinical guidelines also take into account evidence that more intensive sessions may be required to effectively support women with high-levels of alcohol

consumption [76, 77] and recommend specialist support outside of the antenatal visit for these women.

Specifically, international and Australian national clinical guidelines recommend the following care elements be provided to all pregnant women as part of routine antenatal care:

1. Assessment of alcohol consumption using a validated tool. A systematic review of validated brief alcohol assessment tools found the Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) to have the highest sensitivity for identifying risky alcohol consumption in pregnant women [97].
2. Advice not to consume alcohol during pregnancy, tailored feedback on current level of consumption and discussion on the risks of alcohol consumption in pregnancy.
3. Referral to drug and alcohol services for specialist medical assessment and treatment if consuming alcohol at high-risk levels where dependence may be present, or to therapeutic support where dependence is not present but additional support may be required to abstain from alcohol during pregnancy [57, 91].

2.3 Public maternity services as a setting for the provision of antenatal care addressing alcohol consumption during pregnancy

In countries that have widespread access to publicly funded health care, public maternity services are an important setting for the implementation of antenatal clinical guideline recommendations related to alcohol consumption during pregnancy. In Australia, 70% of women access antenatal care through a public maternity service [98]. Antenatal care provided by these services is available to almost all pregnant women, regardless of medical or social risks, and is provided for free or at minimal charge. To meet the needs of the diverse range of pregnant women who access these services, different models of antenatal care are provided,

including: hospital and community-based midwifery clinics; hospital medical clinics; midwifery continuity of care group practices; Aboriginal Maternal and Infant Health Services (AMIHS); specialist multi-disciplinary services caring for women with high-risk pregnancies or complex social vulnerabilities; and shared-care models with general practitioners [99]. Antenatal care may be provided in such services by medical and midwifery staff and Aboriginal Health Workers, and can be supported by a range of other health professional groups, such as social workers.

2.4 Provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services

Despite public maternity services being a recommended setting for addressing alcohol consumption during pregnancy, there are limitations in the evidence regarding pregnant women's receipt of care consistent with the guideline recommendations. Three cross-sectional studies have examined the provision of such care using health professional self-report [100-102]. A 2015 survey of 103 Norwegian midwives found that 97% reported mostly or always asking about alcohol consumption at the initial antenatal visit (42% via a validated tool) and 66% reported mostly or always providing a referral to general practitioners when risky alcohol consumption was identified [100]. Lower rates of asking about alcohol consumption (38%) were found in a small study of 55 medical students conducted in 2013 in the United States of America [101]. In a 2014 survey of 166 midwives in seven health regions of Western Australia, 93% of midwives reported asking pregnant women about alcohol consumption, 99% reported that they advised that not drinking is the safest option during pregnancy and 64% informed pregnant women of the potential risks associated with alcohol consumption during pregnancy [102].

A further three cross-sectional studies have examined the provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services using women's self-report [103-105]. In a 1998 Danish study of 439 pregnant women, 51% reported being asked about alcohol consumption and 11% reported being advised that it is safest not to consume alcohol during pregnancy [103]. The study was conducted prior to the release of abstinence-based guidelines by the Danish Health Authority in 1999. A 2016 survey of 5,444 women who had previously attended a public maternity outpatient clinic in Australia reported that 96% of women recalled being asked about alcohol consumption at some point during their antenatal care. Of those women who reported that they had consumed alcohol during pregnancy, 97% received advice that it is safest not to consume alcohol and 62% were told about a relevant support service [104]. The proportion of all women that received advice on alcohol consumption, as per guideline recommendations, was not reported. In a further 2016 study of 223 Australian pregnant women, 92% reported being asked about alcohol and, of those women who reported needing help to manage their alcohol consumption, 10% were offered assistance [105].

Of these six studies reporting on antenatal care addressing alcohol consumption in public maternity services [100-105]: none reported on all the elements recommended by clinical guidelines (assessment, advice and referral); only one specified the antenatal care visit (initial visit or subsequent visit) in which care was received [100]; and no studies specifically reported on care at subsequent antenatal visits. In addition, care provision may have been over estimated [106] in the three studies that utilised health professional self-report [100-102]. Self-report by those receiving healthcare is recommended when measuring clinical guideline adherence as it is subject to less response bias [106, 107]. Given these limitations and variable results across studies, future research is warranted to determine pregnant women's receipt of antenatal care

addressing alcohol consumption during pregnancy consistent with clinical guideline recommendations.

2.5 Characteristics associated with the provision of antenatal care addressing alcohol consumption during pregnancy

A number of international studies have examined characteristics of pregnant women associated with the receipt of recommended care regarding alcohol consumption [103, 108-110]. A 2011 cross-sectional survey of 12,611 postpartum women in the United States of America found women who were of younger age, had not attained a university or college degree and were of a minority ethnicity (African American or other non-white ethnicity) were significantly more likely to report receiving alcohol assessment and advice from their antenatal care provider [108]. Two studies conducted with Danish (N=439) and Swiss (N=368) women found that previous drinking behaviours during pregnancy were not associated with being asked about alcohol consumption by an antenatal care provider [103, 110]. A study in Ghana (N=948) found that multiparous women and women who did not have a history of pregnancy complications were more likely to receive complete guideline recommended care for multiple health topics in their first antenatal visit, however, the association of this characteristic with alcohol care alone was not assessed [109].

There has also been a small number of international studies that have examined the characteristics of maternity services associated with antenatal care addressing alcohol consumption [111, 112]. A 2008 survey of 386 medical and nursing staff in Canada found that providers from smaller centres were significantly more likely to report asking women about alcohol consumption than those located in larger centres [111]. Further, a study of maternal

health providers in France (N=100) found that midwives were significantly more likely to be involved in providing alcohol related care to pregnant women than doctors [112].

Of the studies reporting on maternal and service characteristics associated with care for alcohol consumption in pregnancy, none reported on all elements of clinical guideline recommendations (assessment, advice and referral) and only one defined the type of antenatal visit (initial visit or subsequent visit) being examined. Further, as no studies were conducted in Australia, it is unknown whether the previously reported characteristics of care provision are generalisable to the Australian public maternity service setting. Given such gaps in evidence, future research is warranted to determine whether all women have the same opportunity to receive antenatal care addressing alcohol consumption during pregnancy.

2.6 Pregnant women's acceptability of antenatal care addressing alcohol consumption during pregnancy

A number of qualitative studies undertaken in the United States of America [113], Denmark [103], United Kingdom [114], The Netherlands [115] and Australia [116-118] have explored pregnant women's acceptability of antenatal care addressing alcohol consumption. These studies have found that pregnant women consider antenatal care providers as the most important source of information regarding alcohol consumption during pregnancy [103, 113-116]. Further, it has been reported that pregnant women expect alcohol to be addressed in their antenatal visits and that they believe it is the role of their antenatal care provider to do so [113, 116-118]. Pregnant women have described wanting such care to incorporate clear and consistent advice on the recommendation not to consume alcohol during pregnancy [113, 116] and a comprehensive explanation of the potential risks of alcohol exposure to the fetus [113, 116, 118].

Only one study has quantitatively assessed women's acceptability of receiving antenatal care addressing alcohol consumption [119]. In a study of 1103 Australian women aged 18 to 45 years, nearly all women agreed that antenatal care providers should ask pregnant women about their alcohol consumption (97%) and advise pregnant women to abstain from consuming alcohol (91%) [119]. The study however excluded women who were currently pregnant. With no studies quantitatively assessing pregnant women's acceptability of receiving antenatal care addressing alcohol consumption, it is unknown whether the findings of the qualitative studies described above represent the majority of pregnant women's views. Future research is required to quantitatively assess acceptability of antenatal care addressing alcohol consumption in a large sample of women who are currently pregnant.

2.7 Barriers to routine provision of antenatal care addressing alcohol consumption during pregnancy

The most cited barrier to the provision of antenatal care addressing alcohol consumption during pregnancy in cross-sectional and qualitative studies from a number of countries, including the United Kingdom [120], United States of America [121], Norway [100] and Australia [96, 117, 118, 122] is lack of antenatal care provider (doctor and midwife) knowledge. This includes a lack of knowledge of the: national guideline recommendations for the consumption of alcohol in pregnancy [117, 120]; potential harms of alcohol to the pregnancy and fetus [96, 117, 118]; and the model and procedure for providing alcohol consumption care in antenatal visits [96, 100, 121, 122]. In addition, antenatal provider's perceived lack of skills in assessing pregnant women's alcohol consumption using a validated tool and in providing advice consistent with guideline recommendations have also been reported as a barrier to care in numerous studies in Australia [102, 122, 123] and internationally [120].

A number of barriers relating to antenatal care provider's perceptions of the consequences and salience of care provision have also been cited in cross-sectional and qualitative studies in the United Kingdom [120, 124, 125], Norway [100] and Australia [96, 102, 117, 118, 122, 123]. These include clinician perception that women will not accurately report their alcohol consumption, which limits opportunity for appropriate levels of care to be provided [117, 120, 124] and for positive outcomes to be achieved [100, 124]. A fear that discussing alcohol consumption will appear judgemental and negatively impact the clinician-client relationship has also been reported as a barrier to such care provision [120, 123, 124]. Studies have also identified that antenatal care providers are concerned that asking women about their alcohol consumption will make women feel anxious, particularly those who have consumed alcohol [96, 100, 102, 122, 123, 125], and that providing advice on alcohol-related harms will cause undue stress [117]. Lastly, a perception that providing such care is not within the professional scope of antenatal care providers [123] and is not high priority compared to other competing clinical demands [118, 123, 124] have been identified as barriers.

A small number of clinical environment barriers to addressing alcohol consumption during pregnancy have also been reported. Both in Australia and internationally, the limited time available in antenatal visits to address alcohol consumption [96, 100, 102, 118, 120, 121, 123, 124, 126] is the most cited such environmental barrier. Studies have also reported a lack of clear procedures [120], including relevant referral pathways for pregnant women who are identified as consuming alcohol [120, 121, 123], and a lack of appropriate resources to support such care provision [96, 123].

Despite there being a large evidence-base regarding barriers to the provision of antenatal care addressing alcohol consumption during pregnancy, none of the above studies applied a consolidated implementation framework to barrier assessment [127, 128]. The use of such a framework is recommended to ensure a broad range of factors that exist at both the individual and clinical environment levels are considered when seeking to improve clinical practice [129]. There have also been no studies reporting on maternity managers' barriers despite their critical role in supporting clinical guideline implementation and practice change [130]. To address these limitations and evidence gaps, future research is required to comprehensively assess antenatal provider and manager barriers to the implementation of antenatal clinical guidelines for addressing alcohol consumption during pregnancy using a consolidated theoretical implementation framework.

SECTION 3: PRACTICE CHANGE INTERVENTIONS TO IMPROVE PROVISION OF ANTENATAL CARE ADDRESSING ALCOHOL CONSUMPTION DURING PREGNANCY

3.1 Implementation science and effective strategies

Implementation science is the study of methods to promote the systematic uptake of evidence-based and guideline recommended interventions into routine practice and policy to improve health outcomes [131]. One aspect of implementation science is the evaluation of strategies designed to improve the implementation of such interventions. The use of practice change interventions (also known as implementation strategies, with such terminology used interchangeably throughout this and further chapters) is recommended where: there is an evidence-based intervention that is not being routinely and/or consistently delivered; there is a comprehensive understanding of the barriers to implementing the evidence-based intervention

in a particular setting; and there is theoretical and/or empirical evidence supporting the likely effect of strategy/s addressing the identified barriers and improving provision of the evidence-based intervention (or empirical evidence for similar evidence-based interventions and/or for similar settings where no specific evidence exists) [132]. When developing strategies, it is also recommended that the development process involves local end-user engagement [133] and that principles of equity are integrated to enhance accessibility and reduce health disparities between population groups [134, 135].

Implementation strategies have been compiled in a number of taxonomies, including the Cochrane Effective Practice and Organisation of Care (EPOC) taxonomy [136] and the Expert Recommendations for Implementing Change (ERIC) taxonomy [137]. Evidence regarding the effect of strategies recommended by the taxonomies have been synthesised in Cochrane systematic reviews, including use of such strategies as: local opinion leaders (absolute difference (AD): 11%; interquartile range (IR): 3.5% to 14.6%) [138]; educational meetings (AD: 6.0%; IR: 2.9% to 15.3%) [139]; academic detailing (AD: 5.6%; IR: 3.0% to 9.0%) [140]; audit and feedback (AD: 4.3%; IR: 0.5% to 16.0%) [141]; and point of care reminders (AD: 4.2%; IR: 0.8% to 18.8%) [142]. Further, strategies tailored to address identified determinants of clinical practice (barriers and enablers) have been shown to increase the delivery of recommended care by over 50% (OR: 1.56; 95% CI: 1.27, 1.93; $p<0.001$) [143].

3.2 Effectiveness of implementation strategies in improving care addressing modifiable risk factors in maternity settings

Two systematic reviews have examined the effect of strategies in improving the implementation of clinical guideline recommendations for addressing the modifiable risk factors of gestational weight gain and tobacco smoking in maternity settings [144, 145]. The

first, a 2014 review of strategies to change maternity healthcare professional's delivery of obesity or weight management care identified no eligible completed studies, but one registered trial [146]. The second, a 2019 review of practice change interventions to improve smoking cessation care for pregnant women identified 16 studies [145]. Of these identified studies: 10 used a non-controlled study design; 15 were conducted in high income countries (United States of America, United Kingdom, Australia and The Netherlands); and 12 targeted the intervention at a mixture of health professional types (doctors, midwives, nurses). The number of strategies included in the practice change interventions ranged from one to six, with the most common strategies being: educational meetings (n=13); educational materials (n=9) and reminders (n=8). Overall, 2,518 health professionals and 11,505 women provided data for the review primary outcomes. Nine studies were assessed as good quality, six as fair and one as poor [145].

The review found that practice change interventions were effective in improving smoking cessation care elements as recommended by international and national clinical guidelines, including clinicians: asking about tobacco smoking (Cohen's d=0.47; 95% CI: 0.13, 0.81); advising about quitting (Cohen's d: 0.46; 95% CI: 0.02, 0.9); assessing motivation to quit (Cohen's d: 0.98; 95% CI: 0.51, 1.45); assisting with the quit process (Cohen's d: 0.65; 95% CI: 0.46, 0.83); and arranging referral (Cohen's d: 0.99; 95% CI: 0.2, 1.79) [145]. Sub-group analyses on the review primary outcomes found increased effectiveness for practice change interventions that were theoretically informed in their development (asking about smoking: Cohen's d: 0.62; 95% CI: 0.12, 1.1) and that used at least three implementation strategies (assisting with the quit process: Cohen's d: 0.70; 95% CI: 0.5, 0.9) [145]. However, as the majority of studies included in the review were non-controlled, the strength of evidence was limited. The review was also limited by the pooling of results from studies comparing interventions to usual practice with those comparing alternative implementation strategies,

with the inclusion of the latter potentially contributing to an underestimation of effect size [147].

Prior to this thesis, only one controlled study had examined the effectiveness of a practice change intervention in improving the provision of antenatal care addressing alcohol consumption during pregnancy [148]. The 2013 non-randomised comparative study was conducted with public Obstetrics and Gynaecology Units in four public hospitals in Italy. Antenatal care providers in two of the hospitals received education using an action research approach that incorporated the following components: inviting clinicians to reflect on issues encountered when providing care for alcohol consumption, sharing knowledge and experience amongst colleagues, enhancing teamwork to find solutions, and identifying actions to improve routine care provision. The two other hospitals in the study received no implementation support [148].

For one month following the intervention all pregnant women attending their 38-week gestation visit in the four hospitals were invited to complete a questionnaire about the advice they received. Women attending antenatal care at an intervention hospital were significantly more likely to report receiving advice not to consume alcohol during pregnancy and be informed of the harmful effects of alcohol on the fetus/newborn (RR: 2.66; 95% CI: 1.27, 5.56; p=0.005) [148]. The study however was non-randomised and did not report or adjust for baseline rates of care provision, or possible confounders. It also had a small sample size (N=67), which limits the external validity of the study findings. The practice change intervention was also not developed in accordance with implementation science recommendations [133-135] in that it did not include report of a formative barrier assessment or use a theoretical implementation framework in strategy selection. The study also did not

report whether the practice change intervention produced equitable outcomes among the different subgroups of pregnant women or maternity services.

Further research is required to develop, and evaluate the effectiveness of, a practice change intervention in improving the provision of antenatal care addressing alcohol consumption during pregnancy. As per implementation science recommendations [133-135], such an intervention is recommended to be theoretically, empirically, end-user and equity informed to optimise its benefit for women, birth and longer term health outcomes.

SECTION 4: THESIS AIMS AND STRUCTURE

In brief, this chapter highlighted a number of limitations of existing research evidence on the prevalence of antenatal care addressing alcohol consumption during pregnancy, the barriers that may influence clinician implementation of evidence-based and guideline recommended care, and the strategies that may be effective in increasing the provision of such care.

In light of the evidence and practice gaps highlighted by this introductory chapter, the aims of this thesis are to:

1. Assess pregnant women's reported receipt of antenatal care addressing alcohol consumption during pregnancy consistent with clinical guideline recommendations (assess, advise, refer) at two antenatal visit types (initial and subsequent) in public maternity services;
2. Assess the characteristics of pregnant women and maternity services associated with the receipt of antenatal care addressing alcohol consumption during pregnancy;

3. Quantitatively assess pregnant women's acceptability of receiving guideline recommended care antenatal care addressing alcohol consumption as part of routine antenatal care;
4. Comprehensively assess antenatal provider and maternity manager barriers to the implementation of clinical guideline recommendations for addressing alcohol consumption during pregnancy using a consolidated implementation framework;
5. Synthesise the evidence from controlled studies regarding the effectiveness of implementation strategies in improving guideline recommended care addressing modifiable risk factors (alcohol consumption, tobacco smoking and weight gain) in pregnancy care settings (antenatal and preconception);
6. Develop and evaluate the effectiveness of a theoretical, empirical and end-user informed practice change intervention in improving the provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services;
7. Explore whether the practice change intervention had equitable impacts among different subgroups of pregnant women and maternity services.

To address these aims, this thesis consists of eight chapters in addition to this introductory chapter. Seven of these chapters have been published (Chapters 2, 3, 4, 5, 6, 7 and 8). The ninth and final chapter presents a brief summary of the first eight chapters and a discussion of implications for future research and practice. The chapters and studies that address the thesis aims are as follows:

CHAPTER 2

A cross-sectional survey of pregnant women's reported receipt of antenatal care addressing alcohol consumption during pregnancy, associated characteristics and acceptability of care (Aims 1, 2 and 3).

CHAPTER 3

A survey of antenatal provider and maternity manager barriers to the implementation of clinical guideline recommendations for addressing alcohol consumption during pregnancy using the Theoretical Domains Framework (Aim 4).

CHAPTERS 4 AND 5

A systematic review of implementation strategies to improve preconception and antenatal care addressing tobacco smoking, alcohol consumption and weight management (protocol and review) (Aim 5).

CHAPTERS 6 AND 7

A randomised stepped-wedge controlled trial to determine the effectiveness of a practice change intervention in improving antenatal care addressing alcohol consumption during pregnancy (protocol and trial primary outcomes) (Aim 6).

CHAPTER 8

Sub-group analyses to explore the differential effectiveness of a practice change intervention in improving antenatal care addressing alcohol consumption during pregnancy (Aim 7).

CHAPTER 9

A summary of the findings from the first eight chapters and implications for future research and practice.

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CHAPTER 2

Antenatal care for alcohol consumption during pregnancy: pregnant women's reported receipt of care and associated characteristics

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ABSTRACT

Background: Antenatal clinical guidelines recommend that during initial and subsequent antenatal visits all pregnant women: have their alcohol consumption assessed; be advised that it is safest not to consume alcohol during pregnancy and of the potential risks of consumption; and be offered referrals for further support if required. However, the extent to which pregnant women attending public antenatal services receive guideline recommended care at these visits, and the characteristics associated with its receipt, is unknown. The purpose of this study was to examine: 1) pregnant women's reported receipt of guideline recommended care addressing alcohol consumption during pregnancy; 2) characteristics associated with the receipt of care; and 3) pregnant women's acceptability of care.

Methods: From July 2017 – February 2018 a survey (telephone or online) was undertaken with 1363 pregnant women who had recently visited a public antenatal service in one health district in Australia. Receipt and acceptability of recommended care were assessed via descriptive statistics and associations via logistic regression analyses.

Results: At the initial antenatal visit, less than two thirds (64.3%) of pregnant women reported that they received an assessment of their alcohol consumption and just over one third (34.9%) received advice and referral appropriate to their self-reported level of alcohol consumption since pregnancy recognition. Less than 10% of women received such care at subsequent antenatal visits. Characteristics that significantly increased the odds of receiving all guideline elements at the initial antenatal visit included: less than university attainment (OR: 1.93; 95% CI: 1.12, 3.34), not residing in an advantaged area (OR: 2.11; 95% CI: 1.17, 3.79), first pregnancy (OR: 1.91; 95% CI: 1.22, 2.99) and regional/rural service location (OR: 2.38; 95% CI: 1.26, 4.48); and at subsequent visits: younger age (OR: 0.91; 95% CI: 0.84, 0.99) and

Aboriginal origin (OR: 3.17; 95% CI: 1.22, 8.24). Each of the recommended care elements were highly acceptable to pregnant women (88.3% to 99.4%).

Conclusions: Although care for alcohol consumption is both recommended by clinical guidelines and highly acceptable to pregnant women, its receipt in public antenatal services is suboptimal. There is a need and an opportunity for interventions to support antenatal care providers to routinely and consistently provide such care to all pregnant women.

BACKGROUND

Prenatal alcohol exposure is recognised as a risk factor for a number of adverse pregnancy outcomes including spontaneous abortion, stillbirth, preterm birth, fetal growth restriction and low birth weight, and can result in lifelong cognitive, behavioural and neurodevelopmental disabilities for the child [1]. Although the fetus is most vulnerable to structural damage due to the effects of alcohol exposure in the first trimester [2], exposure to alcohol throughout the duration of pregnancy has been associated with poorer pregnancy outcomes [3]. On this basis, many countries, including Australia, have issued national guidelines recommending that it is safest for women who are pregnant or planning a pregnancy not to consume alcohol [1, 4, 5].

Despite such guidelines, approximately 10% of women globally consume alcohol at any time during pregnancy, with higher prevalence estimates reported in countries with high alcohol consumption rates in the general population (e.g. Ireland: 60%; Denmark: 46%; United Kingdom: 41%) [6]. In Australia, prospective cohort studies and national surveys have reported the prevalence of alcohol consumption at various times during pregnancy to be between 28% and 72% [7–14]. For example, a prospective cohort study of 1570 pregnant women found that 59% of women reported any alcohol consumption during pregnancy with 32% reporting

consumption in the second and/or third trimester [10]. Similarly, a national survey conducted in 2016 found that half of pregnant women consumed alcohol before knowing they were pregnant and 25% continued consuming alcohol following knowledge of their pregnancy [11]. Among those women who consumed alcohol during pregnancy, most reported drinking at a frequency of monthly or less (81%) and an average of one to two standard drinks per occasion (97%) [11].

Systematic review evidence indicates that brief interventions delivered by a range of health professional groups (e.g. general practitioners, specialists, nurses and psychologists) are effective in reducing alcohol consumption in patients attending general practice, primary care and hospital emergency settings [15, 16]. Review evidence from primary care settings also suggests that such brief interventions are cost-effective [17]. For pregnant women specifically, brief and psychosocial interventions have been reported to be effective in increasing abstinence from alcohol and modifying alcohol consumption behaviours during pregnancy [16, 18].

Given such findings and the potential adverse outcomes associated with prenatal alcohol exposure, international [19] and Australian [20–22] antenatal clinical guidelines recommend that all pregnant women be asked about their alcohol consumption using a validated assessment tool and be advised that it is safest not to consume alcohol during pregnancy and of the potential risks associated with consumption. For pregnant women identified as currently consuming alcohol at levels where they may find it difficult to abstain, it is recommended that referrals be offered to therapeutic support services or drug and alcohol services for specialist assessment and treatment [19–22]. It is recommended that this assessment and care be provided by the attending antenatal care provider at the initial antenatal visit as well as in subsequent antenatal visits [19–22]. The aim of such guidelines therefore are to encourage women who have not

consumed alcohol since pregnancy recognition to continue abstaining for the remainder of their pregnancy and to accurately identify women who are currently consuming alcohol so that appropriate support can be offered.

In countries that have widespread use of publicly funded health care, such as Australia and the United Kingdom, public antenatal services are a critical setting for these guideline recommendations to be implemented. For instance, in Australia 70% of women access public antenatal care at some stage throughout their pregnancy, with 55% using an exclusive public antenatal model of care from the point of booking in with the hospital at approximately 14 weeks gestation [23]. Such services cater to a diverse range of population groups, including the most vulnerable, and generally have contact with pregnant women on multiple occasions throughout pregnancy to be able to monitor and respond to risks [24].

Despite public antenatal services being a critical setting, the extent to which pregnant women receive all care elements aligned with current antenatal clinical guideline recommendations at both initial and subsequent antenatal visits in these services is unknown. Internationally, the majority of existing studies describing antenatal care for maternal alcohol consumption have not been specific to the public antenatal setting, but rather have focussed on care provision by a range of health professionals (e.g. general practitioners, obstetrician gynaecologists, paediatricians, midwives, community nurses and allied health) [25–28] or have not defined the setting in which care was received [29–37]. Of the six studies identified specific to the public antenatal setting [38–43], none have reported the prevalence of the individual elements of recommended care (assessment, advice, referral) received across multiple visits (initial and subsequent visits) [19–22]. In addition, half of existing studies have used self-report measures of care provision by antenatal care providers [39–41], which can result in an over-estimate of

care delivery. Client self-report has been suggested as a recommended approach when measuring clinical guideline adherence, as although it may produce more conservative results than clinician self-report, it is subject to less response bias [44].

Studies reporting antenatal care provision in public antenatal services suggests that it is highly variable. For instance, a survey of 103 Norwegian midwives found that 97% mostly or always ask about alcohol consumption at the initial antenatal visit (42% via a validated tool) and 66% mostly or always provide a referral to the woman's general practitioner when risky alcohol consumption is identified [40]. A study of 439 Danish pregnant women found that about half (51%) reported being asked about alcohol consumption and 11% advised that it is safest not to consume alcohol during pregnancy [38], however, the study did not define the visit in which care was received. In an Australian study of 223 pregnant women, 92% reported being asked about alcohol and, of those women who reported consuming alcohol during pregnancy, 10% were offered assistance to manage their alcohol consumption [43]. The study did not report whether the questions women received were consistent with a validated assessment tool. Such studies echo the broader literature in a range of health care settings, which has found that appropriate care in response to screening is often not provided [45]. Given the limitations of existing studies, it is unknown whether current public antenatal care for alcohol consumption during pregnancy aligns with guideline recommendations at both initial and subsequent antenatal visits.

Given the recommendation that assessment and care for alcohol consumption during pregnancy is routinely undertaken with all women, there is also a need to assess if current care is being delivered consistently to all women irrespective of their characteristics or those of the antenatal service. Previous studies have found that women who are younger, do not have a university

degree, are of a minority ethnicity, are attending antenatal care at a smaller centre [27] or seeing a midwife (as opposed to a doctor) [46] are more likely to receive alcohol assessment and advice from their antenatal care provider [34]. Whereas, consistent with the universal screening recommendations of antenatal clinical guidelines, women's actual alcohol consumption behaviours during pregnancy have not been found to be associated with being asked about alcohol consumption [38, 47]. Studies examining adherence to antenatal care guidelines more broadly have also found that women who have had a previous pregnancy and do not have a history of pregnancy complications [48] are more likely to receive guideline care, but the evidence is mixed [43, 49, 50]. No studies have examined the characteristics associated with the receipt of all guideline elements for assessment and care for alcohol consumption during pregnancy at initial and subsequent visits. In the absence of such information, it is unknown whether all women have the same opportunity to receive recommended care for alcohol consumption during pregnancy.

There is also a need to assess pregnant women's acceptability of guideline recommended care for alcohol consumption as this may be an impediment to antenatal care providers delivering such care routinely to all women. Currently, limited studies have examined women's acceptability for each of the care elements recommended by antenatal clinical guidelines [19–22]. For instance, in one Australian study conducted with 1103 women, nearly all women agreed that antenatal care providers should ask pregnant women about their alcohol consumption (97%) and advise pregnant women to abstain from consuming alcohol (91%) [51]. However, the study did not include women who were currently pregnant and did not assess whether acceptability varied by women's alcohol consumption behaviours. Therefore, an assessment of pregnant women's acceptability is required to determine whether it is a potential barrier to routine guideline care provision.

Given the current gaps in evidence, this study was undertaken to examine: 1) pregnant women's reported receipt of antenatal clinical guideline recommended care (assessment, advice and referral) for alcohol consumption during pregnancy at their initial antenatal visit and subsequent antenatal visits; 2) associations between the characteristics of pregnant women and antenatal services and the receipt of recommended care in these visits; and 3) pregnant women's acceptability of such care.

METHODS

Ethics approval

The study was approved by the Hunter New England Human Research Ethics Committee (16/11/16/4.07), the University of Newcastle Human Research Ethics Committee (H-2017-0032) and the Aboriginal Health and Medical Research Council (1236/16). See Appendix 9 for evidence of ethics approvals.

Design and setting

A cross-sectional survey of pregnant women attending antenatal care in three sectors within a health district in New South Wales, Australia was undertaken from July 2017 to February 2018. The services provide public antenatal care to 70% (over 6000 annually) of women giving birth in the district's public hospitals in metropolitan, regional and rural locations.

Participants and recruitment

Public antenatal services

All (n = 5) public antenatal services within the study area were included in the study. Such services provide a range of antenatal care models, including hospital and community-based

midwifery clinics, midwifery group practice continuity of care, specialist medical clinics, AMIHS and multidisciplinary care for women with complex pregnancies or identified vulnerabilities. Care is provided by registered midwives, medical practitioners, Aboriginal Health Workers and students and is supported by a range of other professions, such as social workers. The number and type of antenatal care providers present in each antenatal visit differs by care model.

Pregnant women

Women attending any of the public antenatal services within the study area were eligible to participate in the study if they: were at least 18 years of age; were between 12 and 37 weeks gestation; and had attended a face-to-face antenatal visit in the preceding week for either an initial antenatal visit or a visit between 27 and 28 weeks or 35 and 36 weeks gestation (inclusive). Women were deemed ineligible if either: their antenatal care was through a private obstetrician; they had already been selected to participate in the survey in the past 4 weeks; they had previously declined participation in the survey; or they had given birth or had a negative pregnancy outcome (stillbirth or miscarriage).

Recruitment procedure

All women received written information at their first antenatal visit informing them about the survey and that they might be sampled throughout their antenatal care based on their attendance at the service [see Appendix 10]. The information provided included a toll-free telephone number that women could call to register that they did not want to be sampled for the study. Electronic medical record and appointment data were used to generate a weekly sample of eligible women across the five public antenatal services as a group. From an average of 188 women per week who had an appointment, 150 were on average eligible for sampling. From

these eligible women, 105 (initial antenatal visit: 30; 27–28 weeks gestation: 30; 35– 36 weeks gestation: 45) were randomly selected via a computerised random-number generator and mailed an information statement outlining the purpose of the survey and inviting them to participate [see Appendix 11]. In the information statement women were informed that the study team had not had direct access to their medical records and only information required to invite participation had been provided by the antenatal service.

One week later, non-Aboriginal women were followed-up by telephone and invited to participate in a computer assisted telephone interview (CATI). Based on advice received regarding a culturally appropriate survey approach and as per formal ethics approval, women of Aboriginal or Torres Strait Islander origin and/or women attending or enrolled to attend an AMIHS received a text message after the information statement was mailed and provided the option of completing the survey via CATI or online [see Appendix 12]. Those women who chose to complete the survey online, provided their written consent to participate via text message. Consent was obtained via text message to reduce participant burden by only sending an online survey link to those women who provided their consent to participate in the study. The online survey link was sent to the participant within 48 hours of consent being obtained and was unique to the participant to provide ease of access to the survey and to allow data protection. A reminder that participation was voluntary and that it was possible to decline participation at any stage by not submitting a completed survey was provided on the first screen of the online survey prior to the woman entering into the survey. Women's consent and online survey completion status were saved in the survey database. Women who did not respond to the text were followed up with a telephone call 4 days later and invited to participate in the survey.

As per formal ethics approval, women who received a telephone call inviting participation gave their verbal consent to participate, which was recorded by the CATI interviewer into the survey database prior to the commencement of the survey. Eligibility related to English language proficiency (sufficient to complete the survey unaided) was also assessed at the beginning of the CATI. Women were given the opportunity to decline survey participation at the point of receiving the information statements (via a toll-free number), the text message or at any stage during the survey. All women who declined participation in the CATI were provided the option to complete the survey online. Women received up to 10 phone contact attempts within a 2-week period. Women who chose to complete the survey online were asked to complete the survey within the same two-week period. As per ethics requirements, medical records were checked by a local health district staff member prior to women being called and any women who had given birth or had a negative pregnancy outcome were made ineligible for participation in the study.

Data collection procedures

The survey questions were developed based on previous Australian national and state surveys [11, 42] and surveys conducted in health care settings to assess patient self-report of care receipt [52–54]. The online survey was developed using REDCap [55] and was accessible via email or text message using a unique survey link. CATI surveys were undertaken by trained and experienced female interviewers. The online and CATI surveys were reviewed for cultural appropriateness for Aboriginal and Torres Strait Islander women and pilot tested prior to use. Data regarding antenatal service characteristics were obtained from electronic medical record and appointment systems and linked to individual participant data from the CATI and online surveys. See Appendix 13 for the CATI survey and Appendix 14 for the online mode of the survey.

Measures

Pregnant women's alcohol consumption since pregnancy recognition

All women were asked to report their alcohol consumption since pregnancy recognition using the three item AUDIT-C screening tool (how often have a drink containing alcohol, how many standard drinks consumed on a typical drinking day and how often five or more standard drinks consumed on one occasion) [56]. A systematic review of brief alcohol screening instruments in pregnancy found the AUDIT-C to have the highest sensitivity for identifying risky alcohol consumption among pregnant women [57]. Australian national guidelines classify 'medium risk of harm' in pregnancy as an AUDIT-C score of three to four and 'high risk of harm' in pregnancy as an AUDIT-C score of five plus [58]. Women at medium and high risks of harm are likely to require further support to abstain from alcohol during pregnancy [58].

Receipt of antenatal care for maternal alcohol consumption

All women completed survey items assessing whether they were asked any questions by their antenatal care provider/s about their alcohol consumption during the antenatal visit and, if so, whether they were asked questions consistent with the AUDIT-C [56] (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) (possible responses: yes, no, don't know). All women were also asked whether they were advised that it is safest not to consume alcohol during pregnancy; advised of the potential risks associated with consuming alcohol during pregnancy; and whether they were offered a referral to assist them in managing their alcohol consumption (possible responses: yes, no, don't know). Women completing the survey for the 27–28 or 35–36 week gestation visits were also asked if they had accepted a referral for managing their alcohol consumption in any other antenatal care visit and, if so, whether the

antenatal care provider followed up or discussed the progress of any previously accepted referrals (possible responses: yes, no, don't know).

Characteristics associated with receipt of care

Data were collected on the following characteristics of pregnant women and antenatal services that were identified as potentially associated with provision of antenatal care to address maternal alcohol consumption during pregnancy [27, 34, 38, 46–48].

- *Pregnant women's characteristics*. Women reported: whether they were of Aboriginal or Torres Strait Islander origin; their age; their highest level of education completed; whether this was their first pregnancy; and whether they had consumed alcohol since pregnancy recognition [56]. Women's allocated model of antenatal care (hospital and community-based midwifery clinic, specialist medical clinic, midwifery group practice continuity of care, multidisciplinary care for women with complex medical needs, AMIHS, multidisciplinary care for women with identified vulnerabilities) and residential postal code were obtained from the electronic medical record and appointment systems.
- *Antenatal service characteristics*. The antenatal service's postal code was obtained from the electronic medical records and women reported the type of antenatal care provider seen in their visit with the service (possible responses: midwife, hospital doctor (e.g. specialist obstetrician, registrar), Aboriginal Health Worker, other, don't know).

Acceptability of antenatal care for maternal alcohol consumption

Women's acceptability of receiving assessment and care for alcohol consumption during antenatal care visits was assessed using a 5-point Likert scale (possible responses: strongly agree, agree, unsure, disagree, strongly disagree) and were informed by previous surveys with patients attending a health service [54]. Women reported whether during their antenatal care it was acceptable to be: asked about their alcohol consumption; asked about their alcohol consumption on multiple occasions; advised that it is safest not to consume alcohol during pregnancy; advised of the potential risks associated with alcohol consumption during pregnancy; offered referral to a telephone based counselling service for further support if required; and offered referral to the health district's Drug and Alcohol clinical service for further support if required.

Statistical analyses

All statistical analyses were undertaken using SAS version 9.3 [59]. Condensed response categories were created for women's Aboriginal and Torres Strait Islander origin ('Aboriginal or Torres Strait Islander or both' 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'), women's self-reported alcohol consumption since pregnancy recognition ('yes' (for AUDIT-C score ≥ 1) or 'no' (for AUDIT-C score of 0)) and antenatal care providers seen in the visit ('midwife only' or 'doctor only' or 'midwife and doctor' or 'other provider involved'). Antenatal visits at 27–28 and 35–36 weeks gestation were also condensed to create a 'subsequent antenatal visits' variable. Women's allocated model of antenatal care was used to indicate pregnancy risk level, with hospital and community-based midwifery clinics, midwifery group practice continuity of care and multidisciplinary care for women with social vulnerabilities used to classify 'low risk pregnancy' and specialist medical clinics and multi-disciplinary care for women with complex

medical needs models used to classify 'high risk pregnancy'. Women's residential postal codes were used to determine socio-economic disadvantage using the Index of Relative Socio-Economic Disadvantage (IRSD) [60] with index quintiles collapsed into 'most disadvantaged' (quintiles one and two), 'mid disadvantaged' (quintile three) and 'least disadvantaged' (quintiles four and five). Antenatal service postal code was used to calculate the antenatal service's geographical remoteness ('major city' or 'regional or rural') using the Access/Remoteness Index of Australia [61]. 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).

The following assessment and care delivery outcome variables were created:

- 'assessment (AUDIT-C)': reported receipt of a question consistent with the first AUDIT-C question (for women who reported in the survey that they had not consumed alcohol since pregnancy recognition (i.e. AUDIT-C score = 0)) and reported receipt of all three questions consistent with the AUDIT-C (for women who reported in the survey that they had consumed alcohol since pregnancy recognition (i.e. AUDIT-C score ≥ 1)).
- 'complete advice': 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 (for all women regardless of their alcohol consumption since pregnancy recognition).
- 'referral offered or followed up': reported receipt of referral offer or follow up for women who reported in the survey that they had consumed alcohol at medium or high risk levels since pregnancy recognition (i.e. AUDIT-C score: ≥ 3).

- 'complete care': reported receipt of complete advice (all women) and referral offered or followed up (for women who reported in the survey an AUDIT-C score ≥ 3).
- 'all guideline recommended elements': reported assessment via AUDIT-C (all women) and complete advice (all women) and referral offered or followed up (for women who reported in the survey an AUDIT-C score ≥ 3).

Descriptive statistics were used to describe pregnant women and antenatal service characteristics; receipt of assessment and care; and acceptability of care. Pregnant women's acceptability of care was also assessed for women who had consumed alcohol since pregnancy recognition as a subgroup analysis. Associations between maternal and service characteristics and the receipt of antenatal care for maternal alcohol consumption were assessed using bivariate and multivariable logistic regression analyses. Bivariate analyses (chi square for categorical variables and t-test for continuous variables) were first undertaken to test the individual associations between each of the characteristics with the receipt of three care elements (assessment (AUDIT-C), complete care, and all guideline recommended elements) at the initial antenatal visit and subsequent antenatal visits. The variable 'consumption of alcohol since pregnancy recognition' was not included in any association analyses for the initial antenatal visit as the attending antenatal care provider would not routinely have prior knowledge of a woman's alcohol consumption and as such it is not hypothesised to be associated with the provision of assessment and care at this visit. Multivariable logistic regression analyses were then undertaken to test the associations between all the characteristics with the receipt of three care elements (assessment (AUDIT-C), complete care, and all guideline recommended elements) at the initial antenatal visit and subsequent antenatal visits.

RESULTS

Participants

All (n = 5) public antenatal services in the study area participated. A total of 2840 eligible women were sent an information letter and invited to participate in the survey. On the day of contact, 2546 (90%) women were deemed eligible to participate based on electronic medical record data that they had not given birth or had a negative pregnancy outcome since being sampled or had not refused participation via the toll-free number. Of the 1768 (62%) women who were able to be contacted within the 2-week period, 1712 (97%) were deemed eligible to participate based on English language proficiency and having not given birth or experienced a negative pregnancy outcome as reported by the woman. Of these, 1397 (82%) women consented to participate and 1363 (80%) completed the survey. A lower proportion of Aboriginal and Torres Strait Islander women compared to non-Aboriginal women consented to participate in the survey (58% vs 84%, $p < 0.001$). Pregnant women and antenatal service characteristics are reported in Table 2.1.

Table 2.1 Characteristics of pregnant women and antenatal services (n=1363)

Characteristic	N (%)
Age	
Mean (SD)	29 years (5 years)
Aboriginal, or Torres Strait Islander, or both	80 (6%)
Highest education level completed	
Completed high school or less	398 (29%)
Completed technical certificate or diploma	496 (36%)
Completed university or college degree or higher	469 (34%)
Area index of disadvantage	
Most disadvantaged	574 (42%)
Mid disadvantaged	454 (33%)
Least disadvantaged	335 (25%)
First Pregnancy	571 (42%)
Pregnancy risk level	
Low risk	851 (62%)
High risk	512 (38%)
Consumed alcohol since pregnancy recognition (yes)	133 (10%)
Antenatal service geographic remoteness	
Major city	1146 (84%)
Regional or rural	217 (16%)
Provider/s seen in antenatal visit	
Midwife only	821 (60%)
Doctor only	198 (15%)
Midwife and doctor	298 (22%)
Other provider involved	46 (3%)

Receipt of assessment and care for maternal alcohol consumption in antenatal visits

Asked about alcohol consumption and assessment consistent with AUDIT-C

As shown in Table 2.2, the majority of participants reported being asked about their alcohol consumption (88.8%) and receiving questions consistent with the AUDIT-C assessment (64.3%) at their initial antenatal visit. Significantly lower proportions of women reported being asked about alcohol consumption (14.3%) and assessed via the AUDIT-C (7.8%) at subsequent antenatal visits ($p < 0.001$).

Advice

Nearly two thirds of participants (63.2%) reported being advised at their initial antenatal visit that it is safest not to consume alcohol during pregnancy, 38.5% reported being advised of the potential risks associated with alcohol consumption during pregnancy and 35.1% reported receiving both components of recommended advice (complete advice). At subsequent antenatal visits, significantly lower proportions of women reported receipt of advice that it is safest not to consume alcohol during pregnancy (15.8%), potential risks associated with alcohol consumption during pregnancy (21.0%) and complete advice (8.8%) ($p < 0.001$).

Referral offered or followed up

Two of the participants surveyed after the initial antenatal visit reported that they had consumed alcohol at medium or high-risk levels (i.e. AUDIT-C ≥ 3) since pregnancy recognition. One of these participants reported that she was offered a referral for further support to address her alcohol consumption. Four women surveyed after subsequent antenatal visits reported that they had consumed alcohol at medium or high-risk levels, with none reporting being offered a referral or having a previously accepted referral followed up in their antenatal visit.

Complete care (advice and referral)

At the initial antenatal visit approximately one third of participants (34.9%) reported receiving complete care for alcohol consumption during pregnancy relative to their self-reported alcohol risk level since pregnancy recognition. At subsequent antenatal visits provision of complete care was significantly lower (8.7%, $p < 0.001$).

All guideline elements (assessment, advice and referral)

At the initial antenatal visit just over a quarter (27.9%) of participants reported being assessed consistent with the AUDIT-C, receiving advice and being offered a referral or having a previously accepted referral followed up if at medium or high risk. At subsequent antenatal visits significantly lower proportion of women reported receiving all guideline care elements relative to their identified risk level (3.8%, $p < 0.001$).

Table 2.2 Pregnant women's reported receipt of assessment and care for maternal alcohol consumption at initial and subsequent antenatal visits

Element of care reportedly received	Initial antenatal visit (N=473)			Subsequent antenatal visits (N=890)			Comparison between care at initial and subsequent antenatal visits	
	n	%	95% CI	n	%	95% CI	Adjusted Odds Ratio (95% CI) [a]	p-value
Asked about alcohol consumption	420	88.8	85.63, 91.33	127	14.3	12.13, 16.72	47.61 (33.82, 67.02)	<0.001
Assessment (AUDIT-C)	304	64.3	59.95, 68.59	69	7.8	6.17, 9.70	21.40 (15.71, 29.16)	<0.001
Advised safest not to consume	299	63.2	58.86, 67.56	141	15.8	13.59, 18.39	9.13 (7.04, 11.83)	<0.001
Advised of potential risks	182	38.5	34.09, 42.87	187	21.0	18.46, 23.81	2.35 (1.84, 3.01)	<0.001
Complete advice (safest not to consume and potential risks)	166	35.1	30.79, 39.40	78	8.8	7.08, 10.80	5.63 (4.17, 7.59)	<0.001
Referral offered or followed up [b]	1	50.0	0.00, 100.00	0	0.0	0.00, 0.00	-	-
Complete care (complete advice and referral offered or followed up)	165	34.9	30.58, 39.18	77	8.7	6.98, 10.68	5.66 (4.19, 7.64)	p<0.001
All guideline elements (assessment, complete advice and referral offered or followed up)	132	27.9	23.86, 31.95	34	3.8	2.75, 5.29	9.75 (6.55, 14.50)	p<0.001

[a] Subsequent visit as Referent.

[b] Limited to women who reported in the survey that they had consumed alcohol at medium or high risk of harm levels since pregnancy recognition (AUDIT-C score ≥3) (Initial antenatal visit n=2; Subsequent visit n=4). Not included in 'comparison between care at initial and subsequent antenatal visits' p-value test due to small sample size.

Association between receipt of assessment and care for maternal alcohol consumption and characteristics of pregnant women and antenatal services

All care elements both at the initial and subsequent antenatal visits were found to have characteristics associated with reported care receipt (Tables 2.3 and 2.4). Adjusting for all characteristics, attending antenatal care at a regional or rural location compared to a major city significantly increased the odds of receiving assessment (OR: 2.74; 95% CI: 1.40, 5.33), complete care (OR: 2.04; 95% CI: 1.10, 3.77) and all guideline recommended elements (OR: 2.38; 95% CI: 1.26, 4.48) at the initial antenatal visit. Additionally, completing high school or less or a technical certificate or diploma increased the odds of reporting complete care (OR: 1.82; 95% CI: 1.05, 3.16; OR: 1.82; 95% CI: 1.09, 3.03) and all guideline elements (OR: 1.88; 95% CI: 1.04, 3.40; OR: 1.93; 95% CI: 1.12, 3.34) at the initial antenatal visit. Being a woman's first pregnancy was also significantly associated with receiving complete care (OR: 1.78; 95% CI: 1.16, 2.72) and all guideline elements (OR: 1.91; 95% CI: 1.22, 2.99) at the initial antenatal visit.

Adjusting for all characteristics, identifying as Aboriginal or Torres Strait Islander origin significantly increased the odds of receiving assessment (OR: 2.70; 95% CI: 1.23, 5.92), complete care (OR: 2.40; 95% CI: 1.15, 5.04) and all guideline elements (OR: 3.17; 95% CI: 1.22, 8.24) at subsequent antenatal visits. Being younger also significantly increased the odds of reporting receipt of complete care (OR: 0.91; 95% CI: 0.86, 0.96) and all guideline elements (OR: 0.91; 95% CI: 0.84, 0.99) at subsequent antenatal visits.

Table 2.3 Bivariate and multivariable associations between reported receipt of assessment (AUDIT-C), complete care and all guideline elements and maternal and antenatal service characteristics at the initial antenatal visit (N=473)

Characteristic	Assessment (AUDIT-C)					Complete Care (complete advice and referral offered or followed up)				
	n (%)	Bivariate Unadjusted OR (95% CI)	p-value	Multivariable Adjusted OR (95% CI)	p-value	n (%)	Bivariate Unadjusted OR (95% CI)	p-value	Multivariable Adjusted OR (95% CI)	p-value
Age	29 years (SD: 5 years)	0.97 (0.94, 1.01)	0.13	0.98 (0.94, 1.02)	0.41	28 years (SD: 6 years)	0.92 (0.89, 0.96)	<0.001	0.96 (0.92, 1.00)	0.04
Aboriginal or Torres Strait Islander			0.27		0.53			<0.01		0.04
Yes	18 (75.0%)	1.71 (0.67, 4.39)		1.37 (0.52, 3.61)		15 (62.5%)	3.32 (1.42, 7.77)		2.59 (1.06, 6.31)	
No (referent)	286 (63.7%)					150 (33.4%)				
Education level			0.08		0.17			<0.01		0.04
Completed high school certificate or less	98 (68.1%)	1.61 (1.00, 2.59)		1.50 (0.89, 2.52)		62 (43.1%)	2.42 (1.47, 3.98)		1.82 (1.05, 3.16)	
Completed technical certificate or diploma	120 (67.4%)	1.56 (1.00, 2.45)		1.50 (0.94, 2.40)		67 (37.6%)	1.93 (1.19, 3.12)		1.82 (1.09, 3.03)	
Completed university or college degree or higher (referent)	86 (57.0%)					36 (23.8%)				
Area index of disadvantage			0.14		0.14			0.20		0.30
Most disadvantaged	132 (66.3%)	1.49 (0.94, 2.37)		1.02 (0.61, 1.71)		76 (38.2%)	1.55 (0.96, 2.52)		1.15 (0.65, 2.03)	
Mid disadvantaged	102 (67.6%)	1.58 (0.96, 2.58)		1.55 (0.93, 2.58)		54 (35.8%)	1.40 (0.84, 2.34)		1.51 (0.87, 2.60)	
Least disadvantaged (referent)	70 (56.9%)					35 (28.5%)				

First pregnancy			0.89		0.67			<0.01		<0.01
Yes	124 (63.9%)	0.97 (0.66, 1.43)		0.91 (0.60, 1.38)		84 (43.3%)	1.87 (1.27, 2.74)		1.78 (1.16, 2.72)	
No (referent)	180 (64.5%)					81 (29.0%)				
Pregnancy risk level			0.20		0.49			0.02		0.04
Low risk pregnancy	282 (65.1%)	1.53 (0.79, 2.94)		1.28 (0.63, 2.61)		158 (36.5%)	2.71 (1.17, 6.27)		2.60 (1.05, 6.44)	
High risk pregnancy (referent)	22 (55.0%)					7 (17.5%)				
Antenatal service location			<0.01		<0.01			0.01		0.02
Regional or rural	57 (78.1%)	2.21 (1.22, 3.98)		2.74 (1.40, 5.33)		35 (48.0%)	1.91 (1.15, 3.17)		2.04 (1.10, 3.77)	
Major city (referent)	247 (61.8%)					130 (32.5%)				
Provider/s seen in antenatal visit			0.23		0.14			0.22		0.50
Midwife only	236 (66.5%)	1.62 (0.65, 4.02)		1.99 (0.76, 5.17)		128 (36.1%)	0.56 (0.23, 1.39)		0.53 (0.20, 1.42)	
Midwife and doctor	47 (56.0%)	1.04 (0.39, 2.77)		1.21 (0.44, 3.38)		23 (27.4%)	0.38 (0.14, 1.02)		0.44 (0.15, 1.29)	
Other provider involved	10 (71.4%)	2.05 (0.48, 8.77)		3.11 (0.68, 14.22)		4 (28.6%)	0.40 (0.09, 1.71)		0.41 (0.08, 1.98)	
Doctor only (referent)	11 (55.0%)					10 (50.0%)				

Characteristic	All guideline elements (assessment, complete advice and referral offered or followed up)				
	n (%)	Bivariate Unadjusted OR (95% CI)	p-value	Multivariable Adjusted OR (95% CI)	p-value
Age	28 years (SD: 6 years)	0.94 (0.90, 0.98)	<0.01	0.97 (0.93, 1.02)	0.23
Aboriginal or Torres Strait Islander			0.05		0.20
Yes	11 (45.8%)	2.29 (1.00, 5.26)		1.78 (0.74, 4.28)	
No (referent)	121 (27.0%)				
Education level			<0.01		0.04
Completed high school certificate or less	49 (34.0%)	2.27 (1.33, 3.87)		1.88 (1.04, 3.40)	
Completed technical certificate or diploma	55 (30.9%)	1.96 (1.17, 3.30)		1.93 (1.12, 3.34)	
Completed university or college degree or higher (referent)	28 (18.5%)				
Area index of disadvantage			0.05		0.03
Most disadvantaged	60 (30.2%)	1.78 (1.04, 3.05)		1.28 (0.69, 2.39)	
Mid disadvantaged	48 (31.8%)	1.92 (1.10, 3.37)		2.11 (1.17, 3.79)	
Least disadvantaged (referent)	24 (19.5%)				
First pregnancy			<0.01		<0.01
Yes	69 (35.6%)	1.89 (1.26, 2.84)		1.91 (1.22, 2.99)	
No (referent)	63 (22.6%)				
Pregnancy risk level			0.06		0.12
Low risk pregnancy	126 (29.1%)	2.33 (0.95, 5.68)		2.13 (0.82, 5.53)	
High risk pregnancy (referent)	6 (15.0%)				
Antenatal service location			<0.01		<0.01

Regional or rural	30 (41.1%)	2.04 (1.22, 3.42)		2.38 (1.26, 4.48)	
Major city (referent)	102 (25.5%)				
Provider/s seen in antenatal visit			0.49		0.71
Midwife only	103 (29.0%)	0.76 (0.29, 1.96)		0.74 (0.27, 2.02)	
Midwife and doctor	18 (21.4%)	0.51 (0.18, 1.46)		0.56 (0.18, 1.71)	
Other provider involved	4 (28.6%)	0.74 (0.17, 3.26)		0.87 (0.18, 4.29)	
Doctor only (referent)	7 (35.0%)				

Table 2.4 Bivariate and multivariable associations between reported receipt of assessment (AUDIT-C), complete care and all guideline elements and maternal and antenatal service characteristics at subsequent antenatal visits (N=890)

Characteristic	Assessment (AUDIT-C)					Complete Care (complete advice and referral offered or followed up)				
	n (%)	Bivariate Unadjusted OR (95% CI)	p-value	Multivariable Adjusted OR (95% CI)	p-value	n (%)	Bivariate Unadjusted OR (95% CI)	p-value	Multivariable Adjusted OR (95% CI)	p-value
Age	28 years (SD: 6 years)	0.95 (0.91, 1.00)	<0.05	0.98 (0.93, 1.04)	0.57	27 years (SD: 6 years)	0.88 (0.84, 0.92)	<0.001	0.91 (0.86, 0.96)	<0.01
Aboriginal or Torres Strait Islander			<0.01		0.01			<0.001		0.02
Yes	11 (19.6%)	3.27 (1.61, 6.66)		2.70 (1.23, 5.92)		14 (25.0%)	4.08 (2.11, 7.87)		2.40 (1.15, 5.04)	
No (referent)	58 (7.0%)					63 (7.6%)				
Education level			<0.01		0.04			<0.001		0.07
Completed high school certificate or less	31 (12.2%)	2.32 (1.26, 4.25)		1.96 (1.01, 3.80)		36 (14.2%)	3.12 (1.69, 5.76)		2.01 (1.00, 4.01)	
Completed technical certificate or diploma	20 (6.3%)	1.12 (0.58, 2.16)		0.97 (0.49, 1.94)		25 (7.9%)	1.61 (0.84, 3.08)		1.17 (0.58, 2.34)	
Completed university or college degree or higher (referent)	18 (5.7%)					16 (5.0%)				
Area index of disadvantage			0.39		0.43			0.69		0.97
Most disadvantaged	33 (8.8%)	1.61 (0.81, 3.19)		1.61 (0.76, 3.40)		36 (9.6%)	1.22 (0.67, 2.23)		1.07 (0.53, 2.15)	
Mid disadvantaged	24 (7.9%)	1.43 (0.70, 2.93)		1.50 (0.72, 3.14)		24 (7.9%)	0.99 (0.52, 1.89)		1.00 (0.50, 1.97)	
Least disadvantaged (referent)	12 (5.7%)					17 (8.0%)				
First pregnancy			0.57		0.59			0.13		0.55
Yes	27 (7.2%)	0.87 (0.52, 1.43)		0.86 (0.50, 1.48)		39 (10.3%)	1.44 (0.90, 2.30)		1.17 (0.69, 1.98)	

No (referent)	42 (8.2%)					38 (7.4%)				
Pregnancy risk level			0.52		0.95			0.84		0.33
Low risk pregnancy	35 (8.4%)	1.18 (0.72, 1.92)		1.02 (0.54, 1.94)		37 (8.9%)	1.05 (0.66, 1.67)		0.74 (0.41, 1.35)	
High risk pregnancy (referent)	34 (7.2%)					40 (8.5%)				
Consumed alcohol since pregnancy recognition			0.33		0.63			0.91		0.26
Yes	5 (5.2%)	0.63 (0.25, 1.60)		0.79 (0.30, 2.06)		8 (8.3%)	0.96 (0.44, 2.05)		1.60 (0.71, 3.60)	
No (referent)	64 (8.1%)					69 (8.7%)				
Antenatal service location			0.78		0.85			0.41		0.68
Regional or rural	12 (8.3%)	1.10 (0.57, 2.10)		0.93 (0.44, 1.97)		15 (10.4%)	1.28 (0.71, 2.32)		1.17 (0.56, 2.41)	
Major city (referent)	57 (7.6%)					62 (8.3%)				
Provider/s seen in antenatal visit			0.27		0.73			<0.01		0.03
Midwife only	39 (8.4%)	1.26 (0.65, 2.47)		1.20 (0.52, 2.77)		44 (9.4%)	2.55 (1.13, 5.77)		2.72 (1.07, 6.90)	
Midwife and doctor	13 (6.1%)	0.89 (0.40, 2.01)		0.87 (0.38, 1.99)		18 (8.4%)	2.24 (0.92, 5.50)		2.37 (0.95, 5.95)	
Other provider involved	5 (15.6%)	2.56 (0.84, 7.85)		1.64 (0.48, 5.63)		8 (25.0%)	8.14 (2.71, 24.48)		6.17 (1.83, 20.82)	
Doctor only (referent)	12 (6.7%)					7 (3.9%)				

Characteristic	All guideline elements (assessment, complete advice and referral offered or followed up)				
	n (%)	Bivariate Unadjusted OR (95% CI)	p-value	Multivariable Adjusted OR (95% CI)	p-value
Age	26 years (SD: 5 years)	0.88 (0.82, 0.94)	<0.001	0.91 (0.84, 0.99)	0.03
Aboriginal or Torres Strait Islander origin or both			<0.001		0.02
Yes	8 (14.3%)	5.18 (2.23, 12.05)		3.17 (1.22, 8.24)	
No (referent)	26 (3.1%)				
Education level			0.02		0.23
Completed high school certificate or less	17 (6.7%)	3.19 (1.30, 7.81)		1.84 (0.67, 5.05)	
Completed technical certificate or diploma	10 (3.1%)	1.44 (0.54, 3.84)		0.94 (0.33, 2.68)	
Completed university or college degree or higher (referent)	7 (2.2%)				
Area index of disadvantage			0.43		0.69
Most disadvantaged	18 (4.8%)	1.48 (0.61, 3.59)		1.41 (0.51, 3.84)	
Mid disadvantaged	9 (3.0%)	0.90 (0.33, 2.45)		0.98 (0.34, 2.78)	
Least disadvantaged (referent)	7 (3.3%)				
First pregnancy			0.83		0.63
Yes	15 (4.0%)	1.08 (0.54, 2.15)		0.83 (0.38, 1.78)	
No (referent)	19 (3.7%)				
Pregnancy risk level			0.29		0.84
Low risk pregnancy	19 (4.6%)	1.45 (0.73, 2.89)		0.92 (0.39, 2.17)	
High risk pregnancy (referent)	15 (3.2%)				
Consumed alcohol since pregnancy recognition			0.85		0.30

Yes	4 (4.2%)	1.11 (0.38, 3.21)		1.83 (0.59, 5.70)	
No (referent)	30 (3.8%)				
Antenatal service location			0.48		0.82
Regional or rural	7 (4.9%)	1.36 (0.58, 3.19)		1.12 (0.41, 3.08)	
Major city (referent)	27 (3.6%)				
Provider/s seen in antenatal visit			0.11		0.48
Midwife only	22 (4.7%)	2.89 (0.85, 9.78)		2.70 (0.67, 10.84)	
Midwife and doctor	6 (2.8%)	1.68 (0.41, 6.83)		1.71 (0.41, 7.12)	
Other provider involved	3 (9.4%)	6.03 (1.16, 31.35)		3.35 (0.54, 20.60)	
Doctor only (referent)	3 (1.7%)				

Acceptability of receiving assessment and care for maternal alcohol consumption in antenatal visits

Participants reported high levels of acceptability for their alcohol consumption to be assessed (98.7%) in antenatal visits, with 88.3% of participants agreeing that it was acceptable to have their alcohol consumption assessed on multiple occasions throughout pregnancy. Reported acceptability of being provided with advice that it is safest not to consume alcohol during pregnancy (98.6%) and of the potential risks (99.3%) was also high. Almost all women reported that it would be acceptable for a referral to be offered to telephone counselling (99.0%) or a drug and alcohol service (99.4%) for further support for alcohol consumption if required. Care was also found to be highly acceptable among women who reported that they had consumed alcohol since pregnancy recognition. Of these women: 96.2% reported that they would find assessment acceptable; 82.7% that assessment on multiple occasions was acceptable; 92.5% that being provided with advice that it is safest not to consume alcohol during pregnancy was acceptable; 99.3% that being provided with advice on potential risks was acceptable; 98.5% that being offered a referral to a telephone counselling service was acceptable; and 99.3% that being offered a referral to a drug and alcohol service was acceptable.

DISCUSSION

This is the first comprehensive study of pregnant women's reported receipt and acceptability of guideline recommended care for alcohol consumption and the factors associated with receiving such care in the Australian public antenatal care setting. At the initial antenatal visit, less than two thirds of pregnant women reported having their alcohol consumption assessed according to guidelines and approximately one third reported receiving the appropriate care (advice and referral) for their self-reported alcohol risk level. Most women reported that they did not receive assessment and care at subsequent antenatal visits. Reported receipt of all

guideline elements were significantly associated with specific characteristics of pregnant women and/or antenatal services, including age, Aboriginal origin, education attainment level, first pregnancy, pregnancy risk level and the antenatal service location and provider seen, indicating that recommended care was not undertaken routinely for all women. A high proportion of pregnant women agreed that the provision of such assessment and care in their antenatal visits is acceptable, including those women who reported consuming alcohol since pregnancy recognition. These findings suggest that antenatal clinical guideline recommendations are currently not being universally provided and that additional strategies are required to ensure all women routinely receive the appropriate care for alcohol consumption during pregnancy [62].

A higher proportion of pregnant women reported being asked about their alcohol consumption than reported being specifically asked questions consistent with the AUDIT-C [56] (recommended validated tool). These findings are consistent with a Norwegian study that found most midwives asked about alcohol consumption, but less than half did so using a validated assessment tool [40]. The AUDIT-C assessment tool was included in the electronical medical record system used by antenatal care providers at the time of the study. Therefore, while it is possible that a small proportion of antenatal care providers may have assessed alcohol consumption using an assessment tool other than the AUDIT-C, it is potentially more likely that the assessment questions are not being asked as intended [40]. These results suggest that although system prompts may be beneficial in supporting antenatal clinicians use validated assessment tools, as a single support strategy they are unlikely to be sufficient in improving assessment according to guidelines. Further implementation support may be required to ensure that alcohol consumption behaviours are accurately identified so that care can be provided that is appropriate to a woman's level of alcohol consumption risk [19–22].

Broadly, the study found lower rates of antenatal care provision regarding maternal alcohol consumption than previous studies in this setting. Lower reported rates of advice that it is safest not to consume alcohol during pregnancy (63.2% initial visit; 15.8% subsequent visits) were found in this study compared to all previous studies that were conducted after the release of abstinence-based guidelines for pregnant women in Australia (97– 99%) [39, 42]. The study also found a lower prevalence of reported referral of women who reported consuming alcohol at medium or high-risk levels since pregnancy recognition (50.0% initial visit; 0.0% subsequent visits) compared to a previous study of Norwegian midwives (66% initial visit) [40]. A possible explanation for these different findings may be different populations, the use of different health systems and/or different data collection methods. The previous studies used clinician self-report, which is more susceptible to response bias and an overestimate of the prevalence of care provision [44] than data collected from client surveys, which may produce more conservative results. These results suggest that antenatal services may benefit from comprehensive implementation support, such as educational meetings and materials [63, 64], electronic prompts and reminders [65], local opinion leaders [66–68], audit and feedback [69], academic detailing [70, 71], performance monitoring [72] and leadership [66] to provide guideline recommended care for alcohol consumption during pregnancy.

Reported receipt of care was found to differ between the initial and subsequent antenatal visits and each of the elements were found to vary within the visit type. The findings related to high prevalence of care at the initial antenatal visit are similar to a Norwegian study, which reported that 97% of midwives mostly or always ask about alcohol at the initial antenatal visit and 66% mostly or always provide a referral when risky alcohol consumption is identified [40]. Further, the finding that most women at the initial antenatal visit are assessed for alcohol consumption,

whereas only a small proportion receive any advice or referral related to alcohol consumption, is supported by numerous studies examining the prevalence of antenatal care for alcohol consumption during pregnancy [38, 40, 43] and literature from health care settings more broadly [45]. There are a number of potential reasons for lower prevalence of care in response to assessment at the initial antenatal visit, including that the focus of such visits is on comprehensive assessment and history taking and that there is often a lack of formalised care pathways [73]. In addition, repeat assessment and care at subsequent antenatal visits for risk factors that were not identified in the initial antenatal visit are often not prioritised even though patterns of alcohol consumption can change throughout pregnancy and rapport may need to be built over numerous visits in order for women to feel comfortable to disclose alcohol consumption [10]. Support provided to clinicians to improve adherence to guideline recommended care should focus on formalising care pathways in response to assessment and increasing care at subsequent antenatal visits.

A number of maternal and service characteristics were found to be associated with the receipt of recommended care for alcohol consumption during pregnancy, indicating that such care was not provided routinely to all women, by all antenatal care providers. At the initial antenatal visit, women attending antenatal care at a regional/rural location were more likely to report receiving all guideline elements, which is consistent with the findings by Davis et al. [27] and studies examining receipt of care for behavioural risk factors in other health care settings [53]. Pregnant women's reported alcohol consumption since pregnancy recognition was not found to be associated with the provision of assessment and care at subsequent antenatal visits, which is also consistent with previous research [38, 47]. The characteristics that were found to be associated with reported receipt of all guideline elements at subsequent antenatal visits were being younger or being of Aboriginal and Torres Strait Islander origin. These characteristics

are similar to those previously reported in a large study conducted with postpartum women in the United States [34] and consistent with qualitative interviews with Australian midwives regarding decision processes for addressing alcohol consumption at subsequent antenatal visits [33]. Although it is unknown whether the Aboriginal women who participated in the study were different in any way to those who did not, such findings suggest that decision making processes regarding assessment and care for alcohol consumption undertaken at subsequent visits could be based on stereotypes regarding alcohol consumption [34] rather than being directed by universal guideline recommendations. System changes, such as education of antenatal care providers to address stereotypes [74] and electronic prompts reiterating universal screening recommendations [65, 75], may support antenatal care providers deliver care routinely to all pregnant women.

There was a high level of acceptability among pregnant women for all elements of guideline recommended care for addressing alcohol consumption during pregnancy. These findings extend that of a previous Australian study that found a high level of acceptability for being asked about alcohol consumption and being advised not to consume alcohol during pregnancy among women generally [51]. These findings are also consistent with previous literature [12, 36, 38, 76, 77], which suggests that pregnant women perceive their antenatal care providers as an important source of information for making informed choices about alcohol consumption during pregnancy. Such findings suggest that barriers to care provision previously reported by antenatal care providers, such as addressing alcohol will cause discomfort [39, 40, 78, 79] and impact on the client-clinician relationship [80–82], may be unfounded. Further research is required to confirm pregnant women's acceptability of guideline elements for maternal alcohol consumption post receipt of such care as direct experience may change perceptions of acceptability [83].

The results of this study should be considered in light of a number of its methodological strengths and limitations. The study was conducted with a large sample of randomly selected pregnant women who completed the survey within 4 weeks of their antenatal visit to limit any potential recall bias. The study is one of few to have utilised pregnant women's self-report, which is reported to limit response bias that may affect health providers' report of care provision [44]. Pregnant women's self-reported alcohol consumption since pregnancy recognition was used to assess whether the antenatal care provider asked the AUDIT-C questions and offered referrals appropriately, however, women may not have provided the same information about their alcohol consumption to their antenatal care provider. As only a small number of respondents reported consuming alcohol at medium and high-risk levels, potential associations with receipt of referral could not be examined. This may have been due to women underreporting the level of alcohol they are consuming during pregnancy, which has been reported by previous studies [30, 34]. Further research is required to identify factors associated with women accurately reporting their level of alcohol consumption during their pregnancy, as accurate reporting of risk is required in order for appropriate support to be offered to assist women abstaining from alcohol during pregnancy. For ethical reasons, the study did not collect information on previous live births and stillbirths and, as such, a woman's first pregnancy is not specifically defined as either parity or gravidity. Lastly, the study was limited to pregnant women aged 18 years and over who were proficient in English, had not experienced an adverse pregnancy outcome (miscarriage or stillbirth) and were receiving the majority of their antenatal care through a public antenatal service within one health district in Australia. Therefore, the extent to which these findings generalise to other women and antenatal services in Australia and internationally is unknown.

CONCLUSIONS

The results of this study indicate that although assessment and care for maternal alcohol consumption is highly acceptable to pregnant women, receipt of such care in public antenatal services is suboptimal and preferentially provided based on the characteristics of pregnant women and antenatal services. Opportunities exist to increase provision of clinical guideline recommended care in public antenatal services through the implementation of comprehensive support strategies for antenatal care providers. Future research is required to investigate the effectiveness of such implementation strategies and their acceptability to antenatal care providers.

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CHAPTER 3

Barriers to the implementation of clinical guidelines for maternal alcohol consumption in antenatal services: a survey using the theoretical domains framework

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ABSTRACT

Issue addressed: The aim of this study was to assess potential barriers to the implementation of clinical guideline recommendations regarding maternal alcohol consumption by antenatal clinicians and managers.

Methods: Cross-sectional surveys of antenatal clinicians and managers employed in a New South Wales Local Health District were undertaken. Survey items were developed based on 11 domains of the Theoretical Domains Framework. Consistent with previous studies, a cut point of less than 4 was applied to mean values of survey items (range: 1-5) to identify domains representing barriers to the implementation.

Results: Thirty-three antenatal clinicians and eight managers completed the surveys. For clinicians, the domains with the lowest mean values included 'environmental context and resources' (ie, complexity of appointments and availability of supporting systems) (mean: 3.13, SD: 0.93); 'social influences' (ie, expectations of others that alcohol will be addressed) (mean: 3.33, SD: 0.68); 'beliefs about capabilities' (ie, confidence in providing guideline recommendations) (mean: 3.51, SD: 0.67); and 'behavioural regulation' (ie, planning and responding to feedback) (mean: 3.53, SD: 0.64). For managers, 'emotion regulation' (ie, stress in managing change) (mean: 2.13, SD: 0.64) and 'environmental context and resources' (ie, complexities of managing change) (mean: 3.13, SD: 0.83) were the lowest scoring domains.

Conclusions: The antenatal service environment and availability of resources appear to be primary barriers to both clinicians and managers implementing guidelines for maternal alcohol consumption.

So what?: In the development of interventions to support the delivery of clinical guideline recommendations addressing alcohol consumption during pregnancy, a broad range of potential barriers at both the clinician and manager levels need to be considered and targeted by effective implementation strategies.

INTRODUCTION

International [1] and Australian [2] clinical guidelines recommend maternal alcohol consumption be addressed with all pregnant women as part of routine antenatal care. Despite this, studies report less than optimal delivery [3-6]. For instance, a survey of 1143 health professionals in Western Australia found that of those providing care to pregnant women, less than half (45%) routinely asked about alcohol consumption and only 13% provided advice consistent with national alcohol guidelines [3]. Such findings are consistent with international literature in countries including Denmark, Norway and the United States [4-6].

Improving the implementation of clinical guideline recommendations for maternal alcohol consumption requires an understanding of barriers to such care provision. The application of a comprehensive framework is recommended in the assessment of implementation barriers to ensure that a range of factors are considered [7]. Despite this, previous studies assessing barriers to the adherence of maternal alcohol guideline recommendations have not utilised comprehensive implementation frameworks, and subsequently have focussed on a narrow range of potential barriers that are clinician focused [5, 8-12]. Nonetheless, the following barriers to the provision of clinical guideline recommendations for maternal alcohol consumption have been reported in the literature: a lack of knowledge [8] or confidence [5, 9-11] in assessing and advising pregnant women about alcohol consumption; a belief that addressing alcohol will cause discomfort [5, 10, 11] or impact on the client-clinician

relationship [9, 12]; and a lack of training [5], time [5, 8, 11, 12] or resources [3, 9]. Other factors suggested by implementation frameworks to potentially impede the implementation of clinical guidelines in general, such as a lack of planning in how to deliver the guidelines in consults and a lack of feedback to help improve care provision [13], have not been assessed. Barriers among managers have also not been assessed despite managers being instrumental to the implementation of clinical guidelines [14].

The aim of this study was to assess antenatal clinician and manager barriers to the implementation of guidelines for addressing maternal alcohol consumption in antenatal services using a survey based on a comprehensive consolidated implementation framework.

METHODS

Study design and setting

Cross-sectional surveys of antenatal clinicians and managers were conducted from April to September 2017 within three sectors of the Hunter New England Local Health District (HNELHD), New South Wales, Australia. The services within these sectors provide public antenatal care to more than 6000 women in metropolitan, regional and rural locations annually, which accounts for approximately 70% of all women giving birth in the district's public hospitals. Ethics approval was obtained from HNELHD Human Research Ethics Committee (no. 16/10/19/5.15) and The University of Newcastle Human Research Ethics Committee (no. H-2016-0422). See Appendix 15 for evidence of ethics approvals.

Sample and recruitment

Managers of antenatal services and clinicians (midwives, medical practitioners and Aboriginal Health Workers) who had provided antenatal care in the last 12 months were eligible to

participate. Potential participants were sent an invitation email via their direct manager, which included an information statement [see Appendix 16] and direct link to the survey. Potential participants received two reminder emails during the study period.

Measures and data collection procedures

All data were collected via online surveys with antenatal clinicians and managers [see Appendix 17]. Demographics collected were as follows: years providing antenatal care or managing antenatal services; current position; years in current position; and employment status. Survey items assessing potential barriers were developed based on 11 domains of the Theoretical Domains Framework (TDF) [15, 16] and were informed by previous surveys with antenatal services [8] as well as previous studies applying the TDF in a number of different health care settings [17, 18]. The TDF consolidates constructs from 33 behaviour change theories and was developed using a consensus and validation process [15, 16]. Previous studies measuring the psychometric properties of surveys applying the TDF in health care settings have demonstrated good content and face validity and internal consistency [16, 19]. Survey items assessed potential barriers via a 5-point Likert scale (strongly disagree to strongly agree). The surveys were reviewed for cultural appropriateness and pilot tested with clinicians prior to use.

Statistical analysis

All analyses were conducted using the statistical program SAS, Version 9.3. Similar to previous studies, mean values were calculated for each domain by summing the scores for each item within the domain and dividing it by the number of domain items. Mean domain scores were used to categorise whether a domain was a potential barrier [20]. To account for any social desirability in responses, a cut-off of less than 4 was used to indicate potential barriers, which is consistent with previous studies applying the TDF [21]. Condensed response

categories were created for years providing antenatal care; years managing antenatal services; current position (Midwifery: registered midwife, clinical midwife specialist, community liaison midwife, clinical midwife educator; Medical: staff specialist, registrar, fellow, junior medical officer); and years in current position.

RESULTS

Participation

Sixteen managers and 110 clinicians were invited to participate in the survey. A total of eight managers (50%) and 33 clinicians (30%) completed the survey. Three clinicians who had completed the survey were deemed ineligible as they had not provided antenatal care within the study region in the last 12 months. There were no significant differences between participants and non-participants in terms of profession type for both antenatal clinicians (P = 0.83, Fisher's exact test) and managers (P = 1.00, Fisher's exact test) based on data from staff rostering records. Participant characteristics are presented in Table 3.1.

Table 3.1 Antenatal clinician and manager characteristics

Characteristic	**n**	**%**
Antenatal clinicians (n=33)		
Years providing antenatal care		
0 to 4	10	30
5 to 9	5	15
10+	18	55
Current position		
Midwifery	23	70
Medical	8	24
Aboriginal Health Worker	2	6
Years in current position		
0 to 4	13	39
5 to 9	9	27
10+	11	33
Employment		
Full time	17	52
Part time	16	48
Managers (n=8)		
Years managing antenatal services		
0 to 4	3	38
5 to 9	1	13
10+	4	50
Current position		
Midwifery Manager	5	63
Staff Specialist	1	13
Health service manager	2	25
Years in current position		
0 to 4	5	63
5 to 9	1	13
10 +	2	25
Employment		
Full time	8	100

Antenatal clinician and manager reported barriers

Table 3.2 presents mean values for each TDF domain. Seven of the 11 TDF domains were identified as potential barriers (mean domain score below 4) by antenatal clinicians and six domains were identified as potential barriers by managers. The domains with the lowest mean values for clinicians were as follows: environmental context and resources (mean: 3.13, SD: 0.93); social influences (mean: 3.33, SD: 0.68); beliefs about capabilities (mean: 3.51, SD: 0.67); and behavioural regulation (mean: 3.53, SD: 0.64). The domains with the lowest mean values for managers were as follows: emotion regulation (mean: 2.13, SD: 0.64) and environmental context and resources (mean: 3.13, SD: 0.83). Mean scores for individual TDF items from the antenatal clinician and manager surveys are presented in Appendix 18.

Table 3.2 Mean scores for theoretical domains framework barriers as reported by antenatal clinicians and managers

Domain	**Definition** [15, 16]	**Antenatal clinicians (n=33)**					**Managers (n=8)**				
		Number of items	Mean	SD	Median	Interquartile Range	Number of items	Mean	SD	Median	Interquartile Range
Knowledge	An awareness of the existence of something.	6	4.08	0.54	4.17	3.83 – 4.33	5	4.53	0.30	4.60	4.30 – 4.80
Skills	An ability or proficiency acquired through practice.	6	3.70	0.60	3.50	3.17 – 4.17	4	4.38	0.45	4.17	4.00 – 4.83
Social/ professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting.	6	4.42†	0.46	4.33	4.17 – 4.83	3	4.54	0.35	4.50	4.33 – 4.83
Beliefs about capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use.	7	3.51†	0.67	3.54	3.00 – 3.93	3	3.84	0.45	3.95	3.65 – 4.15
Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation.	8	3.75‡	0.37	3.75	3.50 – 4.00	4	3.73	0.44	3.70	3.40 – 3.90
Motivation and goals	Mental representations of outcomes or end states that	3	4.26‡	0.63	4.33	4.00 – 4.67	3	4.25	0.53	4.50	3.83 – 4.67

	an individual wants to achieve.										
Memory, attention and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.	5	4.03‡	0.58	4.00	3.80 – 4.40	2	3.69	0.75	4.00	3.00 – 4.25
Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour.	5	3.13‡	0.93	3.20	2.40 – 3.60	4	3.13	0.83	3.50	2.38 – 3.75
Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.	4	3.33‡	0.68	3.25	3.00 – 3.75	4	3.85	0.40	3.90	3.80 – 4.00
Emotion regulation	A complex reaction pattern, involving experiential,	3	3.93‡	0.75	4.00	3.67 – 4.33	1	2.13	0.64	2.00	2.00 – 2.50

	behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event.										
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions.	3	3.53‡	0.64	3.67	3.00 – 4.00	1	4.38	0.52	4.00	4.00 – 5.00

† n=32 due to incomplete survey responses

‡ n=29 due to incomplete survey responses

DISCUSSION

To our knowledge, this is the first study to assess both antenatal clinician and manager barriers to the implementation of clinical guidelines for maternal alcohol consumption in antenatal services across the domains of a comprehensive implementation framework. A number of clinician barriers were found that were similar to those reported in previous literature using a less comprehensive approach, including: a lack of confidence and skill to adequately address alcohol consumption with pregnant women [5, 9-11]; a belief that addressing alcohol consumption could have negative consequences [5, 9-12]; and a lack of available resources to provide such care [3, 9]. In contrast to previous studies [8], clinician's knowledge about the effects of alcohol consumption during pregnancy and the clinical guideline recommendations were not found to be a barrier to care provision. The study also revealed a number of additional barriers not previously identified in the literature, including the antenatal service environment, social influences and behavioural regulation of clinicians, and emotion regulation among managers. The findings underscore the challenge to clinician engagement of women regarding maternal alcohol consumption and provide important formative information for policy makers and practitioners interested in improving maternal and infant health through addressing the alcohol consumption of pregnant women in this setting.

These findings suggest that strategies focusing on enhancing the antenatal service environment to support the implementation of clinical guidelines for addressing maternal alcohol consumption would be beneficial to both clinicians and managers. Such strategies could include the introduction of electronic systems to prompt clinicians to deliver guideline recommendations at the point-of-care [22] and localised procedures and care pathways [23]. In addition, strategies such as educational meetings and materials to support care provision [24], local opinion leaders and champions [25], and academic detailing [13] could address other

identified barriers, such as belief about capabilities, social influences and behavioural and emotional regulation. Systematic reviews suggest that such interventions have been effective in improving guideline implementation in other health settings [13, 22-25].

A number of limitations need to be noted. While based on a validated instrument [15, 16], the survey items were adapted for use in this study and were not re-validated. Future studies should seek to do so. In addition, the study was conducted in a relatively small sample of clinicians and managers with a low response rate. While it does not appear that the clinicians who chose not to participate were different from those who did participate in terms of professional group, further studies with a larger sample and higher response rate are required to confirm these results and potentially improve generalisability of the study findings. While this quantitative study was able to identify the barriers that were most frequently reported by antenatal clinicians and managers, further qualitative research would provide more in-depth and contextual information about the identified barriers to support implementation strategy development.

CONCLUSION

This study provides further evidence of barriers to the implementation of clinical guidelines for addressing maternal alcohol consumption in antenatal services by clinicians, and new evidence on barriers faced by their managers. Identified barriers, such as environmental context and resources, social influences and emotion regulation, should be targeted in the development of intervention strategies to improve clinical guideline adherence for addressing alcohol consumption during pregnancy.

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CHAPTER 4

Implementation strategies to improve preconception and antenatal care for tobacco smoking, alcohol consumption and weight management: a systematic review protocol

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ABSTRACT

Background: Despite existing best practice care recommendations for addressing tobacco smoking, alcohol consumption and weight management in preconception and antenatal care, such recommendations are often not implemented into routine practice. Effective strategies that target known barriers to implementation are key to reducing this evidence to practice gap. The aim of this review is to synthesise the evidence on the effectiveness of implementation strategies in improving the provision of preconception and antenatal care for these modifiable risk factors.

Methods: Randomised and non-randomised study designs will be eligible for inclusion if they have a parallel control group. We will include studies that either compare an implementation strategy to usual practice or compare two or more strategies. Participants may include any health service providing preconception or antenatal care to women and/or the health professionals working within such a service. The primary outcome will be any measure of the effectiveness of implementation strategies to improve preconception and/or antenatal care for tobacco smoking, alcohol consumption and/or weight management (including care to improve nutrition and/or physical activity). Secondary outcomes will include the effect of the implementation strategy on women's modifiable risk factors, estimates of absolute costs or cost-effectiveness and any reported unintentional consequences. Eligible studies will be identified via searching Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, Maternity and Infant Care, CINAHL, ProQuest Dissertations and Theses and other sources (e.g. contacting experts in the field). Study selection, data extraction and risk of bias will be assessed independently by two review authors and differences resolved by a third reviewer. If data permits, we will conduct fixed-effects or random-effects meta-analysis where

appropriate. If studies do not report the same outcome or there is significant heterogeneity, results will be summarised narratively.

Discussion: This review will identify which implementation strategies are effective in improving the routine provision of preconception and antenatal care for tobacco smoking, alcohol consumption and weight management. Such a review will be of interest to service providers, policy makers and implementation researchers seeking to improve women's modifiable risk factors in preconception and antenatal care settings.

Systematic review registration: PROSPERO CRD42019131691

BACKGROUND

The presence of modifiable risk factors prior to conception and during pregnancy can have significant implications for pregnant women and their babies [1]. Three of the most prevalent modifiable risk factors that can adversely impact pregnancy and offspring outcomes are tobacco smoking, alcohol consumption and gestational weight gain outside of recommended ranges (including inadequate nutrition and physical activity) [1]. Internationally, it is estimated that during pregnancy: 10% of women smoke tobacco [2–4], 10% consume alcohol [5] and 68% gain weight outside of recommended ranges [1, 6–8]. However, these rates vary considerably and reported prevalence in some countries and population groups is much higher [1]. Each of these modifiable risk factors is associated with an increased risk of pregnancy complications and poor obstetric outcomes, including spontaneous abortion, small or large for gestational age, preterm birth and need for neonatal intensive care [6, 9–12]. Further negative impacts of these risk factors include poor infant and child outcomes, such as developmental

delay and obesity, which can have long term consequences and increase the risk of chronic diseases in adulthood [6, 9, 13–15]. Clustering of these modifiable risk factors prior to and during pregnancy is also well established, which can increase such risks through cumulative effects [16–18].

Timely access to health care prior to pregnancy (preconception care) and during pregnancy (antenatal or prenatal care) contributes to better maternal and child health outcomes and fewer clinical interventions [1, 19]. Clinical guidelines provide best practice care recommendations for health professionals who see women prior to and during pregnancy [1, 20–23]. Such guidelines recommend that as part of routine preconception and antenatal care, all women are universally assessed for tobacco smoking, alcohol consumption and weight; provided advice; and offered targeted support (e.g. counselling, brief intervention or pharmaceutical support) if required [1, 20–23]. As part of weight management care, it is further recommended that women receive advice and appropriate support for nutrition and physical activity [1, 20–23].

Such guidelines are supported by systematic review evidence that indicates interventions are effective in reducing these risk factors prior to and during pregnancy. For example, psychosocial interventions are effective in increasing smoking cessation during pregnancy [24]; psychological, educational and brief interventions are effective in reducing alcohol consumption and increasing alcohol abstinence during pregnancy [25, 26]; and educational and behavioural interventions targeting nutrition and/or physical activity are effective in preventing excessive gestational weight gain [27, 28]. Preconception care may also be effective in improving risk factors prior to pregnancy [8], including lowering rates of risky alcohol consumption [29].

Despite the existence of clinical guideline recommendations and evidence for interventions addressing modifiable risk factors in preconception and antenatal settings, many women do not routinely receive such best practice care [30]. For example, a study of 1173 women in the UK reported low levels of receipt of preconception advice from general practitioners on tobacco smoking (13%), alcohol consumption (13%) and healthy weight (10%) [31]. An Australian study of 223 pregnant women found that the majority of women reported being asked about smoking (97%) and alcohol (92%) during their antenatal care, but less than half (48%) reported having their weight gain assessed [32]. Of those women who reported requiring further support to manage their risks, 62% were offered assistance for smoking, 10% for alcohol consumption and 36% for weight management [32]. With these varying levels of care provision, clinical guideline recommendations designed to improve pregnancy outcomes are unlikely to achieve their intended benefits and, as such, strategies are needed to reduce the current evidence to practice gap in guideline care.

Implementation frameworks recommend that system and individual level barriers to care provision need to be identified so that appropriate behaviour change techniques are applied when selecting strategies to improve practice [33]. Numerous barriers have previously been reported to impede health professional's provision of care for tobacco smoking, alcohol consumption and weight management in preconception and antenatal care settings, including lack of supporting systems, resources and time within the consult [34–43]; lack of knowledge of the risk factors and care procedures [38, 43]; lack of skills and confidence in delivering care to women and limited training opportunities to address this [35, 36, 39, 41, 43, 44]; and a reluctance to ask women about their health risks due to a perception that it will have a negative effect on the client-clinician relationship [43]. Such barriers present a considerable challenge

for health professionals and managers seeking to improve guideline implementation in these settings [33].

A number of systematic reviews have reported on the effectiveness of implementation strategies in improving care when similar barriers are present in health care settings more broadly, including prompts and system reminders [45], educational meetings and materials [46, 47], educational outreach visits [48, 49], local opinion leaders [50–52] and audit and feedback [53]. Specific to the antenatal setting, one previous review has reported on the effectiveness of strategies in increasing smoking cessation care [54] and another has reported on health provider focussed interventions to support obese pregnant women [55], with the latter review identifying no eligible studies. Despite tobacco smoking, alcohol consumption and weight gain outside of recommended ranges often co-occurring in pregnant women, and preconception and antenatal guideline recommendations and reported barriers to care provision being similar across these modifiable risk factors, no reviews to date have synthesised the evidence for the effectiveness of implementation strategies in increasing preconception and antenatal care across these modifiable risk factors.

Objective

The objective of this review is to determine the effectiveness of implementation strategies in improving the routine provision of preconception and/or antenatal care for tobacco smoking, alcohol consumption and/or weight management (including care to improve nutrition and/or physical activity) to women.

METHODS

The systematic review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO; registration number: CRD42019131691). This review protocol was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) recommendations [56].

Eligibility criteria

Types of studies

Non-randomised and randomised study designs with a parallel control group will be eligible for inclusion. Non-randomised study designs will be included due to the challenges of using randomised designs for complex public health and system focussed interventions [57]. Eligible study designs include the following:

- Randomised studies (e.g. randomised controlled studies, randomised cluster studies, randomised staggered enrolment or stepped-wedge studies);
- Non-randomised studies (e.g. non-randomised controlled studies, non-randomised cluster studies, nonrandomised staggered enrolment or stepped-wedge studies);
- Controlled before-after studies (CBAs) and cluster CBAs; and
- Interrupted time-series studies that have independent control groups.

We will only include studies that (1) compare an implementation strategy that seeks to improve preconception and/or antenatal care for tobacco smoking, alcohol consumption and/or weight management (including care to improve nutrition and/or physical activity) with no intervention or 'usual practice', or (2) compares two or more implementation strategies that seek to improve preconception and/or antenatal care for these risk factors. There will be no restrictions on the length of the study follow up period, country of origin, language of publication or year of study.

Participants

Participants will be services and health professionals responsible for delivering preconception or antenatal care in public or privately operated settings such as primary care, hospital maternity care, specialist medical services, midwifery services or family planning services. Health professionals could include but are not limited to general practitioners, family physicians, obstetrician-gynaecologists, fertility specialists, midwives or nurses. Studies in settings that do not usually provide care to women prior to or during pregnancy, such as community education campaigns, will be excluded.

Implementation strategies

Studies that specifically aim to improve care for the selected risk factors using one or more implementation strategies will be included. Implementation strategies could include, but are not limited to, those described in the Cochrane Effective Practice and Organisation of Care (EPOC) and Expert Recommendations for Implementing Change (ERIC) taxonomies, including clinical practice guidelines, educational meetings, educational materials, local opinion leaders, record system changes, reminders, audit and feedback and monitoring performance [58, 59]. Interventions may be a single strategy (e.g. point of care reminder in a medical record system) or multi-strategy (e.g. provision of educational materials and local opinion leaders).

Outcomes

The primary outcome will be any measure of the effectiveness of implementation strategies to improve preconception and/or antenatal care for tobacco smoking, alcohol consumption and/or weight management (including care to improve nutrition and/or physical activity). For

example, the proportion of health professionals who ask women about their smoking after a system reminder is implemented or the mean number of occasions women report receiving advice on alcohol consumption throughout their pregnancy after health professionals receive educational materials. Data from self-report measures (e.g. by health professionals or women), direct observation by researchers, audits of medical records (e.g. patient pregnancy records) or other methods will be eligible.

Secondary outcomes will include the following:

1. Effect of the implementation strategy on women's tobacco smoking, alcohol consumption, weight, gestational weight gain, nutrition and/or physical activity prior to or during pregnancy. Data could include self-report or physical measurements (e.g. weight gain).
2. Estimates of absolute costs or the cost-effectiveness of the implementation strategies to improve preconception and antenatal care for tobacco smoking, alcohol consumption and/or weight management.
3. Any reported unintentional consequence of the implementation strategy (e.g. impacts on staff attitudes or changes to women's antenatal care schedules).

Search methods

We will perform searches for eligible peer-reviewed and grey literature studies in electronic databases, and a range of other sources.

Electronic sources

The following electronic bibliographic databases will be searched:

- Cochrane Central Register of Controlled Trials (CENTRAL, current issue);
- MEDLINE (including MEDLINE in Process, ePub Ahead of Print and other non-indexed citations),
- Ovid (1946 to present);
- EMBASE, Ovid (1947 to present);
- Maternity and Infant Care, Ovid (1985 year to present);
- CINAHL, EBSCOhost (1980 to present); and
- ProQuest Dissertations and Theses.

Other sources

Searches will also be undertaken in the following sources:

- Reference lists of all included studies for citations of other potentially eligible studies;
- Hand searching of all publications for the past three years in the journals Implementation Science, Journal of Translational Behavioural Medicine, BMC Pregnancy and Childbirth and Midwifery;
- World Health Organization International Clinical
- Trials Registry Platform (www.who.int/trialsearch/);
- Google (first 200 results); and
- Experts in the field and key organisations will be contacted and other relevant websites searched to identify any other potentially eligible studies.

Search strategy

The strategy will include search terms for participant, implementation strategies, study design and outcomes. Modified search filters published in previous Cochrane systematic reviews for

implementation strategies [60, 61] and study design [61, 62] will be utilised. A validated search filter for non-randomised study designs will not be used, which may be a limitation to the strategy. The search strategy is outlined in Appendix 19.

Data collection and analysis

Study selection

Two review authors will independently screen titles and abstracts identified through the search strategy described above. Review authors will not be blind to author or journal information as per the Cochrane Handbook, which acknowledges there is uncertainty that blinding protects against author bias [63]. Studies that do not meet the review eligibility criteria based on the initial title and abstract screen will be excluded. Two review authors will independently review the full text of all remaining studies for eligibility. Study authors will be contacted for clarification for any studies where there is insufficient information to determine eligibility. Where sufficient information is unavailable to determine eligibility, the study will be excluded from the review. The primary reason for exclusion will be recorded for all full-text studies. Abstracts in any language other than English will be translated using Google Translate. Any discrepancies in title and abstract or full-text screening will be resolved by consensus or a third reviewer if required. Study selection will be managed through Covidence.

Data extraction

Two review authors will independently extract information from the eligible studies. Authors extracting data will not be blind to author or journal information as per the Cochrane Handbook, which acknowledges there is uncertainty that blinding protects against author bias [63]. Data will be extracted using a standardised form that will be adapted from previous systematic reviews undertaken by the review team [60, 61]. The form will be piloted prior to use. Study

authors will be contacted for additional information about the characteristics of the strategies implemented where limited detail is provided. Any discrepancies regarding data extraction will be resolved by consensus or a third reviewer if required.

The following information will be extracted:

- Study characteristics: authors, date of publication, country of study, aim of study, setting (preconception or antenatal), participant characteristics (service and/or health professional type), study design, number of experimental conditions and information to assess risk of bias. Implementation strategy characteristics: strategy type (to allow classification against the EPOC taxonomy [58]), theoretical underpinning of the strategy, duration of the implementation strategy, implementation strategy dose (e.g. number of training sessions), implementation strategy reach (e.g. number of clinicians who received training), implementation strategy fidelity (e.g. extent to which training was delivered to protocol) and external contextual factors that may have impacted on strategy implementation (e.g. change in guidelines or risk factor recommendations).
- Study primary and secondary outcomes: data collection method, name of tool or system, validity of measures used, scale of measure, number of participants per comparison group at each time point, effect size and measures of outcome variability.
- Cost or cost effectiveness of the intervention.
- Any unintentional consequences of the implementation strategy (e.g. changes in staff attitudes or changes to antenatal schedules).
- Sources of funding and any potential conflicts of interest.

Assessment of risk of bias

Two review authors will independently assess risk of bias in randomised study designs using the Cochrane Risk of Bias Tool [63]. Each of the following domains will be assigned a 'high', 'low' or 'unclear' bias classification: (1) random sequence generation (selection bias), (2) allocation concealment (selection bias), (3) blinding of participants and personnel (performance bias), (4) blinding of outcome assessment (detection bias), (5) incomplete outcome data (attrition bias), (6) selective outcome reporting (reporting bias) and (7) any other potential sources of bias. For cluster randomised study designs, the following additional criteria will be assessed: recruitment to cluster, baseline imbalance, loss of clusters, incorrect analysis and compatibility with individually randomised controlled studies [63]. For non-randomised study designs, two review authors will independently assess the following risk of bias criteria using the Newcastle Ottawa Scale (NOS): (1) selection, (2) comparability and (3) outcome [64]. Any discrepancies will be resolved by consensus or a third reviewer with expertise in review methodology if required.

GRADE

Two review authors will independently assess the overall quality of the evidence for each of the primary outcomes using the GRADE approach [65] with any disagreements to be resolved by consensus or a third reviewer if required. The GRADE quality ratings (from 'very low' to 'high') will be used to describe the body of evidence with randomised and nonrandomised designs presented separately. Randomised studies will start from a high rating and non-randomised studies will start from a low rating.

Measures of treatment effect

It is anticipated that differences in the types of interventions in included studies may preclude the use of summary statistics to describe the treatment effect. This may necessitate findings

being presented in narrative form. Nonetheless, outcome data will be synthesised using meta-analyses where possible and appropriate to do so. In such cases, the standard estimation of the odds ratio (OR) or risk ratio (RR) and 95% confidence intervals (CI) will be calculated for dichotomous outcomes. For continuous outcomes, mean differences (MDs; where consistent outcome measures are reported) or standardised mean differences (SMDs; where different outcome measures are reported) and 95% CIs will be calculated.

Data synthesis

Clinical heterogeneity will first be assessed to determine whether it is appropriate to combine results in a meta-analysis. If it is deemed that studies cannot be combined in a meta-analysis, a narrative synthesis will be presented. If it is deemed that studies can be combined in a meta-analysis, on the basis of Cochrane Handbook guidance [63], a fixed-effects model will be adopted in the first instance if studies are sufficiently homogenous and OR/RR, MD or SMDs will be calculated. However, if there is evidence of high heterogeneity, a random effects model will be utilised instead. Data from randomised and nonrandomised study designs will be synthesised separately.

Where studies report outcomes using different data collection methods or scales, the one that is judged by the authors to represent the most valid measure will be used for data synthesis. For studies that include multiple intervention or control arms, only the arms that meet the eligibility criteria will be included. In cases where multiple arms are included, a decision will be made to either: (1) collapse all intervention and/or control arms into single pairwise comparisons or (2) conduct bivariate analyses with all eligible arms included and adjust for the repeated inclusion of the same intervention and/or control arm [63]. In studies with multiple follow up points, the data collection point measured furthest from recruitment will be analysed.

Unit of analysis issues

For cluster studies, individual level data that adjusts for clustering will be extracted. In studies where the effects of clustering have not been adjusted for, study authors will be contacted to provide intra-class correlation coefficients (ICCs). Where ICCs are not available, a mean ICC will be estimated from included studies with similar outcomes and used to calculate effective sample sizes.

Dealing with missing data

The proportion of participants lost to follow up will be reported and considered in the risk of bias assessment as potential evidence of attrition bias. Any instances whereby sensitivity analyses have been conducted by study authors using different assumptions to deal with missing data will be recorded. Reported data that has adopted the intention to treat (ITT) principle will be extracted in preference to study data that does not. If an included study has no such ITT data, the data that is available will still be extracted.

Assessment of heterogeneity

Characteristics of studies will be considered for intervention and methodological heterogeneity. If required, visual inspection of forest plots will be undertaken to inspect statistical heterogeneity. If studies are deemed to be sufficiently homogenous based on these initial inspections, heterogeneity for each outcome will be statistically quantified by calculating the I^2 statistic with a cut-point of > 50% to be indicative of substantial heterogeneity [63]. Decisions to perform meta-analysis will be based on discussions between study authors following consideration of these measures of heterogeneity.

Assessment of reporting biases

Published studies will be compared to protocols and registers (where available) to identify instances of potential selective reporting within studies. If meta-analyses are deemed appropriate and there are at least 10 studies included, funnel plots will be generated for each outcome to determine potential publication bias.

Sensitivity analysis

If there are sufficient studies, sensitivity analyses for the primary outcome will be conducted by removing studies with an overall high risk of bias to examine their impact on the effect estimate.

DISCUSSION

This systematic review will synthesise current evidence for the effectiveness of implementation strategies in improving the routine provision of preconception and antenatal care for tobacco smoking, alcohol consumption and/or weight management (including care to improve nutrition and/or physical activity). Such a review will be of benefit to services providing preconception and antenatal care, policy makers and implementation researchers with an interest in reducing the gap between the evidence-base and clinical practice for the prevention of adverse outcomes due to maternal tobacco smoking, alcohol consumption and gestational weight gain outside of recommended ranges.

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CHAPTER 5

The effectiveness of implementation strategies in improving preconception and antenatal preventive care: a systematic review

Published:

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ABSTRACT

Background: Clinical guideline recommendations for addressing modifiable risk factors are not routinely implemented into preconception and antenatal care. This review assessed the effectiveness of implementation strategies in improving health professional provision of preconception and antenatal care addressing tobacco smoking, weight management and alcohol consumption.

Methods: A systematic review of randomised and non-randomised studies with a parallel comparison group was conducted using Cochrane methodology. Eligible studies used implementation strategy/ies targeted at health professionals to improve at least one element of preconception and/or antenatal care for at least one risk factor (smoking: ask, advise, assess, assist, arrange; weight/alcohol: assess, advise, refer) compared to usual practice/control or alternative strategies. Eligible studies were identified via CENTRAL, MEDLINE, EMBASE, Maternity and Infant Care, CINAHL and other sources. Random-effects meta-analyses were conducted where appropriate, with other findings summarised using direction of effect. Certainty of the pooled evidence was assessed using the GRADE approach.

Results: Fourteen studies were included in the review. Thirteen were in the antenatal period and 12 tested multiple implementation strategies (median: three). Meta-analyses of RCTs found that implementation strategies compared to usual practice/control probably increase asking (OR: 2.52; 95% CI: 1.13, 5.59; 3 studies; moderate-certainty evidence) and advising (OR: 4.32; 95% CI: 3.06, 6.11; 4 studies; moderate-certainty evidence) about smoking and assessing weight gain (OR: 57.56; 95% CI: 41.78, 79.29; 2 studies; moderate-certainty evidence), and may increase assessing (OR: 2.55; 95% CI: 0.24, 27.06; 2 studies; low-certainty evidence), assisting (OR: 6.34; 95% CI: 1.51, 26.63; 3 studies; low-certainty evidence) and

arranging support (OR: 3.55; 95% CI: 0.50, 25.34; 2 studies; low-certainty evidence) for smoking. The true effect of implementation strategies in increasing advice about weight gain (OR: 3.37; 95% CI: 2.34, 4.84; 2 non-randomised studies; very low-certainty evidence) and alcohol consumption (OR: 10.36; 95% CI: 2.37, 41.20; 2 non-randomised studies; very low-certainty evidence) is uncertain due to the certainty of evidence to date.

Conclusions: Review findings provide some evidence to support the effectiveness of implementation strategies in improving health professional delivery of antenatal care addressing smoking and weight management. Rigorous research is needed to build certainty in the evidence for improving alcohol and weight gain advice, and in preconception care.

Registration: PROSPERO-CRD42019131691.

BACKGROUND

Maternal tobacco smoking, gestational weight gain outside of recommended ranges and alcohol consumption increase the risk of obstetric complications [1-5] and can lead to adverse health and development outcomes for the child [6]. Clustering of these modifiable risk factors during pregnancy is common [7-9], which further increases the risk and severity of such outcomes [10, 11]. Many countries have adopted guidelines that recommend women who are pregnant or planning a pregnancy should not smoke tobacco or consume alcohol [12]. It is further recommended women eat a healthy diet, be physically active and remain within recommended weight gain ranges during pregnancy [13]. Despite these recommendations, internationally it is estimated that during pregnancy 10% of women smoke [14-16], 10% consume alcohol [17] and 68% gain weight outside of recommended ranges [1, 18, 19].

Systematic review evidence supports the effectiveness of health professional delivered psychosocial interventions in reducing smoking and alcohol consumption during pregnancy [20, 21] and behavioural interventions in preventing excessive weight gain [22, 23]. Routine preconception care may also be effective in modifying these risk factors prior to conception [19, 24]. Consistent with such evidence, clinical guidelines [13, 25-28] recommend that all women receive preconception and antenatal care addressing smoking, weight management (inclusive of nutrition and physical activity) and alcohol consumption. The recommended model for addressing smoking is based on the 5A's behavioural counselling: ask, advise, assess, assist and arrange [29]. The 5As is informed by the transtheoretical model of behaviour change and was developed by the US Department of Health and Human Services as an evidence-based and practical framework to guide clinician provision of smoking cessation counselling [29]. The 5As has since been adapted for other modifiable risk factors, and this adapted version is recommended by preconception and antenatal clinical guidelines for addressing weight management and alcohol consumption: assess, advise and refer [13, 25-28].

Despite the existence of guideline recommendations, the provision of preconception and antenatal care addressing these risk factors is sub-optimal [30-33]. For example, a study of 1173 pregnant women in the United Kingdom found that 13% received preconception advice from a health professional on smoking and alcohol consumption and 10% on recommended weight gain [30]. Similarly, studies in Australia examining antenatal care provision have reported that only 20% of general practitioners routinely address smoking with pregnant women [31] and less than half provide advice on healthy eating (42%) [33], physical activity (39%) [33] and alcohol consumption (32%) [32]. Without routine implementation, the intended

benefits of the guidelines in supporting optimal pregnancies and a healthy start to children's lives will not be fully realised.

Implementation strategies are methods or techniques used to enhance the adoption, implementation and sustainability of evidence-based practices [34]. Cochrane Effective Practice and Organisation of Care (EPOC) developed a taxonomy to classify and organise implementation strategies that are targeted at health professionals, including educational meetings, audit and feedback and reminders (see Table 5.1 for EPOC taxonomy) [35]. Systematic reviews have shown that such strategies typically improve recommended care practices by 5% to 20% [36-42]. Strategies that are developed using theory and that are tailored to address determinants of practice (e.g. context specific barriers to implementation as reported by those responsible for delivering care) may yield larger improvements in the range of 9% to 47% [43-45].

Two previous reviews have examined the effectiveness of implementation strategies in supporting health professionals to provide antenatal care addressing a modifiable risk factor [46, 47]. The first, a 2013 review of strategies to support weight management care identified no eligible studies [48]. In the second review, conducted in 2018, meta-analyses of controlled and non-controlled studies showed that implementation strategies significantly increased the provision of smoking care to pregnant women, including: asking (Cohen's d: 0.47; 95% CI: 0.13, 0.81), advising (Cohen's d: 0.46; 95% CI: 0.02, 0.90) and assisting with quitting (Cohen's d: 0.65; 95% CI: 0.46, 0.83) [47]. Subgroup analyses found that the use of certain intervention components may have had an impact on the pooled effect, such as theoretical/tailored basis to strategy development, a systems-based strategy, educational outreach visits and audit and feedback for asking about smoking [47]. The review however pooled results from studies

comparing implementation strategies to usual practice/control with those comparing alternative strategies, with the latter potentially contributing to an underestimation of effect size. Such pooling also prohibited examination of the comparative effectiveness of different types and combinations of implementation strategies. Since these reviews were published, new studies assessing the effectiveness of implementation strategies to improve antenatal care related to smoking and weight gain have been published but not synthesised [49-53]. Further, no reviews to date have examined the effectiveness of implementation strategies in improving antenatal care addressing alcohol consumption or preconception care addressing any of the three modifiable risk factors.

Objective

The aim of this systematic review was to examine the effectiveness of implementation strategies in improving health professional provision of preconception and/or antenatal care elements addressing three modifiable risk factors: tobacco smoking, weight management (inclusive of care to improve nutrition and/or physical activity) and/or alcohol consumption.

METHODS

The review was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO: CRD42019131691), conducted according to the Cochrane Handbook for Systematic Reviews of Interventions methods [54], and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [55]. Additional information on review methods is available in the published protocol [56].

Eligibility criteria

Study design

Studies were eligible for inclusion if they were randomised (RCTs) or non-randomised controlled trials with a parallel comparison group. Included studies were restricted to those published in English, or where an English translation was available. There were no eligibility criteria based on the year of study publication, country of origin or length of follow up.

Participants

Studies conducted in any health service (e.g. primary care or hospital clinics) and involved any health professionals (e.g. general practitioners or midwives) who are usual providers of preconception and/or antenatal care were eligible for inclusion.

Interventions (implementation strategies)

Studies that aimed to improve preconception and/or antenatal care for the modifiable risk factors of tobacco smoking, weight management or alcohol consumption using one or more of the implementation strategies targeted at healthcare professionals as defined by the EPOC Taxonomy [35] (see Table 5.1) were eligible.

Comparisons

Studies were eligible if they: 1) compared the effectiveness of an implementation strategy to improve preconception and/or antenatal care addressing modifiable risk factors with usual practice or control; or 2) compared alternative implementation strategies to improve such care.

Outcomes

Primary outcomes – provision of recommended care

Studies were eligible for inclusion if they reported any quantitative measure of the effectiveness of implementation strategies in improving at least one element of preconception and/or

antenatal care for at least one of the eligible modifiable risk factors. Preconception was defined as care to women of childbearing age with the explicit aim of improving health for a future pregnancy. Antenatal was defined as care to women who were currently pregnant. In line with guideline recommendations [13, 25-28], eligible care elements and therefore the primary outcomes of this review, were preconception and/or antenatal care for: i) tobacco smoking: ask (identify smoking status), advise (urge smokers to quit and explain risks), assess (willingness to quit), assist (set a quit date, offer/provide nicotine replacement therapy, referral or other supports) and arrange (follow-up) [57]; ii) weight management: assess (identify weight gain against recommendations), advise (weight gain, nutrition and physical activity recommendations) and refer (offer support services); and iii) alcohol consumption: assess (identify alcohol consumption), advise (advise no alcohol and explain risks) and refer (offer support services). The 5A's behavioural counselling model for addressing tobacco smoking (29), and the adapted version for weight management and alcohol consumption, were chosen for classification of the review's primary outcomes as they align with preconception and antenatal clinical guideline recommendations (13, 25-28) and are reflected in the literature base reporting on improvements in care provision for these modifiable risk factors. Nutrition and physical activity care elements were considered eligible outcomes in studies targeting weight management care, whereas other nutrition and physical activity care outcomes (e.g. folate advice) were excluded.

Outcome data could include women or health professional self-report surveys, direct observations, medical record audits or other methods. If studies only included one method of data collection (self-report surveys, direct observations or medical record audit), prioritisation of outcome data by data collection method was not required. However, as a number of studies using self-report surveys included data from both women and health professionals, we

prioritised inclusion of women's self-report as it is considered the more reliable of the two when measuring care practices [58].

Secondary outcomes

The following secondary outcomes of included studies were also synthesised:

1. Women's modifiable risk factors: smoking, gestational weight gain, nutrition, physical activity and/or alcohol consumption prior to, or during, pregnancy;
2. Absolute costs or the cost effectiveness of implementation strategy/ies;
3. Unintentional adverse consequence of implementation strategy/ies.

Search methods

A search strategy was developed in consultation with a research librarian based on search filters published in previous Cochrane implementation reviews [59, 60] [see Appendix 19]. The search strategy was modified as required and executed across the following electronic databases on the 22nd October 2021: Cochrane Central Register of Controlled Trials; MEDLINE; EMBASE; Maternity and Infant Care; CINAHL; ProQuest Dissertations and Theses; and the World Health Organization International Clinical Trials Registry Platform. Other sources searched were: articles published in the last 5 years in Implementation Science, Journal of Translational Behavioural Medicine, BMC Pregnancy and Childbirth and Midwifery (November 2016 to October 2021); the first 200 results from Google Scholar; and the reference lists of all included studies. The searched journals were chosen through consultation with experts in the field. They were deemed most relevant to the fields of implementation science and translational behavioural sciences, and had published a large number of articles relating to the clinical setting/participants of interest for the review. Google Scholar was limited to 200

results as it was a secondary source for the review. A pilot of the strategy had deemed articles beyond this point as very-low relevancy to the review.

Data collection and analysis

Study selection

Following removal of duplicates, two review authors (ED and one of: DT, SM, ML, OW, JD, KB, BT) independently screened the titles and abstracts of all identified records against the eligibility criteria. Two review authors (ED and one of: SM, ML, OW) independently screened the full texts of potentially eligible studies. Eligibility for study selection was assessed using a standardised pre-piloted screening tool and managed through Covidence. Review authors were not blind to author or journal information [54]. Any discrepancies in screening were resolved by consensus, or with a third reviewer.

Data extraction

Two review authors (ED and one of: SM, ML) independently extracted the following data from included studies using a pre-piloted standardised form [59, 60]: study design; participant characteristics; modifiable risk factor/s; implementation strategy/ies; comparison group; care element/s targeted by implementation strategy/ies; primary and secondary outcomes; theoretical basis; process implementation measures; and information to assess risk of bias. Implementation strategies were classified according to the EPOC Taxonomy (see Table 5.1) [35]. Discrepancies in data extraction were resolved by consensus, or with a third reviewer.

Assessment of risk of bias

Two review authors (SM and one of MK, JH) independently assessed the risk of bias of included studies. For randomised studies, the Cochrane Risk of Bias Tool (RoB 1) [54] was

used to assess: i) random sequence generation; ii) allocation concealment; iii) blinding of participants and personnel; iv) blinding of outcome assessments; v) incomplete outcome data; vi) selective outcome reporting; and vii) any other potential sources of bias. For cluster RCTs additional criteria included: recruitment to cluster; baseline imbalance; loss of clusters; incorrect analysis; and compatibility with individual RCTs [54]. For non-randomised studies, the Newcastle-Ottawa Scale (NOS) [61] was used: selection; comparability; and outcome. Discrepancies regarding assessment of bias were resolved by consensus, or with a third reviewer [61].

Assessment of the certainty of evidence

Two review authors (ED, SM) independently assessed certainty of the evidence for each primary outcome synthesised in meta-analysis using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [62]. Domains assessed included: risk of bias; inconsistency; indirectness; imprecision; and publication bias. Discrepancies in GRADE assessments were resolved by consensus, or with a third reviewer.

Data analysis and synthesis

As per the Cochrane Handbook [54], meta-analyses were conducted when outcome measures from at least two studies could be pooled using random-effects models. Primary outcomes were synthesised separately for RCTs and non-randomised studies, by modifiable risk factor (tobacco smoking, weight management, alcohol consumption), recommended care element (tobacco smoking: ask, advise, assess, assist, arrange; weight management/alcohol consumption: assess, advise, refer) and comparator type (usual practice/control, alternative implementation strategies). Dichotomous data was pooled and treatment effects expressed as odds ratios (ORs) using reported effect estimates when available or between group data [63].

Results presented in other formats (e.g. means and standard deviations) were transformed to ORs and 95% Confidence Intervals (CIs) where possible to enable pooling [64]. Studies that reported multiple results for the same outcome (e.g. two components of recommended advice) from the same sample of participants, were combined to create one summary effect for each outcome using recommended formulas [63, 65]. In these analyses, to account for the non-independence of multiple results relating to the same outcome, we assumed a correlation coefficient of 0.7 when calculating the standard error of the summary effect. Sensitivity analyses were conducted with correlation coefficients of 0.8 and 0.9 to test this assumption against the robustness of the findings.

Secondary outcomes were similarly synthesised separately for RCTs and non-randomised studies, and by modifiable risk factor. Outcome data were pooled as either ORs for dichotomous or mean differences for continuous data and 95% CIs reported.

The I^2 statistic for each pooled result was calculated to assess statistical heterogeneity. The I^2 statistic estimates the proportion of variance in a meta-analysis that is attributable to heterogeneity rather than chance. The value of the I^2 statistic ranges between 0% to 100% with higher percentages indicating higher heterogeneity [54]. Unit of analysis errors in cluster trials were examined, and where identified study data was used to calculate design effects and effective sample sizes based on Cochrane guidance [54]. In instances where there was heterogeneity in the comparison group, results from an indivdual study could not be pooled, or only one study contributed results, findings were summarised using direction of effect [66].

RESULTS

Study selection

The search identified 15,203 records (see Figure 5.1). After duplicates were removed, titles and abstracts of 11,514 records were screened, of which 119 were sought for full text review. No articles were excluded at full-text due to an English translation not being able to be sourced. Fourteen studies reported in 15 articles met eligibility criteria and were included. See Appendix 20 for characteristics of included studies.

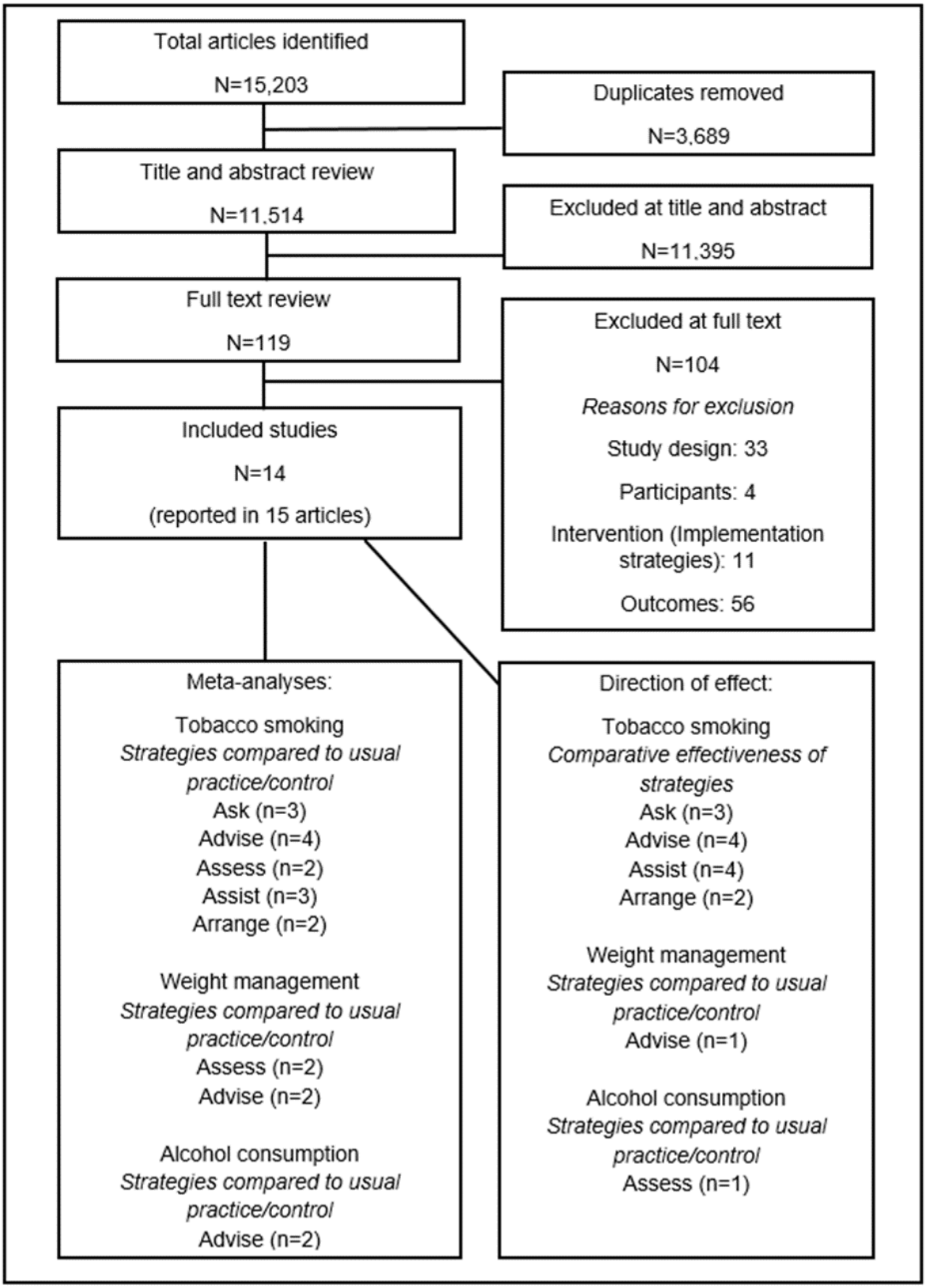

Figure 5.1 PRISMA flow diagram

Table 5.1 Implementation strategies (EPOC Taxonomy) used in the intervention group of included studies

Implementation Strategy	Definition	Number of studies tested
Educational meetings	Courses, workshops, conferences or other educational meetings.	12 [49, 51-53, 67, 69-76]
Educational materials	Distribution to individuals, or groups, of educational materials to support clinical care, i.e., any intervention in which knowledge is distributed.	10 [49-53, 67, 69-71, 73, 76]
Reminders	Manual or computerised interventions that prompt health workers to perform an action during a consultation with a patient, for example computer decision support systems.	5 [50, 68, 69, 72, 74]
Educational outreach visits or academic detailing	Personal visits by a trained person to health workers in their own settings, to provide information with the aim of changing practice.	4 [52, 70-73]
Tailored interventions	Interventions to change practice that are selected based on an assessment of barriers to change, for example through interviews or surveys.	4 [53, 70-72]
Clinical practice guidelines	Systematically developed statements to assist healthcare providers and patients to decide on appropriate health care for specific clinical circumstances.	3 [53, 67, 73]
Audit and feedback	A summary of health workers' performance over a specified period of time, given to them in a written, electronic or verbal format. The summary may include recommendations for clinical action.	1 [70, 71]
Local opinion leaders	The identification and use of identifiable local opinion leaders to promote good clinical practice.	1 [72]
Local consensus process	Formal or informal local consensus processes, for example agreeing a clinical protocol to manage a patient group, adapting a guideline for a local health system or promoting the implementation of guidelines.	1 [51]

Clinical incident reporting	System for reporting critical incidents.	0
Communities of practice	Groups of people with a common interest who deepen their knowledge and expertise in this area by interacting on an ongoing basis.	0
Continuous quality improvement	An iterative process to review and improve care that includes involvement of healthcare teams, analysis of a process or system, a structured process improvement method or problem-solving approach, and use of data analysis to assess changes.	0
Educational games	The use of games as an educational strategy to improve standards of care.	0
Inter-professional education	Continuing education for health professionals that involves more than one profession in joint, interactive learning.	0
Managerial supervision	Routine supervision visits by health staff.	0
Monitoring the performance of the delivery of healthcare	Monitoring of health services by individuals or healthcare organisations, for example by comparing with an external standard.	0
Patient mediated interventions	Any intervention aimed at changing the performance of healthcare professionals through interactions with patients, or information provided by or to patients.	0
Public release of performance data	Informing the public about healthcare providers by the release of performance data in written or electronic form.	0
Routine patient-reported outcome measures	Routine administration and reporting of patient reported outcome measures to providers and/or patients.	0

Included studies

Types of studies

Included studies were published between 1992 and 2020. Ten were RCTs [50, 52, 53, 67-74], of which four were cluster-RCTs [52, 53, 72, 73], and four were non-randomised controlled trials [49, 51, 75, 76]. Studies were conducted in 10 countries: four in the United States [49, 68, 73, 74], three in Australia [50, 53, 70, 71] and one each in the United Kingdom [69], Italy [75], The Netherlands [67], South Africa [76], Ethiopia [52], Brazil [51], and Argentina and Uruguay [72].

Participants

One study focussed on care provision during the preconception period [76] and 13 during the antenatal period [49-53, 67-75]. Seven studies were conducted in primary/community-based services [51-53, 67, 68, 74, 76], four in hospital-based services [49, 50, 70, 71, 75] and three both [69, 72, 73]. The number of services in studies ranged from one [50, 74] to 42 [67]. Health professionals targeted by the implementation strategies included: multidisciplinary teams (n=8; doctors, nurses, midwives, Aboriginal Health Workers) [49, 51-53, 70-73, 75], midwives only (n=2) [67, 69], doctors only (n=1) [74] and public sector workers (n=1) [68]. Two studies did not specify the discipline of the health professional providing care [50, 68].

Interventions (implementation strategies)

A single implementation strategy was tested in two studies [68, 75] and multiple strategies in the remaining 12 studies [49-53, 67, 69-74, 76] (median: three; range: two to five). Nine types of implementation strategies were assessed by the included studies, with educational meetings (n=12) [49, 51-53, 67, 69-76], educational materials (n=10) [49-53, 67, 69-71, 73, 76], reminders (n=5) [50, 68, 69, 72, 74], educational outreach visits or academic detailing (n=4)

[52, 70-73] and tailored interventions (n=4) [53, 70-72] the most commonly assessed (see Table 5.1). Five studies reported the use of a model, theory, or framework in strategy development (either Theoretical Domains Framework and Behaviour Change Wheel [53] or Roger's Diffusion of Innovation Theory [70-73]). Seven studies reported on at least one measure of the implementation process [49, 52, 53, 67, 69-72], with fidelity (n=5) [52, 53, 67, 71, 72] and acceptability (n=3) [49, 53, 67] the most commonly reported.

Comparisons

Ten studies compared implementation strategies to usual practice or a control condition [49-53, 67-69, 75, 76] and four compared different combinations of strategies [70-74].

Outcomes

Primary outcomes – provision of recommended care

Eight studies sought to improve care addressing smoking [53, 67-74], four weight management [49-52] and two alcohol consumption [75, 76]. Outcomes were assessed using women's self-report (n=9) [51, 68, 69, 71-76], health professional self-report (n=2) [53, 70], both women's and health professional's self-report (n=2) [49, 67], direct observations (n=1) [52] and medical record audit (n=1) [50].

Secondary outcomes

Four studies reported the effects of implementation strategies on women's smoking [68, 69, 71, 72], two on weight gain [49, 50] and none on nutrition, physical activity or alcohol consumption. No studies reported estimates of absolute costs or cost-effectiveness of the implementation strategies, or any unintentional adverse consequences.

Risk of bias in included studies

Of the 10 RCTs, random sequence generation resulted in low risk of bias in six studies [50, 52, 67-69, 72] and risk was unclear in four [53, 70, 71, 73, 74]. The processes of allocation concealment was assessed as unclear in six studies [67, 69-74]; low risk in three [50, 52, 68] and high risk in one [53]. All studies were assessed as high risk for performance bias, with none reporting blinding of both participants and personnel. Blinding of outcome assessment was unclear for the majority of studies (n=7) [50, 52, 68, 69, 72-74]. Incomplete reporting of outcome data was rated as high risk in three studies [53, 67, 70, 71]; low in six [50, 52, 68, 69, 72, 74]; and unclear in one [73]. The presence of reporting bias was unclear for most studies (n=8) [50, 52, 67-71, 73, 74]. Two studies were assessed as being at high risk of bias due to contamination [68, 74]. Of the four cluster RCTs [52, 53, 72, 73], there was a high risk of bias in two studies for loss of clusters [53, 73] and in one study for recruitment to cluster [53] and incorrect analysis [73] (see Table 5.2).

In relation to selection bias in non-randomised studies, all of the studies included a representative sample in the intervention group [49, 51, 75, 76] and in three studies the control group/s was drawn from the same service type as the intervention group/s [49, 75, 76] (see Table 5.3). However, three studies did not provide a description of the response rate or characteristics of responders and non-responders [49, 75, 76]. Only two studies indicated the outcome of interest at the start of the study [49, 76]. Comparability of intervention and control groups was a source of bias based on study design [51, 75] and analysis that did not control for confounding factors [49, 51, 75, 76]. Considerable risk of bias was introduced in relation to outcomes. None of the studies used independent blind assessment or self-report of participants who were blind to allocation. Only two studies reported an appropriate statistical test to analyse

the data and presented the outcome measurement (e.g. confidence intervals and/or p-value) [75, 76].

Table 5.2 Summary of risk of bias for randomised studies

Study	Criteria for judging Risk of Bias for RCTs						Additional criteria for Cluster RCTs					Other
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Recruitment to cluster	Baseline imbalance	Loss of clusters	Incorrect analysis	Compatibility with individual RCTs	
Althabe et al. (2017) [72]	Low	Unclear	High	Unclear	Low	Low	Low	Low	Low	Low	Low	-
Bakker et al. (2003) [67]	Low	Unclear	High	High	High	Unclear	NA	NA	NA	NA	NA	-
Bar-Zeev et al. (2019) [53]	Unclear	High	High	High	High	Low	High	Unclear	High	Low	Unclear	-
Brownfoot et al. (2016) [50]	Low	Low	High	Unclear	Low	Unclear	NA	NA	NA	NA	NA	-
Campbell et al. (2006) [71] and Cooke et al. (2001) [70]	Unclear	Unclear	High	High	High	Unclear	NA	NA	NA	NA	NA	-
Hajek et al. (2001) [69]	Low	Unclear	High	Unclear	Low	Unclear	NA	NA	NA	NA	NA	-
Manfredi et al. (2011) [73]	Unclear	Unclear	High	Unclear	Unclear	Unclear	Low	Unclear	High	High	Unclear	-
Omer et al. (2020) [52]	Low	Low	High	Unclear	Low	Unclear	Low	Low	Low	Low	Unclear	-
Secker-walker et al. (1992) [74]	Unclear	Unclear	High	Unclear	Low	Unclear	NA	NA	NA	NA	NA	High[a]
Tsoh et al. (2010) [68]	Low	Low	High	Unclear	Low	Unclear	NA	N/A	NA	NA	NA	High[a]

[a] high risk of contamination

Table 5.3 Summary of risk of bias for non-randomised studies

Study	Selection				Comparability	Outcome			Total score
	Representativeness of the sample in the intervention group/s: Max:*	Selection of the control group/s: Max:*	Non-respondents: Max:*	Demonstration of outcome of interest at start of study: Max:*	Comparability of intervention and control groups on the basis of the design or analysis Max:**	Assessment of outcome: Max:*	Follow-up long enough for the outcome of interest to occur: Max:*	Statistical test for outcome of interest: Max:*	Total score (out of 9)
Aguilera et al. (2017) [49]	*	*	-	*	*	-	-	-	(4) ****
Bazzo et al. (2015) [75]	*	*	-	-	-	-	*	*	(4) ****
Malta et al. (2016) [51]	*	-	*	-	-	-	*	-	(3) ***
Mwansa-Kambafwile et al. (2011) [76]	*	*	-	*	*	-	*	*	(6) ******

Based on a star system (*) with a range of 0 to 9 stars possible. Three domains are tested: 1. Selection of study groups (up to one star allowed for each item) 2. Comparability of the groups (up to two stars allowed) 3. Outcomes (up to one star allowed for each item).

Effect of implementation strategies in improving the provision of recommended preconception and antenatal care addressing modifiable risk factors

Table 5.4 provides an overview of the synthesis and included studies, Table 5.5 the pooled effect estimates and GRADE assessments.

Tobacco smoking

Implementation strategies compared to usual practice/control

Ask: Three RCTs [53, 67, 69] examined the effect of implementation strategies in supporting health professionals to ask about tobacco smoking during pregnancy compared to usual practice/control. Meta-analysis of these studies found a significant positive effect (OR: 2.52; 95% CI: 1.13, 5.59; p=0.024; I^2: 47%; moderate-certainty evidence). The studies tested a combination of either three [67, 69] or four strategies [53], and all included educational meetings and educational materials [53, 67, 69]. Clinical practice guidelines were tested by two studies [53, 67], and reminders [69] and a tailored intervention [53] in one study each.

Advise: Four RCTs [53, 67-69] examined the effect of implementation strategies in supporting health professionals to provide pregnant women with advice to quit smoking compared to usual practice/control. Meta-analysis of these studies found a significant positive effect (OR: 4.32; 95% CI: 3.06, 6.11; p<0.001; I^2: 0%; moderate-certainty evidence). Three of the studies were multi-strategy [53, 67, 69], of which all used educational meetings and educational materials, and in addition some also included clinical practice guidelines [53, 67], reminders [69] and/or tailored intervention [53]. One study used a single strategy of reminders [68].

Assess: Two RCTs [53, 67] examined the effect of implementation strategies in supporting health professionals to assess women's willingness to quit smoking compared to usual

practice/control. Meta-analysis of these studies found higher odds of assessment in the intervention group, although the result was not significant (OR: 2.55; 95% CI: 0.24, 27.06; p=0.439; I^2: 90%; low-certainty evidence). Both studies used multiple implementation strategies, including clinical practice guidelines, educational meetings and educational materials [53, 67], with one study also using tailored intervention [53].

Assist: Three RCTs [53, 67, 69] examined the effect of implementation strategies in supporting health professionals to assist pregnant women with quitting smoking compared to usual practice/control. Meta-analysis of these studies found a significant positive effect (OR: 6.34; 95% CI: 1.51, 26.63; p=0.012; I^2: 90%; low-certainty evidence). The studies tested a combination of three [67, 69] or four strategies [53], and all included educational meetings and educational materials [53, 67, 69]. Clinical practice guidelines were used by two studies [53, 67] and reminders [69], and tailored intervention [53] in one study each.

Arrange: Two RCTs [53, 67] examined the effect of implemention strategies in supporting health professionals to arrange support for smoking cessation compared to usual practice/control. Meta-analysis of these studies found higher odds of arranging support in the intervention group, however this was not significant (OR: 3.55; 95% CI: 0.50, 25.34; p=0.207; I^2: 83%; low-certainty evidence). Both studies used multiple implementation strategies that included clinical practice guidelines, educational meetings and educational materials [53, 67], with one study also using tailored intervention [53].

Comparative effectiveness of implementation strategies

Ask, Advise, Assist and Arrange: Four RCTs [70-74] examined the comparative effectiveness of implementation strategies in supporting health professionals to provide recommended

tobacco smoking care, which were unable to be synthesised in meta-analysis. The first of these studies compared five implementation strategies (audit and feedback, educational materials, educational meetings, educational outreach visits and tailored intervention) to educational materials and found a positive direction of effect for: asking (OR: 1.2; 95% CI: 1.0, 1.5); advising (OR: 1.1; 95% CI: 0.9, 1.3); assisting (OR: 1.3; 95% CI: 0.9, 1.9); and arranging follow-up (OR: 1.07; 95% CI: 0.57, 1.99) [71]. The second study, which examined the effect of educational meetings and reminders compared to educational meetings found a positive direction of effect for: asking (OR: 6.3; 95% CI: 1.8, 22.1); advising (OR: 4.5; 95% CI: 1.9, 10.8); and assisting (OR: 29.9; 95% CI: 14.5, 61.9) [70, 74]. The third study tested the effect of five implementation strategies (educational meetings, educational outreach visits, local opinion leaders, reminders and tailored intervention) compared to a single strategy of educational meetings and found a positive direction of effect for: asking (Difference In Medians (DIM): 29.2; 95% CI: 17.5, 38.0); advising (DIM: 26.2; 95% CI: 13.9, 40.2); assisting (DIM: 21.5; 95% CI: 10.6, 31.8) and arranging follow-up (DIM: 2.7; 95% CI: 0, 17.2) [72]. The last study examined the effect of clinical practice guidelines, educational materials, educational meetings and educational outreach visits compared to all the same strategies other than educational outreach visits [73]. A positive direction of effect was reported for advice (OR: 1.95; 95% CI: 1.32, 2.88) and assistance with quitting smoking (OR: 1.96; 95% CI: 1.13, 3.39).

Weight management

Implementation strategies compared to usual practice/control

Assess: Two RCTs [50, 52] examined the effect of implementation strategies in supporting health professionals to assess pregnant women's weight gain within recommendations compared to usual practice/control. Meta-analysis of these studies found a significant positive

effect (OR: 57.56; 95% CI: 41.78, 79.29; p<0.001; I^2: 0%; moderate-certainty evidence). Both studies tested multiple implementation strategies, with one using educational materials and reminders [50] and the other educational materials, educational meetings and educational outreach visits [52].

Advise: Three studies (one RCT [52] and two non-randomised [49, 51]) examined the effect of implementation strategies in supporting health professionals to advise pregnant women about weight gain recommendations compared to usual practice/control [49, 51, 52]. The RCT [52] used educational materials, educational meetings and educational outreach visits and reported a positive direction of effect (OR: 6.44; 95% CI: 3.14, 13.17). Meta-analysis of the two non-randomised studies found a significant positive effect (OR: 3.37; 95% CI: 2.34, 4.84; p<0.001; I^2: 0%; very low-certainty evidence). Both studies tested a combination of educational materials and educational meetings [49, 51], with one study using additional strategies of local consensus process and tailored intervention [51].

Alcohol consumption

Implementation strategies compared to usual practice/control

Assess: One non-randomised study [76] examined the effect of multiple implementation strategies in supporting health professionals to assess alcohol consumption in preconception care compared to usual practice/control. The study used educational materials and educational meetings and reported a positive direction of effect (OR: 1.15, 95% CI: 0.17, 1.03) [76].

Advise: Two non-randomised studies [75, 76] examined the effect of implementation strategies in supporting health professionals to provide preconception and antenatal advice not to consume alcohol compared to usual practice/control. Meta-analysis of these two studies found

a significant positive effect (OR: 10.36; 95% CI: 2.37, 41.20; I^2: 83%; very low-certainty evidence). The study in the preconception period used educational meetings and educational materials [76], and the one in antenatal used educational meetings [75].

No studies reported on the effect of implementation strategies in supporting health professionals provide tobacco smoking and weight management care or referrals for alcohol consumption during the preconception period. There were no studies reporting on increasing referrals for weight management and alcohol consumption in antenatal care.

Table 5.4 Overview of Synthesis and Included Studies (OSIS)

Study ID	Study design	Preconception /antenatal care	Participants	Implementation strategies	Comparator	Outcomes	Method of synthesis
Tobacco smoking							
Bakker et al. (2003) [67]	RCT	Antenatal care	Private midwifery practices Midwives	Clinical practice guidelines Educational meetings Educational materials	Usual practice/control	Ask Advise Assess Assist Arrange	Meta-Analysis Meta-Analysis Meta-Analysis Meta-Analysis Meta-Analysis
Bar-Zeev et al. (2019) [53]	Cluster RCT	Antenatal care	Aboriginal Medical Services General Practitioners, midwives, Aboriginal Health Workers and other allied health providers	Clinical practice guidelines Educational meetings Educational materials Tailored intervention	Usual practice/control	Ask Advise Assess Assist Arrange	Meta-Analysis Meta-Analysis Meta-Analysis Meta-Analysis Meta-Analysis
Hajek et al. (2001) [69]	RCT	Antenatal care	Midwifery services in hospital and community trusts Midwives	Educational meetings Educational materials Reminders	Usual practice/control	Ask Advise Assist	Meta-Analysis Meta-Analysis Meta-Analysis
Tsoh et al. (2010) [68]	RCT	Antenatal care	Community prenatal clinics Prenatal healthcare providers	Reminders	Usual practice/control	Advise	Meta-Analysis
Althabe et al. (2017) [72]	Cluster RCT	Antenatal care	Antenatal care clinics Midwives and Obstetrician/ Gynaecologists	Educational meetings Educational outreach visits, or academic detailing Local opinion leaders Reminders Tailored intervention	Educational meetings	Ask Advise Assist Arrange	Direction of effect Direction of effect Direction of effect Direction of effect
Campbell et al. (2006) [71]; Cooke	RCT	Antenatal care	Public hospital antenatal clinics	Audit & feedback Educational materials	Educational materials	Ask Advise	Direction of effect Direction of effect

et al. (2001) [70]			Doctors and midwives	Educational meetings Educational outreach visits, or academic detailing Tailored intervention		Assist Arrange	Direction of effect Direction of effect
Secker-walker et al. (1992) [74]	RCT	Antenatal care	Maternal infant care clinic Obstetric and family practice residents	Educational meetings Reminders	Educational meetings	Ask Advise Assist	Direction of effect Direction of effect Direction of effect
Manfredi et al. (2011) [73]	Cluster RCT	Antenatal care	Maternal and child health public health clinics Doctors and nurses	Clinical practice guideline Educational materials Educational meetings Educational outreach visits, or academic detailing	Clinical practice guideline Educational materials Educational meetings	Advise Assist	Direction of effect Direction of effect
Weight management							
Brownfoot et al. (2016) [50]	RCT	Antenatal care	Antenatal clinics in a tertiary obstetric hospital Antenatal care providers	Educational materials Reminders	Usual practice/control	Assess	Meta Analysis
Omer et al. (2020) [52]	Cluster RCT	Antenatal care	Antenatal care units in community health centres Health officers, nurses and midwives	Educational materials Educational meetings Educational outreach visits, or academic detailing	Usual practice/control	Assess Advise	Meta Analysis Direction of effect
Aguilera et al. (2017) [49]	Non-randomised	Antenatal care	Obstetrics practices Physicians and nurses	Educational meetings Educational materials	Usual practice/control	Advise	Meta Analysis
Malta et al. (2016) [51]	Non-randomised	Antenatal care	Primary care services and family health units Doctors and nurses	Educational materials Educational meetings Local consensus process Tailored intervention	Usual practice/control	Advise	Meta Analysis
Alcohol consumption							
Bazzo et al. (2015) [75]	Non-randomised	Antenatal care	Hospital Obstetrics and Gynecology units	Educational meetings	Usual practice/control	Advise	Meta Analysis

			Midwives				
Mwansa-Kambafwile et al. (2011) [76]	Non-randomised	Preconception care	Public healthcare services Public sector healthcare workers	Educational materials Educational meetings	Usual practice/control	Assess Advise	Direction of effect Meta Analysis

Table 5.5 Effect of implementation strategies in improving the provision of preconception and antenatal care addressing modifiable risk factors

Outcome	Study design	Implementation strategies	Comparator	Meta-analysis OR (95% CI; p)	I^2	Certainty of the evidence	Results of studies not in meta-analysis
Tobacco smoking							
Ask	RCT	Clinical practice guidelines; Educational materials; Educational meetings; Reminders; Tailored intervention	Usual practice/control	2.52 (1.13, 5.59; p=0.024)	47%	Moderate[1]	-
Advise	RCT	Clinical practice guidelines; Educational materials; Educational meetings; Reminders; Tailored intervention	Usual practice/control	4.32 (3.06, 6.11; p<0.001)	0%	Moderate[1]	-
Assess	RCT	Clinical practice guidelines; Educational materials; Educational meetings; Tailored intervention	Usual practice/control	2.55 (0.24, 27.06; p=0.439)	90%	Low[1,2,3]	-
Assist	RCT	Clinical practice guidelines; Educational materials; Educational meetings; Reminders; Tailored intervention	Usual practice/control	6.34 (1.51, 26.63; p=0.012)	90%	Low[1,2]	-
Arrange	RCT	Clinical practice guidelines; Educational materials; Educational meetings; Tailored intervention	Usual practice/control	3.55 (0.50, 25.34; p=0.207)	83%	Low[1,2,3]	-
Ask	RCT	Audit & feedback; Educational materials; Educational meetings; Educational outreach visits, or academic detailing; Tailored intervention	Educational materials	-	-	-	1.2 (1.0, 1.5)[a]
		Educational meetings; Reminders	Educational meetings	-	-	-	6.3 (1.8, 22.1)[a]
		Educational meetings; Educational outreach visits, or academic detailing; Local opinion leaders; Reminders; Tailored intervention	Educational meetings	-	-	-	29.2 (17.5, 38.0)[b]
Advise	RCT	Audit & feedback; Educational materials; Educational meetings; Educational outreach visits, or academic detailing; Tailored intervention	Educational materials	-	-	-	1.1 (0.9, 1.3)[a]

		Educational meetings; Reminders	Educational meetings	-	-	-	4.5 (1.9, 10.8)[a]
		Educational meetings; Educational outreach visits, or academic detailing; Local opinion leaders; Reminders; Tailored intervention	Educational meetings	-	-	-	26.2 (13.9, 40.2)[b]
		Clinical practice guideline; Educational materials; Educational meetings; Educational outreach visits, or academic detailing	Clinical practice guideline; Educational materials; Educational meetings	-	-	-	1.95 (1.32, 2.88)[a]
Assist	RCT	Audit & feedback; Educational materials; Educational meetings; Educational outreach visits, or academic detailing; Tailored intervention	Educational materials	-	-	-	1.3 (0.9, 1.9)[a]
		Educational meetings; Reminders	Educational meetings	-	-	-	29.9 (14.5, 61.9)[a]
		Educational meetings; Educational outreach visits, or academic detailing; Local opinion leaders; Reminders; Tailored intervention	Educational meetings	-	-	-	21.5 (10.6, 31.8)[b]
		Clinical practice guideline; Educational materials; Educational meetings; Educational outreach visits, or academic detailing	Clinical practice guideline; Educational materials; Educational meetings	-	-	-	1.96 (1.13, 3.39)[a]
Arrange	RCT	Audit & feedback; Educational materials; Educational meetings; Educational outreach visits, or academic detailing; Tailored intervention	Educational materials	-	-	-	1.07 (0.57, 1.99)[a]

		Educational meetings; Educational outreach visits, or academic detailing; Local opinion leaders; Reminders; Tailored intervention	Educational meetings	-	-	-	2.7 (0.0, 17.2)[b]
Weight management							
Assess	RCT	Educational materials; Educational meetings; Educational outreach visits, or academic detailing; Reminders	Usual practice/control	57.56 (41.78, 79.29; p<.001)	0%	Moderate[1]	-
Advise	RCT	Educational materials; Educational meetings; Educational outreach visits, or academic detailing	Usual practice/control	-	-	-	6.44 (3.14, 13.17)[a]
Advise	Non-randomised	Educational materials; Educational meetings; Local consensus process; Tailored intervention	Usual practice/control	3.37 (2.34, 4.84; p<0.001)	0%	Very-low[1,2]	-
Alcohol consumption							
Assess	Non-randomised	Educational materials; Educational meetings	Usual practice/control	-	-	-	1.15 (0.17, 1.03)[a]
Advise	Non-randomised	Educational materials; Educational meetings	Usual practice/control	10.36 (2.37, 41.20; p=0.002)	83%	Very-low[1,4]	-

Reasons for downgrading certainty of the evidence ratings: [1] risk of bias; [2] inconsistency; [3] imprecision; [4] indirectness

[a] Odds Ratio (95% CI); [b] Absolute difference in medians (95% CI)

Secondary outcomes

Effect of implementation strategies on pregnant women's modifiable risk factors

Four RCTs [68, 69, 71, 72] examined the effect of implementation strategies on quit smoking outcomes during pregnancy. Meta-analysis of these studies found that implementation strategies to improve care practices significantly increased the odds of cessation by 43% (OR: 1.43; 95% CI: 1.09, 1.88; p=0.009; I^2: 16%). The four studies tested either a single (reminders) [68] or a combination of multiple implementation strategies (audit and feedback, educational materials, educational meetings, educational outreach visits, local opinion leaders, reminders and tailored intervention) [69, 71, 72].

Two studies [49, 50] reported on pregnant women's weight gain within recommendations, with no effect found in either the RCT that used educational materials and reminders (OR: 1.04; 95% CI: 0.67, 1.64) [50] or the non-randomised trial that used educational materials and educational meetings (OR: 0.99; 95% CI: 0.63, 1.55) [49]. The RCT also reported no effect in weight gained per week between intervention and control groups (mean difference: 0.01; 95% CI: -0.03, 0.05) [50].

Implementation costs/cost-effectiveness and unintentional adverse consequences

No studies reported estimates of the absolute costs or cost-effectiveness or unintentional adverse consequences of the implementation strategies.

DISCUSSION

This systematic review examined the effectiveness of implementation strategies in improving health professional's provision of guideline recommended preconception and antenatal care addressing tobacco smoking, weight management and alcohol consumption. Meta-analyses

combined with GRADE assessments to assess the certainty of the evidence indicated that implementation strategies probably increase asking and advising about smoking and assessing weight gain in pregnancy compared to usual practice/control, and may increase assessing, assisting and arranging support for smoking. While the pooled effect estimates for weight gain and alcohol consumption advice were also in a positive direction, the certainty of the evidence was assessed as very-low, implying that the true effects are not known. There was a positive direction of effect for multiple implementation strategies versus single strategy (either educational meetings or materials) in improving smoking care. Meta-analyses of modifiable risk factor outcomes found increased odds of quitting smoking, though no improvements in pregnant women's gestational weight gain.

The finding that implementation strategies probably increase elements of smoking and weight management antenatal care is consistent with broader Cochrane systematic review evidence regarding the effect of implementation strategies in healthcare settings [36-42]. All but one of the studies contributing data to these outcomes tested multiple implementation strategies, with a median of three strategies used. Strategies for improving asking and advising about smoking included educational materials, educational meetings, reminders, clinical practice guidelines and tailored intervention. Similarly, educational materials, educational meetings and reminders were used to increase assessment of weight gain, with the addition of educational outreach visits. These strategies are consistent with the previous antenatal care smoking review [47], which found that three or more implementation strategies, theoretical/tailored strategy development and inclusion of a systems-based strategy were among the components of implementation that may have led to a positive impact. Such review findings support policymaker and health service adoption of multiple implementation strategies, such as educational materials, educational meetings and reminders, to increase the provision of

recommended smoking care and weight gain assessment to pregnant women by health professionals.

There was a positive direction of effect for multiple implementation strategies versus a single strategy in supporting health professionals deliver recommended smoking care to pregnant women. Further, two of the three studies specifically selected implementation strategies that targeted barriers reported by health professionals [70-72], which is a recommended step in the design of implementation trials [77]. Frequently clinical guidelines released by government or professional bodies are simply accompanied by a single strategy, such as the distribution of educational materials (e.g. health professional handouts) or education (e.g. online training module) [78]. However, previous research has shown that selecting implementation strategies that target the specific barriers cited by health professionals can increase various evidence-based care practices by over 50% [79]. Such findings suggest clinical guideline concordant care for pregnant women could be maximised if multiple implementation strategies are used, including those that target the specific barriers cited by health professionals.

This review highlighted gaps in the evidence-base for how to improve preconception and antenatal care to address modifiable risk factors. Whilst the pooled effect estimates for weight gain and alcohol consumption advice were positive, the very-low certainty of evidence ratings imply that new studies in this area could substantially change the estimate. Further, no studies were identified that examined the effect of implementation strategies in improving any element of preconception care addressing smoking and weight management, or referrals for alcohol consumption and weight management during the antenatal period. Given the critical importance of women entering pregnancy in optimal health and being supported to modify their risk factors during pregnany, priority research is required to inform implementation

strategies for these specific care elements. Futher, there was the lack of information across all included studies regarding the cost and unintended adverse consequences of implementation strategies. Such information, which is essential for guiding policy and practice decision making and investment [80], should be assessed and reported in future studies.

The findings of this review need to be considered in light of a number of strengths and limitations. The review adopted best practice systematic review methods and employed a broad inclusion criteria, which enabled a comprehensive synthesis of the evidence-base. However, there is potential that eligible articles were missed as the search was conducted in English only and articles without an English translation available were made ineligible. This may have contributed to the small number of studies found in low and middle income countries, and without such representation, the external validity of the review findings are largely limited to high income countries. The generalisability of the review findings to preconception care are also limited as only one study was identified in this setting. There is currently no agreed definition of what constitutes the preconception population in the literature base [81], and this, as well as the more restricted definition used in this review, may have contibuted to the lack of studies that were identified. The review also restricted eligible study designs to those that had a parallel comparison group. This omitted non-control studies that may have provided further information useful for understanding implementation strategies used in improving guideline recommended care addressing modifiable risk factors. Reviewer interpretation was used to classify strategies to the EPOC taxonomy, which may have introduced variability during synthesis due to the inconsistencies in terminology used across studies. It is possible that strategies not incorporated within the EPOC taxonomy were also missed through this process.

The interpretation and utility of the review findings were limited by the characteristics of the included studies. No studies for any of the risk factors tested the same combination of strategies, which prohibited the examination of specific individual strategies and strategy combinations. Further, there was heterogeneity in the types of services (e.g. hospital and community based) and health professional groups (e.g. midwives and medical staff) targeted by the implementation strategies in the included studies, and two studies did not not specify the discipline of the health professionals who participated. Such heterogeneity and missing data, as well as the small number of included studies, prohibited synthesis by the distinct service and health professional groupings.

Meta-analysis was not possible for all outcomes, and where possible only a small number of studies (2 to 4) were able to be synthesised, which is likely to have impacted on the ability of the random effects meta-analyses to reliably estimate the between-study variation. As per recommendations for synthesising results from implementation trials in healthcare settings [54, 82], non-randomised study designs were included. However, as only non-randomised studies were found that examined the effect of implementation strategies in improving alcohol consumption care, this limits certainty in the evidence-base for these specific outcomes.

CONCLUSIONS

Review findings suggest adoption of multiple implementation strategies, including educational materials, educational meetings and reminders, by policy makers and health services to increase health professional provision of asking and advising about tobacco smoking and assessing weight gain in pregnancy. Rigorous research is needed as a priority to build certainty in the evidence for improving alcohol consumption and weight gain advice during the antenatal

period, and to examine the effect of implementation strategies in preconception care where limited studies were identified.

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CHAPTER 6

A practice change intervention to improve antenatal care addressing alcohol consumption by women during pregnancy: Research protocol for a randomised stepped-wedge cluster trial

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ABSTRACT

Background: Despite clinical guideline recommendations, implementation of antenatal care addressing alcohol consumption by pregnant women is limited. Implementation strategies addressing barriers to such care may be effective in increasing care provision. The aim of this study is to examine the effectiveness, cost and cost-effectiveness of a multi-strategy practice change intervention in increasing antenatal care addressing the consumption of alcohol by pregnant women.

Methods: The study will be a randomised, stepped-wedge controlled trial conducted in three sectors in a health district in New South Wales, Australia. Stepped implementation of a practice change intervention will be delivered to sectors in a random order to support the introduction of a model of care for addressing alcohol consumption by pregnant women. A staged process was undertaken to develop the implementation strategies, which comprise of: leadership support, local clinical practice guidelines, electronic prompts and reminders, opinion leaders, academic detailing (audit and feedback), educational meetings and educational materials, and performance monitoring. Repeated cross-sectional outcome data will be gathered weekly across all sectors for the study duration. The primary outcome measures are the proportion of antenatal appointments at 'booking in', 27–28 weeks gestation and 35–36 weeks gestation for which women report (1) being assessed for alcohol consumption, (2) being provided with brief advice related to alcohol consumption during pregnancy, (3) receiving relevant care for addressing alcohol consumption during pregnancy, and (4) being assessed for alcohol consumption and receiving relevant care. Data on resources expended during intervention development and implementation will be collected. The proportion of women who report consuming alcohol since knowing they were pregnant will be measured as a secondary outcome.

Discussion: This will be the first randomised controlled trial to evaluate the effectiveness, cost and cost-effectiveness of implementation strategies in improving antenatal care that addresses alcohol consumption by pregnant women. If positive changes in clinical practice are found, this evidence will support health service adoption of implementation strategies to support improved antenatal care for this recognised risk to the health and wellbeing of the mother and child.

Trial registrations: Australian and New Zealand Clinical Trials Registry, No. ACTRN12617000882325 (date registered: 16/06/2017).

BACKGROUND

Maternal alcohol consumption during pregnancy is associated with a number of adverse obstetric, fetal and child outcomes with lifelong consequences. These include Fetal Alcohol Spectrum Disorder (FASD), miscarriage, stillbirth, preterm birth, congenital anomalies, and low birth weight [1]. No safe level of prenatal alcohol exposure has been established for the fetus and therefore many countries, including Australia, have national guidelines recommending that the safest option is for women to abstain from alcohol consumption when trying to conceive, during conception and during pregnancy [1–3].

Despite this recommendation, 10% of women worldwide consume alcohol during pregnancy, with notably higher prevalence estimates in regions with high levels of general alcohol consumption, such as the World Health Organisation European Region (prevalence estimate of alcohol consumption in pregnancy, 25%) [4]. In Australia, national surveys and prospective cohort studies report the prevalence of maternal alcohol consumption at any time during

pregnancy to be between 35 and 72% [5–10]. For example, a prospective cohort study of 1403 women attending antenatal clinics in the Australian states of New South Wales and Western Australia found that 61% of women consumed alcohol between conception and pregnancy recognition, often at risky levels. Of these women, approximately 30% continued to drink alcohol once they were aware they were pregnant [10]. Similarly, a study of 1570 women attending public antenatal clinics in Melbourne, Australia, found that just over half (54%) of women consumed alcohol in the first trimester, and half of these women continued to consume alcohol throughout the remainder of their pregnancy [8].

Health services providing antenatal care represent an opportune setting to address maternal alcohol consumption during pregnancy. Systematic review evidence shows that psychological and educational interventions for pregnant women may reduce alcohol consumption and increase abstinence from alcohol [11]. Additional evidence suggests that clinician assessment of alcohol consumption and brief interventions, including motivational interviewing, may also reduce the risk of an alcohol-exposed pregnancy [12–18]. Efforts to reduce alcohol consumption during pregnancy in antenatal settings is also acceptable to women, with 97% of Australian women indicating that they wanted information about alcohol use during pregnancy and would be willing to change their alcohol consumption if advised to do so [19]. Consistent with this evidence, international, [20] as well as Australian national [21, 22] and state clinical guidelines [23, 24] recommend that health professionals providing antenatal care use a validated tool to assess alcohol consumption for all pregnant women at the initial visit and throughout the antenatal period, provide brief advice about the potential harms of alcohol consumption during pregnancy and recommend abstinence, and refer women to specialist services if they require assistance to stop consuming alcohol.

Despite clear recommendations in clinical guidelines, implementation of antenatal care addressing maternal alcohol consumption during pregnancy is limited. Internationally, studies show that pregnant women are not routinely assessed for their alcohol consumption during antenatal consultations are not consistently provided with information regarding the effects of alcohol consumption during pregnancy and receive inconsistent advice regarding alcohol intake [25–27]. For instance, in Canada, only 50% of health professionals report providing advice to pregnant women regarding the consumption of alcohol [28] and, in the UK, only two thirds of women reported receiving such advice from a midwife [29]. In Australia, a study of 1143 of health professionals who provide antenatal care found that fewer than half (45%) routinely asked about alcohol consumption during pregnancy, only 25% provided information on the effects of alcohol consumption during pregnancy, and only 13% provided advice consistent with national drinking guidelines [30, 31]. A more recent study involving 166 midwives in Western Australia found that while almost all midwives (93%) asked pregnant women about their alcohol consumption, only 54% used a standardised assessment tool [32].

A small number of studies have been conducted to assess barriers to the provision of care addressing maternal alcohol consumption during pregnancy. These barriers include a lack of systems and/or tools to prompt clinician assessment of alcohol consumption, concerns about patient sensitivity and stigmatisation, lack of staff time, need for staff training, limited access to or knowledge of clinical and patient resources, including culturally appropriate resources for Aboriginal and Torres Strait Islander women, lack of referral options, a perceived lack of skill in delivering care, and a lack of understanding of the importance of providing such care to all women [33–36]. Additionally, the literature on clinical guideline implementation more broadly indicates that other barriers (including commitment to change from organisational leaders/champions, perceived value/need and readiness to change, skills, ability and

confidence, and an absence of systems and tools to support/prompt care delivery) commonly impede changes in professional practice [37].

Cochrane reviews of strategies to improve the implementation of recommended clinical practices suggest that a variety of both organisational and individually focused strategies may be effective. These strategies include leadership, local clinical practice guidelines, electronic prompt and reminder systems, local opinion leaders, educational meetings and educational materials, academic detailing, including audit and feedback, and, monitoring the performance of the delivery of healthcare [38–41]. The effectiveness of such strategies in improving the implementation of guideline recommendations is, however, highly variable [38–42] and, to maximise effectiveness, it is recommended that strategies are selected that target specific barriers to the implementation of recommended clinical practices [43–45]. Implementation frameworks such as the Theoretical Domains Framework have been developed to aid the selection of targeted evidence-based implementation strategies [46, 47].

No controlled trials have been conducted to test the effectiveness, cost and cost-effectiveness of implementation strategies in increasing the provision of recommended antenatal care that addresses maternal alcohol consumption during pregnancy. Accordingly, the aim of this study is to examine the effectiveness, cost and cost-effectiveness of a multi-strategy practice change intervention in increasing maternity clinician provision of care addressing the consumption of alcohol by women during their pregnancy.

METHODS

Study design and setting

The study will be a randomised stepped-wedge controlled trial design conducted in three sectors (clusters) in the Hunter New England Local Health District in New South Wales, Australia. The sectors are geographically defined groupings of antenatal facilities with common operational management. As shown in Figure 6.1, repeated cross-sectional outcome data will be gathered on a weekly basis across all three sectors for the duration of the study (34 months). Baseline (current practice/control phase) data will be collected for each of the three sectors from 7 months prior to the commencement of the intervention in the first sector to the start of the intervention in each sector. Stepped implementation of a 7-month practice change intervention will be delivered in a randomly selected order at six monthly intervals. Follow-up data will continue to be collected for all three sectors 7 months following completion of the practice change intervention in the third sector. The outcomes of the trial will be determined by comparing practice change outcomes between the baseline and follow up periods for the three sectors combined.

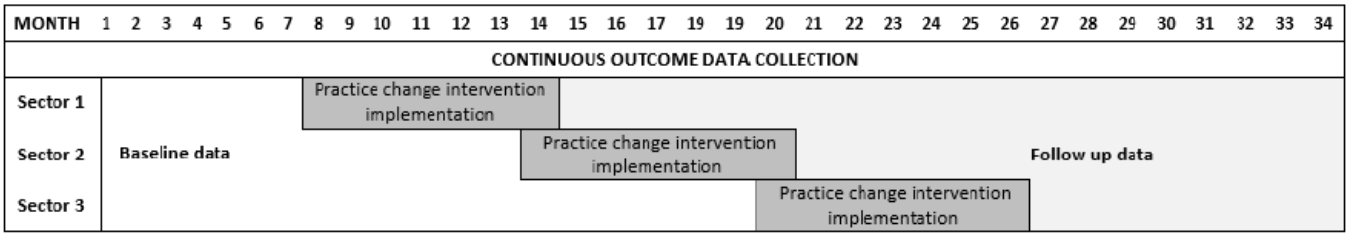

Figure 6.1. Study design

Figure 6.1 shows the trial design and implementation of the trial data collection and intervention components over the course of the 34 months trial period. Repeated cross-sectional outcome data from surveys of pregnant women will be gathered on a weekly basis across all three sectors for the duration of the study. Baseline data will be collected for each of the three sectors from 7 months prior to the commencement of the intervention in the first sector to the start of the intervention in each sector. Stepped implementation of a 7-month practice change intervention will be delivered in a randomly selected order at six monthly intervals. Follow-up data will continue to be collected for all three sectors 7 months following completion of the practice change intervention in the third sector.

A randomised stepped-wedge controlled trial design is recommended for the evaluation of complex practice change interventions in settings such as health services as it provides a number of pragmatic and scientific advantages over a randomised controlled trial design [48, 49]. First, it provides a similar level of evidence as a standard parallel cluster randomised controlled trial (RCT) [50]. Second, although all participants will receive the intervention, its sequential implementation across three sectors provides the capacity to identify secular trends, i.e. changes over time before the intervention is implemented [48]. Third, the design addresses the practical difficulty of recruiting the number of similar antenatal services that would be required for a parallel cluster RCT, instead allowing each cluster to act as its own control [48, 49]. Finally, the design provides an opportunity for all participating services and women to receive the intervention, overcoming ethical and logistical challenges arising from withholding the intervention [50].

Public antenatal services are the largest provider of antenatal health care in Australia, providing services to a diverse population [51]. The antenatal services in the three sectors service urban and rural areas and provide care to over 6000 women annually, accounting for approximately 70% of births in Hunter New England Local Health District public hospitals [52].

Random allocation and blinding

A statistician who is independent of intervention development and implementation will randomly allocate the order in which the intervention is implemented (stepped) across the three health sectors. The random sequence will be generated using a computerised random number generator with allocation undertaken for all three sectors at the one time. Study personnel involved in collecting outcome data will be blind to the allocated order of the delivery of the intervention across the sectors. Participants providing outcome data will not be informed of the

experimental nature of intervention implementation across services and therefore will be blind to the stage of study occurring in the service they attended. Given the practice change nature of the intervention, clinicians in antenatal services will be aware when their service is in the intervention period.

Participant eligibility and recruitment

Antenatal services and clinicians

All public antenatal services in the three sectors will receive the practice change intervention, including midwifery group practices, midwifery clinics, specialist medical services, AMIHS, and multi-disciplinary teams caring for women with complex pregnancies or identified vulnerabilities. The practice change intervention will be provided to all maternity clinicians providing antenatal care in participating services: registered midwives (clinical midwife educators, clinical midwife specialists, clinical midwife consultants, community liaison midwives), medical practitioners (staff specialists in obstetrics, fellows, registrars, resident medical officers, general practice obstetricians), Aboriginal health practitioners, Aboriginal health workers and students. All such clinicians who worked in participating antenatal services for at least one of the 7 months during which the practice change intervention was implemented in their sector will be invited to participate in a post intervention survey.

Pregnant women

It is intended that all pregnant women who attend participating services from the start of the practice change intervention in their health sector will receive the intervention. During the 34-month data collection period, women who attend an individual face-to-face antenatal appointment at three time points (i) the time of the first public antenatal service visit (from this point referred to as the ‘booking in’ visit), (ii) 27–28 weeks gestation, or (iii) 35–36 weeks

gestation, will be eligible to participate in data collection surveys. To be eligible for participation in such surveys, women need to: be aged 18 years or older, be currently pregnant at more than 12 weeks gestation and less than 37 weeks gestation, have a sufficient level of English language proficiency to complete the survey unaided, and be mentally and physically capable of completing the survey. Women will be ineligible to participate in data collection surveys if they: are determined by clinical discretion to be inappropriate to contact for the survey (e.g. due to medical or social issues); and/or are receiving the majority of their antenatal care via a private obstetrician; and/or have given birth or had a negative pregnancy outcome; and/or had already been selected to participate in the survey for that care time point in the past 4 weeks; and/or had previously declined participation in the survey. The number of women deemed ineligible for the above-listed reasons will be recorded and reported.

Each week, a sample of eligible women who attended an antenatal appointment in the past week (for booking in, 27–28 weeks gestation or 35–36 weeks gestation care) will be randomly selected via a computerised random number generator by members of the research team not involved in delivering care to women. Selected women will be mailed a participant information statement explaining the purpose of the survey 1 week prior to receiving a phone call inviting them to participate in the survey [see Appendix 11]. Study posters will be displayed in antenatal clinics and pamphlets distributed in antenatal information packs provided to all women at the time of their booking in appointment [see Appendix 10]. Women identified via the medical record data as being of Aboriginal or Torres Strait Islander origin and/or women who are attending or enrolled to attend an AMIHS will be first contacted by text message and invited to participate [see Appendix 12]. If they do not respond, they will be followed up with a telephone call 4 days later. All women will have the opportunity to decline participation at any point, including opting out during the clinic visit or when they receive information in the

antenatal booking in pack, when they receive the study information letter in the mail, at the time of the phone call or text message, or partway through survey completion. On the morning of the day that a woman is to be contacted via phone call or text message, medical record data will be checked and any women who are identified as having given birth or having had a negative pregnancy outcome will be deemed ineligible and not contacted.

Intervention

Model of care for addressing maternal alcohol consumption in pregnancy

A model of care for addressing alcohol consumption in pregnancy will be implemented in antenatal services across the three participating sectors. The model of care is consistent with international [20] and Australian national [21, 22], and state [23, 24] antenatal clinical practice guidelines and is based on models of assessment and brief intervention that have been shown to reduce the risk of an alcohol-exposed pregnancy [11, 13–18].

As shown in Figure 6.2, the model of care will consist of three key elements – assessment, advice and referral, which will be delivered to women who attend an antenatal clinic appointment the booking in, 27–29 weeks gestation and 35–37 weeks gestation.

1) Assessment of alcohol consumption

The Alcohol Use Disorders Identification Test Consumption (AUDIT-C) tool will be used to assess the alcohol consumption of pregnant women. The tool has shown to be a valid tool for use with pregnant women [53]. Maternity clinicians will ask all women the first AUDIT-C question: ‘How often do you have a drink containing alcohol?’. Those women who provide a response other than ‘Never’, will be asked the remaining two AUDIT-C items: ‘How many standard drinks of alcohol do you have on a typical day when you are drinking?’ and ‘How

often do you have five or more alcohol drinks on one occasion?'. These responses will be used to calculate an 'Alcohol Risk Score' and 'Alcohol Risk of Harm' category (No Risk, Low Risk, Medium Risk, High Risk).

2) Provision of brief advice

All women, regardless of their Alcohol Risk of Harm category, will be provided with advice by their maternity clinician that it is best not to consume alcohol at any time during pregnancy and that alcohol consumption during pregnancy can increase risk of harm to the foetus and the woman. Women will be provided with additional advice based on their Alcohol Risk of Harm category.

3) Referral to specialist services for additional support

Women with a Medium AUDIT-C risk level will be offered a referral to the Get Healthy in Pregnancy telephone-based coaching service. Get Healthy in Pregnancy is a free, state-wide, government-funded telephone coaching service that supports women to make positive health and lifestyle changes [54]. Women can set a goal of alcohol abstinence throughout pregnancy and receive up to ten tailored calls by qualified health coaches. The coaching is based on behaviour change principles designed to assist with goal setting, maintaining motivation and overcoming barriers [54]. Aboriginal women with a Medium AUDIT-C risk level will also be offered the option of referral to counselling services at a local Aboriginal Community Controlled Health Service (ACCHS) (if available). This latter referral pathway was established through consultation with Aboriginal community members and the ACCHS's that provide care for Aboriginal pregnant women in the study region. For women with a High AUDIT-C risk level, direct referral to Hunter New England Local Health District Drug and Alcohol Clinical Services will be provided. Care from such services will involve ongoing clinical support from

a multidisciplinary Drug and Alcohol team throughout pregnancy, including assessment, brief intervention, counselling and withdrawal and post-withdrawal support as clinically indicated. Referral may also be made to residential drug and alcohol treatment services if required (provided by non-government services).

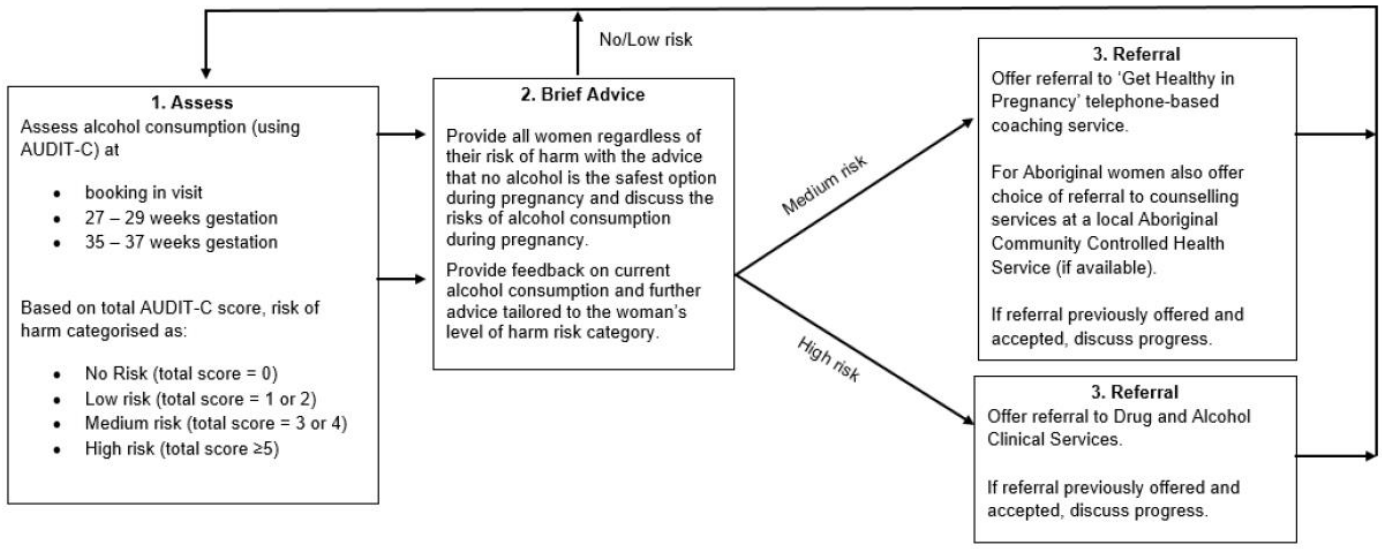

Figure 6.2 Model of care for addressing maternal alcohol consumption during pregnancy

Figure 6.2 shows the model of care for addressing maternal alcohol consumption during pregnancy. This model of care will consist of three key elements—assessment, advice and referral—which will be delivered to women who attend an antenatal clinic appointment booking in, 27–29 weeks gestation and 35–37 weeks gestation. The Alcohol Use Disorders Identification Test Consumption (AUDIT-C) tool will be used to assess the alcohol consumption of pregnant women. All women, regardless of their Alcohol Risk of Harm category, will be provided with advice by their maternity clinician that it is best not to consume alcohol at any time during pregnancy and that alcohol consumption during pregnancy can increase risk of harm to the foetus and the woman. Women will be provided with additional advice based on their Alcohol Risk of Harm category. Women with a Medium AUDIT-C risk level will be offered a referral to the Get Healthy in Pregnancy telephone-based coaching service. Aboriginal women with a Medium AUDIT-C risk level will also be offered the option of referral to counselling services at a local Aboriginal Community Controlled Health Service (ACCHS) (if available). For women with a High AUDIT-C risk level, direct referral to Hunter New England Local Health District Drug and Alcohol Clinical Services will be provided. Care from such services will involve ongoing clinical support from a multidisciplinary Drug and Alcohol team throughout pregnancy, including assessment, brief intervention, counselling and withdrawal and post-withdrawal support as clinically indicated.

Implementation intervention

A series of organisational and individual clinician focused strategies will be used to support clinician implementation of the model of care.

Implementation intervention strategy development

The following staged process was undertaken to develop the implementation strategies:

1. Quantitative anonymous surveys were undertaken with 33 clinicians working in antenatal services across the three sectors and an additional eight managers of maternity services/teams to determine perceived barriers and enablers to their implementation of the model of care for addressing maternal alcohol consumption during pregnancy. The surveys were constructed based on 11 domains of the Theoretical Domains Framework (TDF) [55, 56] and were informed by previous surveys of health professionals [57] and previous studies utilising the TDF across different health care settings [58–60].
2. The priority barriers identified through the clinician and manager surveys were mapped to TDF techniques for behaviour change [43] and a proposed list of implementation strategies was developed based on a review of the literature and advice sought from experts in treatment of alcohol harms, clinical practice change, health service research and behavioural sciences.
3. Consultation with Aboriginal community members, ACCHSs within the participating sectors, AMIHS staff, and Aboriginal population health staff was undertaken to ensure the content of implementation strategies was culturally appropriate for women. Qualitative research (focus groups) was also conducted with Aboriginal mothers (who had attended a public antenatal service in the study region in the last 12 months) and Aboriginal pregnant women to explore experiences of antenatal care in relation to the consumption of alcohol during pregnancy and identify any issues relating to the

provision of such care to ensure the implementation strategies were culturally appropriate.

4. Final refinement of implementation strategies and development of strategy content was undertaken following consultation with key clinicians and managers across the three participating health sectors.

Implementation intervention strategies

Table 6.1 lists the implementation strategies that will be used to support the introduction of the model of care for addressing maternal alcohol consumption during pregnancy (Figure 6.2), including the evidence source and the TDF domains on which each strategy was based and the barriers that the strategy was intended to address.

Table 6.1 Implementation strategies

Implementation strategy	TDF Domain/s [56]	Identified barriers strategy seeks to overcome	Mapped behaviour change techniques [43]	Strategy description
1. Leadership/ managerial supervision [65]	• Professional role • Belief about consequences	• Clinician belief that it is not their responsibility to routinely address alcohol consumption during pregnancy. • Clinician and manager belief that there are more important things to do. • Manager belief that they lack support from colleagues to manage staff performance and that staff are resistant to clinical practice change. • Clinician belief that they will not be held accountable if they do not address alcohol consumption. • Clinician belief that their managers do not expect alcohol care to be delivered.	• Social processes of encouragement, pressure, support • Persuasive communication	• Throughout planning and implementation, monthly meetings will be held with management from antenatal services within each of the participating sectors to gather feedback on planned strategies and elicit support. • Antenatal service managers will be asked to distribute key documents/ communications to staff and attended all training sessions. • Antenatal service managers will have performance measures related to the model of care added to their operational plans.

2. Local clinical practice guidelines [66]	• Knowledge • Environmental context and resources	• Clinician lack of knowledge of the procedure for addressing alcohol consumption, including referral pathways for women requiring further support. • Clinician feedback that IT systems/ forms do not support required care. • Clinician belief that they do not have a clear plan for addressing alcohol consumption during pregnancy and if they have a problem they don't know how to solve it.	• Information regarding behaviour/ outcome • Environmental changes • Goal target specified: behaviour or outcome • Contract • Planning, implementation	• A service level guideline and procedure document will detail the required care for addressing alcohol consumption during pregnancy, including assessment, brief advice and referral pathways. • The guidelines and procedure will be uploaded onto the health service's policy, procedure and guidelines directory and disseminated by service managers to all staff via email and hard copies will be placed in staff common areas.
3. Electronic prompt and reminder system [67]	• Memory, attention and decision processes • Environmental context and resources	• Clinician feedback that they often forget to address alcohol consumption during pregnancy and do not unless the woman expresses it as a priority. • Clinician feedback that IT systems/ forms do not support required care.	• Environmental changes • Prompts, triggers, cues	• Modifications will be made to existing point-of-care and medical record systems used by maternity clinicians to electronically prompt standardised assessment of alcohol consumption using the validated AUDIT-C alcohol screening tool. Brief advice scripts will be displayed

	• Behavioural regulation	• Clinician feedback that there is a lot to cover in antenatal appointments. • Clinician belief that they do not have a clear plan for addressing alcohol consumption during pregnancy and if they have a problem they don't know how to solve it.		on the point-of-care system based on the woman's AUDIT-C risk score, as will prompts and tools for referral to appropriate services.
4. Local opinion leaders/ champions [65, 68, 69]	• Social/ professional role and identity • Motivation and goals • Social influences	• Clinician belief that it is not their responsibility to routinely address alcohol consumption during pregnancy. • Clinician and manager belief that there are more important things to do. • Clinician belief that other staff do not routinely undertake the model of care and there is no one who can provide support if a problem is encountered. • Manager belief that they lack support from colleagues to manage	• Social processes of encouragement, pressure, support • Persuasive communication • Modelling, demonstration of behaviour by others	• Project-specific Clinical Midwife Educators (CMEs) will be appointed to support staff to uptake the model of care and will provide support at a one-on-one, team and service level. The CMEs will be appointed based on their ability to engage and influence staff and model required behaviours. The role of the CME will be to delivery and monitor each of the implementation support strategies and be responsive to the specific implementation needs of each antenatal services.

		staff performance and that staff are resistant to clinical practice change.		• Additional local antenatal clinical leaders will be engaged to provide encouragement and demonstration of required behaviours in each antenatal services as required (e.g. for specific professional disciplines).
5. Educational meetings and educational materials [70, 71]	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequence • Environmental context and resources • Emotion	• Clinician lack of knowledge in the procedure for addressing alcohol consumption, including referral pathways for women requiring further support. • Clinician lack of skill in assessing alcohol consumption during pregnancy using a validated tool and offering referrals to women requiring further support. • Clinician lack of training in addressing alcohol consumption according to guidelines. • Clinician belief that they have limited capability to assess alcohol	• Goal/ target specified behaviour or outcome • Increasing skills- through problem solving, decision-making, goal-setting • Rehearsal of relevant skills • Modelling/ demonstration of behaviour by others • Perform behaviour in different settings	• Training will be provided to all antenatal service clinicians via a 30-minute online training module and face-to-face sessions. Content will be adapted from the accredited 'Women Want to Know' courses [72]. The CME will facilitate clinicians completing the online training and coordinate face-to-face training sessions, which will be rostered into routine clinical meetings and include, lecture style sessions, interactive, case-study based sessions and one-on-one sessions.

		consumption during pregnancy using a validated tool and offer appropriate referrals. • Manager belief that they have limited capability to competently use performance monitoring tools and reports and have conversations with staff regarding performance. • Clinician belief that pregnant women will react negatively if asked about alcohol consumption and that it will have a negative impact on their client-clinician relationship. • Clinician feedback that they are hesitant to address alcohol due to child protection implications. • Clinician belief that they do not have access to appropriate information resources and there is a lack of support services to refer women to.	• Social process of encouragement/ pressure support • Persuasive communication • Information regarding behaviour/ outcome • Coping skills	• Training content will include: – The effects of alcohol consumption during pregnancy and associated health outcomes. – Guideline recommendations for alcohol consumption during pregnancy. – Prevalence of alcohol consumption by pregnant women. – The model of care for addressing alcohol consumption during pregnancy: 1) alcohol consumption assessment; 2) brief advice; and 3) referral for ongoing care. – Effectiveness and acceptability of addressing alcohol consumption during pregnancy in routine antenatal care.

		• Clinician lack of confidence in addressing alcohol consumption in appointment time, when other clinicians are present and when women show lack of interest. • Clinician feedback that they feel nervous and uncomfortable addressing alcohol consumption with women.		– Culturally appropriate practices when addressing alcohol consumption with Aboriginal women. • Clinicians will also be provided with written resources (hardcopy and electronic) to support the model of care, including standard drink measure charts and point-of-care written prompts/ reminders (e.g. stickers in charts).
6. Academic detailing, including audit and feedback [45, 73, 74]	• Behavioural Regulation • Skills • Beliefs about consequences • Social Influences	• Clinician belief that they do not have a clear plan for addressing alcohol consumption during pregnancy and if they have a problem they don't know how to solve it. • Clinician lack of skill in addressing alcohol consumption according to guidelines. • Manager belief that additional burden will be placed on clinicians,	• Goal/ target specified behaviour or outcome • Monitoring • Contract • Planning, implementation • Increasing skills-problem solving, decision-making, goal-setting	• Data from both medical records and telephone surveys conducted with women who attended the antenatal services will be used to provide feedback on levels of care provision for addressing alcohol consumption during pregnancy. • Data will routinely be fed back to antenatal service teams by the CME. The CME will visit service teams in

		that staff will react negatively if performance is discussed and that staff will not take on board feedback about performance. • Manager feedback that it is difficult to release clinicians from clinical work to attend training. • Clinician belief that pregnant women do not expect alcohol to be addressed in antenatal appointments.	• Rehearsal of relevant skills • Social process of encouragement/ pressure support • Feedback • Persuasive communication • Information regarding behaviour and outcome	their antenatal clinics to support discussion of the feedback and development of action plans in response to such in order to improve care. • Women's acceptability of their antenatal service team providing each of the care elements will also be fed back.
7. Monitoring and accountability for the performance of the delivery of healthcare [73]	• Social Influences • Beliefs about capabilities • Environmental context and resources • Memory, attention, decision processes	• Clinician belief that their managers do not expect alcohol care to be delivered. • Manager belief that they have limited capability to competently use performance monitoring tools and reports and have conversations with staff regarding performance. • Manager feedback that they do not have adequate data entered from staff to use for performance	• Social processes of encouragement, pressure, support • Environmental changes • Contract • Prompts, triggers, cues • Feedback	• Antenatal service managers will be supported by the CME to report, interpret and monitor performance measures for the model of care for addressing alcohol consumption during pregnancy. The CME will also support these mangers to disseminate these results to their antenatal service staff through team meetings, emails and other usual communication mechanisms.

		measurement, have competing work tasks and don't have the supports/ resources to manage performance. • Managers' feedback that they forget about tools to manage performance and are less likely to manage performance of staff resistant to change. • Manager feedback that it is stressful to manage performance.		• Performance measures will be built into the existing monitoring and accountability frameworks for antenatal services, including service-level operational plans and performance measures at service manager and team manager level.

Implementation intervention delivery timeline

The intervention strategies listed above will be implemented in each sector for 7 months prior to follow up data collection (Figure 6.1). This will include a 1-month period introducing the practice change and a 6-month intensive practice change intervention. Given their organisational and system focus, all strategies, other than the local opinion leader (Clinical Midwife Educator (CME)) and academic detailing strategies, have the potential to continue to be implemented following the 7-month study intervention period, subject to the operational decisions of the Local Health District.

Control and contamination

Usual care

Prior to implementation of the practice change intervention in each of the three sectors, usual antenatal care for addressing maternal alcohol consumption during pregnancy will be provided. Such care is likely to vary by antenatal service and clinician as no existing health sector-wide guideline or procedure specifies the provision of routine care for addressing alcohol consumption during pregnancy.

Potential for contamination

As the research team will control the initiation and delivery of all the intervention elements, the intervention strategies will not be accessible to antenatal clinicians during the baseline (control) phase. Although potential for contamination during this phase from staff movement between sectors is possible, it is considered to be limited due to the structural and systemic nature of the implementation strategies. Information on movement of clinicians between participating sectors will be collected throughout the study.

Measures

Primary trial outcomes

There are four primary outcomes for this trial. They are the proportion of all antenatal clinic appointments (at 'booking in', 27-28 weeks gestation and 35–36 weeks gestation) for which women report:

1. Being assessed for alcohol consumption and level of risk using the AUDIT-C.
2. Being provided with brief advice related to alcohol consumption during pregnancy.
3. Receiving, relative to their level of risk, the relevant elements of antenatal care for addressing alcohol consumption during pregnancy (advise and refer).
4. Being assessed for alcohol consumption and level of risk using the AUDIT-C and receiving, relative to their level of risk, the relevant elements of antenatal care for addressing alcohol consumption during pregnancy (advise and refer).

Secondary trial outcome

For women attending antenatal appointments at 'booking in', 27–28 weeks gestation and 35–36 weeks gestation, alcohol consumption since pregnancy recognition as measured by total AUDIT-C score will be collected based on self-report of women. AUDIT-C is a validated tool for assessing risk of harm due to alcohol consumption [53].

Process evaluation measures

The acceptability, appropriateness, feasibility, intervention fidelity and reach of the model of care for addressing maternal alcohol consumption in pregnancy and the implementation strategies will be assessed via surveys of women and clinicians and project records. These process measures will be based on an implementation evaluation framework [61] and use validated measures where available [62]. Measures to assess implementation intervention reach

will include participation of antenatal clinical staff in educational meetings, interaction with local opinion leaders, involvement in academic detailing and audit and feedback sessions, and receipts of clinical practice guidelines. To determine reach of the implementation intervention strategies across different groups of clinicians, data will be collected from clinicians on position/profession, level of training, and length of time working in current antenatal service and in antenatal services generally. To assess delivery of the model of care across different demographic groups of women, the following information will be collected from pregnant women: age, highest level of education, employment status, geographical location, Aboriginal or Torres Strait Islander status of woman and baby, household composition, current gestation, gestation at first antenatal clinic visit, whether attending care for first or subsequent pregnancy and alcohol consumption prior pregnancy (via AUDIT-C).

Cost and cost-effectiveness

To provide a measure of the investment required to develop, implement and maintain the effect of the implementation strategies, resource use will be prospectively measured and valued from a public finance perspective. The outcomes from the cost analysis will be (i) an estimate of the cost required to develop the intervention strategies, (ii) the net cost of delivering the implementation intervention (including labour costs for the CME and the clinicians to conduct/participate in each of the implementation strategies, undertaking quality assurance processes, providing managerial oversight), and (iii) assuming a positive trial outcome, the expected incremental cost to maintain effect. Additionally, the cost-effectiveness of the implementation strategies will be assessed relative to the baseline (current practice) phase in each of the three sectors. The incremental cost-effectiveness ratio (ICER) will be calculated as the difference in average cost between the intervention and baseline phases, divided by the

difference in the primary outcome. Sensitivity analyses will test the robustness of results to selected issues and assumptions.

Data collection procedures

Primary and secondary outcome measures

Each week a sample of women who in the past week attended an antenatal clinic for a 'booking in' visit, a visit when they were 27–28 weeks gestation, or a visit when they were 35–36 weeks gestation will be sent a letter providing information about the study and inviting them to participate in a computer assisted telephone interview (CATI) survey [see Appendix 11]. Telephone contact will be attempted with women up to ten times over a 2-week period, including at different times of the day and on weekdays and weekends, in order to elicit consent and completion of the survey. If a woman declines to participate in the CATI, they will be invited to complete the survey online. If they consent to participate in the online survey, they will be sent a survey link via text message. Women who are of Aboriginal or Torres Strait Islander origin and/or are attending or enrolled to attend an AMIHS will be offered via text message the choice of participating in the survey via either CATI or online mode [see Appendix 12].

The CATI survey will be conducted by experienced female interviewers who will receive specific training and undertake practice interviews. The CATI and online survey script are identical in the wording of questions, response options and help provided. Both surveys will be pilot tested prior to starting the study to test comprehension, logic flow and survey length. See Appendix 13 for the CATI survey and Appendix 14 for the online mode of the survey.

Process evaluation

Data for the aforementioned process evaluation measures will be collected via surveys with women (as per procedure described above) and clinicians. Online surveys of clinicians will be conducted at the completion of the intervention in each sector. All eligible clinicians in antenatal services in the participating sectors will be sent a link to an online survey via email, and also given the option to complete the survey on tablet computers/laptops in regular in-services and clinic meetings. Surveys will be completed anonymously. Additional process data to assess intervention fidelity and reach will be collected using project management logs completed by project staff.

Cost and cost effectiveness

Project management logs, including a cost capture template, will be used to prospectively collect data regarding the resources expended during intervention development and implementation.

Overall data management

Management of trial data will be in accordance with a data management protocol, which has been developed and approved by the project's advisory group. Data will be stored securely as per the requirements of the Hunter New England Human Research Ethics Committee, The University of Newcastle Human Research Ethics Committee and the Aboriginal Health and Medical Research Council. Data will only be accessible to primary researchers and statisticians. Confidential participant data will be stored securely and not linked to survey responses.

Sample size and power calculations

It is expected that 70% of invited women will consent to participate in the surveys (based on previous work by the research team [63]). Assuming 48 working weeks a year, and an intra-class correlation of 0.01, a sample of 200 women per month (approximately 67 women per each of the three time points: booking in visit, 27–28 weeks gestation, 35–36 weeks gestation) will give the study 80% power to detect an absolute increase in care provision of 15% in the intervention period (based on a conservative 50% estimate of prevalence of care provision at baseline) in at least one of the four primary outcomes at a 1.25% significance threshold. Assuming there are approximately 190 women eligible per week, a weekly sample of 72 women (i.e. 24 women per time point) with a 70% survey completion rate (n = 50) will result in the required number of women needed per month.

Statistical analysis

Baseline and follow-up primary outcomes data will be analysed using a logistic mixed model to detect change over time in the reported receipt of recommended antenatal care for addressing alcohol consumption during pregnancy. For the secondary trial outcome, linear mixed models will be used to analyse changes in AUDIT-C scores of participants between baselines and follow up periods. The models will have a period term (fixed effect, reflecting pre-post difference, the main indicator of effect) and health sector term (fixed effect). Where appropriate, the models will also include fixed effects for client group (booking in, 27–28 weeks gestation, 35–36 weeks gestation) and a time term (fixed effect, to pick up any secular trend). In the latter models, a client group by period term will detect differences between the client groups in their response to the intervention. Where the interaction terms are significant, subgroup analyses will be reported for each of the three client groups. Descriptive statistics will be used to report on process measures and interventions costs. Process outcomes will be

used to narratively interpret the results of primary outcome analysis. SAS (V9.3 or later) will be used for all statistical analyses.

Research trial governance

A research co-production approach has been employed in the development and design of the study [64]. The conduct of the study will similarly be overseen by an advisory group consisting of researchers, policy makers, practitioners and clinical experts with expertise related to alcohol, health promotion, implementation science, FASD, obstetrics and maternal health. A project team consisting of research staff and practitioners will develop and operationalise implementation strategies and data collection components of the trial according to study protocol. Local clinical experts based at each of the three participating sectors will provide advice on aspects of the model of care and implementation strategies that require sector-specific tailoring.

Aboriginal cultural governance

A series of Aboriginal cultural governance task groups, co-led by Aboriginal and non-Aboriginal staff, will provide guidance on cultural considerations for Aboriginal and Torres Strait Islander people relating to the model of care, implementation strategies, data collection, and interpretation and dissemination of study findings. See Appendix 21 for the trial's Aboriginal data management protocol and Appendix 22 for the Aboriginal cultural governance model.

Trial discontinuation or modification

There are no criteria for trial discontinuation as it is not anticipated that any events would occur that would warrant discontinuing the trial. Any unforeseen adverse events will be reported to

the Hunter New England Human Research Ethics Committee (primary approval committee) and advice sought regarding required action. The trial registration record will be updated with any protocol modifications and any deviations from original protocol will be reported in study outcome papers.

DISCUSSION

Despite the need, there is a clear absence of research evidence of the effectiveness, cost and cost-effectiveness of implementation strategies to improve antenatal care that addresses maternal alcohol consumption during pregnancy. This will be the first randomised controlled trial to evaluate the effectiveness of such intervention strategies. The stepped-wedge design is feasible and acceptable in the context of conducting a trial across multiple antenatal services. The study has strong design elements including random allocation of the order of strategy implementation across the health sectors and blinding of data collection staff. The implementation intervention strategies have been developed based on key implementation science frameworks and using data from surveys with antenatal services staff and managers. A research co-production approach has been employed in the design of the study and will be employed in its conduct and dissemination.

If positive changes in clinical practice are found, the study will provide evidence to support the delivery by health services of the implementation strategies to improve antenatal care addressing this recognised risk to the health and wellbeing of both the mother and child. The methods used in this trial have the potential to provide a framework for the development of initiatives for improving the implementation of models of care, both in the antenatal clinic setting and in other clinical environments.

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CHAPTER 7

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

Published:

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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 visits 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.

Trial registration: 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

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 Figure 7.1). 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].

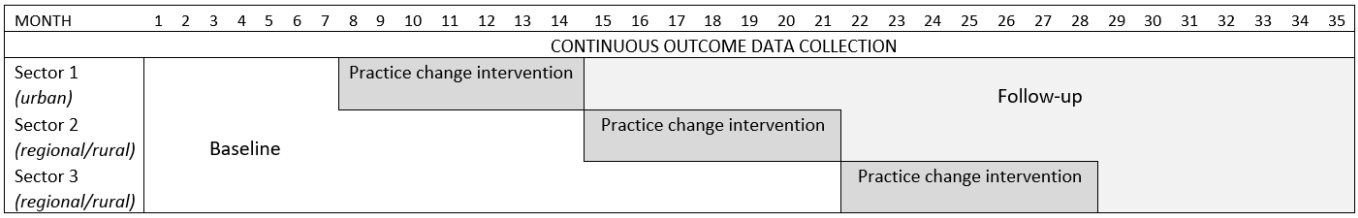


Figure 7.1 Data collection and intervention timeline for the randomised stepped-wedge controlled trial

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) [See Appendices 9 and 15]. 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; 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. 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; 27–28 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 [see Appendix 11]. 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 [see Appendix 12]. 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 Appendix 23 for example model of care with local referral pathways]:

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 [see Appendix 24 for women's pamphlets].
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 [See Appendix 25 for example referral forms]. Follow-up of women who had previously accepted a referral to an abovementioned service at the 27–29 and 35–37 weeks gestation visits.

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] [see Appendix 17]. 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 7.1 for a description of the implementation strategies).

Table 7.1 Implementation Strategies

Implementation strategy	Description
Leadership/ managerial supervision [26] [see Appendix 26]	Bi-monthly meetings were held with maternity service management to elicit operational support for the practice change. Management demonstrated leadership by distributing key documentation and communications to staff, being present at training sessions, and by monitoring performance measures relating to the practice change.
Local clinical practice guidelines [33] [see Appendix 27]	A service level guideline and procedure document that outlined the model of care was uploaded onto the health service's policy and guidelines directory and disseminated by managers to all staff via email and hard copies were placed in staff common areas.
Prompt and reminders [32] [see Appendices 28 and 29]	Modifications were made to the existing point-of-care electronic medical record system used by maternity services. Changes to the system included: an electronic prompt for care at the three antenatal visits; standardised assessment of alcohol consumption using AUDIT-C, auto-calculation of AUDIT-C risk; brief advice scripts based on risk of harm category; and prompts for referral services. Antenatal providers were also provided with written point of care prompts, including stickers in hard-copy medical charts, and assessment prompts printed on a handheld 'pregnancy wheel' used by antenatal providers to determine gestation.
Local opinion leaders/ champions [26-28]	A dedicated CME was appointed in each sector to provide individual, team and service level support in the uptake of the recommended model of care. The CME was responsible for delivering and monitoring the implementation strategies and was appointed based on their ability to engage staff and model the required behaviours. Additional local antenatal clinical leaders were engaged to provide encouragement and demonstration of required behaviours in each maternity service as required.
Educational meetings and educational materials [24, 25]	A 30-minute online training module and a series of face-to-face sessions (including a mix of didactic, interactive, case-study, group and one-on-one sessions) were facilitated by the CME and a content

[see Appendices 30 and 31]	expert. Antenatal providers were also given written educational resources to support the model of care, including standard drinks charts and fact sheets on the harm of alcohol consumption during pregnancy.
Academic detailing, including audit and feedback [29-31] [see Appendix 32]	Data that were collected from medical records and surveys with pregnant women who recently attended a service were fed back to antenatal providers by the CME. The CME supported providers to develop action plans in response to the data for each of the guideline elements (assessment, advice and referral). Data on women's reported acceptability of the model of care was also fed back to services.
Monitoring and accountability for performance [30] [see Appendix 33]	Performance measures for the model of care for addressing alcohol consumption during pregnancy were included in managers' existing monitoring and accountability frameworks, including measures in service-level operational plans and on the health district's performance platform. Managers were supported in interpreting and disseminating the data to their staff through usual communication mechanisms, such as team meetings and email.

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 by 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 [see Appendix 13]/online questionnaires [see Appendix 14] 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 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 $\geq$ 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 $\geq$ 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 $\geq$ 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%.

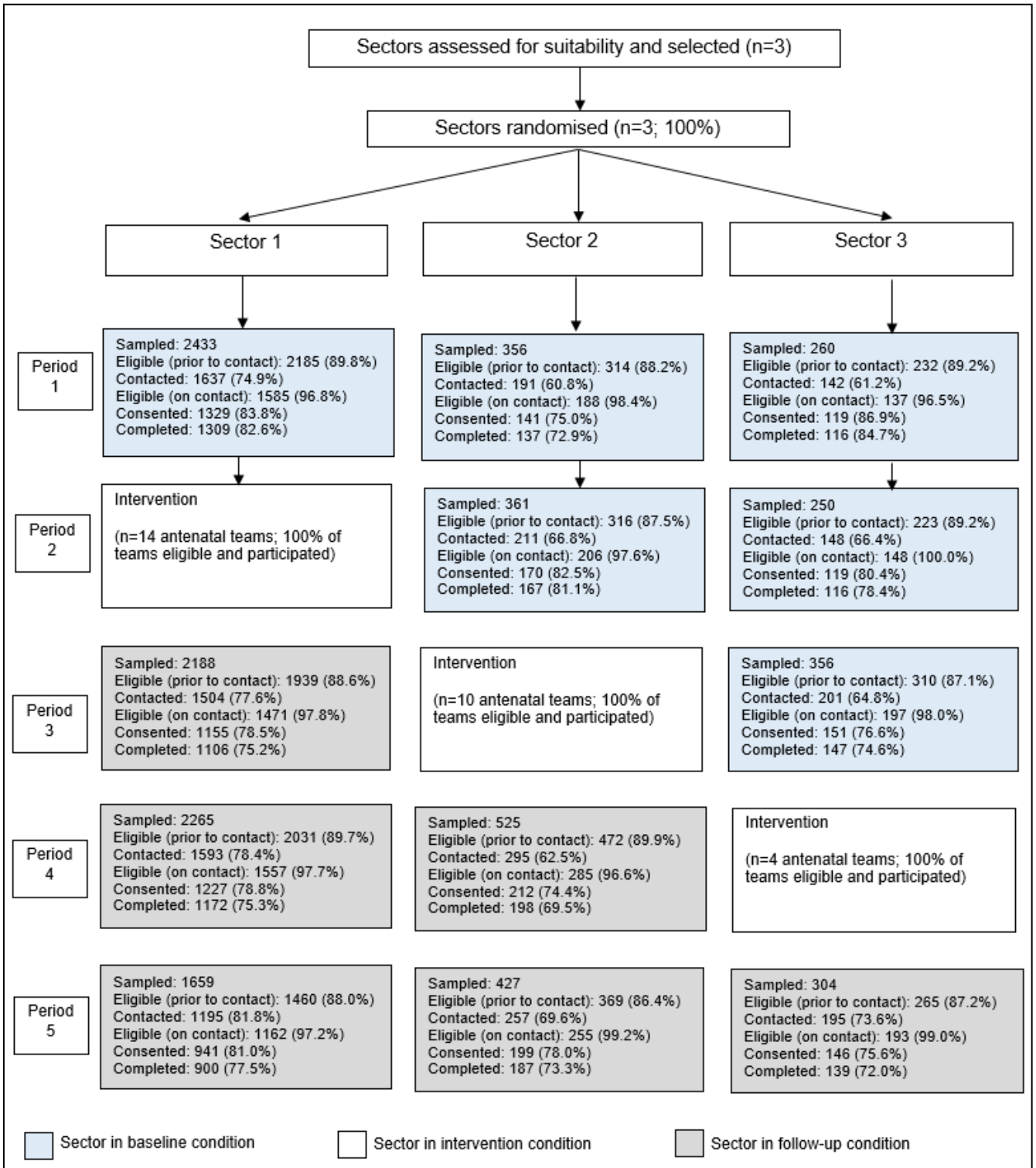
RESULTS

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 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 (233 midwifery; 82 medical; and 14 Aboriginal Health Workers) 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, 7571 (74.8%) were contacted within the two-week contact period. Of the 7386 women who were eligible on contact, 5909 (80.0%) consented to participate and 5694 (77.1%) completed an interview/online questionnaire (see Figure 7.2). 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 7.2).



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).

Figure 7.2 CONSORT Flowchart

Table 7.2 Pregnant women's demographics

	Baseline (N=1992)	Follow-up (N=3702)	Total (N=5694)
	n (%)	n (%)	n (%)
Age			
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 [49] was used for categorising Geographic remoteness and Index of Relative Socio-Economic Disadvantage (IRSD) [50] for Area index of disadvantage.

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

Receipt of antenatal care addressing alcohol consumption during pregnancy

As shown in Table 7.3, 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 7.3, 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 7.4, 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.

Table 7.3 Receipt of antenatal care addressing alcohol consumption during pregnancy overall and by type of antenatal visit

Model of care element	Initial antenatal visit						27 - 28 weeks gestation visit						35 - 36 weeks gestation visit					
	Baseline N=682		Follow-up N=1161		OR (95% CI)	p-value	Baseline N=670		Follow-up N=1139		OR (95% CI)	p-value	Baseline N=637		Follow-up N=1398		OR (95% CI)	p-value
	n	%	n	%			n	%	n	%			n	%	n	%		
Assessment of alcohol consumption (via AUDIT-C)	451	66.1%	821	70.7%	1.45 (1.17, 1.79)	<0.001	67	10.0%	318	27.9%	4.17 (3.11, 5.59)	<0.001	46	7.2%	364	26.0%	5.39 (3.87, 7.50)	<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	81	12.1%	245	21.5%	2.41 (1.82, 3.19)	<0.001	45	7.1%	263	18.8%	3.72 (2.66, 5.22)	<0.001
Advice safest not to consume	447	65.5%	853	73.4%	1.77 (1.43, 2.19)	<0.001	132	19.7%	424	37.2%	2.99 (2.36, 3.78)	<0.001	87	13.7%	465	33.3%	3.88 (2.99, 5.03)	<0.001
Advice on potential risks	268	39.3%	508	43.7%	1.43 (1.17, 1.75)	<0.001	150	22.4%	348	30.5%	1.83 (1.45, 2.30)	<0.001	121	19.0%	393	28.1%	2.01 (1.59, 2.55)	<0.001
Complete care relative to level of alcohol risk (complete brief advice and referral)	243	35.6%	477	41.1%	1.51 (1.23, 1.86)	<0.001	81	12.1%	244	21.4%	2.40 (1.81, 3.18)	<0.001	43	6.8%	263	18.8%	3.92 (2.78, 5.53)	<0.001
Assessment of alcohol consumption and complete care relative to level of alcohol risk	192	28.2%	392	33.8%	1.64 (1.32, 2.04)	<0.001	36	5.4%	151	13.3%	3.43 (2.33, 5.05)	<0.001	23	3.6%	175	12.5%	4.88 (3.10, 7.66)	<0.001

Model of care element	**Total**						**Between group differences**	
	Baseline N=1989		Follow-up N=3698		OR (95% CI)	p-value	Initial vs subsequent antenatal visits	
	n	%	n	%			OR (95% CI)	p-value
Assessment of alcohol consumption (via AUDIT-C)	564	28.4%	1503	40.6%	2.63 (2.26, 3.05)	<0.001	3.20 (2.38, 4.29)	<0.001
Complete brief advice (safest not to consume and potential risks)	371	18.7%	986	26.7%	2.07 (1.78, 2.41)	<0.001	1.91 (1.43, 2.54)	<0.001
Advice safest not to consume	666	33.5%	1742	47.1%	2.62 (2.28, 3.01)	<0.001	1.87 (1.43, 2.43)	<0.001
Advice on potential risks	539	27.1%	1249	33.8%	1.70 (1.49, 1.95)	<0.001	1.32 (1.03, 1.70)	0.03
Complete care relative to level of alcohol risk (complete brief advice and referral)	367	18.5%	984	26.6%	2.10 (1.80, 2.44)	<0.001	1.92 (1.44, 2.56)	<0.001
Assessment of alcohol consumption and complete care relative to level of alcohol risk	251	12.6%	718	19.4%	2.32 (1.94, 2.76)	<0.001	2.43 (1.70, 3.47)	<0.001

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.

Table 7.4 Receipt of antenatal care addressing alcohol consumption during pregnancy by sector

Model of care element	**Sector 1** (urban)						**Sector 2** (regional/rural)					
	Baseline N=1,308		Follow-up N=3,175		OR (95% CI)	p-value	Baseline N=302		Follow-up N=385		OR (95% CI)	p-value
	n	%	n	%			n	%	n	%		
Assessment of alcohol consumption (via AUDIT-C)	346	26.5%	1255	39.5%	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 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)						**Between group differences**		
	Baseline N=379		Follow-up N=138		OR (95% CI)	p-value	Sector 1 vs Sector 2	Sector 1 vs Sector 3	p-value
	n	%	n	%			OR (95% CI)	OR (95% CI)	
Assessment of alcohol consumption (via AUDIT-C)	131	34.6%	66	47.8%	2.31 (1.46, 3.65)	<0.001	1.28 (0.86, 1.91)	0.91 (0.56, 1.47)	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	1.41 (0.95, 2.10)	0.91 (0.56, 1.48)	0.19
Advice safest not to consume	143	37.7%	76	55.1%	2.73 (1.76, 4.22)	<0.001	1.12 (0.78, 1.63)	1.07 (0.67, 1.70)	0.81
Advice on potential risks	122	32.2%	53	38.4%	1.50 (0.99, 2.27)	0.059	1.41 (0.99, 2.01)	0.92 (0.59, 1.43)	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	1.39 (0.94, 2.07)	0.91 (0.56,1.48)	0.21
Assessment of alcohol consumption and complete care relative to level of alcohol risk	61	16.1%	37	26.8%	2.33 (1.42, 3.83)	<0.001	1.47 (0.94, 2.30)	1.10 (0.64, 1.87)	0.25

OR = Odds Ratio; 95% CI = 95% Confidence Interval; Intervention effects adjusted for type of antenatal visit and time (month of antenatal visit); Missing 7 participants who did not provide all data for receipt of care measures.

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 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 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] [see Appendix 2 for full cost, cost-consequence and cost-effectiveness outcomes]. 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.

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CHAPTER 8

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

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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 examined 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.

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.

INTRODUCTION

Alcohol consumption during pregnancy can increase obstetric risk and adversely affect fetal development [1-3]. In recognition of such harms, many countries have released guidelines that recommend pregnant women do not consume alcohol [4-6]. 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%) [7]. 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 [8, 9].

Health services are a critical setting for addressing this risk as most women will access antenatal care [10] and interventions delivered by health professionals are effective in increasing alcohol abstinence during pregnancy [11]. 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 [12, 13]. However, these guideline recommendations are sub-optimally implemented in a number of countries including Australia [14, 15], United States [16], Norway [17] and Denmark [18]. 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 [15]. 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 [15, 19-21]. 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 [15, 21, 22].

Two controlled trials to date have sought to improve the provision of antenatal care addressing alcohol consumption during pregnancy [23, 24]. 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) [23]. 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) [24]. 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; $p<0.001$) [24]. Greater intervention effects were found for the 27-28 weeks and 35-36 weeks gestation antenatal visits compared with the initial antenatal visit [24]. The model of care was also reported to be acceptable to both Aboriginal (95.5%) and non-Aboriginal (98.8%) women [24].

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 [25, 26]. 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? [27-29] 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 [30]. In trials that have demonstrated overall effectiveness, such as the practice change intervention conducted by the author team [24], it is possible that the intervention had a large effect for one subgroup and no or lesser effect for another [30]. 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 [31-33]. 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 [31]. 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 [32]. 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 [33].

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 [23, 24] 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 [34]. 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) [10]. 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 [24].

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 Human Research Ethics Committee: 16/11/16/4.07, 16/10/19/5.15; The University of Newcastle Human Research Ethics Committee: 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 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 [12, 13] 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) [35];

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 [36] 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 [37]; local clinical practice guidelines [38]; electronic prompts and reminders [39]; local opinion leaders/champions [37, 40, 41];

educational meetings and materials [42, 43]; academic detailing (including audit and feedback) [44-46]; and monitoring and accountability for performance [45]. Intervention development was guided by the Theoretical Domains Framework [47, 48] with implementation strategy selection targeting system and individual clinician level barriers elicited from formative surveys with antenatal providers in the participating services [34, 49].

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 [50].

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 [35] 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 [15, 19-21]:

- Pregnant women subgroups. Women reported their age, Aboriginal origin, highest level of education completed, and whether this was their first pregnancy. The AUDIT-C [35] 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.

Statistical analysis

Statistical analyses were undertaken using SAS version 9.3 [51]. 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+) [52]. 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 [24].

- 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 [53] ('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 [54] 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 8.1).

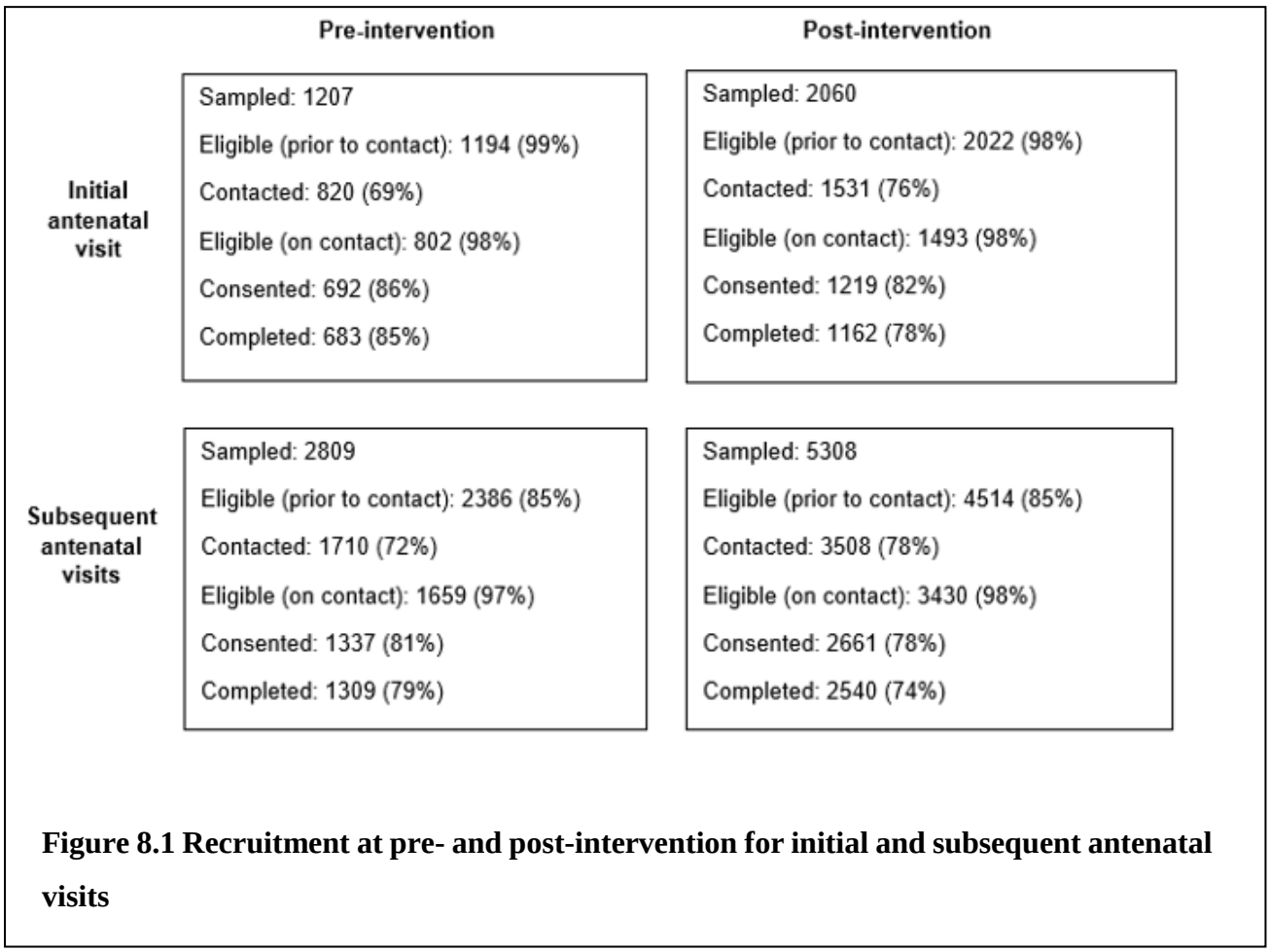

Figure 8.1 Recruitment at pre- and post-intervention for initial and subsequent antenatal visits

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 8.1).

Table 8.1 Characteristics of pregnant women and maternity services at pre- and post-intervention

Characteristics	Initial antenatal visit		Subsequent antenatal visits	
	Pre-intervention (N=683)	Post-intervention (N=1162)	Pre-intervention (N=1309)	Post-intervention (N=2540)
	n (%)	n (%)	n (%)	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%)

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 8.2). 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 8.3). 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.

Table 8.2 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)		243 (35.63%)	477 (41.09%)	1.51 (1.23, 1.86)	
Age				0.06				0.08
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 8.3 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%)	-	

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 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 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 [9, 55, 56], 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 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 [33] 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 [57] 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 [58]. 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% [59]). Mitigating such changes in alcohol consumption behaviours requires the delivery of different advice and support at different points of time. Future research could assess the 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 adaptions that could be tested include training antenatal providers to ask assessment questions in a conversational manner, such as Healthy Conversation Skills [60], 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 [61] and shown to be an effective solution for other health risks and in other settings [62].

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 Better Birth trial that found no significant differences between professional subgroups and adherence to essential birth practices after peer coaching [31]. 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 [32]. 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 [63], 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.

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CHAPTER 9

Thesis findings and implications for future research and practice

This chapter provides a summary of the findings addressing each of the thesis aims and then discusses two key implications for future research and practice.

The aims of this thesis were to:

- assess pregnant women's reported receipt of antenatal care addressing alcohol consumption during pregnancy consistent with clinical guideline recommendations (assess, advise, refer) at two antenatal visit types (initial and subsequent) in public maternity services;
- assess the characteristics of pregnant women and maternity services associated with the receipt of guideline recommended antenatal care addressing alcohol consumption during pregnancy;
- quantitatively assess pregnant women's acceptability of each of the guideline recommended care elements;
- comprehensively assess antenatal provider and manager barriers to the implementation of clinical guideline recommendations for addressing alcohol consumption during pregnancy using a consolidated implementation framework;
- synthesise the evidence from controlled studies regarding the effectiveness of implementation strategies in improving guideline recommended care addressing modifiable risk factors (alcohol consumption, tobacco smoking and weight gain) in pregnancy care focussed settings (preconception and antenatal);
- develop and evaluate the effectiveness of a theoretically, empirically and end-user informed practice change intervention in improving the provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services; and
- explore whether the practice change intervention has equitable impacts across subgroups of pregnant women and types and location of maternity services.

THESIS FINDINGS

Chapter 1. Introduction: The harms of alcohol consumption during pregnancy and strategies to support the implementation of guideline recommended antenatal care in public maternity services

Chapter 1 outlined the direct and indirect harms of alcohol to the individual, other people and broader society and demonstrated the considerable burden of consumption in the general population. Pregnant women were identified as a priority population for reducing such alcohol-related harms due to the range of adverse outcomes associated with maternal alcohol consumption. Although international and national guidelines consistently recommend pregnant women do not consume alcohol, the prevalence of alcohol consumption at any stage during pregnancy was reported to be high (international: 10%; Australia: 55% to 82%).

Both systematic review evidence and international and Australian guidelines and strategies supported the delivery of brief interventions addressing alcohol consumption in antenatal care settings. Clinical guidelines consistently recommend that all pregnant women routinely receive antenatal care that includes three evidence-based elements (assess, advise, refer) delivered at initial and subsequent antenatal visits. Despite such recommendations, a limited number of studies to date suggested that such care is sub-optimally and inconsistently provided in public maternity services. However, as most studies utilised clinician self-report and none reported the delivery of all care elements, including by type of visit, a need for further research to determine pregnant women's self-reported receipt of recommended antenatal care addressing alcohol consumption was identified. Despite a number of qualitative studies reporting that pregnant women consider antenatal care addressing alcohol consumption to be acceptable, a need to quantitatively examine the representativeness of such views in a large sample of pregnant women was also identified.

Evidence of barriers health professionals face in providing antenatal care addressing alcohol consumption was presented. Clinician lack of knowledge and perception that such care could negatively impact the client-clinician relationship, were suggested as key barriers. Few barriers, other than lack of time available in antenatal visits, were identified at the clinical environment level. None of the identified studies utilised a consolidated implementation framework to ensure a comprehensive approach to barrier assessment, or reported on the barriers faced by maternity managers despite their pivotal role in supporting guideline implementation. Given these findings, a need for further research to assess antenatal provider and manager barriers to the implementation of clinical guideline recommendations addressing alcohol consumption using a consolidated implementation framework was identified.

Practice change interventions consisting of evidence-based implementation strategies were identified as a potential solution to addressing barriers to the implementation of antenatal care guidelines. Cochrane review evidence was found to support the effectiveness of such strategies in improving clinician implementation of a range of recommended care practices in various healthcare settings. However, no synthesis of such evidence specific to improving care for modifiable risk factors in pregnancy care settings was identified other than for tobacco smoking. Only one controlled study was identified that had tested an implementation strategy (educational meetings) to improve antenatal care addressing alcohol consumption. Although the study found significant improvements in advice provision (RR: 2.66; 95% CI: 1.27, 5.56; p=0.005), it had a number of limitations, including: non-randomised study design; focus on only one element of the guideline recommendations (advice not to consume and of the potential risks); small sample size (n=67); and the absence of the use of a theoretical framework, empirical evidence and consideration of local context and end-users in the intervention design.

Based on these evidence gaps, the chapter concluded that further research was required to develop and evaluate a theoretically, empirically and locally informed practice change intervention in improving antenatal care addressing alcohol consumption.

Chapter 2. Antenatal care addressing alcohol consumption during pregnancy in public maternity services: pregnant women's reported receipt and acceptability of care and associated characteristics

A cross-sectional study was undertaken to examine pregnant women's reported receipt and acceptability of antenatal care addressing alcohol consumption during pregnancy consistent with international and national clinical guideline recommendations. A survey (telephone or online) was conducted with 1363 pregnant women who had recently attended a public maternity service for an initial or subsequent (27-28 weeks gestation or 35-36 weeks gestation) antenatal visit. The study found that 64.3% of pregnant women reported receiving an assessment of their alcohol consumption consistent with the Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) at the initial antenatal visit and 7.8% at subsequent visits. Just over one third of pregnant women (34.9%) reported receiving complete care (advice and referral) relevant to their self-reported level of alcohol consumption at the initial antenatal visit and 8.7% at subsequent antenatal visits. Pregnant women's reported receipt of all guideline elements (assessment, advice and referral) was low at both visit types (initial antenatal visit: 27.9%; subsequent antenatal visits: 3.8%).

Characteristics that significantly decreased the odds of receiving all guideline elements at the initial antenatal visit were: higher educational attainment; residing in an area of higher advantage; not a first pregnancy; and urban service location. Characteristics that significantly decreased the odds of receiving all guideline elements at subsequent antenatal visits were: older

age and non-Aboriginal origin. Each of the recommended care elements were highly acceptable to pregnant women: assessment of alcohol consumption (98.7%); assessment of alcohol consumption at multiple visits (88.3%); advice not to consume alcohol (98.6%); advice on the potential risks (99.3%); referral to telephone counselling (99.0%); and referral to a drug and alcohol service (99.4%). These findings were consistent with those of previous studies confirming the need for further research to explore and address barriers to antenatal clinician implementation of guideline recommended care addressing alcohol consumption.

Chapter 3. Barriers to the implementation of clinical guidelines addressing alcohol consumption in public maternity services: A cross-sectional survey using the theoretical domains framework

A cross-sectional study was undertaken to comprehensively assess barriers to the provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services. Thirty-three antenatal care providers and eight managers completed a survey that was developed based on 11 domains of the Theoretical Domains Framework (TDF). The TDF domains that were found to impede health professional provision of such antenatal care were: environmental context and resources; social influences; beliefs about capabilities; behavioural regulation; skills; beliefs about consequences; and emotion regulation. For managers, the TDF domains identified as barriers were: emotion regulation; environmental context and resources; memory, attention and decision processes; beliefs about consequences; beliefs about capabilities; and social influences. This was the first study to use a consolidated implementation framework to provide a comprehensive assessment of the barriers faced by antenatal care providers and managers in addressing alcohol consumption with pregnant women. The results provided formative data to assist with the selection of evidence-based

implementation strategies that could be tested to improve antenatal care addressing alcohol consumption in public maternity services.

Chapters 4 and 5. Implementation strategies to improve guideline recommended preconception and antenatal care addressing tobacco smoking, weight management and alcohol consumption: a systematic review (including protocol)

Chapter 4 described the methods and Chapter 5 the results of a systematic review to assess the effectiveness of strategies to improve the implementation of preconception and antenatal care addressing tobacco smoking, weight management and alcohol consumption. The review was conducted in line with the methods recommended by the Cochrane Handbook for Systematic Reviews of Interventions. Eligibility criteria included: randomised and non-randomised study designs with a parallel comparison group; interventions conducted with health services/professionals who are the usual providers of preconception and antenatal care; use of strategies targeting improvements in health professional delivered care as defined by the Cochrane Effective Practice and Organisation of Care taxonomy; comparison group of usual practice/control or alternative strategies; and any quantitative measure of improvements in the guideline recommended care elements for each modifiable risk factor. Electronic databases, relevant journals and reference lists of included studies were searched.

From 15,203 citations, 14 eligible studies were included in the review. Ten of the studies were randomised controlled trials and four non-randomised study designs. Thirteen of the studies were conducted in antenatal care settings and one in preconception care. Eight studies sought to improve care addressing smoking, four weight management and two alcohol consumption. Twelve of the studies tested multiple implementation strategies, with educational meetings and educational materials the most commonly included.

Meta-analyses of randomised studies found that compared to usual practice/control implementation strategies probably increase asking (OR: 2.52; 95% CI: 1.13, 5.59; 3 studies; moderate-certainty evidence) and advising (OR: 4.32; 95% CI: 3.06, 6.11; 4 studies; moderate-certainty evidence) about smoking and assessing weight gain (OR: 57.56; 95% CI: 41.78, 79.29; 2 studies; moderate-certainty evidence), and may increase assessing (OR: 2.55; 95% CI: 0.24, 27.06; 2 studies; low-certainty evidence), assisting (OR: 6.34; 95% CI: 1.51, 26.63; 3 studies; low-certainty evidence) and arranging support (OR: 3.55; 95% CI: 0.50, 25.34; 2 studies; low-certainty evidence) for smoking. Given the very-low certainty in evidence ratings, the true effect of implementation strategies in increasing advice about weight gain (OR: 3.37; 95% CI: 2.34, 4.84; 2 non-randomised studies; very low-certainty evidence) and alcohol consumption (OR: 10.36; 95% CI: 2.37, 41.20; 2 non-randomised studies; very low-certainty evidence) compared to usual practice/control was not known.

The lack of evidence to date hampers the ability of researchers, policy makers and health professionals to select effective strategies for improving the provision of antenatal care addressing modifiable risk factors, particularly for alcohol consumption. The need for further rigorous research to address the identified gaps and build certainity in the evidence-base was highlighted.

Chapter 6. A practice change intervention to improve antenatal care addressing alcohol consumption by women during pregnancy: research protocol for a randomised stepped-wedge cluster trial

Chapter 6 outlined the study methods of a practice change intervention to improve antenatal care addressing alcohol consumption in public maternity services. The randomised stepped-

wedge cluster trial was conducted in three health sectors (one urban, two regional/rural) within HNELHD, New South Wales, Australia. The three sectors are separate geographically defined groupings of maternity services each with their own operational management, and collectively provide care to over 6000 women annually.

All public maternity services within the sectors, including medical clinics, midwifery clinics/services and AMIHS, received seven months of multi-strategy support to implement a recommended model of care for addressing alcohol consumption during pregnancy. The recommended model of care was consistent with international and national antenatal clinical practice guidelines and consisted of three key elements (assess, advise, refer) that were to be provided to women at three antenatal visits (initial antenatal visit, 27-29 weeks gestation and 35-37 weeks gestation). As per implementation science recommendations, a staged process was undertaken to develop the implementation strategies, which included mapping behaviour change techniques and implementation strategies to the barriers identified through the TDF (Chapter 3), and consulting with Aboriginal stakeholders and clinical partners to refine the content and delivery of the implementation strategies for local context. Seven evidence-based implementation strategies were identified by this staged process and included in the practice change intervention: leadership/managerial supervision; local clinical practice guidelines; electronic prompt and reminder system; local opinion leaders/champions; educational meetings and educational materials; academic detailing (including audit and feedback); and monitoring and accountability for the performance of the delivery of healthcare.

All pregnant women attending a public maternity service had the potential to receive the recommended model of care. Weekly cross-sectional data were collected through telephone and online surveys with pregnant women following their initial, 27 to 28 weeks gestation and

35 to 36 weeks gestation antenatal visit for the duration of the study. The primary outcomes were the proportion of pregnant women who reported receipt of: i) assessment of alcohol consumption via AUDIT-C; ii) advice that it is safest not to consume alcohol and of the potential risks; iii) complete care relative to alcohol risk level (advice and referral); iv) all guideline elements relative to alcohol risk level (assessment, advice and referral). Baseline and follow-up periods were compared for the three health sectors combined using logistic regression models.

Chapter 7. Practice change intervention to improve antenatal care addressing alcohol consumption during pregnancy: a randomised stepped-wedge controlled trial

Chapter 7 reported the primary outcomes of the trial described in Chapter 6 as well as pregnant women's acceptability of receiving the recommended model of care addressing alcohol consumption in routine antenatal visits. A total of 5694 telephone and online surveys were completed with pregnant women during the 35-month study period (80% consent rate). The implementation strategies were effective in increasing pregnant women's receipt of: assessment of alcohol consumption via AUDIT-C (OR: 2.63; 95% CI: 2.26, 3.05); advice that it is safest not to consume alcohol during pregnancy and of the potential risks (OR: 2.07; 95% CI: 1.78, 2.41); complete care (advice and referral) relative to level of alcohol risk (OR: 2.10; 95% CI: 1.80, 2.44); and all guideline elements (assessment, advice and referral) relative to level of alcohol risk (OR: 2.32; 95% CI: 1.94, 2.76). Significant differential effects were found between antenatal visit types for all primary outcomes ($p<0.001$), with greater effects for subsequent visits compared to the initial antenatal visit. There were no significant differences in effectiveness by the location of the sector (urban vs regional/rural). The model of care was highly acceptable to all pregnant women who received recommended assessment and/or care

in routine antenatal visits post implementation support (98.8%), including Aboriginal women (95.5%).

The trial demonstrated the effectiveness of a theoretical, empirical and end-user informed practice change intervention in improving antenatal care addressing alcohol consumption during pregnancy in public maternity services. Although effective and a large effect size relative to the literature, only one third of women (33.8%) at follow-up received all guideline elements at the initial antenatal visit and less than 20% at subsequent antenatal visits, demonstrating a need for further research to identify strategies for ensuring all women receive such care. It was further concluded that future research was required to explore the characteristics of pregnant women and maternity services associated with intervention effectiveness to inform the need for, and development of, tailored adaptions to the implementation strategies.

Chapter 8. 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

Post-hoc exploratory subgroup analyses of two of the outcomes presented in Chapter 7 (receipt of alcohol assessment and complete care) measured at two antenatal visit types (initial and subsequent) were conducted. Logistic regression models examined interactions between pre-post intervention differences and subgroups of pregnant women (by age, Aboriginal origin, education level, area index of disadvantage, gravidity and alcohol consumption in pregnancy) and subgroups of maternity services (by geographic remoteness, antenatal service type and provider type/s in antenatal visit) previously reported to be associated with variation in guideline implementation.

No significant differential effects between subgroups of women or type/location of services were found for either outcome at the initial antenatal visit. For subsequent antenatal visits, the intervention effect differed significantly between subgroups based on Aboriginal origin (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 (women who consumed alcohol OR: 1.28; 95% CI: 0.59, 2.78; women who did not consume alcohol OR: 5.22; 95% CI: 4.11, 6.65; $p<0.001$) for assessment of alcohol consumption. The study results suggested that additional equity focussed strategies are required that enable Aboriginal women to benefit equally from practice change interventions seeking to improve antenatal care addressing alcohol consumption. Further, additional strategies are required to increase assessment of alcohol consumption for women consuming alcohol in pregnancy at subsequent visits to ensure that those women at greater risk have their care needs met by public maternity services.

IMPLICATIONS FOR FUTURE RESEARCH AND PRACTICE

The preceding chapters of this thesis demonstrated a need to improve antenatal care addressing alcohol consumption during pregnancy; that such care is acceptable to pregnant women; and that implementation strategies can increase care provision in initial and subsequent antenatal visits. These findings have extended the limited existing research evidence-base and have practical implications for policy makers and maternity services. The following sections will explore two key issues identified to further advance research and practice in this area: i) a need to further increase the proportion of women who receive antenatal care addressing alcohol consumption during pregnancy through iterative care improvement approaches; and ii) a need to sustain care provision after the withdrawal of active implementation support.

Further increasing the proportion of women who receive antenatal care addressing alcohol consumption during pregnancy through iterative improvement approaches

As shown in Chapter 7, the practice change intervention was effective in increasing all guideline recommended elements for addressing alcohol consumption during pregnancy. Compared to a 2015 Cochrane review of implementation strategies tailored to address barriers to evidence-based care provision (OR: 1.56; 95% CI: 1.27, 1.93) [1], greater effects were found across all outcomes overall (OR range: 2.07 to 2.63), with even greater effect sizes found at subsequent antenatal visits (OR range: 2.40 to 5.39). Although the practice change intervention was effective, the majority of women post-intervention still did not report receipt of: assessment of alcohol consumption at subsequent antenatal visits (73.1%); and complete care at the initial (58.9%) and subsequent antenatal visits (80.0%). This highlights the need to identify ways to further increase the proportion of pregnant women who have alcohol consumption addressed as part of routine antenatal care.

Improvements in healthcare are rarely breakthrough in nature; rather they tend to occur gradually over time as new evidence is generated and applied in practice [2]. In the field of implementation science, there has been increasing recognition that implementation interventions need to be further developed, improved and integrated into routine practice following the completion of quality improvement initiatives/effectiveness trials in order to enhance public health outcomes [2]. Iterative improvement to enhance public health outcomes is conceptualised as the progressive data-driven improvement of existing evidence-based interventions and/or their implementation to meet stakeholder-defined impacts within the resource constraints of the setting [2, 3]. Iterative improvement is implicit in quality improvement approaches commonly used in healthcare settings to progressively improve organisational processes, safety and/or patient care outcomes [3]. It is also fundamental to optimisation processes used to enhance the impacts of evidence-based interventions and/or their implementation in achieving set objectives in implementation science [2]. Studies that have used such approaches have demonstrated further increases in the proportion of patients receiving recommended care practices, including smoking cessation counselling in general practice [4] and HIV viral load monitoring in antenatal care [5].

Only one study to date has used an iterative improvement approach to increase the proportion of pregnant women receiving antenatal care addressing alcohol consumption during pregnancy [6]. Between 2007 and 2012, 50 Australian primary health care centres participated in four cycles of quality improvement to incrementally improve care practices for Aboriginal and Torres Strait Islander women. At the commencement of each improvement cycle, a systems assessment and audit of patient records was conducted to identify the need and opportunities for improvement. A longitudinal analysis of 2220 pregnancy records found that effects continued to increase for alcohol screening (cycle 1 OR: 2.6; 95% CI: 2.0, 3.5; cycle 4 OR:

3.9; 95% CI: 2.2, 7.1) and brief counselling (cycle 1 OR: 2.8; 95% CI: 1.7, 4.5; cycle 4 OR: 6.7; 95% CI: 2.3, 20.0) over the four improvement cycles compared to baseline. Over the duration of the study, care provision increased by 18% for alcohol screening (65% to 83%) and 20% for brief counselling (51% to 71%) [6]. The study demonstrated the feasibility of an iterative improvement approach in further increasing the provision of antenatal care addressing alcohol consumption. The study however was non-controlled and the generalisability of results to the public hospital maternity service setting and non-Indigenous populations is unknown.

There are a number of methods and frameworks available to guide the process of iterative improvement, such as Continuous Quality Improvement [7], Multiphase Optimisation Strategy [8], Six Sigma [9] and Plan-Do-Study-Act (PDSA) [10]. PDSA was adapted for healthcare contexts in 1996 from the fields of business and manufacturing [11] and is now one of the most commonly applied methods to guide the iterative improvement of healthcare processes [12]. In PDSA, consecutive iterations of a four-stage cycle provide a framework for ongoing improvement through the testing of changes/additions [13]. The four stages include: i) *Plan* (Plan a change or test aimed at improvement); ii) *Do* (Carry out the change or test); iii) *Study* (Examine the results. What was learnt? What did/did not work?); and iv) *Act* (Adopt or abandon the change. Examine the need to run through the cycle again) [11]. A 2019 systematic review of 120 quality improvement studies using PDSA found that almost all included studies (98%) reported further increases in a range of targeted healthcare practices [13].

Within the field of implementation science, a 2020 scoping review of frameworks to optimise the impact of healthcare and public health initiatives identified 11 frameworks specific to improved implementation [14]. A meta-framework synthesising the steps from these 11 frameworks was developed, with the optimisation phase consistent with the steps described in

PDSA cycles: i) *Plan/Design*; ii) *Do/Change*; iii) *Study/Evaluate/Check*; and iv) *Act (hold or continual improvement),* suggesting use of PDSA for the iterative testing of implementation strategies to further improve antenatal care addressing alcohol consumption during pregnancy is worthy of further investigation.

Applying PDSA to the practice change intervention outlined in this thesis, the trial outcome data presented in Chapter 7 informs the need to *act* on further improvement. In the post-intervention phase, almost three-quarters of women (70.7%) reported being assessed for alcohol consumption at initial antenatal visits, suggesting that testing of additional strategies for this care element may not be required as an initial priority. However, less than half of the pregnant women included in the study reported receipt of an assessment of alcohol consumption at subsequent antenatal visits (26.9%) as well as complete care at the initial (41.1%) and subsequent antenatal visits (20.0%). These findings suggest a need to test whether additional implementation strategies can further improve the provision of these recommended care elements at these time points.

As described in Chapter 6, the practice change intervention was developed using formative research surveys based on the TDF [15, 16], which comprehensively assessed antenatal provider barriers to implementing the recommended model of care. This approach identified 36 barriers to care provision across all 11 assessed domains of the TDF, with 7 strategies being implemented to address these barriers. The pragmatic principles of PDSA promote smaller-scale testing of improvement changes, an approach that lends itself to the next phase following the delivery of an initial comprehensive practice change intervention, such as that delivered in the trial described in Chapters 6 and 7 [12]. Such an approach allows more rapid assessments

to be undertaken and for the development of a more granular understanding of the change pathway, enabling learnings to be applied to consecutive improvement cycles [17-19].

An understanding of the barriers impeding care provision remains key to the selection and planning of implementation strategies in each iterative cycle [20]. Survey approaches using traditional rating scales, such as Likert scales, are the most commonly used method for the identification of barriers to implementing guideline recommended care. However, such approaches do not sufficiently differentiate between barriers in terms of their relative importance and hence priorities to be addressed [21]. Other data collection methods that identify and facilitate the prioritisation of implementation strategies to be tested in successive PDSA cycles are needed.

One potential approach for determining the relative importance of barriers is the use of preference elicitation techniques. Preference elicitation techniques, such as those used in Discrete Choice Experiment (DCE) and Best-Worst Scaling (BWS) methods, originated in mathematical psychology, and have more recently been applied in healthcare contexts [22, 23]. In DCEs, respondents are presented with a hypothetical clinical scenario and asked to choose between two or more alternatives where at least one attribute is systematically varied. The series of choice tasks in turn elicits respondents' preferred attributes given the scenario (for instance, facilitators or barriers to care provision) [22]. BWS also presents a hypothetical clinical scenario, but instead asks respondents to make best and worst (for instance, what would most likely be a barrier/least likely be a barrier) choices within a set of options to identify response rankings [23]. Such techniques have been used to determine the priority factors in implementing shared-care decision making for medical staff [24] and the key determinants for

implementation of electronic medical records in hospitals for use by medical and nursing staff [25].

Only one study to date has tested the effect of an intervention that was developed using preference elicitation surveys [26], however it was targeted at patients and not clinicians. The DCE survey with 325 adult males elicited preferences for service improvement to increase uptake of voluntary medical male circumcision (VMMC) to prevent HIV in Tanzania. The identified priorities informed the development and implementation of three targeted intervention components, including community information booths for partners, age separated waiting areas for patients, and training for healthcare providers. The intervention led to significant differences in uptake of VMMC between adult males in intervention and control groups (intervention: 27.5%; control: 11.5%; PR: 2.39; 95% CI: 1.66, 3.43; $p<0.001$) [26]. Such results demonstrate the feasibility and effectiveness of using preference elicitation techniques to inform the development of interventions. However, as the tested intervention was targeted to address patient preferences, it is currently unknown whether the elicitation of clinician priority barriers to inform the development of implementation strategies would produce similar effects. The testing of such an approach both generally, and within PDSA cycles specifically, could inform implementation strategy development methods and the *plan* and *do* cycles of iterative improvement.

Given the potential of iterative improvement approaches in progressively improving care practices, the availability of methods and frameworks, and emerging novel approaches to developing prioritised and tailored strategies for additional testing, there is a need to conduct iterative trials that incorporate such elements to advance this field. An extension of the practice change intervention outlined in Chapters 6 and 7 of this thesis would provide an opportunity

for such research. As initiatives aimed at ongoing improvement in healthcare settings are often poorly designed [12], it is imperative that such a trial has the scientific rigour to maximise certainty in the findings. A stepped-wedge controlled study design with continuously collected data would be recommended given its scientific and pragmatic advantages in healthcare trials that are implemented at the service level [27, 28].

Sustaining the rate of care provision after the withdrawal of active implementation support

As shown in Chapter 7, the implementation strategies evaluated in the trial were effective in increasing the receipt of guideline recommended antenatal care addressing alcohol consumption during pregnancy. To ensure investment in the development and delivery of the implementation strategies is maximised, and ongoing public health benefits realised, such improvements need to be sustained over time [29]. Sustainability of implementation effect is an emerging area in implementation science and is defined as 'the extent an evidence-based intervention can continue to deliver its intended benefits over an extended period of time after active support from the external donor agency is terminated [30].'

Despite the critical importance of sustainability from both a return on investment and an individual and population health benefit point of view, it is common for the initial effects of implementation to attenuate over time. A 2015 systematic review of the sustainability of health professional's adherence to clinical practice guidelines found that only seven of the 18 included studies demonstrated fully sustained practices more than one year after active implementation support ceased [31]. Of the 11 studies in which practices were not fully sustained, nine reported decreases of more than 10% compared to the rates of provision in the implementation phase. Studies that demonstrated sustained practices over time were more likely to include systems

and organisational level strategies (e.g. changes in the physical structure of the clinic environment and formal integration of care processes into service delivery) as opposed to strategies targeted at the individual clinician level (e.g. educational meetings and audit and feedback) [31].

These findings are also broadly reflected in preliminary and exploratory analyses of the sustainability of improvements in care practices reported in Chapter 7. Such analyses have revealed that the initial effects of the practice change intervention appear to have attenuated over time. An interrupted time series analysis conducted on the trial primary outcomes from the largest sector within the study demonstrated significant reductions in the proportion of women receiving guideline recommended care. The weekly rate of change in reported receipt of assessment was -0.66 (95% CI: -1.1, -0.26; p=0.002) and complete care relative to alcohol risk level -0.64 (95% CI: -1.1, 0.22; p=0.003) for a 17-month period beginning from the end of the implementation support period. For assessment of alcohol consumption, 8% of the initial implementation gains were lost over the 17-month period (45% to 37%) resulting in a sustained benefit of 10%. For complete care relative to alcohol risk, 13% of the initial implementation gains were lost (35% to 22%) resulting in a sustained benefit of 6% [see Appendix 7 for full results].

As described in Chapter 6, the implementation strategies were selected and developed to address identified antenatal provider and maternity manager barriers to implementing recommended antenatal care addressing alcohol consumption at a particular point in time. Four of the seven strategies (local clinical practice guidelines, prompts and reminders, educational meetings and materials, and monitoring and accountability for performance) were integrated into ongoing routine care delivery support systems and resources with the intent that they fully

or partially continued to support care provision post the implementation phase. Despite this partial systems approach to implementation, the decline in intervention effect over time suggests that factors that impede and facilitate sustainability may not have been sufficiently accounted for by these strategies.

A 2020 systematic review of 32 studies examining factors influencing the sustainability of hospital-based interventions found key barriers to sustainability included: staff shortages and/or high turnover of staff; lack of organisational support and strong leadership; workload pressures; complexity of the problem being addressed; and lack of ongoing training opportunities [32]. Identified key facilitators to sustainability were: clear accountability of roles and responsibilities; availability of strong leadership and champions advocating the use of the evidence-based intervention; and provision of adequate organisational level support [32].

A number of models and frameworks have been developed over recent years to establish the theoretical bases of sustainability and guide the development of sustainability strategies [29, 33, 34]. The Dynamic Sustainability Framework (DSF) is one of the most commonly applied frameworks for understanding, and planning for, the sustainability of evidence-based interventions in healthcare settings [29]. The DSF emphasises that there is constant change occurring at three levels: i) the evidence-based intervention (e.g. mode of delivery); ii) practice setting (e.g. information systems, training, staffing and resources); and iii) ecological systems (e.g. policies). Given this constant change, there is a need to continually monitor and assess the fit of the evidence-based intervention and implementation strategies at multiple levels. Maintaining a strong fit between the setting context and the evidence-based intervention and implementation strategies through adaptions is suggested to support the sustainment of improvements in care practices [29].

Applying the DSF to the practice change trial outlined in Chapters 6 and 7 of this thesis, there were no changes observed in the evidence-based intervention and ecological systems that would have required adaptions to be made. However, there were a number of changes at the practice setting level that were not responded to, and hence these could have impacted sustainability of the intervention effect. The immediate decline in effect following implementation may have been due to the project-specific clinical midwifery champion role finishing. Although it was the intent that the role of this position would be taken up by midwife educators as part of their routine duties, the role was not formally transitioned into the role of such staff. The retention of trained champions has been identified as a key facilitator to sustainability and its effectiveness as a strategy in sustaining care practices has been established in a number of empirical studies in maternity and clinical settings [35, 36]. For example, following implementation support consisting of provider training, resources, clinical champion and progress monitoring to improve antenatal and birth practices in Rwanda, the project specific champion role was formally transitioned and integrated into an existing district position [35]. Practice outcomes at 12 months post-intervention were shown to be sustained, including the proportion of women attending at least four antenatal visits (pre-intervention: 12%; immediate post-intervention: 30%; 12 months post-intervention: 30%) and facility-based birth (pre-intervention: 90%; immediate post-intervention: 93%; 12 months post-intervention: 96%) [35]. Formal integration of the champion role into an existing position in maternity services following active implementation support could therefore be one potential strategy to sustain improvements in antenatal care addressing alcohol consumption.

Turnover and changes in clinic staffing may have also contributed to the observed decline in intervention effect. In public maternity services, clinical staff often rotate between antenatal,

birth and postnatal care and there is a large temporary workforce (casual and locum/relief), especially in the regional and rural based services. An assessment of workforce turnover six months post-intervention indicated that almost half of the current antenatal workforce was not working within antenatal care at the time of implementation support and almost half of these new staff had not completed any training relating to the trial model of care. Maintenance of workforce skills through continued training opportunities has been shown to be an effective strategy in sustaining care provision in clinical settings, including maternity services [36, 37]. For example, following the active implementation of the Community-Based Reproductive Health Project to address high maternal mortality in two rural districts in Tanzania, ongoing training opportunities were provided to maintain workforce knowledge and skills [37]. Outcomes were found to be sustained at two- and five-years post cessation of active implementation support, including provision of antenatal care at less than 20 weeks gestation (immediate post-intervention: 32.8%; two years post-intervention: 39.2%; five years post-intervention: 46.9%) and identification of danger signs in pregnancy (immediate post-intervention: 32.6%; two years post-intervention: 32.8%; five years post-intervention: 38.4%) [37]. Providing ongoing training opportunities, such as integrating education into orientation processes for new staff and scheduling booster training sessions for existing staff, would facilitate maintenance of workforce knowledge and could be a potential strategy in sustaining antenatal care practices relating to alcohol consumption in pregnancy.

In line with the principles of DSF, a formal and structured process for ensuring continuous adaption of the model of care and implementation strategies is required to ensure sustainability of its implementation and benefits over the long-term [29]. Systematic adaptations in response to change has been reported as an effective strategy in sustaining improvements in practice [38]. For example, a family obesity project delivered in partnership between Seattle Children's

Hospital and YMCA transitioned from a grant-supported implementation project to usual practice [38]. After the transition, review cycles were planned for and conducted to be able to identify and respond to any changes. Core project components were found to be sustained over a two-year period, including: reduced accessibility of high fat foods (mean score pre-transition: 1.99; two years post-transition: 2.31); role modelling of physical activity (pre-transition: 1.94; two years post-transition: 2.39); and role modelling of healthy eating (pre-transition: 2.38; post-transition: 2.84). After the withdrawal of active implementation support in the trial reported in Chapters 6 and 7, the roles and responsibilities of maternity staff and other organisational groups in continually adapting the evidence-based intervention and implementation strategies in response to change were not formally defined or adopted by the maternity services. A formal plan and mechanism to be able to identify and respond to change may be another potential strategy to sustain improvements in antenatal care addressing alcohol consumption.

The research to date on the effectiveness of sustainability strategies is limited, and those supporting the ongoing provision of antenatal care addressing alcohol consumption during pregnancy have not been reported. Given the critical importance of sustainment to ensure return on investment and ongoing public health benefit, a trial testing the effectiveness of strategies in sustaining care provision over time is warranted. The trial should be based on a sustainability framework and formatively assess factors impeding sustainment of antenatal care addressing alcohol consumption through a variety of methods, such as consultations with maternity services, audits of antenatal schedules, training records, staffing rosters, information systems, resource and policy databases. From the initial assessment presented above, the following strategies could be among those tested: formally transitioning and integrating the champion role into an established position; ongoing training and orientation to maintain workforce knowledge; and establishment of a formal process that enables change to be assessed and

responded to over time. The outcomes of such a sustainability trial should align with those presented in Chapter 7 of this thesis, with segmented regression within an interrupted time-series framework used to assess change in outcomes over time [39]. Such analyses should be conducted separately for each sector as replication of findings will provide greater confidence in intervention effect [39].

CONCLUSIONS

The findings of this thesis support earlier cross-sectional studies that had shown a need to improve the universal provision of antenatal care addressing alcohol consumption during pregnancy in public maternity services. A survey of antenatal providers and maternity managers based on a consolidated implementation framework uncovered a range of barriers impeding such care provision not previously reported in the literature. Whilst the systematic review showed that implementation strategies probably increase elements of evidence-based care for tobacco smoking and weight management, the true effect of such strategies in supporting health professionals provide alcohol consumption care was not known given the very-low certainty of evidence. The first randomised controlled trial examining the effect of implementation strategies in improving guideline recommended care addressing alcohol consumption during pregnancy demonstrated significant improvements at both initial and subsequent antenatal visit types and across urban and regional/rural located health sectors. The intervention was also found to be equitable in its impacts across types of maternity services and most groups of pregnant women. Despite these positive findings, the majority of women post-implementation still did not report receipt of some elements of the model of care. The potential for iterative improvement approaches and sustainability strategies in further improving and sustaining care practices over time need to be explored in order to advance research and practice.

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APPENDICES

APPENDIX 1. Protocol for an economic evaluation and budget impact assessment of a randomised, stepped-wedge controlled trial for practice change support to increase routine provision of antenatal care for maternal alcohol consumption

STUDY PROTOCOL Open Access

Protocol for an economic evaluation and budget impact assessment of a randomised, stepped-wedge controlled trial for practice change support to increase routine provision of antenatal care for maternal alcohol consumption

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Abstract

Background: Antenatal clinical practice guidelines recommend routine assessment of women's alcohol consumption during pregnancy. The delivery of advice and referral when necessary are also recommended. However, evidence suggests there are barriers to the uptake of best-care guidelines. Effective, cost-effective and affordable implementation strategies are needed to ensure the intended benefits of guidelines are realised through addressing identified barriers. This paper describes the protocol for evaluating the efficiency and affordability of a practice change intervention compared to the usual practice in an implementation trial.

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Methods: The effectiveness of the intervention will be evaluated in a stepped-wedge randomised controlled implementation trial, conducted in an Australian setting. An economic evaluation will be conducted alongside the trial to assess intervention efficiency. A budget impact assessment will be conducted to assess affordability. The prospective trial-based economic evaluation will identify, measure and value key resource and outcome impacts arising from the multi-strategy practice change intervention compared with usual practice. The evaluation will comprise (i) cost-consequence analyses, where a scorecard approach will be used to show the costs and benefits given the multiple primary outcomes included in the trial, and (ii) cost-effectiveness analyses, where the primary outcome will be incremental cost per percent increase in participants reporting receipt of antenatal care for maternal alcohol consumption consistent with the guideline recommendations. Intervention affordability will be evaluated using budget impact assessment and will estimate the financial implications of adoption and diffusion of this implementation strategy from the perspective of relevant fundholders. Results will be extrapolated to estimate the cost and cost-effectiveness of rolling out the model of care.

Discussion: Uptake of clinical guidelines requires practice change support. It is hypothesized that the implementation strategy, if found to be effective, will also be cost-effective, affordable and scalable. This protocol describes the economic evaluation that will address these hypotheses.

Trial registration: Australian and New Zealand Clinical Trials Registry, ACTRN12617000882325. Registered on 16 June 2017

Keywords: Cost-effectiveness analysis, Health economics, Antenatal care, Protocol, Budget impact assessment

Contributions to the literature

- Research has shown the development and dissemination of clinical guidelines alone are insufficient to change practice and deliver improved patient outcomes. Further investment in strategies to increase adoption of guideline recommendations is required.
- Given escalating healthcare costs and constrained budgets in public health systems, effective, cost-effective and affordable implementation strategies are needed to ensure the intended benefits of clinical guidelines are realised.
- This protocol details the research methods that will be used to answer the following question: From the Australian healthcare system perspective, what is the cost and cost-effectiveness of the practice change intervention to increase the routine provision of antenatal care for maternal alcohol consumption compared to usual practice, and is it an affordable model for local health services?

Background

To prevent the potential adverse obstetric and foetal outcomes associated with women's alcohol consumption during pregnancy [1], clinical practice guidelines recommend that clinicians routinely assess alcohol consumption and advise all pregnant women that it is safest not to consume alcohol during pregnancy and of the potential harms associated with consumption. Guidelines also recommend clinicians refer to specific services when required [2]. It is also recommended that follow-up care is provided during subsequent antenatal visits. Despite these clear recommendations, the provision of routine antenatal care addressing maternal alcohol consumption during pregnancy is limited [3]. For example, in Canada, approximately 50% of health professionals have reported providing advice to pregnant women regarding the consumption of alcohol [4], and in the UK, two thirds of women reported receiving such advice from a midwife [5]. A 2005 Australian study of 1143 health professionals who provide antenatal care found that fewer than half (45%) routinely asked about alcohol consumption during pregnancy, 25% provided information on the effects of alcohol consumption during pregnancy and only 13% provided advice consistent with national drinking guidelines that recommended no alcohol consumption during pregnancy [6, 7]. A more recent study involving 166 midwives in Western Australia found that while almost all midwives

(93%) asked pregnant women about their alcohol consumption, just over half (54%) used a recommended standardised assessment tool to do so (AUDIT or AUDIT-C) [7–9]. In a recent survey of women who had recently visited public antenatal services in the Hunter New England local health district, Australia, less than two thirds (64%) of pregnant women reported that they received an assessment of their alcohol consumption and just over one third (35%) received advice and referral appropriate to their self-reported level of alcohol consumption since pregnancy recognition at their initial antenatal visit [9]. Less than 10% of women received such care at subsequent antenatal visits [9].

The development and dissemination of clinical guidelines alone are insufficient to change the current practice and deliver improved patient outcomes [10]. Further investment in strategies to increase adoption of guideline recommendations is required [11]. However, decisions about implementation intervention investment should be guided by consideration of effectiveness as well as economic efficiency, equity and affordability [12, 13]. Economic evaluation combines evidence about the cost and benefits of alternative interventions in order to identify investment opportunities that demonstrate value for money [14–16]. Given escalating healthcare costs and constrained budgets in public health systems, economic evaluations contribute significantly to the evidence base informing decision-makers and healthcare funders. Effective, cost-effective and affordable implementation strategies are needed to ensure the intended benefits of clinical guidelines are realised [17]. Similarly, assessment of the budget impact of implementation strategies is warranted to assess the affordability and financial consequences of healthcare practice changes. At present, there is limited evidence regarding the economic cost of adverse foetal and maternal outcomes associated with alcohol consumption during pregnancy [18–21] and no evidence concerning the cost-effectiveness of practice change interventions aiming to improve recommended antenatal care for maternal alcohol consumption [22]. This paper presents a protocol for the economic evaluation of an antenatal practice change intervention to improve care addressing alcohol consumption in pregnancy. The paper aims to answer the following research question: From the Australian healthcare system perspective, what is the cost and cost-effectiveness of the practice change intervention to increase the routine provision of antenatal care for maternal alcohol consumption compared to usual practice, and is it an affordable model for local health services?

The trial

Study design

The multi-strategy practice change implementation trial will be a randomised, stepped-wedge controlled trial. The protocol has been previously published [3]. In brief, the trial will be conducted in all public antenatal services within three sectors across two health districts in New South Wales, Australia. The model of care for addressing alcohol consumption by pregnant women will be delivered to sectors in a random, stepped order. The main outcomes are described below in the "Identification and measurement of outcomes" section and described in detail in Kingsland et al. [3].

Repeated cross-sectional outcome data will be gathered on a weekly basis across the three sectors for a period of 34 months. Baseline data collection, representing usual practice (control), will be collected for the three sectors from 7 months prior to the commencement of the intervention in the first sector to the start of the intervention in each sector. Follow-up data will be collected for the three sectors 7 months following completion of the intervention in the third and last sectors. The outcome results will be determined by comparing practice change outcomes between the baseline and follow-up periods for the three sectors combined.

Usual practice

Usual practice comprises the antenatal care for addressing maternal alcohol consumption during pregnancy that is provided in the baseline period prior to the introduction of the intervention. It is anticipated that such care is likely to vary by antenatal service and clinician. This is due to variability in local practice across the 3 sectors covering metropolitan, regional and rural localities, as well as the lack of an existing health district-wide guideline or procedure specifying the provision of routine care for addressing alcohol consumption during pregnancy.

The development and dissemination of the clinical practice guidelines have already taken place in Australia with the result that their associated costs and effects are common to both intervention and control study periods.

The intervention

A multi-strategy practice change intervention has been developed to support antenatal care staff to implement a model of care consistent with clinical

guidelines. The multiple strategies included in the intervention are presented in Appendix 2: Table 1. The model of care is based on an evidence-informed behavioural counselling framework [23] and includes clinician assessment of patient alcohol risk status using the AUDIT-C tool at the first comprehensive ('booking in') visit and at follow-up antenatal appointments at 27–28 weeks and 35–36 weeks gestation. All pregnant women will be provided with brief advice that it is safest not to consume alcohol during their pregnancy and of the risks associated with alcohol consumption at this time. Women who are at 'medium risk' of harm according to their AUDIT-C score of 3–4 will be offered a referral to the New South Wales Get Healthy in Pregnancy Service, an evidence-based telephone coaching service provided free of charge. Women at 'high risk' of harm from alcohol (AUDIT C score, 5+) will be referred to the Hunter New England Drug and Alcohol Clinical Service.

Methods and analysis

This economic evaluation has been conducted and reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) publication guidelines and good reporting practices [24].

Economic evaluation overview

Cost, cost-consequence and cost-effectiveness analyses will be undertaken comparing the intervention against the usual practice from a public health service perspective. This perspective is justified because ongoing funding for this intervention, especially if it translates into routine practice, will fall on public health services. To further aid decision-makers, budget impact analysis, including scale-up cost scenarios, will be presented alongside the cost-effectiveness findings. Costs will be reported in 2019 Australian dollars ($AUD). The time horizon for the inclusion of relevant costs and consequences will be the course of the trial (34 months). Costs and benefits occurring after 12 months will be discounted using an annual discount rate of 3% in the base case. Annual discount rates of 0 and 5% will be applied in a sensitivity analysis. The conduct, analysis and reporting of the economic analyses will adhere to the cost and economic analysis guidelines [14, 15, 25] and Consolidated Health Economic Evaluation Reporting Standards guidelines [15].

Common to all forms of economic evaluation is the analysis of cost. In this study, costing and budget impact assessments will be conducted to quantify how much more it will cost to pursue implementation efforts to affect practice change. The budget impact assessment will translate the health economic findings into more meaningful and relevant results for healthcare decision-makers and funders. In its simplest form, economic evaluation involves a listing of all cost/benefit implications of the alternatives under consideration, as in cost-consequences analyses [26]. A cost-consequence analysis is employed in this analysis because it provides information for spending decisions when implementation strategies are complex and are expected to have outcomes that are too disparate to be combined meaningfully. In this trial, there are four primary outcomes (see the "Identification and measurement of outcomes" section). Cost-consequence analyses permit value judgements without having to fully specify a relation between all the different measures of outcomes [11]. Cost-effectiveness will depend on the effect of the intervention on care provider behaviour. The greater the difference in expected outcomes between usual practice and the new model of care, and the more widespread the implementation, the more likely a strategy is to be cost-effective. In this study, the likelihood of achieving an outcome difference will be maximised by using a staged process to both understand the barriers to guideline adoption and to develop the implementation strategies [3]. All public antenatal services in the three sectors will receive the practice change intervention, including midwifery group practices, midwifery clinics, specialist medical services, Aboriginal Maternal and Infant Health Services (AMIHS) and multi-disciplinary teams caring for women with complex pregnancies or identified vulnerabilities.

Trial-based economic evaluation and budget impact assessment

Identification and measurement of outcomes

It has been suggested that one of the ways to improve efficiency in conducting economic evaluations of implementation interventions is to confine studies to measures of the care process or intermediate outcomes [11], for example, change in professional guidance adherence or compliance [3]. This approach is based on the premise that the guideline recommendations are cost-effective in and of themselves. In this study, the outcome measures are confined to the care process for efficiency. The implementation trial has four primary outcomes. They are the proportion of all antenatal clinic appointments (at 'booking in', 27–28 weeks gestation and 35–36 weeks gestation) for which women report the following:

1. Being assessed for alcohol consumption and level of risk using the AUDIT-C
2. Being provided with brief advice related to alcohol consumption during pregnancy
3. Receiving, relative to their level of risk, the relevant elements of antenatal care for addressing alcohol consumption during pregnancy (advise and refer)
4. Being assessed for alcohol consumption and level of risk using the AUDIT-C and receiving, relative to their level of risk, the relevant elements of antenatal care for addressing alcohol consumption during pregnancy (advise and refer)

Receipt of care will be measured by participant report during a computer-assisted telephone survey conducted after an antenatal consultation, at each of the three time points [3].

A secondary outcome will also be included. For women attending antenatal appointments at 'booking in', 27–28 weeks gestation and 35–36 weeks gestation, alcohol consumption since pregnancy recognition will be collected. Outcome measurement will be based on self-report of women using the total AUDIT-C score. AUDIT-C is a validated tool for assessing the risk of harm due to alcohol consumption [27].

Identification, measurement and valuation of costs

Cost data pertaining to the development and implementation of the practice change intervention will be collected prospectively using a resource use capture tool in tangent with trial administrative records. The intervention programme logic will be used to identify all the relevant costs directly and indirectly associated with the intervention. The cost capture tool, developed in Microsoft Excel (2013), allows researchers to prospectively document the activity and materials consumed at different phases of the intervention (development, immediate execution and maintenance) from all relevant stakeholders. The cost capture tool includes the following categories: (1) labour (health service and non-health service staff, including overheads to allow for additional costs of employment), (2) materials (non-labour cost items such as stationary, education materials, electronic hardware or software), (3) joint costs (incurred in connection with multiple projects, for example, the maintenance costs of a website portal supporting different interventions; capital costs such as one-off investments such as the purchase of additional office buildings or motor vehicles), and (4) miscellaneous costs (which include costs not easily classified into the other categories, for example, venue hire, travel and overnight accommodation). To maintain a conservative approach to cost estimation, the non-capital implementation costs will not be amortised.

Resource use valuation will be based on the concept of opportunity cost, that is, the value of the benefit forgone in not employing a resource for a different use. Market prices will be used as a proxy for the 'value of benefit' forgone [28].

Costing study

Appendix 3: Table 2 summarises the costs expected to be included in the study. The cost analysis will use measures of arithmetic means, between-group differences and variability of differences [29, 30]. Costs will be calculated individually for each sector in the trial, as well as aggregated across all sites. Intervention component costs will be disaggregated to provide insight into the cost of individual practice change intervention strategies.

Cost-consequence, cost-effectiveness and equity

As outlined above, the range of outcomes measured in the implementation trial is diverse, which lends well to a cost-consequence analysis. The analysis will adopt a scorecard approach to show a comparison of the costs and benefits associated with the intervention and usual practice. An economic summary measure is not calculated. A programme logic model will be developed to describe all possible inputs (costs) and impacts (consequences) associated with the intervention and usual care (Appendix 1: Fig. 1).

The cost-effectiveness analysis will be conducted subject to the assessment of intervention efficacy. The economic summary measure will be an incremental cost-effectiveness ratio (ICER). The ICER represents the additional cost required to achieve an additional unit of benefit [14, 29]. For this study, the ICER will be calculated as the incremental cost per percent change in the proportion of participants reporting that receipt of 'antenatal care for maternal alcohol consumption consistent with guideline recommendations' was provided to them during their antenatal consultation.

Distributional cost-effectiveness analysis (DCEA) is a framework for incorporating health inequality concerns into the economic evaluation of health sector interventions. Full DCEA requires the distribution of direct health benefits to be estimated from a decision-analytic model or trial-based analysis using parameter estimates specific to socio-economic groups. However, a simplified version

providing healthcare decision-makers and stakeholders with an evidence-based technique for evaluating whether new interventions can help to achieve the objective of health inequality reduction can be used when conducting a full DCEA is not practical or feasible [31]. To assess the equity implications of the intervention, the use of distributional cost-effectiveness will be explored in the scenario examining scale-up subject to the availability of requisite data [31, 32].

Budget impact assessment

Economic evaluations and budget impact analyses share many of the same data elements and methodological requirements and should be viewed as complementary. However, there are important differences in their methods and use cases [13]. The budget impact assessment will translate the results of the economic costing study into financial consequences relevant to decision-makers and fundholders within the health districts.

A model will be developed to describe the financial resources associated with the usual practice over the course of health districts' budgeting cycles. This will represent the base case or 'reference case'. The comparative scenario will model the required changes in health service resourcing that are expected to result from the adoption of this alternate model of care, including indirect and downstream impacts on other parts of the health service. Resource use data will be sourced from the implementation trial and costing analysis. All model assumptions and data inputs will be described in full. Justification for the inclusion or exclusion of relevant model parameters will be provided.

The budget impact assessment will adhere to the relevant local and international guidelines, as well as recommended formats for presenting the results so they are most useful to decision-makers [13, 33].

Sensitivity and uncertainty analyses

All analyses will be subject to one-way and probabilistic sensitivity analyses. These analyses test the impacts of plausible variation in data parameters on the cost outcomes and economic summary measure and provide an understanding of which values are associated with the greatest amount of uncertainty. Differences in costs or outcomes that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variabilities in effects that are not reducible by more information will be reported.

In addition, scenario analyses will be undertaken to explore the efficiency and budget impact of the state-wide implementation of the practice change model of care in maternity services across the whole state of NSW.

Discussion

This protocol sets out the plan to assess the cost, efficiency and affordability of a multi-strategy practice change implementation intervention compared to usual practice. The purpose of publishing this protocol is twofold; first, setting an a priori plan for the proposed analyses can reduce potential biases made from ad hoc analytic decisions. Deviations from this protocol will require description and justification in the final analyses. Second, there are benefits to the research and broader community in a greater understanding of economic evaluation, especially with respect to their conduct alongside implementation trials. There is a clear absence of research evidence of the effectiveness, cost, cost-effectiveness and budget impact of implementation strategies to improve antenatal care that addresses maternal alcohol consumption during pregnancy [34]. The application of economic evaluation to health-promoting, implementation interventions is limited [12] while the application of budget impact assessment at the local health service level is completely novel. This will be the first economic evaluation and budget impact assessment of an implementation strategy in this field [22]. It is expected that the practice change intervention will increase the extent to which women are assessed for alcohol consumption during pregnancy and given evidence-based advice and, where appropriate, referral to ongoing support services to avoid the consumption of alcohol for the remainder of their pregnancy. The outcomes of these analyses will then inform the state-wide scale-up of this implementation intervention and the next step in the research translation pathway.

Conclusion

This protocol outlines the assessment of cost, efficiency and affordability of a multi-strategy practice change implementation intervention compared to the usual practice. The outcomes of this economic evaluation will provide insight into the cost, cost-consequence and cost-effectiveness of implementation strategies designed to improve antenatal care addressing the recognised risk of alcohol consumption to the health and wellbeing of both the mother and child [34], and inform future healthcare policy, investment allocation and research.

Appendix 1

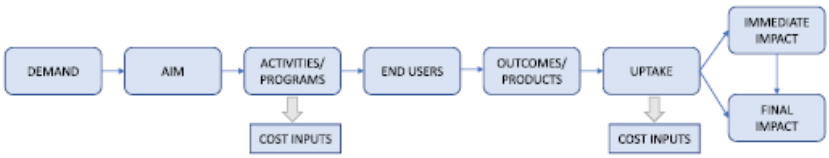

Fig. 1 Example intervention programme logic

Appendix 2

Table 1 Implementation strategy summary

Intervention component	Component details: *A full description of component details has been published elsewhere* [3].
Leadership and management	• Monthly meetings will be held with management from antenatal services to elicit support. • Service managers will be asked to distribute resources to staff and attend training sessions. • Monitoring and reporting of performance measures related to the intervention.
Local clinical practice guidelines	• A service-level guideline and procedure document will detail the model of care, including assessment, brief advice and referral pathways. • This document will be uploaded onto the health service's policy directory, disseminated by managers to all staff via email, and hard copies will be placed in staff common areas.
Electronic prompt and reminder system	• Existing point-of-care and medical record systems used by maternity clinicians will be modified to electronically prompt the use of the AUDIT-C alcohol screening tool. • Brief advice scripts will be displayed on the point-of-care system based on the woman's AUDIT-C risk score, and prompts and tools for referral to appropriate services.
Local opinion leaders/ champions	• Project-specific clinical midwife educators appointed to support staff to uptake the model of care and provide support at a one-on-one, team and service level. • Additional local antenatal clinical leaders will be engaged to provide encouragement and demonstrate required behaviours as required.
Educational meetings and materials	• Training will be provided to all antenatal service clinicians via a 30-min online training module and face-to-face sessions. Clinical midwife educators will facilitate clinicians in completing the online training and coordinate face-to-face training sessions. This will include lecture-style sessions, interactive sessions, case study-based sessions and one-on-one sessions. • Clinicians will be provided with written resources (hardcopy and electronic) to support the model of care, including standard drink measure charts and point-of care written prompts/reminders (e.g. stickers in charts).
Academic detailing	• Data from both medical records and telephone surveys conducted with women who attended the antenatal services will be used to provide feedback on adherence to the agreed model of care. • The clinical midwife educators will visit service teams in their antenatal clinics to provide feedback data and develop action plans to improve adherence.
Monitoring and accountability	• Antenatal service managers will report, interpret and monitor performance measures for the model of care. • These results will be disseminated to antenatal service staff through team meetings, emails and other usual communication mechanisms. • Performance measures will be built into the existing monitoring and accountability frameworks for antenatal services.

Appendix 3

Table 2 Description of resource use data for inclusion in the economic evaluation

Intervention component	Resource use details	Data collection method
Intervention strategy development	• Labour time: health district project/implementation support officer time. • Materials.	• Resource use capture template
Leadership and management	• Labour time: health district project/implementation support officer time, health service clinical staff (management from antenatal services).	• Resource use capture template
Local clinical practice guidelines	• Materials: guideline and procedure document development and provision. • Electronic dissemination.	• Resource use capture template
Electronic prompt and reminder system	• Materials: online/computer-based intervention component. • Electronic dissemination.	• Resource use capture template
Local opinion leaders/ champions	• Labour time: change champion, clinicians and trainers.	• Resource use capture template
Educational meetings and materials	• Labour time: health district project/implementation support officer time, health service clinical staff. • Materials: educational tools and resources.	• Resource use capture template
Academic detailing	• Labour time: project support officer, clinical service staff time.	• Project administrative records • Resource use capture template • REDCap self-report survey
Monitoring and accountability	• Antenatal service managers will report, interpret and monitor performance measures for the model of care. • These results will be disseminated to antenatal service staff through team meetings, emails and other usual communication mechanisms. • Performance measures will be built into the existing monitoring and accountability frameworks for antenatal services.	• Resource use capture template

Abbreviations
AUD: Australian dollars; AUDIT-C: Alcohol Use Disorders Identification Test; BIA: Budget impact assessment; CEA: Cost-effectiveness evaluation; DCEA: Distributional cost-effectiveness analysis; ICER: Incremental cost-effectiveness ratio

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Authors' contributions
JW, AS, MK, EE and AD developed the original research idea. MK and ED managed the trial. AS, PR and ZS provided expert statistical and economic advice and content. MK, JW and ED provided content expertise regarding implementation science. EE and AD provided content expertise regarding maternity care. ZS and PR wrote the manuscript with the support and guidance of all other authors. All authors reviewed and approved the final manuscript and provided feedback.

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Availability of data and materials
There are no datasets associated with this protocol.

Ethics approval and consent to participate
The trial was approved by 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).

Consent for publication
Not applicable.

Competing interests
MK, ED, KC, LW and JW receive salary support from the Hunter New England Clinical Services Nursing and Midwifery, which contributes funding to the project outlined in this protocol. MK receives salary support from a NHMRC Translating Research Into Practice (TRIP) Research Fellowship (APP1150476). EJE is supported by a NHMRC Medical Research Futures Fund Practitioner Fellowship (APP1135959) and NHMRC CRE (APP1110341). All other authors declare that they have no competing interests.

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APPENDIX 2. Cost, cost-consequence and cost-effectiveness evaluation of a practice change intervention to increase routine provision of antenatal care addressing maternal alcohol consumption

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Cost, cost-consequence and cost-effectiveness evaluation of a practice change intervention to increase routine provision of antenatal care addressing maternal alcohol consumption

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Abstract

Background: Implementation of antenatal clinical guideline recommendations for addressing maternal alcohol consumption is sub-optimal. There is a complete absence of evidence of the cost and cost-effectiveness of delivering practice change interventions addressing maternal alcohol consumption amongst women accessing maternity services. The study sought to determine the cost, cost-consequence and cost-effectiveness of developing and delivering a multi-strategy practice change intervention in three sectors of a health district in New South Wales, Australia.

Methods: The trial-based economic analyses compared the costs and outcomes of the intervention to usual care over the 35-month period of the stepped-wedge trial. A health service provider perspective was selected to focus on the cost of delivering the practice change intervention, rather than the cost of delivering antenatal care itself. All costs are reported in Australian dollars ($AUD, 2019). Univariate and probabilistic sensitivity analyses assessed the effect of variation in intervention effect and costs.

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Contributions to the literature

- This is the first trial-based economic evaluation that identified, measured and valued the resources associated with the development and implementation of a practice change intervention to improve delivery of guideline recommended antenatal care addressing alcohol consumption by pregnant women.
- The findings inform decision makers of the cost, cost-consequence and cost-effectiveness of delivering a practice change intervention.
- Resource requirements were highest during the intervention period, however the average cost per woman is expected to decrease over time. Evidence of the cost profile is intended to inform decision makers of when, during the practice change process, different costs and benefits are expected.

Results: The total cost of delivering the practice change intervention across all three sectors was $367,646, of which $40,871 (11%) were development costs and $326,774 (89%) were delivery costs. Labour costs comprised 70% of the total intervention delivery cost. A single practice change strategy, 'educational meetings and educational materials' contributed 65% of the delivery cost. Based on the trial's primary efficacy outcome, the incremental cost effectiveness ratio was calculated to be $32,570 (95% CI: $32,566–$36,340) per percent increase in receipt of guideline recommended care. Based on the number of women attending the maternity services during the trial period, the average incremental cost per woman who received all guideline elements was $591 (Range: $329 - $940) . The average cost of the intervention per eligible clinician was $993 (Range: $640-$1928).

Conclusion: The intervention was more effective than usual care, at an increased cost. Healthcare funders' willingness to pay for this incremental effect is unknown. However, the strategic investment in systems change is expected to improve the efficiency of the practice change intervention over time. Given the positive trial findings, further research and monitoring is required to assess the sustainability of intervention effectiveness and whether economies of scale, or reduced costs of intervention delivery can be achieved without impact on outcomes.

Trial registration: The trial was prospectively registered with the Australian and New Zealand Clinical Trials Registry, No. ACTRN12617000882325 (date registered: 16/06/2017).

Keywords: economic evaluation, maternal and child, health service, alcohol drinking, implementation, cost

Background

Alcohol consumption during pregnancy is associated with adverse obstetric and infant outcomes that can have lifelong social and economic consequences [1, 2]. Specifically, alcohol consumption during pregnancy increases the risk of miscarriage, still birth and Fetal Alcohol Spectrum Disorder (FASD) which is the most common preventable cause of intellectual impairment in the western world [2]. Despite this, the 2019 Australian National Drug Strategy Household survey reports that 55% of Australian women consumed any alcohol during pregnancy, and 14.5% continued to drink once they knew they were pregnant [3]. No safe level of alcohol exposure has been established and Australian national alcohol guidelines recommend women abstain from drinking alcohol whilst pregnant, trying to become pregnant, or breastfeeding [4].

Public maternity services are important settings for the provision of antenatal care to a large proportion of pregnant women [5, 6]. International [7] and Australian [8, 9] antenatal clinical practice guidelines recommend that during initial and subsequent antenatal appointments all pregnant women: have their alcohol consumption assessed; be advised that it is safest not to consume alcohol during pregnancy and of the potential risks of consumption; and be offered referral for additional alcohol treatment services if required [3]. Despite such guideline recommendations, assessment and care for antenatal alcohol consumption in public maternity services is suboptimal [10, 11]. For example, in Canada approximately only half of surveyed health professionals reported providing advice to pregnant women regarding the consumption of alcohol [12]. In the United Kingdom two thirds of women reported receiving such advice from a midwife [13]. In a recent Australian survey less than two thirds of pregnant women reported that they received an assessment of their alcohol consumption and just over one third received advice and referral appropriate to their level of alcohol consumption at their initial antenatal visit [11]. Less than 10% of women received recommended care at subsequent antenatal visits [11]. Practice change strategies have been demonstrated to be effective in increasing the provision of evidence-based care in various clinical settings. Such strategies include educational meetings, local opinion leaders providing expert opinion, audit and feedback and electronic prompt and reminder systems [14–17]. No studies have reported the effectiveness of such strategies in improving the provision of care addressing maternal alcohol consumption by maternity services. Whilst effective, the delivery of these practice change strategies should be considered against their resource requirements [18].

Despite the increasing use of economic evaluation in health services research, its application to the assessment of the cost and cost effectiveness of practice change intervention strategies is limited [18] [19, 20]. A 2019 systematic review by Roberts et al. identified 30 studies that included implementation or improvement as part of an economic evaluation [20]. Of those, 14 were implementation studies and the most common focus was on implementation strategies of new care pathways or novel services [20]. Of these,

seven included a cost-effectiveness analysis (CEA), of which two were conducted in the Australian setting, one was a web-based intervention [21] implementation designed to improve the management of minor head injury in emergency departments [22]. Of the 14 implementation studies identified in this review, only six included specific implementation costs, such as those associated with staff training and education, the impacts of new processes on patient and carer costs and the cost of developing new processes [20]. Another recent systematic review of economic evaluations and cost analyses of guideline implementation strategies identified 235 implementation studies, of which only 10% provided information about implementation costs, with none providing detailed cost information [23]. Furthermore, this review identified 63 studies (27%) that reported an economic evaluation, however, overall the methodological quality was poor and very few included conclusions on the effectiveness or efficiency of implementing the guideline into practice [23]. Similarly, a systematic review of economic evaluations of antenatal nutrition and alcohol interventions and their implementation identified 12 studies, ten addressing nutrition intervention effectiveness and two addressing alcohol interventions [24]. The review found that although the alcohol interventions were cost-effective or cost saving, the cost and cost-effectiveness of the intervention and its associated practice change interventions were not reported, and have not been reported previously [24]. Failure to identify, measure and value explicit costs associated with implementation risks underestimation of the investment required to change practice. This has been identified as a missed opportunity to develop evidence about the importance of fixed and recurring costs associated with practice change interventions [20].

The importance of economic evaluation in the context of implementation science and how these analyses can be most efficiently incorporated into decision-making process has been recognised [19]. To address this evidence gap, a trial-based economic evaluation was conducted of a practice change implementation intervention that aimed to improve delivery of guideline recommended antenatal care addressing alcohol consumption by women during pregnancy. The aims of the economic evaluation were to:

1) Identify, measure and value the cost of developing and delivering a multi-strategy practice change intervention;
2) Report the costs and consequences of a multi-strategy practice change intervention; and
3) Determine the cost-effectiveness of a multi-strategy practice change intervention in improving antenatal care provider adherence to antenatal care guidelines compared to usual care.

The secondary aims for the economic evaluation were to report each of the aims by sector.

Methods

The trial

The practice change intervention trial has been reported by Kingsland et al. [25]. In summary, a randomised stepped-wedge controlled trial of a maternal alcohol practice change intervention was conducted in maternity services in three sectors in the Hunter New England Local Health District (HNELHD), New South Wales, Australia. Combined, the sectors provide antenatal care for approximately 6,100 women annually, accounting for 70% of public hospital births in the district [25]. The sectors provided antenatal care to women in a major city (Sector One: 4300 births per annum) and two regional/rural areas (Sectors Two and Three: 1200 and 600 births per annum respectively). The participating maternity services provided antenatal care for women through 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).

Outcome data were collected over a 35 month period from seven-months prior to commencement of the practice change intervention in the first sector to seven-months following completion of the intervention in the third sector [11]. Stepped delivery of the seven-month intervention period in each of the three sectors occurred in a random order at seven-month intervals [25]. All antenatal care providers who worked in the participating maternity services were eligible to receive the practice change intervention. The trial primary outcome measures were the proportion of antenatal appointments at 'booking in' (initial antenatal , 27–28 weeks gestation and 35–36 weeks gestation for which women report [1] being assessed for alcohol consumption, [2] being provided with brief advice related to alcohol consumption during pregnancy, [3] receiving relevant care for addressing alcohol consumption during pregnancy, and [4] being assessed for alcohol consumption and receiving relevant care [25].

Guideline recommended model of antenatal care

An evidence- and guideline-based model of antenatal care was developed to address alcohol consumption by pregnant women [25]. The model of care involved health care provider assessment of a woman's alcohol risk status using the AUDIT-C tool at the initial antenatal visit, and at follow up antenatal appointments at 27-29 weeks and 35-37 weeks gestation. The model of care also required all pregnant women were to be provided with brief advice indicating it is safest not to consume alcohol during pregnancy and of the risks associated with alcohol consumption. Women who were assessed as being at 'medium risk' of harm (AUDIT-C score: 3-4) were to be offered a referral to the NSW Get Healthy in Pregnancy Service, a free government provided evidence-based telephone coaching service for Aboriginal women, or to a face-to-face counselling service where available. Women who were assessed as being at 'high risk' of harm (AUDIT C score: 5+) were referred to Hunter New England Drug and Alcohol Clinical Services for further assessment and follow-up.

Practice change intervention

A multi-strategy practice change intervention to support the provision of the antenatal model of antenatal care was co-designed with input from health service stakeholders (e.g. senior maternity service staff, drug and alcohol service staff) and Aboriginal health organisations and women, and was guided by an implementation framework [26–29]. The intervention involved seven evidence-based practice change strategies: leadership and management; local clinical practice guidelines; electronic prompt and reminder system; local clinical/academic opinion leaders (change champions); educational meetings and educational materials; academic detailing (including audit and feedback); and monitoring and accountability for the performance of the delivery of health care [25]. Refer to Table 1.

Usual care

Prior to delivery of the practice change intervention in each of the three sectors, usual antenatal care addressing maternal alcohol consumption during pregnancy was provided [11]. An observational study was conducted in 2017-2018 to examine pregnant women's reported receipt of guideline recommended care addressing alcohol consumption during pregnancy [11]. The study found that although assessment and care for maternal alcohol consumption is highly acceptable to pregnant women, receipt of such care in public antenatal services is suboptimal and inconsistent [11].

Economic evaluation

Details of the approach to conducting the economic evaluation have been reported in the economic evaluation protocol [30]. A trial-based economic evaluation was conducted to assess cost, cost-consequence and cost-effectiveness of the development and delivery of the intervention. The analysis was conducted from a health-care provider perspective and was based on opportunity cost. The perspective was chosen as ongoing investment in the intervention, if translated into routine practice, would fall on public health services [30]. Costs incurred in 2017 and 2018 were adjusted for inflation using annual consumer price index [31]. All costs are reported in 2019 Australian dollars ($AUD).

The economic evaluation was conducted and reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) publication guidelines and good reporting practices [32]. Adherence to the CHEERS checklist is available in Supplementary Table 1.

Identification and measurement of outcomes

The economic evaluation was based on the trial primary outcome: the proportion of women at the initial, 27-28 weeks gestation and 35–36 weeks gestation antenatal visits who reported being assessed for alcohol consumption using the Alcohol Use Disorders Identification Test (AUDIT-C) tool, and who received the recommended elements of care (advice and referral) appropriate to their level of risk, as determined by AUDIT-C risk categories for pregnancy [30]. The trial primary outcome and the economic cost data were combined in an incremental cost-effectiveness ratio (ICER) calculated as the incremental cost per percentage increase in self-reported receipt of all guideline elements. ICERS by sector were reported as secondary outcomes.

Identification, measurement and valuation of practice change costs

At present, there are no guidelines for costing practice change interventions that aim to improve the implementation of guideline recommendations in health care settings [33, 34]. A recent pragmatic method for costing implementation strategies using time-driven activity based costing has been proposed by Cidav et al [33]. Time-driven activity-based costing is a micro-costing method widely used in business settings, which delivers

detailed, accurate and transparent information on activity costs designed to inform quality assurance processes and decision making [33, 35, 36]. The costing method involves three parameters; (i) frequency of the activity, (ii) time required to perform one single event of the activity, and (iii) per-hour price of the resources used to perform the activity [33]. The detailed information collected using this approach provides a direct link between the implementation inputs (resources utilized) and implementation outcomes [33]. Cidav's methods were used to inform the identification, measurement and valuation of implementation intervention data in the economic evaluation [33].

Intervention costs were prospectively identified and measured using a time-driven activity based cost-capture tool [30]. The cost-capture tool was developed in Microsoft Excel (2013) and allowed researchers to document the activity and materials consumed at different phases of the trial (development and delivery) and for all relevant stakeholders [30]. The cost-capture tool included the following resource use categories: [1] Labour [2]; Materials; and [3] Miscellaneous costs. Table 2 presents the approach to the valuation of unit costs for each item. Researcher officers involved in the trial delivery completed the cost-capture tool at the time of the cost being incurred throughout the trial duration. Labour, materials, and other implementation costs were captured, with the cost-capture tool built to allow expenses to be allocated to pre-coded cost categories and to one or more pre-coded implementation strategies. Following the reporting convention established in the CHEERs checklist, development and research costs are deemed 'start-up' costs [1]. We excluded development costs in this analysis as they represent the investment made by the research team to formulate the intervention components, and are not representative of the resource use required in 'steady state' operations. However, we separately reported the calculated value of the development costs to inform the upfront investment required to develop this intervention, where no similar model of care exists. Research related costs together with intervention development costs were excluded from the cost-consequence and cost-effectiveness analysis to achieve a focus on the costs and efficiency of the practice change intervention alone.

Cost data were treated as counts of resource use, weighted by unit costs. The cost for each sector was determined by summing the intervention delivery costs relevant to and coded for that sector. A cost per practice change strategy is reported to demonstrate the investment required for each of the seven strategies and to inform future intervention scale up and sustainability. The intervention was wholly additional to usual care, that is, no usual practice activity was displaced as a result of the intervention. Costs to providers, patients and private care providers (including opportunity costs) were not assessed.

Cost-consequence (CCA) and cost-effective analyses (CEA)

The results of the CCA are presented as the total cost of delivering the intervention alongside the range of outcomes reflected in the primary and secondary trial outcomes (consequences). The cost per eligible clinical provider is presented to demonstrate the cost and consequence of the intervention for those intended to provide the evidence-based model of care. Eligible clinical providers were all clinicians within the participating maternity services who provided antenatal care during the intervention period. Eligible clinical providers included midwifery and medical staff as well as Aboriginal Health Workers. It excluded clinicians who were not the primary providers of antenatal care (e.g. dietitians, diabetes educators and drug and alcohol clinicians). Eligible clinical providers were identified through rostering and payroll systems obtained from the participating maternity services. Modelled extrapolation of the self-report survey data was conducted to estimate the proportion of all women attending the participating maternity services who received all guideline elements during the intervention follow-up period. This extrapolation enabled estimation of the incremental cost per woman who received all guideline elements, in each sector. The average cost per woman was calculated as the cost of the practice change intervention, divided by the total number of women who are anticipated to have received all guideline elements based on the sample of women surveyed.

The trial-based CEA aligned the cost of the intervention against self-reported receipt of all guideline elements of antenatal care. The trial outcomes, reported as odds ratios, were converted to risk differences for inclusion in the CEA, e.g. the risk difference for the primary outcome refers to the percentage point (proportion) increase in the self-reported receipt of all guideline elements of antenatal care. This information was used to generate an ICER.

Uncertainty, sensitivity and sub-group analyses of ICERs

ICERs were calculated by sector to enable reporting of the variation in costs and effect sizes between the three sectors. One-way probabilistic sensitivity analyses

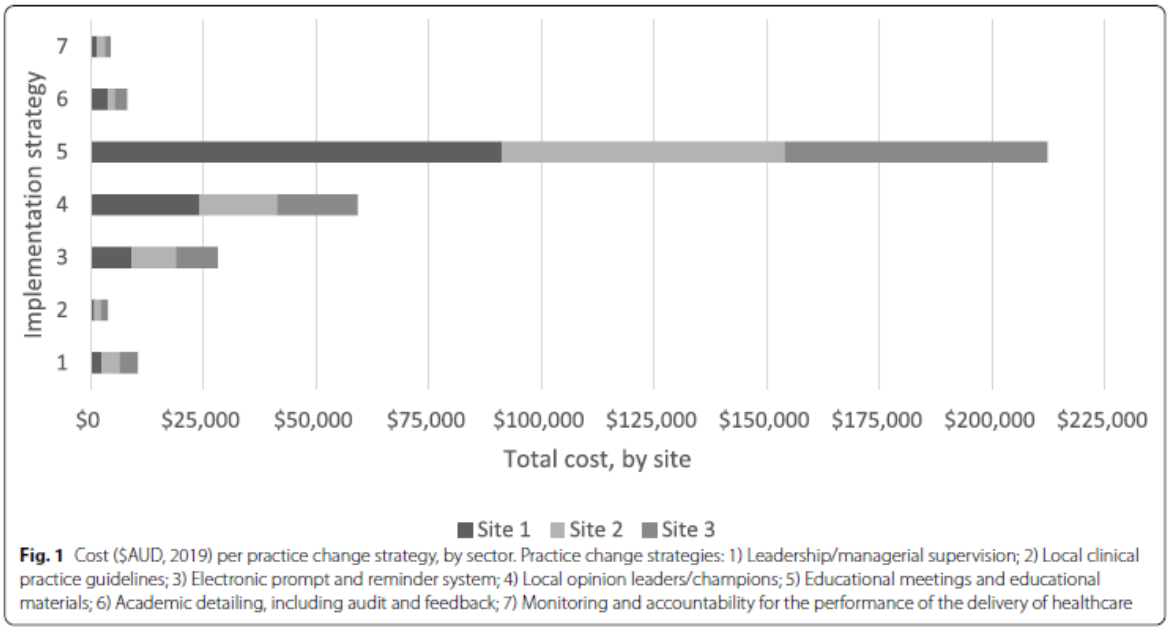

Fig. 1 Cost ($AUD, 2019) per practice change strategy, by sector. Practice change strategies: 1) Leadership/managerial supervision; 2) Local clinical practice guidelines; 3) Electronic prompt and reminder system; 4) Local opinion leaders/champions; 5) Educational meetings and educational materials; 6) Academic detailing, including audit and feedback; 7) Monitoring and accountability for the performance of the delivery of healthcare

assessed the effect of variation in the magnitude of treatment effect using the lower and upper confidence interval limits and variation in costs of intervention components using the lower and upper bounds of staff salaries. Non-parametric bootstrapping was undertaken to derive uncertainty intervals around the estimates for total cost and cost-effectiveness. Results from the sensitivity analyses were visually presented on a cost-effectiveness plane where the joint distribution of incremental costs were plotted against the incremental change in effect size between baseline and follow-up. Refer to Figs. 2 and 3.

Results

Cost

The resources invested to increase compliance with the guideline-based model of care were calculated as being wholly incremental to usual practice. The total cost of the practice change intervention across all three sectors was $367,646 of which $40,871 (11%) were development costs and $326,774 (89%) ($AUD, 2019) were intervention delivery costs. Of the intervention delivery costs, Sector one cost $133,188 (41%) of the practice change intervention costs. Sectors two and three incurred similar proportions of the practice change intervention cost, 30% and 29% respectively. The cost of labour was the main cost driver for the intervention, comprising 70% of the total intervention costs. Refer to Table 3.

Of the seven practice change intervention strategies 'educational meetings and educational materials' comprised 65% of the total intervention cost, followed by 'local opinion leaders/champions' with 18% of the intervention costs. The salary of the clinician midwife educator (CME) was the main cost driver for the 'educational meetings and educational materials' strategy. A CME was employed in each sector for the duration of the 7-month intervention. The CME for Sector one was employed at 1.0 full-time equivalent (FTE), the CME for Sector two at 0.6 FTE and Sector three at 0.4 FTE, relative to the number of births in each Sector. The remaining five intervention strategies each incurred between 1% and 8% of the total intervention costs. Refer to Fig. 1.

Cost-consequence and cost-effectiveness analyses

Significant intervention effects were found for receipt of all guideline elements (risk difference 9.33; 95% CI 7.67–10.98; $p = <0.001$). The increase in receipt of all guideline elements was seen across all three

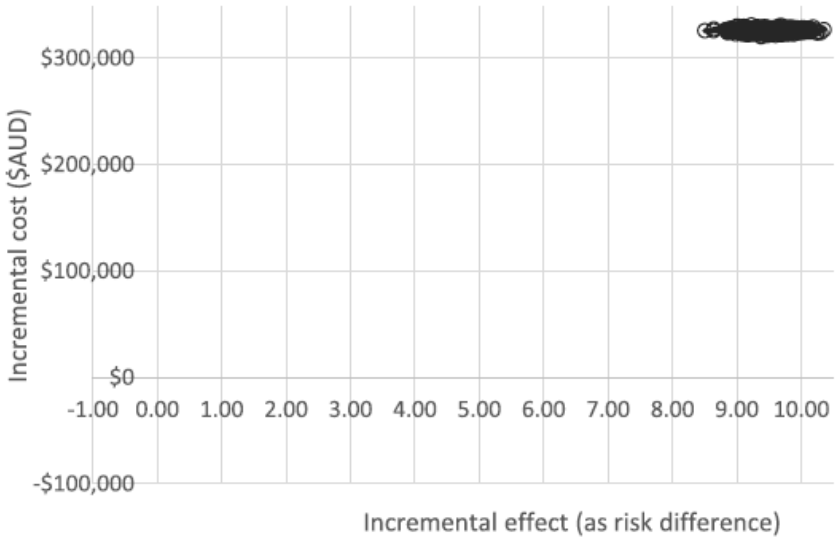

Fig. 2 Cost effectiveness plane

sectors. The average cost of delivering the practice change intervention per eligible clinician was $993 (Range: $640-$1928). Based on the average number of women in the service per month over the trial follow-up period, the extrapolated average cost per woman who received all guideline elements was calculated to be $591 (Range: $329 - $940). Variation in the average cost per woman was associated with variation in the average number of women through each service, per month between sectors. Sector one had a total of 6862 women through the antenatal service during the 21-month follow-up period, an average of 58 women per month reporting receipt of all guideline elements for the duration of the intervention. In comparison, Sector two had an average of 29 women per month reporting receipt of all guideline elements for

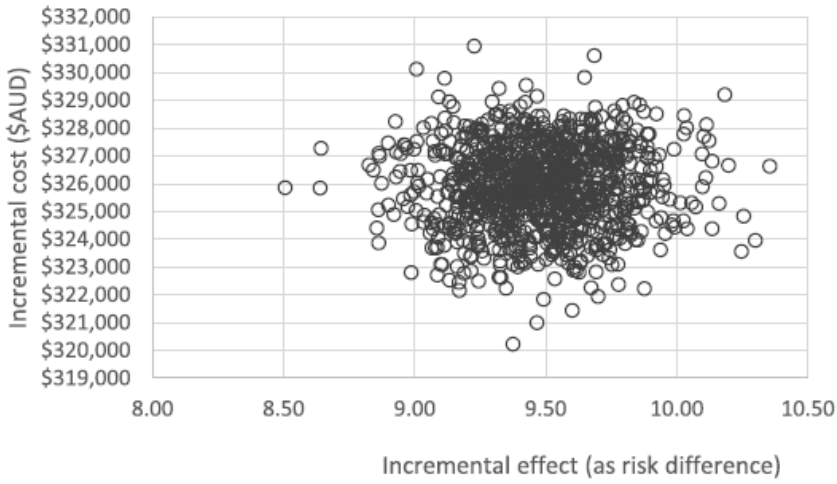

Fig. 3 Cost-effectiveness plane area of interest

a 14-month time period and Sector three had an average of 14 women per month for the seven-month time period. Refer to Table 4.

The calculated ICER per percentage point increase in self-reported receipt of all guideline elements was $32,570 (95% CI: $32,566–$36,340). The incremental cost per percent increase in women receiving all guideline elements ranged from $15,951 (95% CI: $13,109–$20,365) in Sector one and $5,618 (95% CI: $4,261–$8,25) in Sector two. Refer to Table 5.

Sensitivity analysis

The ICER in the sensitivity analysis was $35,024 (95% CI; $29,761 - $42,604), indicating that the ICER was sensitive to variation in labour costs Table 5.

Figures 2 and 3 present the joint distribution of incremental intervention cost and incremental effectiveness. All replications show a positive incremental benefit of the intervention over usual care, at increased cost. Figure 2 is a focussed view demonstrating limited variation of ICER pairs.

Discussion

This economic evaluation outlined the costs, consequences, and cost-effectiveness associated with the first published randomised controlled trial to examine the effectiveness and efficiency of delivering a practice change intervention to improve the implementation of guideline recommended care for maternal alcohol consumption. The intervention was effective at improving reported receipt of all guideline elements of care. The incremental cost of intervention delivery was calculated to be $326,774. Labour (staff time) was the main cost driver and variation in delivery costs across sectors was associated with design differences in labour time and travel costs for each sector.

The average cost over the trial period of delivering the practice change intervention per eligible clinician was $993, and $591 per woman who received all guideline elements. The cost of delivering clinician training was upfront and is not expected to require additional investment beyond the trial horizon. Clinician training modules were developed during the intervention and made permanently available online for staff to access as part of their ongoing clinician training. Further, in an effort to sustain the intervention effect size, implementation strategies were deliberately designed to affect permanent and scalable change within the health system, e.g. the inclusion of specific modules into the state-based e-maternity patient record management system, and performance measures were embedded into the health system. Therefore, these implementation strategies are expected to sustain the effect size post-intervention. As such, the average cost per woman is expected to reduce markedly with continued delivery of this new model of care over time (e.g. beyond the trial time horizon), with increased women receiving antenatal care and with scaling up to involve other maternity services/clinicians. Similarly, with respect to potential ongoing costs (beyond the trial time horizon) associated with this intervention and maintaining the intervention effect size beyond the trial time horizon.

Direct comparison between the results of this and previously reported studies of the cost and cost effectiveness of practice change interventions is not possible given the significant differences in the design and methods of the various studies. Broad comparisons with studies included in previous systematic reviews were also limited as the costs associated with the implementation of the practice change strategies is not often considered [20, 24, 37]. The review by Roberts et al. [20] identified one modelled CEA of a universal alcohol screening and brief intervention program in primary care in England [38]. This analysis compared the health and social care costs verses health benefits and found screening patients for alcohol consumption upon registration with a family doctor would steadily capture up to 96% of the population over a 10-year programme [38]. This study showed that alcohol screening and the provision of brief advice, led by practice nurses, provided cost savings to the health care system of £120m over 30 years [38]. Similar to the methods and findings of the present study, the cost of the intervention was estimated using activity costs and identified that resourcing needs for this intervention would be highest in the early years of the program due to the volume of new patients being screened, and would decrease over time [38]. This study did not include the cost of implementing this model of care into routine practice or addressing barriers to care delivery by relevant health service providers. In comparison, the practice change strategies used in the current study were designed to be embedded into the health care system to maintain the new model of care beyond the intervention delivery and follow-up period. As such, it is plausible that the demonstrated change in practice could be sustained beyond the trial time horizon and the average cost per woman screened would decrease as more women attend the antenatal service. Future studies could include longer

intervention follow-up periods to capture the number of women receiving care over a longer time period, as well as the health and societal benefits for mothers and their infants. Further research is also required to determine the cost of delivering the intervention at scale and whether economies of scale can be achieved in its delivery.

Implementation costs are recognised as an understudied aspect of implementation science [39, 40]. Saldana et al. proposed that one of the reasons implementation costs are not routinely examined is the lack of standard measurement [39]. More recently, Cidav et al. proposed a pragmatic approach to systematically estimating detailed resource use and costs of implementation strategies that combine time-driven activity-based costing with a leading implementation science framework [41] to guide specification and reporting of implementation strategies [33]. One of the key strengths of this study was the use of this time-driven activity based micro-costing to map implementation processes with actions, actors and strategies. This method provides transparent, granular cost estimation and allowed for a cost comparison of the different implementation strategies. It has been proposed that there could be value to using standardised methods for estimating implementation costs as it could allow decision makers responsible for determining the viability and feasibility of adopting new practices to benefit from the ability to generalise across settings [39, 42]. The transparent reporting of activity costs using a published time-driven activity-based costing method is intended to inform researchers and decision makers how specific components of an implementation intervention influence the total cost.

Another strength of this economic evaluation is the identification, measurement and valuation of development costs. That is, once the practice change intervention has been delivered, there are non-recoverable intervention components that remain within each sector. For example, the cost of developing and producing local clinical guidelines, the cost of developing educational materials and the cost of developing site-specific systems level monitoring and accountability measures. Saldana et al. argue development costs are an important consideration in decision making as policy makers must decide ex ante whether to invest in a new model of care and unrecoverable costs must be considered amongst the future benefits [39]. Transparent reporting of costs associated with the practice change intervention is intended to inform decision makers of when, during the practice change process, different costs and benefits can be expected [19].

It was not possible to calculate an ICER for the cost per additional service user (pregnant woman) who received all guideline elements of care. The study was designed and powered to measure effectiveness at the health sector level, thus precluding this ICER calculation. Given this limitation, the average cost per additional service user (pregnant woman) exposed to the recommended treatment was calculated. Another, limitation of the study was that the ICER was calculated on the assumption that the intervention was wholly additional to usual care, that is, no usual practice activity was displaced as a result of the intervention. Identifying, measuring and valuing the cost of usual care was beyond the scope of the trial and hence a limitation of the analysis. The trial time horizon was 35-months, and as such only upfront and short-term costs to health service providers were included. Similarly, the potential impact of increased referrals to drug and alcohol services and the longer-term benefits of alcohol-harm reduction to society at large, was not captured in this trial and is a noted limitation. Future economic evaluations should endeavour to include these components. The range of costs associated with sustaining changes in provider behaviour and maternal alcohol consumption is complex [2], and beyond the scope of the analyses.

Conclusion

The practice change intervention was effective at improving women's reported receipt of all guideline elements of care. The incremental cost of delivering the intervention was calculated to be $326,774. To our knowledge, no similar studies have been published in the literature. The economic evaluation provides information for decision and policy makers regarding the cost, cost-consequence and cost-effectiveness of delivering a practice change intervention to support the introduction of a model of care for addressing alcohol consumption by pregnant women. Given the positive trial findings, further research is required to assess sustainability and determine the cost of delivering the intervention at scale and whether economies of scale can be achieved.

Appendices

Table 1 Implementation Strategy Summary

Intervention component	Component details	Resource use details	Data collection method for costing
Leadership and management	• Monthly meetings were held with management from antenatal services to elicit support. • Service managers distributed resources to staff and attended training sessions. • Performance measures related to the provision of the model of care were monitored and reported on.	**Labour time:** • Health district implementation support officer and manager. • Health service antenatal clinical staff and management.	• Resource use capture template
Local clinical practice guidelines	• A service level guideline and procedure document detailed the model of care, including assessment, brief advice and referral pathways. • The document was uploaded onto the health service's policy directory, disseminated by managers to all staff via email and hard copies were placed in staff common areas.	**Materials:** • Guideline and procedure document development and provision. **Miscellaneous:** • Electronic dissemination. **Labour time:** • Health district implementation support officer and manager. • Health service antenatal clinical staff and management.	• Resource use capture template
Electronic prompt and reminder system	• Existing point-of-care and medical record systems used by maternity clinicians were modified to electronically prompt use of the AUDIT-C alcohol screening tool. • Brief advice scripts were displayed on the point-of-care system based on the woman's AUDIT-C risk score and prompts and tools for referral to appropriate services.	**Materials:** • Computer-based intervention component. **Labour time:** • Health district implementation support officer and manager. • Health service antenatal clinical staff and management.	• Resource use capture template
Local opinion leaders/champions	• Project-specific Clinical Midwife Educators were appointed to support staff to uptake the model of care and provide support at a one-on-one, team and service level. • Additional local antenatal clinical leaders were engaged to provide encouragement and demonstrate required behaviours as required.	**Labour time:** • Health district implementation support officer. • Clinical midwife educator (CME) change champion.	• Resource use capture template
Educational meetings and materials	• Training was provided to all antenatal service clinicians via a 30-minute online training module and face-to-face sessions. Clinical Midwife Educators facilitated clinicians completing the online training and coordinate face-to-face training sessions. This included lecture style sessions, interactive, case-study based sessions and one-on-one sessions. • Clinicians were provided with written resources (hardcopy and electronic) to support the model of care, including standard drink measure charts and point-of care written prompts/reminders (e.g. stickers in charts).	**Labour time:** • Health district implementation support officer. • CME change champion. • Health service clinical staff. • Expert clinicians. **Materials:** • Educational tools and resources	• Resource use capture template • REDCap database
Academic detailing	• Data from both medical records and telephone surveys conducted with women who attended the antenatal services were used to provide feedback on adherence to the agreed model of care. • The Clinical Midwife Educators visited service teams in their antenatal clinics to provide feedback data and developed action plans to improve adherence.	**Labour time:** • Project support officer. • CME change champion. • Clinical service staff time.	• Resource use capture template • REDCap database

Table 1 (continued)

Intervention component	Component details	Resource use details	Data collection method for costing
Monitoring and accountability	• Antenatal service managers reported, interpreted and monitored performance measures for the model of care. • These results were disseminated to antenatal service staff through team meetings, emails and other usual communication mechanisms. • Performance measures were built into the existing monitoring and accountability frameworks for antenatal services.	**Labour time:** • Health district implementation support officer. • Health service antenatal clinical staff and management. **Miscellaneous:** • Electronic dissemination.	• Resource use capture template

Table 2 Approach to valuation of resources, by cost category

Item	Description	Approach to valuation
Labour time	Health service labour time incurred during intervention development and implementation	Staff time was recorded in minutes and NSW Health staff grade was recorded in trial management logs and cost-capture templates. Labour time was valued using NSW Health Award 2019*
	Non-health service labour time incurred during intervention development and implementation	Staff time was recorded in minutes and job title was recorded in trial management logs and cost-capture templates. Labour time was valued using Fair Work Australia Award Wages or University of Newcastle Academic Staff and Teachers or Professional Staff enterprise agreement*
Materials	Material items used during intervention development and implementation. For example, changes to electronic medical records system, printed resources, and stickers	Purchase receipts and trial management logs were used to value material items.
Miscellaneous	Included catering for training sessions and staff travel allowance or use of fleet vehicle	Purchase receipts and trial management logs were used to value all miscellaneous items.

*Labour time was costed at 1.3 to account for additional overhead costs (on-costs) associated with employment

Table 3 Total intervention cost disaggregated by sector, resource use category and practice change strategy

	Total	Sector 1	Sector 2	Sector 3
Total intervention costs				
Total intervention development and practice change cost	$367,646	$154,927	$112,985	$99,733
Practice change intervention development cost	$40,871	$21,739	$13,883	$5,250
Practice change intervention delivery cost	$326,774	$133,188	$99,103	$94,483
Costs: by resource use category				
Labour cost	$229,566	$102,468	$64,692	$62,406
Material cost	$75,424	$25,338	$25,043	$25,043
Miscellaneous cost	$21,785	$5,383	$9,368	$7,034
Cost by strategy				
Leadership/managerial supervision	$10,528	$2,599	$3,940	$3,990
Local clinical practice guidelines	$3,875	$876	$1,484	$1,515
Electronic prompt and reminder system	$28,286	$9,171	$9,830	$9,285
Local opinion leaders/champions	$59,255	$24,126	$17,366	$17,763
Educational meetings and educational materials	$212,260	$91,224	$62,888	$58,148
Academic detailing, including audit and feedback	$8,100	$3,834	$1,715	$2,551
Monitoring and accountability for the performance of the delivery of healthcare	$4,471	$1,358	$1,881	$1,232

Table 4 Cost-consequence results (baseline to follow-up)

	Total	Sector 1	Sector 2	Sector 3
Cost				
Practice change intervention cost	$326,774	$133,188	$99,103	$94,483
Consequences				
Women reporting receipt of all guideline elements at baseline				
Mean (%) across all sites	13%	-	-	-
Women reporting receipt of all guideline elements				
Risk difference, post vs baseline (95% CI)*	9.33	8.35	17.64	12. 21
	(p <0.001)	(p <0.001)	(p <0.001)	(p <0.001)
	7.67–10.98	6.54–10.16	12.01–23.26	4.47–19.95
Eligible antenatal providers who received the intervention				
Total	329	208	72	49
Proportion	100%	63%	22%	15%
Average cost per eligible provider	$993	$640	$1,376	$1,928
Women reporting receipt of all guideline elements of care				
Time period (follow-up data collection)	Sept 2018 – May 2019	Sept 2018 – May 2020	Apr 2019 – May 2020	Nov 2019 – May 2020
Number of months	21	21	14	7
Proportion women who reported receiving all guideline elements	19%	18%	31%	27%
Total number of women who received antenatal care	8539	6862	1302	375
Total number of women who received all guideline elements	1658	1215	402	101
Average cost per woman	$591	$329	$493	$940
Average number of women who received all guideline elements, per month	79	58	29	14

* The primary outcome was reported as an odds ratio in the primary outcome's manuscript. For the purpose of economic evaluation, it was converted to risk difference for inclusion in an ICER

Table 5 Incremental cost-effectiveness ratios for the primary and secondary outcomes

	ICER	95% CI	
ICER for women reporting receipt of all guideline elements			
Total	$32,570	$32,566 - $36,340	
ICER per sector			
Sector 1	$15,951	$13,109	$20,365
Sector 2	$5,618	$4,261	$8,252
Sector 3	$7,738	$4,736	$21,137

Abbreviations

AUD: Australian dollars; AUDIT-C: Alcohol Use Disorders Identification Test; BIA: Budget impact assessment; CEA: Cost-effectiveness evaluation; DCEA: Distributional cost-effectiveness analysis; ICER: Incremental cost-effectiveness ratio.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13012-021-01180-6.

Additional file 1.

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Authors' contributions

MK, EE, JW, AS, AD, LW, TS and PR developed the original research concept and developed the study design. MK, EE, ED are responsible for overseeing data collection. ZS conducted the analysis. PR oversaw the analysis and provided feedback. ZS and PR developed the draft manuscript. All authors made substantial contributions to the manuscript development, read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The trial was approved by 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).

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

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Publisher's Note

A full description of component details has been published elsewhere [43].

APPENDIX 3. Enhancing clinician participation in quality improvement training: implementation and impact of an evidence-based initiative to maximise antenatal clinician participation in training regarding women's alcohol consumption during pregnancy

RESEARCH Open Access

Enhancing clinician participation in quality improvement training: implementation and impact of an evidence-based initiative to maximise antenatal clinician participation in training regarding women's alcohol consumption during pregnancy

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Abstract

Background: There are significant challenges in ensuring sufficient clinician participation in quality improvement training. Clinician capability has been identified as a barrier to the delivery of evidence-based care. Clinician training is an effective strategy to address this barrier, however, there are significant challenges in ensuring adequate clinician participation in training. This study aimed to assess the extent of participation by antenatal clinicians in evidence-based training to address alcohol consumption during pregnancy, and to assess differences in participation by profession.

Methods: A 7-month training initiative based on six evidence-based principles was implemented in a maternity service in New South Wales, Australia. Descriptive statistics described participation in training (% attending: any training; six evidence-based principles of training; all principles). Regression analyses examined differences by profession.

Results: Almost all antenatal clinicians participated in some training (182/186; 98%); 69% participated in ≥1 h of training (μ = 88.2mins, SD:56.56). The proportion of clinicians participating in training that satisfied each of the six principles ranged from 35% (training from peers and experts) to 82% (training was educational and instructional). Only 7% participated in training that satisfied all principles. A significantly higher proportion of midwifery compared to medical clinicians participated in training satisfying five of the six training principles.

Conclusions: A training initiative based on evidence-based principles resulted in almost all clinicians receiving some training and 69% participating in at least 1 h of training. Variability between professions suggests training needs to be tailored to such groups. Further research is required to determine possible associations with care delivery outcomes.

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Trial registration: Australian and New Zealand Clinical Trials Registry, No. ACTRN12617000882325 (date registered: 16/06/2017).

Keywords: Training, Quality improvement, Maternity, Alcohol

Background

Internationally, clinical practice guidelines recommend the implementation of antenatal care addressing alcohol consumption by pregnant women [1, 2]. However, research from countries including Canada [3], the United Kingdom [4] and Australia [5–10] indicates provision of such care is limited, including lack of routine assessment of alcohol consumption by pregnant women [5–7] and inconsistent provision of advice on potential harms of such consumption [3–6].

Clinician capability has been identified as a significant barrier to clinicians routinely providing recommended best practice care [11]. In Australia and internationally, studies have found lack of knowledge [12], skill [7, 10, 13] and confidence [10, 11] to be significant barriers to the provision of care according to care delivery guidelines generally [14], as well as a barrier to clinicians providing recommended antenatal care addressing alcohol consumption during pregnancy [7, 11, 12].

Clinician training has been identified in multiple systematic reviews as a key intervention strategy for addressing clinician barriers related to the implementation of evidence-based care [15, 16]. A Cochrane systematic review of 81 trials including over 11,000 health professionals found increased compliance with recommended clinical practice guidelines (improvements in compliance from 2.9 to 15.3%, median of 6%) following educational meetings [15]. A further Cochrane systematic review that included 69 studies involving more than 15,000 health professionals in educational outreach visits (onsite education/training) found that such training increased compliance with desired practice by 5.6% (risk difference; interquartile range 3.0 to 9.0%) [16].

Significant challenges have been reported in ensuring all targeted clinicians participate in training [17–19]. Reviews have reported an average of only 53% of targeted clinicians participate in training in clinical settings generally [15] and 15–75% of clinicians in maternity service settings [17, 20, 21]. Reviews have reported that factors contributing to less than optimal training participation including organisational constraints (e.g. available resources, time) [18, 19, 22], lack of tailoring to local context and different users [21], lack of integration of training into routine organisational meetings and opportunities [18], and lack of organisational support for training to occur [22]. To address these barriers and maximise the effectiveness of training, Cochrane and other systematic reviews recommend that clinician training initiatives address the following six principles: varied structure (one-on-one and group) [22]; multiple modes (online and face-to-face) [23]; multiple formats (interactive and didactic) [15]; mixed content (educational and instructional) [15, 20, 23, 24]; varied facilitators (peers and experts) [16, 25]; and total training of ≥1 h [22]. Participating in training based on these principles individually has been shown to significantly improve practice outcomes, including improvements in care [16, 22, 25–28], increased patient-centred skills [20], and positive effect on patient health behaviours and health status [20]. However, no studies could be located of training initiatives that included all six evidence-based principles, nor any studies of clinician participation in such a training initiative.

We could locate a few studies that incorporated some, but not all of the recommended principles in the design of training programs. For instance, a study in general practice in Australia covered four of six of these evidence-based principles. This study included a weekly group-based training sessions with duration ≥1 h (2.5 h per session, for 6 weeks) that had multiple formats (didactic and interactive), mixed content (educational and instructional) and varied facilitators (peers and experts). This training resulted in 41% of the General Practitioners ($N = 108$) that had self-selected into the training receiving all components of the training program (totalling 15 h of training) [29]. The study did not report receipt of the incorporated evidence-based principles of training. A further study, also in general practices in Australia, qualitatively evaluated a multicomponent training program that included content that was delivered through multiple modes (online and face-to-face), with mixed content (educational and instructional) and included peer delivery. Fifteen general practitioners self-selected into the training program, however the percentage of practitioners who participated in the training was not reported, nor was receipt of the incorporated evidence-based principles of training [30]. The ability to achieve sufficient clinician participation in a training initiative implementing all six evidence-based principles of training has not been reported.

The aims of this study were to assess the extent of participation by antenatal clinicians in evidence-based

training on care for women for alcohol consumption during pregnancy, and to assess any differences in participation by profession.

Methods

Study design

A post-test evaluation of a training program was undertaken utilising data collected during implementation. The study was undertaken as part of a trial to assess the effectiveness of a multi-strategy practice change intervention in increasing clinician delivery of antenatal care addressing women's alcohol consumption [31]. Clinician training was one of seven practice change strategies that formed the intervention.

Study setting

The study was conducted in a large metropolitan maternity service in New South Wales, Australia that provides care to over 4000 women annually [32].

Ethics

Ethics approval was obtained from HNELHD Human Research Ethics Committee (no. 16/10/19/5.15), The University of Newcastle Human Research Ethics Committee (no. H-2016-0422) and Aboriginal Health and Medical Research Council (1236/16).

Participants

Eligible participants were all clinicians within the participating maternity service who provided antenatal care between February and August 2018. Participants included Clinical Midwife Educators, registered midwives, midwifery students, Aboriginal Health Workers, and medical staff (including Consultants, Registrars; Resident Medical Officers (RMOs), and; general practitioners attending the service as visiting medical officers). To identify eligible staff, employee information was obtained from the organisation's learning and development unit, and rostering and payroll information was obtained from maternity services. For the length of the training initiative, checks were undertaken of the above information sources each fortnight to identify new eligible staff. Various methods were used to offer and promote training components to staff across clinical professions, including: verbal or written (i.e. email) invitations from key antenatal staff (e.g. Midwifery Unit Managers, Clinical Midwife Educators, Medical Education Fellows, and Senior Medical Consultants), and visual promotional materials (e.g. posters detailing what training sessions were being held, when and where) in common areas such as staff tea rooms, meeting rooms or hospital-based lecture rooms. All eligible staff were invited and encouraged to attend any and all components of the training program.

Training initiative

A seven-month training initiative was implemented between January and August 2018.

Four steps were undertaken to develop the initiative.

Step 1. Review of principles of training

Findings from Cochrane and other systematic reviews were examined to identify recommended principles of effective clinical training initiatives (see Table 1) [15, 16, 20–28, 33, 34]. A multi-layered approach to training was developed, with the intention of addressing all recommended training principles in the training initiative across multiple training components.

Step 2. Consultations with Maternity Services and review of existing maternity training systems and opportunities

Consultations were held with key antenatal staff (e.g. Midwifery Unit Managers, Clinical Midwife Educators, Medical Education Fellows, and Senior Medical Consultants). Consultations involved: discussion of potential facilitators of training (e.g. peers, experts), a review of existing training systems (e.g. mandatory full training days, staff online health learning platforms, roles of staff in existing educator positions), and identification of suitable times and locations to implement the training with antenatal clinicians within existing routine training and clinical procedures and opportunities. This included consideration of different clinical professions and service types (hospital-based clinician, outreach clinics, and Aboriginal Maternal and Infant Health Service (AMIHS).

Step 3. Embedding cultural safety and inclusion across all training areas

Consultation with and participation of Aboriginal women, community members, Aboriginal Maternal Infant Health Service (AMIHS) staff, and Aboriginal health district staff was led by Aboriginal team members to ensure the lived experience and perspective of Aboriginal women was embedded in the training. This included training addressing: the creation of culturally safe clinical environments; all women (Aboriginal and non-Aboriginal) being asked about their alcohol consumption at multiple time points as a component of routine antenatal care; sensitive and open conversation styles; understanding when to apply clinical discretion; referrals to Aboriginal culturally appropriate support services; clinician competence and confidence in referring Aboriginal women to such support services, and knowledge and use of culturally appropriate resources.

A Clinical Midwife Educator (CME) was appointed full time to facilitate the face-to-face training

Table 1 Summary of findings from systematic reviews regarding recommended principles of effective health professional training initiatives

Principle	Description of principle	Evidence
Mixed content (educational and instructional)	• Include educational content on serious patient outcomes • Include instructional content on use of Electronic Health Information (EHI)	• Improved training attendance when content/outcomes are perceived as serious [15, 20] • Improved effects if clinicians are provided with an EHI platform and trained in use of the platform [23]
Adequate total duration (total minutes received)	• Duration of at least 1 h	• Improved outcomes with total training duration of at least 1 h providing there is adequate follow-up and monitoring of progress [22]
Varied facilitators (peers and experts)	• Include sessions conducted by a peer • Include session(s) conducted by an expert	• Slightly improved level of change when educational sessions are conducted by a peer compared to a non-peer [16] • Some support for the use of a local opinion leader/expert opinion in practice change initiatives [25]
Multiple formats (interactive and didactic)	• Include a mix of interactive and didactic training	• Improved outcomes with mixed interactive and didactic/lecture-based educational meetings rather than inclusion of only didactic or only interactive sessions [15]
Multiple modes (online and face-to-face)	• Include both online and face-to-face training	• Insufficient evidence to support online learning only [23]
Varied structures (one-on-one and group)	• Include a mix of groupings	• Significant effects for both one-on-one or group delivered training [22]

components for the 7-month training initiative, including on-site training support in antenatal clinics.

Step 4. Refinement of the training program

Information obtained through steps 1 to 3 were synthesised: evidence based principles of training (Step 1) were matched to training opportunities and trainers identified during consultations with Maternity Services (Step 2). Information obtained from consultation with and participation of Aboriginal women, community members, Aboriginal Maternal Infant Health Service (AMIHS) staff, and Aboriginal health district staff (Step 3) informed key content requirements for each training component. The resulting training program is detailed in Table 2.

Data collection instruments and procedures

A training participation database was developed utilising REDCap [38]. The database was used to record details of eligible clinicians, the components of training they attended, and their receipt of the recommended principles of training. Clinician training participation data were entered into the database by a research team member, for face-to-face sessions this was based on paper-based records of attendance self-completed by clinicians and validated by the facilitator or team leader in attendance on completion of each training session. For online training sessions, completion records were downloaded from the online platform and entered into the database by a research team member on a weekly basis.

Data collection measures

Clinician participation in training

Information regarding training participation recorded in the database included: training session completed/attended, date of completion, training structure (one-on-one, group), mode (online, face-to-face), format (interactive, didactic), content (educational, instructional), facilitator (peer, expert) (all yes/no) and duration. These data were used to report on the following eight training participation outcomes.

Proportion of staff attending:

1. any training
2. training that was mixed content (educational and instructional)
3. training of adequate total duration (≥ 1 h)
4. training with varied facilitators (peers and experts)
5. training in multiple formats (interactive and didactic)
6. training through multiple modes (online and face-to-face)
7. training of varies structures (one-on-one and group)
8. training that satisfied all of the above six principles of training.

Clinician characteristics

Clinician characteristics data were extracted from records obtained from roster and payroll data systems.

Table 2 Summary of the training program

Program component/session	Content (educational/instructional)	Facilitator (Peer/ Expert)	Format (Interactive/didactic)	Structure (One-one-one/ group)	Mode (face-to-face/ online)	Duration (mins)
Online training module 'Antenatal Care for Alcohol Consumption during Pregnancy'	Developed through HETI and adapted from the Women Want to Know project content developed by the Foundation for Alcohol Research and Education (FARE) in collaboration with leading health professionals across Australia including the College of Midwives and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Educational: - Serious outcomes, effects/harms of alcohol consumption during pregnancy. - All elements of care (assess, advise, refer). - Myths, beliefs, assumptions - Skills for effective and/or sensitive conversations. Instructional: - Fitting in to practice: encouraging adoption of evidence-based guidelines. - Using eMaternity (e.g., navigation, completion of AUDIT-C).	NA	Interactive	One-on-one	Online	~ 45 mins
Overview presentation	Educational: - Serious outcomes, effects/harms of alcohol consumption during pregnancy. - All elements of care (assess, advise, refer). Instructional: - Fitting in to practice: encouraging adoption of evidence-based guidelines. - Using eMaternity (e.g. navigation, completion of AUDIT-C).	Peer (CME)	Didactive	Group	Face-to-face	20–30 min
Expert presentation	Educational: - Serious outcomes, effects/harms of alcohol consumption during pregnancy including less well known consequences (i.e. those in addition to FASD e.g. low birth weight, stillbirth, later effects in childhood and into adulthood etc.). - All elements of care (assess, advise, refer). - Myths, beliefs, assumptions.	Expert [35]	Didactive Educational material: 2 page summary of presentation produced and distributed to clinicians (educational materials)	Group	Face-to-face	60 mins
Case study session	Educational: - All elements of care (assess, advise, refer). Instructional: - Fitting in to practice: encouraging adoption of evidence-based guidelines.	Peer (CME)	Interactive Educational materials: Case study handouts distributed to clinicians	Group	Face-to-face	15–20 min

Table 2 (continued)

Program component/session	Content (educational/instructional)	Facilitator (Peer/ Expert)	Format (Interactive/didactic)	Structure (One-one-one/ group)	Mode (face-to-face/ online)	Duration (mins)
One-on-one support from an assigned clinical midwife educator when in the antenatal clinic(s)	The following content could be covered at any time in this session: Educational: - Serious outcomes, effects/harms of alcohol consumption during pregnancy - All elements of care (assess, advise, refer) Instructional: - Fitting in to practice: encouraging adoption of evidence-based guidelines. - Using eMaternity (e.g. navigation, completion of AUDIT-C). - Resources for use with women distributed: Foundation for Alcohol Research and Education (FARE) women's brochure [36], Stay Strong and Healthy Postcard [37], and NSW Standard Drinks Charts.	Peer (CME)	Interactive	One-on-one	Face-to-face	5–20 min
Final summary presentation (to conclude intensive support period)	Educational: - All elements of care (assess, advise, refer). Instructional: - Fitting in to practice: encouraging adoption of evidence-based guidelines.	Peer (CME)	Didactic	Group	Face-to-face	30–45 min

Data were extracted on the following characteristics: clinician position, clinical team and service type (core hospital-based clinician, outreach clinics, and AMIHS).

Statistical analysis

All analyses were conducted using SAS (Version 9.3). Clinician position data were used to create three clinician profession groups (midwifery, medical and Aboriginal Health Workers).

Variables were created to determine the receipt of each principle: 'both one-on-one and group mode' (Yes/No); 'both interactive and didactic format' (Yes/No); 'both face-to-face and online type' (Yes/No); 'educational and instructional content' (Yes/No); training obtained > 1 h (Yes/No); and, 'all principles of training' (Yes for all).

Descriptive statistics were used to examine clinician characteristics and clinician participation in training. Exact logistic regression was used to investigate associations between clinician participation for each of the six principle of training and 'all principles of training' and clinician profession group (midwifery, medical and Aboriginal Health Workers).

Table 3 Descriptive characteristics of clinicians and service types within the priority cohort ($N = 186$)

Characteristic	n (%)
Clinician profession groups and positions	
Midwifery	125 (67.20%)
Clinical Midwife Educator	13 (6.99%)
Clinical Midwife Specialist/Consultant	29 (15.60%)
Clinical Nurse Consultant	2 (1.08%)
Managers	8 (4.30%)
Registered Midwife	72 (38.17%)
Student Midwife	3 (1.61%)
Aboriginal Health Workers	10 (5.38%)
Medical	51 (27.42%)
Consultant	4 (2.15%)
Fellow	2 (1.08%)
General Practitioner	3 (1.61%)
Medical Officer	20 (10.75%)
Registrar	12 (6.45%)
Staff specialist	8 (4.30%)
Service type	
Central hospital-based clinic	138 (74.19%)
Outreach clinics	29 (15.60%)
Aboriginal Maternal and Infant Health Service (AMIHS)	19 (10.21%)

Results

Clinician sample and characteristics

One-hundred and eighty-six antenatal clinicians were identified as eligible for training. As shown in Table 3, approximately two thirds (67.20%) were midwifes, just over a quarter (27.42%) medical staff and 5.38% Aboriginal Health Workers.

Ninety eight percent ($n = 182$) of the eligible clinicians participated in some training (μ: 88.2 mins/clinician, SD: 56.56 mins/clinician; M: 75 mins/clinician; Min: 0 mins; Max: 278 mins), with 68.8% participating in ≥1 h. The proportion of clinicians participating in training that satisfied each training principle varied between 35% (received training from varied facilitators – i.e., from both peers and expert facilitators) and 82%

Table 4 Clinician participation in training that satisfied principles of training

Principles of training	n (%)
Varied structures	
One-on-one training	88 (47.31%)
Group training	157 (84.41%)
Both one-on-one and group	**69 (37.10%)**
Multiple modes	
Online training	84 (45.16%)
Face-to-face training	176 (94.62%)
Both online and face-to-face	**78 (41.94%)**
Multiple formats	
Interactive training	142 (76.34%)
Didactic training	147 (79.03%)
Both interactive and didactic	**108 (58.06%)**
Mixed content	
Educational	181 (97.31%)
Instructional	154 (82.8%)
Both educational & instructional	**153 (82.26%)**
Varied Facilitators	
Peer facilitators	173 (98.3%)
Expert facilitator	64 (36.36%)
Both peer and expert	**61 (34.66%)**
Training duration	
< 1 h	58 (31.18%)
≥ 1 h	**128 (68.82%)**
Receipt of principles of training	
Received no principles	18 (9.68%)
One principle	25 (13.44%)
Two principles	16 (8.60%)
Three principles	36 (19.35%)
Four principles	29 (15.59%)
Five principles	49 (26.34%)
All six principles	**13 (6.99%)**

(received training that mixed content – i.e., was both educational and instructional in content). Only 7% participated in training that satisfied all principles of training (Table 4).

Association between clinician participation in training that satisfied training principles and clinician profession group

Significant differences in clinician participation in training that satisfied the training principles were found by

Table 5 Clinician participation in training that satisfied training principles, by clinician profession group

	Midwifery $N=125$	Medical $N=51$	Aboriginal Health Workers (AHW) $N=10$	Regression Analysis		
Principle of training	**n (%)**	**n (%)**	**n (%)**	**Medical vs. Midwifery OR [CI] (*p*)**	**AHW vs. Midwifery OR [CI] (*p*)**	***p***
Varied structures						
One-on-one	50 (40.00%)	34 (66.67%)	4 (40.00%)	OR: 2.98 [1.44; 6.35] ($p=0.002$)	OR: 1.00 [0.20; 4.46] ($p=1.00$)	0.005
Group	108 (86.40%)	39 (76.47%)	10 (100.00%)	OR: 0.51 [0.21; 1.29] ($p=0.17$)	OR: 2.13 [0.41; ∞] ($p=0.49$)	0.12
Both one-on-one and group	**42 (33.60%)**	**23 (45.10%)**	**4 (40.00%)**	**OR: 1.62 [0.79; 3.32] ($p=0.21$)**	**OR: 1.31 [0.26; 5.89] ($p=0.92$)**	**0.35**
Multiple modes						
Online	77 (61.60%)	2 (3.92%)	5 (50.00%)	OR: 0.03 [0.00; 0.11] ($p=<0.001$)	OR: 0.63 [0.14; 2.87] ($p=0.69$)	<0.001
Face-to-face	116 (92.80%)	50 (98.04%)	10 (100.00%)	OR: 3.86 [0.51; 173.38] ($p=0.32$)	OR: 1.03 [0.19; ∞] ($p=0.98$)	0.41
Both online and face-to-face	**72 (57.60%)**	**1 (1.96%)**	**5 (50.00%)**	**OR: 0.01 [0.00; 0.09] ($p=<0.001$)**	**OR: 0.74 [0.16; 3.38] ($p=0.88$)**	**<0.001**
Multiple formats						
Interactive	99 (79.20%)	36 (70.59%)	7 (70.00%)	OR: 0.63 [0.28; 1.44] ($p=0.30$)	OR: 0.62 [0.13; 3.94] ($p=0.73$)	0.37
Didactic	102 (81.60%)	36 (70.59%)	9 (90.00%)	OR: 0.54 [0.24; 1.25] ($p=0.16$)	OR: 2.02 [0.26; 92.76] ($p=0.88$)	0.18
Both interactive and didactic	**81 (64.80%)**	**21 (41.18%)**	**6 (60.00%)**	**OR: 0.38 [0.18; 0.78] ($p=0.007$)**	**OR: 0.82 [0.18; 4.15] ($p=1.00$)**	**0.016**
Mixed content						
Educational (e.g. serious outcomes, effects/harms of alcohol consumption during pregnancy	117 (93.60%)	37 (72.55%)	10 (100.00%)	OR: 0.18 [0.06; 0.51] ($p=<0.001$)	OR: 0.91 [0.16; ∞]] ($p=1.00$)	<0.001
Instructional (e.g. using eMaternity including navigation and completion of AUDIT C)	117 (93.60%)	46 (90.20%)	10 (100.00%)	OR: 0.63 [0.17; 2.58] ($p=0.62$)	OR: 0.91 [0.16; ∞] ($p=1.00$)	0.59
All content	**116 (92.80%)**	**34 (66.67%)**	**10 (100.00%)**	**OR: 0.16 [0.06; 0.41] ($p=<0.001$)**	**OR: 1.03 [0.91; ∞] ($p=0.98$)**	**<0.001**
Varied facilitators						
Peer	115 (99.14%)	48 (96.00%)	10 (100.00%)	OR: 0.21 [0.00;4.14] ($p=0.43$)	OR: 0.09 [0.00;∞] ($p=1.00$)	0.34
Expert	41 (35.34%)	18 (36.00%)	5 (50.00%)	OR: 1.03 [0.48;2.16] ($p=1.00$)	OR: 1.82 [0.39;8.41] ($p=0.55$)	0.69
Both peer and expert	**40 (34.48%)**	**16 (32.00%)**	**5 (50.00%)**	**OR: 0.89 [0.41;1.91] ($p=0.90$)**	**OR: 1.89 [0.41;8.74] ($p=0.51$)**	**0.55**
Adequate total duration						
≥ 1 h	**94 (75.20%)**	**26 (50.98%)**	**8 (80.00%)**	**OR: 0.35 [0.16;0.72] ($p=0.004$)**	**OR: 1.32 [0.24;13.38] ($p=1.00$)**	**0.006**
All principles of training	**12 (9.60%)**	**0 (0.00%)**	**1 (10.00%)**	**OR: 0.13 [0.00; 0.66] ($p=0.028$)**	**OR: 1.05 [0.02; 8.80] ($p=1.00$)**	**0.035**

clinician profession group. A higher proportion of midwifery compared to medical clinicians received the following principles of training: multiple modes; multiple formats; ≥1-h duration of training; both elements, and; all principles of training. See Table 5.

Discussion

This study aimed to assess the extent of antenatal clinician participation in a multi-component evidence-based training initiative designed based on six principles of training, and to assess differences in participation by profession. The comprehensive training initiative was effective in achieving substantial levels of clinician participation, with 98% of clinicians participating in some training and approximately two thirds of clinicians (68%) participating in at least 1 h of training across the training components. Few clinicians (7%) received training that satisfied all evidence-based principles of training. The training principles related to content (82%), duration (68%) and format (58%) were able to be satisfied for more than half of antenatal staff, whereas the principles related to mode (42%), structure (37%) and facilitator (35%) were not.

As noted in systematic reviews, data on level of participation in training is not often clearly reported in included studies (44%) [15]. For those studies that have reported training participation, reported participation rates for training with maternity services clinicians range from 15 to 75% [17, 20, 21]. The present study found the proportion of staff to receive any training to be 98%; a result notably high in comparison to these past studies. None of these past studies reported on training participation in terms of any of the principles of training that were reported in this study.

There were a number of factors that may have resulted in different levels of clinician participation in training incorporating each of the principles. In terms of facilitator, 98% of staff received training from a peer, whereas only 36% received training provided by an expert. This may have been due to less opportunities (two face to face group sessions) provided by an expert, compared to the 7-month presence of a Clinical Midwife Educator as a peer facilitator. The use of additional modes (e.g. online or pre-recorded sessions) for delivering expert-delivered training may be needed to be implemented to enable this principle to be satisfied by a greater proportion of staff.

In respect to structure, 84% of staff attended a group session compared to only 47% of staff participating in one-on-one training sessions. This was impacted by logistical challenges in reaching all 186 target staff with one-on-one sessions, including changing rosters, staff rotations, limited dedicated time for such sessions and complexity of opportunistic one-on-one sessions at outreach sites. In contrast, group training sessions, are able to be justifiably attended for training purposes. If the principle of mixed structure (one-on-one and group) is to be satisfied, there needs to be identification of further opportunities for one-on-one training in such clinical settings as well as organisational support and recognition to allow time to be dedicated to such sessions and their role in training legitimised.

In terms of training mode, 95% of staff were able to attend face-to-face training. Such training was able to be provided with greater flexibility in terms of session length and format, which may have assisted with reach. This compared to online training which was only undertaken by 45% of staff. Digital literacy could have contributed and has been identified in existing literature [39]. Also, limited availability of computers within clinical spaces that were able to be utilised to undertake training and limited time allowed to undertake online training were both recognised issues identified by participating clinicians that may have contributed to this result. Additional dedicated computing resources may be required to overcome these barriers and assist in the principle of mixed mode (online and face-to-face) being satisfied.

There were significant differences in receipt of principles of training by clinical profession with a higher proportion of midwifery compared to medical receiving the following principles of training: multiple modes; multiple formats; ≥1-h duration of training; and mixed content. Despite being offered the same training opportunities no medical staff received training that satisfied all training principles. This aligns with barriers to participation in training by medical staff cited in related literature including: organisational constraints (e.g. available resources and organisational support for training to occur) [18, 19, 22], lack of tailoring to different contexts and users [21], and lack of time to participate in training due to increasing workloads, pressures and staff shortages [18]. During consultations held with maternity staff during planning of the training program, consideration was given to potential differences in training needs by clinical profession. It was noted that medical staff required delivery of the training content in short (5–15 min) sessions to fit within existing shifts and training schedules, compared to midwifery staff who had longer blocks of time (30–120 min) available within existing schedules (e.g. mandatory full training days). Despite adapting training to such profession-specific needs, difficulty securing time for training with medical staff was a key barrier in ensuring this profession group received the same duration of training as midwifery staff and therefore exposure to training that satisfied the training principles. This variability of receipt of training suggests further research is

needed to better understand the barriers that different professions (particularly medical staff) face in participating in training programs and to test the effectiveness of strategies to overcome such barriers.. To encourage greater uptake of training for medical staff, it is likely that such strategies will need to include protected time for staff to complete training programs and funding to backfill clinical shifts.

The study has a number of strengths including delivery of training as part of routine clinical education, the use of observed training attendance data and coding of training content based on evidence-based principles. The study should also be considered in light of its design and methodological characteristics. The study was undertaken within a single maternity service in a metropolitan hospital. It is unknown how comparable the training opportunities or clinician response in this setting are to other clinical settings without further evaluation across multiple sites. However, the hospital setting in which this trial was conducted was inclusive of varied antenatal models (hospital based, community outreach, AMIHS) and staffing types. The size of the sample was limited to the number of staff within the service and more precision of the findings would have been achieved with a larger sample.

Conclusions

This comprehensive, multi-component, evidence-based approach to clinician training was effective in achieving substantial clinician participation in training opportunities, and at a level that is greater than previously reported. Variability between professions suggests further tailoring of training is required, particularly for medical staff. Further research is required to determine whether participation in training was able to address the clinician barriers to care delivery that it was designed to address, including knowledge, confidence and skill, and to evaluate the contribution that the training program made to changing clinician practices as a component of a multi-strategy practice change intervention [31]. It is likely well-designed training programs, when delivered together with other practice change strategies, including reminders and audit and feedback, that address other clinician barriers to care delivery will increase levels of recommended care [40].

Abbreviations

RMOs: Resident Medical Officers; AMIHS: Aboriginal Maternal and Infant Health Service; CME: Clinical Midwife Educator; EHI: Electronic Health Information; AHW: Aboriginal Health Workers.

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Authors' contributions

JD led the development of the manuscript, design and coordination of the study, supported by ML and MK. ML, ED, BT, BW, SC, DW, SW, SH, EE, JW, MK, participated in critical review of the manuscript content; and participated in the conception, design and co-ordination of the study. JD, ML, ED, BT, BW, CS, DW, MK contributed to the development of the data collection methods and conduct of data collection. CL provided statistical support; participated in critical review of the manuscript; and participated in the conception and design of the study. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated during and analysed during the current study are not publically available due to requirements pertaining to confidentiality and privacy of study participants, but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

All methods were undertaken in accordance with the Declaration of Helsinki and approval has been granted by Hunter New England Local Health District Human Research Ethics Committee (approval number: 16/10/19/5.15, date of approval: 10/11/2016), The University of Newcastle Human Research Ethics Committee (approval number: H-2016-0422, date of approval: 02/10/2016) and Aboriginal Health and Medical Research Council (approval number: 1236/16, date of approval: 03/02/2017). Informed consent to participate in the study was obtained from participants.

Consent for publication

Not applicable.

Competing interests

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Publisher's Note

APPENDIX 4. Predictors of alcohol use during pregnancy in Australian women

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Predictors of alcohol use during pregnancy in Australian women

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Abstract

Introduction. *This paper aimed to document alcohol use during pregnancy and determine predictors of ongoing use, including knowledge and agreement with national alcohol guideline recommendations.* ***Methods.*** *Pregnant women (n = 1179) attending public antenatal services in a Local Health District in NSW, Australia, were surveyed about their alcohol use before pregnancy and after pregnancy recognition, and awareness of, and agreement with, national alcohol guidelines and health-related statements. Respondent characteristics, drinking behaviour and predictors of ongoing drinking during pregnancy were assessed.* ***Results.*** *Most women consumed alcohol before pregnancy (79.3%) but the majority (82.0%) stopped following pregnancy recognition. Half the ongoing drinkers only drank on special occasions. Most (63.6%) women were aware of the national guidelines: 78.1% knew the recommendation that consuming no alcohol in pregnancy is safest, 4.6% thought some alcohol was safe and 17.3% were unsure. Predictors [OR (95%CI)] of ongoing drinking were older age [1.11 (1.07, 1.15)]; medium [2.42 (1.46, 4.00)] or high-risk drinking pre-pregnancy [3.93 (2.35, 6.56)]; and agreement that: avoiding alcohol in pregnancy is safest [0.05 (0.006, 0.47)]; avoiding alcohol is important for baby's health [0.14 (0.06, 0.31)] and pregnancy is a good time to change alcohol use for mother's health [0.29 (0.13, 0.63)].* ***Discussion and Conclusions.*** *Results emphasise the importance of asking about special occasion drinking, the link between pre-pregnancy drinking and ongoing drinking during pregnancy, and the need to understand why women disagree with the national guideline. To ensure guidelines have their intended benefit, interventions to promote behaviour change relating to alcohol consumption during pregnancy are warranted.* [Tsang TW, Kingsland M, Doherty E, Anderson AE, Tully B, Crooks K, Symonds I, Tremain D, Dunlop AJ, Wiggers J, Elliott EJ. Predictors of alcohol use during pregnancy in Australian women. *Drug Alcohol Rev* 2022;41:171–181]

Key words: alcohol consumption, women, pregnant, guideline adherence, attitude.

Background

Although the harms of prenatal alcohol exposure are well documented [1–3] and guidelines worldwide recommend alcohol abstinence [4], alcohol use during pregnancy remains common. Nearly 10% of pregnancies globally are alcohol-exposed, varying by country and socio-economic status [5]. Age, parity, education, remoteness, health risk behaviours, partner's alcohol use and attitudes towards alcohol use in pregnancy predict such consumption [6–8], with the strongest predictor being pre-pregnancy drinking patterns [9,10].

Australian cohorts have provided valuable information about alcohol use in pregnancy, including how

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best to ask about alcohol use (e.g. special occasions/difficult times, before pregnancy recognition) [8,11]. These studies reported alcohol use in pregnancy in 59–72% of women [8,9,11], with 61–87% drinking prior to pregnancy recognition, often including binge and special occasion drinking [8,11]. After pregnancy recognition, most women who continued drinking did so at low to moderate levels [8,11,12], 89% ceasing or reducing alcohol consumption [8]. These studies were initiated seven to 10 years ago and may not reflect current drinking patterns among pregnant Australian women.

Australian national guidelines to reduce health risks from drinking alcohol developed by the National Health and Medical Research Council (NHMRC) (2009) recommend abstinence from alcohol as the safest option during pregnancy, when planning a pregnancy or breastfeeding, because a safe level of alcohol consumption in pregnancy has not been established [1]. However, previous guidelines condoned low levels of consumption during pregnancy [13], with longitudinal evidence indicating that Australian women were less likely to consume alcohol after pregnancy recognition under abstinence versus low alcohol guidelines [9]. This is unlikely to be due to knowledge of the guideline recommendations alone, with only a small qualitative study suggesting that pregnant women in 2009 may have received conflicting or no advice about alcohol use in pregnancy [14]. A larger, updated study is required to explore the impact of women's knowledge of and attitudes to guidelines on drinking during pregnancy [12]. This would identify groups who are unaware of guidelines and inform strategies to increase knowledge of recommendations and minimise alcohol-exposed pregnancies.

To better understand ongoing drinking in pregnancy and women's knowledge of national guideline recommendations about alcohol use in pregnancy, this study incorporated specific questions about the Australian guidelines for alcohol use during pregnancy [1].

The aims of this study were to determine:

1. Alcohol use before and after pregnancy recognition, including characteristics of women according to their alcohol use behaviour.
2. The proportion and characteristics of pregnant women who:
   a. Are aware of the national guidelines on alcohol use in pregnancy;
   b. Can correctly relay the key recommendation that abstinence is safest;
   c. Agree with three specific health-related statements including the guideline recommendation and benefits for mother and child of avoiding alcohol in pregnancy.
3. The predictors of ongoing alcohol use after pregnancy recognition including demographic characteristics, ability to relay the key guideline recommendation, and agreement with three health-related statements above.

Methods

Ethics

Ethics approval was received from the Hunter New England Human Research Ethics Committee (16/11/16/4.07), Aboriginal Health and Medical Research Council (1236/16) and the University of Newcastle Human Research Ethics Committee (H-2017-0032). A NSW Health Aboriginal Health Impact Statement was endorsed by the Hunter New England Aboriginal Health Unit (12 June 2018).

Design and setting

Cross-sectional survey (July 2017 to March 2018) of women presenting to public antenatal services in three sectors in the Hunter New England Local Health District in NSW, Australia (Figure 1), encompassing a major city, regional and rural areas.

Inclusion/exclusion criteria

All women attending public antenatal services in the participating Local Health District were included in the survey. Women were eligible provided they met the following criteria:

- Aged ≥18 years;
- Pregnant at 12 to <38 weeks gestation;
- Attended a face-to-face antenatal visit in the preceding week for: (i) an initial antenatal visit; (ii) 27- to 28-week gestation visit; or (iii) a 35- to 36-week gestation visit;
- Were sufficiently proficient in the English language to complete the survey unaided.

Women were excluded if they were receiving antenatal care through a private provider, had given birth or had a negative pregnancy outcome (identified from electronic medical records).

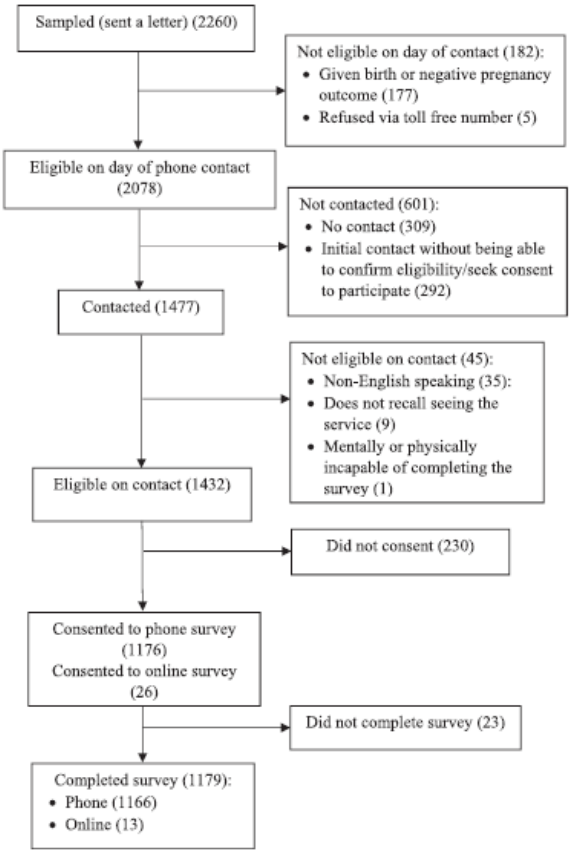

Figure 1. *Recruitment flowchart. Women who elected to give birth at and book into public hospitals, but who were under the care of a private provider for their antenatal care were not contacted (excluded) for this study.*

Recruitment

Eligible women were identified using electronic medical records and appointment data. Every week over an eight-month period (June 2017 to February 2018), a random sample of 105 women was selected using a computerised random number generator and mailed a participant information statement. Non-Aboriginal women were contacted by telephone 1 week after the letter was sent and invited to participate in a computer-assisted telephone interview (CATI). Non-Aboriginal women who declined the CATI were invited to complete the survey online. Aboriginal women and women attending an Aboriginal Maternal Infant Health Service were contacted via text message four days after the letter was sent and provided the option to complete the survey online or via CATI. Ten phone contact attempts were made by interviewers from the health district within two weeks for CATIs and the online survey link remained open for this period. Figure 1 shows the recruitment flowchart.

Data collection

Questions in the CATI and online surveys were based on previous national surveys [15–17] and reviewed for cultural appropriateness for Aboriginal women, led by an Aboriginal Project Officer, a project-specific cultural task group, Aboriginal cultural review group and in consultation with the Population Health Aboriginal Cultural Determinants Committee. The CATI was piloted prior to use and all interviews were conducted by trained and experienced female interviewers from the Hunter New England Local Health District. Aboriginal women were offered the option of a female Aboriginal interviewer. Unique links for the online survey, built using Research Electronic Data Capture (REDCap) [18], were sent to participants via email or text message.

Measures

Self-reported alcohol use prior to pregnancy and after pregnancy recognition was assessed using the Alcohol Use Disorders Identification Test–Consumption (AUDIT-C) [19]. For pre-pregnancy drinking, women were asked to report their 'alcohol use in the 12 months prior to this pregnancy'. Pre-pregnancy AUDIT-C scores were classified as: no risk (score = 0), low risk (score = 1–2), medium risk (score = 3–4) and high risk (score ≥ 5) [20]. Drinking during pregnancy was assessed by asking women to report their 'alcohol use since you found out you were pregnant' and classified as 'low to medium risk' (score = 1–4) or 'high risk' (score ≥ 5) [21]. Women were asked about alcohol consumption during special occasions after pregnancy recognition, including the number of special occasions they attended and consumed alcohol and the average number of standard drinks consumed on each occasion. Participants were classified as drinking on 'special occasions only' if they did not report any alcohol consumption via the AUDIT-C but reported drinking on a special occasion. AUDIT-C and special occasion drinking data were used to classify women into the following groups: non-drinkers (did not drink before or after pregnancy recognition or had missing pre-pregnancy drinking data); women who stopped drinking (drank prior to pregnancy but not after pregnancy recognition); and ongoing drinkers [drank both prior to pregnancy and after pregnancy recognition

(AUDIT-C score of ≥1 and/or reported special occasion drinking during pregnancy)].

Women were asked 'Are you aware that Australia has alcohol guidelines for pregnancy?' and if so, 'Are you able to tell me what the guidelines recommend?' (open-ended question). Responses were *Correct* if the respondent indicated that the recommendation for pregnancy was no alcohol; as *Incorrect* if the woman responded that any level other than no alcohol was recommended; and *Unsure* if the respondent indicated they were not sure or did not know.

Women were read three health-related statements and asked to report their agreement with each on a 5-point Likert scale (Strongly disagree to Strongly agree): (i) Not drinking alcohol is the safest option during pregnancy; (ii) Not drinking alcohol during pregnancy is one of the most important things I can do for my baby's health; and (iii) Pregnancy is a good time for women to change their alcohol use to improve their own health. Of these, the first was based on the 2009 Australian guideline recommendation [1], while the other two were attitude-based statements related to the baby's health (ii) and mother's own health (iii).

Characteristics associated with the ongoing drinking versus stopped drinking groups after pregnancy recognition were identified. Specific characteristics considered were consistent with previous reports of predictors of alcohol use in pregnancy: age, Aboriginal origin, highest level of education and first pregnancy [9,10,17,22]. Women's geographic remoteness and index of disadvantage [23] was based on residential postal code. Geographic remoteness was classified as major city or inner/outer regional/remote. Index of disadvantage was classified in three groups: (i) Most disadvantaged (quintiles 1 and 2); (ii) Mid-disadvantaged (quintile 3); and (iii) Least disadvantaged (quintiles 4 and 5) [17]. Women with correct knowledge of the national guidelines (that no alcohol is safest); agreement ('agreed' or 'strongly agreed') with each of the three health-related statements; and pre-pregnancy alcohol use were also identified. Non-drinkers were omitted because the reasons for their abstinence (e.g. culture and religion [5]) would unlikely be useful for informing future prevention strategies for women who do consume alcohol.

Statistical analysis

Analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were reported for the total cohort, and stratified by non-drinkers, stopped drinking and ongoing drinkers. Associations between pre-pregnancy drinking (AUDIT-C risk category) and drinking during pregnancy (AUDIT-C, special occasion drinking, whether they stopped or continued drinking during pregnancy) were examined using chi-square tests. Demographic characteristics of the three groups were compared using one-way analysis of variance for continuous variables and Tukey's Honestly Significant Difference test post-hoc. The Kruskal-Wallace H test was used for non-parametric data and Pearson's chi-square tests for categorical data (using standardised residuals for post-hoc testing where there was >1° of freedom). For categorical data where ≥20% of cells had an expected count <5, Fisher's exact test was used.

Associations between demographic characteristics and guideline awareness/knowledge were explored using independent samples *t*-tests for continuous variables, and Pearson's chi-square tests for categorical variables. Characteristics of women who were aware (versus unaware) of the national guidelines, and between women who could correctly (versus incorrectly) relay the recommendation that no alcohol is safest in pregnancy were examined, and characteristics which differed between groups at $P < 0.20$ were used in forced-entry logistic regression models. Characteristics explored as independent predictors of guideline awareness and knowledge were age, education level, first pregnancy, index of disadvantage, pre-pregnancy drinking level and whether women stopped or continued to consume alcohol during pregnancy.

Frequencies of agree/unsure/disagree responses were recorded for the three health-related statements. Associations between drinking patterns pre-pregnancy and post-pregnancy recognition and agreement with the statements were explored using Pearson's chi-square tests for categorical data (using standardised residuals for post-hoc testing). For categorical data where ≥20% of cells had an expected count <5, Fisher's exact test was used.

Differences in characteristics between the women with ongoing drinking versus those who stopped were assessed using chi-square tests for categorical variables or independent samples t-tests for continuous variables, and only those characteristics which were statistically different between the groups at $P \leq 0.20$ were considered for inclusion as potential predictors. Strength of correlation between variables was examined using Kendall's tau or Spearman's rank order correlation. Variables which were not strongly correlated (correlation coefficient < 0.50) were used in a forced entry (multivariable) logistic regression model. To account for multiple tests, statistical significance was defined as $P < 0.01$.

Results

The demographic details for the cohort of 1179 women are presented in Table 1. The proportions of

Table 1. *Demographics of the cohort of women presenting to antenatal services* (n = *1179)*

Characteristic	Total cohort ($n = 1179$)	Non-drinkers ($n = 244$)	Stopped drinking ($n = 767$)	Ongoing drinkers ($n = 168$)	Notes
Age, years					*P* value: differences between non-drinkers, stopped drinking and ongoing drinkers $F(2,1176) = 21.77$, $P < 0.0001$*, Eta^2: 0.04
Mean ± SD	29.28 ± 5.33	28.8 ± 5.6	28.9 ± 5.2	31.7 ± 5.0[a]	
Median (range)	29 (18–46)	29 (18–42)	29 (18–44)	31 (19–46)	
IQR	26–33	25–33	25–33	29–35	
Marital status, n (%)	$n = 1178$		$n = 766$		χ^2: 5.92, $P = 0.21$, Cramer's V: 0.05
Never married	110 (9.3)	26 (11)	76 (10)	8 (5)	
Married/living together	1030 (87.4)	208 (85)	668 (87)	154 (92)	
Separated/divorced	38 (3.2)	10 (4)	22 (3)	6 (4)	
First pregnancy, *n* (%)	493 (41.8)	77 (32)[a]	349 (46)	67 (40)	χ^2: 15.10, $P < 0.001$*, Cramer's V: 0.11
Education level completed, n (%)					χ^2: 14.21, $P = 0.01$*, Cramer's V: 0.08
High school or less	364 (30.9)	91 (37)	237 (31)	36 (21)[a]	
Technical certificate or diploma	416 (35.3)	69 (28)	278 (36)	69 (41)	
Uni/college degree or higher	399 (33.8)	84 (34)	252 (33)	63 (38)	
Employment status, n (%)					χ^2: 60.98, $P < 0.0001$*, Cramer's V: 0.16
Employed FT	327 (27.7)	43 (18)[a]	239 (31)	45 (27)	
Employed PT/casual	340 (28.8)	62 (25)	219 (29)	59 (35)	
Unemployed	112 (9.5)	32 (13)	70 (9)	10 (6)	
Cannot work: health reasons	11 (0.9)	4 (2)	5 (1)	2 (1)	
Home duties	199 (16.9)	69 (28)[a]	109 (14)	21 (13)	
Student	37 (3.1)	11 (5)	23 (3)	3 (2)	
Other	2 (0.2)	0	2 (0.3)	0	
Mat leave: FT employed prior	77 (6.5)	6 (3)[a]	54 (7)	17 (10)	
Mat leave: PT employed prior	74 (6.3)	17 (7)	46 (6)	11 (7)	
Aboriginal/Torres Strait Islander origin, *n* (%)	72 (6.1)	20 (8)	45 (6)	7 (4)	χ^2: 3.04, $P = 0.22$, Cramer's V: 0.05
Index of disadvantage, n (%)					χ^2: 9.45, $P = 0.05$, Cramer's V: 0.06
Most disadvantaged	507 (43.0)	111 (46)	334 (44)	62 (37)	
Mid disadvantaged	392 (33.2)	83 (34)	258 (34)	51 (30)	
Least disadvantaged	280 (23.7)	50 (21)	175 (23)	55 (33)[a]	
Women's geographical remoteness, n (%)					$P = 0.45$
Major city	862 (73.1)	180 (74)	553 (72)	129 (77)	
Inner/outer Regional/remote Australia	317 (26.9)	64 (26)	214 (28)	39 (23)	
Pregnancy risk level,[b] *n* (%)					Fisher's exact test: 13.42, $P = 0.01$*, Cramer's V: 0.08
High risk	414 (35.1)	105 (43)[a]	253 (33)	56 (33)	
Low risk	743 (63.0)	131 (54)	501 (65)	111 (66)	
No risk level determined (AMIHS)	22 (1.9)	8 (3)	13 (2)	1 (1)	

*Statistical significance indicated by $P < 0.05$. [a]Indicates values which were significantly different to others, based on standardised residuals. [b]Pregnancy risk level was based on antenatal service used (High risk: Medical clinic, women with vulnerabilities, women with complex medical needs; Low risk: Midwives clinic, midwifery group practice); Non-drinkers group includes three women who were missing pre-pregnancy AUDIT-C data but who did not drink during pregnancy. Comparisons between the three groups were made using one-way analysis of variance for continuous variables and Tukey's Honestly Significant Differences test post-hoc. The Kruskal-Wallace H test was used for non-parametric data, and Pearson's chi-square tests for categorical data (using standardised residuals for post-hoc testing). Fisher's exact test was used for categorical data where ≥20% cells had an expected count <5. AMIHS, Aboriginal maternal infant health; FT, full time; IQR, interquartile range; PT, part time.

women in our cohort from each geographic region was comparable to the NSW female population in 2016 data [available at: http://www.healthstats.nsw.gov.au/Indicator/dem_pop_aria (Accessed 8 Feb 2021)]: Major cities 73.1% (our cohort) vs. 75.0% (NSW); Regional/remote: 26.9% (our cohort) versus 25.0% (NSW) (Table 1).

Alcohol use before and after pregnancy recognition

Of the 1179 women, 244 (20.7%) were classified as non-drinkers during pregnancy. Table 2 shows the patterns of drinking (AUDIT-C risk classification) in 1176 women during pregnancy [three 'non-drinkers' had missing pre-pregnancy drinking (AUDIT-C) data]. Most women were low- or medium-risk drinkers prior to pregnancy (57.1%), with similar proportions reporting no drinking (20.9%) or high-risk drinking (22.0%). Nine-hundred and thirty-five (79.3%) reported drinking before pregnancy: 767 (82.0%) of these stopped drinking following pregnancy recognition and 168 (18.0%) continued drinking (14.2% of the total sample). One woman who continued drinking reported high-risk drinking.

Most women stopped drinking regardless of their pre-pregnancy drinking risk level, although five women who reported no drinking prior to pregnancy reported drinking after pregnancy recognition (2.0%).

Special occasion drinking after pregnancy recognition

In the ongoing drinking group, most (66.7%) reported alcohol use when asked the AUDIT-C; however, the remaining 33.3% only reported drinking alcohol when asked about drinking on special occasions (Table 2). Of the 168 women who reported drinking after pregnancy recognition, 103 (61.3%) reported special occasion drinking. Of these, 56 (54.4%) women reported special occasion drinking only and did not report any alcohol consumption when asked using the AUDIT-C (Table 2). Pre-pregnancy non-drinkers and low-risk drinkers also reported special occasion drinking, with 1.2% and 3.6% respectively reporting only special occasion drinking during pregnancy (Table 2). The

Table 2. *Drinking patterns before and during pregnancy* (n = *1176)*

	Pre-pregnancy drinking (AUDIT-C)				
Drinking during pregnancy	No risk ($n = 246$)	Low risk ($n = 333$)	Medium risk ($n = 338$)	High risk ($n = 259$)	Sig
AUDIT-C, n (%)					Fisher's exact: 87.57, $P < 0.0001$*, Cramer's V: 0.19
No exposure	241 (98)	302 (91)	278 (82)	187 (72)	
Low to medium risk exposure	5 (2)[a]	31 (9)	60 (18)	71 (27)[a]	
High risk exposure	0	0	0	1 (0.4)	
Drank on special occasions, *n* (%)	4 (2)[a]	20 (9)	39 (16)	40 (22)[a]	χ^2: 34.33, $P < 0.0001$*, Cramer's V: 0.20
Classification, n (%)					χ^2: 1190.53, $P < 0.0001$*, Cramer's V: 0.71
Non-drinker ($n = 241$)	241 (98)[a]	0[a]	0[a]	0[a]	
Stopped drinking ($n = 767$)	0[a]	302 (91)[a]	278 (82)[a]	187 (72)	
Ongoing drinking:					
Continued drinking ($n = 112$)	2 (1)[a]	19 (6)[a]	43 (13)	48 (19)[a]	
Special occasion only drinking ($n = 56$)	3 (1)[a]	12 (4)	17 (5)	24 (9)[a]	

*Statistical significance indicated by $P < 0.05$. [a]Indicates values which were significantly different to others, based on standardised residuals. Non-drinker group in this table does not include three women who had missing pre-pregnancy AUDIT-C data. AUDIT-C score categories prior to pregnancy: No risk (score of 0), Low risk (score of 1–2), Medium risk (score of 3 to 4), High risk (score ≥ 5) [20]. AUDIT-C risk categories during pregnancy were as follows: score 1 to 4 = 'Low to medium risk exposure', scores ≥5 = High risk [21]. Special occasion drinking was accounted for in these figures. AUDIT-C, Alcohol Use Disorders Identification Test–Consumption.

number of special occasions at which alcohol was consumed ranged from 1 to 10 (median: 1, interquartile range: 1–2), and 91.3% drank 1–2 standard drinks per special occasion. Eight women (7.8%) drank 3–4 drinks per special occasion and one woman (1.0%) reported consuming 5–6 per special occasion.

Characteristics according to alcohol use behaviour during pregnancy

Non-drinkers were more likely than other groups to be undergoing their first pregnancy and to list 'Home duties' as their employment status (with fewer employed full-time, including prior to maternity leave). A higher proportion of non-drinkers had high-risk pregnancies, based on antenatal service type use (Table 1). Being of Aboriginal origin was not associated with alcohol use behaviour in pregnancy (non-drinker/stopped drinking/ongoing drinking; $P = 0.22$), and a higher proportion of Aboriginal women were non-drinkers (27.8%) compared to non-Aboriginal women (20.2%; $P = 0.13$). Ongoing drinkers were older ($P < 0.0001$) and more likely to have attained an education level beyond high school than the other groups ($P = 0.01$; Table 1).

Awareness of guidelines and ability to correctly relay the key recommendation

Of women, 63.6% (748/1177) were aware of national guidelines on alcohol use during pregnancy but 21.9% of these women (163/745) were unable to correctly relay the recommendation that no alcohol is safest.

Of women who reported awareness of the guidelines, 78.1% (582/745) knew the guidelines recommended abstinence from alcohol, but 17.3% were 'not sure' about that recommendation, and 4.6% of women said they believed the guidelines stated that some alcohol was acceptable. There was no association between correct knowledge of the key guideline recommendation and whether a woman stopped or continued drinking during pregnancy ($P = 0.28$).

Characteristics of women who were aware versus unaware of the national guidelines ($n = 934$)

Based on standardised residuals, there was a trend towards more high-risk drinkers (pre-pregnancy) and fewer medium risk drinkers being unaware of the guidelines (low-risk: 37.0%; medium-risk: 30.2%; high-risk: 40.2%; χ^2: 6.98; $P = 0.031$). No other significant differences were observed between the aware/unaware groups, although education level met our criteria for inclusion in a logistic regression model with $P < 0.20$ (χ^2: 3.74; $P = 0.154$). Education level and pre-pregnancy drinking level were entered into a forced-entry logistic regression model with guideline awareness ('yes' =0; 'no/unsure' =1) as the dependent (predicted) variable (model $P = 0.04$; Nagelkerke R^2: 0.014). This showed that pre-pregnancy drinking level was a significant predictor of awareness of the national guidelines [low-risk: referent; medium risk: odds ratio (OR) 0.73 (95% confidence interval [CI] 0.53–1.01; $P = 0.060$); high-risk: OR 1.12 (95% CI 0.80–1.57; $P = 0.498$); $P = 0.038$]. Education level did not predict guideline awareness ($P = 0.253$).

Characteristics of women who correctly versus incorrectly relayed the key guideline recommendation ($n = 599$)

Women who were unable to correctly relay the key guideline recommendation were less likely to have a university/college degree or higher (22.6%) and were more likely to have completed high school or less (39.5%) (χ^2: 14.8; $P = 0.001$). There was a trend for this group to be younger than those who could correctly relay the guideline recommendation (correct: 29.6 ± 5.1 years; incorrect/unsure: 28.7 ± 5.6 years; $P = 0.098$). The groups did not differ in other characteristics at $P < 0.20$. Education level and age were entered into a forced-entry logistic regression model with guideline knowledge ('correct' = 0; 'incorrect' = 1) as the dependent variable (model $P = 0.002$; Nagelkerke R^2: 0.039). This showed that women with lower education levels were more likely to relay the key guideline recommendation incorrectly [high school or less: OR 2.60 (95% CI 1.51–4.48; $P = 0.001$); technical certificate or diploma: OR 1.89 (95% CI 1.11–3.11; $P = 0.019$; university/college degree or higher: referent); $P = 0.003$]. In this model, age was not a significant predictor of knowledge [OR 0.99 (95% CI 0.95–1.03); $P = 0.640$].

Agreement with the three health-related statements

Almost all women strongly agreed or agreed with three health-related statements as read to them, particularly with the statement that not drinking alcohol is the safest option during pregnancy (Table 3). Compared to non-drinkers and women who stopped drinking, a higher proportion of ongoing drinkers disagreed with or were unsure of their agreement with the statements (Table 3).

Table 3. *Women's agreement with three health-related statements from the national guideline for alcohol use in pregnancy*

	Non-drinking ($n = 243$), n (%)	Stopped drinking ($n = 766$), n (%)	Ongoing drinkers ($n = 168$), n (%)	Sig
Agreement: Not drinking alcohol is the safest option during pregnancy ($n = 1177$)				Fisher's exact: 35.84, $P < 0.0001$*, Cramer's V: 0.16
Strongly agree/agree	242 (99.6)	765 (99.9)	156 (92.9)	
Unsure	1 (0.4)	1 (0.1)[a]	10 (6.3)[a]	
Disagree	0	0	2 (1.2)[a]	
Agreement: Not drinking alcohol during pregnancy is one of the most important things I can do for my baby's health ($n = 1177$)			$n = 143$	Fisher's exact: 62.62, $P < 0.0001$*, Cramer's V: 0.20
Strongly agree/agree	242 (99.6)	756 (98.7)	143 (85.1)	
Unsure	0[a]	8 (1.0)	12 (7.1)[a]	
Disagree/strongly disagree	1 (0.4)	2 (0.3)[a]	13 (7.7)[a]	
Agreement: Pregnancy is a good time for women to change their alcohol use to improve their own health ($n = 1177$)				Fisher's exact: 18.60, $P < 0.001$*, Cramer's V: 0.10
Strongly agree/agree	233 (95.9)	745 (97.3)	150 (89.3)	
Unsure	5 (2.1)	12 (1.6)	11 (6.5)[a]	
Disagree/strongly disagree	5 (2.1)	9 (1.2)	7 (4.2)[a]	

*Statistical significance indicated by $P < 0.05$ using Pearson's chi-square tests. [a]Indicates values which were significantly different to others, based on standardised residuals.

Predictors of ongoing alcohol use during pregnancy

Bivariate analyses showed that women in the ongoing drinking group were older than those who stopped drinking ($P < 0.0001$). Additionally, higher proportions in the ongoing drinking group were 'Unsure' or disagreed with each of the three health-related statements compared to those in the stopped drinking group ($P < 0.0001$; Table 3). Other characteristics included as predictor variables (with $P \leq 0.20$) were education level completed ($P = 0.05$), first pregnancy ($P = 0.184$) and index of disadvantage ($P = 0.071$).

No strong correlations were found between the predictor variables above (correlation coefficients <0.5). Therefore, they were all used in a forced entry multivariable logistic regression model (Model χ^2: 145.70, Nagelkerke $R^2 = 0.240$, $P < 0.0001$) (Table 4).

Discussion

This study addresses gaps in previous research relating to predictors of ongoing alcohol use in pregnancy, including the relationship between drinking and knowledge of and agreement with national guidelines and health-related statements. Reported rates of alcohol use are amongst the highest reported globally [5]. Older age, disagreement with/uncertainty about health-related statements related to alcohol use in pregnancy, and medium- or high-risk alcohol use prior to pregnancy predicted ongoing alcohol use during pregnancy. Of all women, 63.6% were aware of the national guidelines on alcohol use in pregnancy, 49.4% of all women knowing the recommendation that abstinence is safest.

Of the pregnant women recruited from public antenatal clinics, 79.0% reported drinking in the 12 months prior to pregnancy. Prior drinking is a predictor of drinking during pregnancy. As many pregnancies are unplanned there is potential for prenatal exposure in these pregnancies. This rate is higher than similar Australian and international studies [8,11]. A higher proportion of women were in the most disadvantaged socio-economic status group, which may in part account for higher rates of alcohol use prior to pregnancy. However, national data suggest that women in the highest socio-economic status and educational groups are more likely to continue alcohol use in pregnancy [24]. Our finding may also be related to higher rates of alcohol consumption amongst women in the Hunter New England Local Health District compared with the state average [25].

The study also demonstrated the importance of detailed questioning. The special occasion drinking

Table 4. *Multivariable logistic regression model details: Predictors of ongoing drinking during pregnancy*

Independent (predictor) variables	OR (95% CI)	*P*
Age	1.11 (1.07–1.15)	<0.0001*
Education completed		0.82
High school or less	0.91 (0.54–1.52)	0.72
Technical certificate or diploma	1.07 (0.68–1.66)	0.78
Uni/college degree or higher (ref)		
First pregnancy	0.89 (0.60–1.34)	0.58
Index of disadvantage		0.15
Most disadvantaged	0.68 (0.43–1.08)	0.11
Mid-disadvantaged	0.65 (0.40–1.05)	0.08
Least disadvantaged (ref)		
Agreement: Not drinking alcohol is the safest option during pregnancy	0.05 (0.006–0.47)	0.01*
Agreement: Not drinking alcohol during pregnancy is one of the most important things I can do for my baby's health	0.14 (0.06–0.31)	<0.0001*
Agreement: Pregnancy is a good time for women to change their alcohol use to improve their own health	0.29 (0.13–0.63)	0.002*
Pre-pregnancy drinking level		<0.0001*
Low risk (ref)		
Medium risk	2.42 (1.46–4.00)	0.001*
High risk	3.93 (2.35–6.56)	<0.0001*

*Statistical significance indicated by $P < 0.01$ and 95% CI excluding one. Agreement variables used in the model were binary [agree vs. unsure/disagree (referent)]. CI, confidence interval; OR, odds ratio.

question detected that one-third (33.3%) of the women with ongoing alcohol consumption during pregnancy would have been missed if the AUDIT-C alone was used. A similar method of questioning was used in the AQUA study, resulting in the detection of binge drinking in an additional 6.2% of women after conception but prior to pregnancy recognition [11]. In our study, we asked women to report any special occasions where any amount of alcohol was consumed, while in the AQUA study women were asked to report special occasions (or difficult times) where they consumed more than their usual amount of alcohol [where binge drinking (≥50 g AA per occasion) was reported] [11]. We showed that most pregnant women (91.3%) consumed alcohol at low levels at special occasions (one to two drinks). No safe level of prenatal alcohol exposure has been established, even when alcohol use ceases upon pregnancy recognition, and data suggest that even low levels of prenatal alcohol exposure can affect brain development, resulting in psychological and behavioural problems [26] and facial dysmorphology [11]. An under-estimate of alcohol consumption in pregnancy may have occurred in previous studies which did not include questions on special occasion drinking [5]. Further investigations of different measures (including measure types and wording) and their impact on responses are warranted in this population.

Although compliance with the NHMRC guidelines was previously reported [12,27], this study was the first to explore pregnant women's knowledge of and agreement with the then (2009) national guidelines on alcohol use in pregnancy. Although 63.6% of women were aware of the guidelines, one-fifth of those women were unable to correctly relay the key recommendation. Half of all women were either unaware of or unable to correctly relay the key recommendation. This highlights a large gap in knowledge about public health recommendations that should be investigated and addressed. Women without tertiary levels of education were less likely to relay the key recommendation correctly, suggesting the need for education about alcohol harms in pregnancy in schools to ensure these women are informed. Women with tertiary education were more likely to continue drinking during pregnancy regardless of knowledge of the potential harms, presenting challenges for effective alcohol interventions in this subpopulation. Further studies should seek to identify what factors influence these behaviours despite knowledge of alcohol harm, including attitude/belief-change strategies at a societal level [6].

Women who continued to drink throughout pregnancy were less likely to agree with the health-related statements than women who stopped drinking. They were also older and drank at higher risk levels before pregnancy recognition, consistent with previous reports [6,8–10]. A 2006 survey of non-pregnant Australian women revealed that intention to consume alcohol in a future pregnancy was higher in women with: neutral or positive attitudes towards alcohol use in pregnancy; a history of alcohol consumption during a previous pregnancy and higher and more frequent current alcohol use [6]. In our study, agreement with any of the individual health-related statements was a strong predictor of alcohol cessation in pregnancy, independent of prior or correct knowledge of the guideline's key recommendation.

The low correlation between knowledge, attitude and behaviour change has been long recognised [28]. Indeed, public health interventions aimed at reducing alcohol consumption and/or increasing pregnant women's knowledge about potential harms of alcohol have not

translated to significant changes in alcohol use [29,30]. Efforts to lower rates of alcohol use in pregnancy must include a focus on both attitude and behaviour change, and raising awareness about the public health recommendations, amongst other prevention strategies [31]. This could be achieved through targeted support of women who consume alcohol so that individual attitudes can be accommodated in interventions such as motivational interviewing. Change beyond the individual is also required: to 'culture' and what is considered socially acceptable/favourable, considering lessons from the anti-smoking campaign strategies [32].

The positive attitudes pregnant women have towards drinking in pregnancy are influenced by personal experiences of their own or of family and friends [33,34]; relaxation or stress relief [33]; and by their perceptions of confusing and inconsistent advice [33,35]. This poses major challenges to attitude change, as it is common for people to reject a message that contradicts their existing attitudes/beliefs [36]. Additionally, pre-pregnancy drinking (a strong risk factor for alcohol use during pregnancy) may reflect habitual behaviour, which is also difficult to change [10]. Devising multifaceted strategies to effectively challenge these attitudes is warranted, and would need to be pervasive, consistent and sustained.

Education campaigns, resources and systems have been developed for health professionals [e.g. *Women Want to Know* (http://fare.org.au/women-want-to-know/), *Alcohol and Pregnancy Project* [37], *FASD Australia Hub* (www.fasdhub.org.au)]. Our current project [38] aims to improve professionals' knowledge, skill and confidence in asking and advising women about alcohol use in pregnancy. Clinical practice improvements must be supported by the antenatal service environment (e.g. electronic prompts and standardised procedures and care pathways) and ongoing in-house education [39] to encourage embedded, standardised and consistent practice. Underpinning these efforts must be legislative change to enable evidence-based, community-wide interventions proven to minimise alcohol harms [31].

Limitations of this study included the potential for recall and reporting bias in reported alcohol use and reliance on self-report of alcohol use; excluding women under the care of a private provider for their antenatal care; and our high proportion of mostly disadvantaged women. Another potential limitation was the participation of 57% of all eligible women identified. Study strengths included the randomly selected, large sample of pregnant women recruited through public antenatal services covering three geographical areas, the use of an open-ended question to assess knowledge of the guideline's key recommendation (that no alcohol is safest), and the inclusion of questions about special occasion drinking during pregnancy which detected alcohol use by women who would otherwise have been classified as non-drinkers during pregnancy using the AUDIT-C alone.

Conclusion

Compared to women who ceased drinking alcohol during pregnancy, women who continued were older, consumed alcohol at medium or high-risk levels pre-pregnancy, and were less likely to agree with the health-related statements about alcohol use during pregnancy. This indicates ineffectiveness of existing public health messaging and the need for evidence-based campaigns and interventions which are subsequently evaluated.

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Conflict of Interest

None to declare.

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APPENDIX 5. Written information and health professionals are the information sources about alcohol use in pregnancy most often used by pregnant women

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Written information and health professionals are the information sources about alcohol use in pregnancy most often used by pregnant women

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Abstract

Introduction: Alcohol use in pregnancy remains common in Australia, despite national guidelines recommending that pregnant women abstain. The aims of this study were to investigate where pregnant women obtain information about alcohol use in pregnancy and the relationship between the information source used and women's demographic characteristics and alcohol use.

Methods: In this cross-sectional survey of pregnant women attending public maternity services in the Hunter New England region (New South Wales), women were asked, 'Where did you get information to help you make decisions about alcohol use during pregnancy?'. The number and types of information sources were analysed using descriptive statistics. Associations between women's information sources, and their demographic characteristics and alcohol use in pregnancy were assessed using chi-square tests and logistic regression.

Results: Of 4511 pregnant women surveyed, 80.1% used at least one type of information source (range 0–5). Written/electronic information (45.4%), health providers (37.6%) and family/friends (19.5%) were the sources most reported. Higher use of written/electronic information, antenatal health providers and family/friends was associated with first pregnancy, younger age and higher education. The type of information source used was associated with alcohol use in pregnancy. Women who reported alcohol use were more likely to receive information from written/electronic sources. Almost 20% of women (older, multiparous [>1 pregnancy] and more highly educated) obtained no information regarding alcohol use in pregnancy.

Discussion and Conclusions: Antenatal providers should routinely provide information on alcohol use in pregnancy, including for women least likely to access available information.

KEYWORDS
alcohol consumption, antenatal care, consumer, health information, pregnancy

1 | INTRODUCTION

Prenatal alcohol exposure (PAE) can result in adverse outcomes for the pregnancy and child, including miscarriage, stillbirth, prematurity and neurodevelopmental and behavioural disorders such as foetal alcohol spectrum disorder (FASD) [1, 2]. In Australia and internationally, guidelines to prevent foetal harm from PAE recommend that women do not consume alcohol during or when planning pregnancy [3]. Worldwide, approximately 10% of pregnant women use alcohol, rates differing by country and socio-economic status [2]. In Australia PAE rates of 35% to 82% are reported [4–7]. Women who are older and who regularly consume alcohol at medium to high-risk levels (including binge drinking) before pregnancy are more likely to consume alcohol during pregnancy [4, 8–10].

Reportedly, one reason that women consume alcohol during pregnancy is lack of awareness of harms or misinformation/misconceptions about alcohol use in pregnancy [11, 12]. In our previous study, we found that 78.1% of pregnant women who were aware of national guidelines on alcohol use during pregnancy knew that abstaining from alcohol in pregnancy was safest [10]. However, few studies to date have reported the source(s) of information used by women to obtain information about alcohol consumption in pregnancy. Identifying where women obtain information on health risk behaviours during pregnancy can assist in determining if information is obtained from authoritative sources (e.g., government guidelines, healthcare professionals) and whether there is opportunity to reinforce guideline recommendations in information sources commonly used by women.

Two international studies have explored the sources of information on alcohol use in pregnancy used by pregnant women. In a Danish study of 439 pregnant women, only 16.2% reported receiving information about alcohol use in pregnancy from their health professional (general practitioner, midwives and obstetricians) [13]. More women reported receiving information from mass media (65%) and relatives (40%) [13]. In an Israeli study ($N = 802$) 60.5% of pregnant women reported that they received education about alcohol use in pregnancy from a public or private physician (37.4%), nurse (17.2%) or social media (5.9%) [14]. Neither study reported associations between the use of different types of information sources and women's characteristics, including their alcohol consumption during pregnancy.

No studies have reported on the information sources used by Australian pregnant women regarding alcohol consumption. Two studies, however, have reported on where non-pregnant women obtain such information. In the first, a study of 1103 non-pregnant women of childbearing age, it was found that although women preferred to receive information about alcohol use in pregnancy from their health professional, women mainly obtained information from brochures (16%) and media programs/articles (13%) [15].

In the second, a retrospective study involving 317 pregnant women in Victoria, Australia, 55.8% of women reported receiving preconception health information from their health professional, although women aged <25 years or with an unplanned pregnancy were less likely to access such information [16]. The preconception information received included advice on drug and alcohol cessation [16], but neither the proportion of women receiving information specific to alcohol use nor their use of other information sources was reported.

Neither of these studies reported on the information sources used by women once they were pregnant and neither sought to determine associations between the types of information sources used and the characteristics of women, including their demographics and their alcohol use. Such information is required to inform public health strategies to improve adherence to national recommendations and reduce rates of PAE and its consequences.

Thus, the aims of the current study were to identify the:

1. number and type of information sources that pregnant Australian women used to obtain information and advice about alcohol use in pregnancy;
2. associations between characteristics (clinical, demographic) of pregnant women and the number and types of information sources used regarding alcohol use in pregnancy; and
3. associations between number and type of information sources used and women's alcohol use during pregnancy.

2 | METHODS

2.1 | Design

Cross-sectional survey (July 2017 to November 2019) with pregnant women attending public maternity services in three sectors (covering metropolitan, regional and rural areas) of the Hunter New England Local Health District in New South Wales.

2.2 | Inclusion/exclusion criteria

All women who attended public antenatal services in the participating sectors of the Hunter New England Local Health District were eligible to participate if they were at

least 18-years-old, pregnant at 12 to <38 weeks gestation and able to complete the survey in English [17]. Women were excluded if they were receiving antenatal care through a private provider, had already given birth or had a negative pregnancy outcome [17].

2.3 | Recruitment

Eligible women were identified using electronic medical records and antenatal appointment data [10, 17]. Every week between 17 July 2017 and 25 November 2019, a sample of 105 women was selected using a computerised, random number generator and mailed a participant information statement. Aboriginal women were contacted by text message 4 days after the letter was sent and invited to participate in the survey via computer assisted telephone interview (CATI) or online. Non-Aboriginal women were contacted by telephone 7 days after the letter was sent and invited to complete the survey via telephone or if the telephone interview was declined, online [17]. Up to 10 attempts to contact women were made over a 2-week period.

2.4 | Data collection and measures

Data from CATI and online surveys were collected using REDCap [18, 19]. CATI surveys were undertaken by trained, experienced female interviewers [17]. Survey questions were based on previous Australian surveys [5, 7, 20] and were co-developed, piloted and reviewed for cultural appropriateness by the study's Cultural Review Group, led by Aboriginal and Torres Strait Islander women.

Women reported their demographic and clinical details, including age, level of education, Aboriginal or Torres Strait Islander origin, and parity. Women's residential postcodes were obtained from electronic medical records to determine area index of disadvantage based on the Socio-Economic Indexes for Areas [21] and remoteness, based on the accessibility/remoteness index of Australia [22].

Women reported their alcohol consumption during the 12 months before pregnancy and since pregnancy recognition using the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) tool [23]. Special occasion drinking during pregnancy was assessed by asking women, 'Were there any special occasions (e.g., a wedding, anniversary, birthday) since you found out you were pregnant where you consumed any alcohol?'.

Regarding sources of information on alcohol use in pregnancy, women were asked the open-ended question: 'Where do you get information from to help you make decisions about alcohol use during pregnancy?'.

2.5 | Analysis

Condensed response categories were created for the following demographics of pregnant women: Aboriginal and Torres Strait Islander origin (yes/no), education level (high school or less/technical certificate or diploma/university or college degree or higher), first pregnancy (yes/no), index of disadvantage (most/mid/least disadvantaged), remoteness (regional or remote/major city) and age (≤24 years/≥25 years). For alcohol use measures, total AUDIT-C score was classified as no risk (score = 0), low-medium risk (score = 1–4) or high risk (score ≥5) [24], and special occasion drinking as yes/no.

For Aim 1, the information sources used by pregnant women to obtain information about alcohol use in pregnancy were classified using thematic analysis [25]. The data collected from the CATIs were reviewed and initial codes generated by the study team. If multiple information sources were reported by a participant, each information source was classified separately. Initial codes were then reviewed and collated if appropriate (by Tracey W. Tsang, Melanie Kingsland, Emma Doherty, reviewed by all co-authors), resulting in the 12 classifications listed below.

1. Antenatal health provider: any antenatal health provider or health service/clinic, antenatal and parenting courses, community health service, Aboriginal Maternal and Infant Health Services, Aboriginal Community Control Health Organisation, hospital doctor, nurse, fertility specialist.
2. Other health provider: naturopath, psychologist, Mothersafe, counsellor, psychiatrist, pharmacist, Australian Breastfeeding Association.
3. Family and friends.
4. Colleagues: workplace colleagues, support groups, work-related knowledge.
5. Written information—Health: health service websites and materials, research studies, hospital posters, guidelines, textbooks.
6. Written information—Alcohol industry: labels on alcohol products.
7. Written information—Undefined: internet, books, brochures/pamphlets.
8. Media: traditional and social media, apps.
9. Self-knowledge/education: studies (university/school/course), common sense, culture/religion, community, family/personal experience, non-drinker.
10. Other sources: cannot be classified in above categories (e.g., 'course', 'classes', 'community centre').

11. Unknown: information was obtained but respondent could not recall the source.
12. None: No information was sought.

Descriptive statistics were used to describe the number and proportion of information sources used. Any information source type from the list of 12 above which was used by ≥20% women was considered among the most frequently used source types and explored in the subsequent analyses (Aims 2 and 3).

For Aim 2, the relationships between types of information sources used and demographic/clinical characteristics of pregnant women were assessed using a two-step process. First, bivariate analyses (Pearson's chi-square tests, Pearson's chi-square test, Mann–Whitney *U* tests on medians, Kruskal–Wallis tests with Dunn's pairwise post-hoc tests or Kendall rank correlation) were used. Subsequently, multivariate analysis using individual variables found in the above analyses to be related to each information source at $p < 0.20$, were included as predictor variables in forced-entry binary logistic regression models, with the information source type as the dependent (predicted) variable.

For Aim 3, bivariate analyses were used to test for associations between the type/number of information sources used and alcohol use during pregnancy (AUDIT-C and special occasion drinking). Chi-square or Fishers exact tests were used for categorical variables (source type), and Mann–Whitney *U* and Kruskal–Wallis tests for continuous variables (number of information sources). Results were considered statistically significant at $p < 0.05$. Analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA).

3 | RESULTS

3.1 | Participant characteristics

A total of 8078 pregnant women were randomly selected to participate in the survey. On the day of attempted contact, 7481 (92.6%) remained eligible to participate based on medical record data indicating they had not given birth or had a negative pregnancy outcome. Of the 5747 (76.8%) women who could be contacted, 5590 (97.3%) were deemed eligible. Of these women, 4637 (83.0%) consented and 4511 (80.7%) completed the survey by CATI (4438) or online (73).

Demographic characteristics of participants are presented in Table 1. Of the 4511 women who participated in the survey, most were aged 26 to 33 years, resided in a major city (70.4%), were employed full- or part-time (70.5%), had completed tertiary education (70.6%), were multiparous (i.e., had given birth more than once; 60.7%) and were in the most (46.0%) or mid-disadvantaged (31.2%) group for socio-economic status. Aboriginal

TABLE 1 Respondent demographics ($N = 4511$)

Characteristic	Total cohort ($N = 4511$)
Age, years	
Mean ± SD	29.6 ± 5.2
Median (range)	30 (18–51)
Interquartile range	26–33
Aboriginal or Torres Strait Island background, *N* (%)	($N = 4508$) 276 (6.1)
First pregnancy, *N* (%)	($N = 4510$) 1771 (39.3)
Education level completed, *N* (%)	($N = 4508$)
High school or less	1326 (29.4)
Technical cert or diploma	1601 (35.5)
Uni/college degree or higher	1581 (35.1)
Index of disadvantage (NSW 2016), *N* (%)	($N = 4509$)
Most disadvantaged	2075 (46.0)
Mid disadvantaged	1409 (31.2)
Least disadvantaged	1025 (22.7)
Marital status, *N* (%)	($N = 4506$)
Never married	454 (10.1)
Married/living together	3938 (87.4)
Separated/divorced	111 (2.5)
Widowed	3 (0.1)
Remoteness, *N* (%)	($N = 4509$)
Major city	3174 (70.4)
Inner/outer regional	1327 (29.4)
Remote/very remote	8 (0.2)
AUDIT-C score pre-pregnancy[a], *N* (%)	($N = 4481$)
No risk	858 (19.1)
Low-medium risk	2694 (60.1)
High risk	929 (20.7)
AUDIT-C score during pregnancy[a], *N* (%)	($N = 4508$)
No risk	4059 (90.0)
Low-medium risk	447 (9.9)
High risk	2 (0)
Special occasion drinking during pregnancy, *N* (%)	($N = 4158$) 394 (9.5)

Abbreviations: AUDIT-C, Alcohol Use Disorders Identification Test-Consumption; NSW, New South Wales.

[a]AUDIT-C scores were categorised as follows: no risk (0), low-medium risk (1–4), high risk (≥5).

TABLE 2 Sources of information on alcohol use in pregnancy

Information source	Total cohort ($N = 4511$)
N information sources reported	($N = 4509$)
Mean ± SD	1.2 ± 0.9
Median (range)	1 (0–5)
Interquartile range	1–2
Written/electronic information, *N* (%)	($N = 4509$)
Health	61 (1.4)
Alcohol industry	12 (0.3)
Undefined	1970 (43.7)
Health provider, *N* (%)	
Antenatal ($N = 4509$)	1687 (37.4)
Other	9 (0.2)
Family/friends, *N* (%)	878 (19.5)
Traditional/social media, *N* (%) ($N = 4509$)	419 (9.3)
Self-knowledge/education, *N* (%)	($N = 4509$)
	243 (5.4)
Colleagues, *N* (%)	($N = 4509$)
	73 (1.6)
Unknown source, *N* (%)	($N = 4509$)
	36 (0.8)
Other source, *N* (%)	($N = 4509$)
	3 (0.1)
No information sought, *N* (%)	($N = 4509$)
	898 (19.9)

Note: NB. Several women used multiple sources of information so % does not add up to 100%.

women comprised 6.1% of participants. In the 12 months before pregnancy, 80.8% of women consumed alcohol, 20.7% of whom reported high-risk drinking (Table 1). The proportion of women who did not consume alcohol increased from 19.1% (in the 12-months before pregnancy) to 90.0% during pregnancy. When the AUDIT-C was used, 10.0% (449/4508) reported using alcohol during pregnancy. An additional 185 women were identified as consuming alcohol only at special occasions. These 185 women were classified as 'No risk' using the AUDIT-C and constituted 4.9% of the 'AUDIT-C: No risk' group.

3.2 | Number and type of information sources on alcohol use in pregnancy

Most (80.1%) women used at least one information source and the majority (72.5%) used 1–2 different sources to obtain information on alcohol use in pregnancy (range 0–5) (Table 2). Written/electronic information (45.4%) and information from health providers (37.6%) and family/friends (19.5%) were the most frequently reported information sources. The remaining information sources were used by <20%. Approximately one-fifth (19.9%) of women did not recall any information sources on alcohol use in pregnancy.

3.3 | Association between pregnant women's characteristics and use of information sources on alcohol use in pregnancy

Results of the logistic regression analyses are presented in Table 3.

3.3.1 | Written/electronic information

First pregnancy (odds ratio [OR] 1.21; 95% confidence interval [CI] 1.07 to 1.37; $p = 0.003$) and higher education level (high school or less: OR 0.59 [95% CI 0.51 to 0.70]; $p < 0.001$) were statistically significant predictors of use of written/electronic information on alcohol use in pregnancy.

3.3.2 | Antenatal health provider

Women in their first pregnancy (OR 1.21 [95% CI 1.06 to 1.37]; $p = 0.004$), of younger age (OR: 0.75 [95% CI 0.63 to 0.89]; $p = 0.001$), and with socioeconomic disadvantage ($p = 0.020$, Table 3) were more likely to identify an antenatal care provider as a source of information on alcohol use in pregnancy.

3.3.3 | Family/friends

Advice on alcohol use in pregnancy was more often obtained from family/friends by women who were in their first pregnancy (OR 1.48 [95% CI 1.27 to 1.72]; $p < 0.001$), younger (OR 0.77 [95% CI 0.63 to 0.95]; $p = 0.014$) and had university level education (compared to high school or less: OR 0.71 [95% CI 0.58 to 0.87]; $p = 0.004$) (Table 3).

3.3.4 | Did not seek any information

Women were significantly less likely to seek/recall information on alcohol use in pregnancy if they were multiparous (OR 0.75 [95% CI 0.64 to 0.88]; $p < 0.001$), attained

TABLE 3 Associations between women's characteristics and information sources on alcohol use in pregnancy

Predictor variables	Women reporting information source, %	OR (95% CI)	*p*
Written/electronic information: Model R^2: 0.027, $p < 0.001$*			
First pregnancy			0.003*
Yes	48.1	1.21 (1.07 to 1.37)	
No	43.4	-	
Index of disadvantage			0.183
Most disadvantaged	42.5	0.86 (0.73 to 1.01)	0.066
Mid disadvantaged	46.2	0.92 (0.78 to 1.08)	0.320
Least disadvantaged	49.7	-	
Education level completed			<0.001*
High school or less	36.5	0.59 (0.51 to 0.70)	<0.001*
Technical cert or diploma	46.3	0.87 (0.75 to 1.00)	0.052
Uni/college degree or higher	51.5	-	
Remoteness			0.092
Regional/remote	41.3	0.89 (0.77 to 1.02)	
Major city	46.9	-	
Aboriginal or Torres Strait Islander			0.679
Yes	40.0	0.95 (0.73 to 1.22)	
No	45.6	-	
Age			0.058
≥25 years	46.6	1.18 (0.99 to 1.41)	
≤24 years	38.9	-	
Antenatal health provider: Model R^2: 0.014, $p < 0.001$*			
First pregnancy			0.004*
Yes	40.6	1.21 (1.06 to 1.37)	
No	35.4	-	
Education level completed			0.287
High school or less	40.2	1.13 (0.96 to 1.33)	0.135
Technical cert or diploma	38.0	1.10 (0.95 to 1.28)	0.220
Uni/college degree or higher	34.5	-	
Aboriginal or Torres Strait Islander			0.149
Yes	44.0	1.20 (0.94 to 1.55)	
No	37.0	-	
Age			0.001*
≥25 years	35.6	0.75 (0.63 to 0.89)	
≤24 years	45.7	-	
Index of disadvantage			0.020*
Most disadvantaged	39.9	1.16 (0.99 to 1.36)	0.061
Mid disadvantaged	35.1	0.96 (0.81 to 1.14)	0.664
Least disadvantaged	35.4	-	
Family/friends: Model R^2: 0.018, $p < 0.001$*			
First pregnancy			<0.001*
Yes	23.7	1.48 (1.27 to 1. 72)	
No	16.7	-	

(Continues)

TABLE 3 (Continued)

Predictor variables	Women reporting information source, %	OR (95% CI)	*p*
Education level completed			0.004*
High school or less	17.3	0.71 (0.58 to 0.87)	0.001*
Technical cert or diploma	19.6	0.88 (0.73 to 1.05)	0.151
Uni/college degree or higher	21.3	-	
Age			0.014*
≥25 years	18.7	0.77 (0.63 to 0.95)	
≤24 years	23.0	-	
Aboriginal or Torres Strait Islander			0.062
Yes	23.2	1.33 (0.99 to 1.79)	
No	19.2	-	
Remoteness			0.165
Regional/remote	17.8	0.89 (0.75 to 1.05)	
Major city	20.2	-	
Did not seek any information: Model R^2: 0.016, $p < 0.001$*			
First pregnancy			<0.001*
Yes	16.6	0.75 (0.64 to 0.88)	
No	22.0	-	
Education level completed			<0.001*
High school or less	23.3	1.50 (1.24 to 1.81)	<0.001*
Technical cert or diploma	18.7	1.06 (0.89 to 1.28)	0.509
Uni/college degree or higher	18.2	-	
Index of disadvantage			0.189
Most disadvantaged	19.3	1.00 (0.82 to 1.21)	0.959
Mid disadvantaged	21.5	1.15 (0.94 to 1.41)	0.171
Least disadvantaged	18.8	-	
Age			0.004*
≥25 years	20.6	1.38 (1.11 to 1.71)	
≤24 years	16.6	-	

Abbreviations: CI, confidence interval; OR, odds ratio.
*$p < 0.05$.

an education level of high school or less (OR 1.50 [95% CI 1.24 to 1.81]; $p < 0.001$) and older (OR 1.38 [95% CI 1.11 to 1.71]; $p = 0.004$) (Table 3).

3.3.5 | Number of different types of information sources accessed

Higher education (KWt (df): 47.8 (2); $p < 0.0001$) and first pregnancy ($U = 2183046.0$; $p < 0.0001$) were significantly associated with use of a larger number of information sources on alcohol use in pregnancy.

3.4 | Associations between information sources and alcohol use during pregnancy

3.4.1 | Alcohol use disorders identification test-consumption

Women who consumed alcohol during pregnancy at low-medium risk levels were more likely to have used written/electronic information (57.7%) than those in the no risk (43.9%) or high-risk groups (50.0%; $p < 0.001$; Table 4). However, the high-risk group had only two women. A Kruskal–Wallis *H* test showed a significant difference between groups in number of sources reported

TABLE 4 Information sources about alcohol use in pregnancy used (%) and alcohol use after pregnancy recognition

Information source	No risk ($N = 4057$)	Low-medium risk ($N = 447$)	High risk ($N = 2$)	p	Special occasions = yes ($N = 394$)	Special occasions = no ($N = 3763$)	p
Antenatal health provider	37.5	36.2	50.0	0.816	36.3	37.9	0.519
Written/electronic	43.9	57.7	50.0	<0.001*	54.3	44.3	<0.001*
Family/friends	19.2	21.7	50.0	0.154	19.0	19.6	0.805
No information sought	20.3	16.3	0	0.106	15.2	21.1	0.006*
N sources used	1 (0 to 5)	1 (1 to 4)	2 (1 to 3)	0.003*	1 (0 to 5)	1 (0 to 5)	0.017*

*$p < 0.05$.

($X^2(2)$ 11.42, $p = 0.003$). Post-hoc analysis showed the significant difference was between the low-medium risk and no risk groups ($p = 0.004$; Table 4), where low-medium risk drinkers referred to a larger number of sources.

3.4.2 | Special occasion drinkers

Women who reported special occasion drinking during pregnancy were more likely to seek information about alcohol use in pregnancy than those who reported no special occasion drinking (Table 4). Compared to women who did not drink at special occasions, those who did obtained information from written/electronic sources (54.3% vs. 44.3%; $p < 0.001$) more frequently and also used a larger number of sources (U: 961262.5, $p = 0.017$).

4 | DISCUSSION

This Australian study is the first to report on information sources used by pregnant women to obtain information on alcohol use in pregnancy. Pregnant women reported that written/electronic information, health providers and family/friends were the information sources most frequently used. Most women used 1–2 information sources, but some used up to five different types of information sources. Approximately one-fifth did not seek or use any information about alcohol use in pregnancy. The information sources used by women varied according to characteristics including, education, age and gravidity. First pregnancy, younger age and higher education were associated with more frequent receipt of information from written/electronic information, antenatal health providers and family/friends. Women who were older, had lower levels of education and had one or more previous pregnancies were less likely to obtain any information about alcohol use in pregnancy. Women who consumed alcohol during pregnancy versus abstainers were more likely to obtain information on alcohol use from written/electronic sources, and to use a larger number of sources.

Our findings contrast with the Danish study in which higher proportions of pregnant women used information from mass media (TV, newspapers and/or weekly magazines; 65%) and relatives (40%) and only 16.2% reported receiving information on alcohol use from health professionals (general practitioners, midwives, obstetricians) [13]. This may be due to cultural, social or health system differences between Denmark and Australia, for example, Denmark was among the five countries with highest estimated prevalence of alcohol use during pregnancy [2]. It may also reflect changes over time in how information is accessed (the Danish study was conducted 23 years ago). Our study findings were more consistent with the Israeli study: health providers were recalled as an information source by 37.4% women in our study and 54.6% in the Israeli study [14]. Similarly, social media was recalled as a source of information on alcohol use in pregnancy by <10% women in both studies. The difference in the proportion that recalled health providers as information sources may also be due to differences in culture, health systems and survey methodologies, with response options being prompted in the Israeli study.

The most recalled information source, used by 45.4% pregnant women, was written/electronic information. This shows this is an important information source, particularly for women in their first pregnancy, with higher levels of education, and who consume alcohol during pregnancy. For women who consume alcohol during pregnancy, it is imperative that the information they receive is correct. We require more information about the sources of the written/electronic information (e.g., a government, other similar authority or other source), and whether the information contained is consistent with guideline recommendations.

Health-care providers were the second-most used information source, recalled by 37.6% pregnant women. This rate was lower among women who were not having

their first pregnancy, ≥25 years of age and least disadvantaged. As the second-most used information source, after written/electronic information, health-care providers have a crucial opportunity both to provide advice and to refer pregnant women to reliable and professional written sources of information consistent with guidelines. Health-care providers should be supported to routinely provide advice to all pregnant women. This idea is consistent with guidelines [26], is supported by pregnant women and women of childbearing age generally [13, 15, 27, 28] and has been shown can be embedded into routine care through clinical practise change interventions [29]. In our study, 20% of women did not receive any information. They were more likely to be multiparous and have lower education attainment. The risk of such women missing out on information could be addressed if its provision was embedded into routine care.

The Australian Government recently committed funding for Australia's first national campaign to raise awareness of alcohol harms in pregnancy (launched in November 2021; https://fare.org.au/fare-welcomes-federal-government-commitment-to-fetal-alcohol-spectrum-disorder/). Our study findings suggest that one focus of the campaign should be to ensure that reputable websites (e.g., the FASD Hub and government health department sites) have high search engine optimisation rankings for information about alcohol use in pregnancy. Also, the message that women who are pregnant or planning a pregnancy should not drink alcohol must be highly visible to the general public (e.g., through warning labels on all alcohol products as mandated from 2023; and through television, radio and other media; billboards/posters as proposed in the national campaign) and include specific awareness raising for those people who support pregnant women, including their partners and friends. Initiatives including the Pregnant Pause campaign (https://www.pregnantpause.com.au/) could potentially play an important role in ensuring family and friends provide an environment that supports pregnant women not to drink and receive the correct information about alcohol use in pregnancy.

4.1 | Study limitations and strengths

Strengths of this study include its large, representative sample from three geographical areas (metropolitan, rural, remote); high survey response rate; and use of open-ended questions rather than restricted or cued responses about information sources used. Limitations included the fact that in many responses 'written information' was poorly defined, so it is possible use of 'written information—Health' (from reputable sources, e.g., health service websites and materials, research studies, hospital posters, guidelines, textbooks) was underestimated. Our use of open-ended questions could also be considered a limitation, because it meant that participants did not need to be precise in their answers and resulted in some important details being omitted. Also, we did not explore the accuracy of the advice attributed to each source type, or how the information was obtained, that is if the information was actively sought by women or received (offered) passively. Additionally, although we had a good response rate, we cannot rule out the possibility of non-response bias and do not know if drinkers versus non-drinkers were more likely to respond to the survey.

5 | CONCLUSIONS

In this large, random, representative sample of pregnant women recruited from public maternity services, the most frequent sources of information women used about alcohol use in pregnancy were written/electronic information, antenatal health providers and family/friends. Women who were older, had lower levels of education and had one or more previous pregnancies were less likely to obtain any information about alcohol use in pregnancy. These findings could inform approaches to targeted and tailored education campaigns and materials. They highlight the importance of antenatal health providers initiating conversations about alcohol use in pregnancy with all women so that opportunities for brief advice, support and referral are not missed.

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CONFLICT OF INTEREST

None to declare.

ETHICS STATEMENT

The study received ethics approval from the Hunter New England Human Research Ethics Committee (16/11/16/4.07), Aboriginal Health and Medical Research Council (1236/16) and the University of Newcastle Human Research Ethics Committee (H-2017-0032).

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APPENDIX 6. Effectiveness of a practice change intervention in reducing alcohol consumption in pregnant women attending public maternity services

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Effectiveness of a practice change intervention in reducing alcohol consumption in pregnant women attending public maternity services

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Abstract

Background: The aim of this study was to examine the effect of a practice change intervention to support the implementation of guideline-recommended care for addressing alcohol use in pregnancy on self-reported alcohol use during pregnancy.

Methods: A randomized, stepped-wedge controlled trial in three clusters (sectors) within the Hunter New England Local Health District (NSW, Australia). We evaluated a practice change intervention that supported the introduction of a new model of care for reducing alcohol use in pregnancy, consistent with local and international guidelines, and implemented in random order across the sectors. Each week throughout the study period, pregnant women who attended any public antenatal services within the previous week, for a 27–28 or 35–36 week gestation visit, were randomly sampled and invited to participate in the survey. The intended intervention for all women was Brief advice (to abstain from alcohol and information about potential risks). Women identified as medium-risk alcohol consumers using the Alcohol Use Disorder Identification Test-Consumption (AUDIT-C) were to be offered referral to a phone coaching service, and women identified as high-risk were to be offered referral to a Drug and Alcohol Service. Rates of self-reported alcohol use (AUDIT-C risk level and special occasion drinking) were summarized and compared in groups of women pre-intervention and post-intervention using multivariable logistic regression.

Results: Surveys were completed by 1309 women at pre-intervention and 2540 at post-intervention. The majority of women did not drink during pregnancy (pre-intervention: 89.68%; post-intervention: 90.74%). There was no change in the proportion of women classified as No risk from drinking (AUDIT-C score = 0) or Some risk from drinking (AUDIT-C score ≥ 1) pre- or post-intervention ($p = 0.08$). However, a significant reduction in special occasion drinking was observed (pre-intervention: 11.59%; post-intervention: 8.43%; $p < 0.001$).

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Conclusions: Special occasion drinking was reduced following implementation of guideline-recommended care. Failure to change other patterns of alcohol use in pregnancy may reflect barriers to implementing the model of care in antenatal care settings and the need to address other social determinants of alcohol use.

Trial registration: Australian and New Zealand Clinical Trials Registry (registration number: ACTRN12617000882325; date: 16 June 2017).

Keywords: Alcohol Consumption, Pregnancy, Antenatal Care, Australia, Intervention study

Background

With international recognition of the potential harms of prenatal alcohol exposure (PAE), including increased risk of birth defects, neurodevelopmental disorders and FASD [1, 2], guidelines in several countries recommend abstention from alcohol by women who are pregnant or planning a pregnancy [3–5]. Despite consensus that alcohol use in pregnancy causes harm, the estimated global prevalence of PAE is 9.8% with region-based variations, estimates being lowest in the World Health Organization (WHO) Eastern-Mediterranean region and highest in the European region [6]. In Australia, 34.7% to 82.0% of pregnancies are alcohol-exposed [1, 7–9]. Although most women stop drinking alcohol after pregnancy recognition, 18.0% to 25.2% continued to drink throughout pregnancy [1, 10]. Continued alcohol consumption in pregnant Australian women is associated with older age, pre-pregnancy alcohol consumption, alcohol use in a previous pregnancy, and a positive attitude towards alcohol use in pregnancy [10, 11].

The WHO [12] and national clinical guidelines [13] recommend that women receive, as early as possible and throughout pregnancy: i) assessment of alcohol use using a validated tool; ii) advice not to consume alcohol and information about the potential risks to themselves and their baby; and iii) referral to specialist support if required. This is based on systematic review evidence that shows that pregnant women who receive brief psychosocial interventions delivered by healthcare providers are more than twice as likely not to consume alcohol during pregnancy (OR: 2.31; 95% CI: 1.61, 3.32; $p < 0.001$) [14].

Public maternity services are a critical setting for these guideline recommendations addressing alcohol use in pregnancy to be implemented, given the large proportion of pregnant women that attend. Despite this, such care has not been routinely provided to pregnant women in antenatal settings, within Australia and internationally, with low clinician provision of assessment (42%-64%) [15–17], advice (11%-35%) [17, 18] and referral (10%-50%) [17–19].

Two controlled trials have been conducted to evaluate the effectiveness of practice change interventions to support the implementation of clinical guideline recommendations for addressing alcohol consumption during pregnancy in public maternity services. The first, a 2015 trial of action-research and training in four Italian public hospitals, found a significant improvement in health professional knowledge related to alcohol and its use in pregnancy, and in the probability of pregnant women receiving correct advice (intervention: 53% vs control: 20%; RR: 2.66; 95% CI: 1.27, 5.56). However, no significant improvements were observed in the pregnant women's opinions or attitudes towards alcohol use [20] and the effect of the intervention on women's alcohol consumption during pregnancy was not reported.

The second was a trial conducted by our group in public maternity services in a single local health district in Australia in 2017–2020 [21]. In this study a multi-strategy practice-change intervention consisting of seven evidence-based implementation strategies increased women's reported receipt of guideline recommended care elements at three visit types (initial antenatal visit; 27–28 weeks gestation; and 35–36 weeks gestation): assessment of alcohol use using a validated tool (the AUDIT-C) (from 28.4% at Baseline to 40.6% at Follow-up), provision of advice (from 18.7% to 26.7%), complete care relative to the level of alcohol risk (advice and referral) (from 18.5% to 26.6%), and provision of all guideline elements (assessment, advice and referral) (from 12.6% to 19.4%) [22].

Although the intervention was effective in increasing assessment and care provision, its effect on reducing alcohol use in pregnancy has not yet been reported. The aim of the study reported in this paper is to assess the efficacy of the practice change intervention in reducing the proportion of pregnant women consuming alcohol during pregnancy.

Methods

The protocol has been detailed previously [21]. Relevant details are summarized here. All aspects of the study design, conception through to dissemination was inclusive of Aboriginal peoples to inform cultural inclusion, safety and appropriateness and project governance embedded cultural governance model led by Aboriginal peoples.

Design and setting

A randomized stepped-wedge controlled trial was conducted in all public maternity services in three sectors within the Hunter New England Local Health District (HNELHD; NSW, Australia) between July 2017 to May 2020. The three sectors comprised one major city (Sector 1: 4300 births/year or 70% of births in the district) and two regional/rural areas (Sector 2: 1200 births/year; Sector 3: 600 births/year). Stepped implementation of the seven-month practice change intervention was initiated in each sector in random order, six months apart. Pre-intervention (baseline) surveys were conducted in the seven-month period preceding the implementation of the practice change intervention at the first sector (with usual practice used as the Control) and Post-intervention (follow-up) surveys occurred up to seven months after the completion of the intervention period in the third sector (Fig. 1) [21]. The randomized stepped-wedge design was chosen for this trial for several reasons including that it provides a similar level of evidence as a parallel cluster randomized controlled trial (RCT); enables the ability to identify secular trends (changes over time) before the intervention is implemented through the sequential implementation of the intervention across three sectors; allows each cluster to act as its own control, thus addressing the practical difficulty of recruiting the number of similar antenatal services required for a parallel cluster RCT; and that it gives all participating services and women the opportunity to receive the intervention [21].

Randomisation and blinding

Randomisation of the order of intervention delivery to the three sectors was undertaken by an independent statistician (CL) using a computerised random number generator. Randomisation was non-stratified. Study personnel involved in outcome data collection were blinded to the intervention order. Antenatal providers could not be blinded to intervention status due to the nature of the practice change intervention.

Eligibility and recruitment

Maternity services and care providers

The practice change intervention was implemented in all maternity services within the three sectors according to their stepped allocation. Service types included hospital and community-based midwifery services, 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. Within these services, all antenatal care providers (midwifery and medical staff, and Aboriginal health workers) were eligible to receive the implementation strategies. Clinicians who were not the primary providers of antenatal care were not targeted for the intervention.

Pregnant women

All women who attended the participating maternity services had the potential to receive the recommended model of care. During the study period, women were eligible to participate in surveys if they met the following criteria:

- Aged ≥ 18 years
- Were pregnant and between 12–37 weeks gestation
- Had attended a face-to-face antenatal visit in the preceding week for either a visit at 27–28 weeks or 35–36 weeks gestation.

Exclusion criteria were: antenatal care with a private obstetrician; prior selection to participate in the survey within the past four weeks; previously declined participation; had given birth; or had a negative pregnancy outcome (stillbirth or miscarriage) as identified from electronic medical records.

Over the study period, a random sample of 75 eligible women who in the preceding week had attended a 27–28 or 35–36 week gestation antenatal visit were selected each week, using a computerized random number generator. Women were identified using electronic medical records and appointment data, and selected women were mailed an information statement inviting them to

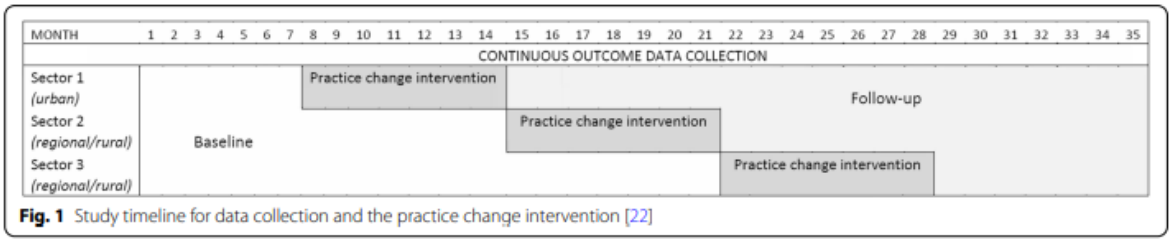

Fig. 1 Study timeline for data collection and the practice change intervention [22]

participate in a computer-assisted telephone interview (CATI). Non-Aboriginal women were telephoned one-week after the letter was sent, with an online survey offered to those who declined the CATI. In accordance with advice from Aboriginal partners regarding a culturally appropriate recruitment method for Aboriginal women, Aboriginal women and those attending an Aboriginal Maternal Infant Health Service were contacted via text message four days after the letter was sent and invited to complete the survey either online or via CATI. Up to 10 attempts over two weeks were made to contact each woman.

Control group

Prior to the intervention period, each sector maintained its own usual practice.

Intervention

Model of care

A new model of care for addressing alcohol use in pregnancy was developed (Fig. 2). The model of care was based on evidence from systematic reviews [14, 23, 24], and international [12] and national [1] clinical guideline recommendations. It consisted of routine assessment of all women for alcohol consumption in pregnancy using the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C). Based on this assessment, brief advice was provided for women with no/low risk AUDIT-C score (score = 0–2), women with AUDIT-C score = 3–4 (medium risk) were to receive Brief Advice + Referral to a telephone coaching service. High-risk women (AUDIT-C score ≥ 5) were to be provided Brief Advice + offered a referral to Drug and Alcohol Clinical Services [21, 25]. Aboriginal women identified as medium or high risk were offered a choice of referrals to Aboriginal Drug and Alcohol Clinical Services or other self-determined, culturally safe Drug and Alcohol Clinical Services, such as local Aboriginal Community Controlled Health Service. This model of care was to be implemented at the initial antenatal visit ('Booking in' visit) and at subsequent antenatal appointments at 28 weeks and 36 weeks [21]. Here, we report the subsequent (28- and 36-week gestation) antenatal appointment data from women surveyed pre- and post-intervention.

Implementation strategies

A practice change intervention was implemented over a seven-month period at each of the three participating health sectors to support delivery of the model of care. The intervention consisted of the following seven evidence-based implementation strategies: leadership/managerial supervision [26]; local clinical practice guidelines [27]; an electronic prompt and reminder system [28]; local opinion leaders/champions [26, 29, 30]; educational meetings and materials [31–33]; academic detailing including audit and feedback [34–36]; and monitoring and accountability for the performance of the delivery of healthcare [21, 35]. The development of the practice change intervention has been described in more detail elsewhere [22].

Data collection

Survey questions were based on previous national surveys and reviewed for cultural appropriateness by Aboriginal women [8, 37, 38]. All interviews were conducted by trained and experienced female interviewers and Aboriginal women were offered the option to undertake the interview with an Aboriginal interviewer.

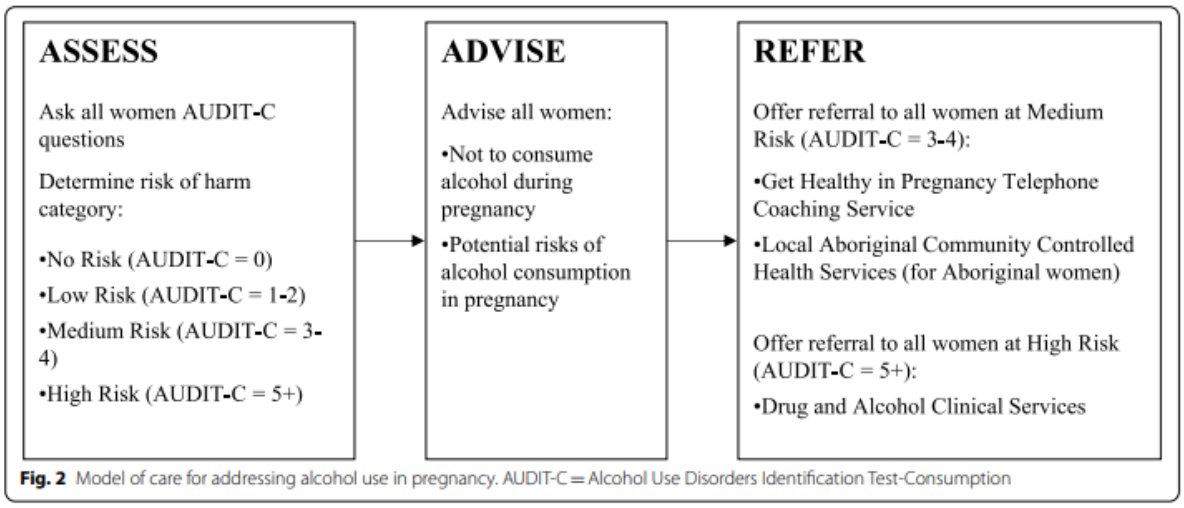

Fig. 2 Model of care for addressing alcohol use in pregnancy. AUDIT-C = Alcohol Use Disorders Identification Test-Consumption

The online survey was built using Research Electronic Data Capture (REDCap) [39], and participants were provided a unique online survey link via email or text message.

Measures

Self-reported alcohol use was assessed 12 months prior to pregnancy (at their initial antenatal visit – reported for demographic information only); and at subsequent antenatal visits (weeks 28 or 36; defined as alcohol use since the woman "found out [they] were pregnant" – included in analyses pre- and post-intervention).

1. AUDIT-C, scored according to AUDIT-C instructions and Australian alcohol use in pregnancy guidelines cut-points [25, 40]:
    a Total score and component scores
    b Total score classified as No Risk (score = 0) versus Some Risk (score ≥ 1); and Higher risk (score ≥ 3)
2. AUDIT-C components:
    a drinking frequency ("How often would you have a drink containing alcohol?")
    b drinks per occasion ("How many standard drinks of alcohol would you drink on a typical day when you were drinking?")
    c ≥ 5 drinks on an occasion ("How often would you have five or more standard drinks on one occasion?")
3. Special occasion drinking ("Were there any special occasions (e.g., a wedding, anniversary, birthday) since you found out you were pregnant where you consumed any alcohol?")

Demographic details collected included whether the woman had ever previously been pregnant (first pregnancy: Yes/No), age, socioeconomic disadvantage based on residential postal code (Most disadvantaged included quintiles 1 and 2, and Least disadvantaged included quintiles 4 and 5 from the Index of Relative Socio-Economic Disadvantage (SEIFACAT 2016)) [17]; education level attained; Aboriginal/Torres Strait Islander origin; marital status; employment status; low/high risk antenatal service based on the woman's antenatal care type (high risk = specialist medical clinics, multi-disciplinary care for women with complex medical needs; low risk = midwifery clinics); and health sector within HNELHD (Greater Newcastle/Peel/Lower Mid-North Coast) [17].

Statistical analysis

Statistical analysis was conducted using SAS version 9.3. Demographic characteristics were summarized using descriptive statistics. Differences in self-reported alcohol consumption in women attending public maternity services were explored pre-intervention compared to post-intervention. Separate multivariable logistic regression models were used for each of the binary alcohol outcome variables (AUDIT-C score [No risk vs. Some risk]; Special occasion drinking [Yes/No]), controlling for parity, socioeconomic disadvantage, alcohol use pre-pregnancy (AUDIT-C score), education level, age, health sector and month of antenatal visit.

The number of women with AUDIT-C score ≥ 3 (medium to high risk) was so few pre-intervention ($N = 6$) and post-intervention ($N = 5$) that we combined medium and high-risk drinkers, and classified AUDIT-C data as No risk (score = 0) versus Some risk (score ≥ 1) for analysis.

The intervention effects were reported as odds ratios or mean difference with 95% confidence intervals (95%CI), or Pearson's chi-square statistic, and p values.

Power calculation

With a sample of 1308 and 10.3% at risk of some drinking pre-intervention, a post-intervention sample of 2539 allowed a detectable difference of 3.1% in at risk drinking, with 80% power and an alpha of 0.05.

Results

Figure 3 shows recruitment data for the pre- and post-intervention periods. At pre- and post-intervention, 2809 and 5308 women were selected to participate respectively. Similar proportions were eligible, contacted, consented, and then completed the surveys at the two timepoints (Fig. 3). Surveys were completed by 79% of eligible women pre-intervention ($N = 1309$) and 74% eligible women post-intervention ($N = 2540$).

Demographic details of the women at both time-points are displayed in Table 1 and were similar between groups surveyed pre- and post-intervention. Women were aged approx. 30y, with 40% in their first pregnancy. Most were educated at a tertiary level, married or in a relationship, and employed. According to AUDIT-C assessment, 80.0% and 80.5% women consumed alcohol in the 12 months prior to pregnancy at pre- and post-intervention respectively.

Difference in alcohol use

Due to small numbers, and failure to satisfy the requirement of independence of observations for Mann–Whitney U tests, intervention effects were not explored for

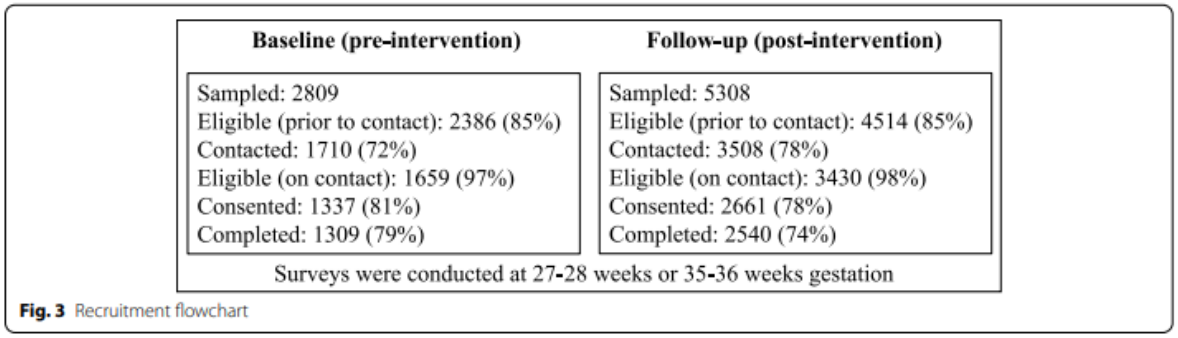

Fig. 3 Recruitment flowchart

all alcohol use outcomes including: drinking frequency, number of drinks per occasion, and frequency of consuming ≥ 5 drinks on one occasion. The median AUDIT-C score pre- and post-intervention was 0 (Table 2). There was no statistically significant effect of the intervention on the proportion of women in each AUDIT-C risk category (No risk versus any risk; $p = 0.08$). However, a significant reduction was observed in the proportion with special occasion drinking (Pre-intervention: 11.59%; Post-intervention: 8.43%; OR: 0.60 (95%CI: 0.46 to 0.79); $p < 0.001$) (Table 2).

Discussion

This study was the first to explore whether a practice change intervention that resulted in improvements in routine antenatal care and screening translated into reductions in alcohol consumption for pregnant women. A statistically significant improvement was observed in self-reported special occasion drinking but not in overall risk level of alcohol consumption (AUDIT-C).

The design of the model of care was informed by international and national antenatal clinical practice guidelines [21], and systematic review evidence on effective interventions for increasing abstinence during pregnancy [23]. A formative cross-sectional survey of antenatal clinicians and managers within the participating public maternity services on barriers to care provision informed the practice change strategies [41]. Although the practice change intervention significantly improved women's reported receipt of advice and care [22] post-intervention rates of care provision remained low. This suggests that barriers to implementation of the model of care into routine practice persisted [22, 41]. Efforts to refine the implementation strategies are needed to ensure all women receive evidence-based care. This should include reassessment of priority barriers and facilitators of care delivery and development of additional implementation strategies based on effective behaviour change techniques [42].

However, despite low numbers receiving the intervention intended, there was a significant reduction in the proportion of women reporting special occasion drinking after the intervention. It is possible that special occasion drinking behaviour is easier to change because it is not habitual like regular drinking. Special occasion drinking may be considered infrequent behaviour, and in contrast, regular drinking may be considered 'habitual,' and more resistant to change despite knowledge of the potential harms [43]. Our finding reinforces the importance of asking pregnant women about special occasion drinking, in line with recommendations by Muggli et al., who reported high rates of binge level special occasion drinking in pregnant women [8]. In the present cohort, 33.3% women who reported drinking during pregnancy only consumed alcohol on special occasions, mostly (91.3%) at low levels (1–2 drinks per occasion) [10]. This indicates that special occasion drinking should be defined not only as binge level drinking, but as any amount of alcohol during special occasions, to maximise detection of risk to the unborn child. This is an important outcome because any amount of alcohol has the potential to harm the unborn child and no safe lower limit has been established.

One possible reason why we did not observe any significant change in the proportion of women who reported "regular" alcohol use during pregnancy (AUDIT-C) is that information alone does not change behaviour. Previous research by our group [10, 44, 45] and others [20, 46, 47] suggests that attitudes to alcohol use in pregnancy are more important determinants of maternal behaviour than knowledge of alcohol harms. Additionally, although we observed a significant increase in health providers who implemented all recommended components of the intervention in clinical practice, there is still potential for increasing the proportion of women receiving the recommended care. Although we did not measure attitudinal change in this trial, we previously reported in this cohort that a positive attitude towards alcohol use in pregnancy was predictive of ongoing alcohol use in pregnancy [10].

Table 1 Demographics of women surveyed before the practice change intervention (pre-intervention) and post-intervention

Characteristic	Pre-intervention ($N=1309$)	Post-intervention ($N=2540$)
Age (y)	[$n=1308$] 29.4 ± 5.3 Median: 29 (18 to 45)	[$n=2538$] 30.3 ± 5.1 Median: 30 (18 to 51)
First pregnancy	[$n=1308$] 547 (41.8%)	[$n=2538$] 1016 (40.0%)
Socioeconomic disadvantage[a]:		[$n=2539$]
Most disadvantaged	826 (63.1%)	1298 (51.1%)
Least disadvantaged	483 (36.9%)	1241 (48.9%)
Education level:	[$n=1307$]	[$n=2535$]
Highschool or less	379 (29.0%)	615 (24.3%)
TAFE certificate or diploma	488 (37.3%)	899 (35.5%)
University, CAE, degree or higher	440 (33.7%)	1021 (40.3%)
Aboriginal/Torres Strait Islander origin (mother)	[$n=1308$] 80 (6.1%)	[$n=2538$] 115 (4.5%)
Aboriginal/Torres Strait Islander origin (baby)	[$n=1305$] 128 (9.8%)	[$n=2534$] 204 (8.1%)
Marital status:	[$n=1307$]	[$n=2537$]
Never married	143 (10.94%)	199 (7.84%)
Married/living together in a relationship	1125 (86.07%)	2289 (90.22%)
Separated/divorced	38 (2.91%)	46 (1.81%)
Widowed	1 (0.08%)	2 (0.08%)
Refused	0	1 (0.04%)
Employment status:	[$n=1308$]	[$n=2538$]
Employed full-time	292 (22.32%)	682 (26.87%)
Employed part-time/casual	301 (23.01%)	640 (25.22%)
Unemployed	134 (10.24%)	254 (10.01%)
Can't work: health reasons	15 (1.15%)	19 (0.75%)
Home duties	236 (18.04%)	339 (13.36%)
Student	41 (3.13%)	55 (2.17%)
Other	10 (0.76%)	10 (0.39%)
On maternity leave: employed full-time prior	144 (11.01%)	300 (11.82%)
On maternity leave: employed part-time/casual prior	135 (10.32%)	239 (9.42%)
Antenatal service[b]:		[$n=2531$]
High risk	708 (54.09%)	1302 (51.44%)
Low risk	581 (44.39%)	1190 (47.02%)
AMIHS	20 (1.53%)	39 (1.54%)
Health sector:		
Greater Newcastle (urban)	860 (65.70%)	2180 (85.83%)
Peel (regional/rural)	201 (15.36%)	268 (10.55%)
Lower Mid-North Coast (regional/ rural)	248 (18.95%)	92 (3.62%)
AUDIT-C score in 12 months before pregnancy (median (range))	[$n=1298$] 2 (0 to 12)	[$n=2518$] 3 (0 to 12)

AMIHS Aboriginal Maternal and Infant Health Service, *AUDIT-C* Alcohol Use Disorders Identification Test-Consumption

[a] Socioeconomic disadvantage was classified using the Index of Relative Socio-Economic Disadvantage (SEIFACAT 2016). Most disadvantaged included quintiles 1 and 2, and Least disadvantaged included quintiles 4 and 5

[b] High risk antenatal services included medical clinic, women with vulnerabilities, and women with complex medical needs; Low risk antenatal services were midwifery clinics

The model of care to address alcohol use in pregnancy focused on clinical care, and did not address social aspects of alcohol use. Women's ability to make positive life changes to protect their baby from harm is mediated by social and structural determinants of their health and wellbeing, including peer drinking, social relationships

Table 2 Alcohol use during subsequent antenatal visits before and after implementation of the practice change intervention

Alcohol use during pregnancy measure	Pre-intervention ($n=1308$)	Post-intervention ($n=2539$)	Mean difference, OR (95%CI), or X^2	*p*
AUDIT-C score:				
Median (range)	0 (0 to 7)	0 (0 to 5)	-	-
AUDIT-C score[a]:			No vs Some risk:	0.08
No risk (0) (N (%))	1173 (89.68)	2304 (90.74)	0.80 (0.62, 1.03)	
Some risk (≥ 1) (N (%))	135 (10.32)	235 (9.26)		
Higher risk (≥ 3) (N (%))	6 (0.46)	5 (0.20)		
Drinking frequency		[$n=2538$]	-	-
Never (N (%))	1173 (89.68)	2303 (90.71)		
Monthly or less (N (%))	111 (8.49)	202 (7.96)		
2-4x/month (N (%))	19 (1.45)	33 (1.30)		
2-3x/week (N (%))	4 (0.31)	0		
≥ 4x/week (N (%))	1 (0.08)	0		
N drinks per occasion:	[$n=135$]	[$n=235$]	-	-
1–2 (N (%))	133 (98.52)	230 (97.87)		
3–4 (N (%))	1 (0.74)	2 (0.85)		
5–6 (N (%))	1 (0.74)	2 (0.85)		
7–9 (N (%))	0	1 (0.43)		
≥ 10 (N (%))	0	0		
Frequency of ≥ 5 drinks on 1 occasion:	[$n=135$]	[$n=235$]	-	-
Never (N (%))	132 (97.78)	230 (97.87)		
< Monthly (N (%))	1 (0.74)	5 (2.13)		
Monthly (N (%))	2 (1.48)	0		
Weekly (N (%))	0	0		
Daily or almost daily (N (%))	0	0		
Special occasion drinking[1] (N (%))	[$n=1087$] 126 (11.59)	214 (8.43)	OR: 0.60 (0.46 to 0.79)	< 0.001*

95%CI 95% confidence interval, *AUDIT-C* Alcohol Use Disorders Identification Test-Consumption, *OR* odds ratio

[a] Logistic regression models were adjusted for parity, disadvantage, AUDIT-C score pre-pregnancy, education, health sector, month of appointment, and age

and norms, stigma, trauma and other stressors [48]. Assessment of and support for these contributors to ongoing drinking, in addition to implementation of a standard model of antenatal care based on guideline recommendations, may prove more effective in reducing alcohol use during pregnancy than addressing any one factor alone. Although the standard model of antenatal care currently includes referral to services that address these social aspects of alcohol use (e.g., Drug and Alcohol Services), the observed rate of referral was low [22]. To ensure women have access to the most effective care, it is important to increase clinician's offer of referral for women consuming alcohol in pregnancy at medium to high risk levels as well as women's uptake of these services.

This study had many strengths. It was a multi-site randomized trial with a stepped-wedge design, tested in public antenatal services in rural and urban sites with a large sample of pregnant women. We also used two different outcome measures to assess alcohol consumption (AUDIT-C and special occasion drinking). A number of potential limitations need to be mentioned. In this study we report secondary outcomes that were not specifically powered in the study design. Although the study was adequately powered to detect differences of 3.1%, based on a pre-intervention prevalence of 'at risk' alcohol use (AUDIT C score ≥ 1) during pregnancy of 10.3%, the intervention did not significantly reduce the proportion of women reporting regular drinking. Additionally, although we controlled for potential confounders and our study was adequately powered, we cannot be certain that the reduction in special occasion drinking was a result of the intervention.

Conclusions

Our results show that the implementation of a practice change intervention to support the introduction of a model of evidence-based care does reduce special occasion drinking, but not other patterns of alcohol use in pregnancy. The barriers to implementing the model

of care in antenatal service settings, as well as barriers experienced by individual women to changing their alcohol use behaviour, must be identified and addressed so that all women receive evidence-based care and are supported to abstain from alcohol consumption during pregnancy.

Abbreviations

95%CI: 95% Confidence interval; AMIHS: Aboriginal Maternal and Infant Health Services; AUDIT-C: Alcohol Use Disorders Identification Test-Consumption; CATI: Computer-assisted telephone interview; FASD: Fetal alcohol spectrum disorder; HNELHD: Hunter New England Local Health District; NHMRC: National Health and Medical Research Council; NSW: New South Wales; OR: Odds ratio; PAE: Prenatal alcohol exposure; REDCap: Research Electronic Data Capture; SEIFACAT: Socio-economic indexes for areas categories; Wks: Weeks.

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Authors' contributions

Authors JW and MK led the overall development of the research study and TWT led the development of the manuscript. BT led the cultural governance for the study and coordinated the cultural review group. EJE, TWT and AD provided the rationale and expertise on alcohol consumption during pregnancy. ED, BT, AD, IS and CR contributed to the development of the model of care and implementation support strategies. ED and BT contributed to the development of data collection methods. LW, JA and CL provided overall guidance for the study design and data analysis. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was registered with the Australian and New Zealand Clinical Trials Registry (registration number: ACTRN12617000882325; date: 16/06/2017). This study received ethics approval from the Hunter New England Human Research Ethics Committee (16/11/16/4.07, 16/10/19/5.15), Aboriginal Health and Medical Research Council (1236/16) and the University of Newcastle Human Research Ethics Committee (H-2017–0032, H-2016–0422).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

APPENDIX 7. Longitudinal exploration of the rate, time-points and extent of change in care delivery following a successful antenatal care practice change intervention: A secondary analysis

Hall A, Doherty E, Nathan N, Wiggers J, Attia J, Tully B, Elliott E J, Oldmeadow C, Chiu S, Kingsland M. Under Review – BMC Health Services Research.

ABSTRACT

Background: Sustainment of evidence-based care is required to ensure ongoing population benefits. We demonstrated practice change related to addressing alcohol use in pregnancy after implementation of a strategy to improve antenatal care. Evidence suggests the impact of strategies reduce over time. It is important to document if and when recommended care reduces so timely support for sustainment can be provided.

Methods: An interrupted time series analysis of outcomes from the largest sector in a randomised stepped-wedge controlled trial. The analysis explored the rate, time points and extent of change in women's reported receipt of recommended antenatal care for alcohol consumption, following delivery of an effective practice change intervention. Survey data from all women collected across the 31-month study period were analysed.

Results: A total of 4,909 (82% consented) women were surveyed. The proportion of all pregnant women receiving recommended care reduced significantly per week following the withdrawal of implementation support, for three of the four outcomes : assessment of alcohol consumption (% change: -0.66; 95% CI: -1.1, -0.26; p=0.002), advice not to consume alcohol during pregnancy and of potential risks (% change: -0.63; 95% CI: -1.1, 0.22; p = 0.003), and complete care relevant to alcohol risk level (advice and referral) (% change: -0.64; 95% CI: -1.1, -0.22; p = 0.003). A reduction in the fourth outcome was also observed but was not

statistically significant: all guideline elements relevant to alcohol risk level (% change: -0.36; 95% CI: -0.72, 0.00; $p = 0.050$). Similar results were observed regardless of timing of antenatal visit. Break-point analysis found a more rapid decline occurred for most outcomes from the end of implementation until approximately 30 weeks post-implementation. A smaller percentage of women were receiving recommended care at the end of the post-implementation phase compared to the end of active implementation; although rates were still higher post-implementation than what was observed pre-implementation.

Conclusions: Receipt of recommended antenatal care for alcohol consumption declined after active implementation support was withdrawn. The findings suggest the need for ongoing monitoring of care delivery and introduction of additional sustainability strategies at key time points post withdrawal of implementation support.

INTRODUCTION

Alcohol consumption during pregnancy carries adverse effects for the pregnant woman and unborn child (1). Guidelines recommend abstinence from alcohol during pregnancy to prevent such harms (2-4). However, a systematic review estimates that approximately 10% of women globally consume alcohol at some point during their pregnancy (5). To support women to abstain from alcohol consumption during pregnancy, clinical practice guidelines (6-8) recommend that health care providers: (i) routinely **assess** alcohol consumption by all pregnant women throughout their antenatal care using a validated tool; (ii) **advise** all women on the potential harms of alcohol consumption during pregnancy and recommend abstinence; and (iii) **refer** women to support services appropriate to their level of risk to assist in abstaining from alcohol consumption. However, the provision of all three elements of care is less than optimal, with recent reports from Australia finding that only up to 27% of health care providers assess

women's alcohol use using a validated tool, 18% provide advice, and 17% refer women to appropriate support, with these levels of care varying depending on the type of antenatal visit (initial or subsequent) (9).

Effective implementation strategies are needed to support health care providers in delivering recommended antenatal care addressing alcohol consumption by pregnant women. In a recent randomised stepped-wedge controlled trial, it was found that a multi-strategy practice change intervention was effective in increasing the proportion of women who reported receiving: assessment of alcohol consumption via the Alcohol Use Disorders Identification Test - Consumption (AUDIT-C) tool (OR: 2.63; 95% CI: 2.26, 3.05; $p<0.001$); advice not to consume alcohol and information about the potential risks (OR: 2.07; 95% CI: 1.78, 2.41; $p<0.001$); and care appropriate to their alcohol risk level (advice and referral) (OR: 2.10; 95% CI: 1.80, 2.44; $p<0.001$) (10). Furthermore, the odds of pregnant women receiving all aspects of guideline recommended care (assess, advise and refer) appropriate to their level of alcohol risk increased by more than two-fold (OR: 2.32; 95% CI: 1.94, 2.76; $p<0.001$) following the intervention (10).

To be an effective practice change or implementation intervention, its impact needs to result in the continued delivery of guideline recommended care long-term, beyond provision of initial implementation support. This is commonly referred to as sustainment (11). Sustainment is an important part of the implementation process, as long-term delivery of evidence-based care is required for public health benefits to be fully realised and the resources dedicated to initial implementation efforts maximised (12). Emerging evidence suggests that once initial implementation support or funding is withdrawn, the impact of effective implementation strategies may diminish over time (13-15). For example, in a systematic review of trials

assessing the sustainment of health professional's adherence to clinical practice guidelines, only seven of 18 evaluations illustrated 100% sustainment of professional adherence more than one year after active implementation (14). Sustainment may also vary across the individual components of the evidence-based intervention or model of care being implemented, with some components found to be sustained at a higher level than others (13). There is no agreed definition of what constitutes a successful rate of sustainment (16). However, recent definitions of sustainability emphasise the need for the target behaviour change or practice to be maintained to a level that continues to produce benefits for individuals or the system (13, 16, 17). In a recent study examining rates of sustainment, sustainment was defined as the delivery of services to an acceptable degree for at least two years (16), while the systematic review by Ament et al (14) considered sustainment successful if adherence to clinical practice guidelines more than one year after implementation support was fully maintained (i.e. 100%).

Although the effects of implementation interventions often reduce over time, little is known about when, how quickly and to what extent such reductions occur. According to the Dynamic Sustainability Framework, sustainability is a dynamic process that is impacted by the continually changing environment in which the evidence-based intervention or model of care is being delivered (12). Thus, to ensure that sustained delivery is optimised and appropriate support is provided, continuous monitoring, evaluation and refinement of the intervention and implementation strategies is required (12).

To adequately assess and understand the complex process of sustainability, longitudinal designs (13, 18) and statistical analyses that allow for modelling of complex, non-linear relationships are necessary (18). Measurement of sustainment should also be considered from the outset of the implementation process, rather than after the end of the study, when it may be

too late or difficult to identify when improvements or additional support may be needed (12). However, due to short funding periods and the difficulties of undertaking continual data collection, such long-term assessments are rarely undertaken (18). Studies that do undertake longer-term assessments, over multiple time-points, provide an opportunity to evaluate the ongoing effects of an implementation intervention, and if and when enhancements or additional support may be needed to ensure sustainment is achieved. Several examples exist where data across multiple time-points have been used to gain a greater understanding of how implementation effects change over time (19, 20). In a study by MacBride-Stewart et al (20) interrupted time series was used to examine how prescribing rates changed during and following a 12-month quality improvement intervention. This study found an improvement in high-risk non-steroidal anti-inflammatory drugs at the end of the intervention period, but also that such effects began to wane in the 12-months following the intervention phase. The authors argued that such findings highlight the need for ongoing monitoring and the potential for future sustainability support to ensure sustained impact (20). In a cluster randomised controlled trial by Levi et al (19) post-hoc analyses examining thrombolysis rates across time provided an understanding of how the implementation effects changed over time, illustrating initial improvements towards the end and directly after active implementation support, followed by rapid declines thereafter. This analysis highlighted the need for more extensive and perhaps prolonged support to ensure sustained behaviour change in the provision of thrombolysis treatment (19). These studies illustrate the advantages of assessing implementation effects across time in terms of understanding the potential for sustainment and if and when additional support and improvements may be needed. We are unaware of any similar studies addressing the sustainment of antenatal care addressing alcohol consumption.

The randomised controlled stepped-wedge trial undertaken by Doherty et al (10) provides a unique opportunity to undertake a secondary analysis of women's receipt of guideline recommended care in relation to alcohol consumption over time, following completion of active implementation support provided to public maternity services in three sectors. While the primary analysis of this trial followed recommended practice for evaluating a stepped-wedge design (21), it only informs us as to whether the level of recommended care received by women is on average higher across the entire post-implementation period combined, compared to the pre-implementation period combined. It does not tell us whether the observed increase in recommended care continued at a high rate over time, or whether it changes, particularly after active implementation support has ended. In this study many, but not all the practice change strategies were intended to continue to support the delivery of the recommended model of care following the implementation period, with the primary exceptions being the withdrawal of the clinical champion and educator and the provision of academic detailing and audit and feedback. Thus, an examination of how care continued to be delivered post active implementation support will provide an opportunity to assess whether implementation effects are being sustained, or if and when additional support may be needed to support long-term sustainment.

As evidence suggests that the delivery of recommended care often reduces once initial implementation support has ended (13-15, 19), it is important to identify the rate, time-points and extent of change in care delivery that may occur. Doing so will allow for appropriate and timely support to be provided to services to ensure that the optimal delivery of evidence-based care is continued long-term; that subsequent patient benefits continue; and we capitalise on the resource and efforts expended during active implementation. The continual data collection that is undertaken as part of a stepped-wedge design provides a unique opportunity to examine changes in outcomes over time through such methods as segmented regression analysis.

Segmented regression allows for the estimation of the rate at which outcomes occur during different segments of data collection (22). Such analysis allows for more detailed assessment of rate, points of and extent of change in outcomes over time, and hence whether and when additional support may be required to help facilitate the sustained delivery of recommended care long-term.

To explore if and how the effects of the successful practice change intervention reported by Doherty et al (10) change over time, we conducted a secondary analysis of data collected from the largest sector from the original stepped wedge trial. The overall objective was to investigate the rate, time points and extent of change in the receipt of guideline-recommended antenatal care addressing alcohol consumption post-implementation. The specific aims were to:

1. Assess the rate of change in the receipt of care in the post-implementation phase for all antenatal visits combined (primary analysis);
2. Assess the rate of change in the receipt of care in the post-implementation phase separately by antenatal visit (i.e. initial and subsequent visits);
3. Identify specific points during the post-implementation phase where the rate of change in the receipt of care is more rapid;
4. Describe the extent of care receipt at the end of each implementation phase and directly following key time-points identified from the break-point analysis for all antenatal visits combined.

METHODS

Study Design and setting

We conducted an exploratory secondary analysis of an existing dataset collected during a randomised stepped-wedge controlled trial, which assessed the effect of a multi-strategy practice change intervention on the delivery of recommended antenatal care addressing alcohol consumption by women during pregnancy by health care providers (10, 23) (Registration number: ACTRN12617000882325, date registered: 16/06/2017). Human research ethics approval was obtained from Hunter New England Human Research Ethics Committee (HNELHD: 16/11/16/4.07), the University of Newcastle (H-2017-0032) and the Aboriginal Health and Medical Research Council (1236/16). Data from the largest sector participating in the stepped-wedge trial were re-analysed using an interrupted time-series model.

All public maternity services within three sectors of the Hunter New England Local Health District of New South Wales Australia, participated in the stepped-wedge trial. For this secondary analysis only data from sector one were re-analysed as insufficient data were available from sectors two and three to conduct a reliable time-series analysis. Furthermore, as the focus of the paper was changes over time, we could reliably not conduct this analysis across all three sectors combined because each sector moved through the different phases of implementation at different time-points. Finally, sector one had the largest sample (n=4909) as well as the longest period of data collection for the post-implementation period (~17 months), making it the most suitable sector for exploring possible changes in recommended care following active implementation. For sector one, pre-implementation data collection began in July 2017 for a period of 8.5 months, followed by delivery of the implementation intervention for 7 months. Post-implementation data collection continued for approximately 20.5 months following the initial implementation support period. However, for this secondary analysis the last four months of data were excluded due to unexpected disruptions to antenatal care caused by the Covid-19 pandemic (see Figure 1).

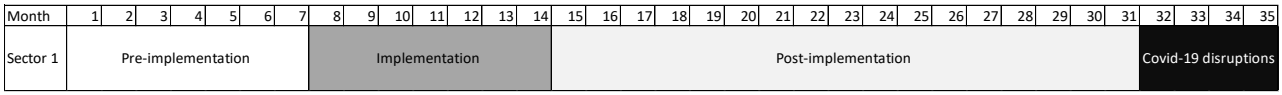

Figure 1. Overview of study phases illustrating the number of month's data collection for each of the phases of pre-implementation, implementation and post-implementation

Participants

The practice change intervention was implemented in all public maternity services, comprising of 19 antenatal care teams, within the sector.

Pregnant women were eligible to complete a study survey if they: attended the maternity service for either their first antenatal visit, their 27-28 week gestation visit or their 35-36 week gestation visit in the preceding week; were 18 years or older; were 12 to 37 weeks gestation; had a sufficient level of English to complete the survey; were mentally and physically capable of completing the survey; and were receiving the majority of their antenatal care via the public health system. Women who: had already given birth, had a negative pregnancy outcome, had already completed a survey within the last four weeks, or had declined participation previously were ineligible to participate in the survey.

Every week during the study period a random sample of 105 eligible women from all three sectors combined was generated using the appointment system and medical record data, with approximately 75% of the total sample recruited from sector 1. Selected women were sent a study information sheet, and non-Aboriginal women were called one week later and invited to complete the survey via computer assisted telephone interview (CATI) or online if they declined the CATI. Women who identified as Aboriginal or Torres Strait Islander origin and/or

were attending an AMIHS were sent a text inviting them to complete the survey via CATI or online.

Model of care

Health care providers were supported to provide women with the following three elements of guideline recommended care during their antenatal visits at three time points: the initial antenatal visit, 27-29 weeks gestation and 35-37 weeks gestation:

1) *Assessment of alcohol consumption using a validated tool:* Health care providers were to use the three item AUDIT-C tool (24) to assess all pregnant women's alcohol consumption.

2) *Provision of brief advice regarding the potential harms of alcohol consumption during pregnancy and recommend abstinence: All* women were to be advised that it is safest not to consume alcohol during pregnancy; and of the potential risks associated with alcohol consumption during pregnancy.

3) *Referral of women to appropriate support services based on their level of alcohol consumption risk:* Women with alcohol consumption classified as medium risk (AUDIT-C score: 3-4) were to be referred to the free government Get Healthy in Pregnancy telephone coaching service (25) with Aboriginal women also offered referral to counselling at Aboriginal Community Controlled Health Services. Women with alcohol consumption classified as High Risk (AUDIT-C score: 5 +) were to be referred to the Drug and Alcohol service provided by the health district.

Practice change intervention

To support the implementation of this model of care, a multi-strategy practice change intervention was delivered over a 7-month period. The intervention is described in full in the study protocol (23) and primary outcome paper (10) and was designed to address the key impediments to increasing and sustaining the delivery of the recommended model of care assessed using the Theoretical Domains Framework (9). Strategy selection, content and delivery were informed by current evidence, behaviour change experts, practitioner input and cultural inclusion informed by Aboriginal women, Aboriginal health staff and local community members and organisations. Broadly, the strategies included: leadership and managerial supervision, development of local clinical practice guidelines, electronic prompts, and reminders, dedicated clinical champions, provision of educational materials and meetings, academic detailing and audit and feedback, and monitoring and accountability for the performance of the delivery of healthcare. Five of the seven strategies were designed to be integrated within the maternity service's usual systems and processes, and thus were intended to continue to support the delivery of the recommended model of care either in full or partially following the initial implementation period. Only the dedicated clinical champion and educator and the provision of academic detailing and audit and feedback strategies were not continued once the initial implementation period was completed.

Data collection and outcomes

Data from pregnant women were collected continuously on a weekly basis for the entire 35-month study period (see Figure 1).

Characteristics of participating women

Via the self-report surveys (CATI or online) women reported on their: age, Aboriginal and Torres Strait Islander origin, education, employment, marital status, first/subsequent pregnancy

status, and the antenatal care providers they saw during their visit. Women also completed the AUDIT-C (24) as a measure of their alcohol consumption risk level. The AUDIT-C is a three-item, validated tool for assessing alcohol consumption, which asks: how often do you currently consume alcohol?; how many standard drinks do you consume on a typical drinking day?; and how often do you consume 5 or more standard drinks? Each question is answered on a five-point scale. A total score is calculated by summing item responses, with scores ranging from 0 to 12. Total scores are classified into the following categories of alcohol risk of harm during pregnancy: No Risk (0); Low Risk (1-2); Medium Risk (3-4); and High Risk (5+) (26).

Receipt of recommended model of care

Women were asked to indicate (yes, no or don't know) whether they received each of the elements of recommended care during their recent antenatal visit. Specifically, they were asked: (i) if their health care provider assessed their alcohol consumption with question/s consistent with the AUDIT-C, (ii) if they were advised not to consume alcohol during pregnancy as well as the potential risks associated with consuming alcohol, and (iii) if they were offered referral for further support for abstaining from alcohol consumption during pregnancy.

The primary outcomes for this study were the proportion of women, who received: i) assessment via-the AUDIT-C; ii) both components of advice (i.e. advised not to consume alcohol while pregnant and of the potential risks associated with consuming alcohol); iii) complete care appropriate to alcohol risk level (both components of advice and offer of referral if medium or high risk); and iv) all components of guideline recommended care appropriate to alcohol risk level (i.e. assessment and complete care). Consistent with the primary outcomes of the trial all outcomes were assessed across all visits combined (i.e. initial antenatal visit, 27-

29 weeks gestation and 35-37 weeks gestation) (10). However, due to significant differences in the effects observed on outcomes in the later appointments (i.e. 27-29 weeks gestation and 35-37 weeks gestation) (10), we also assessed all outcomes separately for initial and subsequent visits (i.e. 27-29 weeks gestation and 35-37 weeks gestation).

Statistical analysis

All analyses were conducted in R version 4.1.0 (27). Linear segmented regression models were conducted for each of the outcomes across all visits combined (primary analysis), as well as separately for initial and subsequent visits (i.e., visits at 27-29 weeks gestation and 35-37 weeks gestation). Data were initially assessed for autocorrelation, which was not present. To estimate the rate of receipt of care across implementation phases, three segments were specified in each model, one for each of the implementation phases of the trial (i.e., pre-implementation, implementation, and post-implementation). A break point analysis was also conducted to estimate additional segments in the post-implementation phase where rates changed more rapidly. The breakpoint analysis was only undertaken for all antenatal visits combined. The extent of recommended care received by women for each of the elements of care for the last four weeks of each implementation phase (i.e., pre-implementation, implementation, and post-implementation) and following any significant break-points identified, was estimated. An alpha level of 0.05 was used to determine statistical significance for all comparisons. No adjustments for multiple testing were made due to the exploratory nature of this study.

RESULTS

Participants

For sector one, 9474 women were sampled over the entire study period, of which 5996 (63%) were able to be contacted and considered eligible to participate on the day of contact. Of all

eligible women contacted, 4927 (82%) consented to complete a study survey, of whom 4909 (82%) completed the survey. The characteristics of participating women were similar across the three implementation phases (see Table 1).

Table 1. Sector and participant characteristics

Characteristics	Pre-implementation	Implementation	Post-implementation
Months of data collection	8.5	6.25	16.5
Total number of responses	1,309	1,028	2,572
Participants			
Age			
18-<25	240 (18%)	138 (13%)	375 (15%)
25-<35	840 (64%)	687 (67%)	1634 (64%)
35+	228 (17%)	203 (20%)	563 (22%)
Aboriginal and/or Torres Strait Islander origin	70 (5%)	61 (6%)	117 (5%)
Education level			
Completed high school or less	362 (28%)	285 (28%)	652 (25%)
TAFE or diploma	481 (37%)	366 (36%)	893 (35%)
University	465 (36%)	377 (37%)	1026 (40%)
Employment status			
Employed	908 (69%)	755 (73%)	1898 (74%)
Not employed	400 (31%)	272 (26%)	674 (26%)
Marital status			
Married or partnered	1152 (88%)	901 (88%)	2297 (89%)
Single	155 (12%)	126 (12%)	274 (11%)
Geographic remoteness			
Major city	1148 (88%)	880 (86%)	2291 (89%)
Inner/outer regional/remote	161 (12%)	147 (14%)	282 (11%)
Area of disadvantage			
Least disadvantaged	732 (56%)	577 (56%)	1414 (55%)
Most disadvantaged	577 (44%)	450 (44%)	1157 (45%)
First pregnancy	552 (42%)	402 (39%)	1033 (40%)

Aim 1: Rate of change in the receipt of care in the post-implementation phase for all antenatal visits

Table 2 presents the average weekly change in the proportion of all women, for all antenatal visits combined (i.e., initial visit; 27-29 weeks gestation and 35-37 weeks gestation), reporting receipt of each element of guideline recommended care for the post-implementation phase. In these tables positive values represent an average weekly increase in the receipt of care, while negative values represent an average weekly decrease in the receipt of care. A visual representation of the change for all components of guideline recommended care appropriate to alcohol risk level (i.e. assessment and complete care) across all three phases of implementation (i.e. pre-implementation, implementation and post-implementation) is shown in Figures 2-8.

Following an increase in recommended care during the implementation phase, all outcomes illustrate a significant decrease in the rate of care receipt during the post-implementation phase except for "assessment of alcohol and level of risk using the AUDIT-C and complete care relative to risk level", which had a non-significant decrease with an average change of -0.36% (95%: -0.72, 0.00) per week (see Figure 2). For all other outcomes, the average weekly decrease in the receipt of care was statistically significant and ranged from -0.63% (95% CI: -1.10, -0.22) for "complete brief advice" to -1.00% (95% CI: -1.40, -0.52) for "advice safest not to drink" (see Table 2). A potential outlier in the post-implementation phase was observed for the outcome "assessment for alcohol consumption and level of risk using the AUDIT-C"; however, sensitivity analysis removing the outlier did not result in a meaningful difference in the results observed (-0.66% to -0.63% per week, see Figure 4). As this outlier was not identified as an error, following best practice it was not removed from the analysis.

Aim 2: Rate of change in the receipt of care in the post-implementation phase separately by antenatal visit

Initial visit only

For women who attended their initial antenatal visit, there was a similar trend to what was observed in the primary analysis for most outcomes. With two exceptions all outcomes illustrated a significant decrease in the receipt of recommended care once initial implementation ended (see Table 2). However, compared to the primary analysis, there was minimal change in the rate to which women attending their initial visit received "assessment of alcohol consumption and level of risk using the AUDIT-C", with a non-significant decrease observed for this outcome (Table 2).

Subsequent visits only

For women who attended a subsequent antenatal visit, all outcomes illustrated a significant decrease in the receipt of recommended care once initial implementation ended (see Table 2).

Aim 3: Identify specific points during the post-implementation phase where the rate of change in the receipt of care is more rapid

The results from the break point analysis are illustrated in Figures 9-13. For all outcomes except "assessment of alcohol consumption and level of risk using the AUDIT-C", an immediate and rapid decline in the receipt of care in the post-implementation phase was observed, until approximately 30 weeks post-implementation. From 30 weeks post-implementation the rates of care appear to stabilise. Conversely, the break-point analysis for outcome "assessment of alcohol consumption and level of risk using the AUDIT-C" illustrates an immediate decline up until approximately 60 weeks when rates begin to stabilise, when all data are included. However, when a potential outlier is removed the break-point analysis suggests an immediate

and rapid decline until approximately 9 weeks post-implementation. As this outlier was not identified as an error, following best practice it was not removed from the analysis.

Aim 4. The extent of care receipt at the end of each implementation phase and directly following key time-points identified from the break-point analysis for all antenatal visits combined

Table 3 presents the percentage of women receiving care for the last four weeks of each implementation phase (i.e., pre-implementation, implementation, and post-implementation) and for the four weeks following 30-weeks post-implementation, as this was identified as a significant break-point for all but one of the outcomes. As shown in Table 3 the extent of recommended care received by women at the end of the implementation period was higher for all care elements compared to the end of the pre-implementation phase. However, a subsequent decrease was observed for all but one care element from the end of the implementation phase to 30 weeks post-implementation, after which the percentage of women receiving care appeared similar to that at the end of the post-implementation phase. Comparatively, the percentage of women receiving "assessment of alcohol consumption and level of risk using the AUDIT-C" appeared to be similar at the end of implementation and at 30-weeks post-implementation, with a larger decrease seen at end of the post-implementation phase.

Table 2. Weekly change in the delivery of recommended care across the post-implementation phase for all antenatal visits combined and separately by initial visit and subsequent visits

Outcome	**Post-implementation % change per week (95% CI)**		
	All visits combined	**Initial visit**	**Subsequent visits**
Assessment of alcohol consumption and level of risk using the AUDIT-C	-0.66 (-1.1, -0.26; *p* = 0.002)*	-0.20 (-0.86, 0.46; *p*=0.5)	-1.0 (-1.4, -0.53; *p* < 0.001)*
Complete brief advice (safest not to consume and potential risks)	-0.63 (-1.1, -0.22; *p* = 0.003)*	-1.1 (-1.9, -0.33; *p*=0.006)*	-0.50 (-1.00, -0.01; *p* = 0.044)*
Component one of brief advice: advice safest not to drink	-1.00 (-1.4, -0.52; *p* <0.001)*	-1.0 (-1.7, -0.22; *p*=0.011)*	-1.1 (-1.7, -0.49; *p*<0.001)*
Component two of brief advice: advice on potential risks	-0.80 (-1.3, -0.28; *p* = 0.003)*	-1.2 (-2.0, -0.37; *p*=0.005)*	-0.75 (-1.4, -0.09; *p*=0.025)*
Complete care relative to risk level (complete brief advice and referral)	-0.64 (-1.1, -0.22; *p* = 0.003)*	-1.1 (-1.9, -0.31; *p*=0.007)*	-0.51 (-1.00, -0.02; *p* = 0.040)*
Assessment of alcohol consumption and level of risk using the AUDIT-C and complete care relative to risk level	-0.36 (-0.72, 0.00; *p* = 0.050)	-0.47 (-1.2, 0.25; *p*=0.2)	-0.40 (-0.76, -0.03; *p* = 0.034)*

*Statistically significant rate of weekly change at p <0.05

Table 3. Percentage of women reporting receipt of recommended care elements for the last four weeks in each implementation phase and at 30-weeks post-implementation for all antenatal visits combined

Outcome	Percentage of women reporting receipt of each recommended care elements			
	Pre-implementation (n=178 women)	Implementation (n=161 women)	30-weeks post-implementation (n=177 women)	End of post-implementation (n= 126 women)
Assessment of alcohol consumption and level of risk using the AUDIT-C	27% (n=48)	45% (n=73)	44% (n=77)	37% (n=46)
Complete brief advice (safest not to consume and potential risks)	16% (n=29)	35% (n=57)	25% (n=44)	22% (n=28)
Component one of brief advice: advice safest not to drink	32% (n=57)	56% (n=90)	45% (n=79)	41% (n=52)
Component two of brief advice: advice on potential risks	21% (n=37)	41% (n=67)	31% (n=54)	29% (n=36)
Complete care relative to risk level (complete brief advice and referral)	16% (n=28)	35% (n=57)	25% (n=44)	22% (n=28)
Assessment of alcohol consumption and level of risk using the AUDIT-C and complete care relative to risk level	11% (n=19)	25% (n=41)	16% (n=29)	17% (n=22)

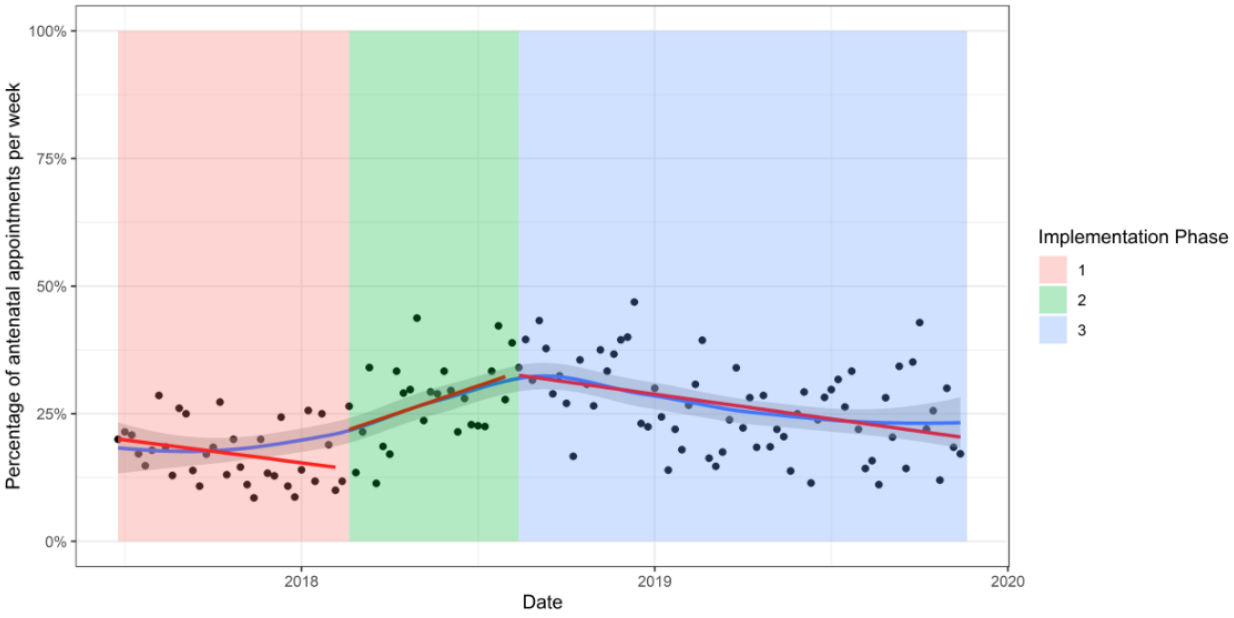

Figure 2. Fitted values of a linear segmented regression model including all antenatal appointments for outcome assessment of alcohol consumption and level of risk using the AUDIT-C and complete care relative to risk level

Figure 3. Fitted values of a linear segmented regression model including all antenatal appointments for outcome assessment for alcohol consumption and level of risk using the AUDIT-C

Figure 4. Fitted values of a linear segmented regression model including all antenatal appointments for outcome assessment for alcohol consumption and level of risk using the AUDIT-C excluding outlier

Figure 5. Fitted values of a linear segmented regression model including all antenatal appointments for outcome brief advice regarding the risks of consuming alcohol during pregnancy

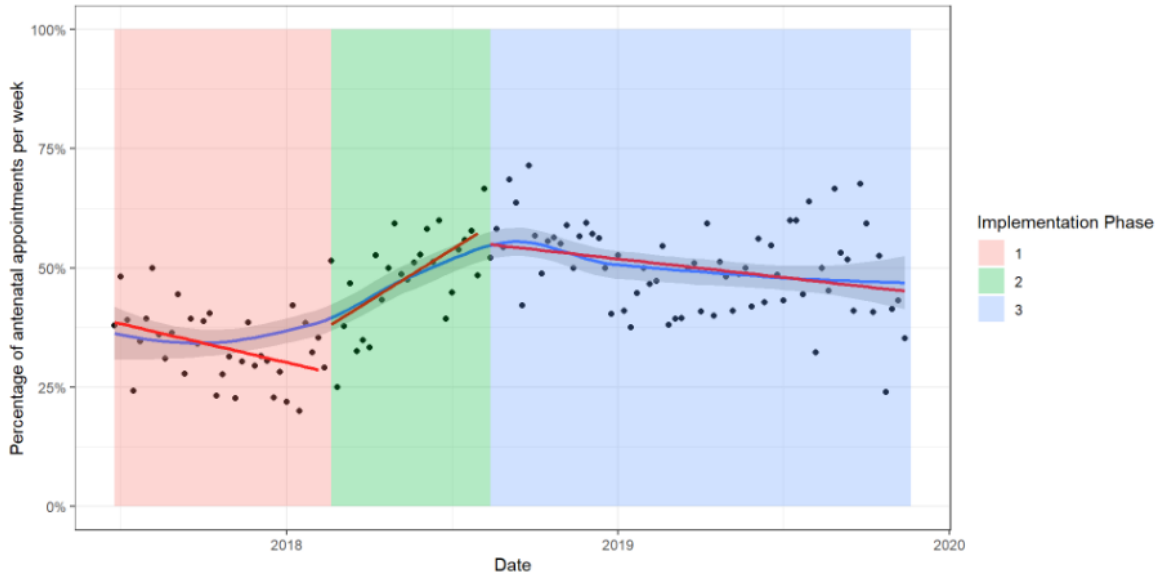

Figure 6. Fitted values of a linear segmented regression model including all antenatal appointments for outcome component of brief advice: advice not to drink

Figure 7. Fitted values of a linear segmented regression model including all antenatal appointments for outcome component of brief advice: advice on potential risks

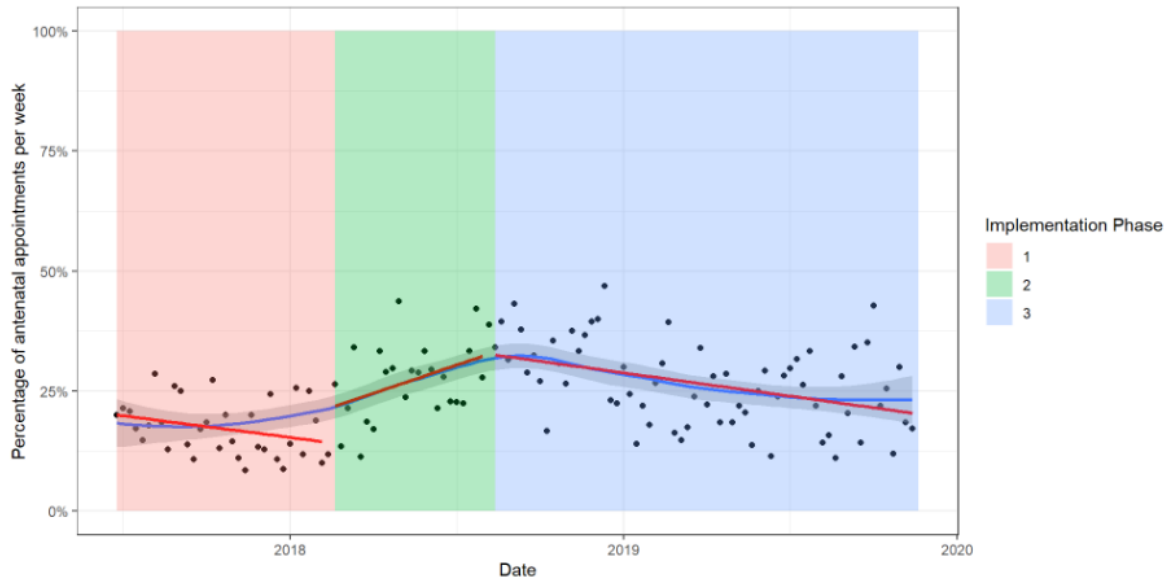

Figure 8. Fitted values of a linear segmented regression model including all antenatal appointments for outcome complete care relative to risk level (complete brief advice and referral)

Figure 9. Fitted values of break-point analysis including all antenatal appointments for outcome assessment for alcohol consumption and level of risk using the AUDIT-C

Figure 10. Fitted values of break-point analysis including all antenatal appointments for outcome assessment for alcohol consumption and level of risk using the AUDIT-C excluding outlier

Figure 11. Fitted values of break-point analysis including all antenatal appointments for outcome brief advice regarding the risks of consuming alcohol during pregnancy

Figure 12. Fitted values of break-point analysis including all antenatal appointments for outcome complete care relative to risk level (complete brief advice and referral)

Figure 13. Fitted values of break-point analysis including all antenatal appointments for outcome assessment of alcohol consumption and level of risk using the AUDIT-C and complete care relative to risk level

DISCUSSION

This study used existing data from a stepped-wedge randomised controlled trial to explore rate, time-points and extent of change in recommended antenatal care delivery in an effective practice change intervention (i.e. implementation intervention). It overcomes existing limitations of the field by using an appropriate analytic approach to explore changes that occur in outcomes across the implementation process, using recently collected data (18). Consequently, this study helps to identify if and when the implementation intervention effects may reduce ("wash out"), and thus when additional support may be required. Encouragingly, rates of care receipt were positively influenced by the implementation intervention, as demonstrated by the results from the primary analysis of the stepped wedge trial (10) and as illustrated by results of this study. However, rates for all outcomes declined after the implementation phase ended, with immediate and more rapid declines appearing to occur for all but one outcome until approximately 30 weeks following the completion of initial implementation support. For these latter outcomes, from this point, the prevalence of care seemed to stabilise, although longer follow-up assessment is needed to confirm if further reductions occur. For most outcomes the pattern of decline following withdrawal of initial implementation support was seen across all antenatal visits, despite a greater average effect being found for women attending subsequent antenatal visits in the primary analysis of this stepped wedge trial (10).

These findings illustrate an immediate decline in women's receipt of recommended care once active implementation support ended, regardless of what antenatal visit women were attending, and despite the intervention including a number of implementation strategies that were ongoing through integration with existing resources and systems. The findings are consistent with evidence from systematic reviews and individual trials that have identified a decline in

implementation following the withdrawal of funding or completion of initial implementation support (14, 15, 19, 28). The findings highlight the difficulties in sustaining long-term changes in clinical care, which are likely impacted by a range of organisational and outer environmental factors that can change rapidly overtime (29, 30). As suggested by the Dynamic Sustainability Model ongoing evaluation/monitoring and adaptation of the intervention and implementation support may be needed to ensure that successful practice changes, like the one observed in this trial, continue to fit and are integrated within changing clinical environments (30). In this specific instance, additional support may need to be considered within 30 weeks of active implementation ending.

Although it is likely that an array of contextual factors impact on the declines observed in this study, our understanding of the clinical setting following this implementation trial and existing evidence suggests that two possible factors may have had an impact on sustainment of care delivery gains following the completion of the implementation trial. The first, is a lack of capacity or capability for clinicians to provide recommended care due to withdrawal of the specifically trained clinical champion who educated and supported clinicians during this trial and the provision of academic detailing and audit and feedback, with evidence suggesting that clinical champions in particular are influential to sustainment (13, 31). The second factor relates to reductions in the number of staff who had been exposed to the initial implementation intervention due to regular clinical rotations and workforce turnover. Post-implementation surveys with staff 12 weeks after the intervention found that only approximately 70% of staff who received training were still providing antenatal care. The high rotation of staff from antenatal clinics may reduce the impact of a number of the implementation strategies, including educational meetings, academic detailing, and support from clinical champions (32). Additional strategies, such as booster education for existing staff and inclusion of training in

the orientation of new staff may need to be provided to help support long-term implementation and ensure all staff continue to be aware and are appropriately trained to provide recommended care.

While it is likely, as in this study, many implementation strategies are designed with an intention of maintaining evidence-based care, to date, limited research has been conducted on the use and effect of sustainability specific strategies to address declines in the continued delivery of recommended care following effective implementation support. Consequently, there is limited guidance on how to specifically address the issues of sustaining recommended antenatal care addressing alcohol consumption during pregnancy. We are aware of one systematic review that assessed sustainability strategies, which focused on evidence-based public health interventions (33). Only six of the 26 included studies reported the use of strategies specifically to support sustainment (33). Furthermore, the effect of such strategies was not assessed, providing limited knowledge as to which strategies maybe most effective in supporting sustained improvements in care delivery. Further research is required that involves the development and conduct of specific sustainability trials aimed at supporting the long-term receipt of recommended care generally, and addressing pregnant women's consumption of alcohol specifically (34).

Several limitations should be acknowledged when interpreting the results of this study. First, this is a secondary analysis, thus the design and sample size were not developed a-priori to undertake this study. Consequently, the findings should be interpreted as hypothesis and concept generating only. Second, only one of the three sectors from the primary trial was included in this study, due to small sample sizes within the other two sectors. Finally, we only assessed implementation rates up until 17 months post-implementation, which is contrary to

recommendations that sustainment should be considered from two-years post-implementation. However, our finding that care delivery reduced by the end of the 17 month post-implementation period highlights the need to consider issues relating to sustainment earlier in the implementation continuum.

CONCLUSIONS

This secondary analysis provided an opportunity to explore the rate, time points and extent of change in women's receipt of recommended antenatal care addressing alcohol consumption during pregnancy, following withdrawal of effective implementation support. Consistent with previous research on intervention sustainment we found that the effects of a multi-strategy practice change intervention declined after active implementation was completed, however for most outcomes this decline appears to stabilise from approximately 30 weeks post-implementation. The results suggest the potential need for additional sustainability strategies initially after withdrawal of implementation support to ensure that the benefits of delivering guideline recommended care are continued long-term.

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APPENDIX 8. Iterative delivery of an implementation support package to increase and sustain the routine provision of antenatal care addressing alcohol consumption during pregnancy: study protocol for a stepped-wedge cluster trial

Open access Protocol

BMJ Open

Iterative delivery of an implementation support package to increase and sustain the routine provision of antenatal care addressing alcohol consumption during pregnancy: study protocol for a stepped-wedge cluster trial

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ABSTRACT

Introduction Antenatal care addressing alcohol consumption during pregnancy is not routinely delivered in maternity services. Although a number of implementation trials have reported significant increases in such care, the majority of women still did not receive all recommended care elements, and improvements dissipated over time. This study aims to assess the effectiveness of an iteratively developed and delivered implementation support package in: (1) increasing the proportion of pregnant women who receive antenatal care addressing alcohol consumption and (2) sustaining the rate of care over time.

Methods and analysis A stepped-wedge cluster trial will be conducted as a second phase of a previous trial. All public maternity services within three sectors of a local health district in Australia will receive an implementation support package that was developed based on an assessment of outcomes and learnings following the initial trial. The package will consist of evidence-based strategies to support increases in care provision (remind clinicians; facilitation; conduct educational meetings) and sustainment (develop a formal implementation blueprint; purposely re-examine the implementation; conduct ongoing training). Measurement of outcomes will occur via surveys with women who attend antenatal appointments each week. Primary outcomes will be the proportion of women who report being asked about alcohol consumption at subsequent antenatal appointments; and receiving complete care (advice and referral) relative to alcohol risk at initial and subsequent antenatal appointments. Economic and process evaluation measures will also be reported.

Ethics and dissemination Ethical approval was obtained through the Hunter New England (16/11/16/4.07, 16/10/19/5.15) and University of Newcastle Human Research Ethics Committees (H-2017-0032, H-2016-0422) and the Aboriginal Health and Medical Research Council (1236/16). Trial findings will be disseminated to health service decision makers to inform the feasibility of conducting additional cycles to further improve antenatal care addressing alcohol consumption as well as at scientific conferences and in peer-reviewed journals.

Trial registration number Australian and New Zealand Clinical Trials Registry (ACTRN12622000295741).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This will be the first controlled trial to evaluate the effectiveness of an iteratively developed and delivered implementation support package in increasing and sustaining the routine provision of antenatal care addressing alcohol consumption during pregnancy.
⇒ The implementation support package was developed based on an assessment of outcomes and learnings following the initial trial and consists of evidence-based implementation and sustainability strategies.
⇒ The stepped-wedge cluster study design is appropriate for implementation trials that deliver implementation support at a service level and offers pragmatic and scientific strengths to the study.
⇒ Data will be collected through surveys of women who recently attended an antenatal appointment, which is subject to less response bias than health-professional self-report of clinical adherence and provides complete outcome data unlike medical records.
⇒ The order in which the sectors receive the implementation support package will be non-randomised.

INTRODUCTION

Alcohol consumption during pregnancy can lead to adverse obstetric (risk of placental abruption, miscarriage and preterm birth[1–3]) and child outcomes (birth defects,

developmental delays and fetal alcohol spectrum disorder[4–6]). Many countries have released guidelines that recommend no alcohol consumption in pregnancy.[7] Despite such recommendations, the global prevalence of alcohol consumption during pregnancy has been estimated at 10%, with higher prevalence estimates reported in a number of high-income countries, including Ireland (60%), Denmark (46%), the UK (41%) and Australia (36%).[8]

Systematic review evidence shows that pregnant women who receive brief psychosocial interventions from healthcare providers are more than two times as likely not to consume alcohol during pregnancy (OR: 2.31; 95% CI 1.61 to 3.32; p<0.001).[9] Consistent with such evidence, clinical guidelines recommend that all women at initial and subsequent antenatal appointments receive: (1) assessment of alcohol consumption; (2) advice not to consume alcohol and discussion of the risks and (3) referral to specialist services for further assessment, diagnosis of alcohol use disorders and treatment if required.[10 11] Public maternity services are a critical setting for these guidelines to be implemented as they provide care to the majority of pregnant women in many countries, including Australia.[12 13] However, clinician adherence to the guideline recommendations in these services is low (assessment: 42%–64%[14–16]; advice: 11%–35%[16 17]; referral: 10%–50%[16 18] and all guideline elements: 4%–28%[16]).

Two controlled trials to date have tested the effectiveness of implementation strategies in increasing the provision of antenatal care addressing alcohol consumption during pregnancy.[19 20] The first trial conducted in 2013 with four Italian Obstetrics and Gynaecology Units found that training significantly increased the proportion of pregnant women who received guideline consistent alcohol advice from their midwife (intervention: 53% vs control: 20%; Risk Ratio: 2.66; 95% CI 1.27 to 5.56).[19] The second trial, conducted with all public maternity services in three sectors of a single local health district in Australia between 2017 and 2020, found that an implementation support package consisting of seven evidence-based strategies significantly increased the proportion of pregnant women who reported receipt of: assessment of alcohol consumption via the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) tool (pre-implementation: 28.4%; post implementation: 40.6%; OR: 2.63; 95% CI 2.26 to 3.05; p<0.001); advice not to consume alcohol and discussion of the potential risks (pre-implementation: 18.7%; post implementation: 26.7%; OR: 2.07; 95% CI 1.78 to 2.41; p<0.001); complete care (advice and referral) relative to women's alcohol risk level (pre-implementation: 18.5%; post implementation: 26.6%; OR: 2.10; 95% CI 1.80 to 2.44; p<0.001); and all guideline elements (assessment, advice and referral) relative to alcohol risk level (pre-implementation: 12.6%; post implementation: 19.4%; OR: 2.32; 95% CI 1.94 to 2.76; p<0.001).[20] The effect sizes in both studies were at the upper end of implementation trial outcomes as reported in Cochrane systematic reviews.[21–30] However, half or fewer reported receipt of the recommended care elements after implementation support, leaving many women without the intended benefits of the clinical guidelines. Such a finding is consistent with the clinical practice change literature generally, which indicates that despite significant effect sizes in trials, the interventions do not result in the majority of patients receiving guideline recommended care.

Improvements in healthcare are rarely breakthrough in nature, rather they tend to occur gradually as new evidence is generated and applied.[31] Public health approaches to addressing health risks recognise that multiple steps are required for improvements to occur (eg, defining the problem, understanding the determinants of the problem, designing strategies and implementing/evaluating strategies) and that often such steps need to be repeated as the evidence-base is built over time.[32] This is also evident in quality improvement approaches used in healthcare settings to improve processes, safety and patient care outcomes.[33] In such approaches, systematic modifications are iteratively made until stakeholder defined outcomes are met and/or sustained practices are achieved.[34] Implementation trials that have used such approaches have demonstrated improvements in the proportion of patients receiving evidence-based interventions, including smoking cessation counselling in general practice[35] and HIV viral load monitoring in antenatal care.[36]

There has been one study to date that has used an iterative improvement approach to increase the proportion of pregnant women receiving antenatal care addressing alcohol consumption during pregnancy.[37] Fifty Australian primary healthcare centres participated in four cycles of continuous quality improvement between 2007 and 2012 to improve pregnancy care for Aboriginal and Torres Strait Islander women. At the beginning of each cycle, a systems assessment and audit of patient records was conducted to identify opportunities for improvement. A longitudinal analysis of 2220 pregnancy records found that effects continued to increase for alcohol screening (cycle 1 OR: 2.6; 95% CI 2.0 to 3.5; cycle 4 OR: 3.9; 95% CI 2.2 to 7.1) and brief counselling (cycle 1 OR: 2.8; 95% CI 1.7 to 4.5; cycle 4 OR: 6.7; 95% CI 2.3 to 20.0) over the four cycles compared with baseline. Over the duration of the study, care provision increased by 18% for screening (65%–83%) and 20% for counselling (51%–71%).[37] The study, however, was non-controlled and the generalisability of results to the public hospital maternity service setting and non-Indigenous populations is unknown.

A further limitation of successful controlled implementation trials generally, is that observed effect sizes do not persist.[38] For example, in the Australian controlled trial described earlier, a time series analysis that explored the rate of weekly change in recommended alcohol care delivery outcomes for 17 months after the implementation found significant decreases in both assessment (−0.66%; 95% CI −1.1 to −0.26; p=0.002) and complete

care (−0.64%; 95% CI −1.1 to −0.22; p=0.003).[20] No specific sustainability strategies were incorporated into the implementation support package delivered in the trial. This suggests that factors that commonly impede sustainment of care delivery change may not have been sufficiently addressed by the trial implementation support package[39] and that specific sustainability strategies may be required to ensure achieved effect sizes are maintained.[40] A limited number of studies have tested the effect of sustainability strategies in maintaining improvements in evidence-based interventions in maternity service settings,[41 42] with none specific to alcohol care. Such studies have found maintenance of workforce skills through ongoing training and mentoring opportunities, leadership buy-in and reviews of progress against improvement goals have sustained improvements in a range of antenatal care practices for periods between 1 and 5 years.[41 42]

The need to find effective strategies to both improve and sustain the routine provision of antenatal care addressing alcohol consumption during pregnancy remains. Given the potential of an iterative care delivery improvement approach and the inclusion of specific sustainment strategies to achieve this, and the limited research to date testing the effectiveness of such approaches, an implementation trial will be conducted to assess the effectiveness of an implementation support package including such approaches in: (1) increasing the proportion of pregnant women who receive guideline recommended antenatal care addressing alcohol consumption and (2) sustaining the rate of care over time.

METHODS AND ANALYSIS

The study methods were developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (online supplemental additional file 1).

Study design and setting

This trial follows on from a randomised stepped-wedge cluster trial that was conducted in public maternity services in three sectors within the Hunter New England Local Health District (HNELHD), New South Wales, Australia, between 2017 and 2020 (referred as the 'initial trial' from this point forward).[20] This trial will also use a stepped-wedge cluster study design and be conducted with the same services that participated in the initial trial to further enhance care delivery. The stepped-wedge cluster study design provides scientific and pragmatic advantages for conducting implementations trials in health settings, including: providing the same level of evidence as standard parallel cluster controlled trials; addressing the practical difficulty of recruiting enough equivalent maternity services required for parallel cluster controlled trials and increasing study efficiency by using each group as its own control.[29 43]

As shown in figure 1, continuous cross-sectional outcome data will be collected with weekly random samples of pregnant women who have recently attended an antenatal appointment with a participating maternity service. Delivery of a 3-month implementation support package will occur sequentially at the three sectors, which will provide outcome data periods of variable lengths for each sector. As per the initial trial, the intervention effect for aim one will be determined by comparing the overall proportion of women who report recommended care between pre-implementation and post implementation periods for the three sectors combined. This will be assessed 6 months after implementation completion in the last sector. For aim two, an additional 4 months of post implementation data will be collected for all three sectors to allow for a more prolonged assessment of care delivery sustainment. The primary outcomes will be reanalysed using a multiple baseline design to explore the rate of change over time as the measure of sustainment.

The study is being conducted in three geographically and administratively distinct sectors. The maternity services within these sectors provide antenatal care to 6100 women annually (70% of births in the district). Sectors 1 and 2 are located in regional/rural areas (1200 and 600 births, respectively) and sector 3 in a major city (4300 births per annum).[44]

Participant blinding

Research staff collecting outcome data will be blind to the order in which the three sectors receive the implementation support package. Participants will not be informed of the experimental nature of the implementation rollout and therefore will be blind to the stage of the study in

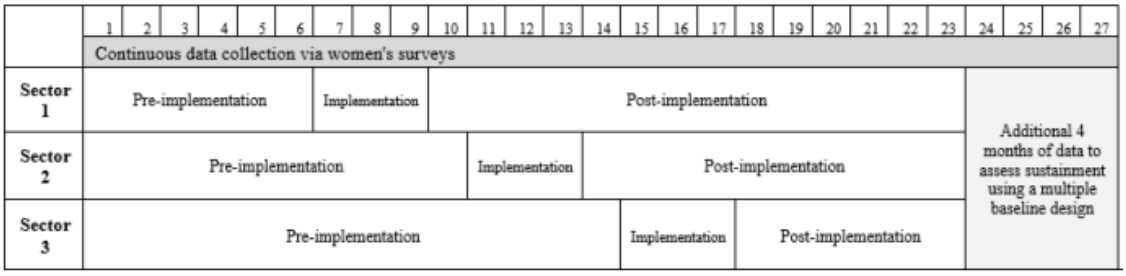

Figure 1 Data collection and study design.

the maternity service they attend. Given that maternity service staff will receive the implementation support package, they will be aware when their service is in the implementation period.

Participant eligibility and recruitment

Maternity services and staff

As per the initial trial, all maternity services within the three sectors will receive the implementation support package. These services include: midwifery led services and clinics; medical led clinics; and Aboriginal Maternal Infant Health Services (AMIHS). All antenatal care providers in these services (midwifery and medical staff and Aboriginal Health Workers) will be eligible to receive implementation support. This trial will also extend to maternity service staff who are in positions that support the ongoing availability and usage of the implementation strategies (maternity unit managers, administrative staff and clinical midwifery educators (CMEs)). All antenatal care providers will be invited to participate in surveys prior to implementation. All maternity service staff targeted to receive the implementation support package will be invited to participate in post implementation surveys.

Pregnant women

All women who attend an antenatal appointment at a participating maternity service have the potential to receive assessment and care addressing alcohol consumption as part of usual antenatal care. Women are eligible to participate in data collection following attendance at their: (1) initial antenatal appointment or (2) 27–28 weeks gestation appointment or (3) 35–36 weeks gestation appointment. Further eligibility criteria: aged 18 years or older; 12–37 weeks gestation; sufficient level of English to complete the survey and mentally and physically capable of completing the survey. Ineligibility criteria: receiving the majority of antenatal care through a private provider; given birth; negative pregnancy outcome; selected to participate in the data collection in the preceding 4 weeks or previously declined participation in the surveys. The number and characteristics of women deemed ineligible will be reported.

Each week, all eligible women from sector 1 and sector 2 will be sampled. For sector 3, a random sample of eligible women will be generated via a computerised random-number generator by members of the research team not involved in delivering care to women. All women will be sampled in sector 1 and sector 2 given the smaller number of women who attend these services. To enhance representativeness of the data collected, all women who are identified in the medical record data as being of Aboriginal and/or Torres Strait Islander origin (the term Aboriginal will be used from this point) and women who are attending or enrolled to attend an AMIHS will also be selected.

All women will receive a study information flyer in their usual antenatal information packs. Selected women will be sent a participant information statement outlining the purpose of the survey 1 week prior to receiving a telephone call inviting participation in the survey. As per advice from Aboriginal stakeholders regarding a culturally appropriate recruitment method for Aboriginal women, Aboriginal women and/or women attending or enrolled to attend an AMIHS will be contacted by text message 3 days after the information statement is sent and invited to participate in the survey via telephone or online modes. If no response is received, a telephone call will be attempted 4 days later. On the day that a woman is to be contacted to invite participation, medical record data will be checked and any women who have given birth or had a negative pregnancy outcome will be deemed ineligible.

Model of care and implementation support package

Evidence-based model of antenatal care

The evidence[9 45] and guideline-based[10 11] model of antenatal care found to be acceptable to Aboriginal (95%) and non-Aboriginal pregnant women (99%) and to antenatal care providers (78%–91%) in the initial trial[20] will be delivered to all pregnant women attending an initial antenatal appointment, 27–29 weeks and 35–37 weeks antenatal appointment (figure 2). The model of care is based on the Screening, Brief Intervention and Referral to Treatment public health approach to the management of substance abuse[46] and consists of three key elements:

- Assess: assess all women's alcohol consumption using the AUDIT-C tool.[47] Women's responses will be used to assign a risk of harm category: 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+).
- Advise: advise all women not to consume alcohol during pregnancy and discuss the potential risks.
- Refer: offer women at medium risk a referral to the free government funded Get Healthy in Pregnancy telephone-based coaching service, which supports women to make positive changes to their health, including abstaining from alcohol during pregnancy.[48] Also offer Aboriginal women at medium risk a referral to counselling services delivered through local Aboriginal Community Controlled Health Services. Offer women at high risk a referral to HNELHD Drug and Alcohol Clinical Services, which provide further assessment and diagnosis of alcohol use disorders, brief intervention, treatment and withdrawal support as clinically indicated.

Implementation support package

The initial trial delivered a comprehensive implementation support package that sought to increase the proportion of pregnant women receiving all elements of the model of antenatal care. As the majority of pregnant women in that trial (89.0%) were found to have been asked about alcohol consumption at the initial antenatal appointment, the implementation support package in this trial will not specifically seek to improve this care element.[20] The trial implementation support package

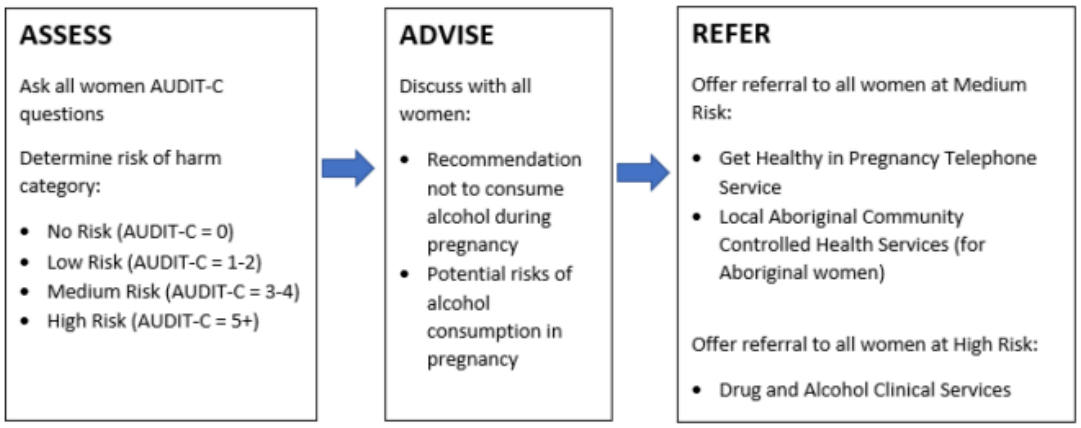

Figure 2 Evidence-based model of antenatal care recommended for provision at the initial and subsequent antenatal appointments. AUDIT-C, Alcohol Use Disorders Identification Test- Consumption.

will incorporate strategies that specifically address its two aims based on an assessment of outcomes and learnings from the initial trial. As per implementation science recommendations,[49] the support package will be targeted to the specific barriers and context of the local maternity service setting. See figure 3 for a description of the implementation support packages used in the initial trial and those proposed for this trial, and figure 4 for the logic model of this trial.

Initial trial
Strategies to increase the proportion of pregnant women who receive recommended care (7 months)
Leadership/ managerial supervision
Meetings were held every 2 months with maternity service management to elicit operational support for the practice change.
Local clinical practice guidelines
A service level guideline and procedure document that outlined the model of care (with local referral options) was uploaded onto the health service's policy and guidelines directory and disseminated.
Remind clinicians
Modifications were made to the existing point-of-care electronic medical record system used by maternity services. Antenatal providers were also provided with written point of care prompts.
Local opinion leaders/ champions
A dedicated CME was appointed in each sector to provide individual, team and service level support in the uptake of the recommended model of care.
Educational meetings and educational materials
A 30-minute online training module and a series of face-to-face sessions (including a mix of didactic, interactive, case-study, group and one-on-one sessions) (~1 hour) were facilitated by the CME.
Academic detailing, including audit and feedback
Data that were collected from medical records and surveys with pregnant women who recently attended a service were fed back to antenatal providers by the CME and used to develop action plans.
Monitoring and accountability for performance
Performance measures for the model of care for addressing alcohol consumption during pregnancy were included in managers' existing monitoring and accountability frameworks.
Strategies to sustain the rate of care over time
No specific sustainability strategies

Current trial
Strategies to increase the proportion of pregnant women who receive recommended care (2 months)
Remind clinicians
Point of care prompts will be included on women's hard-copy medical records. Prompts will fit with each service's usual clinical workflow and include a place to record that action was taken in the appointment. Staff who are usually responsible for resource ordering and medical record file management will receive instructive support.
Facilitation
A CME will facilitate peer-to-peer interactive problem solving to identify behavioural cues for providing assessment and care within the clinical workflow of antenatal appointments. Action plans that document the identified cues will be developed and examples included in training for new antenatal providers.
Conduct educational meetings
A single 15-minute educational meeting will be conducted. A credible source (Paediatrician with expertise in FASD) will provide persuasive education on the harms of alcohol consumption to increase salience of the issue. A CME will then guide a discussion focusing on reframing the purpose of providing assessment and care for alcohol consumption in antenatal visits.
Strategies to sustain the rate of care over time (1 month)
Develop a formal implementation blueprint
A formal implementation blueprint that plans for sustainability will be developed. The plan will define the roles and responsibilities of maternity services and the supporting agency in sustaining implementation and ensuring the ongoing availability, use and maintenance of the strategies.
Purposely re-examine the implementation
A process for reviewing the formal implementation blueprint will be developed. The first review will occur at six months and provide a mechanism to identify whether adaptions to the model of care and strategies are required.
Conduct ongoing training
Existing CME's will receive support and resources to schedule and conduct orientation training for new staff and top-up training for existing staff (schedule to be determined by, and fit with, usual service training).

Figure 3 Implementation support packages used in initial and current trial. CME, clinical midwifery educator. FASD, fetal alcohol spectrum disorder.

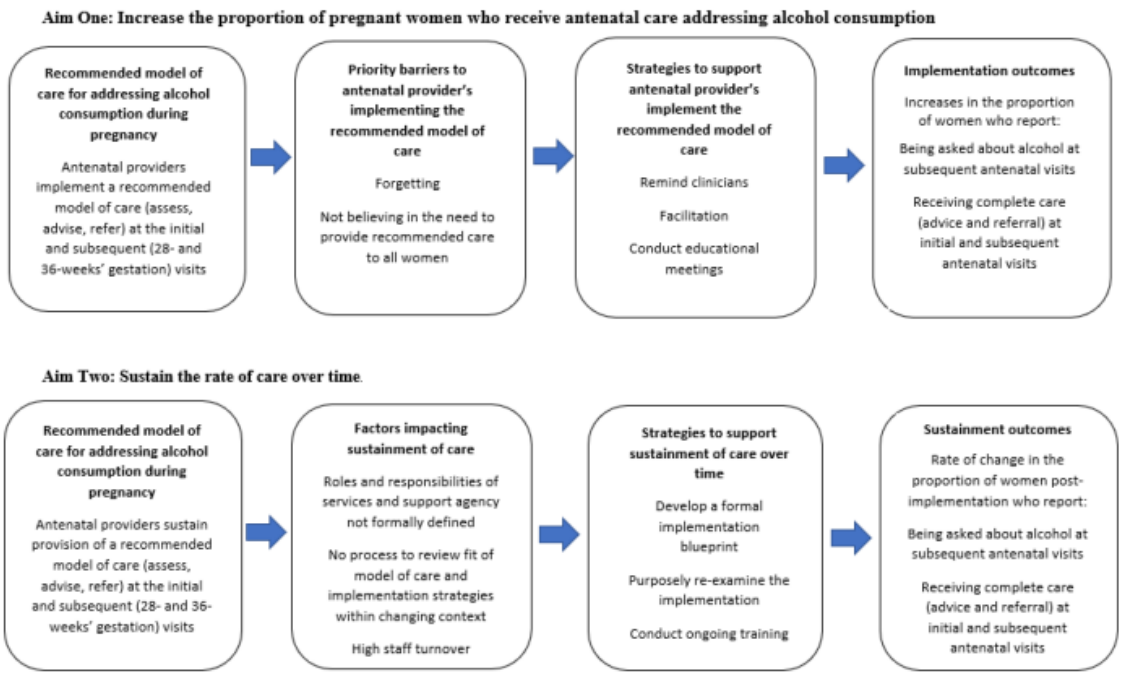

Figure 4 Logic model.

Strategies to increase the proportion of pregnant women who receive antenatal care addressing alcohol consumption

In the initial trial, formative research using the theoretical domains framework (TDF)[50 51] was conducted to comprehensively assess a range of barriers to implementing the recommended model of care. To address change in barriers (or their relative importance) over time, surveys were conducted with antenatal providers in the three sectors following completion of the trial to identify the highest priority barrier/s to delivering two care elements (assessment at subsequent antenatal appointments and advice discussion) using a best-worst scaling method.[52] Two priority barriers were found: (1) forgetting and (2) not believing there is a need to provide alcohol focused care to all women. Forgetting had been identified as a barrier in the initial formative research using the TDF, but its relative importance among all identified barriers had not been ascertained due to the survey method used. Not believing in the need to provide alcohol focused care to all women was not previously identified.

Similar to the initial trial, the priority barriers were defined in terms of the TDF[50 51] and Capacity, Opportunity, Motivation-Behaviours model[53] and mapped to intervention functions and behaviour change techniques (BCTs) using the behaviour change wheel.[53] Process evaluation data collected in the initial trial was used to inform the delivery of the implementation strategies. Components of strategies that had achieved high level/wide reach and were rated as acceptable and appropriate by antenatal providers were incorporated into the delivery of strategies. Clinical representatives and Aboriginal health staff provided expertise to finalise the strategies and embed cultural appropriateness for Aboriginal women (see online supplemental additional file 2 for development of implementation strategies).

Based on the above intervention development methods, the following strategies, defined according to the Expert Recommendations for Implementing Change taxonomy,[54] will be delivered: remind clinicians; facilitation and conduct educational meetings. The initial trial implemented reminders as a strategy built into the electronic medical record system. This strategy did not reach all maternity service types (eg, home visits) and profession types (eg, some medical and Aboriginal Health staff did not use the electronic medical record system). To address this, stickers for hard-copy medical records were implemented reactively during the initial trial and were subsequently rated as the most useful resource by antenatal providers (range: 72%–85%). The stickers, were primarily designed and used to record care provision (rather than prompt) and only included assessment of alcohol consumption (not advice or referral). Their availability and usage were also dependent on administrative staff who were not provided with implementation support. These two issues will be addressed in the remind clinicians strategy used in this trial.

Two additional implementation strategies (facilitation; conduct educational meetings) will involve BCTs not used in the initial trial. A CME will deliver peer-to-peer facilitation to support antenatal providers identify

behavioural cues for providing assessment and care in the clinical workflow of subsequent antenatal appointments. A CME will conduct educational meetings that will use a credible source to deliver persuasive information on the harms of alcohol consumption during pregnancy and provide new perspective on the purpose of assessment of alcohol consumption at subsequent appointments and having advice discussions with all women using framing/reframing techniques.[53]

Strategies to sustain the rate of care over time

A process for developing strategies to sustain the rate of care over time was undertaken guided by principles of the dynamic sustainability framework (DSF).[55] The DSF seeks to address change in three areas: the evidence-based intervention (eg, mode of delivery); practice setting (eg, information systems, training and staffing) and ecological systems (eg, policies). To determine the changes that had occurred in each of these areas since the initial trial, consultations were undertaken with clinical representatives, and audits of antenatal schedules, training records, staffing rosters, information systems, and resource and policy databases were conducted.

Although it was found that there had been a marked increase in antenatal appointments delivered via telehealth in response to the COVID-19 pandemic, telehealth care delivery guidelines included alcohol care being delivered irrespective of appointment mode. An assessment of systems and resources available to support care provision indicated that the majority of strategies implemented in the initial trial were still fully or partially available. An assessment of workforce turnover indicated that almost half of the current antenatal care workforce was not employed at the time of the initial trial and almost half of these new staff had not completed any of the training made available through the initial trial strategy. In addition, no formal process that defined the roles and responsibilities of specific groups or staff in ensuring the ongoing availability and use of supporting systems and resources, nor a formal process for identifying when adaptions to the model of care and implementation strategies may be required to address changes in circumstances. To address these factors, three strategies were selected based on the sustainability literature and in consultation with experts in the field: develop a formal implementation blueprint; purposely re-examine the implementation and conduct ongoing training[54] (see online supplemental additional file 3 for development of strategies).

Implementation delivery timeline

The implementation support package will be delivered in each of the sectors sequentially for a period of 3 months (see figure 1). Strategies aimed at increasing the proportion of women who receive antenatal care addressing alcohol consumption will be delivered in the first 2 months of the implementation. Strategies aimed at sustaining the rate of care will be developed, agreed to and implemented in the third month. Given the focus on embedding sustainability, the implementation support package has the potential to continue supporting care provision following the 3-month implementation.

Control and contamination

Usual care

In the pre-implementation data collection phase for each of the three sectors, usual antenatal care for addressing alcohol consumption during pregnancy will be provided. Strategies available to support care provision include: national and local clinical practice guidelines; electronic medical record prompts; online education module and performance data entered into the health service's monitoring system quarterly. Care provision is likely to vary by maternity service and clinician.

Potential for contamination

As the research team will control implementation delivery, the implementation support package will not be accessible to maternity services during the pre-implementation (control) phase.

Patient and public involvement

Pregnant women's acceptability of the model of care was considered in the development of the evidence-based intervention for this trial. Antenatal care provider's feedback on the initial implementation support package and new consultations with clinical representatives informed the iterative development of this trial's support package. Consultations with Aboriginal health staff were undertaken to embed cultural appropriateness for Aboriginal women across all components of the trial. A Cultural Review Group containing only Aboriginal members, including health service and community representatives, will review all dissemination products.

Measures

Primary trial outcomes

The proportion of all pregnant women who report:

- Being asked about alcohol consumption at subsequent antenatal visits.
- Receiving complete care (advice and referral) relative to level of alcohol risk at subsequent antenatal visits.
- Receiving complete care (advice and referral) relative to level of alcohol risk at the initial antenatal visit.

Process measures

Fidelity, penetration/reach and acceptability will be assessed in accordance with the implementation evaluation framework specified by Proctor *et al*.[56] Measures to assess penetration/reach will include the proportion of eligible staff who were exposed to each of the strategies. Acceptability of the strategies will be measured from the perspective of maternity staff. Sustainment at the provider and inner-context levels will be measured from the perspective of maternity staff using the three-item Provider REport of Sustainment Scale.[57] Changes occurring at the outer contextual level (eg, social, political and

economic factors) that may influence practices will be monitored and reported.

Within-trial economic analyses

A trial-based cost-effectiveness analysis will calculate the incremental cost per unit change in the primary trial outcomes and cost-consequence analysis will disaggregate results by sector. To assess the affordability of sustaining care over time within the resource and budget constraints of the health service, a budget impact analysis will also be conducted. All analyses will be conducted and reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards publication guidelines and good reporting practices guidelines.[58]

Data collection procedures

Primary outcome measures

Telephone contact will be attempted with sampled women up to 10 times over a 2-week period in order to elicit consent and completion of the survey. Women who decline participation in the telephone survey will be offered the online survey. Aboriginal women and/or women attending or enrolled to attend AMIHS will be offered the choice of telephone or online mode at first contact. The telephone survey will be computer assisted and be conducted by trained female interviewers. The questions and response options will be identical in the telephone and online surveys. All data collected will be recorded in the online Research Electronic Data Capture (REDCap).[59 60]

Process measures

Process measures will be collected through surveys with maternity staff and project management logs. Surveys of maternity service staff will be conducted pre-implementation (sustainment only) and post implementation in each sector (penetration/reach, acceptability and sustainment). Eligible staff will be sent a link to an online survey via email as well as given the option to complete the survey on tablet computers or pen and paper during regular clinic meetings. Additional process data will be collected by project staff during the implementation period and recorded in project management logs.

Costs

Resource use associated with the implementation support package will be prospectively identified, measured and valued using a cost capture template to be developed in REDCap.[59 60] Implementation resources are expected to include labour and materials to support maternity service staff. Costs associated with implementation will be recorded separately from those used for sustainability.

Sample size and power calculations

Assuming that 225women will complete a survey per month (approximately 150 for subsequent antenatal visit time points and 75 for the initial antenatal visit time point), we will have 80% power to detect an absolute increase of approximately (1) 15% in being asked about alcohol consumption at subsequent antenatal visits (baseline prevalence of 42%); (2) 13% in complete care at subsequent antenatal visits (baseline prevalence of 23%) and (3) 21% in complete care at initial antenatal visits (baseline prevalence of 45%). This is assuming an Intraclass Correlation Coefficient of 0.01 and an alpha level of 1.67% (Bonferroni adjusted for the three primary outcomes).

Statistical analyses

To address the first aim, pre–post differences in the proportion of women reporting receipt of care for each of the three primary outcomes will be compared using generalised linear models with a binomial distribution and logit link function. These models will compare the odds of receiving care at post implementation versus pre-implementation. Each model will contain a term for period (pre-implementation or post implementation), sector (1, 2, 3), antenatal visit for the outcomes on subsequent antenatal visits (28 weeks gestation, 36 weeks gestation) and time (in months). An alpha level of 1.67% will be used to determine statistical significance. The OR and 95% confidence limit from the term for period will be presented as the intervention effect.

For the second aim, segmented regression within an interrupted time-series framework will be used to assess women's receipt of care over time, and whether this improves and sustains following the delivery of the implementation support package. These analyses will be on the same three primary outcomes assessed in the pre–post difference analyses and will be conducted separately for each of the three sectors. Replication of findings across the three sectors will provide greater confidence in the intervention effect.[61] Three segments will be specified in each segmented regression, one for each of the study phases (ie, pre-implementation, implementation and post implementation). The rate of change in the receipt of care will be estimated for each of the three segments.

Exploratory secondary analyses will also be conducted to examine trial outcomes relative to initial trial findings, including a comparison of the proportion of pregnant women receiving guideline recommended care and rate of change per month of implementation support.

Research trial governance

The conduct of the trial will be overseen by an advisory group consisting of researchers, practitioners and clinical experts with expertise related to alcohol consumption during pregnancy, clinical practice change, sustainability, maternity services, Aboriginal heath and health economics. A project team consisting of research staff and a project dedicated CME will operationalise all components of the trial according to study protocol.

Aboriginal cultural governance

Cultural governance will be embedded across the trial to be inclusive of Aboriginal people's perspective. Aboriginal cultural task groups that are led by an Aboriginal project team member will provide guidance on the delivery of

the implementation support package. A Cultural Review Group containing only Aboriginal members will review all dissemination products.

Trial status

Recruitment of Sector One will commence April 2022 and recruitment of the last Sector will be completed in December 2022. Data collection will be completed by December 2023 and data analysis will commence January 2024.

ETHICS AND DISSEMINATION

Ethical approval was obtained through the Hunter New England Human Research Ethics Committee (16/11/16/4.07, 16/10/19/5.15); the University of Newcastle Human Research Ethics Committee (H-2017-0032, H-2016-0422) and the Aboriginal Health and Medical Research Council (1236/16). Any modifications to the protocol will be submitted to the above-mentioned ethics committees for approval prior to implementation. There are no predetermined criteria for trial discontinuation. Any unforeseen adverse events will be reported to the Hunter New England Human Research Ethics Committee (primary approval committee). The trial registry will be updated with any protocol modifications and any deviations from the original protocol will be reported.

Participation in the women and staff surveys will be voluntary. Potential participants will receive information about the study prior to providing verbal informed consent for surveys conducted via phone or written consent for surveys completed via online/pen paper modes. Women will have the opportunity to decline participation at any point, including after receiving the study information flyer or participant letter; at the time of the telephone call or text message; or partway through survey completion. Staff will also have the opportunity to decline participation at any point. A data management protocol that was developed and approved by the advisory group for the initial trial will be used in this trial. All data will be stored securely as per the requirements of the approving ethics committees and confidential identifying participant information will not be linked to survey responses. Data will only be accessible to the project team.

Trial findings will be disseminated to health service decision makers to inform the feasibility of conducting additional cycles to further improve antenatal care addressing alcohol consumption. Findings will also inform the use of iterative improvement approaches for other antenatal care guidelines in maternity services that have low adherence. Trial findings will be disseminated to key stakeholder groups, including clinical representatives and Aboriginal partners and community organisations. Finally, outcomes will be disseminated through peer-reviewed publications and at national and international conferences.

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Contributors ED, MK, NN, AH and JW led the overall development of the research protocol and ED led the development of the manuscript. JW, LW, MK and ED contributed to the development of the rationale and background for the protocol. ED, LW, MK, NN, AH and TM contributed to the development of the implementation support package. BT facilitated the provision of cultural advice and establishment of cultural governance structures. IS contributed clinical expertise relevant to the maternity services setting. EJE, AJD and TWT contributed clinical expertise relevant to alcohol consumption in pregnancy. ED and MK contributed to the development of data collection methods generally and PR and OW contributed to the development of data collection methods specific to the cost and cost-effectiveness measures. AH and JA provided overall guidance for the study design and data analysis. All authors read and approved the final manuscript.

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Patient consent for publication Not applicable.

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Additional File 2. Development of strategies to increase the proportion of pregnant women who receive assessment at subsequent antenatal visits and care at all antenatal visits.

Priority barrier	**COM-B (source of behaviour) & TDF domains**	**Intervention function**	**Behaviour Change Technique (BCT)**	**Mechanism of Action (MoA)**	**Implementation strategy** [47]	**Strategy description**	**Sustainability of technique**
I forget to assess alcohol consumption at subsequent antenatal visits I forget to explain the risks of alcohol consumption in pregnancy to all women	COM-B: Physical opportunity TDF: Environmental context and resources	• Environmental restructuring	• Restructuring the physical environment • Prompts, triggers, cues	• Environmental context and resources • Memory, attention and decision processes • Behavioural cueing	Remind clinicians	• Point of care prompts for assessment of alcohol consumption at subsequent antenatal visits and advice on the risks of alcohol consumption in pregnancy will be included on women's medical records. • The placement of the prompts will fit with each service's usual clinical workflow. • The prompts will include a place to record that action was taken in the visit.	Staff who are usually responsible for ordering resources and managing medical record files in each of the services will receive instruction in the ordering and placement of the prompts in the women's medical records.
	COM-B: Psychological capability TDF: Memory, attention and decision making	• Enablement	• Action planning	• Behavioural cueing	Facilitation	• A CME will facilitate a process of peer-to-peer interactive problem solving and support with antenatal providers to identify behavioural cues for providing assessment and care within antenatal visit clinical workflow. • Action plans that document the identified cues in clinical workflow will be developed.	Examples of identified behavioural cues will be included in existing training and resources for new antenatal providers.

Priority barrier	**COM-B (source of behaviour) & TDF domains**	**Intervention function**	**Behaviour Change Technique (BCT)**	**Mechanism of Action (MoA)**	**Implementation strategy** [47]	**Strategy description**	**Sustainability of technique**
I don't believe alcohol needs to be assessed at subsequent visits I don't believe the risks of alcohol consumption need to be explained to all women	COM-B: Reflective motivation TDF: Beliefs about consequences	• Education • Persuasion	• Information about health consequences • Credible source • Framing/ reframing	• Beliefs about consequences • Intention • Attitude towards the behaviour • Perceived susceptibility/ vulnerability	Conduct educational meetings	• Information on the harms of alcohol consumption in pregnancy will be delivered by an expert in FASD. • A CME will guide a discussion with antenatal providers to reframe the purpose of providing assessment and care for alcohol consumption in multiple antenatal visits.	Maternity services will be supported to incorporate this education into existing resources and schedules.

Additional File 3. Development of strategies to sustain the rate of care over time

Factor potentially impacting sustainability	Sustainability strategy	Description
The roles and responsibilities of maternity services and support agencies in ensuring the ongoing availability and usage of the implementation strategies had not been formally defined	Develop a formal implementation blueprint	• A formal implementation blueprint that plans for sustainability will be developed and agreed to by maternity service leads in consultation with the supporting agency (Population Health Unit within the same Local Health District as the maternity services). • The plan will define the roles and responsibilities of maternity services in the continued provision of the model of care as part of routine practice. • The plan will define the roles and responsibilities of key maternity service groups/positions (maternity leadership, administrative staff, CME's) and the supporting agency in ensuring the ongoing availability, use and maintenance of the strategies implemented to support practice.
No process to review the fit of the model of care within current maternity service context and to audit the availability, usage and maintenance of the implementation strategies	Purposely re-examine the implementation	• A process for reviewing the formal implementation blueprint will be developed and agreed to by maternity service leads in consultation with the supporting agency. • The review will provide a mechanism to identify whether adaptions to the model of care and strategies supporting practice need to be made. • The first review will occur six months after the commencement of the intervention in each maternity service.
High staff turnover in maternity services	Conduct ongoing training	• Existing CME's in each of the services will receive support and resources to schedule and conduct orientation training for new staff and top-up training for existing staff.

APPENDIX 9. Women's survey ethics approvals

14 December 2016

Professor John Wiggers
HNE Population Health
Wallsend Campus

Dear Professor Wiggers,

Re: Antenatal Alcohol Pregnant Women's Computer Assisted Telephone Interviews (CATI) (16/11/16/4.07)

HNEHREC Reference No: 16/11/16/4.07
NSW HREC Reference No: HREC/16/HNE/538

Thank you for submitting the above application for single ethical review. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **16 November 2016** and again on **14 December 2016.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and following acceptance of the requested clarifications and revised Participant Information Statement and Survey Questions by Dr Nicole Gerrand Manager, Research Ethics & Governance, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007),* to which the Committee is obliged to adhere, includes the requirement that the Committee monitors the research protocols it has approved. Ethics Approval will be ongoing subject to the following conditions:

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals. A proforma for the annual report will be sent at the beginning of the month of the anniversary of approval. Your review date is **December 2017.**
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement:

Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009
https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e112_nhmrc_position_statement_monitoring_reporting_safety_clinical_trials.pdf

- Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
NEAF [Submission Code: AU/1/78C9216]		
Audit Information Statement and Consent Form	Version 2	16 December 2016
Women's Information Statement	Version 2	16 December 2016
Antenatal Alcohol Initiative Support Services Directory	No Version	undated
Women's CATI Script	Version 2	undated
Study Flyer	No Version	undated
Poster	No Version	undated
Leaflet	No Version	January 2016
Medical Records Instructions and Tool	No Version	undated
Information Leaflet	No Version	undated

Approval has been granted for this study to take place at the following site:

- **Maternity Services, Hunter New England Local Health District**

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **16/11/16/4.07** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Dr A. Vertigan
Deputy Chair
Hunter New England Human Research Ethics Committee

RESEARCH INTEGRITY UNIT

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Registration of External HREC Approval

To Chief Investigator or Project Supervisor:	**Professor John Wiggers**
Cc Co-investigators / Research Students:	**Dr Tracy Tsang** **Ms Sarah Ward** **Ms Amy Anderson** **Professor Chris Rissel** **Professor Elizabeth Elliott** **Ms Sharni Goldman** **Ms Melanie Kingsland** **Doctor Luke Wolfenden** **Professor John Attia** **Conjoint Associate Professor Adrian Dunlop** **Prof IAN Symonds** **Doctor Andrew Searles** **Ms Carol Azzopardi** **Ms Karen Gillham** **Ms Penny Reeves**
Re Protocol:	**Effectiveness of a practice change intervention to increase the provision of recommended antenatal care regarding maternal alcohol use during pregnancy**
Date:	**09-Feb-2017**
Reference No:	**H-2017-0032**
External HREC Reference No:	**16/11/16/4.07**

Thank you for your **Initial Application** submission to the Research Integrity Unit (RIU) seeking to register an External HREC Approval in relation to the above protocol.

Your submission was considered under an **Administrative Review** by the Ethics Administrator.

I am pleased to advise that the decision on your submission is **External HREC Approval Noted** effective **09-Feb-2017**.

As the approval of an External HREC has been noted, this registration is valid for the approval period determined by that HREC.

Your reference number is **H-2017-0032**.

PLEASE NOTE:
As the RIU has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's RIU, via RIMS.

Linkage of ethics approval to a new Grant

Registered External HREC approvals cannot be assigned to a new grant or award (ie those that were not identified in the initial registration submission) without confirmation from the RIU.

Best wishes for a successful project.

Mr Alan Hales
Manager, Research Compliance, Integrity and Policy

For communications and enquiries:
Human Research Ethics Administration

Research & Innovation Services
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RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
NHMRC (National Health & Medical Research Council)/Partnership Projects(**)	A practice change intervention to increase the provision of antenatal care addressing maternal alcohol consumption during pregnancy: a stepped-wedge trial	Wiggers, John	G1500584

AH&MRC ETHICS COMMITTEE

3rd February 2017

Professor John Wiggers
Hunter New England Local Health District
Locked Bag 10
WALLSEND NSW 2287

Dear Professor John Wiggers,

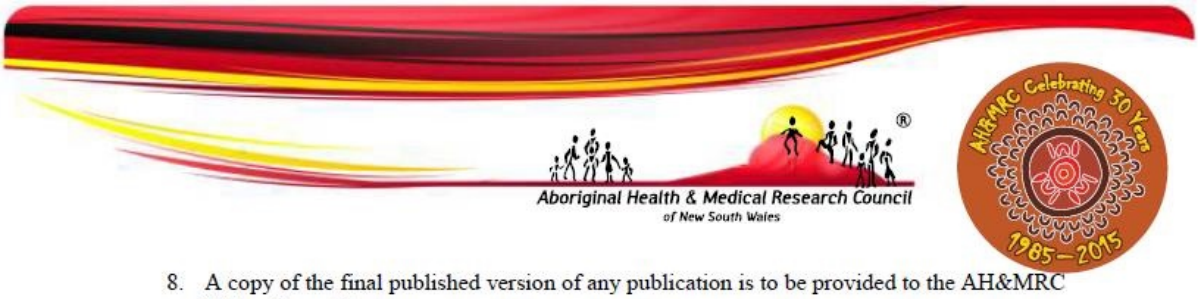
RE: 1236/16 Effectiveness of a practice change intervention to increase the provision of antenatal care addressing maternal alcohol consumption during pregnancy.

The Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee has considered your original application, received on 21st of November 2016.

The Committee agreed to approve the application, subject to the Standard Conditions and Special Conditions of Approval below:

Standard Conditions of Approval (where applicable to the project)

1. The approval is for a period from **3rd February 2017** until **3rd February 2018** (12 months after), with extension subject to providing an Annual Progress Report on the research by **3rd February 2018.**
2. All research participants are to be provided with a relevant Participant Information Statement and Consent Form in the format provided with your application.
3. Copies of all signed consent forms must be retained and made available to the Ethics Committee on request. A request will only be made if there is a dispute or complaint in relation to a participant.
4. Any changes to the staffing, methodology, timeframe, or any other aspect of the research relevant to continued ethical acceptability of the project must have the prior written approval of the Ethics Committee.
5. The AH&MRC Ethics Committee must be immediately notified in writing of any serious or unexpected adverse effects on participants.
6. The research must comply with:
   - the *AH&MRC Guidelines for Research in Aboriginal Health – Key Principles;*
   - *National Statement on Ethical Conduct in Research Involving Humans* (April 2007 – updated March 2014);
   - the *NSW Aboriginal Health Information Guidelines.*
7. The final draft report from the research, and any publication or presentation where data or findings are presented, must be provided to the AH&MRC Ethics Committee to be reviewed for compliance with ethical and cultural criteria prior to:
   - any submission for publication; and/or
   - any dissemination of the report.



8. A copy of the final published version of any publication is to be provided to the AH&MRC Ethics Committee.

Please acknowledge receipt of this letter and your acceptance of the above conditions within fourteen (14 days).

Please find attached an Annual Progress Report pro forma for use at the end of the approval period.

We appreciate your agreement that the research findings will be made available in order to assist the future development of policy and programs in Aboriginal health.

On behalf of the AH&MRC Ethics Committee,

Yours sincerely,

Val Keed

Chairperson

AH&MRC Ethics Committee

APPENDIX 10. Women's survey flyer

Do you want to help improve the antenatal care pregnant women receive around alcohol?

Telephone surveys are being conducted with pregnant women to ask about the care and advice they received in their antenatal visits for alcohol use during pregnancy.

You may receive a letter in the mail during your pregnancy inviting you to participate in a telephone survey. The survey can take up to 30 minutes depending on your answers.

The survey information will be used to help improve antenatal care for alcohol use during pregnancy and for research.

Doing this survey is entirely your choice. If you do not wish to participate, phone **1300 670 561**. Say your full name and address and you will not be contacted.

You can also choose to opt out of this survey when you receive the letter or at the beginning of the phone call.

If you do not wish to participate this will not change the care you receive from maternity services.

If you have any questions about this survey, please call John Wiggers on 4924 6247.

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 16/11/19/4.07 and the Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee, Reference 1236/16.

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

NSW GOVERNMENT Health Hunter New England Local Health District

APPENDIX 11. Women's survey information statements

Information Statement

Phone Survey for pregnant women having antenatal care with Hunter New England Local Health District maternity services – Regarding alcohol and pregnancy

30 June 2022

[Full Name]
[Address Line 1]
[Address Line 2]

Dear [First Name],

Hunter New England Local Health District (HNELHD) Population Health and the University of Newcastle in partnership with HNELHD Maternity Services are conducting telephone surveys with pregnant women. These surveys will ask women about the care and advice they received in their antenatal visits around alcohol use in pregnancy, such as whether they were asked if they drink alcohol or given information about alcohol use during pregnancy.

You should have received a flyer in the information pack provided to you at booking in or seen posters in the antenatal clinic rooms informing you that we are undertaking these phone surveys.

Who will be contacted?
Women who recently had an antenatal care visit with a HNELHD maternity service may be contacted by phone and invited to participate in the survey up to three times during their pregnancy. Your name was selected at random and the people sending this letter have not had access to your medical information.

What is the phone survey about?
If you are happy to do the survey, you will be asked some questions about any care you received in your antenatal visit around alcohol use and whether you find such care acceptable. We will also ask you about your alcohol use prior to and during pregnancy and whether any other health practice provided you with care/advice around alcohol use prior to booking in with the hospital. You will also be asked questions about any costs you may have had in accessing other services for assistance with alcohol use and who provides your antenatal care. This information will be used to help us improve the antenatal care pregnant women receive in HNELHD maternity services. You may be selected up to three times during your pregnancy as we are interesting in care regarding alcohol throughout pregnancy. Subsequent surveys will be shorter as some questions will not be asked again.

What will happen to the information you give us?
All the answers you give are strictly confidential. Your name and personal information will not be stored in the same place as the answers you give to the survey. When the survey is finished, everyone's names and contact details will be destroyed.

Reports that are based on the survey information will not identify individual women or their answers. The survey information will only be used for the purposes of quality assurance and for research. It will also be presented at scientific conferences, be published within scientific journals or form part of student's theses.

Do you have to talk to us?
Doing this survey is your choice. You can stop the survey at any time. If you do not want to receive a call, you can phone a free number **1300 670 561**. Say your full name and address and you will be removed from the survey list and we will not call you. This can be done at any time and so if, in the unlikely event, there is a complication or unforeseen outcome in your pregnancy you can withdraw from the study immediately by phoning us.

If you do not want to do the survey, it won't change the care you receive from HNELHD maternity services.

It is not anticipated that answering this survey will upset you, but if you choose to do the survey and anything does upset you, you can discuss it with your GP or at your next antenatal visit or call Lifeline on 13 11 14 or Beyond Blue on 1300 22 4636.

Where can I get more information about alcohol and pregnancy?
If you would like to know where to get more information about alcohol use in pregnancy; you can talk to your antenatal care provider (e.g. midwife or doctor) and/or Australian Government Department of Health website;
http://www.alcohol.gov.au/internet/alcohol/publishing.nsf/Content/wwtk-cons-leaflet.

What happens now?
Within the next week, you will be called and invited to take part in the survey. Alternatively if you wish schedule the call at a time that best suits you during the week you can call **4924 6477** to set up an appointment. Depending on the answers you provide, the phone survey can take about 30 minutes to complete.

If you have any questions about this survey, please call John Wiggers on 4924 6247.

Thank you for your time and consideration.

Yours sincerely

Professor John Wiggers
Director, Hunter New England Population Health
Professor, School of Medicine and Public Health, University of Newcastle

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 16/11/19/4.07.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHED-HREC@hnehealth.nsw.gov.au

Concerns can also be directed to The Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee, PO Box 1565 Strawberry Hills, NSW 2012 (02) 9212 4777, email ethics@ahmrc.org.au (Reference1236/16).

Information Statement

Survey for pregnant women having antenatal care with Hunter New England Local Health District maternity services – Regarding alcohol and pregnancy

30 June 2022

[Full Name]
[Address Line 1]
[Address Line 2]

Dear [First Name],

Hunter New England Local Health District (HNELHD) Population Health and the University of Newcastle in partnership with HNELHD Maternity Services are conducting surveys with pregnant women. These surveys will ask women about the care and advice they received in their antenatal visits around alcohol use in pregnancy, such as whether they were asked if they drink alcohol or given information about alcohol use during pregnancy. You should have received a flyer in the information pack provided to you at booking in or may have seen posters in the antenatal clinic rooms informing you that we are undertaking these surveys.

Who will be contacted?
Women who recently had an antenatal care visit with a HNELHD maternity service may be contacted and invited to participate in the survey up to three times during their pregnancy. Your name was selected at random and the people sending this letter have not had access to your medical information.

What is the survey about?
If you are happy to do the survey, you will be asked some questions about any care you received in your antenatal visit around alcohol use and whether you find such care acceptable. We will also ask you about your alcohol use prior to and during pregnancy and whether any other health practice provided you with care/advice around alcohol use prior to booking in with the hospital. You will also be asked questions about any costs you may have had in accessing other services for assistance with alcohol use and who provides your antenatal care. This information will be used to help us improve the antenatal care pregnant women receive in HNELHD maternity services. You may be selected up to three times during your pregnancy as we are interesting in care regarding alcohol throughout pregnancy. Subsequent surveys will be shorter as some questions will not be asked again.

How can you participate?
You can choose to complete the survey either via phone with a trained interviewer or online on your mobile phone or computer. Both surveys ask the same questions. Depending on the answers you provide, the survey can take about 30 minutes to complete.

What will happen to the information you give us?
All the answers you give are strictly confidential. Your name and personal information will not be stored in the same place as the answers you give to the survey. When the survey is finished, everyone's names and contact details will be destroyed. Reports that are based on the survey information will not identify individual women or their answers. The survey information will only be used for the purposes of quality assurance and for research. It will also be presented at scientific conferences, be published within scientific journals or form part of student's theses.

Do you have to take part in the survey?
Doing this survey is your choice. You can stop the survey at any time If you do not want to participate, you can phone a free number **1300 670 561**. Say your full name and address and you will be removed from the survey list. This can be done at any time and so if, in the unlikely event, there is a complication or unforeseen outcome in your pregnancy you can withdraw from the study immediately by phoning us. If you do not want to do the survey, it won't change the care you receive from HNELHD maternity services.

It is not anticipated that answering this survey will upset you, but if you choose to do the survey and anything does upset you, you can discuss it with your GP or at your next antenatal visit or call Lifeline on 13 11 14 or Beyond Blue on 1300 22 4636.

Where can I get more information about alcohol and pregnancy?
If you would like to know where to get more information about alcohol use in pregnancy; you can talk to your antenatal care provider (e.g. midwife or doctor) and/or Australian Government Department of Health website;
http://www.alcohol.gov.au/internet/alcohol/publishing.nsf/Content/wwtk-cons-leaflet.

What happens now?
In the next few days you will receive a text asking if you would like to complete the survey. If you choose to participate by phone you will receive a text back letting you know the name of the interviewer that will call you and the phone number they will call you from. You can expect a call within a week of the text. Alternatively if you wish schedule the call at a time that best suits you during the week you can call **4924 6477** to set up an appointment.

If you choose to complete the survey online you will receive a text with the survey link. You can access this link directly on your mobile phone or via a computer. The text message will let you know how long the survey link will remain active for.

If you do not wish to complete the survey you can opt out via text message or by calling the phone number above. If you do not respond to the text you will receive a follow up phone call 5 days later.

If you have any questions about this survey, please call John Wiggers on **4924 6247**. Thank you for your time and consideration.

Yours sincerely

Professor John Wiggers
Director, Hunter New England Population Health
Professor, School of Medicine and Public Health, University of Newcastle

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 16/11/19/4.07.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950 email HNELHED-HREC@hnehealth.nsw.gov.au

Concerns can also be directed to The Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee, PO Box 1565 Strawberry Hills, NSW 2012 (02) 9212 4777, email ethics@ahmrc.org.au (Reference1236/16.)

APPENDIX 12. Women's survey text messages to Aboriginal women and women attending AMIHS

Initial text message

Hunter New England Health and University of Newcastle are conducting surveys with pregnant women to ask whether they received any care or advice for alcohol use in their antenatal visits. If you wish to participate, reply 1 for phone survey or 2 for online survey. Reply 3 to opt out. We will follow up with a call in 5 days if we haven't received a response.

[Characters = 312] *2 texts*

Responses

1 – Thank you. You will receive a call from [Interviewer's name] off [Interviewer's phone number] within the next week.

[Characters = 116] *1 text*

2 – Thank you. You can complete the survey here [link]. The survey will be active until [date].

[Characters = 89] *1 text*

3 – Thank you. You will not be contacted to complete the survey.

[Characters = 60] *1 text*

Prompt text – online survey

This is a reminder for the online survey about antenatal care for alcohol use. The survey will be active until [date]. You can complete the survey here [link].

[Characters = 161] *2 texts*

APPENDIX 13. Women's survey – Computer Assisted Telephone Interview

Note: Questions not relevant to this thesis and logic skips have been removed to aid reading.

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We are doing phone surveys with women who recently had an antenatal care
visit with Hunter New England Health.
Your name was selected at random. Please don't worry we have not had direct
access to your medical records to get your information.
******************** INFORMATION SCREEN ITEM ******************************
Feedback from the survey will be used to help improve the quality of care
that pregnant women receive in their antenatal consults. We'd like to ask
you some questions about the care you may have received around alcohol use
at your antenatal visit.
As well as any costs associated with accessing other services for
assistance with alcohol use.
******************** INFORMATION SCREEN ITEM ******************************
Just a reminder the interview is voluntary and if you feel uncomfortable at
any time, let me know and we can move on to the next question or stop the
survey. All information you provide will be kept anonymous and is strictly
confidential. Completing this interview will have no impact on the care you
receive from our services.
******************** INFORMATION SCREEN ITEM ******************************
We do not anticipate to upset you in anyway, by asking these questions,
however if you are upset after this call, we can provide you with the phone
number for Lifeline and Beyond Blue for free counselling support.
There are also other support services if you become distressed during the
interview.
INTERVIEWER NOTE: if participants ask for the phone numbers.
Lifeline: 13 11 14; Beyond Blue: 1300 22 4636).
******************** INFORMATION SCREEN ITEM ******************************
To begin with I would like to ask some questions about you to make sure
that the information we collect represents all women who see
Hunter New England Health for antenatal care.
******************** INFORMATION SCREEN ITEM ******************************
Are you of Aboriginal or Torres Strait Islander origin?
PROMPT: Read out response options if required
1       Yes, Aboriginal origin
2       Yes, Torres Strait Islander origin
3       Yes, both Aboriginal and Torres Strait Islander origin
4       No
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
You have the option of completing the survey with an Aboriginal or Non
Aboriginal staff member which would you prefer?
PROMPT: Read out response options if required
1       Don't care happy to continue            (All staff)
2       Prefer Aboriginal staff member          (All staff)
3       Prefer Non Aboriginal staff member      (Laura Only)
****************** SINGLE CHOICE - CATI VERSION ****************************
Will your baby identify as Aboriginal and/or
Torres Strait Islander origin?
1       Yes, Aboriginal origin
2       Yes, Torres Strait Islander origin
3       Yes, both Aboriginal and Torres Strait Islander origin
4       No
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
What is your age?
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******************** NUMERIC OR DATE ENTRY - CATI VERSION *****************
What is your current employment status?
1       Employed full time
2       Employed part time or casual
3       Unemployed
4       Can't work - health reasons
5       Home duties
6       Student
7       Retired
8       Other
9       Currently on mat leave – employed FT prior to leave
10      Currently on mat leave – employed PT or casual prior to leave
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
What is your present marital status?
PROMPT: Read out response options if required
1       Never married
2       Married or living together in a relationship
3       Separated
4       Divorced
5       Widowed
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
What is the highest level of education you have achieved?
PROMPT: Read out response options if required
1       Never attended school
2       Some primary school
3       Completed primary school
4       Some high school
5       School certificate, Intermediate, Yr 10, 4th Form
6       Completed HSC, Leaving, Year 12 or 6th Form
7       TAFE certificate or diploma
8       University, CAE, Degree or higher
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
Is this your first pregnancy?
1       Yes
2       No
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
How many weeks gestation are you currently?
******************** NUMERIC OR DATE ENTRY - CATI VERSION *****************
The next few questions ask about your past and current alcohol use.
Once again, this information is completely confidential and being gathered
to make sure our services are providing the best quality of care around
alcohol use for pregnant women.

First I would like to ask you about your alcohol use in the 12 months prior
to this pregnancy.
******************** INFORMATION SCREEN ITEM ******************************
How often would you have a drink containing alcohol?
INTERVIEWER NOTE:
Ask the participant to pick the one that best fits how often they
drank(alcohol use in the 12 months prior to this pregnancy)
1       Never
2       Monthly or less
3       2 to 4 times a month
4       2 to 3 times a week
5       4 or more times a week
6       Don't know
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.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
How many standard drinks of alcohol would you drink on a typical day when
you were drinking?
A standard drink is 1 schooner of light beer, 1 middy of full strength
beer, 1 100ml glass of wine or 1 30ml nip of spirits.
INTERVIEWER NOTE:
If the participants responds with an amount less than 1 drink (i.e. half a
glass) code as Option 1 (1 to 2 drinks)
(ALCOHOL USE IN THE 12 MONTHS PRIOR TO THIS PREGNANCY)
1       1 to 2
2       3 to 4
3       5 to 6
4       7 to 9
5       10 or more
6       Don't know
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
How often would you have five or more standard drinks on one occasion?
INTERVIEWER NOTE:
Ask the participant to pick the one that best fits how often they
drank(alcohol use in the 12 months prior to this pregnancy)
1       Never
2       Less than monthly
3       Monthly
4       Weekly
5       Daily or almost daily
6       Don't know
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
Now I would like to ask you about your alcohol use since you found out you
were pregnant. Once again, this information is completely confidential and
being gathered to make sure our services are providing the best quality of
care around alcohol use for pregnant women. The results will not be
reported back to your antenatal service or anyone else.
******************* INFORMATION SCREEN ITEM *******************************
How often do you have a drink containing alcohol?
INTERVIEWER NOTE:
Ask the participant to pick the one that best fits how often they
drink(your alcohol use since you found out you were pregnant)
1       Never
2       Monthly or less
3       2 to 4 times a month
4       2 to 3 times a week
5       4 or more times a week
6       Don't know
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
How many standard drinks of alcohol do you drink on a typical day when you
are drinking? A standard drink is 1 schooner of light beer, 1 middy of full
strength beer, 1 100ml glass of wine or 1 30ml nip of spirits.
INTERVIEWER NOTE:
If the participants responds with an amount less than 1 drink (i.e. half a
glass) code as Option 1 (1 to 2 drinks)(YOUR ALCOHOL USE SINCE YOU FOUND
OUT YOU WERE PREGNANT)
1       1 to 2
2       3 to 4
3       5 to 6
4       7 to 9
5       10 or more
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6       Don't know
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ****************************
How often do you have five or more standard drinks on one occasion?
INTERVIEWER NOTE:
Ask the participant to pick the one that best fits how often they
drink(your alcohol use since you found out you were pregnant)
1       Never
2       Less than monthly
3       Monthly
4       Weekly
5       Daily or almost daily
6       Don't know
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ****************************
Another way to think about your alcohol use since finding out you were
pregnant is to think back on any special occasions you may have celebrated
in that time.
Were there any special occasions (e.g. a wedding, anniversary, birthday)
Since you found out you were pregnant where you consumed any alcohol?
1       Yes
2       No
3       Don't know
.R      REFUSED
***************** SINGLE CHOICE - CATI VERSION ****************************
On how many special occasions did you consume alcohol since finding out you
were pregnant?
******************** NUMERIC OR DATE ENTRY - CATI VERSION *****************
On average, approximately how many standard drinks of alcohol did you
consume during each special occasion?
A standard drink is 1 schooner of light beer, 1 middy of full strength
beer, 1 100ml glass of wine or 1 30ml nip of spirits.
INTERVIEWER NOTE:
If the participants responds with an amount less than 1 drink (i.e. half a
glass) code as Option 1 (1 to 2 drinks)
1       1 to 2
2       3 to 4
3       5 to 6
4       7 to 9
5       10 or more
6       Don't know
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ****************************
I would now like to ask you some questions about any antenatal care you may
have received during the last four weeks from
^team^ around alcohol.
******************* INFORMATION SCREEN ITEM ******************************
Do you recall having an antenatal care visit with ^team^ during the last
four weeks? This may have been with a midwife or doctor. The visit could
have been at a hospital, local community health centre or in your home.
1       Yes
2       No
3       Don't know
.R      Refused
******************* INFORMATION SCREEN ITEM ******************************
Which care providers have you seen in your visits with ^team^ in the last
four weeks?
1       Midwife
2       Hospital Doctor (Specialist, Obstetrician, Registrar)
3       Aboriginal Health Worker
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4       Other (Please specify)
-1      Don't know
.R      Refused
********************MULTIPLE CHOICE - CATI VERSION*************************
What would be the other care provider have you seen in the last four weeks.
******************* OPEN ENDED ENTRY ITEM ********************************
What is the main type of antenatal care you are receiving for this
pregnancy?
INTERVIEWER NOTE:
Read out each response option and its definition and ask the participant to
choose the model the best applies
1       Midwifery continuity of care
2       Midwives clinic
3       AMIHS (Aboriginal Maternal Infant Health Service)
4       Hospital doctors clinic
5       Shared Care – Hospital Doctor/General Practitioner (GP)
6       Shared Care – Hospital Midwife/General Practitioner (GP)
7       Shared Care – Hospital Midwife/Hospital Doctor
8       General Practitioner (GP)
9       Private Obstetrician
10      Don't know
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
Next we'd like to know whether ^team^ asked you any questions relating to
alcohol in any of your antenatal care visits in the last four weeks. At any
time in the last four weeks did ^team^ ask you about your alcohol use?
1       Yes
2       No
3       Don't know
.R      Refused
*********************** CALCULATION ITEM ***********************************
Were you asked how often you have a drink containing alcohol?
1       Yes
2       No
3       Don't know
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
Were you asked how many standard drinks of alcohol you would drink on a
typical day when you are drinking?
1       Yes
2       No
3       Don't know
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
Were you asked how often you would have five or more standard drinks on one
occasion?
1       Yes
2       No
3       Don't know
.R      Refused
****************** SINGLE CHOICE - CATI VERSION ****************************
At any time in the last four weeks did ^team^ advise you that not drinking
is the safest option during pregnancy?
1       Yes
2       No
3       Don't know
.R      Refused
*********************** CALCULATION ITEM ***********************************
Were you advised anything different than not to drink during pregnancy?
1       Yes
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2       No
3       Don't know
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ***************************
What were you advised?
********************** CALCULATION ITEM *********************************
Were the potential risks of drinking alcohol during pregnancy explained to
you?
1       Yes
2       No
3       Don't know
.R      Refused
************************NULL ITEM - DOES NOTHING************************
We will be sending you an information leaflet about alcohol use in
pregnancy after today's call.
If you would like to find out more in the meantime, you could talk to your
midwife or doctor at your next antenatal care visit or I could give you the
link to the Australian Government Department of Health website, which has
information and resources about alcohol and pregnancy.
www.alcohol.gov.au and click on 'Women Want to Know'.
****************** INFORMATION SCREEN ITEM ******************************
At any time in the last four weeks did ^team^ offer you a referral to a
service for alcohol use?
1       Yes
2       No
3       Don't know
.R      Refused
********************** CALCULATION ITEM *********************************
Where were you offered a referral to?
1       Get Healthy in Pregnancy Telephone Coaching Service
2       HNE Drug & Alcohol service eg nurse, counsellor, clinic
3       Safe Start (to connect women to HNE D&A service)
4       Aboriginal Medical Service (AMS)
5       Unsure of the name of the service
6       Other
-1      Don't know
.R      Refused
******************MULTIPLE CHOICE - CATI VERSION**************************
Can you please tell me what 'other' service you were referred to?
************************NULL ITEM - DOES NOTHING************************
Did you accept the offer to the ^SCAL3_[0]^ ?
If selected (Other specify) = ^orefe2^
1       Yes
2       No
3       Don't know
.R      Refused
********************** CALCULATION ITEM *********************************
Had you already accepted a referral for alcohol use in any other antenatal
care visit that was more than four weeks ago?
INTERVIEWER NOTE: Select all referrals that were accepted.
If NO referrals accepted, select NO).
1       Yes Get Healthy in Pregnancy Telephone Coaching Service
2       Yes HNE Drug & Alcohol service eg nurse, counsellor, clinic
3       Yes Safe Start (to connect women to HNE D&A service)
4       Yes Aboriginal Medical Service (AMS)
5       Yes Unsure of the name of the service
6       Yes Other
-1      No
-2      Don't know
.R      Refused
```

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******************MULTIPLE CHOICE - CATI VERSION*************************
Can you please tell me what 'other' service you already accepted an offer
to?
*************************NULL ITEM - DOES NOTHING*************************
At any stage in the last four weeks, did ^team^ discuss your progress with
the referral you had previously accepted with the ^SCAL3_[0]^ ?
If selected (Other specify) = ^oACCa^
1       Yes
2       No
3       Don't know
.R      Refused
*************************NULL ITEM - DOES NOTHING*************************
Has ^team^, given you any written information about alcohol?
1       Yes
2       No
3       Don't know
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ****************************
What information were you given?
1       Pamphlet
2       Information downloaded from internet
3       Personalised information (e.g. clinician notes)
4       Other
-1      Don't know
.R      Refused
******************MULTIPLE CHOICE - CATI VERSION*************************
Can you please tell me what 'other' information you were given?
****************** OPEN ENDED ENTRY ITEM *********************************
Have you used any other service for alcohol advice or support during this
pregnancy?
1       Yes
2       No
3       Don't know
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ****************************
What other service have you used?
1       Alcohol Drug & Information Telephone Service (ADIS)
2       Drug & Alcohol Service (Hunter New England)
3       Drug & Alcohol Service (Aboriginal Medical Service /AMS)
4       Drug & Alcohol Service (Other)
5       Detox clinic (Hunter New England)
6       Detox clinic (Other)
7       Support group e.g. Alcoholics Anonymous
8       Psychologist
9       Other (Please specify)
-10     Don't know
.R      Refused
******************MULTIPLE CHOICE - CATI VERSION*************************
Can you please tell me what 'other' service you have used?
****************** OPEN ENDED ENTRY ITEM *********************************
We would now like to get your thoughts on antenatal care for alcohol use in
pregnancy.
Please respond to these questions by answering strongly agree, agree,
unsure, disagree and strongly disagree.
****************** OPEN ENDED ENTRY ITEM *********************************
Alcohol use should be addressed with all pregnant women in antenatal care
visits. - would you say that you
1       Strongly Agree
2       Agree
3       Unsure
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4       Disagree
5       Strongly disagree
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ***************************
It is acceptable for all pregnant women to be asked about their alcohol use
in antenatal care visits.  - would you say that you
1       Strongly Agree
2       Agree
3       Unsure
4       Disagree
5       Strongly disagree
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ***************************
It is acceptable for all pregnant women to be asked about their alcohol use
in antenatal care visits on multiple occasions.
- would you say that you.
1       Strongly Agree
2       Agree
3       Unsure
4       Disagree
5       Strongly disagree
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ***************************
I would feel comfortable during my antenatal care visits answering
questions about my alcohol use. - would you say that you
1       Strongly Agree
2       Agree
3       Unsure
4       Disagree
5       Strongly disagree
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ***************************
It is acceptable for all pregnant women to be advised that not drinking is
the safest option during pregnancy in antenatal care visits.
- would you say that you
1       Strongly Agree
2       Agree
3       Unsure
4       Disagree
5       Strongly disagree
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ***************************
I would feel comfortable being advised in my antenatal care visits that not
drinking is the safest option during pregnancy.
- would you say that you
1       Strongly Agree
2       Agree
3       Unsure
4       Disagree
5       Strongly disagree
.R      Refused
***************** SINGLE CHOICE - CATI VERSION ***************************
It is acceptable for all pregnant women to be advised on the potential
risks of drinking alcohol during pregnancy in antenatal care visits.
- would you say that you
1       Strongly Agree
2       Agree
3       Unsure
4       Disagree
5       Strongly disagree
```

.R Refused
********** SINGLE CHOICE - CATI VERSION **********
It is acceptable for pregnant women to be offered a referral in antenatal care visits to a telephone based coaching service for further support for alcohol use if required. - would you say that you
1 Strongly Agree
2 Agree
3 Unsure
4 Disagree
5 Strongly disagree
.R Refused
********** SINGLE CHOICE - CATI VERSION **********
It is acceptable for pregnant women to be offered a referral in antenatal care visits to Drug and Alcohol services for further support for alcohol use if required. - would you say that you
1 Strongly Agree
2 Agree
3 Unsure
4 Disagree
5 Strongly disagree
.R Refused
**********END LOOP - CATI**********
We are nearly at the end of the survey, thank you so much for all the information you have provided so far.
I am now going to ask you some general questions about alcohol and pregnancy.
********** INFORMATION SCREEN ITEM **********
Where do you get information from to help you make decisions about alcohol use during pregnancy?
1 General Practice (GP)
2 Aboriginal Medical Service (AMS)
3 Midwife
4 Obstetrician
5 Family
6 Friends
7 Internet
8 Books
9 Brochures/pamphlets
10 Traditional Media (eg. TV, newspapers)
11 Social Media (eg. Facebook, Instagram)
-12 Don't get information from anywhere
13 Other
-14 Don't know
.R Refused
**********MULTIPLE CHOICE - CATI VERSION**********
Can you please tell me the 'other' way you get information to help you make decisions about alcohol use during pregnancy?
********** OPEN ENDED ENTRY ITEM **********
Are you aware that Australia has alcohol guidelines for pregnancy?
INTERVIEWER NOTE:
If the participant asks what the guidelines are you can tell them that the National Guidelines state that for women who are pregnant or planning a pregnancy, the safest option is not to drink alcohol.
1 Yes
2 No
3 Don't know
.R Refused
********** SINGLE CHOICE - CATI VERSION **********
Are you able to tell me what the guidelines recommend?
DO NOT READ OUT OPTIONS

INTERVIEWER NOTE:
If participant says no drinking alcohol during pregnancy record as NO ALCOHOL.
If participant has a different response, record as OTHER in next screen
1 No alcohol
2 Other Response (Please specify)
3 Don't know
.R Refused
********** OPEN ENDED ENTRY ITEM **********
I am now going to ask you how you feel about some statements about alcohol and pregnancy.
Please respond to these questions by answering strongly agree, agree, unsure, disagree and strongly disagree.
********** INFORMATION SCREEN ITEM **********
Not drinking alcohol is the safest option during pregnancy.
Would you say that you
1 Strongly Agree
2 Agree
3 Unsure
4 Disagree
5 Strongly disagree
.R Refused
********** SINGLE CHOICE - CATI VERSION **********
Not drinking alcohol during pregnancy is one of the most important things I can do for my baby's health. Would you say that you
1 Strongly Agree
2 Agree
3 Unsure
4 Disagree
5 Strongly disagree
.R Refused
********** SINGLE CHOICE - CATI VERSION **********
Pregnancy is a good time for women to change their alcohol use to improve their own health. Would you say that you
1 Strongly Agree
2 Agree
3 Unsure
4 Disagree
5 Strongly disagree
.R Refused
********** INFORMATION SCREEN ITEM **********
Thankyou very much for talking with us today.
Is there anything else you would like to tell me before we finish?
1 Yes
2 No
3 Don't know
.R Refused
********** OPEN ENDED ENTRY ITEM **********
If you want to contact someone regarding this survey, you can call John Wiggers on (phone 4924 6247). John's contact details are also listed on the bottom of the information letter.
Thanks again for participating. Goodbye.

APPENDIX 14. Women's survey – Online mode

Alcohol Use in Pregnancy

This survey is for women who recently had an antenatal care visit with Hunter New England Health.

Feedback from this survey will be used to help improve the quality of care that pregnant women receive.

The survey will include questions about the care you may have received around alcohol use at your antenatal visit, as well as any costs associated with accessing other services for assistance with alcohol use.

The survey can take up to 30 minutes based on your answers. You can save the survey at any time and return to complete it later. This survey is voluntary, you can move on to the next question or stop the survey if you wish.

All information you provide will be kept anonymous and is strictly confidential. Completing this survey will have no impact on the care you receive from our services.

We do not anticipate this survey will upset you in anyway, however if you are upset after completing the survey, you can contact Lifeline on 13 11 14 or https://www.lifeline.org.au/ or Beyond Blue on 1300 22 4636 or https://www.beyondblue.org.au/ for free counselling support.

Please Note: Your name was selected at random. We have not had direct access to your medical records to get your information.

Please complete the survey below.

Thank you!

Team	_____
Selected before	◯ Yes ◯ No
Completed survey before	◯ Yes ◯ No
Time Point	◯ Booking in ◯ 28 weeks ◯ 36 weeks

First we would like to ask some questions about you

Are you of Aboriginal or Torres Strait Islander origin?

◯ Yes, Aboriginal origin
◯ Yes, Torres Strait Islander origin
◯ Yes, both Aboriginal and Torres Strait Islander origin
◯ No
◯ Prefer not to say

Will your baby identify as Aboriginal and/or Torres Strait Islander origin?

◯ Yes, Aboriginal origin
◯ Yes, Torres Strait Islander origin
◯ Yes, both Aboriginal and Torres Strait Islander origin
◯ No
◯ Prefer not to say

What is your age?

_____

What is your current employment status?

- ◯ Employed full time
- ◯ Employed part time or casual
- ◯ Unemployed
- ◯ Can't work - health reasons
- ◯ Home duties
- ◯ Student
- ◯ Retired
- ◯ Other
- ◯ Currently on maternity leave - employed full time prior to leave
- ◯ Currently on maternity leave - employed part time or casual prior to leave
- ◯ Prefer not to say

What is your present marital status?

- ◯ Never married
- ◯ Married or living together in a relationship
- ◯ Separated
- ◯ Divorced
- ◯ Widowed
- ◯ Prefer not to say

What is the highest level of education you have achieved?

- ◯ Never attended school
- ◯ Some primary school
- ◯ Completed primary school
- ◯ Some high school
- ◯ School certificate, Intermediate, Yr 10, 4th Form
- ◯ Completed HSC, Leaving, Year 12 or 6th Form
- ◯ TAFE certificate or diploma
- ◯ University, CAE, Degree or higher
- ◯ Prefer not to say

Is this your first pregnancy?

- ◯ Yes
- ◯ No
- ◯ Prefer not to say

How many weeks gestation are you currently?

_____

The next questions are about your alcohol use in the 12 months prior to this pregnancy.

How often would you have a drink containing alcohol?

- ◯ Never
- ◯ Monthly or less
- ◯ 2 to 4 times a month
- ◯ 2 to 3 times a week
- ◯ 4 or more times a week
- ◯ Don't know
- ◯ Prefer not to say

How many standard drinks of alcohol would you drink on a typical day when you were drinking?

A standard drink is 1 schooner of light beer, 1 middy of full strength beer, 1 100ml glass of wine or 1 30ml nip of spirits.

NOTE: If you drank less than one standard drink, please select the first response option (1 to 2 standard drinks).

- ◯ 1 to 2
- ◯ 3 to 4
- ◯ 5 to 6
- ◯ 7 to 9
- ◯ 10 or more
- ◯ Don't know
- ◯ Prefer not to say

How often would you have five or more standard drinks on one occasion?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily
- ◯ Don't know
- ◯ Prefer not to say

The next questions are about your alcohol use since you found out you were pregnant.

This information is completely confidential and being gathered to make sure our services are providing the best quality of care around alcohol use for pregnant women. The results will not be reported back to your antenatal service or anyone else.

How often do you have a drink containing alcohol?

- ◯ Never
- ◯ Monthly or less
- ◯ 2 to 4 times a month
- ◯ 2 to 3 times a week
- ◯ 4 or more times a week
- ◯ Don't know
- ◯ Prefer not to say

How many standard drinks of alcohol do you drink on a typical day when you are drinking?

A standard drink is 1 schooner of light beer, 1 middy of full strength beer, 1 100ml glass of wine or 1 30ml nip of spirits.

NOTE: If you drank less than one standard drink, please select the first response option (1 to 2 standard drinks).

- ◯ 1 to 2
- ◯ 3 to 4
- ◯ 5 to 6
- ◯ 7 to 9
- ◯ 10 or more
- ◯ Don't know
- ◯ Prefer not to say

How often do you have five or more standard drinks on one occasion?

- ◯ Never
- ◯ Less than monthly
- ◯ Monthly
- ◯ Weekly
- ◯ Daily or almost daily
- ◯ Don't know
- ◯ Prefer not to say

Another way to think about your alcohol use since finding out you were pregnant is to think about alcohol consumption in the past month or to think back on any special occasions you may have celebrated since finding out you were pregnant.

In the past month, did you have a drink containing alcohol?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

On how many days in the past month did you consume a drink containing alcohol?

_____

On average, approximately how many standard drinks of alcohol did you consume during each special occasion?
A standard drink is 1 schooner of light beer, 1 middy of full strength beer, 1 100ml glass of wine or 1 30ml nip of spirits.

NOTE: If you drank less than one standard drink, please select the first response option (1 to 2 standard drinks).

- ◯ 1 to 2
- ◯ 3 to 4
- ◯ 5 to 6
- ◯ 7 to 9
- ◯ 10 or more
- ◯ Don't know
- ◯ Prefer not to say

Were there any special occasions (e.g. a wedding, anniversary, birthday) since you found out you were pregnant where you consumed any alcohol?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

On how many special occasions did you consume alcohol since finding out you were pregnant?

_____

On average, approximately how many standard drinks of alcohol did you consume during each special occasion?
A standard drink is 1 schooner of light beer, 1 middy of full strength beer, 1 100ml glass of wine or 1 30ml nip of spirits.

NOTE: If you drank less than one standard drink, please select the first response option (1 to 2 standard drinks).

- ◯ 1 to 2
- ◯ 3 to 4
- ◯ 5 to 6
- ◯ 7 to 9
- ◯ 10 or more
- ◯ Don't know
- ◯ Prefer not to say

The next questions are about any antenatal care you may have received during the last four weeks from [team].

This may have been with a Midwife, Doctor or Aboriginal Health Worker. The visit could have been at a hospital, local community health centre or in your home.

Do you recall having an antenatal care visit with [team] in the last four weeks?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Which care providers have you seen in these visits in the last four weeks?

NOTE: You can choose more than one option

- ☐ Midwife
- ☐ Hospital Doctor (Specialist, Obstetrician, Registrar)
- ☐ Aboriginal Health Worker
- ☐ Other
- ☐ Don't know
- ☐ Prefer not to say

What other care providers have you seen?

_____

What type of antenatal care are you receiving for this pregnancy?

- ◯ Midwifery continuity of care
- ◯ Midwives clinic
- ◯ AMIHS (Aboriginal Maternal Infant Health Service)
- ◯ Hospital doctors clinic
- ◯ Shared Care - Hospital Doctor/General Practitioner (GP)
- ◯ Shared Care - Hospital Midwife/General Practitioner (GP)
- ◯ Shared Care - Hospital Midwife/Hospital Doctor
- ◯ General Practitioner (GP)
- ◯ Private Obstetrician
- ◯ Don't know
- ◯ Prefer not to say

The next section is about whether the [team] asked you any questions around alcohol in the last four weeks.

At any time in the last four weeks did [team] ask you about your alcohol use?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the midwife ask you questions about alcohol in those antenatal care visits?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Hospital Doctor (Specialist, Obstetrician, Registrar) ask you questions about alcohol in those antenatal care visits?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Aboriginal Health Worker ask you questions about alcohol in those antenatal care visits?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the [oacala] ask you questions about alcohol in those antenatal care visits?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Were you asked how often you have a drink containing alcohol?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Were you asked how many standard drinks of alcohol you would drink on a typical day when you are drinking?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Were you asked how often you would have five or more standard drinks on one occasion?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

The next section is about any advice you received from [team] for alcohol in the last four weeks.

At any time in the last four weeks did [team] advise you that not drinking is the safest option during pregnancy?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Midwife provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Hospital Doctor (Specialist, Obstetrician, Registrar) provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Aboriginal Health Worker provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the [oaca1a] provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Were you advised anything different than not to drink during pregnancy?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

What were you advised?

Did the Midwife provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Hospital Doctor (Specialist, Obstetrician, Registrar) provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Aboriginal Health Worker provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the [oacala] provide you with this advice?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Were the potential risks of drinking alcohol during pregnancy explained to you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Midwife explain the potential risks to you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Hospital Doctor (Specialist, Obstetrician, Registrar) explain the potential risks to you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Aboriginal Health Worker explain the potential risks to you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the [oacala] explain the potential risks to you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

The next section is about any referrals you have been offered for alcohol from [team].

At any time in the last four weeks did [team] offer you a referral to a service for alcohol use?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did the Midwife offer you a referral to a service for alcohol use?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did the Hospital Doctor (Specialist, Obstetrician, Registrar) offer you a referral to a service for alcohol use?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did the Aboriginal Health Worker offer you a referral to a service for alcohol use?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did the [oaca1a] offer you a referral to a service for alcohol use?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Where were you offered a referral to?

NOTE: You can choose more than one option.

☐ Get Healthy in Pregnancy Telephone Coaching Service
☐ HNE Drug & Alcohol service (eg nurse, counsellor, clinic)
☐ Safe Start (to connect with HNE Drug & Alcohol services)
☐ Aboriginal Medical Service (AMS)
☐ Unsure of the name of the service
☐ Other
☐ Don't know
☐ Prefer not to say

What is the name of the service you were offered a referred to?

_____

Did you accept the offer to the Get Healthy in Pregnancy Telephone Coaching Service?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did you accept the offer to the HNE Drug & Alcohol service eg nurse, counsellor, clinic?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did you accept the offer to the Safe Start (to connect women to HNE D&A service)?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did you accept the offer to the Aboriginal Medical Service (AMS)?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did you accept the offer to the service (unsure of the name)?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Did you accept the offer to the [orefe2]?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Had you previously accepted a referral for alcohol in an antenatal care visit that occurred more than four weeks ago?

NOTE: You can choose more than one option.

- ☐ Yes, Get Healthy in Pregnancy Telephone Coaching Service
- ☐ Yes, HNE Drug & Alcohol service (eg nurse, counsellor, clinic)
- ☐ Yes, Safe Start (to connect to HNE Drug & Alcohol service)
- ☐ Yes, Aboriginal Medical Service (AMS)
- ☐ Yes, Unsure of the name of the service
- ☐ Yes, Other
- ☐ No
- ☐ Don't know
- ☐ Prefer not to say

What is the name of the service you accepted a referral to?

_____

At any stage in the last four weeks, did [team] discuss your progress with the referral you had previously accepted with the Get Healthy in Pregnancy Telephone Coaching Service?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

At any stage in the last four weeks, did [team] discuss your progress with the referral you had previously accepted with the HNE Drug & Alcohol service eg nurse, counsellor, clinic?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

At any stage in the last four weeks, did [team] discuss your progress with the referral you had previously accepted with Safe Start (to connect women to HNE D&A service)?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

At any stage in the last four weeks, did [team] discuss your progress with the referral you had previously accepted with the Aboriginal Medical Service (AMS)?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

At any stage in the last four weeks, did [team] discuss your progress with the referral you had previously accepted with the Service (unsure of the name)?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

At any stage in the last four weeks, did [team] discuss your progress with the referral you had previously accepted with the [oacca]?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Midwife discuss your referral progress with you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Hospital Doctor (Specialist, Obstetrician, Registrar) discuss your referral progress with you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the Aboriginal Health Worker discuss your referral progress with you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Did the [oacala] discuss your referral progress with you?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

The next questions are around any written information given to you by the [team].

Has [team] given you any written information about alcohol?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

What information were you given?

NOTE: You can choose more than one option.

- ☐ Pamphlet
- ☐ Information downloaded from internet
- ☐ Personalised information (e.g. clinician notes)
- ☐ Other
- ☐ Don't know
- ☐ Prefer not to say

What other information were you given?

The next questions ask about any other services you may have used for alcohol advice or support.

Have you used any other service for alcohol advice or support during this pregnancy?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

What other service have you used?

NOTE: You can choose more than one option.

- ☐ Alcohol Drug & Information Telephone Service (ADIS)
- ☐ Drug & Alcohol Service (Hunter New England)
- ☐ Drug & Alcohol Service (Aboriginal Medical Service)
- ☐ Drug & Alcohol Service (Other)
- ☐ Detox clinic (Hunter New England)
- ☐ Detox clinic (Other)
- ☐ Support group e.g. Alcoholics Anonymous
- ☐ Psychologist
- ☐ Other
- ☐ Don't know
- ☐ Prefer not to say

What is the other service you have used?

The next section is a series of statements to get your thoughts on antenatal care for alcohol use in pregnancy.

Alcohol use should be addressed with all pregnant women in antenatal care visits.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

It is acceptable for all pregnant women to be asked about their alcohol use in antenatal care visits.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

It is acceptable for all pregnant women to be asked about their alcohol use in antenatal care visits on multiple occasions.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

I would feel comfortable during my antenatal care visits answering questions about my alcohol use.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

It is acceptable for all pregnant women to be advised that not drinking is the safest option during pregnancy in antenatal care visits.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

I would feel comfortable being advised in my antenatal care visits that not drinking is the safest option during pregnancy.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

It is acceptable for all pregnant women to be advised on the potential risks of drinking alcohol during pregnancy in antenatal care visits.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

It is acceptable for pregnant women to be offered a referral in antenatal care visits to a telephone based coaching service for further support for alcohol use if required.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

It is acceptable for pregnant women to be offered a referral in antenatal care visits to Drug and Alcohol services for further support for alcohol use if required.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

The next section asks some general questions about alcohol and pregnancy.

Where do you get information from to help you make decisions about alcohol use during pregnancy?

NOTE: You can choose more than one option.

- ☐ General Practice (GP)
- ☐ Aboriginal Medical Service (AMS)
- ☐ Midwife
- ☐ Obstetrician
- ☐ Family
- ☐ Friends
- ☐ Internet
- ☐ Books
- ☐ Brochures/pamphlets
- ☐ Traditional Media (eg. TV, newspapers)
- ☐ Social Media (eg. Facebook, Instagram)
- ☐ Don't get information from anywhere
- ☐ Other
- ☐ Don't know
- ☐ Prefer not to say

What is the other way you get information?

Are you aware that Australia has alcohol guidelines for pregnancy?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Are you able to tell me what the guidelines recommend?

Are you able to tell me what the guidelines recommend?

- ◯ No alcohol is the safest option during pregnancy
- ◯ Other
- ◯ Don't know
- ◯ Prefer not to say

Can you provide more information as to what the guidelines say?

The next questions involve statements about alcohol and pregnancy.
Please indicate how you feel about the following statements.

Not drinking alcohol is the safest option during pregnancy.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

Not drinking alcohol during pregnancy is one of the most important things I can do for my baby's health.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

Pregnancy is a good time for women to change their alcohol use to improve their own health.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Unsure
- ◯ Disagree
- ◯ Strongly disagree
- ◯ Prefer not to say

We will be sending you an information leaflet about alcohol use in pregnancy.

If you would like to find out more in the meantime, you could talk to your midwife or doctor at your next antenatal care visit.

Alternatively the Australian Government Department of Health website has information and resources about alcohol and pregnancy.

To access this information go to www.alcohol.gov.au and click on 'Women Want to Know'.

Would you like us to send you an information leaflet about alcohol use in pregnancy?

- ◯ Yes
- ◯ No

Can you please confirm you address?

In trying to improve the quality of care that pregnant women receive in their antenatal care visits, we would also like to check medical records to see if the notes, including referral services, that are recorded agree with what women say about the care they receive

Only medical notes about antenatal care for alcohol will be examined. None of your other medical information will be looked at or recorded.

Please read the attached information letter

[Attachment: "Consent Letter.pdf"]

- I understand the purpose of this audit.
- I give permission for my medical records to be accessed to provide information about the antenatal care I received relating to alcohol.
- I understand that I have the right to withdraw from the audit at any time and do not have to give a reason for withdrawing.
- I understand that the information I provide will be confidential, and that only the research team will have access to it.

Do you agree for your medical record to be included in this project?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Signature: _____

Date: _____

Do you agree for your medical records to be included in the audit?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

Do you agree for us to send you a consent letter?

- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Prefer not to say

When you receive the consent letter please read it and then if you are willing to consent, sign it and return it in the reply paid envelope provided.
If you have any questions, please call the number provided on the letter.

Can you please confirm your address?

We may also be conducting further research to improve antenatal care around other health risks like smoking and healthy weight in pregnancy.
Any further research could be conducted up until 2020.

Do you agree to being contacted for any future research we conduct?

◯ Yes, happy to participate
◯ No, don't wish to participate
◯ Don't know
◯ Prefer not to say

Can you please confirm your contact details?
(Mobile, Home phone, work phone)

Thank you for your responses. Your input has been extremely valuable.
Please select submit to save your answers and finish the survey.

Is there anything else you would like to add?

◯ Yes
◯ No
◯ Don't know
◯ Prefer not to say

Please provide your comments

APPENDIX 15. Clinician and Manager surveys ethics approvals

10 November 2016

Professor John Wiggers
Director
Hunter New England Population Health
Hunter New England Local Health District

Dear Professor Wiggers

Re: Antenatal staff consultations to inform a Hunter New England Local Health District quality improvement initiative to increase the routine provision of recommended antenatal care for alcohol use in pregnancy (16/10/19/5.15)

HNEHREC Reference No: 16/10/19/5.15
NSW HREC Reference No: LNR/16/HNE/495
SSA Reference No: LNRSSA/16/HNE/496

Thank you for submitting the above study for single ethical review. This project was considered to be eligible to be reviewed as Low and Negligible risk research, and so was reviewed at an Executive Meeting of the Hunter New England Human Research Ethics Committee on **10 November 2016.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and, following acceptance of the requested clarifications and revised manager interview information statement, clinician interview information statement, and CATI information statement by Dr Nicole Gerrand Manager, Research Ethics & Governance Office, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007),* to which the Committee is obliged to adhere, include the requirement that the Committee monitors the research protocols it has approved. Ethics Approval will be ongoing subject to the following conditions:

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals, or, 2 months after the proposed closure date of the project if this date is less than 12 months. A proforma for the annual report will be sent. Your review date is **November 2017.**
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009* https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e112_nhmrc_position_statement_monitoring_reporting_safety_clinical_trials.pdf
  - Unforeseen events that might affect continued ethical acceptability of the project.
- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
LNR NEAF [Submission Code AU/6/C869210]	-	-
Manager Interview Information Statement	2	10 November 2016
Clinician Interview Information Statement	2	10 November 2016
CATI Information Statement	2	10 November 2016
Manager Interview Protocol	1	13 October 2016
Clinician Interview Protocol	1	13 October 2016
CATI Script	1	13 October 2016
CATI email	1	13 October 2016

Approval has been granted for this study to take place at the following site:

- **Hunter New England Population Health**

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **16/10/19/5.15** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

Human Research Ethics External HREC Registration

H Human Research Ethics Administration <human-ethics@newcastle.edu.au>

Today, 9:33 AM

Professor John Wiggers <john.wiggers@hnehealth.nsw.gov.au>; Sharni Goldman; Professor Ian Symonds <ian.symonds@adelaide.edu.au>; Amy Anderson; Adrian Dunlop; +5 more

Reply all

Inbox

BC04b Ext HREC Registr...
16 KB

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Further to your recent submission to the Human Research Ethics Committee (HREC), it is my pleasure to attach notification of registration.

Human Research Ethics Administration

Project Details:
CI Full Name: Professor John Wiggers
Protocol Number: H-2016-0422
Protocol Title: Antenatal staff consultations to inform a Hunter New England Local Health District quality improvement initiative to increase the routine provision of recommended antenatal care for alcohol use in pregnancy.

Your research grants and ethics records are now available in the Research Information Management System (RIMS). Go to: **https://rims.newcastle.edu.au/login.asp** and use your university number plate and login to access.

APPENDIX 16. Clinician and Manager surveys information statements

CLINICAL STAFF CONSULTATIONS TO INFORM A CLINICAL PRACTICE CHANGE FOR ADDRESSING ALCOHOL USE IN PREGNANCY

INFORMATION FOR MATERNITY STAFF

As a clinician working in maternity services, your feedback is needed to help inform a clinical practice change for addressing alcohol use in pregnancy that will be implemented in maternity services in the Hunter New England Local Health District (HNELHD). This clinical practice change is being undertaken by HNE Population Health and the University of Newcastle in partnership with HNE Maternity services to support services to provide evidence-based recommended care for alcohol use in pregnancy including alcohol screening, brief advice and referral.

You and your maternity colleagues will have a large role to play in this clinical practice change, so it is important that your feedback is considered at this time. To ensure appropriate resources are provided to HNE maternity services to support this clinical practice change, it is important to consult with you about potential issues in delivering recommended care for alcohol use in pregnancy, as well as factors that you think may help to address these issues.

You are invited to provide input on these issues and the broader clinical practice change via participating in an online survey. You will be asked to comment on issues in the survey including:

- Antenatal training, resources and clinical support;
- Guidelines, policies and procedures for addressing alcohol use in pregnancy;
- Your experiences and clinical practice regarding alcohol use in pregnancy;
- Supports and resources that would assist clinicians to deliver recommended care for alcohol use in pregnancy.

The survey takes approximately 15-20 minutes to complete and can be accessed via the online link attached to this email. Alternatively, should you wish to complete the survey via paper based form a paper copy of the survey and a reply paid envelope can be mailed to your workplace.

Please note participating in this survey is voluntary. All feedback provided by maternity clinicians will be treated with confidentiality and will be used by the support team to guide appropriate strategies and resources to support services to make clinical practice improvements regarding alcohol use in pregnancy.

Thank you for considering this invitation to provide input during consultations.

For any questions or further information regarding staff consultations and the clinical practice change, please contact:
John Wiggers, Hunter New England Population Health
Phone: 02 4924 6247
Email: John.Wiggers@hnehealth.nsw.gov.au

Staff consultations have been approved by the HNELHD Human Research Ethics Committee, reference number: 16/10/19/5.15. Should you have any concerns or complaints about the manner in which these consultations have been conducted, please contact John Wiggers or Nicole Gerrand: telephone (02) 49214950, email: Hnehrec@hnehealth.nsw.gov.au

CONSULTATIONS TO INFORM A CLINICAL PRACTICE CHANGE FOR ADDRESSING ALCOHOL USE IN PREGNANCY

INFORMATION FOR MATERNITY SERVICE MANAGERS

As you are aware, a clinical practice change regarding recommended antenatal care for alcohol use in pregnancy is being undertaken in maternity services across the HNELHD. This clinical practice change is being undertaken by HNE Population Health and the University of Newcastle in partnership with HNE maternity services As a manager, you play a central role in the success of this clinical practice change through managing performance. As a result, it is important your views are considered during the planning phase.

The support team wishes to identify potential issues you perceive in managing the performance of this clinical practice change, as well as factors that that you think may help to address these issues. This is to ensure managers are provided with appropriate support.

You are invited to provide input on these issues via participating in a brief survey. You will be asked to comment on:

- Your use of HNELHD Excellence tools to manage performance in your antenatal service including: Measures in SMaRTA Viewer; Operational Plans, Performance Reports, 90 Day Action Plans, Monthly Accountability Meetings (MAMS), Performance Conversations with Staff, and Leader Rounding.
- Potential issues in managing performance during the introduction of a clinical practice change in your service, and
- The support you may need to manage performance for the upcoming clinical practice change for addressing alcohol use in pregnancy.

The survey takes approximately 10-15 minutes to complete and can be accessed via the online link attached to this email. Alternatively, should you wish to complete a paper survey one can be provided.

Thank you for considering this invitation to provide input during consultations.

Please note participating in this survey is voluntary. All feedback provided by maternity service managers will be treated with confidentiality and will be used by the support team to guide appropriate strategies and resources to support managers in implementing this clinical practice change.

For any questions or further information regarding the clinical practice change please contact:
John Wiggers, Hunter New England Population Health
Phone: 02 4924 6247
Email: John.Wiggers@hnehealth.nsw.gov.au

Staff consultations have been approved by the HNELHD Human Research Ethics Committee, reference number: 16/10/19/5.15 . Should you have any concerns or complaints about the manner in which these consultations have been conducted, please contact John Wiggers or Dr Nicole Gerrand: telephone (02) 49214950, email Hnehrec@hnehealth.nsw.gov.au

APPENDIX 17. Clinician and Manager surveys

Clinician Survey

CLINICAL STAFF CONSULTATIONS TO INFORM AN ANTENATAL ALCOHOL QUALITY IMPROVEMENT INITIATIVE

WHAT IS RECOMMENDED CARE FOR ALCOHOL USE IN PREGNANCY?

The following clinical guidelines recommend that maternal alcohol use be routinely addressed as part of best practice antenatal care:

- *Clinical Practice Guidelines: Antenatal Care – Module I* (National)
- *Clinical Guidelines for the Management of Substance use During Pregnancy, Birth and the Postnatal period* (NSW)

"Addressing alcohol use in pregnancy" is defined by the guidelines as:

i. Assessing alcohol consumption for all pregnant women using a validated tool, such as the AUDIT-C;
ii. Providing all pregnant women with brief advice about alcohol use in pregnancy, including alcohol related risks to the fetus and that not drinking is the safest option; and
iii. Referral of pregnant women to specialist services if they require further assistance for alcohol use in pregnancy.

Instructions

Questions should be answered by selecting the relevant box. There are no right or wrong answers for this survey - it is your honest answers that are most important. Some of the questions may seem repetitive, but they are all subtly different and help to provide a more in-depth understanding of your views. The questions have been based on consultations with HNE maternity clinicians, and previous surveys with health professionals regarding alcohol use in pregnancy.

Thank you for taking the time to complete this survey.

Please tell us some information about yourself and role.

Have you provided antenatal care in the last 12 months, or are you likely to provide it in the next 12 months?

Yes ☐
No ☐ ***- Go to Info 1.0***

Are you currently providing antenatal care?
For example - currently on antenatal rotation

Yes ☐
No ☐

In What HNELHD do you currently work?

Greater Newcastle Sector ☐
Peel Sector ☐
Lower Mid North Coast Sector ☐
None of the above ☐ ***- Go to Info 1.0***

Info 1.0

Thank you for your time. The remainder of this survey only needs to be completed by clinicians who provide antenatal care in the Greater Newcastle, Peel or Lower Mid North Coast health sectors.

How many years have you been providing antenatal care?

<1 ☐
1-2 ☐
3-4 ☐
5-9 ☐
10+ ☐

What is your position?

Registered midwife ☐
Clinical midwife specialist (CMS) ☐
Clinical midwife consultant (CMC) ☐
Community liaison midwife (CLM) ☐
Aboriginal Health Worker ☐
Staff Specialist ☐
Obstetrician ☐
Consultant ☐
Visiting Medical Officer (VMO) ☐
Registrar ☐
Fellow ☐
Junior Medical Officer ☐
Student ☐
Other (please write) _____

How many years have you worked in your current position?

<1 ☐
1-2 ☐
3-4 ☐
5-9 ☐
10+ ☐

What is your employment status currently?

Full time ☐
Part time ☐
Casual ☐
Student ☐
Other (please write) _____

Have you completed HNE Aboriginal Cultural Respect Education (CRE) Training?

Yes ☐
No ☐

Have you completed HNE Aboriginal Identification Training?

Yes ☐
No ☐

To what extent do you agree or disagree with these statements, please tick one option per question.

For your reference, **"addressing alcohol use in pregnancy"** includes:

i. Assessing alcohol consumption using a validated tool, such as the AUDIT-C;
ii. Providing brief advice about the risks of alcohol use to the fetus and recommending that not drinking is the safest option during pregnancy;
iii. Offering specialist service referral for women who require further assistance for alcohol consumption in pregnancy.

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1. Strong evidence supports the clinical guideline recommendation that alcohol use should be addressed as part of routine antenatal care.	☐	☐	☐	☐	☐
2. There is a strong rationale that women should be advised that not drinking is the safest option for the health of the fetus.	☐	☐	☐	☐	☐
3. I know of the potential health consequences for the fetus that may result from alcohol use during pregnancy.	☐	☐	☐	☐	☐
4. I know the procedure for addressing alcohol use during pregnancy in accordance with clinical guidelines.	☐	☐	☐	☐	☐
5. I know the appropriate referral pathways to offer women who consume alcohol at *high risk* levels during pregnancy.	☐	☐	☐	☐	☐
6. I know the appropriate referral pathways to offer women who consume alcohol at *moderate risk* levels during pregnancy.	☐	☐	☐	☐	☐
7. I feel competent in:					
a. asking pregnant women about their alcohol use during pregnancy.	☐	☐	☐	☐	☐
b. assessing pregnant women's alcohol consumption using a validated tool, such as the AUDIT-C.	☐	☐	☐	☐	☐
c. providing pregnant women with brief advice regarding alcohol related risk to the fetus and that not drinking is the safest option.	☐	☐	☐	☐	☐
d. offering pregnant women who require further assistance to address their alcohol use referrals to appropriate support services.	☐	☐	☐	☐	☐
8. I have been adequately trained in how to address alcohol use in pregnancy according to clinical guidelines.	☐	☐	☐	☐	☐
9. I am able to have conversations with pregnant women around alcohol use in pregnancy in a sensitive, non-judgemental manner.	☐	☐	☐	☐	☐

10. All health professionals providing routine antenatal care should address alcohol use in pregnancy according to clinical guidelines.	☐	☐	☐	☐	☐
11. I currently address alcohol use in pregnancy according to clinical guidelines as part of routine antenatal care.	☐	☐	☐	☐	☐
12. It is part of my professional role to:					
a. ask pregnant women about their alcohol use during pregnancy.	☐	☐	☐	☐	☐
b. assess pregnant women's alcohol consumption using a validated tool, such as the AUDIT-C.	☐	☐	☐	☐	☐
c. provide pregnant women with brief advice regarding alcohol related risks to the fetus and that not drinking is the safest option.	☐	☐	☐	☐	☐
d. offer pregnant women who require further assistance to address their alcohol use referrals to appropriate support services.	☐	☐	☐	☐	☐
13. It is not my responsibility to address alcohol use in pregnancy as part of routine antenatal care.	☐	☐	☐	☐	☐
14. I am confident in:					
a. asking pregnant women about their alcohol use during pregnancy.	☐	☐	☐	☐	☐
b. assessing pregnant women's alcohol consumption using a validated tool, such as the AUDIT-C.	☐	☐	☐	☐	☐
c. providing pregnant women with brief advice regarding alcohol related risk to the fetus and that not drinking is the safest option.	☐	☐	☐	☐	☐
d. offering pregnant women who require further assistance to address their alcohol use referrals to appropriate support services.	☐	☐	☐	☐	☐
15. I am confident I can address alcohol use in pregnancy in the time allocated to antenatal appointments.	☐	☐	☐	☐	☐
16. I am confident I can address alcohol use in pregnancy during antenatal appointments even if the woman shows a lack of interest in discussing alcohol.	☐	☐	☐	☐	☐
17. I am not confident in addressing alcohol use in pregnancy during antenatal appointments when other health professionals are present.	☐	☐	☐	☐	☐
18. Addressing alcohol use in pregnancy enables women who require further assistance for their alcohol use to get appropriate support.	☐	☐	☐	☐	☐
19. Addressing alcohol use in pregnancy will enable changes in drinking behaviours and improve outcomes for the mother and baby.	☐	☐	☐	☐	☐

20. Regardless of how I approach the issue, pregnant women will feel uncomfortable or judged if I address alcohol use in pregnancy with them during antenatal appointments.	☐	☐	☐	☐	☐
21. Regardless of how I approach the issue, pregnant women who have consumed any alcohol during their pregnancy will feel anxious or guilty if I address alcohol use with them.	☐	☐	☐	☐	☐
22. There is no harm in me advising a pregnant woman that she can consume alcohol at low levels during pregnancy.	☐	☐	☐	☐	☐
23. Addressing alcohol use in pregnancy will have a negative effect on my client-clinician relationship with the woman.	☐	☐	☐	☐	☐
24. I am hesitant to address alcohol use in pregnancy as it may have implications in regards to child protection issues.	☐	☐	☐	☐	☐
25. My manager will hold me accountable if I do not address alcohol use in pregnancy in my antenatal appointments.	☐	☐	☐	☐	☐
26. I aim to address alcohol use in pregnancy with all pregnant women as part of my routine antenatal care.	☐	☐	☐	☐	☐
27. I have more important things to do in antenatal appointments than address alcohol use in pregnancy.	☐	☐	☐	☐	☐
28. I want to provide the best antenatal care for maternal alcohol use so I can support positive pregnancy outcomes for women and their babies.	☐	☐	☐	☐	☐
29. I often forget to address alcohol use in pregnancy during antenatal appointments.	☐	☐	☐	☐	☐
30. I am less likely to address alcohol use in pregnancy if the woman is multipara.	☐	☐	☐	☐	☐
31. Whether I address alcohol use in pregnancy is dependent upon the woman's demographics and antenatal history.	☐	☐	☐	☐	☐
32. If discussing alcohol is not a priority expressed by the woman, I do not address it during antenatal appointments.	☐	☐	☐	☐	☐
33. I do not address alcohol use in pregnancy because most women already know not to drink alcohol during pregnancy.	☐	☐	☐	☐	☐
34. It is difficult for me to address alcohol use in pregnancy because there is a lack of support services that I can refer pregnant women to for further assistance with alcohol use.	☐	☐	☐	☐	☐
35. It is difficult for me to address alcohol use in pregnancy because there is poor communication between maternity services and drug and alcohol services.	☐	☐	☐	☐	☐
36. It is difficult for me to address alcohol use in pregnancy because the IT systems/forms	☐	☐	☐	☐	☐

that I use in antenatal appointments do not provide the necessary supports.					
37. It is difficult for me to address alcohol use in pregnancy because I have a lot to cover in antenatal appointments.	☐	☐	☐	☐	☐
38. It is difficult for me to address alcohol use in pregnancy because I do not have access to appropriate information resources (e.g. pamphlets for woman, standard drink charts)	☐	☐	☐	☐	☐
39. My manager expects me to address alcohol use in pregnancy as part of routine antenatal care.	☐	☐	☐	☐	☐
40. Pregnant women expect me to address alcohol use in pregnancy during their antenatal care.	☐	☐	☐	☐	☐
41. Other maternity staff with whom I work do not address alcohol use in pregnancy as part of routine antenatal care.	☐	☐	☐	☐	☐
42. There are health professionals who can support me if I have difficulties when addressing alcohol use in pregnancy during antenatal appointments.	☐	☐	☐	☐	☐
43. Addressing alcohol use with pregnant women makes me feel nervous / anxious.	☐	☐	☐	☐	☐
44. I feel comfortable addressing alcohol use in pregnancy with pregnant women in antenatal appointments.	☐	☐	☐	☐	☐
45. It is stressful for me to address alcohol use in pregnancy during antenatal appointments	☐	☐	☐	☐	☐
46. I have a clear plan for how I am going to address alcohol use in pregnancy in antenatal appointments.	☐	☐	☐	☐	☐
47. If I encounter a problem when addressing alcohol use in pregnancy, I know how to solve it.	☐	☐	☐	☐	☐
48. If I received professional feedback about the way I address alcohol use in pregnancy, I would use it to improve the quality of the antenatal care I provide.	☐	☐	☐	☐	☐
49. As a health professional it is my job to provide antenatal care in line with clinical guidelines and procedures.	☐	☐	☐	☐	☐
50. As a health professional it is my job to provide antenatal care in line with the priorities outlined in my service's operational plan.	☐	☐	☐	☐	☐
51. As a health professional it is my job to meet the performance measure targets that relate to antenatal care delivery.	☐	☐	☐	☐	☐
52. I see 'Rounding' as an opportunity to improve antenatal care practices.	☐	☐	☐	☐	☐
53. I am committed to providing culturally safe and appropriate antenatal care to pregnant Aboriginal women.	☐	☐	☐	☐	☐

54. Providing culturally safe and appropriate antenatal care to pregnant Aboriginal women is a priority for my service.	☐	☐	☐	☐	☐
55. I am able to have conversations with Aboriginal women around alcohol use in pregnancy in a sensitive, non-judgemental manner.	☐	☐	☐	☐	☐
56. I know the appropriate referral pathways to offer Aboriginal women who consume alcohol at *high risk* levels during pregnancy.	☐	☐	☐	☐	☐
57. I know the appropriate referral pathways to offer Aboriginal women who consume alcohol at *moderate risk* levels during pregnancy.	☐	☐	☐	☐	☐
58. I feel competent in:					
a. asking pregnant Aboriginal women about their alcohol use during pregnancy.	☐	☐	☐	☐	☐
b. assessing pregnant Aboriginal women's alcohol consumption using a validated tool, such as the AUDIT-C.	☐	☐	☐	☐	☐
c. providing pregnant Aboriginal women with brief advice regarding alcohol related risk to the fetus and that not drinking is the safest option.	☐	☐	☐	☐	☐
d. offering pregnant Aboriginal women who require further assistance to address their alcohol use referrals to appropriate support services.	☐	☐	☐	☐	☐
59. I have been adequately trained in how to address alcohol use in pregnancy with Aboriginal women in a culturally sensitive manner.	☐	☐	☐	☐	☐
60. I have access to resources (e.g. culturally appropriate pamphlets for Aboriginal women) to support culturally safe communication with Aboriginal women regarding alcohol use in pregnancy.	☐	☐	☐	☐	☐
61. The IT systems/forms I use in my antenatal appointments guide and support culturally safe communication with pregnant Aboriginal women regarding alcohol use.	☐	☐	☐	☐	☐
62. There are more important things to address in antenatal appointments with Aboriginal women than alcohol use in pregnancy.	☐	☐	☐	☐	☐
63. As a health professional it is my job to meet the performance measure targets that relate to antenatal care delivery for Aboriginal women.	☐	☐	☐	☐	☐
64. It is an expectation of my manager that I meet Close the Gap measures that relate to antenatal care.	☐	☐	☐	☐	☐
65. There are health professionals who can support me to provide culturally safe and appropriate antenatal care to pregnant Aboriginal women.	☐	☐	☐	☐	☐
66. I feel comfortable addressing alcohol use in pregnancy with pregnant Aboriginal women in antenatal appointments.	☐	☐	☐	☐	☐

67. When addressing alcohol use with pregnant Aboriginal women, it is important to a apply a holistic approach that considers the woman's unique social and cultural needs.	☐	☐	☐	☐	☐
68. It is acceptable for maternity staff to ask all pregnant women about their alcohol use in antenatal appointments.	☐	☐	☐	☐	☐
69. It is acceptable for maternity staff to assess all pregnant women's alcohol consumption using a validated tool, such as the AUDIT-C.	☐	☐	☐	☐	☐
70. It is acceptable for maternity staff to provide all pregnant women with brief advice regarding alcohol related risk to the fetus and that not drinking is the safest option.	☐	☐	☐	☐	☐
71. It is acceptable for maternity staff to offer pregnant women who require further assistance to address their alcohol use referrals to appropriate support services.	☐	☐	☐	☐	☐
72. It is acceptable for maternity staff to address alcohol use with pregnant women on multiple occasions throughout their antenatal care.	☐	☐	☐	☐	☐

73. Please describe the care and advice you currently provide about alcohol use in pregnancy to women during their antenatal appointments.

74. If relevant, please detail any training you have received around alcohol use in pregnancy, and where this training came from.

75. What resources / supports would assist you to address alcohol use in pregnancy in line with antenatal care guidelines?
(E.g. training / professional development; information resources to give to pregnant women about alcohol; changes to antenatal IT systems or forms, etc.)

76. What resources/ supports would assist you to address alcohol use in pregnancy in a culturally appropriate way for Aboriginal women?
(e.g. training & professional development; Aboriginal support staff; knowledge of local Aboriginal support services for pregnant women; culturally appropriate information resources to give to pregnant Aboriginal women about alcohol; etc.)

77. Please add any further comments you may have about addressing alcohol use in pregnancy.

Thank you for completing this survey

Manager Survey

MANAGER CONSULTATIONS TO INFORM A CLINICAL PRACTICE CHANGE FOR ADDRESSING ALCOHOL USE IN PREGNANCY

This survey seeks your views on managing staff performance in your service when introducing a clinical practice change. In particular, this survey asks about Excellence tools, which for your reference include: measures in SMaRTA Viewer; Operational Plans; performance reports; 90 day action plans; monthly accountability meetings (MAMs); leader rounding; and performance conversations with staff.

HNELHD is committed to Closing the Gap between Aboriginal and non-Aboriginal health. As such, this practice change will include specific performance outcomes relating to care provision for Aboriginal women.

The information you provide will help to identify the support and resources managers may need to implement the upcoming clinical practice change for addressing alcohol use in pregnancy.

Instructions

Questions should be answered by selecting the relevant box. There are no right or wrong answers for this survey - it is your honest answers that are most important. Some of the questions may seem repetitive, but they are all subtly different and help to provide a more in-depth understanding of your views. The questions have been based on consultations with HNE maternity clinicians, and previous surveys with health professionals regarding alcohol use in pregnancy.

Thank you for taking the time to complete this survey.

Please tell us some information about yourself and role.

For how many years have you been a maternity services manager?

<1 ☐
1-2 ☐
3-4 ☐
5-9 ☐
10+ ☐

What is your position?

Staff Specialist ☐
Consultant ☐
Midwife Unit Manager ☐
Nurse Unit Manager ☐
Health Manager ☐
Other (please write) _____

How many years have you worked in your current position?

<1 ☐
1-2 ☐
3-4 ☐
5-9 ☐
10+ ☐

In what HNELHD Health Sector do you currently work?

Greater Newcastle Sector ☐
Peel Sector ☐
Lower Mid North Coast Sector ☐

What is your employment status currently?

Full-time
Part-time
Other (please write) _____

Have you completed Aboriginal Cultural Respect Education (CRE) Training?

Yes ☐
No ☐

Have you completed Aboriginal Identification Training?

Yes ☐
No ☐

To what extent do you agree or disagree with these statements, please tick one option per question

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1. I know what steps to take in my service when introducing clinical practice change.	☐	☐	☐	☐	☐
2. The organisation I work for has provided me with professional development in regards to clinical management skills.	☐	☐	☐	☐	☐
3. I am aware of the Excellence tools that are available to support me as a manager when introducing clinical practice change in my service.	☐	☐	☐	☐	☐
4. I am competent in managing the introduction of clinical practice change in my service.	☐	☐	☐	☐	☐
5. I have been adequately trained in how to use Excellence tools to monitor how my service is tracking.	☐	☐	☐	☐	☐
6. I am able to have professional conversations with my clinical staff about performance issues.	☐	☐	☐	☐	☐
7. I am competent with using the following Excellence tools:					
a. SMaRTA Viewer measures	☐	☐	☐	☐	☐
b. Operational Plans	☐	☐	☐	☐	☐
c. Performance reports	☐	☐	☐	☐	☐
d. 90 day action plans	☐	☐	☐	☐	☐
e. Monthly Accountability Meetings (MAMs)	☐	☐	☐	☐	☐
f. Leader Rounding with Staff	☐	☐	☐	☐	☐
g. Performance Conversations with Staff	☐	☐	☐	☐	☐

8. It is part of my professional role to drive clinical practice change in my service.	☐	☐	☐	☐	☐
9. It is part of my professional role to use Excellence tools to manage staff performance during a clinical practice change.	☐	☐	☐	☐	☐
10. It is not the responsibility of my service to address alcohol use in pregnancy as part of routine antenatal care.	☐	☐	☐	☐	☐
11. Strong evidence supports the clinical guideline recommendation that alcohol use should be addressed as part of routine antenatal care.	☐	☐	☐	☐	☐
12. There is a strong rationale that women should be advised that not drinking is the safest option for the health of the fetus.	☐	☐	☐	☐	☐
13. I know of the potential health consequences for the fetus that may result from alcohol use during pregnancy.	☐	☐	☐	☐	☐
14. I am confident I can manage the introduction of a clinical practice change for addressing alcohol use in pregnancy.	☐	☐	☐	☐	☐
15. I am confident I can engage my clinical staff in clinical practice change, even if they are resistant to change.	☐	☐	☐	☐	☐
16. I am concerned clinical practice change puts additional workload burdens on clinicians.	☐	☐	☐	☐	☐
17. Clinical practice change contributes to improvements in service delivery.	☐	☐	☐	☐	☐
18. Clinical staff will react negatively if I discuss performance issues with them.	☐	☐	☐	☐	☐
19. I will be held accountable by my manager if my service does not meet performance targets.	☐	☐	☐	☐	☐
20. If I provide staff with professional feedback about performance, they will take it on board to improve the quality of service delivery.	☐	☐	☐	☐	☐
21. I have more important things to manage in my service than a clinical practice change around alcohol use in pregnancy.	☐	☐	☐	☐	☐
22. I want to drive clinical practice change in my service to improve the quality of the antenatal care provided to women.	☐	☐	☐	☐	☐

23. I aim to meet all my service's performance targets.	☐	☐	☐	☐	☐
24. I often forget to use Excellence tools to manage performance in my service.	☐	☐	☐	☐	☐
25. I am more likely to drive clinical practice change in my service if I agree with the underlying rationale for the change.	☐	☐	☐	☐	☐
26. I am less likely to manage the performance of a clinical practice change if my staff are resistant to the change.	☐	☐	☐	☐	☐
27. It is difficult for me to drive clinical practice change in my service because I have many other competing work tasks.	☐	☐	☐	☐	☐
28. It is difficult for me to manage performance because I have problems with getting clinical staff to enter data that is used in performance measurement.	☐	☐	☐	☐	☐
29. It is hard for me to implement clinical practice change in my service as I have difficulty freeing my staff from clinical work to attend relevant training.	☐	☐	☐	☐	☐
30. I do not have the necessary supports / resources (e.g. training in performance management) that I need to manage performance in my service.	☐	☐	☐	☐	☐
31. I have colleagues who can support me if I encounter difficulties managing performance in my service.	☐	☐	☐	☐	☐
32. My staff expect me to be a leader for clinical practice change in my service.	☐	☐	☐	☐	☐
33. In the organisation where I work, higher levels of management give support for clinical practice change in service delivery.	☐	☐	☐	☐	☐
34. My manager expects me to manage the performance of my service.	☐	☐	☐	☐	☐
35. My staff are resistant to clinical practice change.	☐	☐	☐	☐	☐
36. It is stressful for me to manage performance in my service.	☐	☐	☐	☐	☐
37. I put plans in place to manage clinical practice change in my service.	☐	☐	☐	☐	☐

38. I am committed to ensuring my service provides culturally safe and appropriate care to Aboriginal women.	☐	☐	☐	☐	☐
39. I ensure my staff have completed mandatory HNE Health cultural respect training to promote cultural competence.	☐	☐	☐	☐	☐
40. My antenatal service provides a culturally safe environment for Aboriginal women by…					
Displaying Aboriginal and Torres Strait Islander flags	☐	☐	☐	☐	☐
Displaying Indigenous artwork	☐	☐	☐	☐	☐
Naming meeting room(s) in local Aboriginal language	☐	☐	☐	☐	☐
Displaying Aboriginal specific health posters	☐	☐	☐	☐	☐
41. I am competent with using the following Excellence tools to manage service delivery outcomes for aboriginal women:					
a. SMaRTA Viewer measures	☐	☐	☐	☐	☐
b. Operational Plans	☐	☐	☐	☐	☐
c. Performance reports	☐	☐	☐	☐	☐
d. 90 day action plans	☐	☐	☐	☐	☐
e. Monthly Accountability Meetings (MAMs)	☐	☐	☐	☐	☐
f. Leader Rounding with Staff	☐	☐	☐	☐	☐
g. Performance Conversations with Staff	☐	☐	☐	☐	☐
42. Providing culturally safe and appropriate antenatal care to pregnant Aboriginal women is a priority for my service.	☐	☐	☐	☐	☐

43. I want to drive clinical practice change in my service to improve the quality of antenatal care provided to Aboriginal women.	☐	☐	☐	☐	☐
44. Appropriate support is available to me if I need assistance with managing the delivery of culturally appropriate care to Aboriginal women in my service.	☐	☐	☐	☐	☐
45. I am able to have professional conversations with my staff around culturally appropriate service delivery to pregnant Aboriginal women.	☐	☐	☐	☐	☐
46. I am competent in managing my service to provide culturally appropriate care for Aboriginal pregnant women.	☐	☐	☐	☐	☐
47. I aim to manage my service to meet Close the Gap measures that relate to antenatal care.	☐	☐	☐	☐	☐
48. I will be held accountable if my service does not meet performance measures for antenatal care delivery for Aboriginal women.	☐	☐	☐	☐	☐
49. It is part of my professional role to drive culturally appropriate service delivery to Aboriginal women in my service.	☐	☐	☐	☐	☐

50. Please describe how you currently use Excellence tools to manage performance when introducing a clinical practice change in your service.

51. What supports / resources would assist you to manage a clinical practice change for addressing alcohol use in pregnancy in you service? (E.g. training & professional development, additional support staff for implementing the change, etc.)

52. What resources / supports would assist your service to address alcohol use in pregnancy in a culturally appropriate way for Aboriginal women? (E.g. training & professional development, Aboriginal support staff, etc.)

53. Please add any further comments you would like to make about managing this clinical practice change to address alcohol use in pregnancy.

Thank you for completing this survey

APPENDIX 18. Clinician and Manager surveys individual mean scores

Mean scores for individual items from the Theoretical Domains Framework as reported by antenatal clinicians (n=33)

Domain	Definition	Item	Mean	SD	Median
Knowledge	An awareness of the existence of something.	Strong evidence supports the clinical guideline recommendation that alcohol use should be addressed as part of routine antenatal care.	4.30	1.19	5.00
		There is a strong rationale that women should be advised that not drinking is the safest option for the health of the fetus.	4.70	0.77	5.00
		I know of the potential health consequences for the fetus that may result from alcohol use during pregnancy.	4.42	0.56	4.00
		I know the procedure for addressing alcohol use during pregnancy in accordance with clinical guidelines.	3.67	0.85	4.00
		I know the appropriate referral pathways to offer women who consume alcohol at high risk levels during pregnancy.	3.72	0.89	4.00
		I know the appropriate referral pathways to offer women who consume alcohol at moderate risk levels during pregnancy.	3.64	0.82	4.00
Skills	An ability or proficiency acquired through practice.	I am competent in asking pregnant women about their alcohol use during pregnancy.	4.18	0.64	4.00
		I am competent in assessing pregnant women's alcohol consumption using a validated tool, such as the AUDIT-C.	2.94	1.09	3.00
		I am competent in providing pregnant women with brief advice regarding alcohol related risk to the fetus and that not drinking is the safest option.	4.15	0.83	4.00
		I am competent in offering pregnant women who require further assistance to address their alcohol use referrals to appropriate support services.	3.79	0.89	4.00
		I have been adequately trained in how to address alcohol use in pregnancy according to clinical guidelines.	2.84	1.14	3.00
		I am able to have conversations with pregnant women around alcohol use in pregnancy in a sensitive, non-judgemental manner.	4.25	0.57	4.00
Social/ professional role and identity†	A coherent set of behaviours and displayed personal qualities of an	All health professionals providing routine antenatal care should address alcohol use in pregnancy according to clinical guidelines.	4.53	0.57	5.00
		It is part of my professional role to ask pregnant women about their alcohol use during pregnancy.	4.69	0.47	5.00

	individual in a social or work setting.	It is part of my professional role to assess pregnant women's alcohol consumption using a validated tool, such as the AUDIT-C.	4.06	0.96	4.00
		It is part of my professional role to provide pregnant women with brief advice regarding alcohol related risks to the fetus and that not drinking is the safest option.	4.63	0.49	5.00
		It is part of my professional role to offer pregnant women who require further assistance to address their alcohol use referrals to appropriate support services.	4.68	0.65	5.00
		It is not my responsibility to address alcohol use in pregnancy as part of routine antenatal care *(reverse scored).*	3.94	1.50	4.50
Beliefs about capabilities†	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use.	I am confident in asking pregnant women about their alcohol use during pregnancy.	4.09	0.78	4.00
		I am confident in assessing pregnant women's alcohol consumption using a validated tool, such as the AUDIT-C.	3.03	1.18	3.00
		I am confident in providing pregnant women with brief advice regarding alcohol related risk to the fetus and that not drinking is the safest option.	4.24	0.69	4.00
		I am confident in offering pregnant women who require further assistance to address their alcohol use referrals to appropriate support services.	3.76	0.99	4.00
		I am confident I can address alcohol use in pregnancy in the time allocated to antenatal appointments.	2.62	1.27	2.00
		I am confident I can address alcohol use in pregnancy during antenatal appointments even if the woman shows a lack of interest in discussing alcohol.	3.14	0.99	3.00
		I am not confident in addressing alcohol use in pregnancy during antenatal appointments when other health professionals are present *(reverse scored)*.	3.66	1.08	4.00
Beliefs about consequences‡	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation.	Addressing alcohol use in pregnancy enables women who require further assistance for their alcohol use to get appropriate support.	4.14	0.88	4.00
		Addressing alcohol use in pregnancy will enable changes in drinking behaviours and improve outcomes for the mother and baby.	4.00	0.85	4.00
		Regardless of how I approach the issue, pregnant women will feel uncomfortable or judged if I address alcohol use in pregnancy with them during antenatal appointments *(reverse scored)*.	3.57	0.74	4.00

		Regardless of how I approach the issue, pregnant women who have consumed any alcohol during their pregnancy will feel anxious or guilty if I address alcohol use with them *(reverse scored).*	3.03	0.87	3.00
		There is no harm in me advising a pregnant woman that she can consume alcohol at low levels during pregnancy *(reverse scored)*.	4.59	0.57	5.00
		Addressing alcohol use in pregnancy will have a negative effect on my client-clinician relationship with the woman *(reverse scored)*.	3.79	0.49	4.00
		I am hesitant to address alcohol use in pregnancy as it may have implications in regards to child protection issues *(reverse scored)*.	3.86	0.69	4.00
		My manager will hold me accountable if I do not address alcohol use in pregnancy in my antenatal appointments.	3.00	1.04	3.00
Motivation and goals‡	Mental representations of outcomes or end states that an individual wants to achieve.	I aim to address alcohol use in pregnancy with all pregnant women as part of my routine antenatal care.	4.21	0.86	4.00
		I have more important things to do in antenatal appointments than address alcohol use in pregnancy *(reverse scored)*.	3.97	0.98	4.00
		I want to provide the best antenatal care for maternal alcohol use so I can support positive pregnancy outcomes for women and their babies.	4.62	0.49	5.00
Memory, attention and decision processes‡	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.	I often forget to address alcohol use in pregnancy during antenatal appointments *(reverse scored)*.	3.52	1.15	4.00
		I am less likely to address alcohol use in pregnancy if the woman is multipara *(reverse scored)*.	4.24	0.44	4.00
		Whether I address alcohol use in pregnancy is dependent upon the woman's demographics and antenatal history *(reverse scored)*.	4.24	0.91	4.00
		If discussing alcohol is not a priority expressed by the woman, I do not address it during antenatal appointments *(reverse scored)*.	3.93	0.80	4.00
		I do not address alcohol use in pregnancy because most women already know not to drink alcohol during pregnancy *(reverse scored)*.	4.21	0.82	4.00
Environmental context and resources‡	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities,	It is difficult for me to address alcohol use in pregnancy because there is a lack of support services that I can refer pregnant women to for further assistance with alcohol use.	3.45	1.15	4.00
		It is difficult for me to address alcohol use in pregnancy because there is poor communication between maternity services and drug and alcohol services *(reverse scored).*	3.66	1.08	4.00

	independence, social competence, and adaptive behaviour.	It is difficult for me to address alcohol use in pregnancy because the IT systems/forms that I use in antenatal appointments do not provide the necessary supports *(reverse scored).*	3.10	1.26	3.00
		It is difficult for me to address alcohol use in pregnancy because I have a lot to cover in antenatal appointments *(reverse scored).*	2.55	1.27	2.00
		It is difficult for me to address alcohol use in pregnancy because I do not have access to appropriate information resources (e.g. pamphlets for woman, standard drink charts) *(reverse scored).*	2.90	1.14	3.00
Social influences‡	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.	My manager expects me to address alcohol use in pregnancy as part of routine antenatal care.	3.72	0.75	4.00
		Pregnant women expect me to address alcohol use in pregnancy during their antenatal care.	3.34	0.77	3.00
		Other maternity staff with whom I work do not address alcohol use in pregnancy as part of routine antenatal care *(reverse scored).*	2.86	0.95	3.00
		There are health professionals who can support me if I have difficulties when addressing alcohol use in pregnancy during antenatal appointments.	3.38	1.08	4.00
Emotion regulation‡	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event.	Addressing alcohol use with pregnant women makes me feel nervous / anxious *(reverse scored).*	3.86	0.83	4.00
		I feel comfortable addressing alcohol use in pregnancy with pregnant women in antenatal appointments.	3.86	0.95	4.00
		It is stressful for me to address alcohol use in pregnancy during antenatal appointments *(reverse scored).*	4.07	0.75	4.00
Behavioural regulation‡	Anything aimed at managing or changing objectively observed or measured actions.	I have a clear plan for how I am going to address alcohol use in pregnancy in antenatal appointments.	3.24	0.87	3.00
		If I encounter a problem when addressing alcohol use in pregnancy, I know how to solve it.	3.24	0.99	3.00
		If I received professional feedback about the way I address alcohol use in pregnancy, I would use it to improve the quality of the antenatal care I provide.	4.10	0.62	4.00

† n=32 due to incomplete survey responses

‡ n=29 due to incomplete survey responses

Mean scores for individual items from the Theoretical Domains Framework as reported by managers of antenatal services (n=8)

Domain	Definition	Item	Mean	SD	Median
Knowledge	An awareness of the existence of something.	I know what steps to take in my service when introducing clinical practice change.	4.00	0.53	4.00
		I am aware of the Excellence tools that are available to support me as a manager when introducing clinical practice change in my service.	4.50	0.76	5.00
		Strong evidence supports the clinical guideline recommendation that alcohol use should be addressed as part of routine antenatal care.	4.88	0.35	5.00
		There is a strong rationale that women should be advised that not drinking is the safest option for the health of the fetus.	4.63	0.52	5.00
		I know of the potential health consequences for the fetus that may result from alcohol use during pregnancy.	4.63	0.52	5.00
Skills	An ability or proficiency acquired through practice.	The organisation I work for has provided me with professional development in regards to clinical management skills.	4.63	0.52	5.00
		I have been adequately trained in how to use Excellence tools to monitor how my service is tracking.	4.13	0.64	4.00
		I am able to have professional conversations with my clinical staff about performance issues.	4.38	0.52	4.00
Social/ professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting.	It is part of my professional role to drive clinical practice change in my service.	4.38	0.52	4.00
		It is part of my professional role to use Excellence tools to manage staff performance during a clinical practice change.	4.38	0.74	4.50
		It is not the responsibility of my service to address alcohol use in pregnancy as part of routine antenatal care *(reverse scored)*.	4.88	0.35	5.00
Beliefs about capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use.	I am competent in managing the introduction of clinical practice change in my service.	4.00	0.00	4.00
		I am competent with using the following Excellence tools: SMaRTA Viewer measures.	3.25	1.16	3.50
		I am competent with using the following Excellence tools: Operational Plans.	3.50	0.93	4.00
		I am competent with using the following Excellence tools: Performance reports.	3.63	0.74	4.00
		I am competent with using the following Excellence tools: 90 day action plans.	3.63	0.74	4.00

		I am competent with using the following Excellence tools: Monthly Accountability Meetings (MAMs).	4.00	0.93	4.00
		I am competent with using the following Excellence tools: Leader Rounding with Staff.	4.38	0.74	4.50
		I am competent with using the following Excellence tools: Performance Conversations with Staff.	3.75	1.49	4.00
		I am confident I can manage the introduction of a clinical practice change for addressing alcohol use in pregnancy.	4.13	0.35	4.00
		I am confident I can engage my clinical staff in clinical practice change, even if they are resistant to change.	4.13	0.35	4.00
Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation.	I am concerned clinical practice change puts additional workload burdens on clinicians *(reverse scored)*.	2.75	1.28	2.50
		Clinical practice change contributes to improvements in service delivery.	4.13	0.64	4.00
		Clinical staff will react negatively if I discuss performance issues with them *(reverse scored)*.	3.38	0.92	3.00
		I will be held accountable by my manager if my service does not meet performance targets.	4.63	0.52	5.00
		If I provide staff with professional feedback about performance, they will take it on board to improve the quality of service delivery.	3.75	0.46	4.00
Motivation and goals	Mental representations of outcomes or end states that an individual wants to achieve.	I have more important things to manage in my service than a clinical practice change around alcohol use in pregnancy *(reverse scored)*.	3.88	0.99	4.00
		I want to drive clinical practice change in my service to improve the quality of the antenatal care provided to women.	4.63	0.52	5.00
		I aim to meet all my service's performance targets.	4.25	0.46	4.00
Memory, attention and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.	I often forget to use Excellence tools to manage performance in my service *(reverse scored)*.	3.75	1.04	4.00
		I am less likely to manage the performance of a clinical practice change if my staff are resistant to the change *(reverse scored)*.	3.63	0.74	4.00
Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills	It is difficult for me to drive clinical practice change in my service because I have many other competing work tasks *(reverse scored)*.	2.88	1.25	3.00
		It is difficult for me to manage performance because I have problems with getting clinical staff to enter data that is used in performance measurement *(reverse scored)*.	3.00	1.20	3.50

	and abilities, independence, social competence, and adaptive behaviour.	It is hard for me to implement clinical practice change in my service as I have difficulty freeing my staff from clinical work to attend relevant training *(reverse scored)*.	3.00	0.93	3.00
		I do not have the necessary supports / resources (e.g. training in performance management) that I need to manage performance in my service *(reverse scored)*.	3.63	0.74	4.00
Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.	I have colleagues who can support me if I encounter difficulties managing performance in my service.	3.75	1.16	4.00
		My staff expect me to be a leader for clinical practice change in my service.	4.13	0.35	4.00
		In the organisation where I work, higher levels of management give support for clinical practice change in service delivery.	4.25	0.71	4.00
		My manager expects me to manage the performance of my service.	4.25	0.46	4.00
		My staff are resistant to clinical practice change *(reverse scored)*.	2.88	0.83	3.00
Emotion regulation	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event.	It is stressful for me to manage performance in my service *(reverse scored)*.	2.13	0.64	2.00
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions.	I put plans in place to manage clinical practice change in my service.	4.38	0.52	4.00

APPENDIX 19. Systematic review search strategies

MEDLINE, EMBASE, MATERNITY AND INFANT CARE, AND CINAHL

Note: The relevant syntax to each database was used.

1. Pregnancy/ or Pregnan*.tw.
2. Matern*.tw.
3. Gestation*.tw.
4. Preconcept*.tw.
5. Trying to conceive.tw.
6. 1 or 2 or 3 or 4 or 5
7. Midwifery/ or Midwi*.tw. or Nurse Midwives/
8. Obstetric*.tw. or Obstetrics/
9. Physicians, Family/ or Family Practice/ or General Practic*.tw. or General Practice/ or General Practitioners/
10. clinician*.tw.
11. ((health or healthcare) adj2 (profession* or work*)).mp.
12. Prenatal Care/ or (antenatal or prenatal).tw.
13. Preconception Care/
14. Perinatal Care/ or perinatal.tw.
15. Maternal Health Services/ or Maternity.tw. or Family Planning Services/
16. (family planning or fertility specialist*).tw.
17. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. implement*.mp.
19. dissemin*.mp.
20. adopt*.mp.
21. practice*.mp.
22. organi?ational change*.mp.
23. diffus*.mp.
24. (system* adj2 change*).mp.
25. quality improvement*.mp.

26. transform*.mp.
27. translat*.mp.
28. transfer*.mp.
29. uptake*.mp.
30. sustainab*.mp.
31. institutionali*.mp.
32. routin*.mp.
33. maintenance.mp.
34. capacity.mp.
35. incorporat*.mp.
36. adher*.mp.
37. integrat*.mp.
38. scal*.mp.
39. ((polic* or guideline or practice* or program* or innovate*) adj5 (performance or feedback or audit* or monitor* or academic detailing or prompt* or reminder* or medical record* or record system* or incentive* or penalt* or mandat* or communicat* or social market* or professional development or network* or leadership* or opinion leader* or champion* or consensus* or change manage* or train* or educat* or resource* or material* or equipment or guideline)).mp.
40. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
41. Fetal Alcohol Spectrum Disorders/
42. Alcohol Abstinence/ or Alcohol*.tw.
43. Drinking behaviour/ or Alcohol Drinking/ or Drinking/ or drink*.tw. or Binge Drinking/
44. Ethanol.tw. or Ethanol/
45. (Smok* adj2 (prevent* or reduc* or cessation or cease* or cigarette or tobacco)).mp.
46. Tobacco/ or Tobacco Smoking/ or Tobacco.tw.
47. Cigarette*.tw. or Tobacco Products/
48. Smoking Cessation/ or Nicotine Replacement.tw. or NRT.tw. or Smoking/
49. Weight gain/ or Weight gain.tw.
50. Nutri*.tw.
51. Diet.tw. or Diet/ or Healthy Diet/

52. (Food.tw. or Food/) and Nutrition/
53. Eat*.tw. or Eating/
54. Energy Intake.tw. or Energy Intake/
55. Physical Activit*.tw.
56. Exercise/ or Exercise.tw.
57. Sedentary Lifestyle/ or Physical Inactivit*.tw.
58. (Sedentary adj2 (Behavio* or Lifestyle)).mp.
59. Fitness.tw. or Physical Fitness/
60. 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59
61. Randomized Controlled Trial/
62. Controlled Clinical Trial/
63. Clinical Trials as Topic/
64. Random Allocation/
65. Evaluation Studies/
66. Comparative Study/
67. random*.tw.
68. trial.tw.
69. groups.tw.
70. placebo.tw.
71. experiment*.tw.
72. (time adj series).tw.
73. (pretest or pre test or posttest or post test).tw.
74. impact.tw.
75. change*.tw.
76. evaluat*.tw.
77. effect*.tw.
78. 'before and after'.tw.
79. intervention*.tw.
80. program*.tw.

81. compare*.tw.
82. (control or controls* or controla* or controle* or controli or controll*).tw.
83. (Stepped wedge or staggered enrol*).tw.
84. 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83
85. Ask*.tw.
86. Screen*.tw. or Mass Screening/
87. Assess*.tw. or Risk Assessment/
88. Advi?e.tw. or Health Education/
89. Assist*.tw.
90. Arrang*.tw.
91. (Refer*.tw. or Referral.mp.)
92. brief intervention.tw. or Motivational Interviewing/ or Psychotherapy, Brief/
93. 5A*.tw.
94. SBIRT.tw.
95. ((Care or practi?e*) adj (best or evidence* or recomm*)).tw.
96. 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95
97. 6 and 17 and 40 and 60 and 84 and 96

COCHRANE CENTRAL REGISTER OF CONTROLLED TRIALS

"pregnancy" or Matern* or Gestation* or Preconcept* or “Trying to conceive”

AND

Midwifery or Obstetric or “General Practic*” or clinician* or “health professional” or “prenatal care” or “antenatal care” or “preconception care” or maternity or “family planning”

AND

implement or dissemin or adopt or practice or “organisational change*” or diffus* or “system change” or “quality improvement*” or transform* or translat* or transfer* or uptake* or sustainab* or institutionali* or routin* or maintenance or capacity or incorporat* or adher* or integrat* or scal* or polic* or guideline or practice* or program* or innovate* or performance or feedback or audit* or monitor* or “academic detailing” or prompt* or reminder* or “medical record*” or “record system*” or incentive* or penalt* or mandat* or communicat* or “social market*” or “professional development” or network* or leadership*

or “opinion leader*” or champion* or consensus* or “change manage*” or train* or educat* or resource* or material* or equipment

AND

“Fetal Alcohol Spectrum Disorders” or alcohol or drinking or ethanol or tobacco or smok* or cigarette or “weight gain” or diet or nutri* or eating or “energy intake” or “Physical Activit*” or exercise or fitness

AND

Ask* or Screen* or Assess* or advise or advice or assist or arrang* or refer* or “brief intervention” or “motivational interviewing” or 5A* or SBIRT* or Care

PROQUEST DISSERTATIONS AND THESES

(Preconception OR prenatal) AND (midwife OR professional) AND (alcohol OR weight OR smoking) AND (implement OR adopt) AND care.

WHO INTERNATIONAL CLINICAL TRIALS REGISTRY

TITLE: preconception or prenatal or antenatal or pregnan* or profession* or midwi* or doctor*

CONDITION: alcohol or smoking or weight

INTERVENTION: adopt* or implement* or train* or resource* or educat* or guideline* or chang* or polic* or perform* or audit or feedback or prompt* or remind* or incentive or champion or program or quality improvement or mandat*

APPENDIX 20. Characteristics of included studies

Study ID Country Trial design	Participants	Implementation strategies and Comparisons	Primary Outcomes – Effect of implementation strategies on improving the provision of preconception and antental care addressing modifiable risk factors			Secondary outcomes measured and reported
			Data Collection	Measures	Outcomes reported	
Aguilera et al. (2017) **Country:** USA **Study design:** Non-randomised controlled trial	**Setting**: antenatal care **Services:** obstetrics practices (N=4) **Health professionals:** doctors and nurses **Allocation:** 2 practices to intervention and 2 to comparison condition	**Risk factor:** weight **Implementation strategies:** • educational meetings • educational materials **Comparison:** • usual practice/control **Theoretical basis:** not reported **Implementation measures:** acceptability	**Method:** health professional and women surveys **Scale:** health professional: 5 point likert scale (never to always); women: 0-1 (no, yes) **Sample for outcomes:** **Health professional** N=22 IV: 11; C: 21 **Women** N=332 IV: 183; C: 149	**Health professional** **Advise:** discuss appropriate amount of weight gain during pregnancy; discuss risks of inadequate weight gain; discuss risks of excess weight gain % (most of the time and always categories) C vs IV **Women** **Advise:** received advice about weight gain during pregnancy; discussion on the risks of gaining too much or not enough weight % C vs IV	**Health professional** **Advise:** 73% vs 100%[b;] 45% vs 54% [b]; 45% vs 72% [b] **Women** **Advise:** 66.4% vs 92.3%***; 51.5% vs 64.3%*	Secondary analysis of 308 medical records. The proportion of women within weight recommendations (C vs IV) 36.9% vs 36.5%[a]
Althabe et al. (2017) **Country:** USA **Study design:** Two-arm parallel cluster randomised trial	**Setting**: antenatal care **Services:** antenatal clinics (N=20 clusters) **Health professionals:** midwives and obstetrician/ gynaecologists **Allocation:** 10 clusters allocated to intervention and 10 to comparison condition.	**Risk factor:** tobacco smoking **Implementation strategies:** • educational meetings • educational outreach visits, or academic detailing • local opinion leaders • reminders • tailored intervention **Comparison:**	**Method:** women surveys **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=6828 IV: 3342 (pre: 1551; post: 1791); C: 3486 (pre: 1757; post: 1729)	**Ask:** asked about tobacco use (at > one visit) **Advise:** advised about tobacco use (at > one visit) **Assess:** assessed late quitters and continuous smokers are ready to quit (at > one visit) **Assist:** assisted late quitters and continuous smokers in the quitting process (at > one visit)	**Ask:** 3.9 vs 33.1, 29.2 (17.5; 38.0)** **Advise:** 2.6 vs 29.0, 26.4 (13.9; 40.2)** **Assess:** 5.3 vs 20.2, 14.9 (2.5; 32.7)* **Assist:** 3.5 vs 25.0, 21.5 (10.6; 31.8)** **Arrange:** 0.0 vs 2.7, 2.7 (0.0; 17.2)*	Sub-sample of women (IV: 863; C: 835) who quit or continued smoking during pregnancy and submitted cotinine analysis of saliva within 12 hours postpartum. Quit smoking during pregnancy (C vs IV OR (95%

		• educational meetings **Theoretical basis:** Roger's Diffusion of Innovations Theory **Implementation measures:** fidelity		**Arrange:** arranged follow-up with late quitters and smokers (at > one visit) MRC C vs IV, AD (95% CI)		CI), ROR (95% CI)) 0.58 (0.43; 0.78) vs 0.74 (0.55; 1.00); 1.29 (0.84; 1.97)[a]
Bakker et al. (2003) **Country:** The Netherlands **Study design:** RCT	**Setting:** antenatal care **Services:** private midwifery practices (N=42) **Health professionals:** midwives **Allocation:** 22 clinics to intervention and 20 to comparison condition	**Risk factor:** tobacco smoking **Implementation strategies:** • clinical practice guidelines • educational meetings • educational materials **Comparison:** • usual practice/control **Theoretical basis:** not reported **Implementation measures:** fidelity, acceptability, feasability	**Method:** health professional and women surveys **Scale:** health professional: 5 point likert scale (never to always); women: 0-1 (no, yes) **Sample for outcomes:** **Health professional** N=69 IV: 37; C: 32 **Women:** N=95 IV: 44; C: 51	**Health professional** **Ask:** ask about smoking behaviour **Advise:** advice to quit smoking; consequences of smoking during pregnancy **Assess:** discuss barriers **Assist:** set a quit date **Arrange:** aftercare M (SD) C vs I, B (SE) **Women** **Ask:** ask about smoking at intake **Advise:** advice to quit **Assess:** discuss barriers **Assist:** set a quit date M (SD) C vs IV, B (SE)	**Health professional** **Ask:** 5.00 (0.00) vs 4.91 (0.37), -0.07 (0.07)[a] **Advise:** 4.19 (1.03) vs 4.60 (0.77), 0.50 (0.24)*; 4.50 (0.95) vs 4.31 (0.99), -0.21 (0.26)[a] **Assess:** 2.91 (1.15) vs 3.49 (1.12), 0.54 (0.30) [a] **Assist:** 1.63 (1.10) vs 3.63 (1.19), 1.69 (0.28)*** **Arrange:** 2.84 (0.99) vs 3.97 (0.89), 1.10 (0.25)*** **Women** **Ask:** 0.72 (0.29) vs 0.91 (0.18), 0.17 (0.05)** **Advise:** 0.64 (0.36) vs 0.85 (0.25), 0.22 (0.07)** **Assess:** 0.11 (0.18) vs 0.38 (0.29), 0.25 (0.05)*** **Assist:** 0.03 (0.16) vs 0.33 (0.34), 0.22 (0.06)***	Not reported
Bar-Zeev et al. (2019)	**Setting:** antenatal care	**Risk factor:** tobacco smoking	**Method:** health professional suvey	**Ask:** smoking status; nicotine dependence	**Ask**: 98.7% vs 90.0%, 0.22 (0.01; 3.39)[a;] 35.6%	Not reported

Country: Australia **Study design:** Step-wedge cluster RCT	**Services:** Aboriginal Medical Services (N=6) **Health professionals:** general practitioners, midwives, Aboriginal Health Workers and other allied health providers **Allocation:** 6 services randomised into 3 clusters with the intervention delivered sequentially to each cluster	**Implementation strategies:** • clinical practice guidelines • educational meetings • educational materials • tailored intervention Comparison: • usual practice/control **Theoretical basis:** Behaviour Change Wheel and Theoretical Domains Framework **Implementation measures:** fidelity, acceptability	**Scale:** 5 point likert scale (never to always) **Sample for outcomes:** pre=45; post=20 Matched pairs=15	**Advise:** brief advice to quit if smoking **Assess:** discuss psychological context of smoking **Assist:** provide cessation support to smokers; recommend/prescribe NRT; refer to Quitline; refer to other specialist smoking cessation service **Arrange:** follow-up within two weeks % (often/always) pre vs post, OR (95% CI)	vs 60.0%, 3.09 (0.90; 10.65) [a] **Advise:** 63.6% vs 85.0%, 4.69 (0.92; 24.04) [a] **Assess:** 53.4% vs 45.0%, 0.72 (0.20; 2.61) [a] **Assist:** 48.9% vs 60.0%, 1.89 (0.49; 7.23) [a]; 35.6% vs 30.0%, 0.91 (0.23; 3.62) [a;] 40.0% vs 40.0%, 1.06 (0.30; 3.73) [a]; 35.5% vs 35.0%, 1.03 (0.29; 3.65) [a] **Arrange:** 31.1% vs 35.0%, 1.23 (0.33; 4.63) [a]	
Bazzo et al. (2015) **Country:** Italy **Study design:** Comparative study	**Setting:** antenatal care **Services:** hospital obstetrics and gynecology units (N=4) **Health professionals:** midwives **Allocation:** 2 units to intervention and 2 to comparison condition	**Risk factor:** alcohol consumption **Implementation strategies:** • educational meetings **Comparison:** • usual practice/control **Theoretical basis:** not reported **Implementation measures:** not reported	**Method:** women survey **Scale:** open ended, categorised into correct advice 0-1 (no, yes) **Sample for outcomes:** N=67 IV:32; C: 35	**Advise:** information on harmful effects on the fetus/newborn and/or completely abstain from alcohol during pregnancy % C vs IV, RR (95% CI)	**Advise:** 20.0% vs 53.1%, 2.66 (1.27; 5.56)**	Not reported
Brownfoot et al. (2016) **Country:** Australia	**Setting:** antenatal care **Services:** antenatal clinics in a tertiary	**Risk factor:** weight **Implementation strategies:** • educational materials • reminders	**Method:** Medical record audit **Scale:** no scale **Sample for outcomes:** N=782	**Assess:** Number of times record of being weighed during pregnancy M (SD), C vs IV	**Assess:** 1.8 (0.71) vs 5.6 (2.3)***	614 medical records had a weight recorded and were able to be

Study design: RCT	obstetrics hospital (N=1) **Health professionals:** antenatal care providers **Allocation:** 386 women randomised to the intervention and 396 to comparison condition	**Comparison:** • usual practice **Theoretical basis:** not reported **Implementation measures:** not reported	IV: 386; C: 396			audited for weight gain outcomes. M (SD) weight gain per week, C vs IV 0.53 kg (0.24) vs 0.54 kg (0.28)[a]
Campbell et al. (2006) **Country:** Australia **Study design:** RCT	**Setting:** antenatal care **Services:** public hospitals (N=23; included in outcomes analyses N=22) **Health professionals:** doctors and midwives **Allocation:** 11 clinics to intervention and 11 to comparison condition	**Risk factor:** tobacco smoking **Implementation strategies:** • audit & feedback • educational materials • educational meetings • educational outreach visits, or academic detailing • tailored intervention **Comparison:** • educational materials **Theoretical basis:** Roger's Diffusion of Innovations Theory **Implementation measures:** fidelity	**Method:** women survey **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=10994 IV: 6318 (pre: 3475; post: 2843) C: 4676 (pre: 2374; post: 2302 (weighted N at post timepoints)	**Ask:** smoking status; discussed smoking at more than one visit **Advise:** advice stop smoking completely; risk of smoking in pregnancy **Assist:** methods could use to quit; discuss definite quit date % (either midwife or doctor), C vs IV	**Ask:** 91.6% vs 92.9%[a;] 12.4% vs 14.4%[a] **Advise:** 38.7% vs 41.1%[a;] 63.8% vs 64.5%[a] **Assist:** 24.8% vs 30.0%[a]; 4.3% vs 5.8%[a]	Smoking status was assessed for all women via self-report survey, corrected using expired air carbon monoxide (CO) data (>9 ppm indicated smoking). % C vs IV % quit (sub-sample of smokers who indicated smoking at first antenatal visit N=3121): 6.4% vs 10.5% [a] % current smokers (N=10954): 28.2% vs 24.8% [a]
Cooke et al. (2001) **Country:** Australia	**Setting:** antenatal care **Services:** public hospital antenatal clinics (N=23)	**Risk factor:** tobacco smoking **Implementation strategies:** • audit & feedback	**Method:** health professional survey **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=187	**Ask:** assessment of smoking **Advise:** advice to quit; education about risk	**Ask:** 97% vs 95%, 0.39[a] **Advise**: 34% vs 46%, 2.92[a]; 92% vs 93%, 0.03[a] **Assist:** 74% vs 86%, 3.92*; 47% vs 62%,	Not reported

Study design: RCT	**Health professionals:** doctors and midwives **Allocation:** 11 clinics to intervention and 12 to comparison condition	• educational materials • educational meetings • educational outreach visits, or academic detailing • tailored intervention **Comparison:** • educational materials **Theoretical basis:** Roger's Diffusion of Innovations theory **Implementation measures:** penetration, adoption, sustainability	IV: 86; C: 101	**Assist:** methods to quit; encourage support person to assist, negotiate quit date; referral **Arrange:** Follow-up discussion % C vs IV, t-test	3.90*; 23% vs 47%, 10.94***; 55% vs 53%, 0.07[a] **Arrange:** 68% vs 70%, 0.08[a]	
Hajek et al. (2001) **Country:** UK **Study design:** RCT	**Setting:** antenatal care **Services:** midwifery services in hospitals and community trusts (N=9) **Health professionals:** midwives **Allocation:** Of the 290 midwives who agreed to take part in the trial, 92 who were allocated to intervention and 86 allocated to the comparison condition 'participated'	**Risk factor:** tobacco smoking **Implementation strategies:** • educational meetings • educational materials • reminders **Comparison:** • usual practice/control **Theoretical basis:** not reported **Implementation measures:** feasibility	**Method:** women's survey **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=771 IV: 387 (unmotivated smokers: 100; motivated smokers: 287) C*:* 384 (unmotivated smokers: 81; motivated smokers: 303)	**Ask:** discussed smoking; discussed smoking more than once **Advise:** advised to set a date and stop abruptly; explained why smoking is dangerous **Assist:** offered to find a buddy % unmotivated smokers C vs IV; % motivated smokers C vs IV	**Ask:** 100% vs 100% [a]; 98% vs 99%[a]; 38% vs 50%*; 40% vs 47% [a] **Advise:** 13% vs 29%*; 13% vs 64%***; 78% vs 94%**; 81% vs 95%*** **Assist:** 5% vs 42%***; 8% vs 68%***	Smoking status assessed with 1120 women via survey and CO reading (with CO-reading<10 p.p.m indicating abstinence) % C vs IV Point prevalence abstinence at birth: 20% vs 22%[a] Continuous abstinence (last 12 weeks of pregnancy) at birth: 17% vs 17%[a] Continuous abstinence at 6

						months post-birth: 8% vs 7%[a]
Malta et al. (2016) **Country:** Brazil **Study design:** Non-randomised controlled trial	**Setting:** antenatal care **Services:** primary care and family health units (N=17) **Health professionals:** doctors and nurses **Allocation:** 23 health professionals to intervention (one was excluded from outcome analyses) and 20 health professionals to comparison condition	**Risk factor:** weight (healthy eating and physical activity) **Implementation strategies:** • educational materials • educational meetings • local consensus process • tailored intervention **Comparison:** • usual practice/control **Theoretical basis:** not reported **Implementation measures:** not reported	**Method:** women surveys **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=281 IV: 140; C: 141	**Advise:** Healthy eating; Leisure-time walking % C vs I, PR (95% CI)	**Advise:** 19.1% vs 50.7%, 2.65 (1.82; 3.83)***; 33.3% vs 58.6%, 1.75 (1.34; 2.31)***	Not reported
Manfredi et al. (2011) **Country:** USA **Study design:** Cluster RCT	**Setting:** antenatal care **Services:** maternal and child health public health clinics (N=12; included in outcomes analyses N=8) **Health professionals:** doctors and nurses **Allocation:** 12 clinics allocated to 3 conditions. Only 2 of these conditions were	**Risk factor:** tobacco smoking **Implementation strategies:** • clinical practice guideline • educational materials • educational meetings • educational outreach visits, or academic detailing **Comparison:**	**Method:** women surveys **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=854 IV: 371 (pre: 189; post: 182) C: 483 (pre: 188; post: 295)	**Advise:** health professional advice **Assist:** receipt of adjunct counselling % (AOR) C vs IV	**Advise**: 54.2% (1.11) vs 69.8% (1.20)[a] **Assist:** 9.5% (9.38) vs 17% (11.50)[a]	Not reported

	relevant for the presented outcome analyses (4 clinics for intervention and 4 for comparison condition).	• clinical practice guideline • educational materials • educational meetings **Theoretical basis:** Roger's Diffusion of Innovations theory **Implementation measures:** not reported				
Mwansa-Kambafwile et al. (2011) **Country:** South Africa **Study design:** Controlled before and after study	**Setting:** preconception care **Services:** public healthcare services (N=3 municipalities) **Health professionals:** public sector healthcare workers **Allocation:** 2 municipalities were allocated to intervention and 1 to comparison condition	**Risk factor:** alcohol consumption **Implementation strategies:** • educational materials • educational meetings **Comparison:** • usual practice/control **Theoretical basis:** not reported **Implementation measures:** not reported	**Method:** women survey **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=375 IV: 284 (pre: 120; post: 164) C: 91 (pre: 31; post: 60)	**Assess:** assess alcohol consumption **Advise:** advised effects of maternal alcohol consumption on an unborn baby % C vs IV, OR (95% CI) (% not reported for assess outcome)	**Assess:** 1.15 (0.17; 1.03)[a] **Advise:** 26.1% vs 87.9%, 5.07 (1.37; 6.96)*	Not reported
Omer et al. (2020) **Country:** Ethopia **Study design:** Cluster RCT	**Setting:** antenatal care **Servcies:** antenatal units in health centres (N=20)	**Risk factor:** weight **Implementation strategies:** • educational materials • educational meetings	**Method:** observations **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=80 IV: 40; C: 40	**Assess:** measured weight; monitored gestational weight gain **Advise:** discussed possible options to practice recommendations; recommended achievable actions % C vs IV, DID impact estimator (95% CI)	**Assess:** 2.50% vs 9.17%, 9.1 (0.47; 17.85)***; 0.00% vs 40.00%, 38.3 (26.43; 50.22)*** **Advise:** 4.20% vs 41.70%, 32.5 (19.99; 45.00)***; 38.30% vs	Not reported

	Health professionals: health officers, nurses and midwives **Allocation:** matched pairs 10 to intervention and 10 to comparison condition	• educatinal outreach visits, or academic detailing **Comparison:** • usual practice/control **Theoretical basis:** not reported **Implementation measures:** fidelity			80.00%, 31.6 (11.79; 51.53)**	
Secker-walker et al. (1992) **Country:** USA **Study design:** RCT	**Setting:** antenatal care **Services:** maternal infant care clinic (N=1) **Health professionals:** obstetric and family practice residents **Allocation:** 125 women who smoked at least one cigarette per day allocated to intervention and 125 to comparison condition	**Risk factor:** tobacco smoking **Implementation strategies:** • educational meetings • reminders **Comparison:** • educational meetings **Theoretical basis:** not reported **Implementation measures:** not reported	**Method:** women surveys **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=250 women IV: first visit: 125; second visit: 103 C: first visit: 125; second visit: 102	**Ask:** talked about smoking first visit; talked about smoking second visit **Advise:** advised to quit first visit; advised to quit second visit **Assist:** set a quit date first visit; set a quit date second visit % C vs IV	**Ask:** 95% vs 98%[a]; 66% vs 96%*** **Advise:** 92% vs 96%[a]; 52% vs 91%*** **Assist:** 14% vs 80%***; 7% vs 74%***	
Tsoh et al. (2010) **Country:** USA **Study design:** RCT	**Setting:** antenatal care **Services:** community prenatal clinics (N=5) **Health professionals:** community clinicians **Allocation:** 23 pregnant smokers were allocated to	**Risk factor:** tobacco smoking **Implementation strategies:** • reminders **Comparison:** • usual practice/control **Theoretical basis:** not reported	**Method:** women surveys **Scale:** 0-1 (no, yes) **Sample for outcomes:** N=42 IV: 23; C: 19	**Advise:** advice at one or both visits % C vs IV	**Advise:** 78.9% vs 95.7%**	Women self-reported smoking status at baseline and 2 month follow-up (N=42). 30 day abstinence (% C vs IV) 15.4% vs 42.5%[a]

	intervention and 19 to comparison condition	**Implementation measures:** not reported				Mean decrease in number of days smoked: 1.1 vs 14.3** Mean decrease in cigarettes smoked on a typical day: -0.1 vs 3.9[a]

APPENDIX 21. Aboriginal data management protocol

Scope of protocol

This protocol covers research and service data generated from/used by the Maternal Alcohol NHMRC Trial (MAT) as well as any program variation, additional/included research or projects partnering with the MAT.

Reporting research or service data identifying or pertaining to Aboriginal people or Aboriginal services is key to identifying and understanding gaps in service access, health risk factors and health outcomes for Aboriginal people compared to non-Aboriginal people.

As such, it is expected that:

1. **All dissemination (papers, presentations, reports, media etc.) for the Maternal Alcohol Trial and related programs include research and/or service data identifying or pertaining to Aboriginal people or Aboriginal services.**
2. **This protocol will be applied to all dissemination (papers, presentations, reports, media etc.) for the Maternal Alcohol Trial and related programs.**

Purpose of protocol

Any program variation, additional/included research or projects partnering with the Maternal Alcohol NHMRC Trial (MAT), will adhere to and must comply with the Maternal Services Projects Aboriginal Data Protocol.

In the context of the MAT, the purpose of this protocol is to:

1. Briefly describe the trial background
2. Describe guiding principles for the use of Aboriginal information
3. Provide an overview of data ownership
4. Describe potential data sources
5. Outline the process for use and dissemination of Aboriginal data, including
    a. service data, and;
    b. research data
6. Outline the process for ethical approval for all forms of dissemination of Aboriginal data
7. Provide guidelines for authorship on resulting publications/presentations
8. Outline procedures for requests for external release of Aboriginal data
9. Specify data storage and security standards
10. Outline requests for data access under GIPA Act 2009

1. Background to Maternal Alcohol NHMRC Trial

Alcohol consumption during pregnancy can cause harm to both the woman, her fetus and child[1]. Adverse outcomes of alcohol consumption during pregnancy include Fetal Alcohol Spectrum Disorders (FASD), miscarriage, low birth weight and premature birth [2], with potential longer-term impacts on adult health and well-being[3].

As there is no known 'safe' level of maternal alcohol consumption during pregnancy, NHMRC guidelines recommend that pregnant women do not consume alcohol prior to and during pregnancy [1]. Despite this, between 28-72% Australian women report drinking alcohol at any time during pregnancy [4-11].Aboriginal women are less likely than non-Aboriginal women to drink alcohol during pregnancy (19 to 44%), but those

who drink are more likely to drink at harmful levels (10 to 19%) [1] Such higher levels of risk sit within a broader social and economic context of disadvantage.

Research [12]and clinical practice guidelines [13-16] suggest that the provision of assessment and care (advice and referral), may increase abstinence from and reduce consumption of alcohol by pregnant women. However, previous studies indicate that antenatal care providers do not routinely provide such care to pregnant women [17-20].

The aim of this study is to determine the effectiveness of a practice change intervention in increasing the provision of routine antenatal care regarding maternal alcohol consumption during pregnancy.

The data collection procedures undertaken to collect data for the primary outcome measures for this trial involves collecting data from women who have recently attended an appointment with an antenatal service. Women who consent to participate in this data collection process undertake a survey either by phone or online, during which they are asked questions related to the care they received in their appointment related to alcohol consumption and their current and past alcohol consumption.

2. Guiding principles for the use of Aboriginal or Torres Strait Islander information

All MAT program data identifying or pertaining to Aboriginal people or Aboriginal Maternal Infant Health Strategy (AMIHS) services will be collected, stored, reported and disseminated in accordance with the principles outlined below [21].

a) The management of health and health-related information about Aboriginal peoples will be ethical, meaningful and useful to Aboriginal peoples.
b) Information about the health of Aboriginal peoples and the services they receive will be used to support improved health and better planning and delivery of health services.
c) The analysis, interpretation and reporting of Aboriginal health and health-related information will occur collaboratively between Aboriginal and non-Aboriginal stakeholders.
d) For the reporting of all Aboriginal data, adequate background and context will be provided to prevent potential misrepresentation, misinterpretation or reinforcement of negative stereotypes of Aboriginal peoples.
e) The privacy and confidentiality of Aboriginal peoples and health service providers will be protected in accordance with the NSW Health Information Privacy Code of Practice, as endorsed by the Privacy Committee of NSW, and any other legislation or guidelines pertaining to the NSW health sector.
f) When reporting data collected from Aboriginal people, all users of MAT data will adhere to the NSW Aboriginal Health Information Guidelines.

3. Data ownership

The MAT is funded for four (4) years (2016-2019), with primary data collection being undertaken from mid 2016-mid 2020. Funding is provided by the National Health and Medical Research Council (NHMRC) Partnership Grant and is administered by the University of Newcastle. Regarding research data, the University of Newcastle has ultimate ownership and control of such data arising from the MAT, as governed by the NHMRC funding contract and guidelines. For service data, permission for use will be determined through consultation with the relevant health service data custodians. The Chief Investigator of the trial, Professor John Wiggers, will be responsible for, and have oversight of the data.

The Chief Investigator and MAT team[1] recognise the notion that ownership holds significance for Aboriginal peoples. Custodianship of information about Aboriginal peoples confers a number of responsibilities including determining when and where information disclosure and utilisation are appropriate. This protocol has been developed on the basis that Aboriginal peoples have rights and responsibilities of ownership regarding their health and health-related information. This includes the right to protect and care for the use of this information, the right to determine culturally appropriate forms for its reporting, and the right to grant or withhold permission from other agencies or organisations for its use.

4. Data sources

A number of data sources will be utilised during the MAT to:

- inform the development of a best practice model of care for addressing alcohol consumption during pregnancy, including ensuring that the model of care in culturally appropriate and safe.
- Inform the development of practice change strategies to support health professionals address alcohol consumption during pregnancy within Hunter New England LHD, including ensuring such strategies are culturally appropriate.
- monitor the implementation of practice change strategies
- evaluate the success of the practice change strategies in improving implementation of the recommended model of care for addressing alcohol consumption during pregnancy and reducing alcohol consumption during pregnancy
- evaluate the acceptability of the model of care and practice change strategies
- describe women who are attending antenatal services across the HNELHD in terms of marital status, employment status and Aboriginal identity question and to assess initiative outcomes in terms of benefits to women across different demographic groups.

These data sources will include, but not be limited to the following sources of data, which include both routinely collected service data and data specifically collected for the purposes of this initiative ('research data'):

1) **Routinely-collected service data:**
   - **eMaternity records -** electronic medical record system used in NSW LHDs to record antenatal care of women. All HNE health service providers are responsible for entering data into eMaternity.
   - **Referral service data** - service records of services referred to as a pathway in the model of care (e.g. Get Healthy in Pregnancy telephone coaching service; Drug and Alcohol clinical services)

2) **Research data:**
   - **Surveys with pregnant women**

   Aboriginal women, women attending AMIHS or who have accepted an AMIHS model of care have the option of participating in either an online or telephone survey on the antenatal care they received for alcohol consumption. Client contact list is extracted from eMaternity, iPM (appointment database) and CHIME databases (community health database). This data will be used to evaluate the practice change initiative.
      - **Telephone surveys**– Self-report client evaluation survey delivered via computer assisted telephone interviewing (CATI).
      - **Online surveys -** Self-report client evaluation survey developed in REDCap, a secure online platform, and delivered via a link to the survey

   - **Staff surveys -** self-report surveys with health professionals providing care to pregnant women.

  - Online (Select Survey and REDCap) and paper quantitative surveys conducted with staff of HNELHD maternity services in 3 sectors and will include doctors, midwives, AMIHS Midwives, Aboriginal Health Workers (AHW) and student midwives.
  - Qualitative, semi-structured interviews with a purposive sample of staff of HNELHD maternity services in 3 sectors and will include doctors, midwives, AMIHS Midwives, Aboriginal Health Workers (AHW) and student midwives.

- **Aboriginal women's focus groups** – Small focus groups (4-6 participants) conducted to provide a culturally appropriate and safe environment to collect the views of Aboriginal women who have attended HNELHD Maternity services. Small focus groups will explore women's experiences of being asked about and receiving care for alcohol consumption during pregnancy. Participants will be recruited through existing mothers groups to whom the researchers have existing relationships, with the help of the convener.

- **Project databases** – project data collection processes recording the implementation of practice change strategies, including training records (REDCap database).

- **Surveys of postnatal women** - Follow up phone and online surveys of postnatal women one or more months following pregnancy will be undertaken to collect data on care received for alcohol, smoking and gestational weight management and addressing such risk factors in a multi-health risk approach.

Medical record audit – For women who participate in the online or phone survey and consent to an audit of their records. The audit will assess women's recorded assessment and care receipt, including referrals to other sources.

All data collected by any other means, associated with MAT will adhere without exception to this data protocol.

5. Use of Aboriginal data

5.1 Data Integrity

The MAT Chief Investigator (Prof John Wiggers) has ultimate responsibility for the accuracy of MAT data and ensuring the scientific rigour of the data (including appropriate sample size for sub group reporting).

5.2 Governance and consultation

It is imperative that there is Aboriginal participation and engagement during all steps of the evaluation process. For the MAT (and associated projects) this will be facilitated through the MAT cultural task groups (data collection and dissemination) and any relevant sub-committees including community representatives, Aboriginal community members and partners. The MAT Cultural Review Group will oversee the review of project reports, papers, presentations and any other publications or materials generated from the trial.

5.3 Data access

All Hunter New England Local Health District (HNELHD) employees, and University of Newcastle employees and students must sign a privacy and confidentiality agreement specific to data access (see Appendix 4). Employees must comply with the terms of this agreement when accessing or using Aboriginal data. The terms of this agreement incorporate compliance with the Health Records and Information Privacy Act 2002, as well as any other relevant NSW Health policy, including the Antenatal Alcohol Initiative Data Management Protocol 2017.

5.4 Data analysis and dissemination

All data from the MAT, including data from Aboriginal participants, will be examined and reported in group form only, to prevent identification of an individual's data. Any data from Aboriginal participants will be reviewed and approved by the MAT Cultural Review Group.

5.4.1 Internal dissemination

Internal dissemination is defined as dissemination within maternity services engaged in the MAT across HNELHD or within the MAT research team. For example, data used by the MAT team for the purpose of monitoring of the MAT implementation during the trial period and reported to relevant staff and managers across the LHD and the HNELHD Executive Leadership Team (ELT). Where such data include Aboriginal data the process for approval for dissemination of these data is: collated and checked by the MAT team, approved by the Chief Investigator and approved by the members of the MAT Aboriginal Dissemination Cultural Task Group (MATADCTG), and the MAT Cultural Review Group whilst project is active. In the event the MAT Aboriginal dissemination cultural task group has disbanded or unavailable the data will be sent to the Population Heath Aboriginal Cultural Determinants Committee (PH ACDC). This does not include data owned by Maternity Services and uploaded into SMaRTA viewer through normal performance monitoring processes that would occur independent of the MAT.

5.4.2 External dissemination

Data from the MAT (and associated programs) may be disseminated externally including via presentations as part of training and communication as well as via publication in peer reviewed journals, conference presentations and PhD theses. Where such data include Aboriginal data the process for approval for dissemination of these data is:

- Data and draft documents and presentations will be collated and checked by the MAT (or associated programs) Program Manager. Once the data, presentation or document has been finalised it will be presented to PH ACDC and the MAT Aboriginal dissemination cultural task group and MAT Cultural Review Group for guidance on interpretation, cultural appropriateness advice and approval regarding dissemination and publication of findings.

- If at any time in subsequent years, should the afore-mentioned, nominated groups/committees have disbanded or be unavailable, the use of data relating to the MAT program or associated programs covered in this protocol must follow the same process with the equivalent bodies to ensure the cultural safety, integrity and context of the data being used. To fail to do so could potentially harm individuals, communities and organisations.

6. Ethical approval process for collection and publication of Aboriginal data

Where Aboriginal data collected for the purposes of the MAT (and associated programs) has a specific research component and or data collected will be disseminated via peer reviewed publication in journals or at conferences, ethics approval with the following bodies must be current:

a) Hunter New England Human Research Ethics Committee (HNE HREC)

b) Aboriginal Health and Medical Research Council (AH&MRC) of New South Wales (NSW) Ethics Committee

c) University of Newcastle Human Research Ethics Committee (UoN HREC).

7. Authorship

In acknowledgement of the expert input of Aboriginal community members, staff and organisations, Hunter New England Population Health (HNEPH) acknowledges that Aboriginal health research is not possible

without the important contribution made by Aboriginal partners at all levels from community members, cultural advisors through to investigators. Aboriginal people are essential in shaping the research methodology concept and design and they also provide expert guidance and review which informs the interpretation and integrity of a research project.

HNEPH further acknowledges the importance of providing opportunities for Aboriginal people to develop research skills and to also be authors of the resulting publications.

Authorship of papers will be in line with the HNE Population Health Authorship Guidelines. (See Appendix 2. Authorship Guidelines).

8. Procedures for requests for external data release

Requests for access to data, including Aboriginal data, may be made by partners of the MAT (e.g. Aboriginal Community Controlled Health Services (ACCHS)) or by other organisations, services or individuals external to the MAT and HNEPH (e.g. media, external researchers, community organisations).

Requests for data, including Aboriginal data, by organisations, services or individuals external to the MAT Project Team and HNEPH should be made in writing using the Aboriginal Data Access Request form (See Appendix 3.). The requests will be reviewed by Chief Investigator, Prof John Wiggers, the MAT Program Manager, PH ACDC and the MAT Cultural Review Group, Aboriginal dissemination cultural task group with decisions regarding approval or non-approval and reasons for non-approval communicated to the MAT Program Manager.

The MAT Program Manager will communicate the result of the request to the applicant.

Requestors will have an opportunity to appeal a non-approval, with the request reviewed again through the process described above.

If access is approved, the MAT Program Manager will provide data access to approved applicants. Approved applicants will be required to sign a confidentiality agreement prior to data release (See Appendix 4).

Prior to external dissemination, approved external users of data will need to provide a draft version of any output (paper, report, presentation etc.) for review and approval by the process outlined above in section 5.4.2 to ensure that the principles and processes outlined in this data protocol are adhered to.

9. Data storage and security

All MAT data, including Aboriginal data will be treated as strictly confidential. Participant's names will not be recorded with the information provided. Participant's names will not be recorded with their answers, and individual participants' answers will not be provided to staff in any HNELHD maternity Service. The MAT team will ensure that any data prepared for sharing has identifying variables removed (e.g. women's first and last name, address, and phone number).

Electronic data files will be stored on a restricted share drive with only the MAT team having access to these files. Hard copy documents (e.g. CATI log sheets) will be stored in a locked filing cabinet at Hunter New England Population Health, Booth Building, Wallsend.

The information will be stored for at least 7 years after the completion of the project. This will allow any queries about the data reported in publications to be answered. After 7 years electronic files will be deleted

from the computer system and hard copies securely shredded. However, de-identified data files may be stored for longer in archived form if additional publications are required beyond the 7 year period.

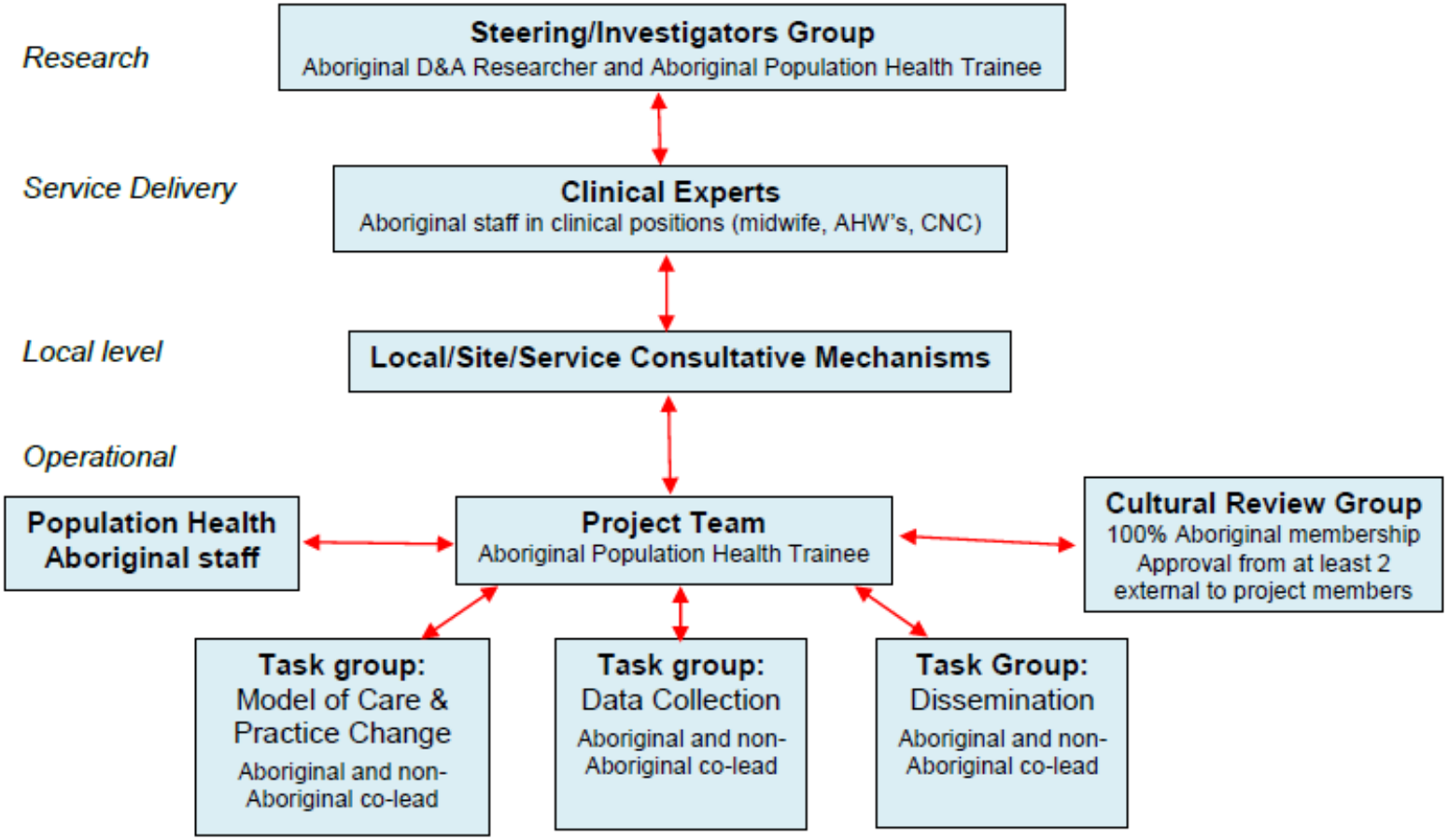
10. Requests for data access under GIPA Act 2009

Advice from the HNELHD regarding the security of the MAT (and associated programs) and reports in the context of the Government Information (Public Access) (GIPA) Act 2009 [22] has been obtained. https://www.legislation.nsw.gov.au/acts/2009-52.pdf

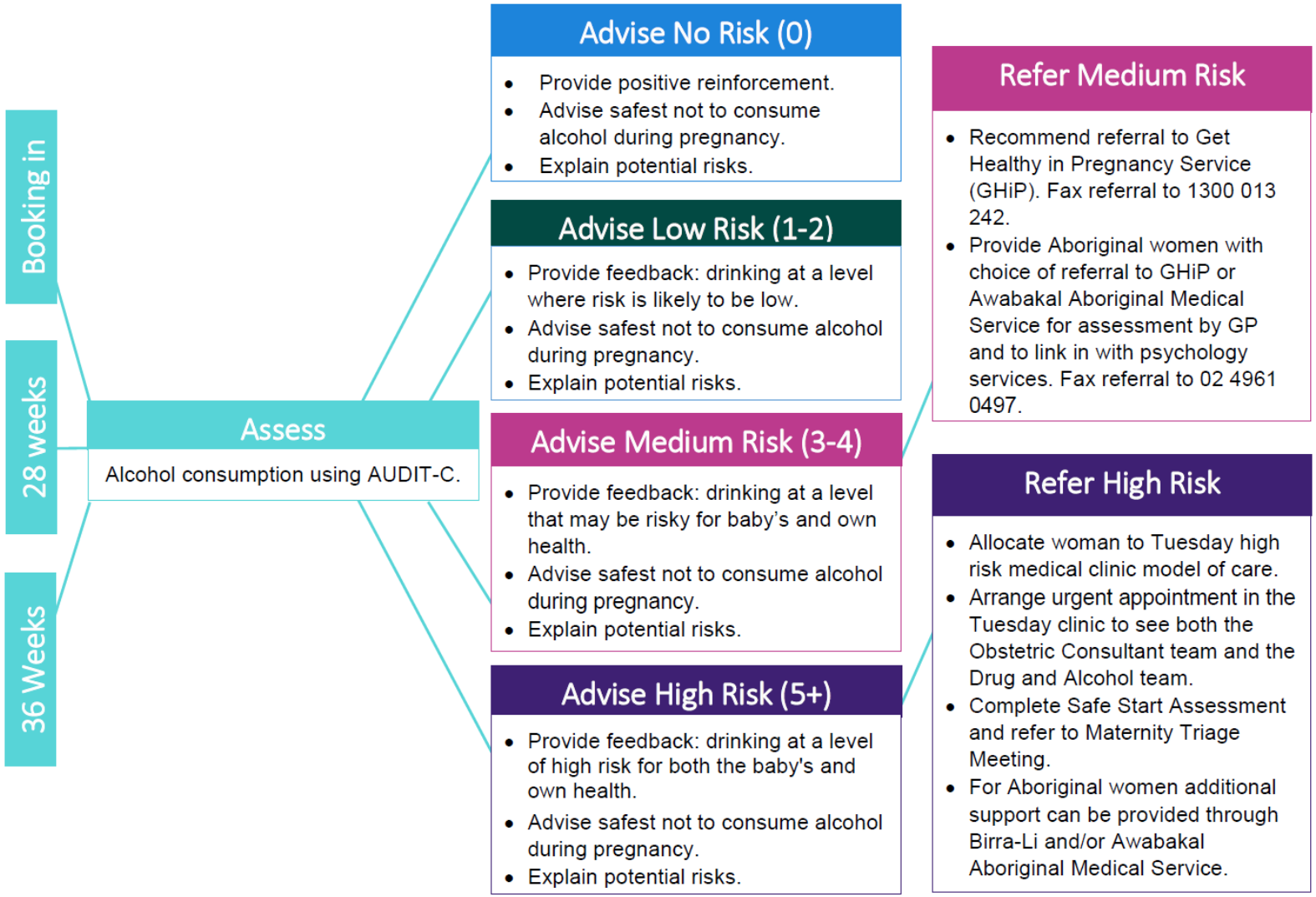
HNELHD has indicated whilst they cannot guarantee any research findings or data collected as part of the study could be released in response to a request made under the GIPA Act, there are a number of provisions within section 14 the GIPA Act that allow for data not to be disclosed on the grounds of public interest considerations that would likely outweigh the public interest in disclosure of the information.

Recommendations to minimize the risk of data being disclosed under the GIPA Act:
1. All reports or documents containing individual level data collected as part of the MAT (and associated programs) study will be marked 'confidential'.
2. All reports or documents containing individual level data collected as part of MAT (and associated programs) study will be marked 'for research purposes only'.

APPENDIX 22. Cultural governance model



APPENDIX 23. Example model of care with local referral pathways

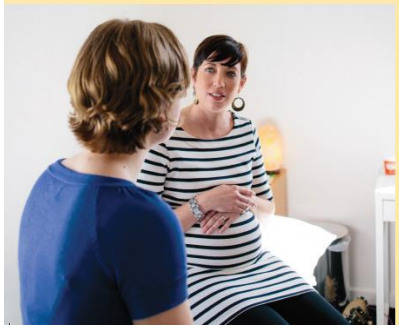


APPENDIX 24. Women's pamphlets

Dispelling myths about pregnancy and alcohol

- There is no safe amount to drink during pregnancy. Having one or two drinks on a special occasion has **not** been found to be safe for developing babies.
- There is no safe time to drink during pregnancy. The baby's brain continues to develop throughout pregnancy. Drinking alcohol at any time will affect the developing brain.
- There is no safe type of alcohol to drink. Wine, beer and spirits all pass through the placenta to your baby.
- The concentration of alcohol in your blood is the same as the concentration in your breastmilk.
- Alcohol is not a healthy way to relieve stress.
- "Everything in moderation" does not apply to alcohol in pregnancy. Any alcohol you drink will pass through the placenta to your baby.

No safe amount.
No safe time.
No safe type.



If you are concerned about any of the issues raised in this leaflet you should consult a health professional.

Further information and support

Pregnancy, Birth and Baby Helpline
1800 822 438
www.pregnancybirthbaby.org.au

National FASD Hub
www.fasdhub.org.au

NOFASD Australia
www.nofasd.org.au

National Alcohol and Other Drug Hotline
1800 250 015
www.drughelp.gov.au

National Health and Medical Research Council
Australian guidelines to reduce health risks from drinking alcohol
www.nhmrc.gov.au/health-topics/alcohol-guidelines

Australian Breastfeeding Association
1800 686 268
www.breastfeeding.asn.au

Feedsafe: App to assist breastfeeding mothers
www.feedsafe.net

Lifeline
13 11 14
www.lifeline.org.au

This leaflet has been developed as part of the Women Want to Know project by the Foundation for Alcohol Research and Education (FARE), in collaboration with leading health professional bodies across Australia. The Women Want to Know project is funded by the Australian Government Department of Health.
Published 2018

fare Foundation for Alcohol Research & Education

women want to know about pregnancy & alcohol

Australian Government
Department of Health

Information you might not know about

pregnancy & alcohol

Pregnancy is an exciting time, a time when many women want to know what they can do to ensure that they stay healthy and give their baby the best start in life.

One thing that is important in keeping you and your baby healthy is to avoid drinking alcohol while pregnant, planning pregnancy or breastfeeding. This leaflet will help you make an informed choice and give you the best advice for you and your baby.

If you are pregnant or planning pregnancy, experts advise no amount of alcohol is safe.

The National Health and Medical Research Council, Australia's peak body on developing national health advice, recommends that for women who are pregnant, planning pregnancy or breastfeeding, not drinking alcohol is the safest option.

This is because no amount of alcohol has been proven as safe. The evidence is clear: alcohol causes birth defects. All alcohol crosses the placenta harming the baby.

If you have consumed alcohol while pregnant and are concerned, or are having trouble stopping drinking, you should talk to your doctor, midwife or obstetrician.

Talking about alcohol

Many women don't know exactly when they become pregnant and many pregnancies are not planned – so it is possible that you might have been drinking alcohol before you were aware of your pregnancy.

Talking about your drinking may seem daunting, but health professionals speak to lots of people about these issues and they want the best for you and your baby.

It is also important to talk to someone if you think you might be struggling with depression, stress or anxiety. Your health professional can refer you to services in your area to support you and your baby to be healthy. Some support services are listed on the back page.

Risks from drinking alcohol during pregnancy

- Increased risk of stillbirth, premature birth and low birth weight
- Increased risk of miscarriage
- Increased risk of birth defects
- Damage to the baby's brain causing conditions known as Fetal Alcohol Spectrum Disorder, or FASD

Fetal Alcohol Spectrum Disorder – Facts

For most children with FASD there are no visible signs but they can have brain damage causing:

- Physical and emotional developmental delay
- Impaired speech and language development
- Learning problems, eg. poor memory
- Difficulty controlling behaviour

The effects of FASD are lifelong.

When planning a pregnancy

Alcohol can reduce fertility and greatly increase the time it takes to get pregnant.

If you have stopped using contraception and are trying to get pregnant, you should consider not drinking alcohol at all.

When pregnant

It is never too late to stop drinking alcohol during pregnancy.

People might ask why you are not drinking. If you're not ready to announce your pregnancy, try saying:

- I'm on a health kick and have given up alcohol
- No thanks, I'm not drinking tonight
- I have a big day tomorrow so no thanks

If you're happy to tell people, simply say: No thanks, not while I'm pregnant.

Make the pledge to go alcohol free during your pregnancy or the pregnancy of a loved one. www.pregnantpause.com.au

If it is difficult for you to stop drinking you should speak to your health professional for support.

When breastfeeding

Not drinking alcohol is the safest option. Alcohol enters the breast milk and may stay there for several hours.

Alcohol can decrease the flow of milk and cause your baby to be unsettled.

Alcohol in breastmilk can affect the baby's brain and spinal cord development.

No alcohol during pregnancy is the safest choice.

Tips when out with friends

It can be hard when you're pregnant and people pressure you to drink alcohol.

If you're not ready to tell people you're pregnant you could say - No thanks...

- I'm not drinking tonight.
- I have to drive.
- I have to get up early tomorrow.
- I can't afford to drink at the moment.
- I have a big day/ early meeting tomorrow.
- I'm not feeling that great so I'd rather not.

Or get a friend to support you and say

- We're on a health kick together and not drinking alcohol.

If people know you're pregnant or you're happy to tell them you can say:

- not while I'm pregnant. I'm looking after my bub.

Drinking alcohol when you are pregnant can harm your baby. No alcohol is the safest choice.

Find out more at www.yourroom.com.au

StayStrongAndHealthy

This resource is a modified reproduction of the Women Want to Know resources, developed by the Foundation for Alcohol Research and Education (FARE) and funded by the Australian Government Department of Health 2014.

APPENDIX 25. Example referral forms

Disclaimer: By completing this form you consent to this information being sent to the Get Healthy Information and Coaching Service®, and consent for the Service staff to contact you.

Referrer Details (print or stamp below)

Name: Nicole Bennett
Profession: Midwifery Unit Manager
Organisation/Hospital: John Hunter Hospital
Address (for feedback letters):
Lockout Road New Lambton
Postcode: 2299
Phone Number:
Email:

Patient details
Please print or affix patient sticker on top

First Name: Mary
Surname: Smith
DOB: 20.12.1990
Gender: ☐ Female ☐ Male
Address: 102 Main Street
Suburb: Lambton
Postcode: 2299
Tel. home:
Tel. mobile:
Email:
Are you of Aboriginal or Torres Strait Islander origin?
- ◉ No
- ☐ Yes, Aboriginal
- ☐ Yes, Torres Strait Islander
- ☐ Yes, both Aboriginal and Torres Strait Islander

Preferred goal

- ☐ Physical Activity ☐ Weight Management
- ☐ Healthy Eating ◉ Alcohol Reduction

Is an interpreter required?
☐ No ☐ Yes
Specify language:

When is the best time to call?
◉ am ☐ pm

Are you pregnant? ☐ No ◉ Yes

General comments
Please describe any health condition(s)/ impairment(s) which may affect what the patient eats or how physically active they can be:

AUIDT- C completed score 4 identified as medium risk

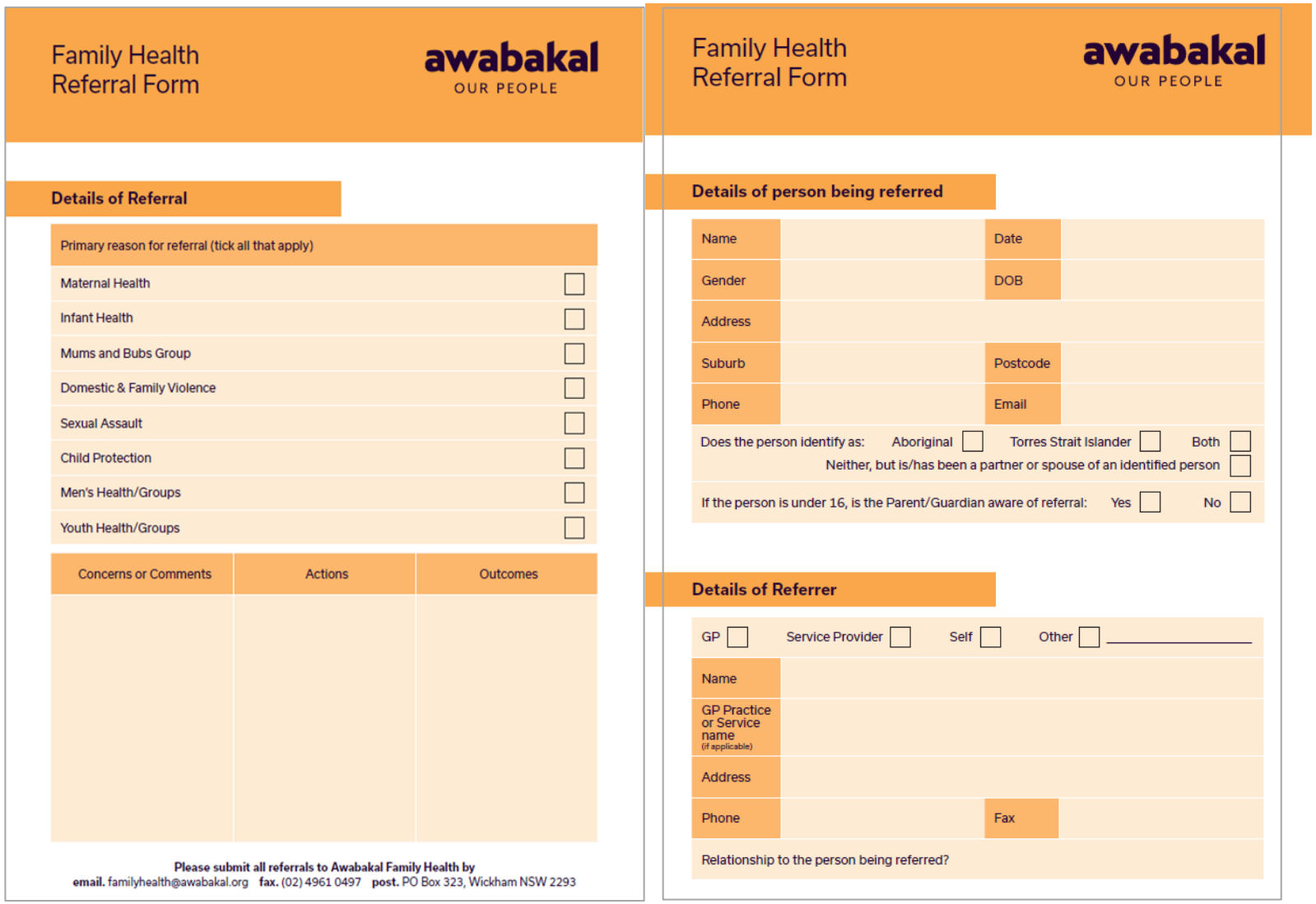
Current body measurements (Optional)

Waist circumference (cm):
Height (cm):
Weight (kg):

If pregnant:
Pre-pregnancy weight (kg):
Gestational Age (wks): 28 Weeks

Feedback letters (optional)

◉ I, the health professional named above, would like feedback letters on the above patient's contact with the Service.
Date:



Family Health Referral Form

awabakal OUR PEOPLE

Details of Referral

Primary reason for referral (tick all that apply)	
Maternal Health	☐
Infant Health	☐
Mums and Bubs Group	☐
Domestic & Family Violence	☐
Sexual Assault	☐
Child Protection	☐
Men's Health/Groups	☐
Youth Health/Groups	☐

Concerns or Comments	Actions	Outcomes

Please submit all referrals to Awabakal Family Health by
email. familyhealth@awabakal.org **fax.** (02) 4961 0497 **post.** PO Box 323, Wickham NSW 2293

Family Health Referral Form

awabakal OUR PEOPLE

Details of person being referred

Name		Date	
Gender		DOB	
Address			
Suburb		Postcode	
Phone		Email	

Does the person identify as: Aboriginal ☐ Torres Strait Islander ☐ Both ☐
Neither, but is/has been a partner or spouse of an identified person ☐

If the person is under 16, is the Parent/Guardian aware of referral: Yes ☐ No ☐

Details of Referrer

GP ☐ Service Provider ☐ Self ☐ Other ☐ _____

Name			
GP Practice or Service name (if applicable)			
Address			
Phone		Fax	

Relationship to the person being referred?

Substance Use in Pregnancy and Parenting Service (SUPPS) - Tamworth Referral Form

Email: HNELHD-NorthernSUPPS@hnehealth.nsw.gov.au
Fax: 6766 8083
Phone: 1300 660 059

FAMILY NAME	MRN
GIVEN NAMES	☐ MALE ☐ FEMALE
D.O.B. _____/_____/_____	M.O.
ADDRESS	
LOCATION	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

Prior to proceeding, has client consented to this referral ☐ Yes

Mothers Details		**Father/Partners Details**	
Name:		**Name:**	
DOB:	**Age:**	**DOB:**	**Age:**
Address:		**Address:**	
Phone Number:		**Phone Number:**	
Country of birth:		**Country of birth:**	
☐ Aboriginal ☐ Torres Strait Islander ☐ Both ☐ Neither Interpreter Required: ☐ Yes ☐ No Language spoken: _____		☐ Aboriginal ☐ Torres Strait Islander ☐ Both ☐ Neither Interpreter Required: ☐ Yes ☐ No Language spoken: _____	
If postnatal Referral: **Infant Name:** **DOB:** **MRN:** **Will the baby identify as Aboriginal or Torres Strait Islander?** ☐ Yes ☐ No			
GP Name:		**Address:**	
Current Pregnancy EDC:			
EDPS:	**Q10:**	**Date:**	
Antenatal Care:		**Next Appointment:**	
Sibling Details (Please record additional siblings on paper and attach to this form			
Sibling 1:	**DOB:**	**Sibling 2:**	**DOB:**
Sibling 3:	**DOB:**	**Sibling 4:**	**DOB:**
Current Substance Use (Including last 12 months- including prescribed medication)			

Substance	**Date of last Use**	**Please provide details (method, frequency, treatment)**

Substance Use in Pregnancy and Parenting Service (SUPPS) - Tamworth Referral Form

Email: HNELHD-NorthernSUPPS@hnehealth.nsw.gov.au
Fax: 6766 8083
Phone: 1300 660 059

FAMILY NAME	MRN
GIVEN NAMES	☐ MALE ☐ FEMALE
D.O.B. _____/_____/_____	M.O.
ADDRESS	
LOCATION	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

Vulnerabilities	**Past**	**Current**
Current or history of child protection/FACS issues? ☐ Yes ☐ No		
FACS/CWU Report? ☐ Yes ☐ No **Date:** **Reference:** Case Worker:		
Mental Health Issues – Diagnosis/medication/treatment (Emotional/behavioral) _____ _____		
Current or history of domestic & family violence: _____ _____		
Domestic Violence screening attended: ☐ Yes ☐ No Date of last screen: _____		
Has the client been referred to Safe Start? ☐ Yes ☐ No **Has the referral been discussed with the client?** ☐ Yes ☐ No **Have there been any worker safety concerns related to home visiting?** ☐ Yes ☐ No		

Referrer Details	
Name:	**Position:**
Agency:	**Contact Number:**

I,_____ (name of patient/client) authorise the exchange of information between Drug and Alcohol Clinical Services (DACS) Substance Use in Pregnancy and Parenting Service (SUPPS) and referrer

Client signature:_____ Date:_____

Office Use Only	Date Referral Received:

APPENDIX 26. Leadership/managerial supervision strategy – example agenda of meetings with site managers and memo sent from site leadership to maternity service staff

Screening and management of alcohol consumption in pregnancy: practice change initiative

Peel Sector Meeting 24/10/18
9.00am – 10.00am
Peel Sector General Manager's Office

AGENDA

Attendees: Catharine Death, Cathy Hastings, Richard Leighton, Merryl Chaffey, Melanie Kingsland, Sophie Curtin, Emma Doherty

Apologies: Kylie Whitford, Lilach Leibenson

Items for Discussion	Document	Lead
• Welcome and Introductions		All
• Overview of initiative and purpose of meetings	DOC A. Overview DOC B. Current care provision	Mel
• Guideline and Procedure	DOC C. Guideline and Procedure	Emma
• CME role and training		Sophie
• Approval of proposed SMaRTA Viewer performance measures	DOC D. Performance Measures	Mel
• Management communication of Guideline and Procedure and Training		Mel
• Potential barriers		Sophie
• Next meeting/frequency of meetings		Mel

Health
Hunter New England
Local Health District

Memo

TO	Midwives and Medical staff JHH Maternity Gynaecology Services
FROM	Carol Azzopardi
TEL	DATE 05/03/2018
SUBJECT	**SCREENING AND MANAGEMENT OF ALCOHOL CONSUMPTION DURING PREGNANCY**

A new Guideline and Procedure (G&P) has been issued regarding the screening and management of alcohol consumption during pregnancy. The G&P is attached and can be accessed via the HNE Policy, Procedures and Guideline (PPG) Directory
http://intranet.hne.health.nsw.gov.au/__data/assets/pdf_file/0019/178102/HNELHD_GandP_18_02_Maternity_-_Screening_Management_of_Alcohol_Consumption_During_Pregnancy.pdf

The G&P is effective immediately. It relates to all staff providing care to all women in our antenatal services. The G&P is supported by eMaternity, including prompts for screening for alcohol consumption using AUDIT-C, brief advice scripts and referral prompts.

Laminated flowcharts are in clinic rooms and pamphlets for women are available in your services usual resource location for inclusion in all booking in packs.

An online HETI module 'Antenatal Care for Alcohol Consumption during Pregnancy' has been developed for training in the G&P. This module is assigned learning and will appear on your My Health Learning homepage (alternatively search for the module using 'alcohol' or 'pregnancy'). It is expected that all staff who provide care in our antenatal services complete this module. Managers will be monitoring completion. Face-to-face training sessions will be undertaken with staff from this week.

Brendon Williams (Clinical Midwife Educator) is supporting the implementation of the G&P until August 2018. Brendon is available to support all staff to undertake training and will be in clinics to provide assistance and answer any questions.

Compliance with the new G&P will be monitored by managers using eMaternity reports.

Kind Regards,

Carol Azzopardi
Maternity & Gynaecology Service Manager JHH
Snr Midwifery & Woman's Health Advisor WHAM Network

Hunter New England Local Health District
ABN 63 598 010 203

Lookout Road, New Lambton
Locked bag 1, HRMC, NSW 2310
Tel 02 4921 4388 Fax 02 4921 4394
Website www.hnehealth.nsw.gov.au

APPENDIX 27. Local clinical practice guidelines strategy

Maternity – Screening and management of alcohol consumption during pregnancy HNELHD GandP 18_02

Guideline and Procedure

NSW GOVERNMENT Health Hunter New England Local Health District

Maternity – Screening and management of alcohol consumption during pregnancy

Sites where Guideline and Procedure applies	John Hunter Hospital, Peel Sector and Manning Hospital, including AMIHS services. (Refer to the implementation schedule on page 7 for further information regarding other sites)
This Guideline and Procedure applies to:	
1. Adults	Yes
2. Children up to 16 years	Yes - potential for guidelines to apply to clients under 16 years
3. Neonates – less than 29 days	No
Target audience	All maternity care providers working in antenatal services: midwives, obstetricians, medical officers, Aboriginal health practitioners, Aboriginal health workers, midwifery and medical students.
Description	This document outlines the screening and management of alcohol consumption during pregnancy.

Go to Procedure

Keywords	Alcohol, AUDIT-C, antenatal, pregnancy, screening, management, assessment, advice, referral, best practice
Document registration number	HNELHD GandP 18_02
Replaces existing document?	No

Related Legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHSS) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics:

- National Health and Medical Research Council 2009, Australian Guidelines: To Reduce Health Risks from Drinking Alcohol. Commonwealth of Australia. Canberra.
- Department of Health 2018, Clinical Practice Guidelines: Pregnancy Care. Australian Government Department of Health. Canberra.
- NSW Ministry of Health 2014, Clinical Guidelines for the Management of Substance Use During Pregnancy, Birth and the Postnatal Period (GL2014_022). NSW Ministry of Health. North Sydney.
- *See Reference Section for Additional Related Documents – page 6*

Prerequisites (if required)	Guideline will be followed by maternity care providers who have been trained in the screening and management of maternal alcohol consumption.
Guideline and Procedure note	This document reflects what is currently regarded as safe and appropriate practice. The guideline section does not replace the need for the application of clinical judgment in respect to each individual patient. If staff believe that the procedure/s should not apply in a particular clinical situation they must seek advice from their unit manager/delegate and document the variance in the patient's health record.
Position responsible for the Guideline and Procedure and authorised by	Dr Henry Murray, Clinical Leader, Women's Health and Maternity Network (WHAM)
Contact person	Nicole Bennett, Midwife Manager, Maternity and Gynecology Outpatient Service
Contact details	Nicole.Bennett@hnehealth.nsw.gov.au Ph: 492 13922
Date authorised	13 February 2018
This document contains advice on therapeutics	No
Issue date	16 February 2018
Review date	16 February 2021

Note: Over time links in this document may cease working. Where this occurs please source the document in the PPG Directory at: http://ppg.hne.health.nsw.gov.au/

PURPOSE AND RISKS

If best practice alcohol care is not routinely provided in antenatal services this could result in negative maternal and infant health outcomes. High level and/or frequent intake of alcohol during pregnancy increases the risk of Fetal Alcohol Spectrum Disorder (FASD), miscarriage, stillbirth, premature birth and low birth weight with potential longer term impacts on child and adult health and wellbeing. For the woman, it increases the risk of injury in the short term and chronic disease in the longer term. There is no known safe level of maternal alcohol consumption at any stage during pregnancy.

Risk Category: *Clinical Care & Patient Safety*

GLOSSARY

Acronym or Term	Definition
AUDIT-C	Alcohol Use Disorders Identification Test - Consumption
eMaternity	Electronic medical record for all women from their first hospital visit in pregnancy through to postnatal care in the home

GUIDELINE

This Guideline does not replace the need for the application of clinical judgment in respect to each individual patient.

Australian National Health and Medical Research Council (NHMRC) guidelines recommend that it is safest for pregnant women to not consume alcohol during pregnancy as no safe level of consumption has been determined. There is strong evidence indicating that the risk of harm to the embryo and fetus is higher with high alcohol intake, including episodic intoxication. The potential for risk with low level intake is unclear and it is impossible to determine the variation in effects due to the influence of other maternal and fetal factors.[1]

Australian and New South Wales (NSW) clinical practice guidelines for antenatal care recommend alcohol consumption be addressed as part of routine antenatal care.[2,3] The guidelines recommend:

- All women's alcohol consumption be assessed via a validated tool.
- All women be provided with the advice that no alcohol during pregnancy is the safest option as no safe level of alcohol consumption has been determined for the fetus.
- Women identified as consuming risky levels of alcohol be given priority access to therapeutic services, such as counselling.
- Women identified as consuming alcohol at high risk levels or where dependence is suspected be provided priority access to drug and alcohol treatment services for comprehensive assessment and withdrawal monitoring.
- Maternity providers be sensitive to cultural issues that influence the acceptability of care.

PROCEDURE

Procedure Steps (see Appendix One for John Hunter Hospital Maternity Services procedure flowchart and Appendix Two for Peel Sector Maternity Services procedure flowchart):

1. Assess all women's alcohol consumption using the AUDIT-C tool in eMaternity

- Complete AUDIT-C tool in eMaternity at the following visits (see Appendix Five for eMaternity Alcohol AUDIT-C guide):
  - First hospital visit (booking in) - Medication, Alcohol and Drugs folder
  - 28 weeks gestation - Antenatal visit folder
  - 36 weeks gestation - Antenatal visit folder

Note: If woman's first hospital visit (booking in) is at 28 or 36 weeks gestation, complete AUDIT-C as part of booking in process. You do not need to re-enter data into the Antenatal visit folder for the same visit.

- A non-judgmental approach without any preconceived ideas of what the woman's responses may be is important when assessing alcohol consumption in order to elicit an accurate assessment.
- Questions should be answered in terms of standard drinks. Information on the definition of a standard drink for different types of alcoholic drinks should be provided to the woman (see Appendix Three for standard drinks chart).
- Any reported alcohol consumption that is not a full standard drink should be recorded to the nearest full measurement. For example, a response of half a standard drink is to be recorded as one standard drink.
- Ask the woman the AUDIT-C questions and provide her with the response options as they are written. Ask the woman to select the response that best fits her alcohol consumption since finding out she is pregnant.

Question	Score				
	0	1	2	3	4
How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times per month	2 – 3 times per week	4+ times per week
How many standard drinks of alcohol do you drink on a typical day when you are drinking? *(only applicable if any alcohol consumption indicated in first question)*	1 – 2	3 – 4	5 – 6	7 – 9	10+
How often do you have 5 or more standard drinks on one occasion? *(only applicable if any alcohol consumption indicated in first question)*	Never	Less than monthly	Monthly	Weekly	Daily or almost daily

- A total score is generated based on the responses provided and a level of harm risk category assigned
  - Score 0 = No risk of harm
  - Score 1 – 2 = Low risk of harm
  - Score 3 - 4 = Medium risk of harm
  - Score 5 + = High risk of harm

Note: The above provides the minimum schedule for alcohol assessment throughout the antenatal period. Alcohol can also be discussed outside of this schedule if clinically judged appropriate for the individual woman.

2. Provide all women regardless of their level of harm risk category with brief advice

- Following AUDIT-C being completed, eMaternity will provide a script of advice to guide discussions with the woman (see Appendix Four).
- Advise all women:
  - Provide feedback on level of risk
  - Advise not drinking during pregnancy is the safest option
  - Explain potential risks associated with alcohol consumption during pregnancy: impaired placental function, miscarriage, low birth weight, birth defects, preterm birth, stillbirth, Fetal Alcohol Spectrum Disorder (FASD).
- Answer any questions or concerns the woman may have.
- Provide all women with a brochure to take home for further information at the first hospital visit (booking in).
  - Information for women about pregnancy and alcohol brochure (download from eMaternity resources section)
  - Stay Strong and Healthy postcard for Aboriginal women https://yourroom.health.nsw.gov.au/

Maternity – Screening and management of alcohol consumption during pregnancy HNELHD GandP 18_02

3. Refer

John Hunter Hospital and Birra-Li AMIHS

- No Risk of Harm or Low Risk of Harm
  - No action required.

- Medium Risk of Harm

1. Get Healthy in Pregnancy (GHiP) Service.
   - Complete the GHiP Health Professional Referral Form and fax to 1300 013 242.
     - List the manager of antenatal services as the referrer except when there is a known lead midwife.
     - Select alcohol reduction as the preferred goal. Note: this goal refers to alcohol abstinence for pregnant women.
     - Indicate that feedback letters on the woman's contact with GHiP are to be received.

2. Hunter Primary Care Psychology Services (Drug and Alcohol program).
   - Complete the Hunter Primary Perinatal Psychology Service Referral Form and fax to (02) 4929 7072.
     - In the background section indicate that the referral is for alcohol counselling and include the results of the AUDIT-C assessment.

3. Awabakal Aboriginal Medical Service
   - Complete the Awabakal Family Health Referral Form and fax to (02) 4961 0497 or email familyhealth@awabakal.org
     - Select Maternal Health as the primary reason for referral.
     - In the Concerns or Comments section note that the woman is pregnant and has indicated moderate level of alcohol consumption.
     - In the Actions section note that the referral is to see the GP for assessment and to link in with the Psychology service.

- High Risk of Harm
  - Allocate to Tuesday high risk medical clinic model of care.
  - Arrange urgent appointment in the Tuesday clinic to see both the Obstetric Consultant team and the Drug and Alcohol team.
  - Complete Safe Start Assessment and refer to Maternity Triage Meeting (Intake meeting).
  - For Aboriginal women additional support can be provided through relevant Aboriginal services.
    - Birra-Li Aboriginal Maternal Infant Health Service (AMIHS) for women allocated to AMIHS model of care.
    - Awabakal Aboriginal Medical Service. To make a new referral, complete the Awabakal Family Health Referral Form and fax to (02) 4961 0497 or email familyhealth@awabakal.org
      - Select Maternal Health as the primary reason for referral.
      - In the Concerns or Comments section note that the woman is pregnant and has indicated a high level of alcohol consumption. Also note that the woman has been referred to the Hunter New England Tuesday clinic to see the Obstetric Consultant team and the Drug and Alcohol Team.
      - In the Actions section note that the referral is to provide relevant additional support to the woman.

Peel Sector (hospital maternity and AMIHS services)

- No Risk of Harm or Low Risk of Harm
    - No action required.

- Medium Risk of Harm
    1. Get Healthy in Pregnancy (GHiP) Service.
        - Complete the GHiP Health Professional Referral Form and fax to 1300 013 242.
            - List the manager of antenatal services as the referrer except when there is a known lead midwife.
            - Select alcohol reduction as the preferred goal. Note: this goal refers to alcohol abstinence for pregnant women.
            - Indicate that feedback letters on the woman's contact with GHiP are to be received.
    2. Hunter New England Substance Use in Pregnancy Service (SUPPS).
        - Email referral to HNELHD-NorthernSUPPS@hnehealth.nsw.gov.au
    3. Hunter New England Drug and Alcohol Clinical Services.
        - Phone 1300 660 059 or send completed HNE Drug and Alcohol Clinical Services (Northern) referral form to fax (02) 6766 9143 or email HNELHD-DACSNEIntake @hnehealth.nsw.gov.au
    4. Hunter New England Aboriginal Drug and Alcohol Services
        - Complete Drug and Alcohol Clinical Services Indigenous Client Referral Form and fax to (02) 6766 9143.
    5. Walhallow Aboriginal Health Services.
        - Phone (02) 6746 2001 to refer woman to service.
    6. Tamworth Aboriginal Medical Service (TAMS)
        - Complete referral forms 'Referral and Consent for Treatment to TAMS Alcohol, Tobacco and other Drug (ATOD) Programme' and 'Consent for Release and Receiving of Information' and fax to (02) 6766 5711.

- High Risk of Harm
    1. Hunter New England Substance Use in Pregnancy Service (SUPPS).
        - Email referral to HNELHD-NorthernSUPPS@hnehealth.nsw.gov.au
    2. Hunter New England Drug and Alcohol Clinical Services.
        - Phone 1300 660 059 or send completed HNE Drug and Alcohol Clinical Services (Northern) referral form to fax (02) 6766 9143 or email HNELHD-DACSNEIntake @hnehealth.nsw.gov.au
    3. Hunter New England Aboriginal Drug and Alcohol Services.
        - Complete Drug and Alcohol Clinical Services Indigenous Client Referral Form and fax to (02) 6766 9143.
    4. For Aboriginal women additional support can be provided through relevant services.
        - AMIHS for women enrolled in an AMIHS model of care.
        - Walhallow Aboriginal Health Service. Phone (02) 6746 2001.
        - Tamworth Aboriginal Medical Service. Fax 'Referral and Consent for Treatment to TAMS Alcohol, Tobacco and other Drug (ATOD) Programme' and 'Consent for Release and Receiving of Information' to (02) 6766 5711.
        - Winanga-Li Aboriginal Child and Family Centre (Gunnedah).
        - Gunnedah Family Support Services.

Manning Hospital (maternity and AMIHS services)

- No Risk of Harm or Low Risk of Harm
    - No action required.

- Medium Risk of Harm
    1. Get Healthy in Pregnancy (GHiP) Service.
        - Complete the GHiP Health Professional Referral Form and fax to 1300 013 242.
            - List the manager of antenatal services as the referrer except when there is a known lead midwife.
            - Select alcohol reduction as the preferred goal. Note: this goal refers to alcohol abstinence for pregnant women.
            - Indicate that feedback letters on the woman's contact with GHiP are to be received.
    2. LMNC Drug and Alcohol Clinical Services.
        - Phone 1300 660 059 or send the Drug and Alcohol LMNC Intake Service Referral Form to fax 6592 9919.
    3. Biripi Aboriginal Medical Service.
        - Phone Biripi Aboriginal Medical Service on (02) 6591 2400 to organise an appointment with the counsellor, drug and alcohol worker, family strengthening worker (social needs focus) and/or connected beginnings worker (health needs focus).
    4. Tobwabba Aboriginal Medical Service.
        - Phone Tobwabba Aboriginal Medical Service on (02) 6555 6271 to organise an appointment with the maternal team. The maternal team can then refer internally to the psychologist service. Women will be supported by an assigned female health worker.

- High Risk of Harm
    1. LMNC Drug and Alcohol Clinical Services.
        - Phone 1300 660 059 or send the Drug and Alcohol LMNC Intake Service Referral Form to fax 6592 9919.
    2. For Aboriginal women additional support can be provided through relevant services.
        - AMIHS for women enrolled in an AMIHS model of care.
        - Biripi Aboriginal Medical Service. Phone (02) 6591 2400 to organise an appointment.
        - Tobwabba Aboriginal Medical Service. Phone Tobwabba Aboriginal Medical Service on (02) 6555 6271 to organise an appointment.

The above outlines referral recommendations for women based on their AUDIT-C score. Clinical discretion should be applied when referring women in circumstances where other psychosocial factors are present or there is a suspicion of under reporting.

Documentation

Document AUDIT-C assessment and any referrals in eMaternity in appropriate sections.

APPENDICES

IMPLEMENTATION

The schedule for implementation at the following maternity services has been determined.

3. February 2018 – John Hunter Hospital, Birra-Li AMIHS
4. October 2018 – Tamworth Hospital, Tamworth AMIHS, Gunnedah Hospital, Gunnedah AMIHS, Qurindi Health One, Quirindi AMIHS
5. April 2019 – Manning Hospital, Taree AMIHS

Further implementation across other maternity services will be determined following this time.

For the services listed above, the following support will be provided to implement the Guideline and Procedure:

1. Awareness of the Guideline and Procedure will be promoted through in service sessions and forums.
2. Online and face to face training will be provided.
3. A Clinical Midwife Educator will be available to support the initial implementation period.

MONITORING COMPLIANCE

1. Data will be exported from eMaternity to monitor staff compliance with the procedure and will inform the review of the Guideline and Procedure either as required or as scheduled.
2. Operational measures will be included in SMaRTA Viewer.
3. Data will be fed back from surveys conducted with women during the initial implementation period.

REFERENCES

1. National Health and Medical Research Council, *Australian Guidelines to Reduce Health Risks from Drinking Alcohol*. 2009, Commonwealth of Australia: Canberra.
2. Australian Health Ministers' Advisory Council 2012, *Clinical Practice Guidelines: Antenatal Care – Module I*. 2012, Australian Government Department of Health and Ageing: Canberra.
3. NSW Ministry of Health, *Clinical Guidelines for the Management of Substance Use During Pregnancy, Birth and the Postnatal Period*. 2014, NSW Ministry of Health: North Sydney.

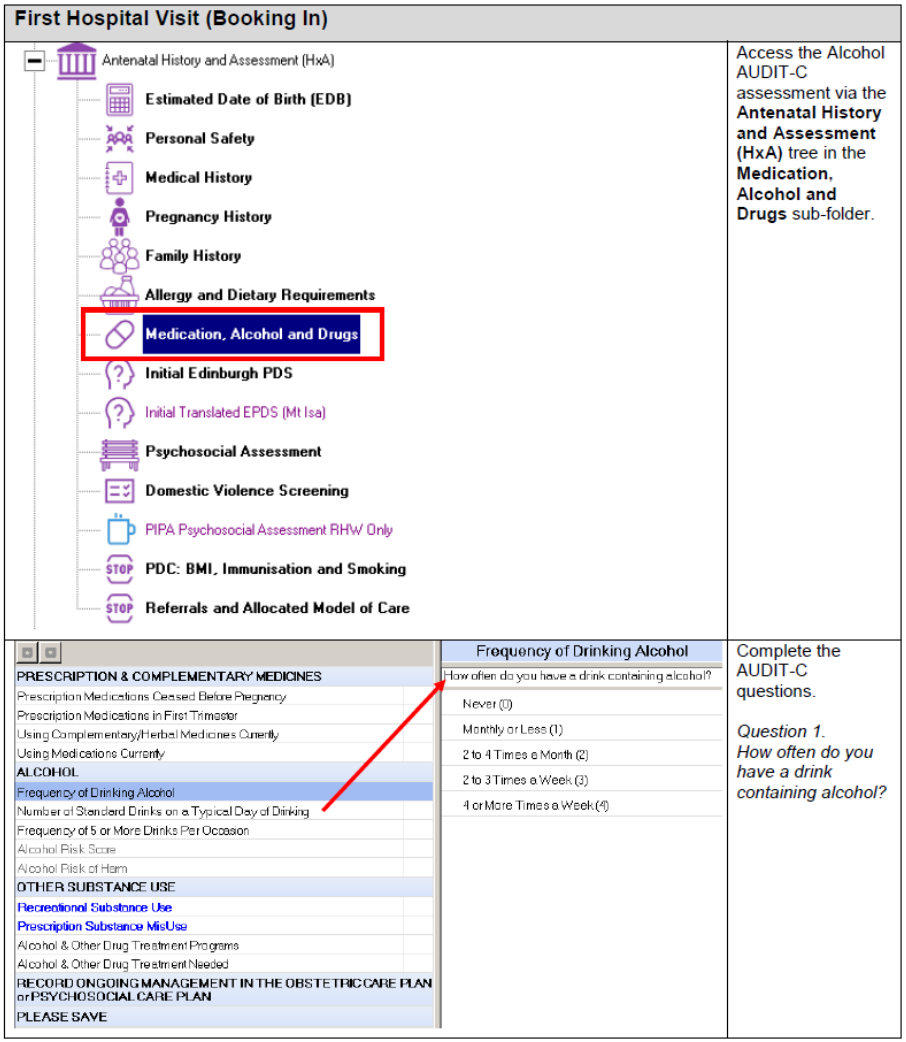
Additional Related Documents

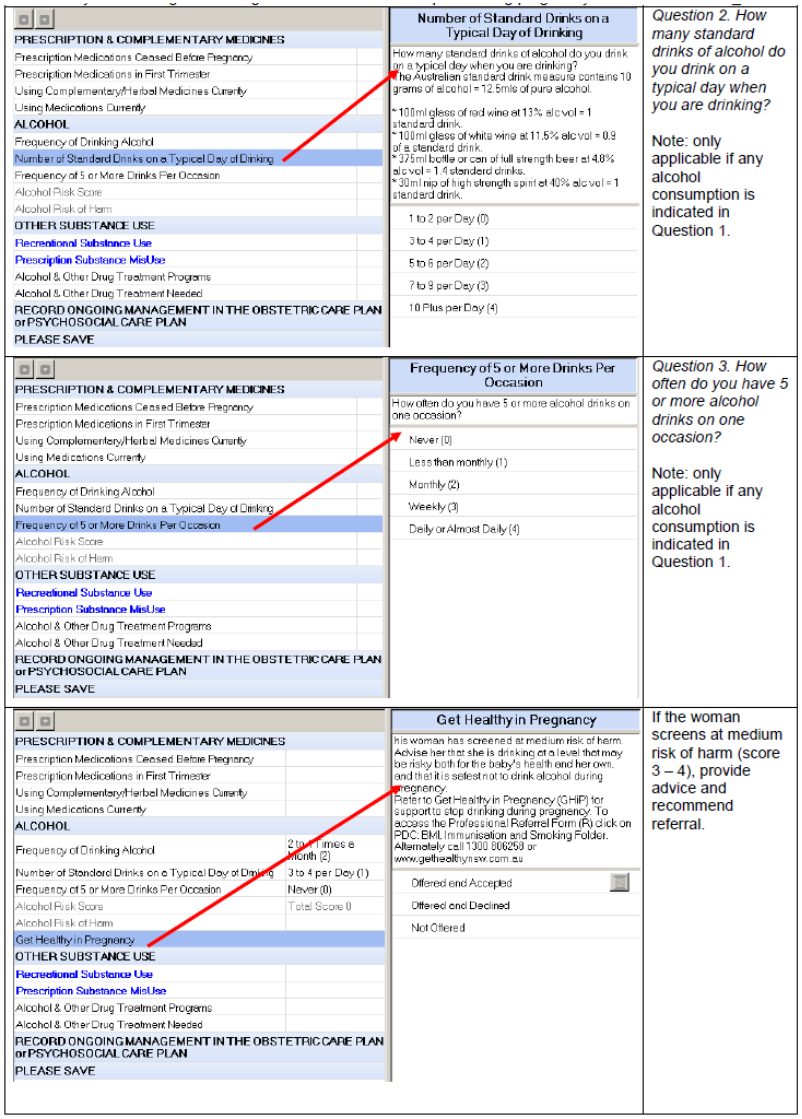
- Haber P, Lintzeris N, Proude E, Lopatko O 2009, Guidelines for the Treatment of Alcohol Problems. Commonwealth of Australia. Canberra.
- The Royal Australian and New Zealand College of Obstetricians and Gynecologists 2014, Alcohol in Pregnancy (C-Obs 54).
- Australian College of Midwives 2013, National Midwifery Guidelines for Consultation and Referral. 3rd Edition Issue 2.
- Bower C, Elliott EJ 2016, on behalf of the Steering Group. Report to the Australian Government Department of Health: Australian Guide to the diagnosis of Fetal Alcohol Spectrum Disorder (FASD).
- NSW Department of Health, 2009, NSW Health/Families NSW Supporting Families Early Package – SAFE START Guidelines: Improving mental health outcomes for parents and infants (GL2010_004). NSW Ministry of Health. North Sydney.

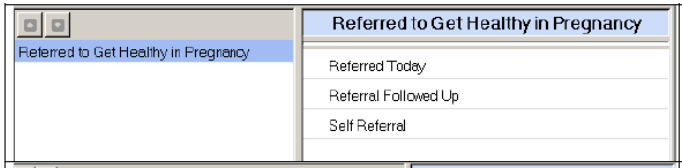
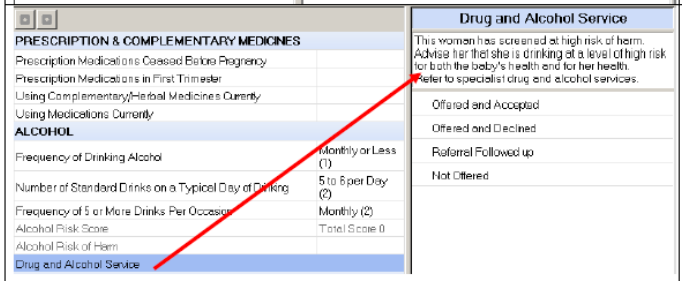
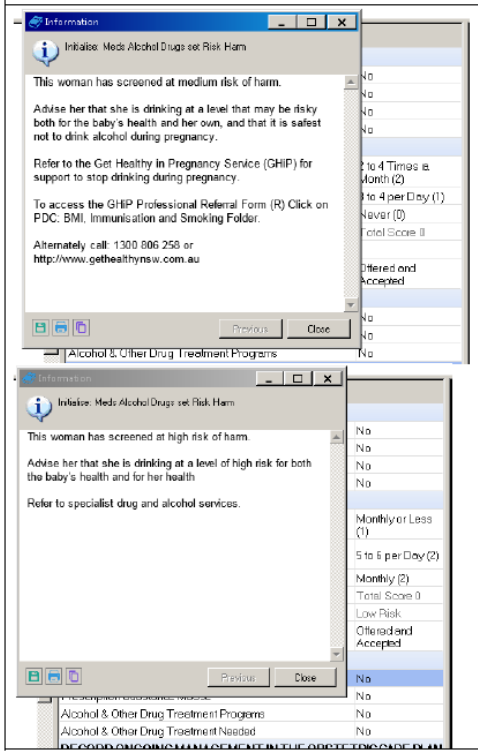
FEEDBACK

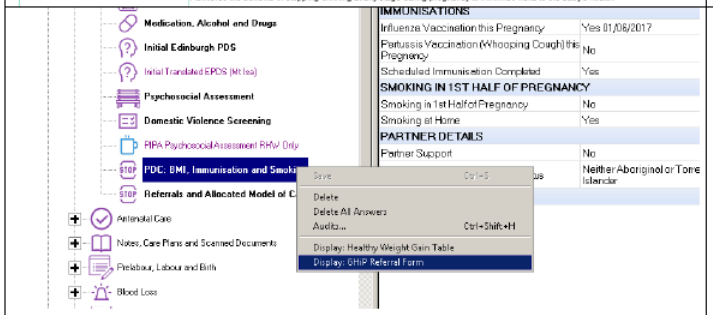
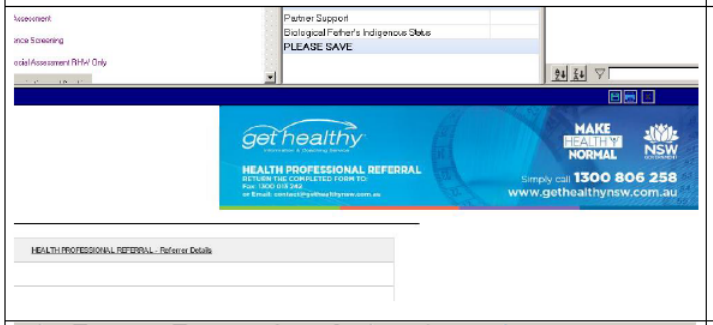
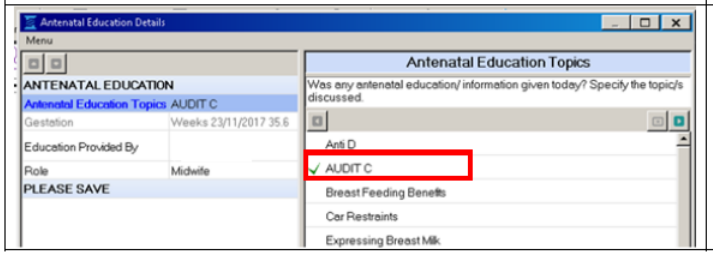
Any feedback on this document should be sent to the Contact Officer listed on the front page.

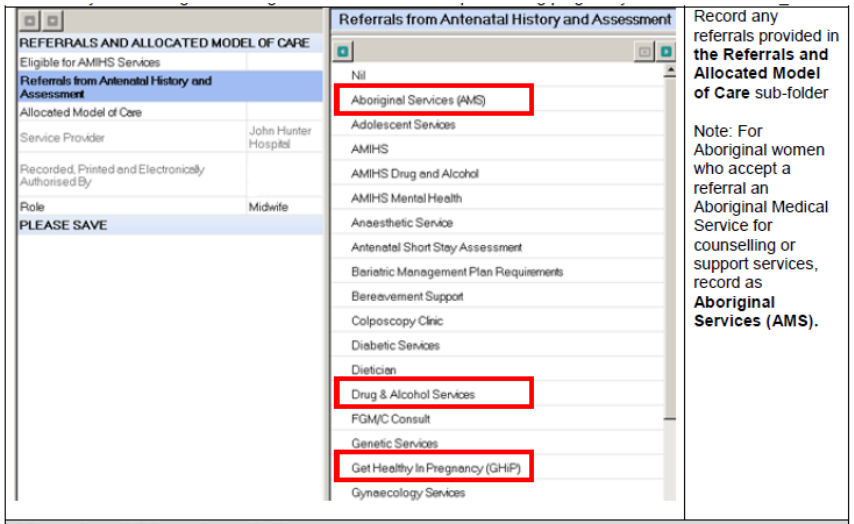
APPENDIX 28. Prompts and reminders strategy – electronic medical record





	If the referral is **Offered and Accepted** record further information about the referral.
	If the woman screens at high risk of harm (score 5+), provide advice and record provision of referral to Drug and Alcohol service.
	Upon saving the **Medication, Alcohol and Drugs** sub-folder referral prompts will be activated for women identified at medium and high risk of harm.

	A brief advice script will appear in the console. Use this script as a guide to provide advice tailored to the woman's level of harm risk category.
	Access the Get Healthy in Pregnancy referral form by right clicking on the **PDC: BMI, Immunisation and Smoking** sub-folder Select **Display: GHiP Referral Form**
	The form can be printed directly from eMaternity by selecting the print button
	Record that advice was provided in the **Antenatal Education** folder.

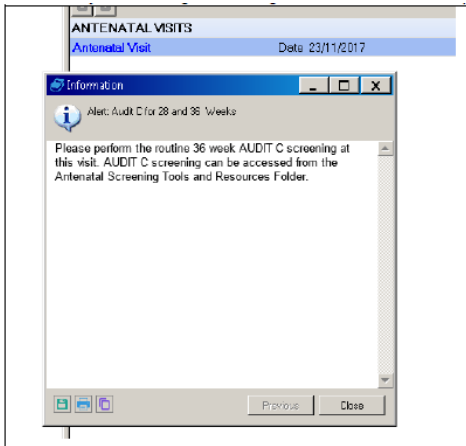


Record any referrals provided in **the Referrals and Allocated Model of Care** sub-folder

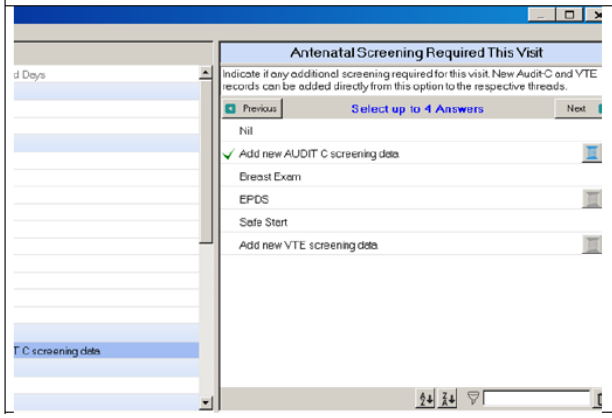
Note: For Aboriginal women who accept a referral an Aboriginal Medical Service for counselling or support services, record as **Aboriginal Services (AMS).**

28 week and 36 week gestation

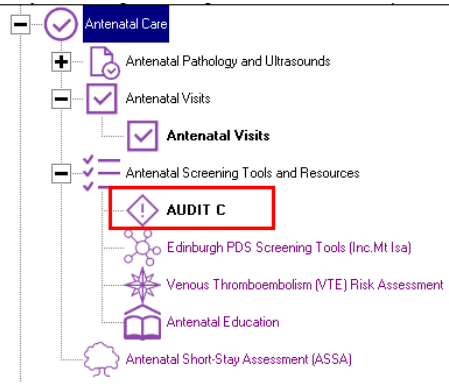
Check previous AUDIT-C risk in **Confidential Considerations**



Upon creating an **Antenatal Visit** for women 27 up to 30 weeks gestation and women 35 up to 38 weeks gestation you will be prompted to complete an alcohol AUDIT-C assessment.

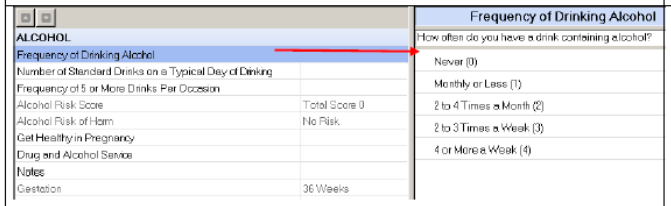


In the **Antenatal Visit** folder select 'Add new AUDIT C screening data' under 'Antenatal Screening Required This Visit.'



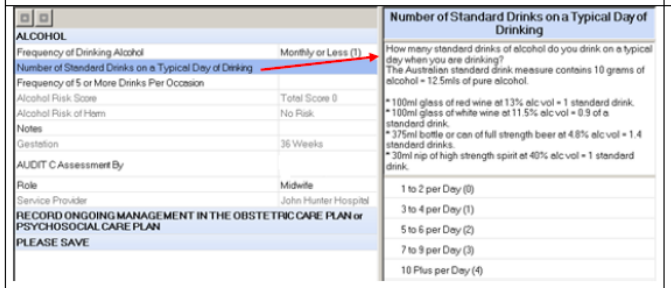
You can also access the AUDIT-C assessment via the **Antenatal Screening Tools and Resources** folder

Note: If you are completing an AUDIT-C assessment outside of the recommended times you will need to add an AUDIT-C subfolder by right clicking on **Antenatal Screening Tools and Resources** and **Add Folder**



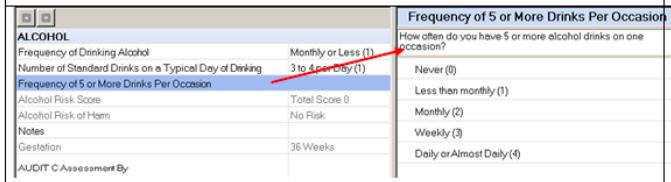
Complete the AUDIT-C questions

Question 1. How often do you have a drink containing alcohol?



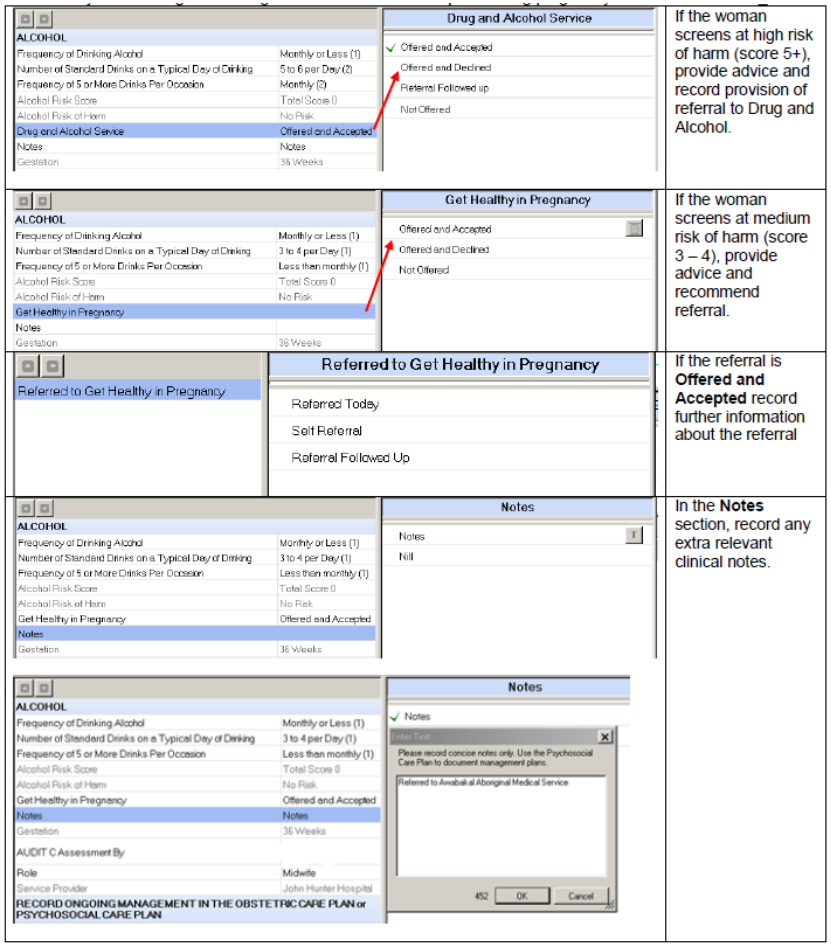
Question 2. How many standard drinks of alcohol do you drink on a typical day when you are drinking?

Note: only applicable if any alcohol consumption is indicated in Question 1.



Question 3. How often do you have 5 or more alcohol drinks on one occasion?

Note: only applicable if any alcohol consumption is indicated in Question 1.

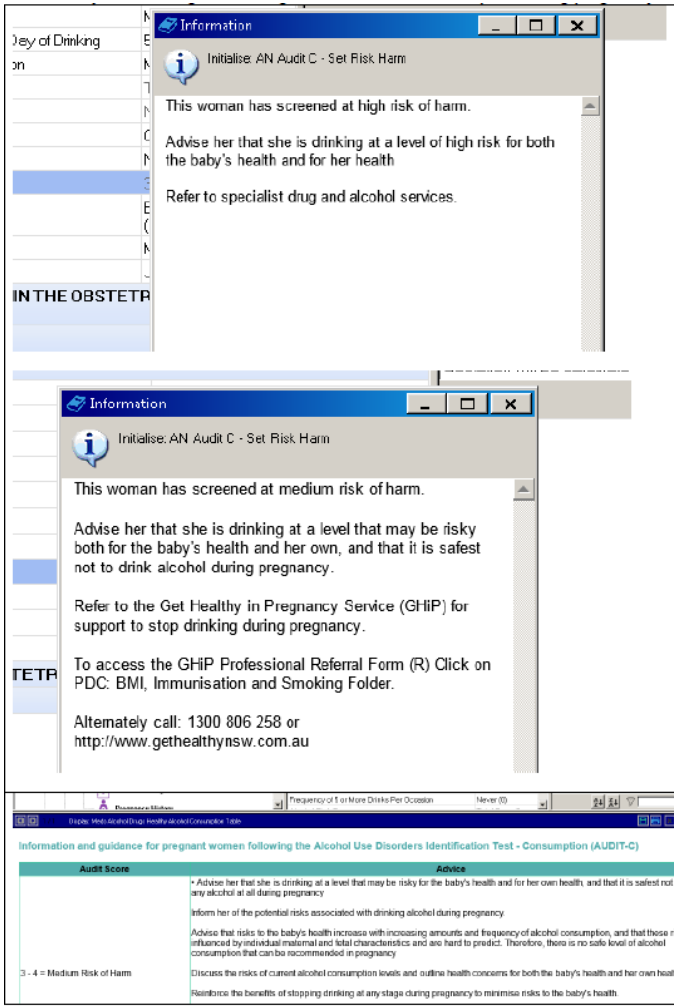


If the woman screens at high risk of harm (score 5+), provide advice and record provision of referral to Drug and Alcohol.

If the woman screens at medium risk of harm (score 3 – 4), provide advice and recommend referral.

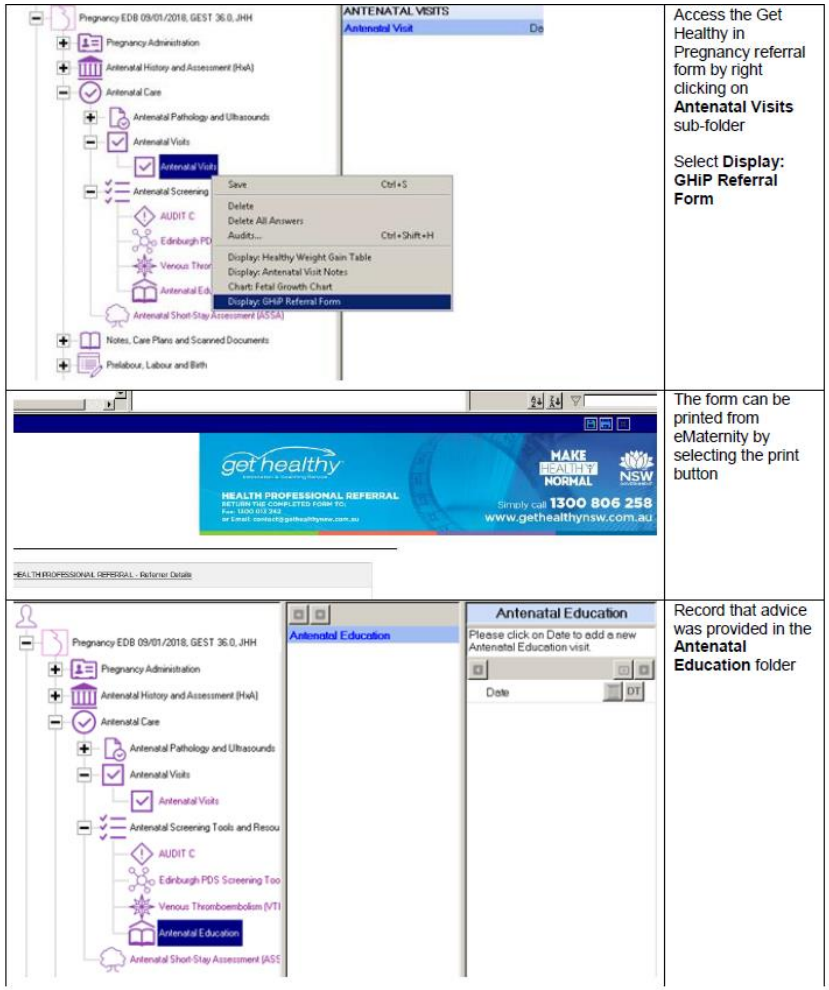
If the referral is **Offered and Accepted** record further information about the referral

In the **Notes** section, record any extra relevant clinical notes.



Upon saving the AUDIT-C folder referral prompts will be activated for women screening at medium and high risk of harm.

A brief advice script will appear in the console. Use this script as a guide to provide advice tailored to the woman's level of harm risk category.

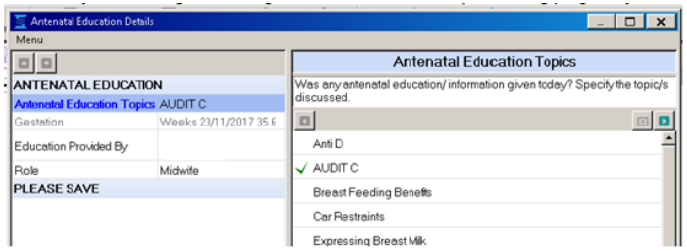


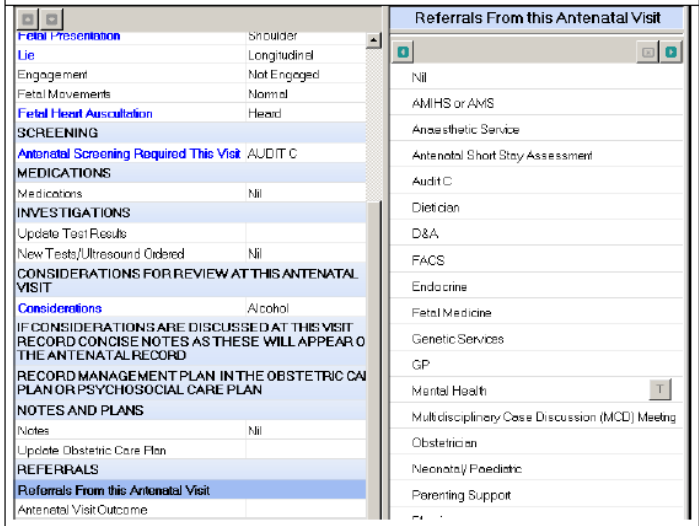
Access the Get Healthy in Pregnancy referral form by right clicking on **Antenatal Visits** sub-folder

Select **Display: GHiP Referral Form**

The form can be printed from eMaternity by selecting the print button

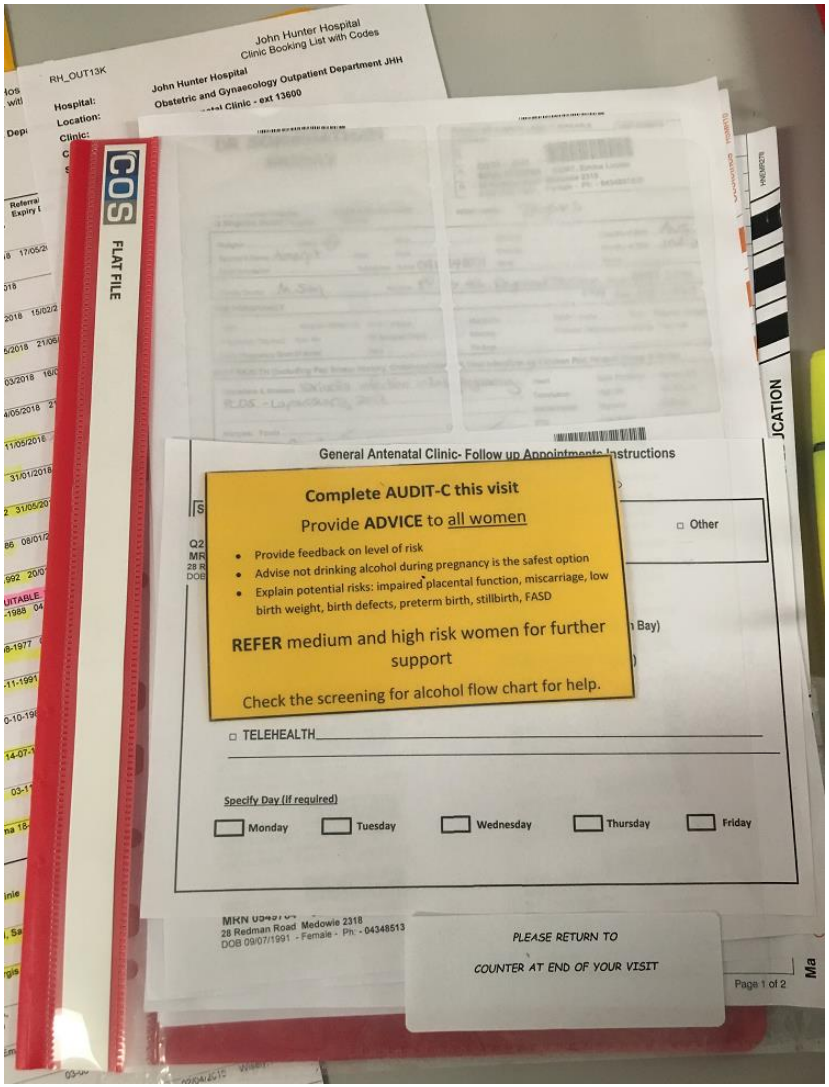
Record that advice was provided in the **Antenatal Education** folder

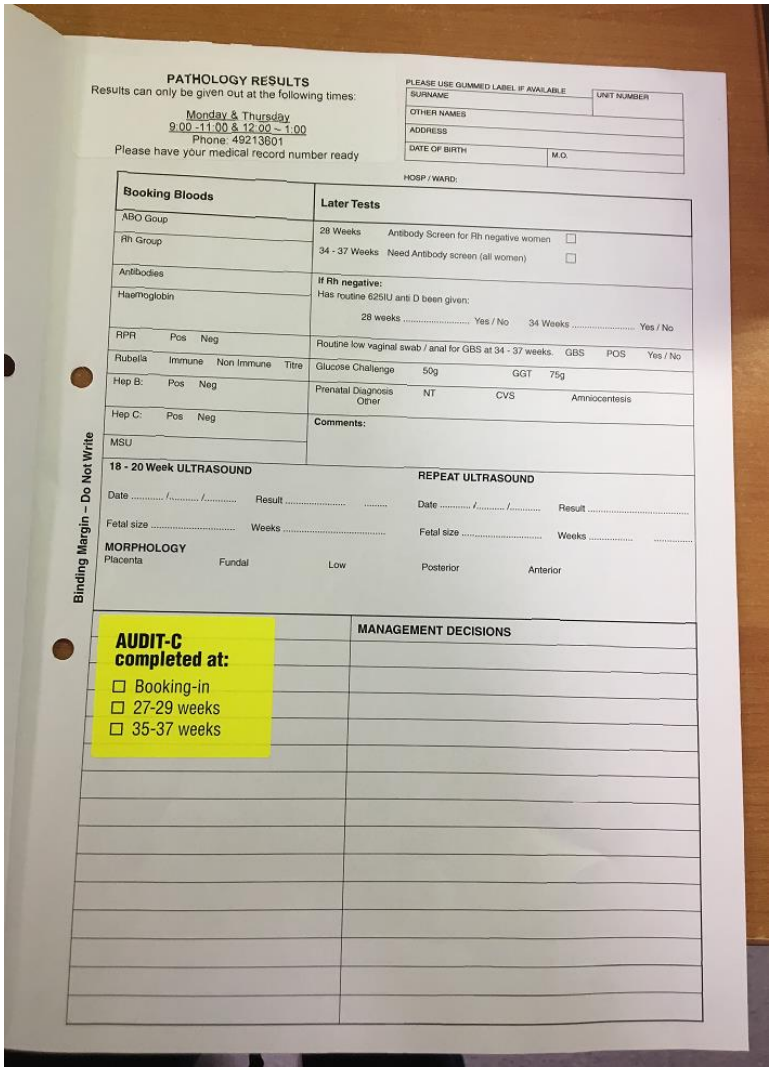




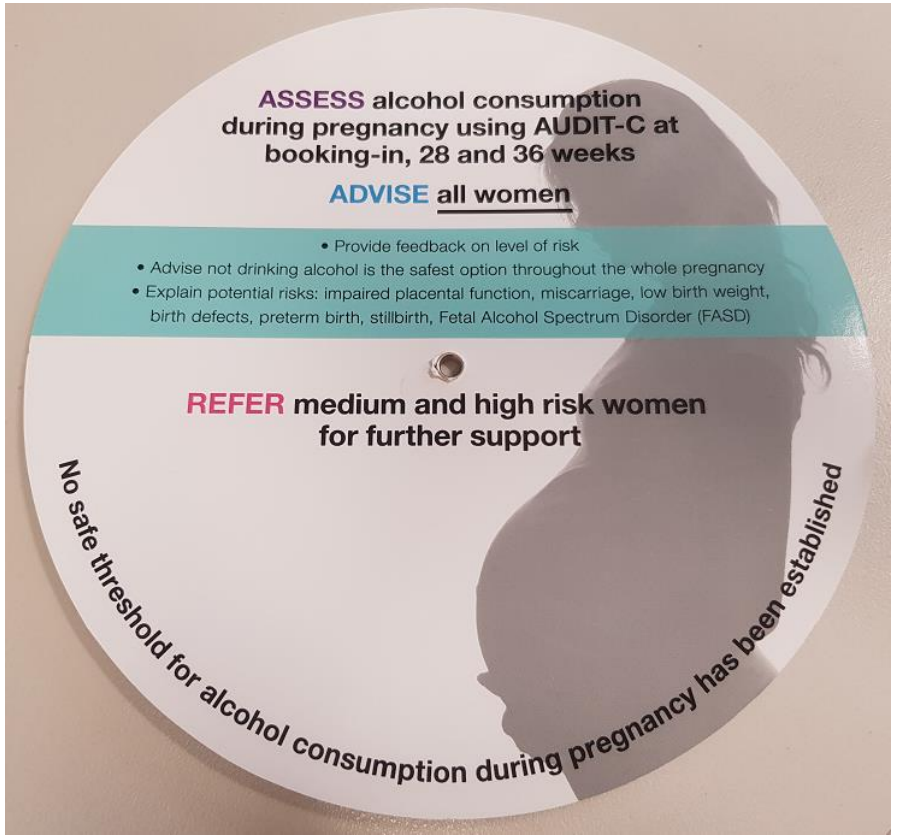
For Aboriginal women who accept a referral to an Aboriginal Medical Service for counselling or support services, record referral provision as **AMIHS or AMS** in the antenatal visits folder.

APPENDIX 29. Prompt and reminders strategy – hard-copy



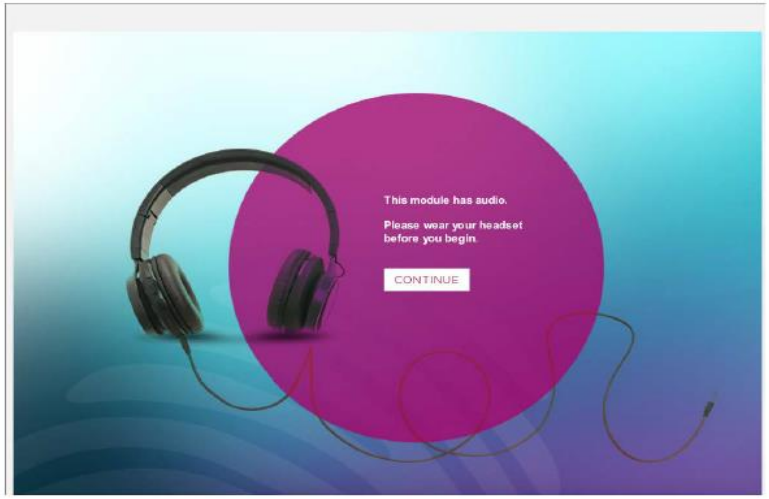


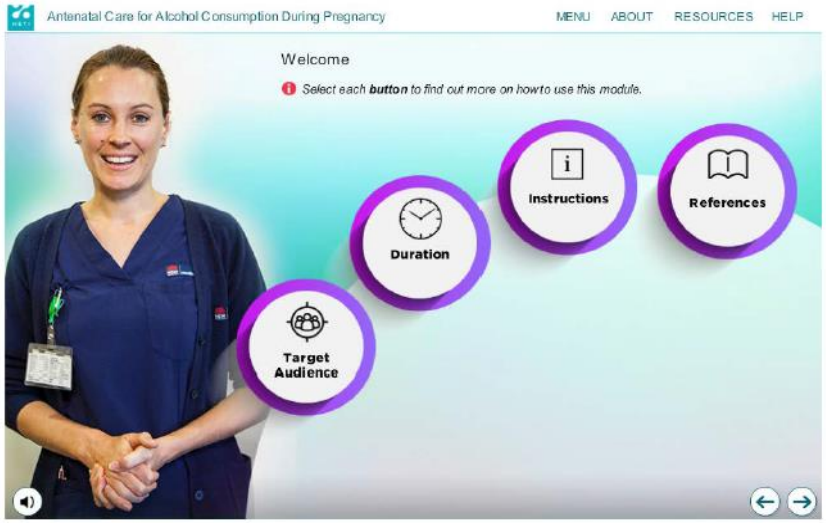

AUDIT-C
ASSESS ADVISE REFER
for alcohol consumption during pregnancy
at booking-in, 28 & 36 week visits
CALCULATED DATE OF BIRTH
FIRST DAY OF LAST MENSTRUAL PERIOD
WEEKS
JANUARY
FEBRUARY
MARCH
APRIL
MAY
JUNE
JULY
AUGUST
SEPTEMBER
OCTOBER
NOVEMBER
DECEMBER

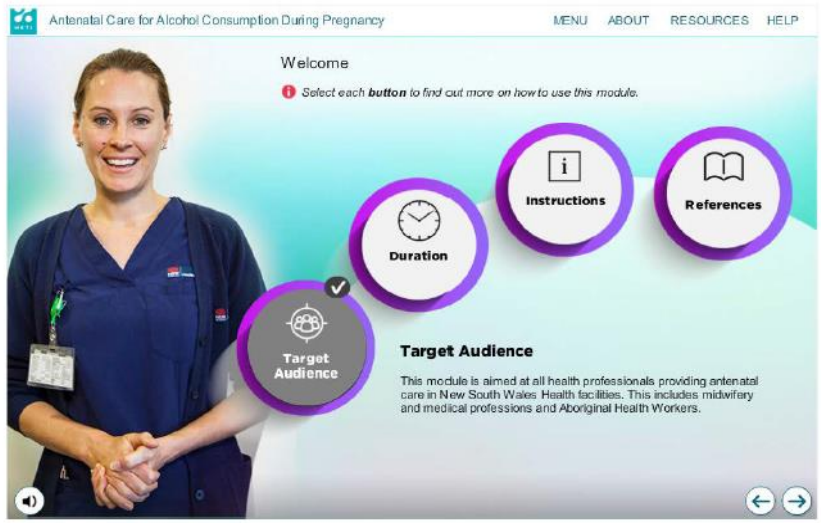

ASSESS alcohol consumption during pregnancy using AUDIT-C at booking-in, 28 and 36 weeks
ADVISE all women
• Provide feedback on level of risk
• Advise not drinking alcohol is the safest option throughout the whole pregnancy
• Explain potential risks: impaired placental function, miscarriage, low birth weight, birth defects, preterm birth, stillbirth, Fetal Alcohol Spectrum Disorder (FASD)
REFER medium and high risk women for further support
No safe threshold for alcohol consumption during pregnancy has been established

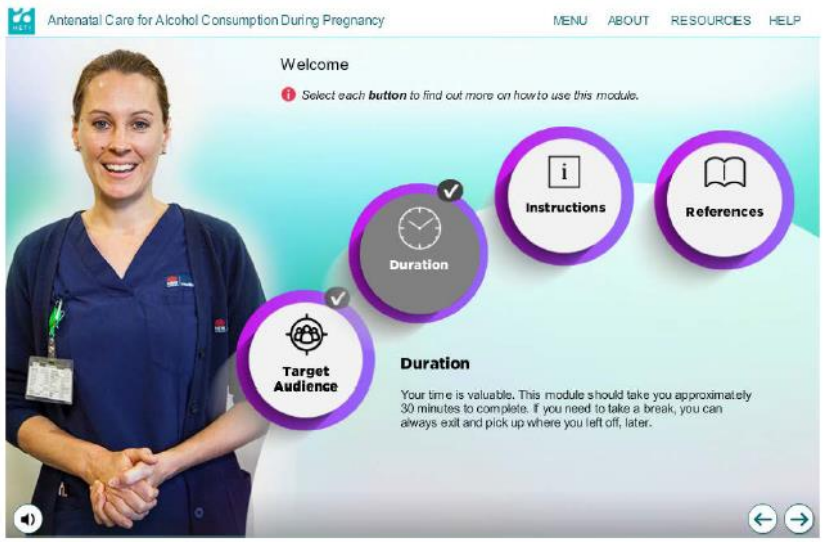
APPENDIX 30. Educational meetings strategy

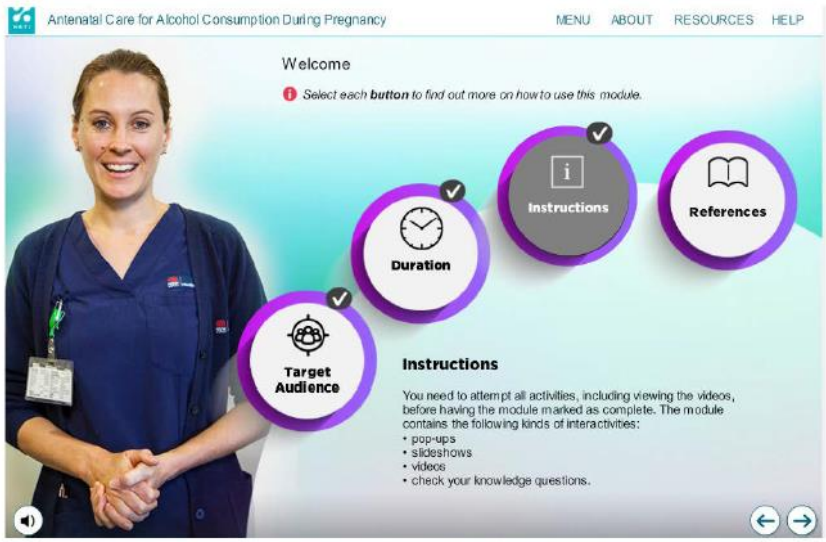
Online training module

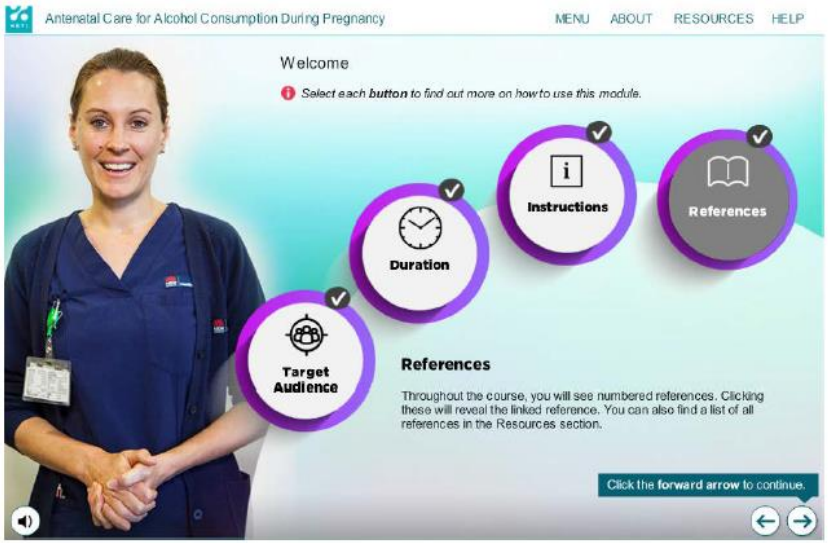






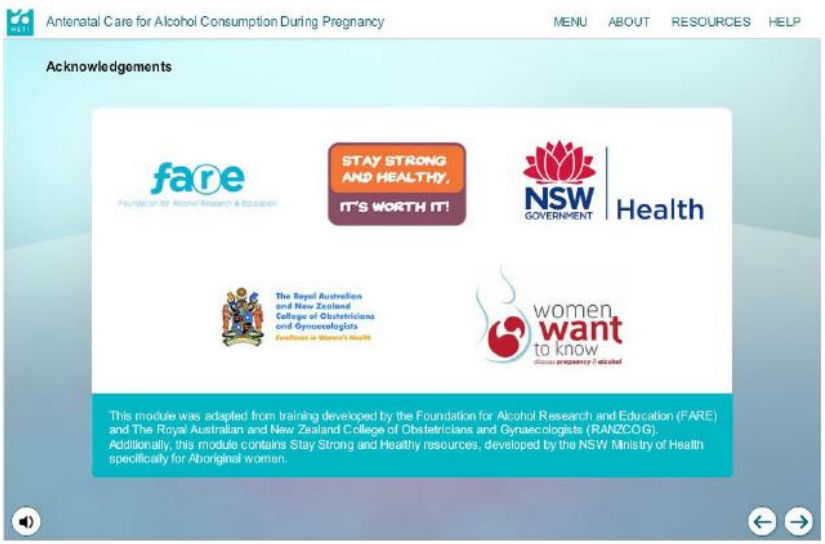

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Welcome
Select each button to find out more on how to use this module.
Target Audience
Duration
Instructions
References
Duration
Your time is valuable. This module should take you approximately 30 minutes to complete. If you need to take a break, you can always exit and pick up where you left off, later.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Welcome
Select each button to find out more on how to use this module.
Target Audience
Duration
Instructions
References
Instructions
You need to attempt all activities, including viewing the videos, before having the module marked as complete. The module contains the following kinds of interactivities:
• pop-ups
• slideshows
• videos
• check your knowledge questions.

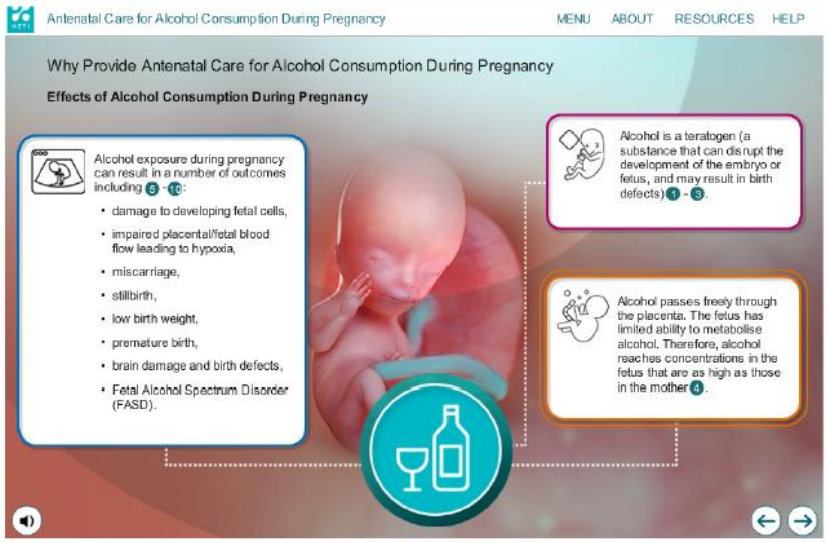

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Welcome
Select each button to find out more on how to use this module.
Target Audience
Duration
Instructions
References
References
Throughout the course, you will see numbered references. Clicking these will reveal the linked reference. You can also find a list of all references in the Resources section.
Click the forward arrow to continue.

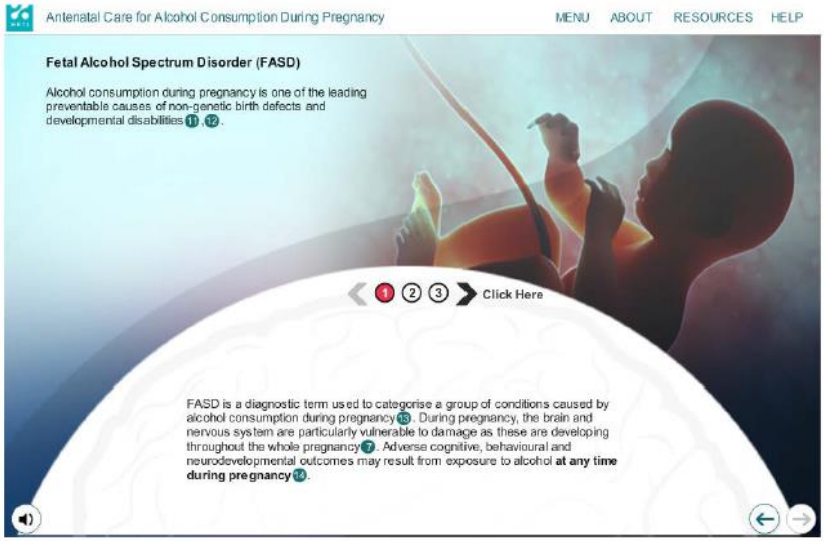

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Notice
Aboriginal and Torres Strait Islander people are advised that this learning module may include images, stories and voices of people who have passed.
Throughout the learning module, reference to both Aboriginal and Torres Strait Islander people may be required at times. However, within New South Wales Health, the term "Aboriginal" is generally used in preference to "Aboriginal and Torres Strait Islander". This is in recognition that Aboriginal people are the original inhabitants of New South Wales.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Acknowledgment of Country
New South Wales Health acknowledges the Aboriginal people of the many traditional lands and language groups that make up our Local Health Districts.
New South Wales Health also acknowledges and pays respect to Elders, both past and present, for they nurture the knowledge, customs and traditions of Aboriginal people.
We all live and work on Aboriginal land.

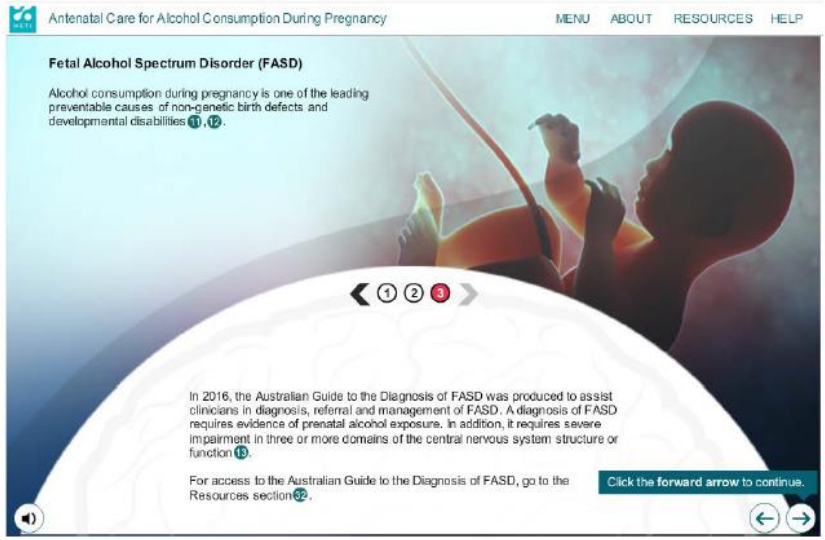

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Acknowledgements
fare
STAY STRONG AND HEALTHY, IT'S WORTH IT!
NSW GOVERNMENT Health
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
women want to know
This module was adapted from training developed by the Foundation for Alcohol Research and Education (FARE) and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Additionally, this module contains Stay Strong and Healthy resources, developed by the NSW Ministry of Health specifically for Aboriginal women.

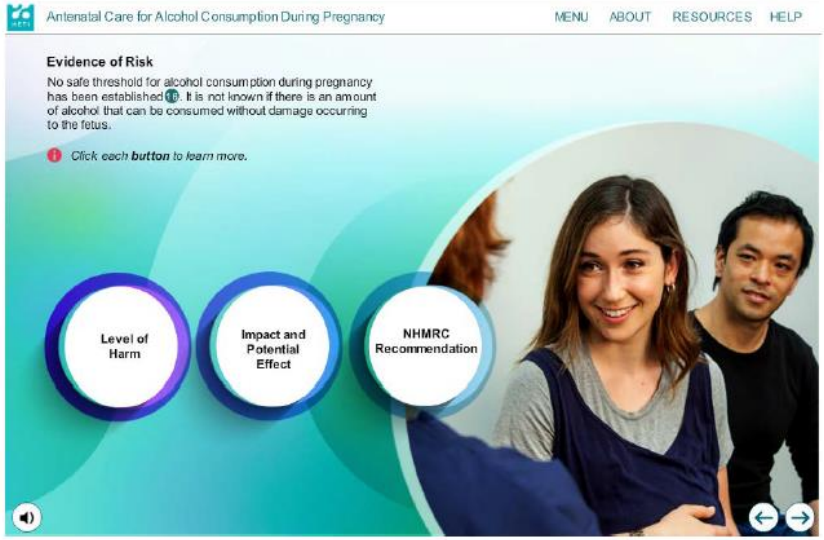

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Learning Outcomes
This module is about pregnancy and alcohol and is aimed at health professionals providing antenatal care to women during pregnancy.
Upon completion of this training module, you will be able to:
• explain the potential effects of alcohol consumption on pregnancy outcomes, the fetus and the child
• communicate the National Health and Medical Research Council (NHMRC) guideline for alcohol consumption during pregnancy
• approach alcohol consumption with pregnant women in a manner that encourages honest disclosure of alcohol consumption
• use the AUDIT-C tool within eMaternity to assess a woman's alcohol consumption during pregnancy
• provide appropriate advice and referral based on AUDIT-C risk level
• describe the considerations for addressing alcohol consumption with Aboriginal women in a culturally safe and sensitive manner.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Why Provide Antenatal Care for Alcohol Consumption During Pregnancy
Effects of Alcohol Consumption During Pregnancy
Alcohol exposure during pregnancy can result in a number of outcomes including 5 - 10:
• damage to developing fetal cells,
• impaired placental/fetal blood flow leading to hypoxia,
• miscarriage,
• stillbirth,
• low birth weight,
• premature birth,
• brain damage and birth defects,
• Fetal Alcohol Spectrum Disorder (FASD).
Alcohol is a teratogen (a substance that can disrupt the development of the embryo or fetus, and may result in birth defects) 1 - 3.
Alcohol passes freely through the placenta. The fetus has limited ability to metabolise alcohol. Therefore, alcohol reaches concentrations in the fetus that are as high as those in the mother 4.

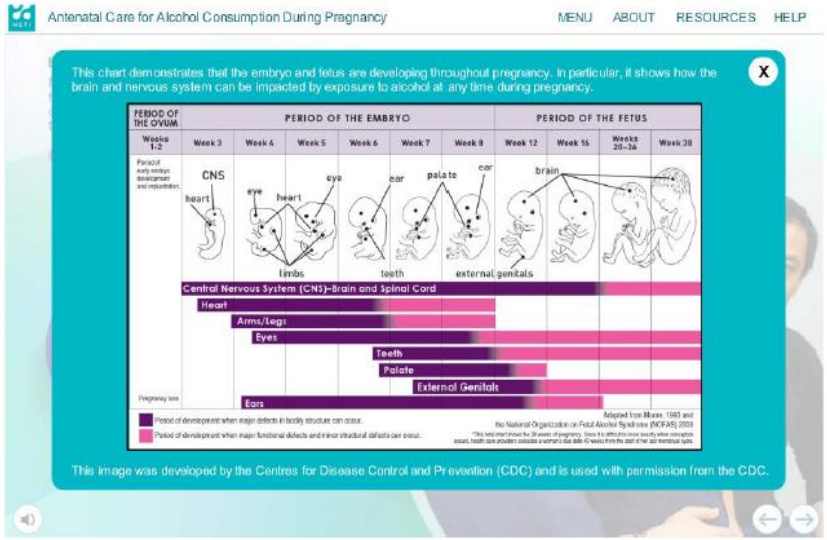

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Fetal Alcohol Spectrum Disorder (FASD)
Alcohol consumption during pregnancy is one of the leading preventable causes of non-genetic birth defects and developmental disabilities 11, 12.
1 2 3 Click Here
FASD is a diagnostic term used to categorise a group of conditions caused by alcohol consumption during pregnancy 13. During pregnancy, the brain and nervous system are particularly vulnerable to damage as these are developing throughout the whole pregnancy 7. Adverse cognitive, behavioural and neurodevelopmental outcomes may result from exposure to alcohol at any time during pregnancy 14.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Fetal Alcohol Spectrum Disorder (FASD)
Alcohol consumption during pregnancy is one of the leading preventable causes of non-genetic birth defects and developmental disabilities 11, 12.
1 2 3 Click Here
The effects of FASD are lifelong and include 13, 15:
• poor memory, attention, executive function, impulse control and hyperactivity
• poor emotional regulation
• impaired language and cognition
• limited adaptive behaviour, social skills and social communication
• impaired growth and abnormal function or structure of the nervous system
• sleeping difficulties
• facial abnormalities (for example, thin upper lip, short palpebral fissure)
• organ damage.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Fetal Alcohol Spectrum Disorder (FASD)
Alcohol consumption during pregnancy is one of the leading preventable causes of non-genetic birth defects and developmental disabilities 11, 12.
1 2 3
In 2016, the Australian Guide to the Diagnosis of FASD was produced to assist clinicians in diagnosis, referral and management of FASD. A diagnosis of FASD requires evidence of prenatal alcohol exposure. In addition, it requires severe impairment in three or more domains of the central nervous system structure or function 13.
For access to the Australian Guide to the Diagnosis of FASD, go to the Resources section 22.
Click the forward arrow to continue.

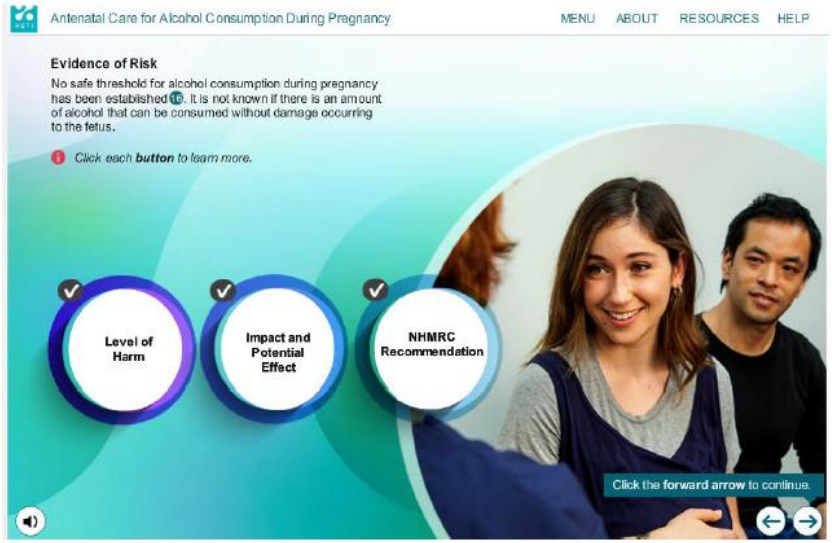

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Evidence of Risk
No safe threshold for alcohol consumption during pregnancy has been established 10. It is not known if there is an amount of alcohol that can be consumed without damage occurring to the fetus.
1 Click each button to learn more.
Level of Harm
Impact and Potential Effect
NHMRC Recommendation


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Evidence of Risk
No safe threshold for alcohol consumption during pregnancy has been established. It is not known if there is an amount of alcohol that can be consumed without damage occurring to the fetus.
Level of Harm
The level of harm to the fetus is related to the:
timing
frequency
quantity of alcohol consumed
Click the icon to view how timing, frequency and quantity of alcohol consumed influences the type of adverse fetal outcomes.
Click here


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
This chart demonstrates that the embryo and fetus are developing throughout pregnancy. In particular, it shows how the brain and nervous system can be impacted by exposure to alcohol at any time during pregnancy.
PERIOD OF THE OVUM
PERIOD OF THE EMBRYO
PERIOD OF THE FETUS
Weeks 1-2
Week 3
Week 4
Week 5
Week 6
Week 7
Week 8
Week 12
Week 16
Weeks 20-36
Week 38
CNS
heart
eye
heart
eye
ear
palate
ear
brain
limbs
teeth
external genitals
Central Nervous System (CNS)-Brain and Spinal Cord
Heart
Arms/Legs
Eyes
Teeth
Palate
External Genitalia
Ears
This image was developed by the Centres for Disease Control and Prevention (CDC) and is used with permission from the CDC.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Evidence of Risk
No safe threshold for alcohol consumption during pregnancy has been established. It is not known if there is an amount of alcohol that can be consumed without damage occurring to the fetus.
Impact and Potential Effect
The impacts of alcohol consumption during pregnancy and the potential effects for children can be complex. This is due to the many contributing individual maternal and fetal characteristics. These characteristics include:
general health
nutritional status
genetic factors
other drug use
psychological wellbeing.
It is also difficult to obtain accurate information on the level and time of alcohol exposure in utero.
Not all pregnancies that are exposed to alcohol will be affected or affected to the same degree. Each woman, each pregnancy and each child are different. Therefore, the level of risk to the fetus is difficult to predict.

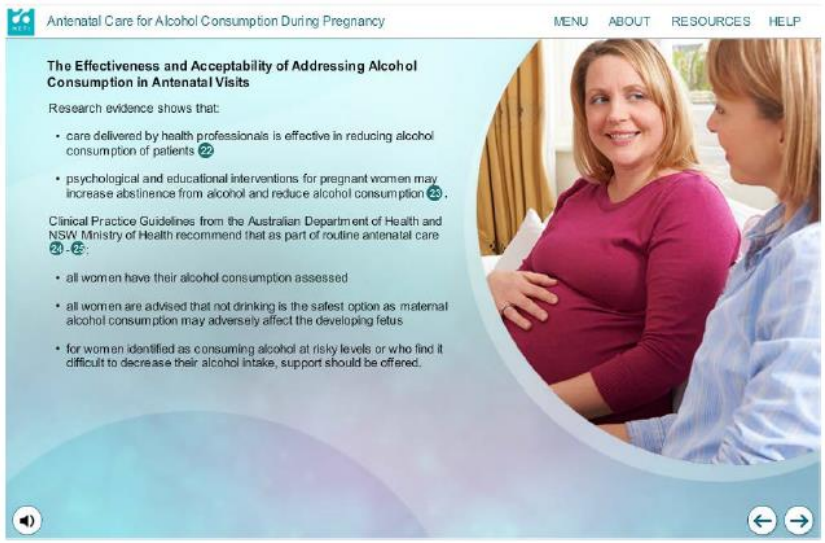

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Evidence of Risk
NHMRC Recommendation
For reasons outlined in the previous slides, the National Health and Medical Research Council (NHMRC) recommends that it is safest not to consume alcohol during pregnancy.
Guideline 4 states: Maternal alcohol consumption can harm the developing fetus or breastfeeding baby. Therefore,
For women who are pregnant or planning a pregnancy, not drinking is the safest option.
For women who are breastfeeding, not drinking is the safest option.
The evidence supporting this recommendation comes from systematic reviews and prospective cohort studies. Refer to the 'Summary of the evidence' included from p.71 of the 2009 NHMRC Alcohol Guidelines.
Australian Government
National Health and Medical Research Council


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Evidence of Risk
No safe threshold for alcohol consumption during pregnancy has been established[16]. It is not known if there is an amount of alcohol that can be consumed without damage occurring to the fetus.
Click each button to learn more.
Level of Harm
Impact and Potential Effect
NHMRC Recommendation
Click the forward arrow to continue.

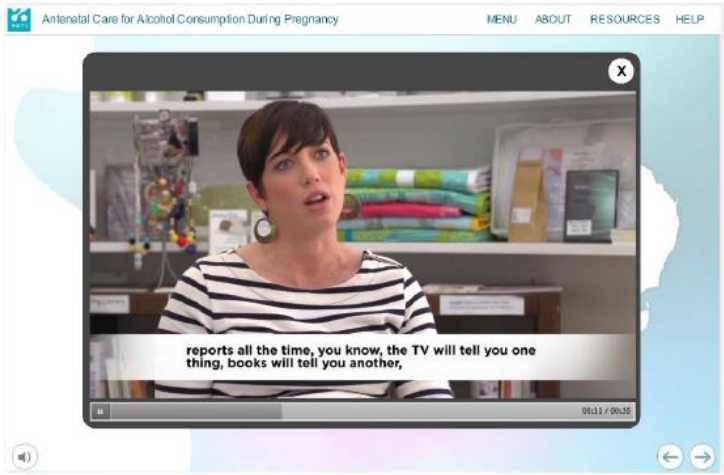

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Alcohol Consumption by Australian Women During Pregnancy
Australian women continue to consume alcohol during pregnancy. In 2016, the National Drug and Strategy Household Survey found that[18]:
1 2 3 Click Here
Close to half (49%) of women surveyed consumed alcohol while pregnant prior to knowledge of their pregnancy.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Alcohol Consumption by Australian Women During Pregnancy
Australian women continue to consume alcohol during pregnancy. In 2016, the National Drug and Strategy Household Survey found that[18]:
1 2 3 Click Here
1 in 4 (25%) women surveyed consumed alcohol while pregnant after knowledge of their pregnancy.

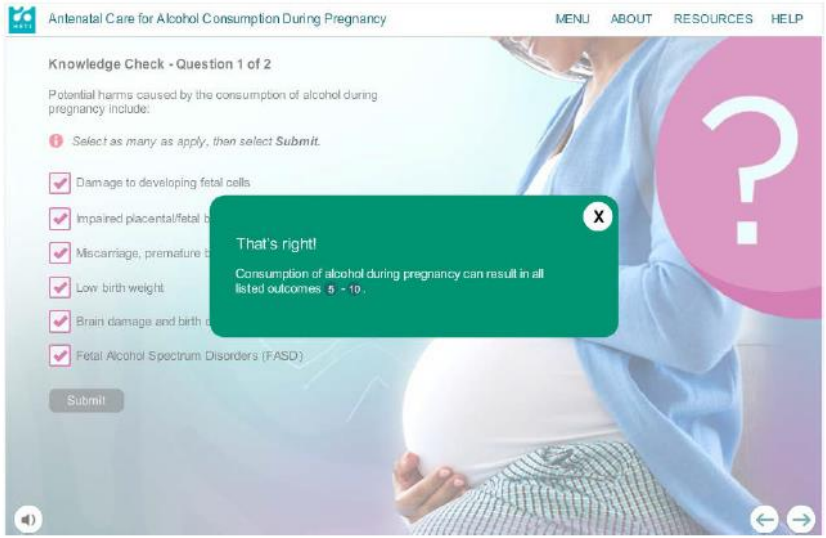

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Alcohol Consumption by Australian Women During Pregnancy
Australian women continue to consume alcohol during pregnancy. In 2016, the National Drug and Strategy Household Survey found that[18]:
1 2 3
Health professionals cannot assume women know guideline recommendations or understand the potential harms of alcohol consumption during pregnancy.
There is a need for alcohol consumption to be addressed as part of routine antenatal care for all women.
Click the forward arrow to continue.

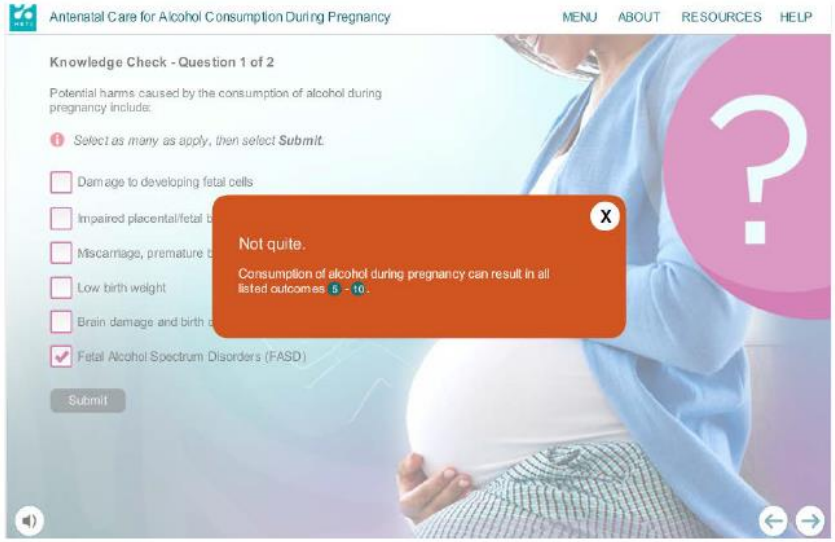


Video – What women want to know about alcohol consumption during pregnancy.

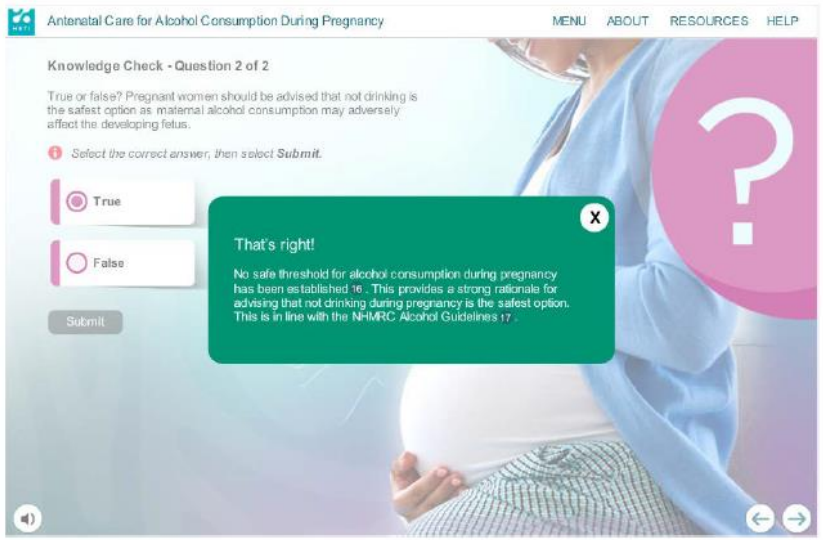


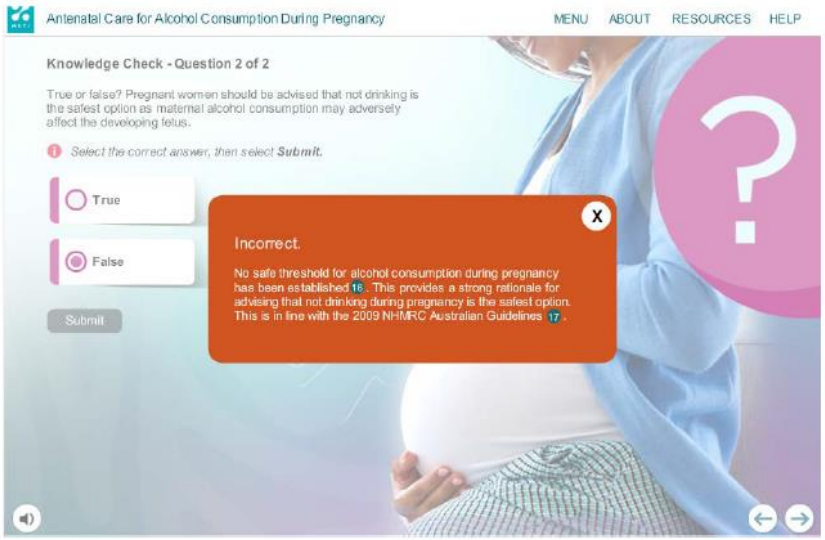

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Knowledge Check - Question 1 of 2
Potential harms caused by the consumption of alcohol during pregnancy include:
Select as many as apply, then select Submit.
Damage to developing fetal cells
Impaired placental/fetal blood flow leading to hypoxia
Miscarriage, premature birth or stillbirth
Low birth weight
Brain damage and birth defects
Fetal Alcohol Spectrum Disorders (FASD)
Submit


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Knowledge Check - Question 1 of 2
Potential harms caused by the consumption of alcohol during pregnancy include:
Select as many as apply, then select Submit.
Damage to developing fetal cells
Fetal Alcohol Spectrum Disorders (FASD)
Submit
That's right!
Consumption of alcohol during pregnancy can result in all listed outcomes 5 - 10.

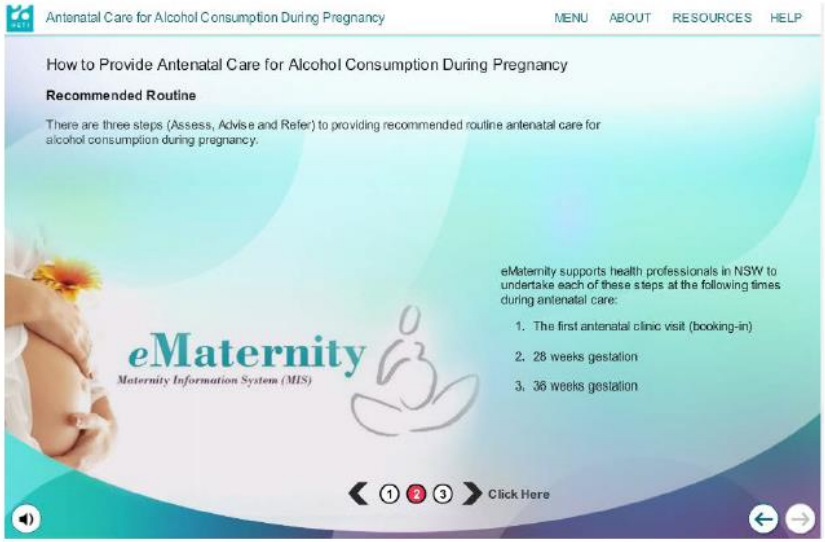

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Knowledge Check - Question 1 of 2
Potential harms caused by the consumption of alcohol during pregnancy include:
Select as many as apply, then select Submit.
Damage to developing fetal cells
Low birth weight
Fetal Alcohol Spectrum Disorders (FASD)
Submit
Not quite.
Consumption of alcohol during pregnancy can result in all listed outcomes 5 - 10.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Knowledge Check - Question 2 of 2
True or false? Pregnant women should be advised that not drinking is the safest option as maternal alcohol consumption may adversely affect the developing fetus.
Select the correct answer, then select Submit.
True
False
Submit

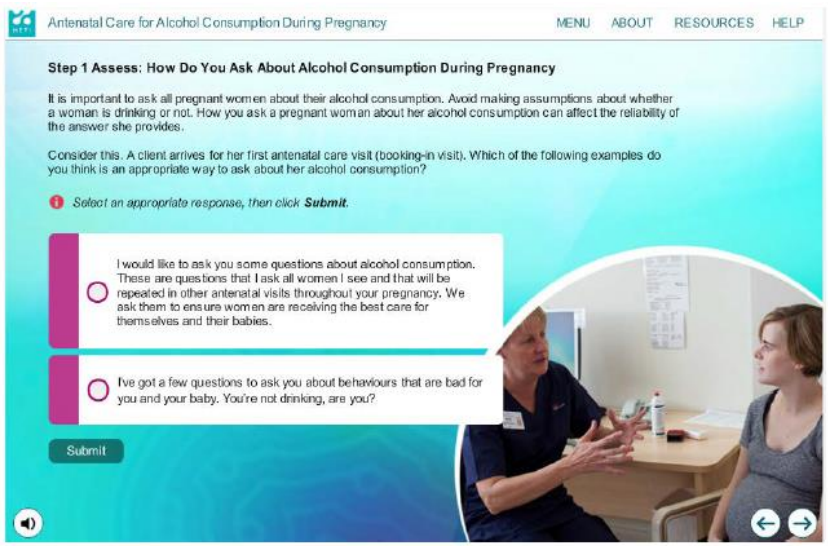

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Knowledge Check - Question 2 of 2
True or false? Pregnant women should be advised that not drinking is the safest option as maternal alcohol consumption may adversely affect the developing fetus.
Select the correct answer, then select Submit.
True
False
Submit
That's right!
No safe threshold for alcohol consumption during pregnancy has been established 16. This provides a strong rationale for advising that not drinking during pregnancy is the safest option. This is in line with the NHMRC Alcohol Guidelines 17.

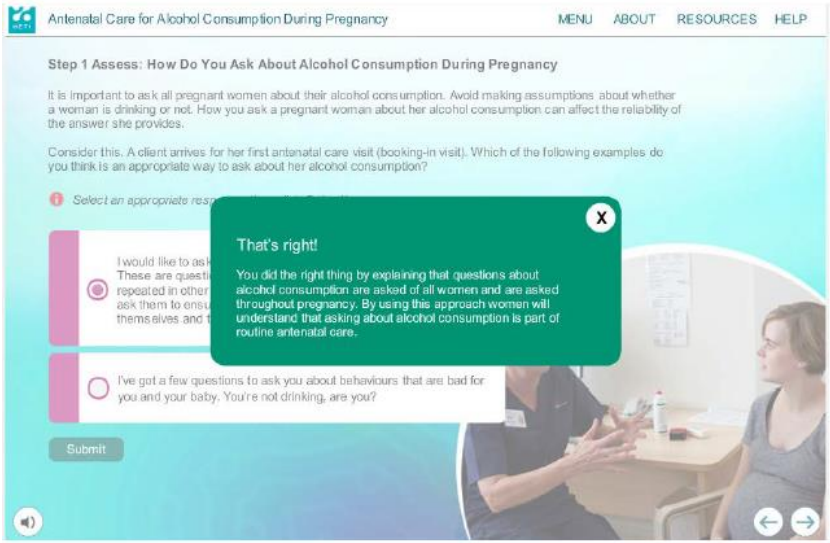

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Knowledge Check - Question 2 of 2
True or false? Pregnant women should be advised that not drinking is the safest option as maternal alcohol consumption may adversely affect the developing fetus.
Select the correct answer, then select Submit.
True
False
Submit
Incorrect.
No safe threshold for alcohol consumption during pregnancy has been established 16. This provides a strong rationale for advising that not drinking during pregnancy is the safest option. This is in line with the 2009 NHMRC Australian Guidelines 17.

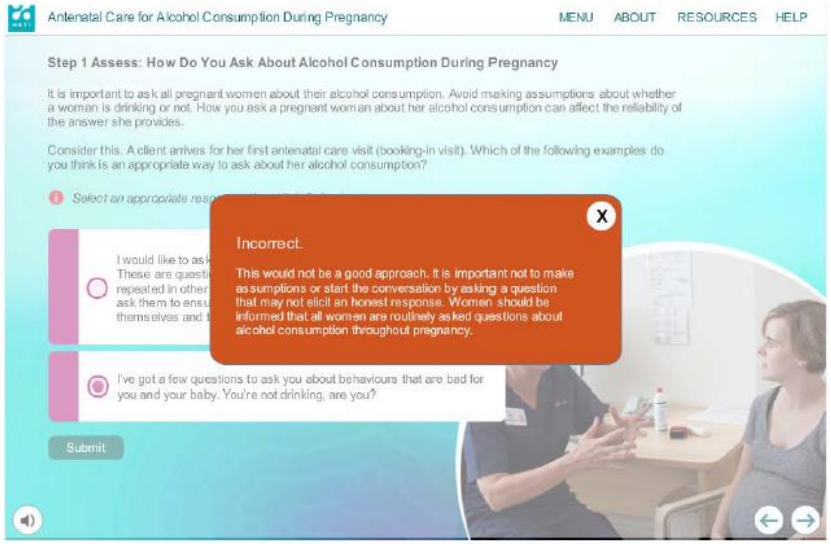

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
How to Provide Antenatal Care for Alcohol Consumption During Pregnancy
Recommended Routine
There are three steps (Assess, Advise and Refer) to providing recommended routine antenatal care for alcohol consumption during pregnancy.
1. Assess
Assess alcohol consumption and determine level of risk of alcohol-related harm by completing the Alcohol Use Disorders Identification Test - Consumption (AUDIT-C).
2. Advise
Provide advice to all women (regardless of level of risk) that it is safest not to consume alcohol during pregnancy. Provide further feedback tailored to level of risk.
3. Refer
If medium or high risk of alcohol-related harm is identified, provide referral to appropriate support services.
1 2 3 Click Here


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
How to Provide Antenatal Care for Alcohol Consumption During Pregnancy
Recommended Routine
There are three steps (Assess, Advise and Refer) to providing recommended routine antenatal care for alcohol consumption during pregnancy.
eMaternity
Maternity Information System (MIS)
eMaternity supports health professionals in NSW to undertake each of these steps at the following times during antenatal care:
1. The first antenatal clinic visit (booking-in)
2. 28 weeks gestation
3. 36 weeks gestation
1 2 3 Click Here

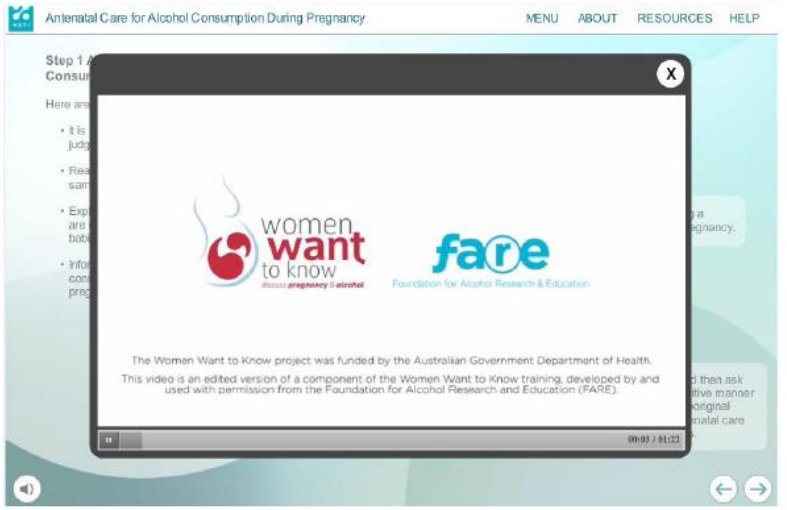

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
How to Provide Antenatal Care for Alcohol Consumption During Pregnancy
Recommended Routine
There are three steps (Assess, Advise and Refer) to providing recommended routine antenatal care for alcohol consumption during pregnancy.
Providing care for alcohol consumption at multiple points during pregnancy allows:
• a number of opportunities for women to feel comfortable and disclose information about their alcohol consumption
• the opportunity to assess whether a woman's alcohol consumption has changed throughout her pregnancy
• the repetition of consistent advice across antenatal visits
• the opportunity to follow up on any referrals previously provided.
Click the forward arrow to continue.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: How Do You Ask About Alcohol Consumption During Pregnancy
It is important to ask all pregnant women about their alcohol consumption. Avoid making assumptions about whether a woman is drinking or not. How you ask a pregnant woman about her alcohol consumption can affect the reliability of the answer she provides.
Consider this. A client arrives for her first antenatal care visit (booking-in visit). Which of the following examples do you think is an appropriate way to ask about her alcohol consumption?
Select an appropriate response, then click Submit.
I would like to ask you some questions about alcohol consumption. These are questions that I ask all women I see and that will be repeated in other antenatal visits throughout your pregnancy. We ask them to ensure women are receiving the best care for themselves and their babies.
I've got a few questions to ask you about behaviours that are bad for you and your baby. You're not drinking, are you?
Submit

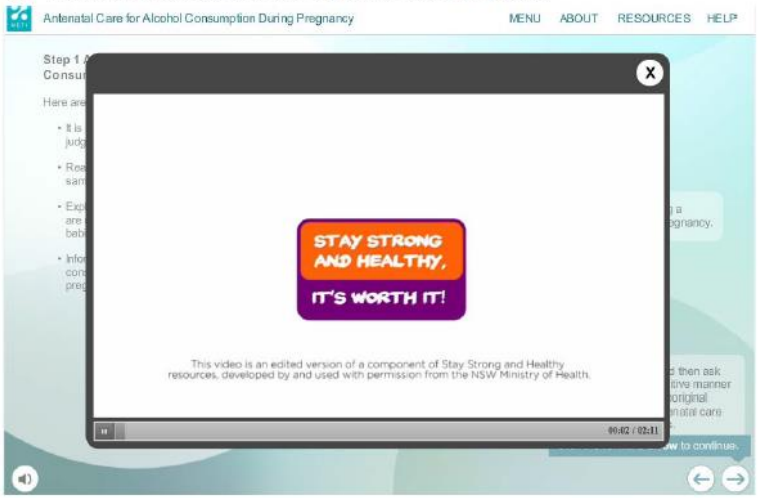

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: How Do You Ask About Alcohol Consumption During Pregnancy
It is important to ask all pregnant women about their alcohol consumption. Avoid making assumptions about whether a woman is drinking or not. How you ask a pregnant woman about her alcohol consumption can affect the reliability of the answer she provides.
Consider this. A client arrives for her first antenatal care visit (booking-in visit). Which of the following examples do you think is an appropriate way to ask about her alcohol consumption?
That's right!
You did the right thing by explaining that questions about alcohol consumption are asked of all women and are asked throughout pregnancy. By using this approach women will understand that asking about alcohol consumption is part of routine antenatal care.
I've got a few questions to ask you about behaviours that are bad for you and your baby. You're not drinking, are you?
Submit

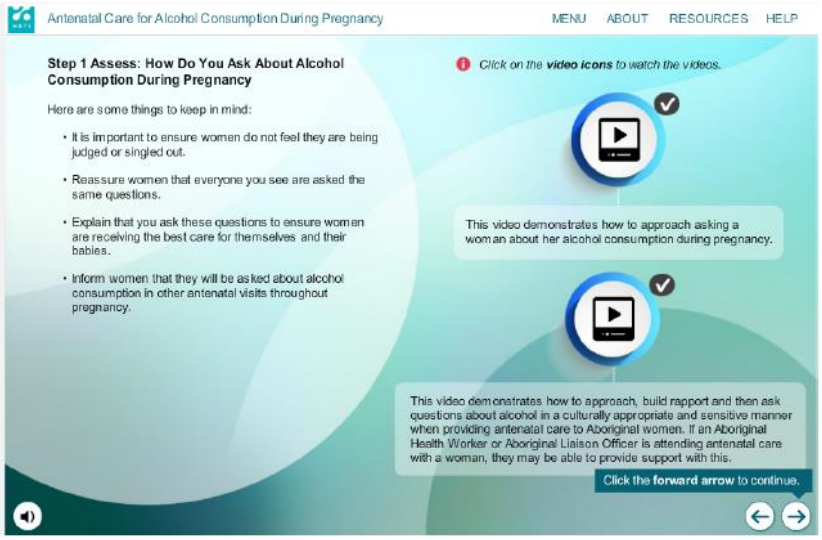

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: How Do You Ask About Alcohol Consumption During Pregnancy
It is important to ask all pregnant women about their alcohol consumption. Avoid making assumptions about whether a woman is drinking or not. How you ask a pregnant woman about her alcohol consumption can affect the reliability of the answer she provides.
Consider this. A client arrives for her first antenatal care visit (booking-in visit). Which of the following examples do you think is an appropriate way to ask about her alcohol consumption?
Incorrect.
This would not be a good approach. It is important not to make assumptions or start the conversation by asking a question that may not elicit an honest response. Women should be informed that all women are routinely asked questions about alcohol consumption throughout pregnancy.
I've got a few questions to ask you about behaviours that are bad for you and your baby. You're not drinking, are you?
Submit

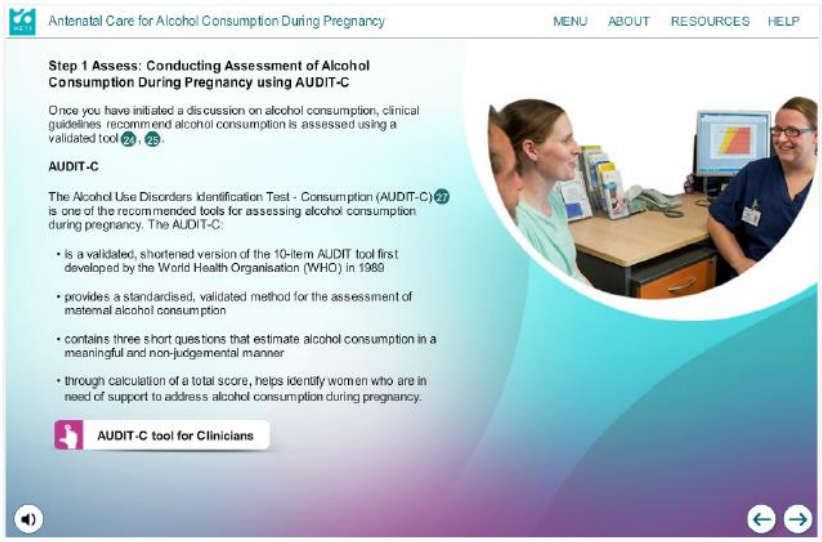
Video – How to approach women about their alcohol consumption.

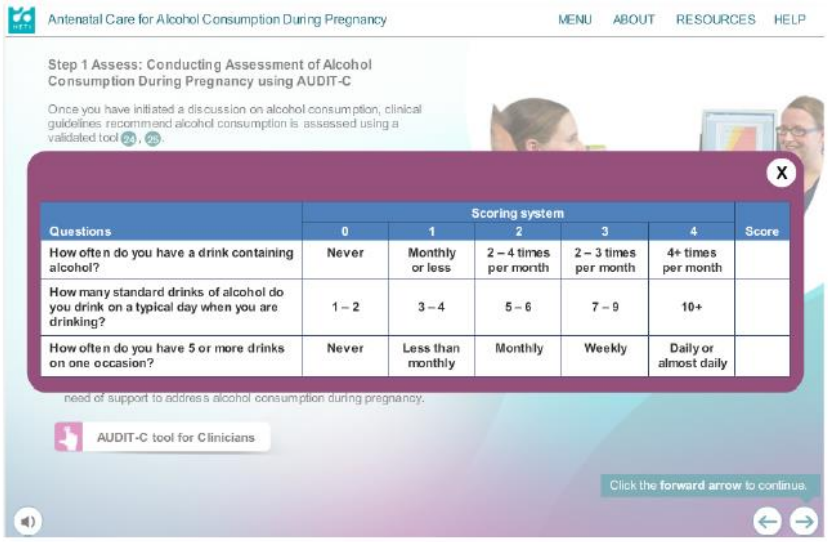


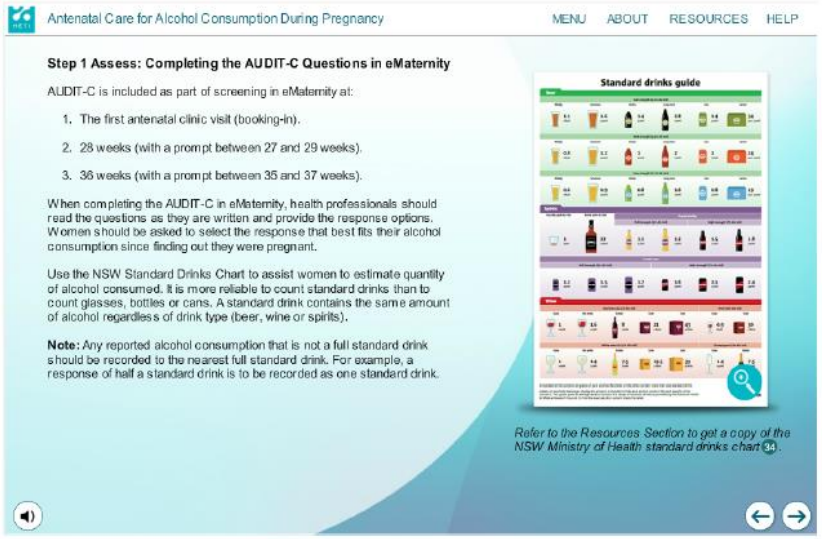
Video – How to build rapport and approach alcohol consumption in a culturally appropriate way.



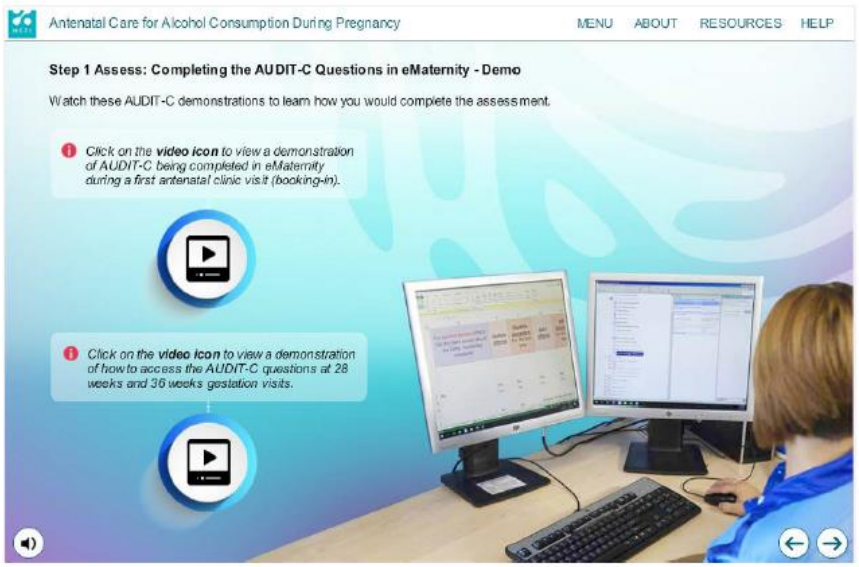



Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: Conducting Assessment of Alcohol Consumption During Pregnancy using AUDIT-C
Once you have initiated a discussion on alcohol consumption, clinical guidelines recommend alcohol consumption is assessed using a validated tool 24, 25.
AUDIT-C
The Alcohol Use Disorders Identification Test - Consumption (AUDIT-C) 27 is one of the recommended tools for assessing alcohol consumption during pregnancy. The AUDIT-C:
• is a validated, shortened version of the 10-item AUDIT tool first developed by the World Health Organisation (WHO) in 1989
• provides a standardised, validated method for the assessment of maternal alcohol consumption
• contains three short questions that estimate alcohol consumption in a meaningful and non-judgemental manner
• through calculation of a total score, helps identify women who are in need of support to address alcohol consumption during pregnancy.
AUDIT-C tool for Clinicians

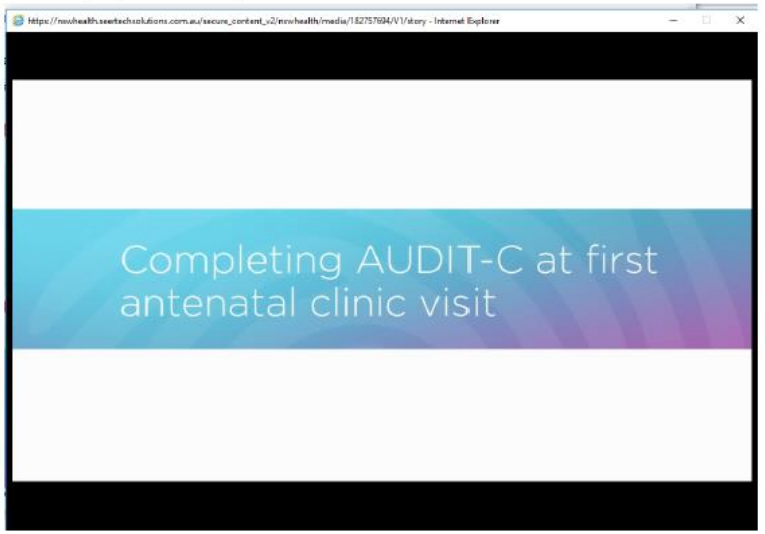

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: Conducting Assessment of Alcohol Consumption During Pregnancy using AUDIT-C
Once you have initiated a discussion on alcohol consumption, clinical guidelines recommend alcohol consumption is assessed using a validated tool 24, 25.
X
Scoring system
Questions | 0 | 1 | 2 | 3 | 4 | Score
How often do you have a drink containing alcohol? | Never | Monthly or less | 2 – 4 times per month | 2 – 3 times per month | 4+ times per month |
How many standard drinks of alcohol do you drink on a typical day when you are drinking? | 1 – 2 | 3 – 4 | 5 – 6 | 7 – 9 | 10+ |
How often do you have 5 or more drinks on one occasion? | Never | Less than monthly | Monthly | Weekly | Daily or almost daily |
need of support to address alcohol consumption during pregnancy.
AUDIT-C tool for Clinicians
Click the forward arrow to continue.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: Completing the AUDIT-C Questions in eMaternity
AUDIT-C is included as part of screening in eMaternity at:
1. The first antenatal clinic visit (booking-in).
2. 28 weeks (with a prompt between 27 and 29 weeks).
3. 36 weeks (with a prompt between 35 and 37 weeks).
When completing the AUDIT-C in eMaternity, health professionals should read the questions as they are written and provide the response options. Women should be asked to select the response that best fits their alcohol consumption since finding out they were pregnant.
Use the NSW Standard Drinks Chart to assist women to estimate quantity of alcohol consumed. It is more reliable to count standard drinks than to count glasses, bottles or cans. A standard drink contains the same amount of alcohol regardless of drink type (beer, wine or spirits).
Note: Any reported alcohol consumption that is not a full standard drink should be recorded to the nearest full standard drink. For example, a response of half a standard drink is to be recorded as one standard drink.
Standard drinks guide
Refer to the Resources Section to get a copy of the NSW Ministry of Health standard drinks chart 34.

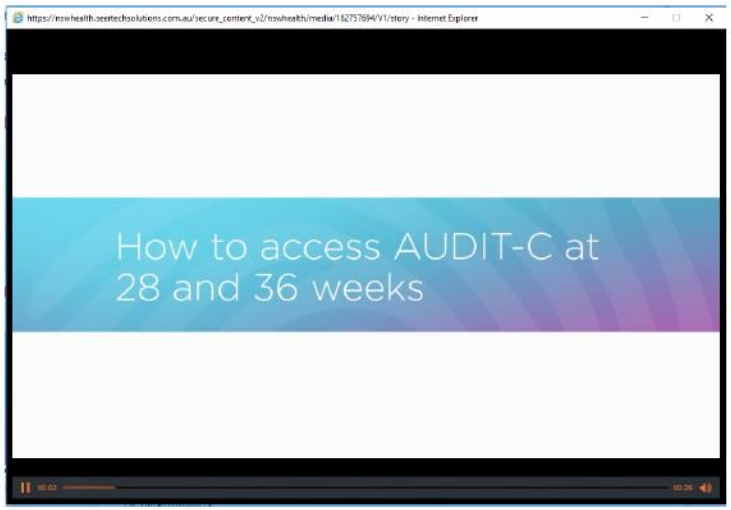

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
X
Standard drinks guide
Beer
Full strength (4.6% Alc Vol)
Middy 1.1 285ml
Schooner 1.6 425ml
Bottle 1.4 375ml
Long neck 2.8 750ml
Can 1.4 375ml
Carton 34 24 x 375 ml
Mid strength (3.5% Alc Vol)
Middy 0.8 285ml
Schooner 1.2 425ml
Bottle 1 375ml
Long neck 2 750ml
Can 1 375ml
Carton 24 24 x 375 ml
Low strength (2.7% Alc Vol)
Middy 0.6
Schooner 0.9
Bottle 0.8
Long neck 1.6
Can 0.8
Carton 19

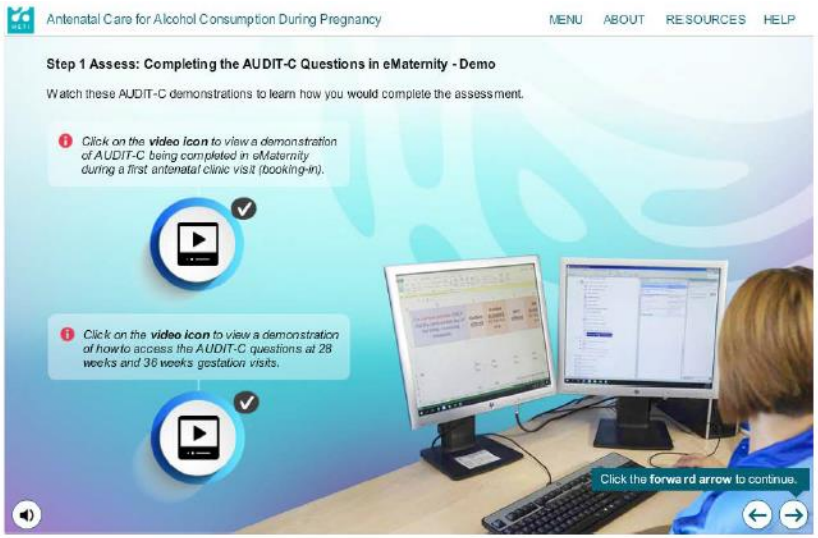


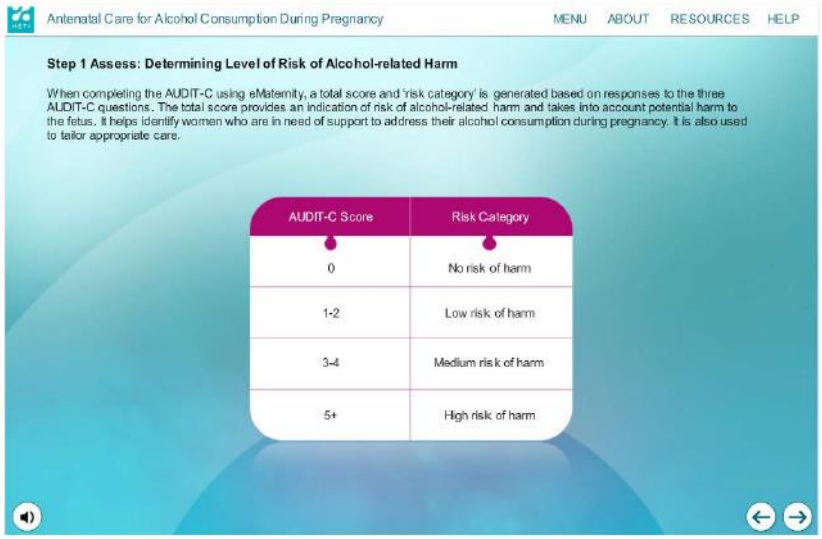
Video – Completing AUDIT-C at first appointment



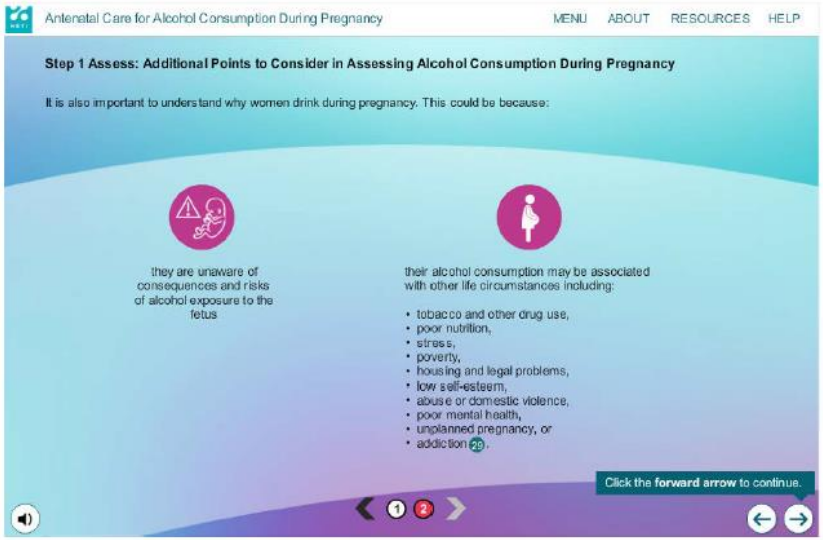
Video – Completing AUDIT – C at 28 and 36 weeks

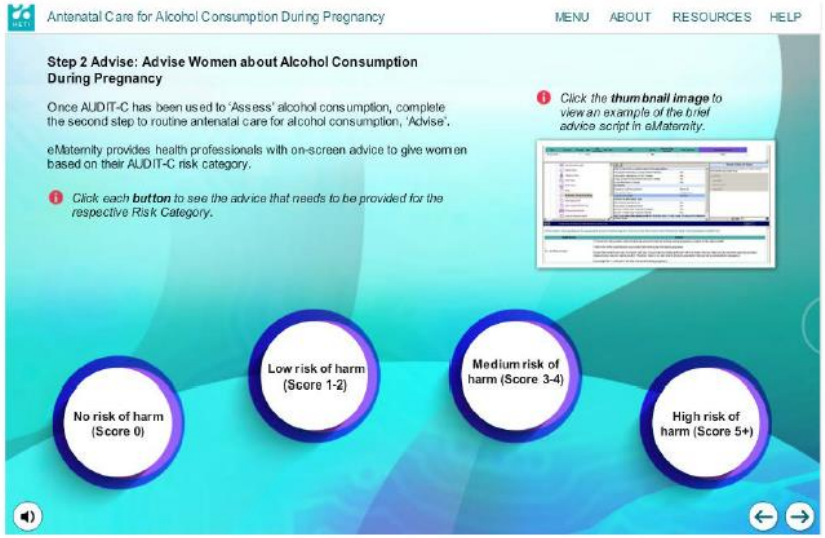


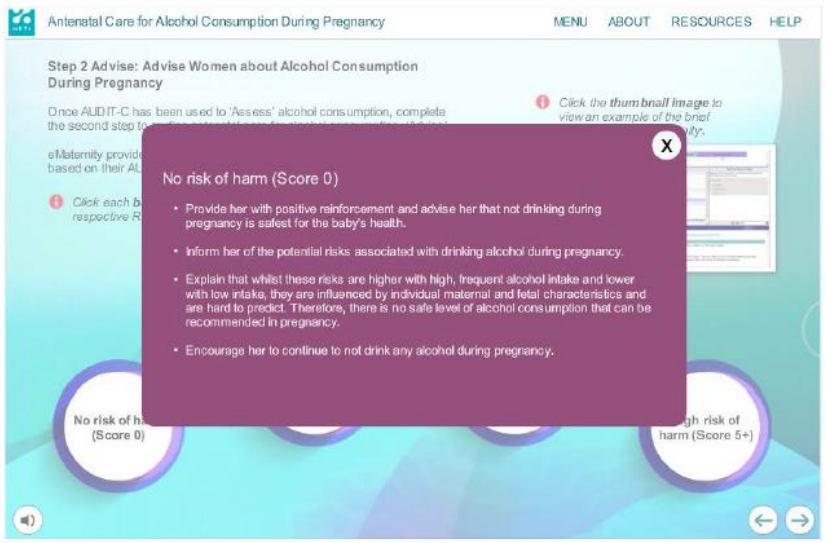


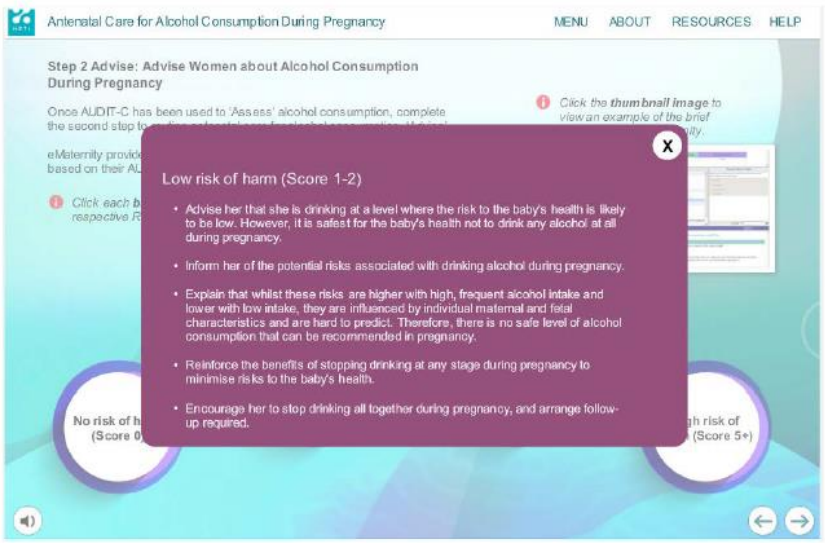

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: Determining Level of Risk of Alcohol-related Harm
When completing the AUDIT-C using eMaternity, a total score and 'risk category' is generated based on responses to the three AUDIT-C questions. The total score provides an indication of risk of alcohol-related harm and takes into account potential harm to the fetus. It helps identify women who are in need of support to address their alcohol consumption during pregnancy. It is also used to tailor appropriate care.
AUDIT-C Score
Risk Category
0
No risk of harm
1-2
Low risk of harm
3-4
Medium risk of harm
5+
High risk of harm

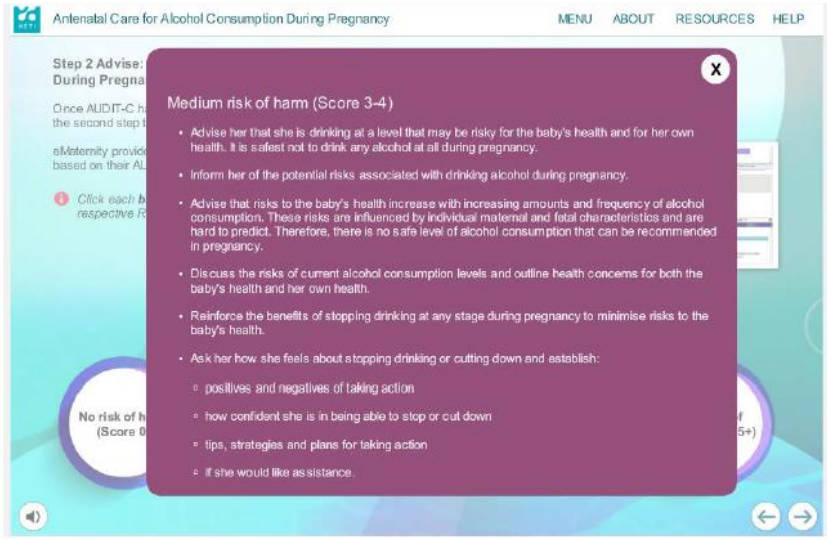

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: Additional Points to Consider in Assessing Alcohol Consumption During Pregnancy
Here are some additional points to keep in mind when assessing alcohol consumption during pregnancy [25].
Be non-judgemental and avoid making assumptions
Listen attentively to the woman's concerns
Refrain from making negative comments or reactions
Focus on the health of the mother and the baby
Make positive comments and acknowledge that the woman is doing the best thing in seeking support during pregnancy
Understand that community, social and family norms may influence perceptions of alcohol consumption
Avoid labelling drinking behaviours (such as 'binge', or 'heavy drinking') as these may not align with the woman's perceptions
1 2
Click Here

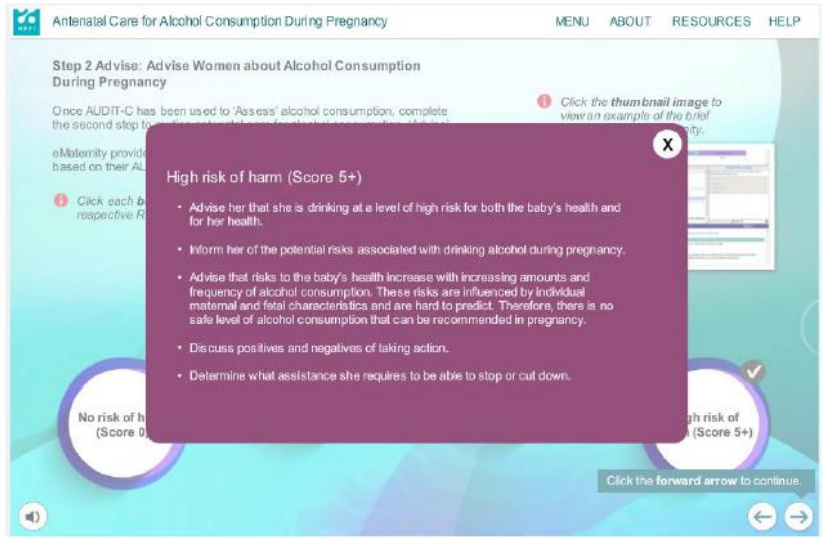

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 1 Assess: Additional Points to Consider in Assessing Alcohol Consumption During Pregnancy
It is also important to understand why women drink during pregnancy. This could be because:
they are unaware of consequences and risks of alcohol exposure to the fetus
their alcohol consumption may be associated with other life circumstances including:
• tobacco and other drug use,
• poor nutrition,
• stress,
• poverty,
• housing and legal problems,
• low self-esteem,
• abuse or domestic violence,
• poor mental health,
• unplanned pregnancy, or
• addiction [26].
Click the forward arrow to continue.
1 2


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 2 Advise: Advise Women about Alcohol Consumption During Pregnancy
Once AUDIT-C has been used to 'Assess' alcohol consumption, complete the second step to routine antenatal care for alcohol consumption, 'Advise'.
eMaternity provides health professionals with on-screen advice to give women based on their AUDIT-C risk category.
Click each button to see the advice that needs to be provided for the respective Risk Category.
Click the thumbnail image to view an example of the brief advice script in eMaternity.
No risk of harm (Score 0)
Low risk of harm (Score 1-2)
Medium risk of harm (Score 3-4)
High risk of harm (Score 5+)


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 2 Advise: Advise Women about Alcohol Consumption During Pregnancy
Once AUDIT-C has been used to 'Assess' alcohol consumption, complete the second step to
Click the thumbnail image to view an example of the brief
eMaternity provide based on their AL
Click each b respective R
No risk of h (Score 0)
gh risk of harm (Score 5+)
No risk of harm (Score 0)
• Provide her with positive reinforcement and advise her that not drinking during pregnancy is safest for the baby's health.
• Inform her of the potential risks associated with drinking alcohol during pregnancy.
• Explain that whilst these risks are higher with high, frequent alcohol intake and lower with low intake, they are influenced by individual maternal and fetal characteristics and are hard to predict. Therefore, there is no safe level of alcohol consumption that can be recommended in pregnancy.
• Encourage her to continue to not drink any alcohol during pregnancy.
X


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 2 Advise: Advise Women about Alcohol Consumption During Pregnancy
Once AUDIT-C has been used to 'Assess' alcohol consumption, complete the second step to
Click the thumbnail image to view an example of the brief
eMaternity provide based on their AL
Click each b respective R
No risk of h (Score 0)
h risk of (Score 5+)
Low risk of harm (Score 1-2)
• Advise her that she is drinking at a level where the risk to the baby's health is likely to be low. However, it is safest for the baby's health not to drink any alcohol at all during pregnancy.
• Inform her of the potential risks associated with drinking alcohol during pregnancy.
• Explain that whilst these risks are higher with high, frequent alcohol intake and lower with low intake, they are influenced by individual maternal and fetal characteristics and are hard to predict. Therefore, there is no safe level of alcohol consumption that can be recommended in pregnancy.
• Reinforce the benefits of stopping drinking at any stage during pregnancy to minimise risks to the baby's health.
• Encourage her to stop drinking all together during pregnancy, and arrange follow-up required.
X


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 2 Advise:
During Pregna
Once AUDIT-C h
the second step t
eMaternity provid
based on their AL
Click each b
respective R
No risk of h (Score 0
5+)
Medium risk of harm (Score 3-4)
• Advise her that she is drinking at a level that may be risky for the baby's health and for her own health. It is safest not to drink any alcohol at all during pregnancy.
• Inform her of the potential risks associated with drinking alcohol during pregnancy.
• Advise that risks to the baby's health increase with increasing amounts and frequency of alcohol consumption. These risks are influenced by individual maternal and fetal characteristics and are hard to predict. Therefore, there is no safe level of alcohol consumption that can be recommended in pregnancy.
• Discuss the risks of current alcohol consumption levels and outline health concerns for both the baby's health and her own health.
• Reinforce the benefits of stopping drinking at any stage during pregnancy to minimise risks to the baby's health.
• Ask her how she feels about stopping drinking or cutting down and establish:
◦ positives and negatives of taking action
◦ how confident she is in being able to stop or cut down
◦ tips, strategies and plans for taking action
◦ if she would like assistance.
X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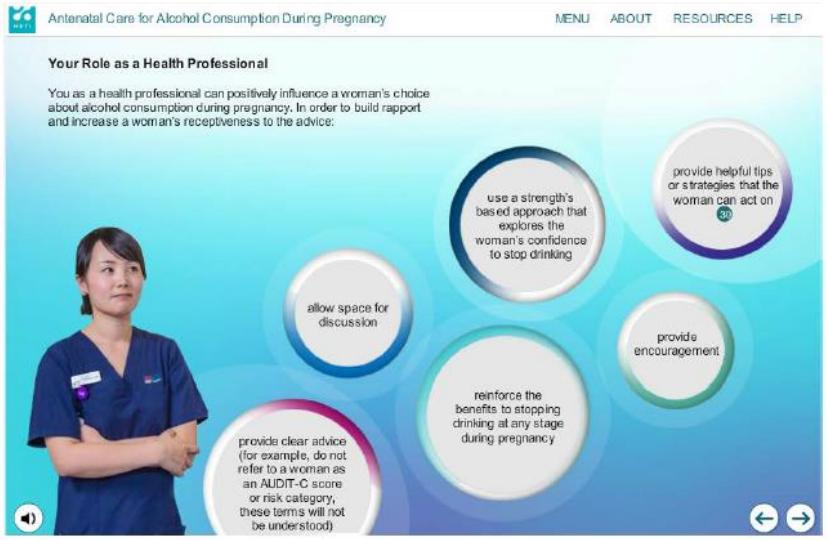
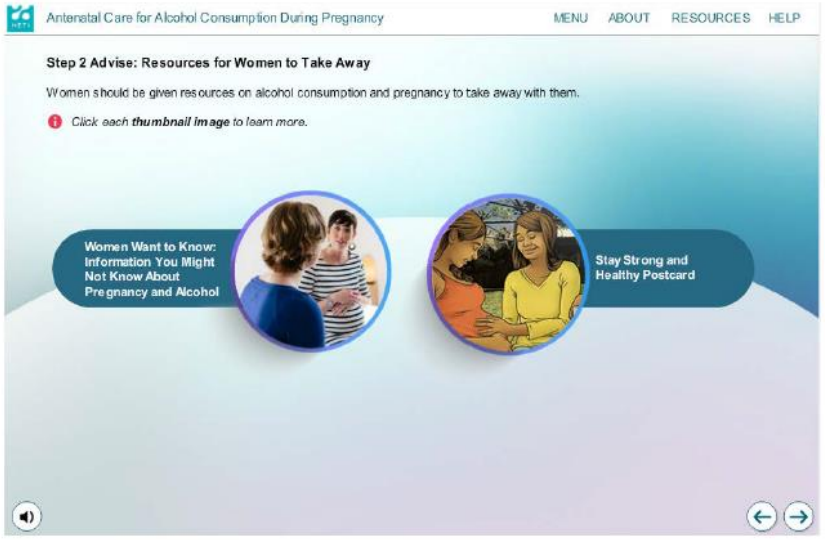
eMaternity provide based on their AL
Click each b respective R
No risk of h (Score 0)
gh risk of (Score 5+)
High risk of harm (Score 5+)
• Advise her that she is drinking at a level of high risk for both the baby's health and for her health.
• Inform her of the potential risks associated with drinking alcohol during pregnancy.
• Advise that risks to the baby's health increase with increasing amounts and frequency of alcohol consumption. These risks are influenced by individual maternal and fetal characteristics and are hard to predict. Therefore, there is no safe level of alcohol consumption that can be recommended in pregnancy.
• Discuss positives and negatives of taking action.
• Determine what assistance she requires to be able to stop or cut down.
X
Click the forward arrow to continue.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Your Role as a Health Professional
You as a health professional can positively influence a woman's choice about alcohol consumption during pregnancy. In order to build rapport and increase a woman's receptiveness to the advice:
use a strength's based approach that explores the woman's confidence to stop drinking
provide helpful tips or strategies that the woman can act on 30
allow space for discussion
provide encouragement
reinforce the benefits to stopping drinking at any stage during pregnancy
provide clear advice (for example, do not refer to a woman as an AUDIT-C score or risk category, these terms will not be understood)


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 2 Advise: Resources for Women to Take Away
Women should be given resources on alcohol consumption and pregnancy to take away with them.
Click each thumbnail image to learn more.
Women Want to Know: Information You Might Not Know About Pregnancy and Alcohol
Stay Strong and Healthy Postcard


Antenatal Care for Alcohol Consumption During Pregnancy
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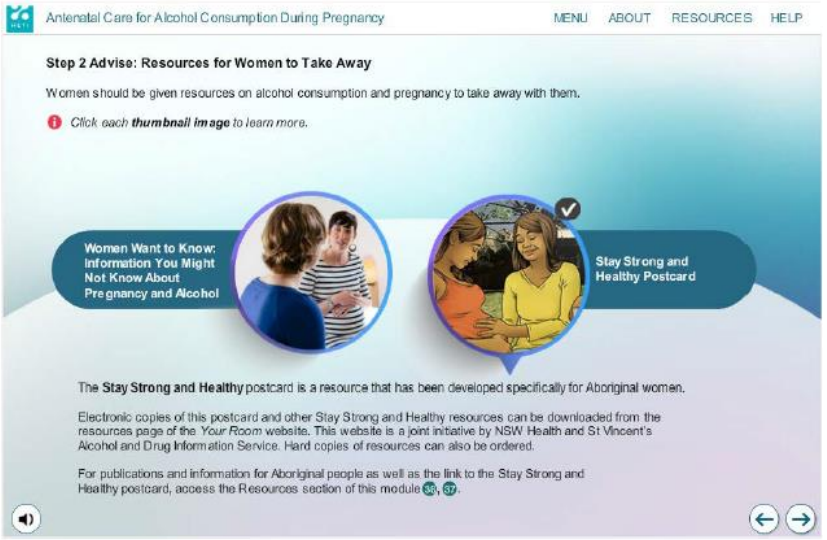
Women Want to Know: Information You Might Not Know About Pregnancy and Alcohol
Stay Strong and Healthy Postcard
This leaflet, developed by FARE, provides information on why it's best to avoid alcohol consumption during pregnancy. It provides hints and tips for saying 'no' to alcohol when out with friends and information on where to go for further information or advice.
Copies of this leaflet can be found within the resources tab of eMaternity. Electronic copies of all the Women Want to Know resources can be downloaded, or hard copies of resources ordered, from the Australian Government Department of Health Alcohol website 36.
Go to the Resources section to access the link to the Australian Government Department of Health Alcohol website.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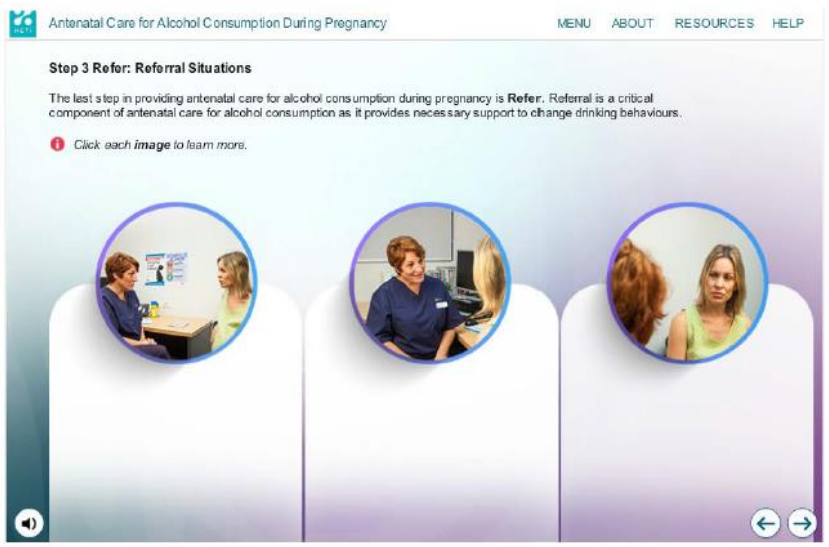
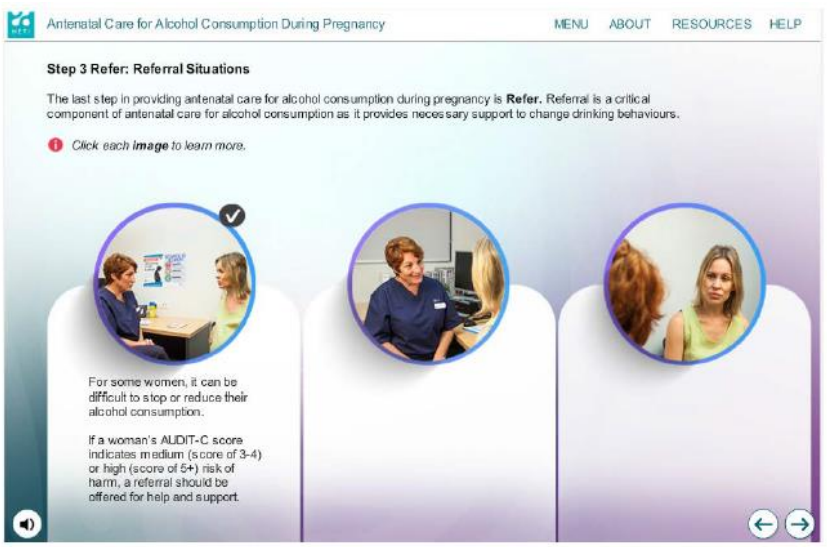
Stay Strong and Healthy Postcard
The Stay Strong and Healthy postcard is a resource that has been developed specifically for Aboriginal women.
Electronic copies of this postcard and other Stay Strong and Healthy resources can be downloaded from the resources page of the Your Room website. This website is a joint initiative by NSW Health and St Vincent's Alcohol and Drug Information Service. Hard copies of resources can also be ordered.
For publications and information for Aboriginal people as well as the link to the Stay Strong and Healthy postcard, access the Resources section of this module 36, 37.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 3 Refer: Referral Situations
The last step in providing antenatal care for alcohol consumption during pregnancy is Refer. Referral is a critical component of antenatal care for alcohol consumption as it provides necessary support to change drinking behaviours.
Click each image to learn more.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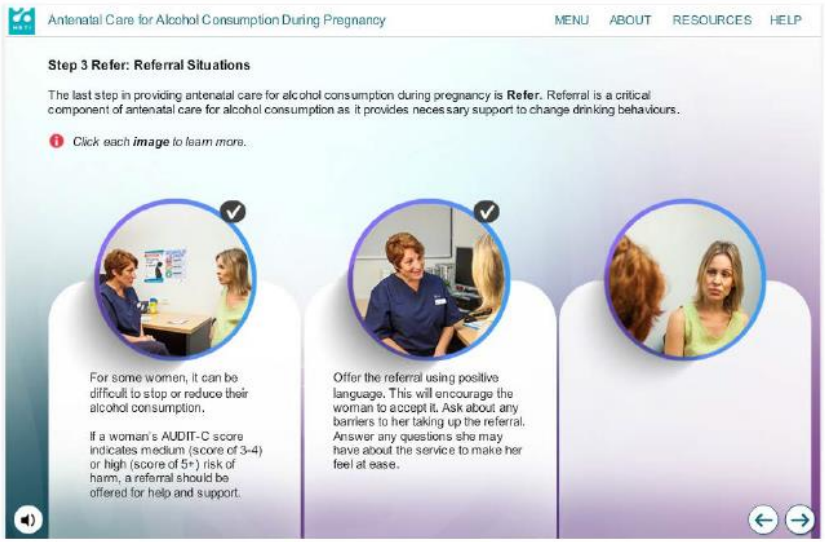
For some women, it can be difficult to stop or reduce their alcohol consumption.
If a woman's AUDIT-C score indicates medium (score of 3-4) or high (score of 5+) risk of harm, a referral should be offered for help and support.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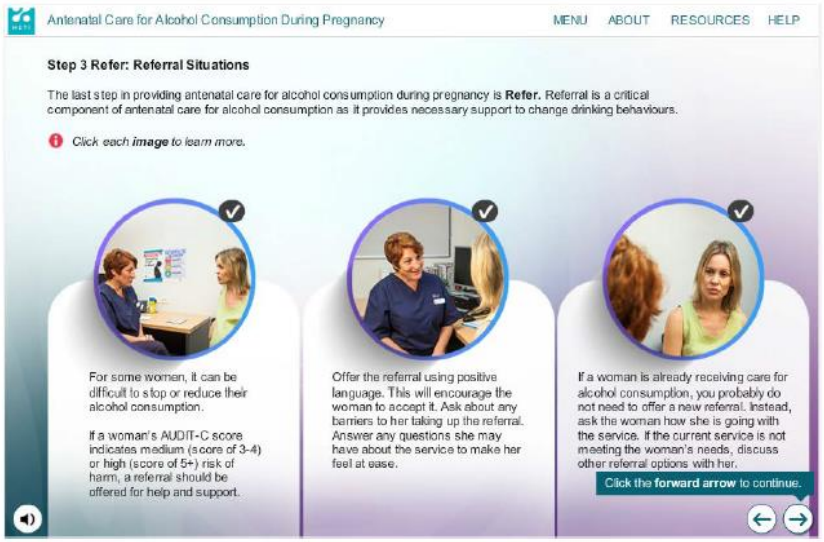
Offer the referral using positive language. This will encourage the woman to accept it. Ask about any barriers to her taking up the referral. Answer any questions she may have about the service to make her feel at ease.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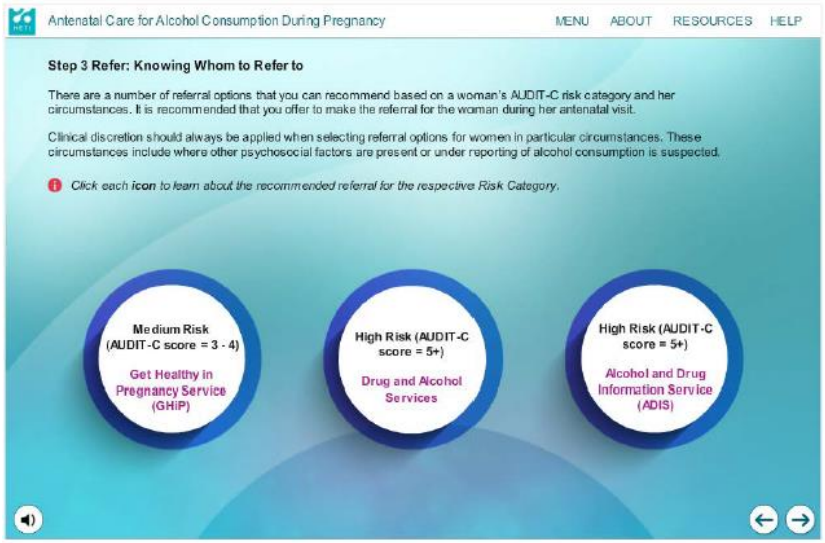
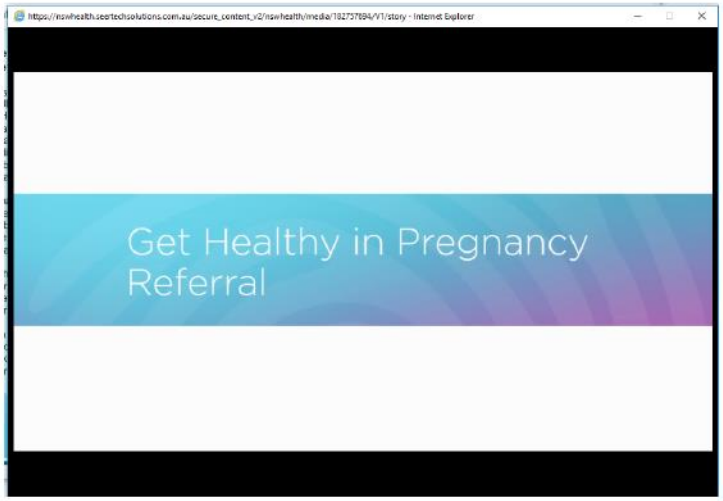
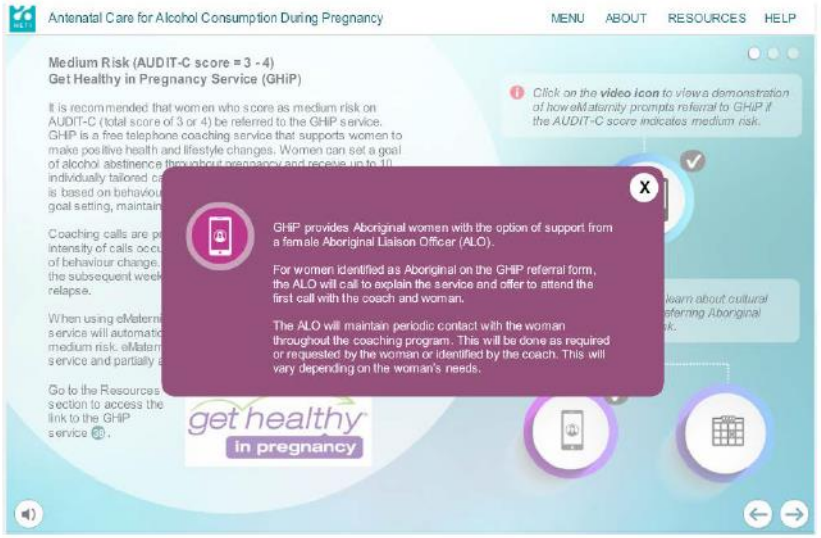
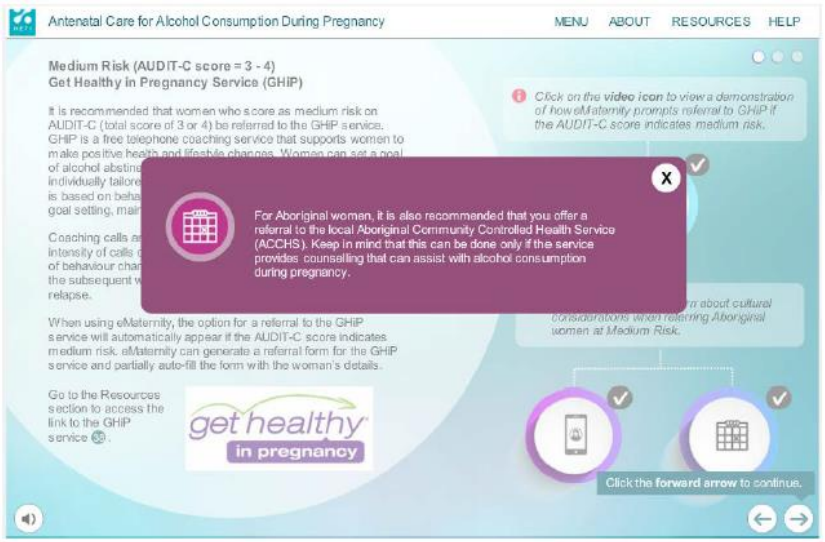
Offer the referral using positive language. This will encourage the woman to accept it. Ask about any barriers to her taking up the referral. Answer any questions she may have about the service to make her feel at ease.
If a woman is already receiving care for alcohol consumption, you probably do not need to offer a new referral. Instead, ask the woman how she is going with the service. If the current service is not meeting the woman's needs, discuss other referral options with her.
Click the forward arrow to continue.

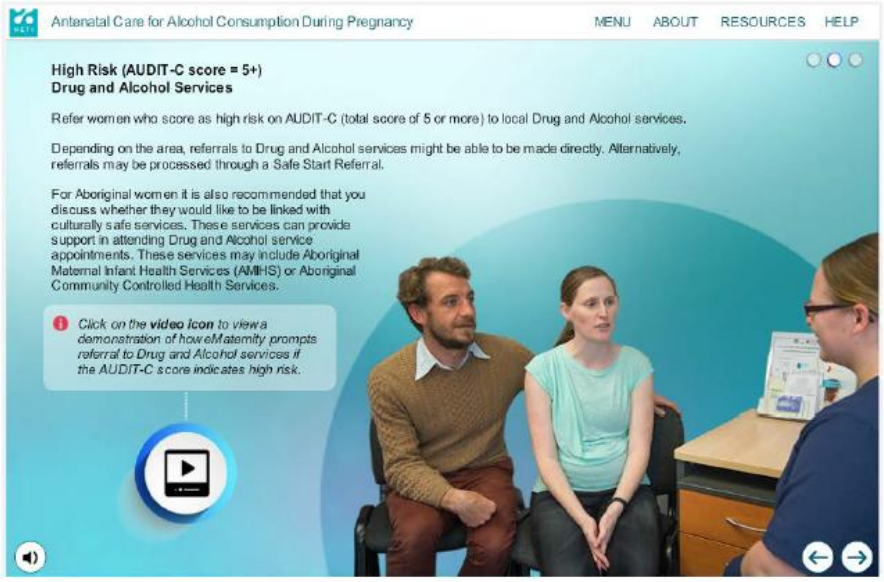


Video – Get Heathy in Pregnancy referral in eMaternity

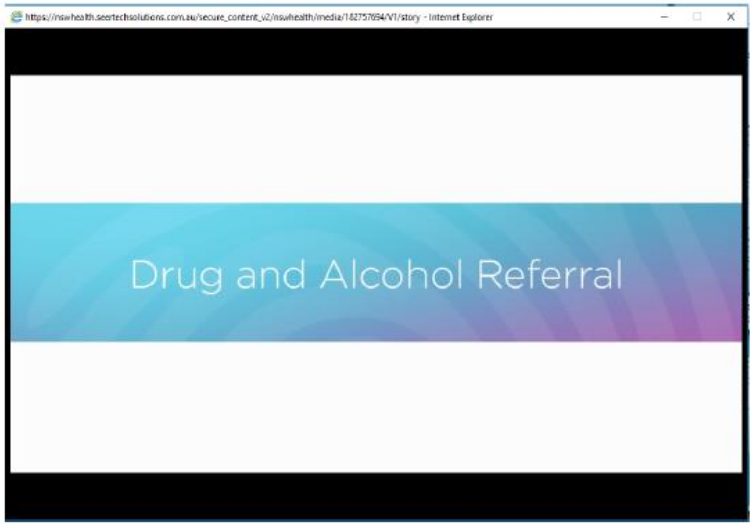


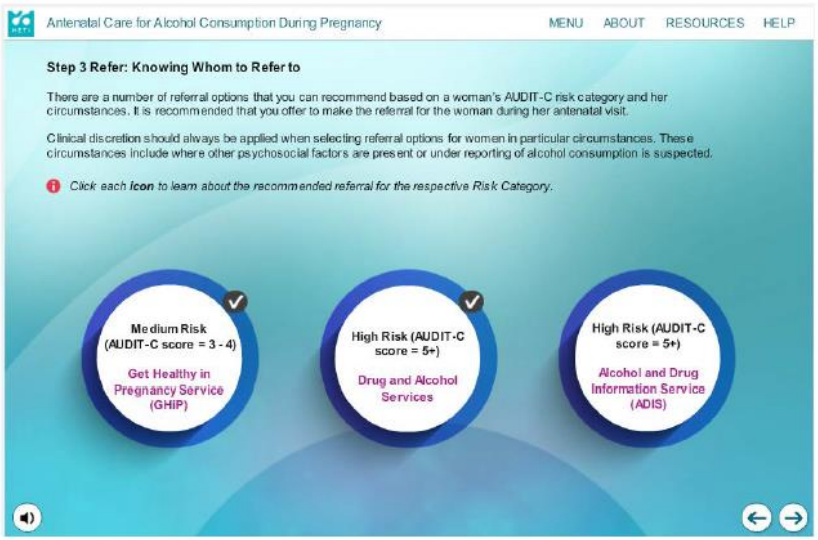


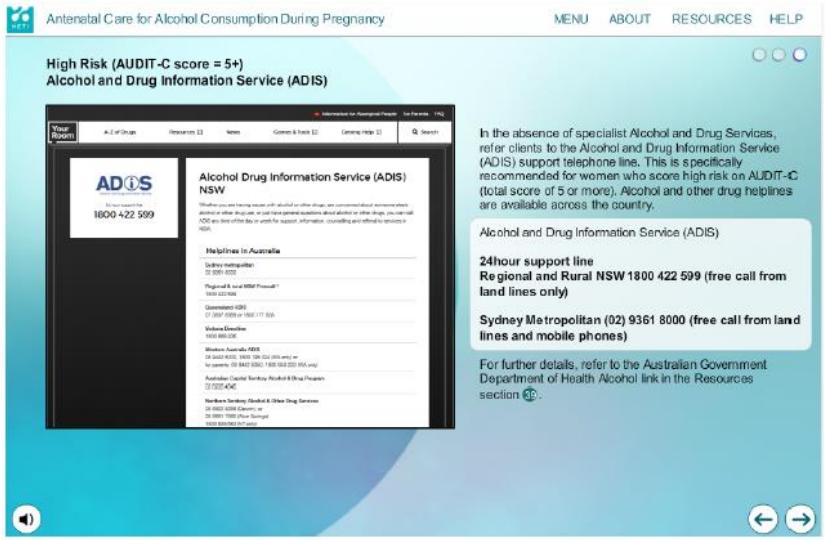


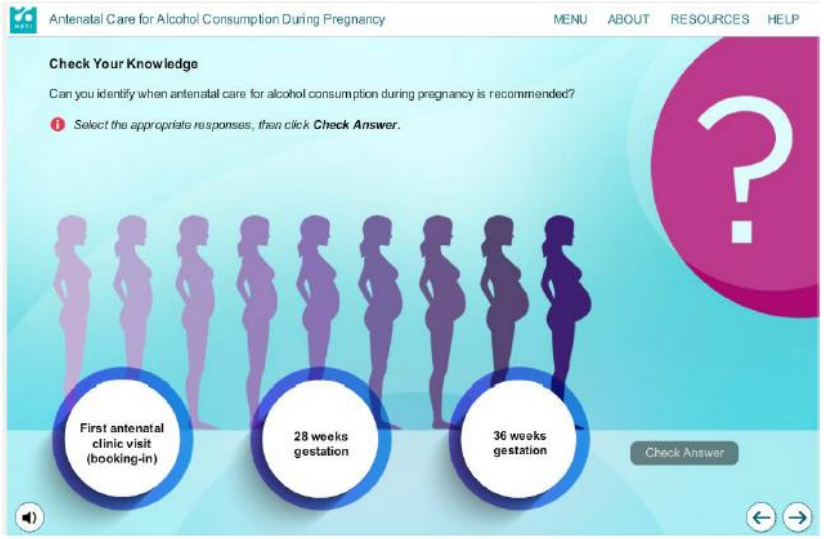


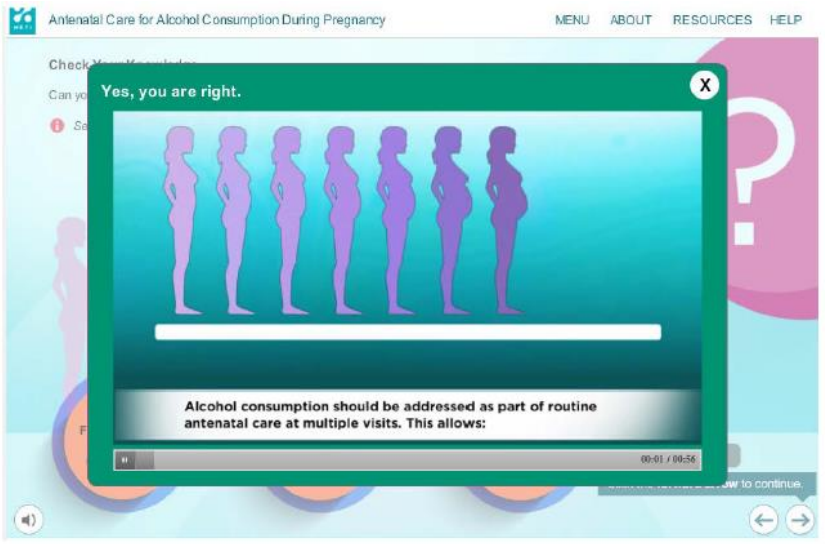
Video – Drug and alcohol referral in eMaternity

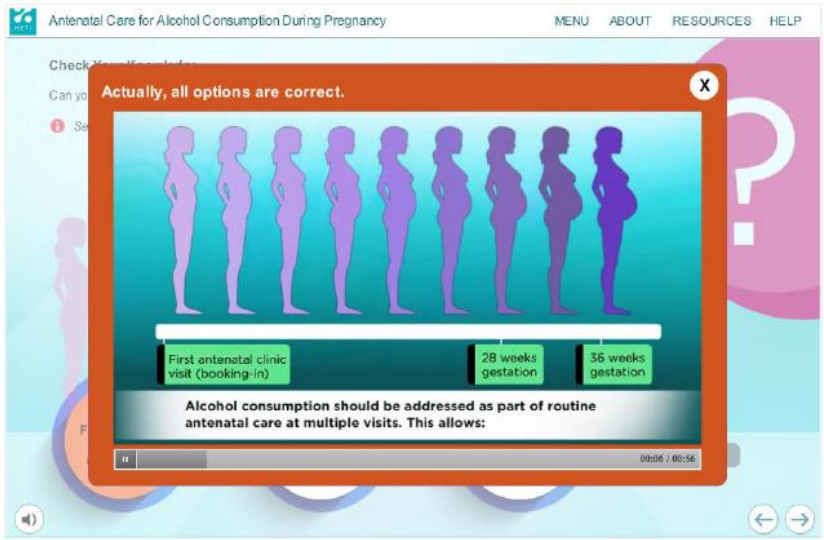


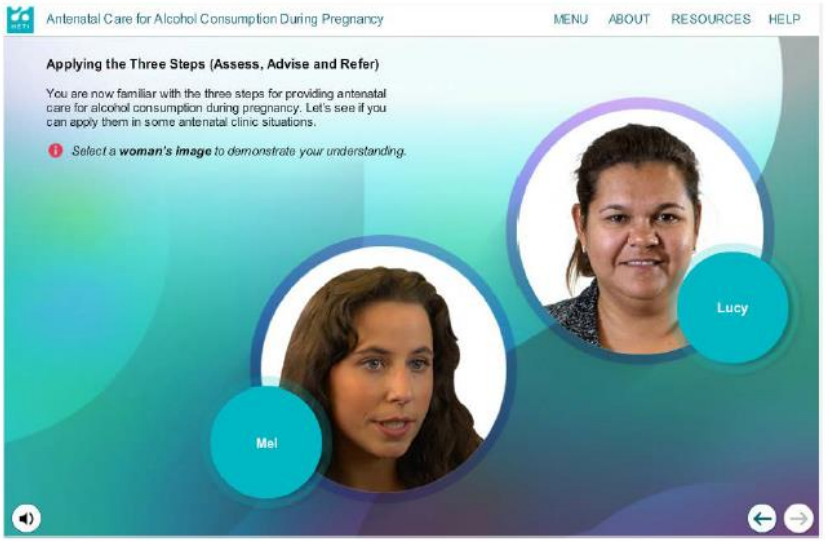

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Step 3 Refer: Knowing Whom to Refer to
There are a number of referral options that you can recommend based on a woman's AUDIT-C risk category and her circumstances. It is recommended that you offer to make the referral for the woman during her antenatal visit.
Clinical discretion should always be applied when selecting referral options for women in particular circumstances. These circumstances include where other psychosocial factors are present or under reporting of alcohol consumption is suspected.
Click each Icon to learn about the recommended referral for the respective Risk Category.
Medium Risk (AUDIT-C score = 3 - 4)
Get Healthy in Pregnancy Service (GHIP)
High Risk (AUDIT-C score = 5+)
Drug and Alcohol Services
High Risk (AUDIT-C score = 5+)
Alcohol and Drug Information Service (ADIS)

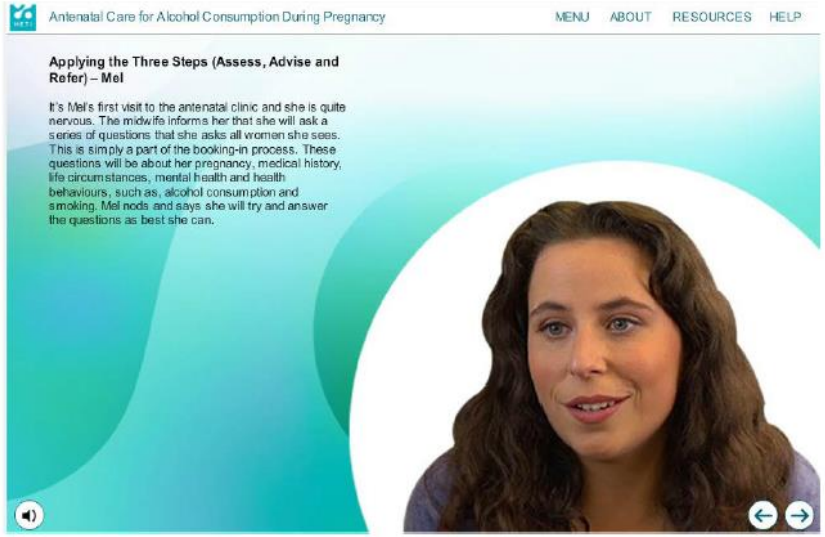

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
High Risk (AUDIT-C score = 5+)
Alcohol and Drug Information Service (ADIS)
ADIS
1800 422 599
Alcohol Drug Information Service (ADIS) NSW
In the absence of specialist Alcohol and Drug Services, refer clients to the Alcohol and Drug Information Service (ADIS) support telephone line. This is specifically recommended for women who score high risk on AUDIT-C (total score of 5 or more). Alcohol and other drug helplines are available across the country.
Alcohol and Drug Information Service (ADIS)
24hour support line
Regional and Rural NSW 1800 422 599 (free call from land lines only)
Sydney Metropolitan (02) 9361 8000 (free call from land lines and mobile phones)
For further details, refer to the Australian Government Department of Health Alcohol link in the Resources section.

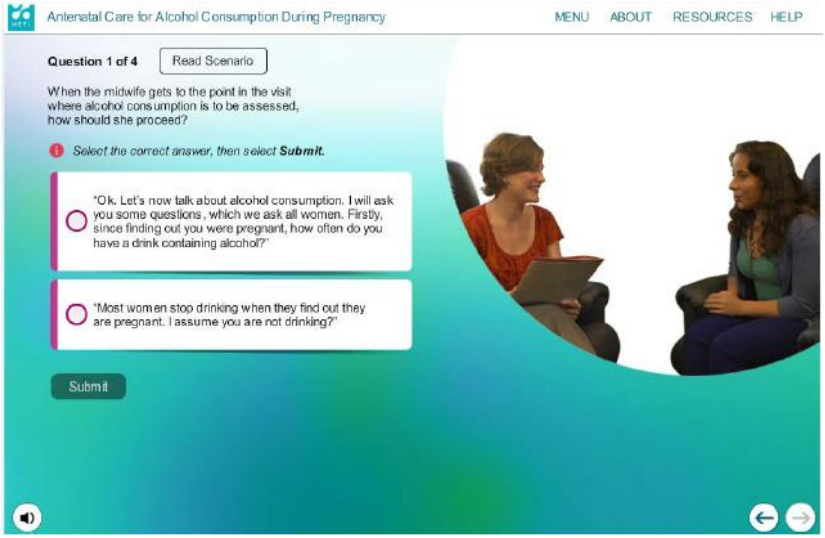

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Check Your Knowledge
Can you identify when antenatal care for alcohol consumption during pregnancy is recommended?
Select the appropriate responses, then click Check Answer.
First antenatal clinic visit (booking-in)
28 weeks gestation
36 weeks gestation
Check Answer

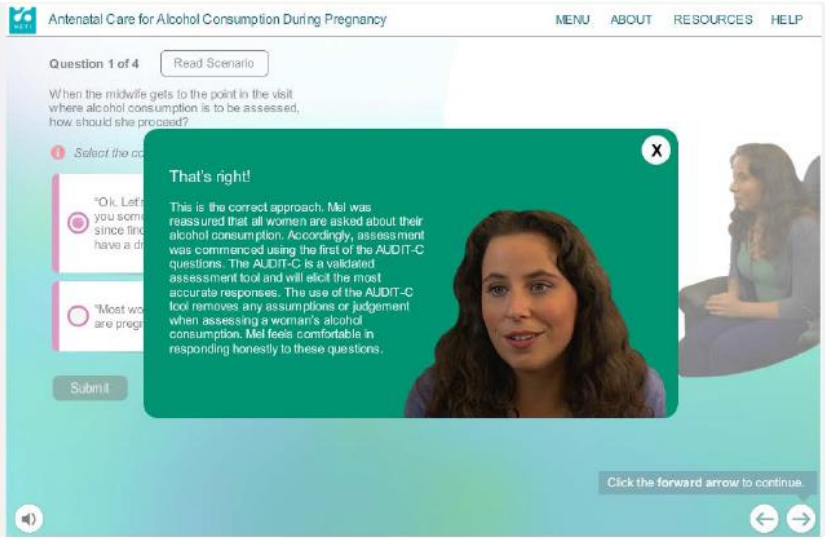

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Yes, you are right.
Alcohol consumption should be addressed as part of routine antenatal care at multiple visits. This allows:
00:01 / 00:56

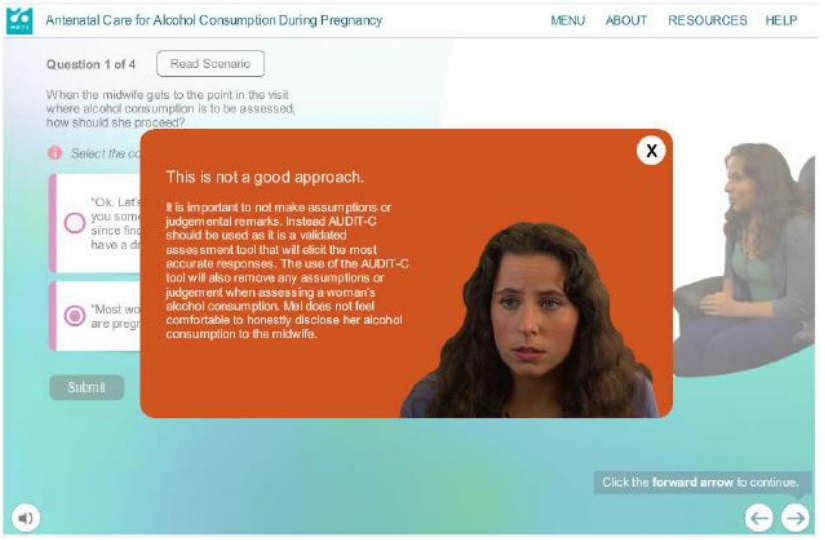

Antenatal Care for Alcohol Consumption During Pregnancy
MENU
ABOUT
RESOURCES
HELP
Actually, all options are correct.
First antenatal clinic visit (booking-in)
28 weeks gestation
36 weeks gestation
Alcohol consumption should be addressed as part of routine antenatal care at multiple visits. This allows:

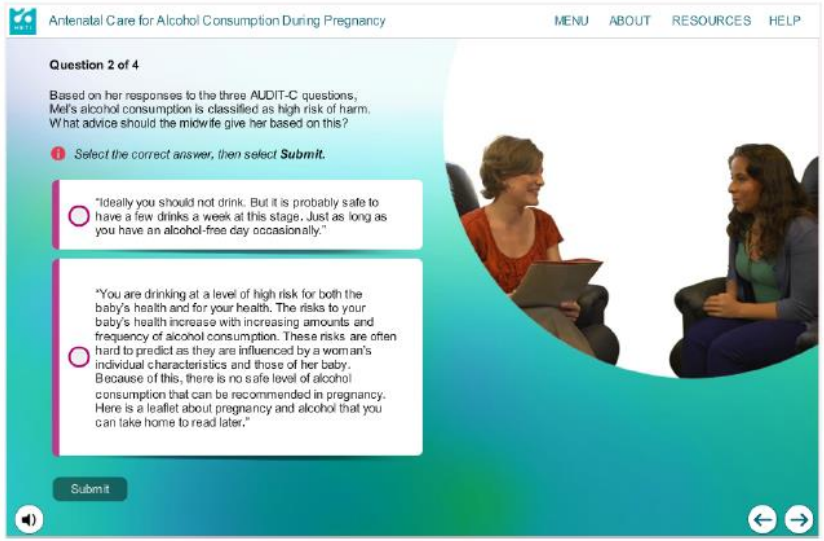

Antenatal Care for Alcohol Consumption During Pregnancy
MENU
ABOUT
RESOURCES
HELP
Applying the Three Steps (Assess, Advise and Refer)
You are now familiar with the three steps for providing antenatal care for alcohol consumption during pregnancy. Let's see if you can apply them in some antenatal clinic situations.
Select a woman's image to demonstrate your understanding.
Lucy
Mel

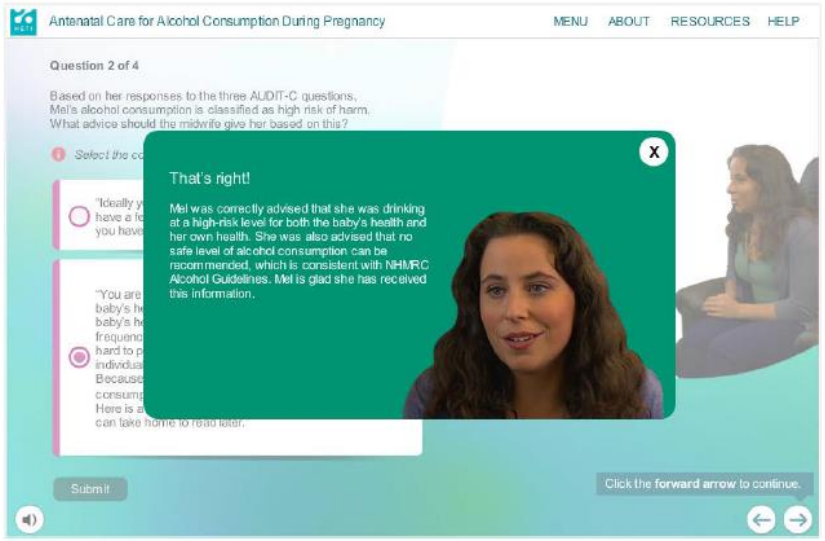

Antenatal Care for Alcohol Consumption During Pregnancy
MENU
ABOUT
RESOURCES
HELP
Applying the Three Steps (Assess, Advise and Refer) – Mel
It's Mel's first visit to the antenatal clinic and she is quite nervous. The midwife informs her that she will ask a series of questions that she asks all women she sees. This is simply a part of the booking-in process. These questions will be about her pregnancy, medical history, life circumstances, mental health and health behaviours, such as, alcohol consumption and smoking. Mel nods and says she will try and answer the questions as best she can.

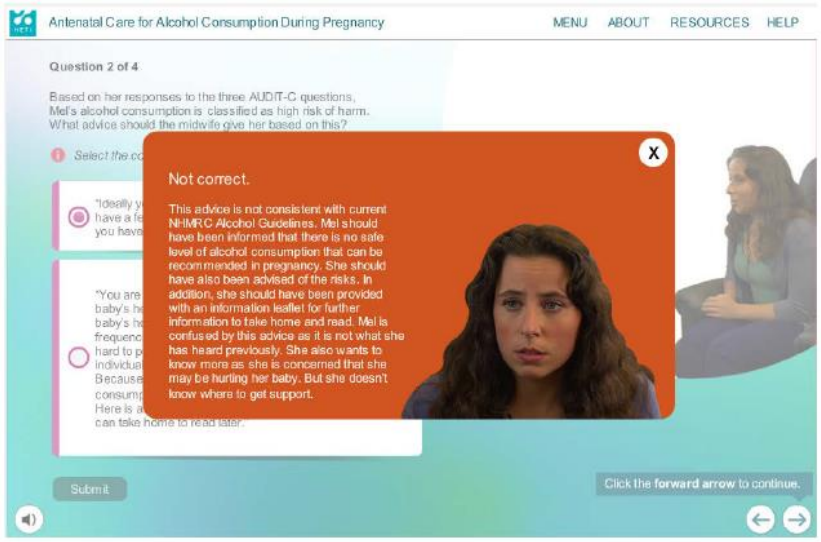

Antenatal Care for Alcohol Consumption During Pregnancy
MENU
ABOUT
RESOURCES
HELP
Question 1 of 4
Read Scenario
When the midwife gets to the point in the visit where alcohol consumption is to be assessed, how should she proceed?
Select the correct answer, then select Submit.
"Ok. Let's now talk about alcohol consumption. I will ask you some questions, which we ask all women. Firstly, since finding out you were pregnant, how often do you have a drink containing alcohol?"
"Most women stop drinking when they find out they are pregnant. I assume you are not drinking?"
Submit

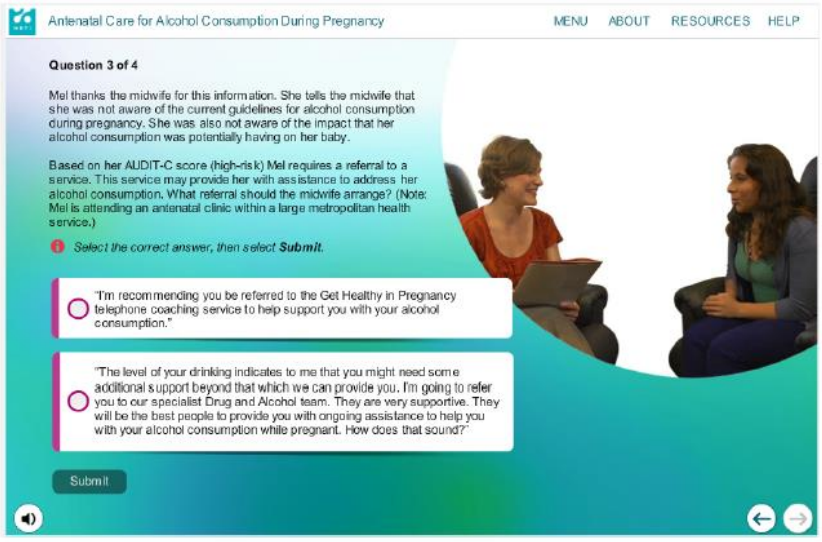

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 1 of 4
Read Scenario
When the midwife gets to the point in the visit where alcohol consumption is to be assessed, how should she proceed?
Submit
That's right!
This is the correct approach. Mel was reassured that all women are asked about their alcohol consumption. Accordingly, assessment was commenced using the first of the AUDIT-C questions. The AUDIT-C is a validated assessment tool and will elicit the most accurate responses. The use of the AUDIT-C tool removes any assumptions or judgement when assessing a woman's alcohol consumption. Mel feels comfortable in responding honestly to these questions.
Click the forward arrow to continue.

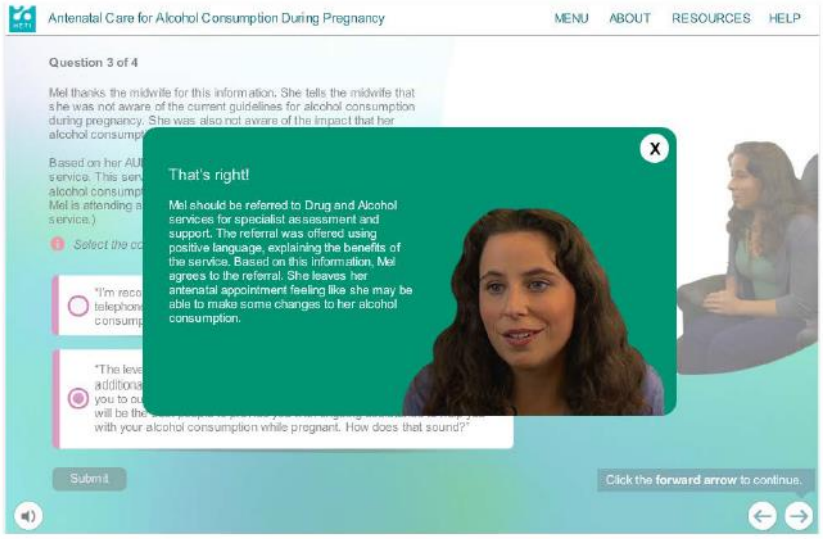

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 1 of 4
Read Scenario
When the midwife gets to the point in the visit where alcohol consumption is to be assessed, how should she proceed?
Submit
This is not a good approach.
It is important to not make assumptions or judgemental remarks. Instead AUDIT-C should be used as it is a validated assessment tool that will elicit the most accurate responses. The use of the AUDIT-C tool will also remove any assumptions or judgement when assessing a woman's alcohol consumption. Mel does not feel comfortable to honestly disclose her alcohol consumption to the midwife.
Click the forward arrow to continue.

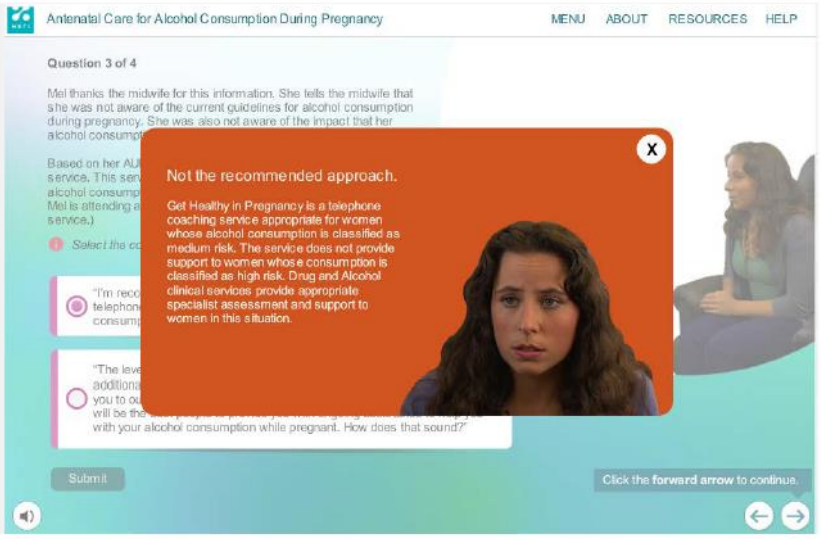

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 2 of 4
Based on her responses to the three AUDIT-C questions, Mel's alcohol consumption is classified as high risk of harm. What advice should the midwife give her based on this?
Select the correct answer, then select Submit.
"Ideally you should not drink. But it is probably safe to have a few drinks a week at this stage. Just as long as you have an alcohol-free day occasionally."
"You are drinking at a level of high risk for both the baby's health and for your health. The risks to your baby's health increase with increasing amounts and frequency of alcohol consumption. These risks are often hard to predict as they are influenced by a woman's individual characteristics and those of her baby. Because of this, there is no safe level of alcohol consumption that can be recommended in pregnancy. Here is a leaflet about pregnancy and alcohol that you can take home to read later."
Submit

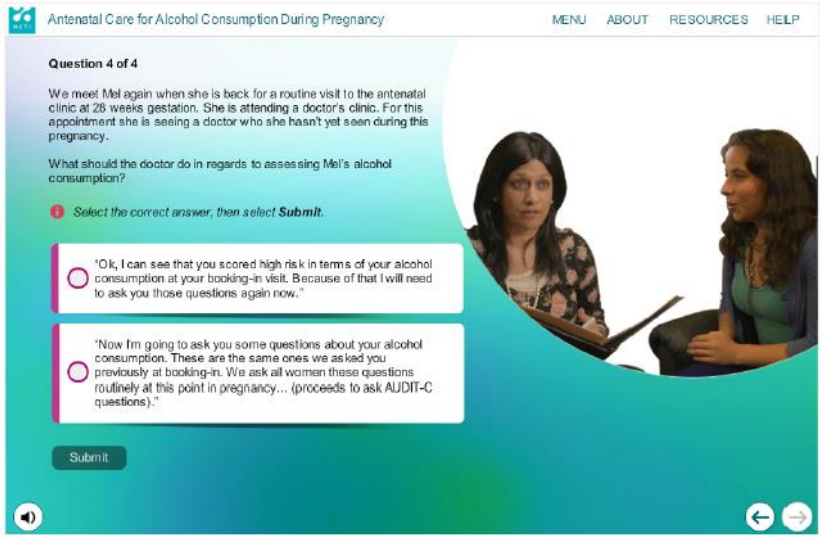

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 2 of 4
Based on her responses to the three AUDIT-C questions, Mel's alcohol consumption is classified as high risk of harm. What advice should the midwife give her based on this?
That's right!
Mel was correctly advised that she was drinking at a high-risk level for both the baby's health and her own health. She was also advised that no safe level of alcohol consumption can be recommended, which is consistent with NHMRC Alcohol Guidelines. Mel is glad she has received this information.
Submit
Click the forward arrow to continue.

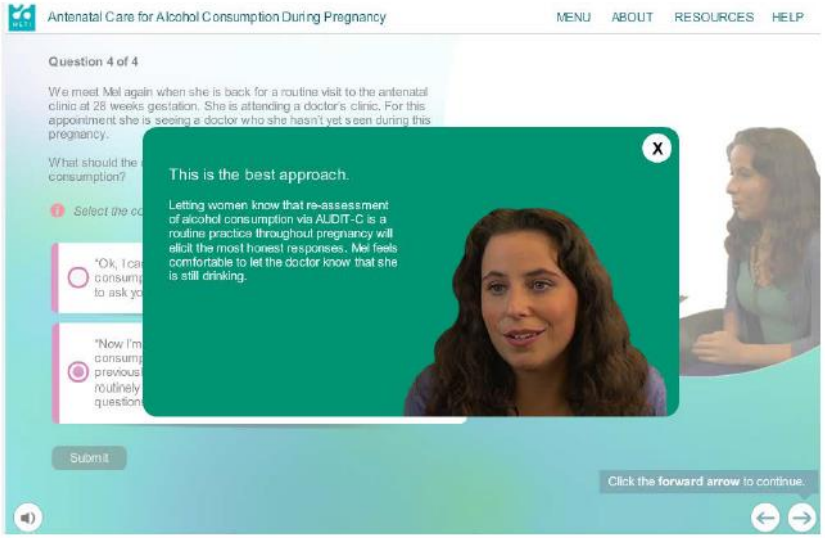

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 2 of 4
Based on her responses to the three AUDIT-C questions, Mel's alcohol consumption is classified as high risk of harm. What advice should the midwife give her based on this?
Not correct.
This advice is not consistent with current NHMRC Alcohol Guidelines. Mel should have been informed that there is no safe level of alcohol consumption that can be recommended in pregnancy. She should have also been advised of the risks. In addition, she should have been provided with an information leaflet for further information to take home and read. Mel is confused by this advice as it is not what she has heard previously. She also wants to know more as she is concerned that she may be hurting her baby. But she doesn't know where to get support.
Submit
Click the forward arrow to continue.

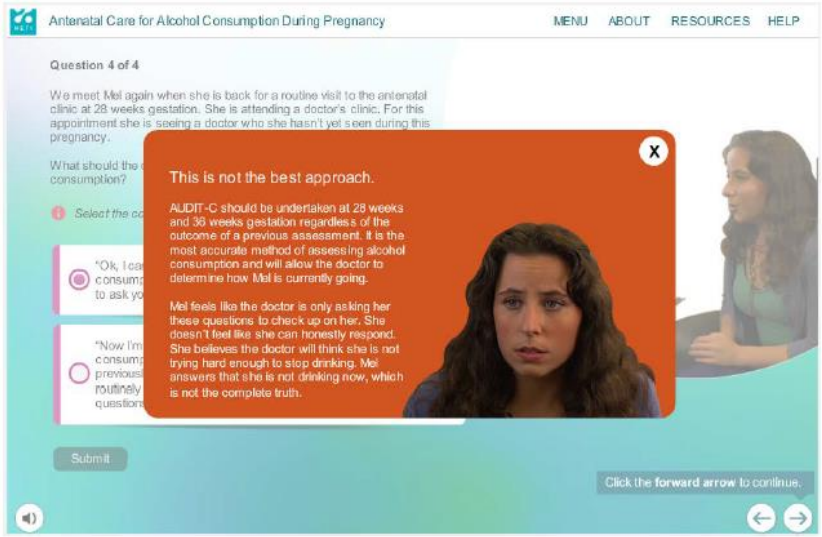

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 3 of 4
Mel thanks the midwife for this information. She tells the midwife that she was not aware of the current guidelines for alcohol consumption during pregnancy. She was also not aware of the impact that her alcohol consumption was potentially having on her baby.
Based on her AUDIT-C score (high-risk) Mel requires a referral to a service. This service may provide her with assistance to address her alcohol consumption. What referral should the midwife arrange? (Note: Mel is attending an antenatal clinic within a large metropolitan health service.)
Select the correct answer, then select Submit.
"I'm recommending you be referred to the Get Healthy in Pregnancy telephone coaching service to help support you with your alcohol consumption."
"The level of your drinking indicates to me that you might need some additional support beyond that which we can provide you. I'm going to refer you to our specialist Drug and Alcohol team. They are very supportive. They will be the best people to provide you with ongoing assistance to help you with your alcohol consumption while pregnant. How does that sound?"
Submit

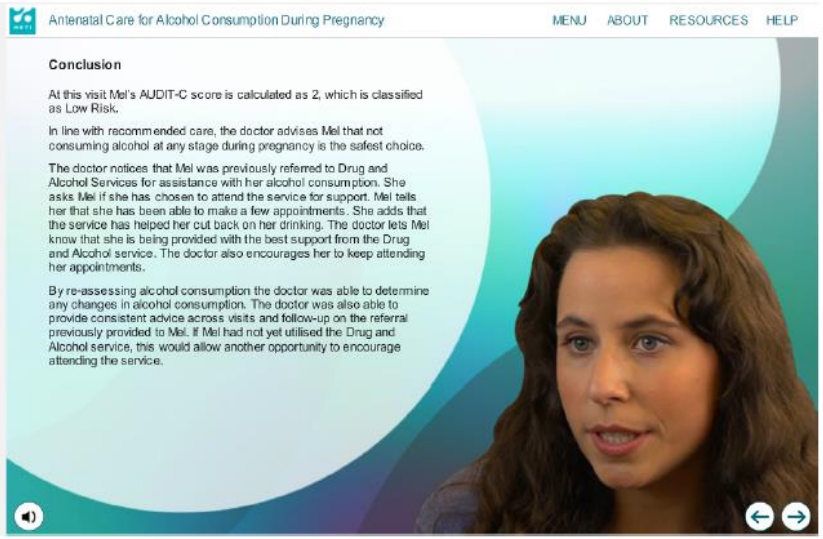

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 3 of 4
That's right!
Mel should be referred to Drug and Alcohol services for specialist assessment and support. The referral was offered using positive language, explaining the benefits of the service. Based on this information, Mel agrees to the referral. She leaves her antenatal appointment feeling like she may be able to make some changes to her alcohol consumption.
Submit
Click the forward arrow to continue.

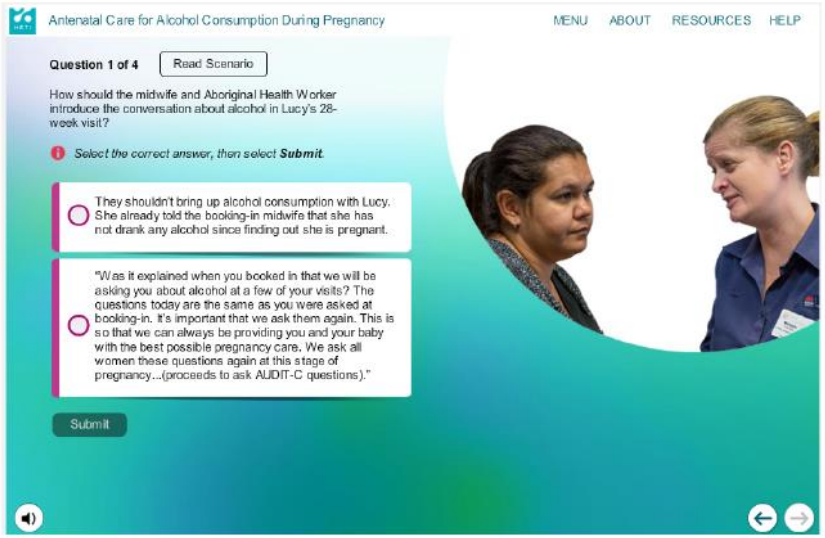

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 3 of 4
Not the recommended approach.
Get Healthy in Pregnancy is a telephone coaching service appropriate for women whose alcohol consumption is classified as medium risk. The service does not provide support to women whose consumption is classified as high risk. Drug and Alcohol clinical services provide appropriate specialist assessment and support to women in this situation.
Submit
Click the forward arrow to continue.

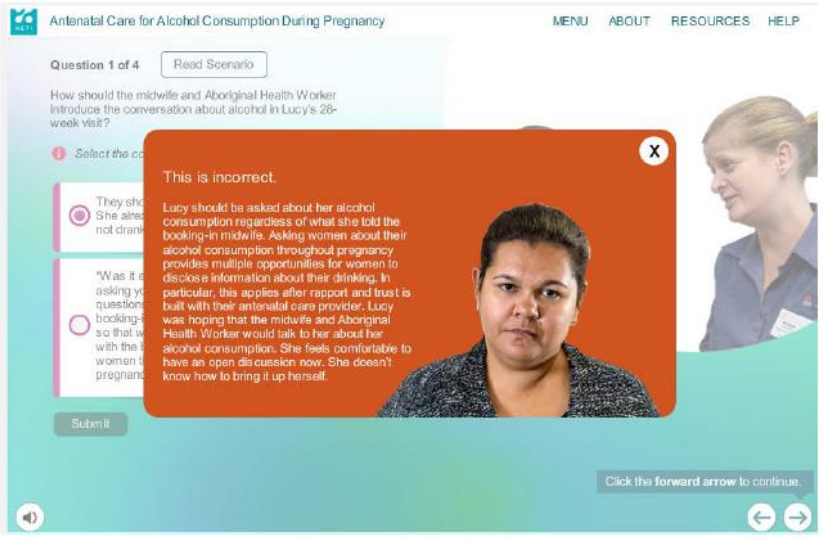

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 4 of 4
We meet Mel again when she is back for a routine visit to the antenatal clinic at 28 weeks gestation. She is attending a doctor's clinic. For this appointment she is seeing a doctor who she hasn't yet seen during this pregnancy.
What should the doctor do in regards to assessing Mel's alcohol consumption?
Select the correct answer, then select Submit.
"Ok, I can see that you scored high risk in terms of your alcohol consumption at your booking-in visit. Because of that I will need to ask you those questions again now."
"Now I'm going to ask you some questions about your alcohol consumption. These are the same ones we asked you previously at booking-in. We ask all women these questions routinely at this point in pregnancy... (proceeds to ask AUDIT-C questions)."
Submit

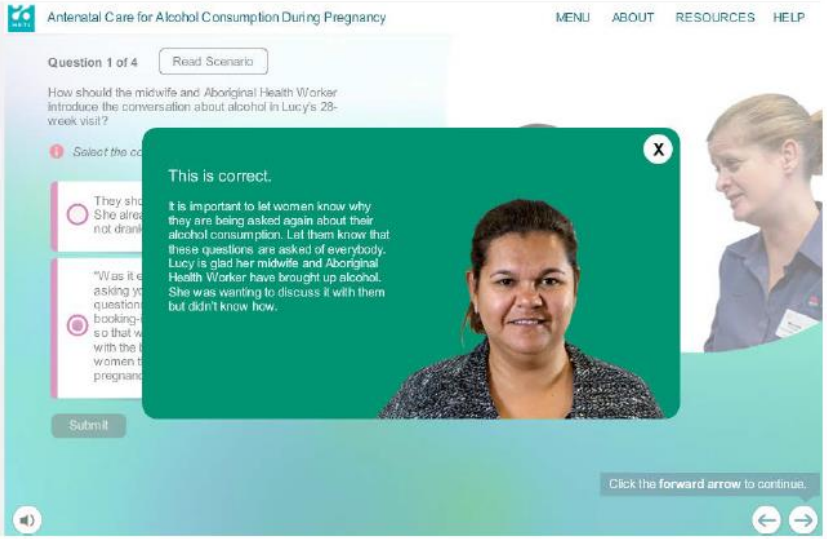

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 4 of 4
This is the best approach.
Letting women know that re-assessment of alcohol consumption via AUDIT-C is a routine practice throughout pregnancy will elicit the most honest responses. Mel feels comfortable to let the doctor know that she is still drinking.
Submit
Click the forward arrow to continue.

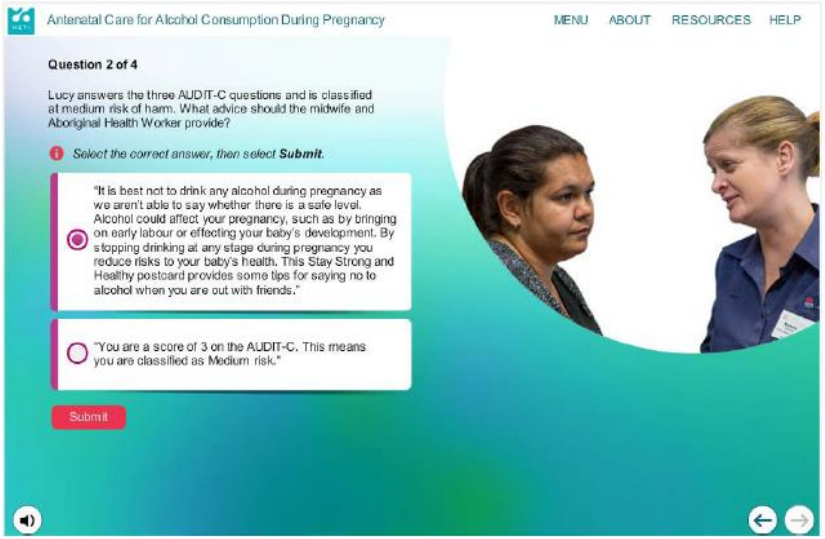

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 4 of 4
This is not the best approach.
AUDIT-C should be undertaken at 28 weeks and 36 weeks gestation regardless of the outcome of a previous assessment. It is the most accurate method of assessing alcohol consumption and will allow the doctor to determine how Mel is currently going.
Mel feels like the doctor is only asking her these questions to check up on her. She doesn't feel like she can honestly respond. She believes the doctor will think she is not trying hard enough to stop drinking. Mel answers that she is not drinking now, which is not the complete truth.
Submit
Click the forward arrow to continue.

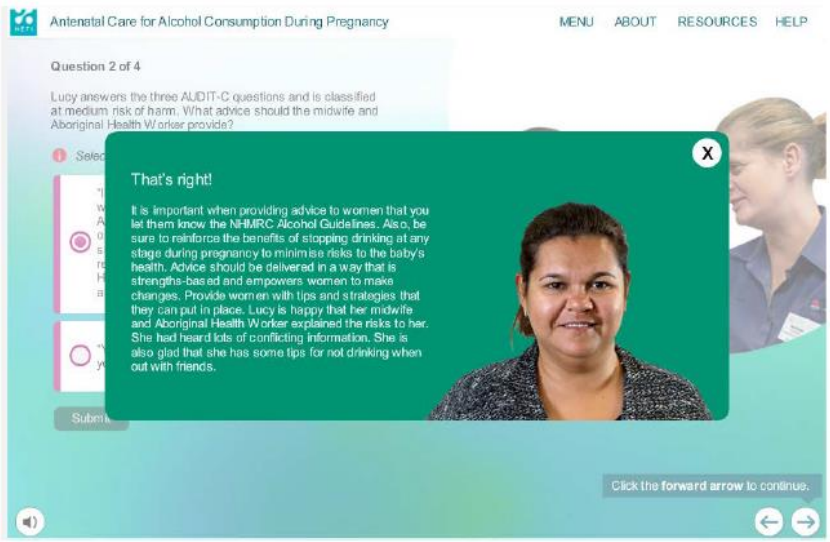

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Conclusion
At this visit Mel's AUDIT-C score is calculated as 2, which is classified as Low Risk.
In line with recommended care, the doctor advises Mel that not consuming alcohol at any stage during pregnancy is the safest choice.
The doctor notices that Mel was previously referred to Drug and Alcohol Services for assistance with her alcohol consumption. She asks Mel if she has chosen to attend the service for support. Mel tells her that she has been able to make a few appointments. She adds that the service has helped her cut back on her drinking. The doctor lets Mel know that she is being provided with the best support from the Drug and Alcohol service. The doctor also encourages her to keep attending her appointments.
By re-assessing alcohol consumption the doctor was able to determine any changes in alcohol consumption. The doctor was also able to provide consistent advice across visits and follow-up on the referral previously provided to Mel. If Mel had not yet utilised the Drug and Alcohol service, this would allow another opportunity to encourage attending the service.

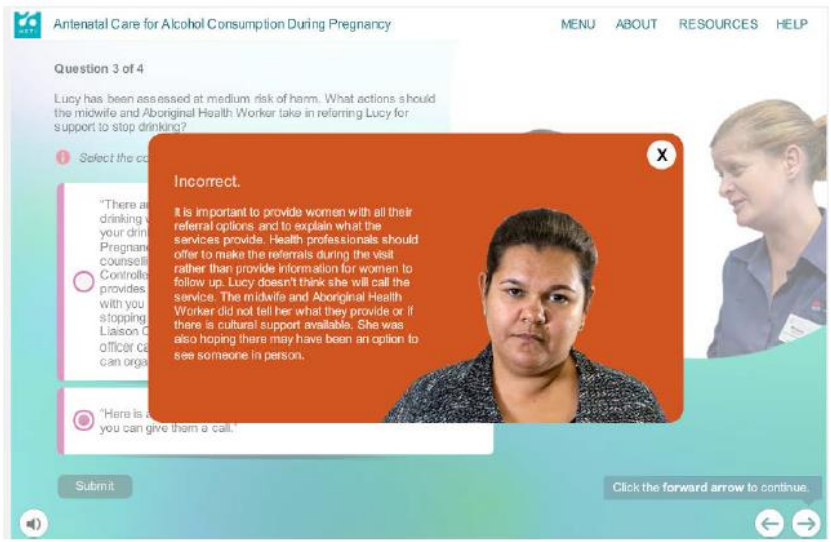

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 1 of 4
Read Scenario
How should the midwife and Aboriginal Health Worker introduce the conversation about alcohol in Lucy's 28-week visit?
Select the correct answer, then select Submit.
They shouldn't bring up alcohol consumption with Lucy. She already told the booking-in midwife that she has not drank any alcohol since finding out she is pregnant.
"Was it explained when you booked in that we will be asking you about alcohol at a few of your visits? The questions today are the same as you were asked at booking-in. It's important that we ask them again. This is so that we can always be providing you and your baby with the best possible pregnancy care. We ask all women these questions again at this stage of pregnancy...(proceeds to ask AUDIT-C questions)."
Submit

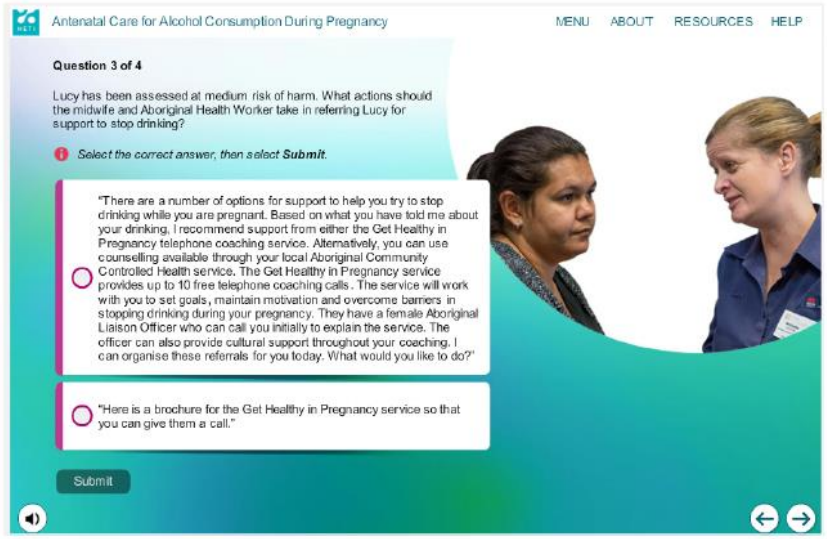

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 1 of 4
Read Scenario
This is incorrect.
Lucy should be asked about her alcohol consumption regardless of what she told the booking-in midwife. Asking women about their alcohol consumption throughout pregnancy provides multiple opportunities for women to disclose information about their drinking. In particular, this applies after rapport and trust is built with their antenatal care provider. Lucy was hoping that the midwife and Aboriginal Health Worker would talk to her about her alcohol consumption. She feels comfortable to have an open discussion now. She doesn't know how to bring it up herself.
Submit
Click the forward arrow to continue.

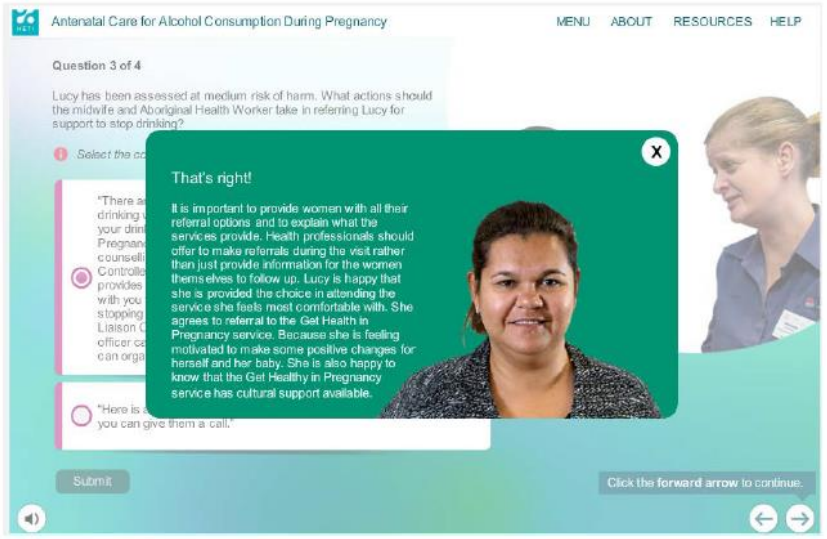

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 1 of 4
Read Scenario
This is correct.
It is important to let women know why they are being asked again about their alcohol consumption. Let them know that these questions are asked of everybody. Lucy is glad her midwife and Aboriginal Health Worker have brought up alcohol. She was wanting to discuss it with them but didn't know how.
Submit
Click the forward arrow to continue.

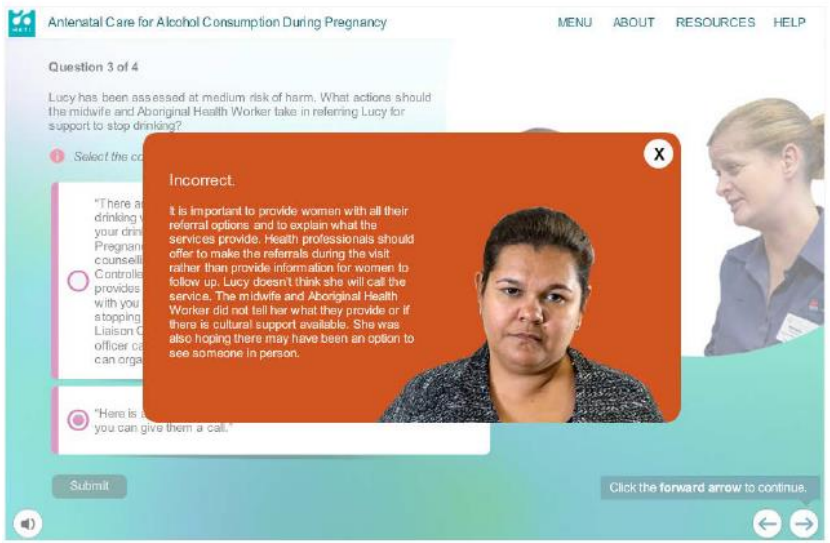

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 2 of 4
Lucy answers the three AUDIT-C questions and is classified at medium risk of harm. What advice should the midwife and Aboriginal Health Worker provide?
Select the correct answer, then select Submit.
"It is best not to drink any alcohol during pregnancy as we aren't able to say whether there is a safe level. Alcohol could affect your pregnancy, such as by bringing on early labour or effecting your baby's development. By stopping drinking at any stage during pregnancy you reduce risks to your baby's health. This Stay Strong and Healthy postcard provides some tips for saying no to alcohol when you are out with friends."
"You are a score of 3 on the AUDIT-C. This means you are classified as Medium risk."
Submit

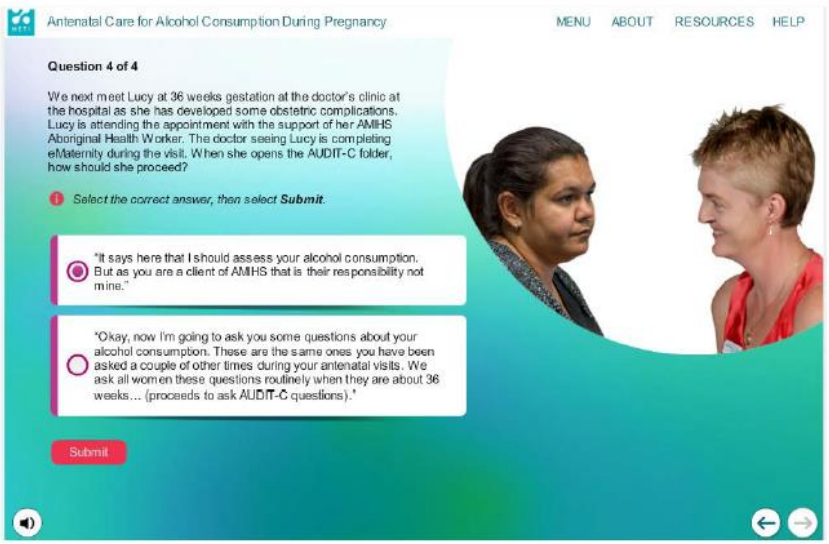

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 2 of 4
Lucy answers the three AUDIT-C questions and is classified at medium risk of harm. What advice should the midwife and Aboriginal Health Worker provide?
That's right!
It is important when providing advice to women that you let them know the NHMRC Alcohol Guidelines. Also, be sure to reinforce the benefits of stopping drinking at any stage during pregnancy to minimise risks to the baby's health. Advice should be delivered in a way that is strengths-based and empowers women to make changes. Provide women with tips and strategies that they can put in place. Lucy is happy that her midwife and Aboriginal Health Worker explained the risks to her. She had heard lots of conflicting information. She is also glad that she has some tips for not drinking when out with friends.
Submit
Click the forward arrow to continue.

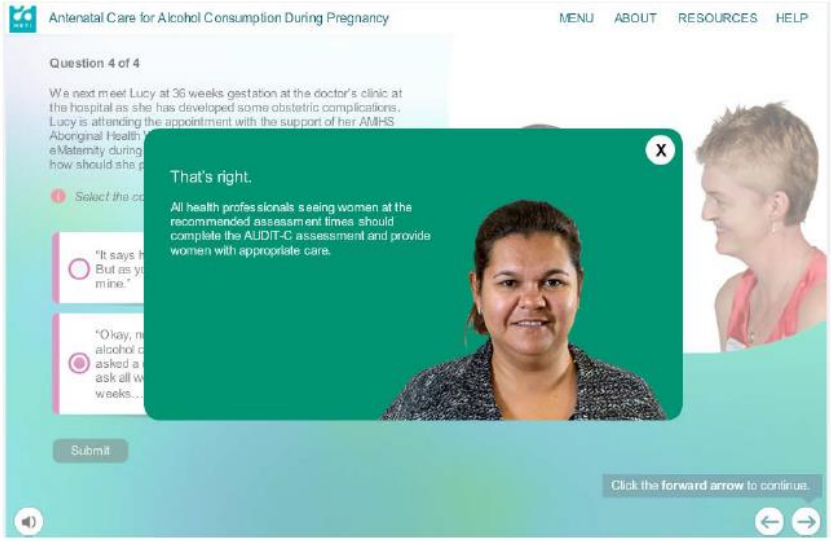

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 3 of 4
Lucy has been assessed at medium risk of harm. What actions should the midwife and Aboriginal Health Worker take in referring Lucy for support to stop drinking?
Incorrect.
It is important to provide women with all their referral options and to explain what the services provide. Health professionals should offer to make the referrals during the visit rather than provide information for women to follow up. Lucy doesn't think she will call the service. The midwife and Aboriginal Health Worker did not tell her what they provide or if there is cultural support available. She was also hoping there may have been an option to see someone in person.
Submit
Click the forward arrow to continue.

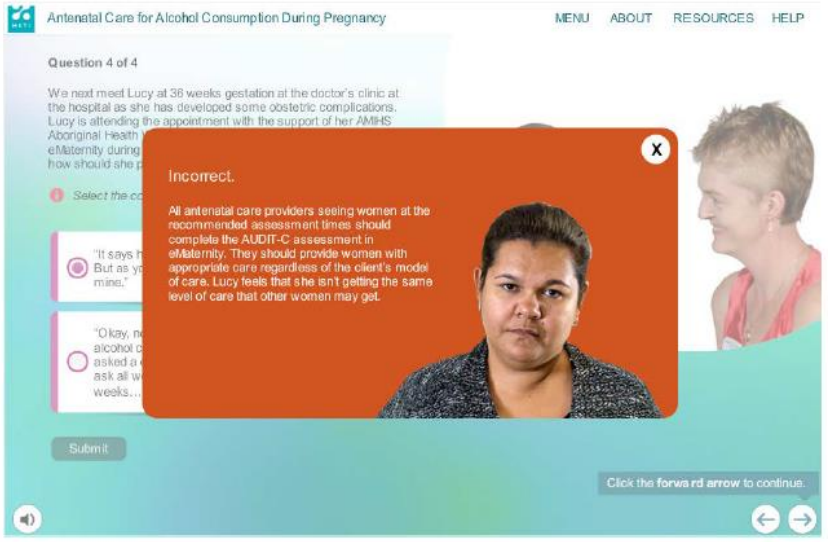

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 3 of 4
Lucy has been assessed at medium risk of harm. What actions should the midwife and Aboriginal Health Worker take in referring Lucy for support to stop drinking?
Select the correct answer, then select Submit.
"There are a number of options for support to help you try to stop drinking while you are pregnant. Based on what you have told me about your drinking, I recommend support from either the Get Healthy in Pregnancy telephone coaching service. Alternatively, you can use counselling available through your local Aboriginal Community Controlled Health service. The Get Healthy in Pregnancy service provides up to 10 free telephone coaching calls. The service will work with you to set goals, maintain motivation and overcome barriers in stopping drinking during your pregnancy. They have a female Aboriginal Liaison Officer who can call you initially to explain the service. The officer can also provide cultural support throughout your coaching. I can organise these referrals for you today. What would you like to do?"
"Here is a brochure for the Get Healthy in Pregnancy service so that you can give them a call."
Submit


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 3 of 4
Lucy has been assessed at medium risk of harm. What actions should the midwife and Aboriginal Health Worker take in referring Lucy for support to stop drinking?
That's right!
It is important to provide women with all their referral options and to explain what the services provide. Health professionals should offer to make referrals during the visit rather than just provide information for the women themselves to follow up. Lucy is happy that she is provided the choice in attending the service she feels most comfortable with. She agrees to referral to the Get Health in Pregnancy service. Because she is feeling motivated to make some positive changes for herself and her baby. She is also happy to know that the Get Healthy in Pregnancy service has cultural support available.
Submit
Click the forward arrow to continue.

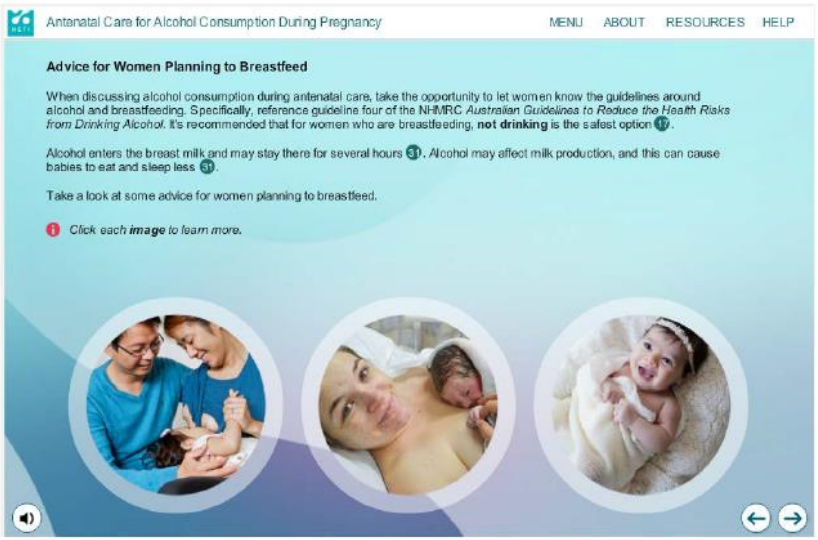

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 3 of 4
Lucy has been assessed at medium risk of harm. What actions should the midwife and Aboriginal Health Worker take in referring Lucy for support to stop drinking?
Incorrect.
It is important to provide women with all their referral options and to explain what the services provide. Health professionals should offer to make the referrals during the visit rather than provide information for women to follow up. Lucy doesn't think she will call the service. The midwife and Aboriginal Health Worker did not tell her what they provide or if there is cultural support available. She was also hoping there may have been an option to see someone in person.
Submit
Click the forward arrow to continue.

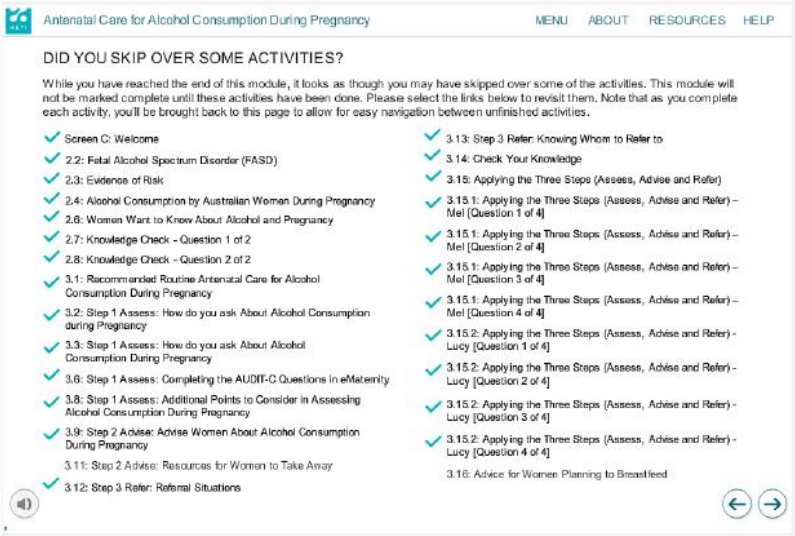

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 4 of 4
We next meet Lucy at 36 weeks gestation at the doctor's clinic at the hospital as she has developed some obstetric complications. Lucy is attending the appointment with the support of her AMIHS Aboriginal Health Worker. The doctor seeing Lucy is completing eMaternity during the visit. When she opens the AUDIT-C folder, how should she proceed?
Select the correct answer, then select Submit.
"It says here that I should assess your alcohol consumption. But as you are a client of AMIHS that is their responsibility not mine."
"Okay, now I'm going to ask you some questions about your alcohol consumption. These are the same ones you have been asked a couple of other times during your antenatal visits. We ask all women these questions routinely when they are about 36 weeks... (proceeds to ask AUDIT-C questions)."
Submit

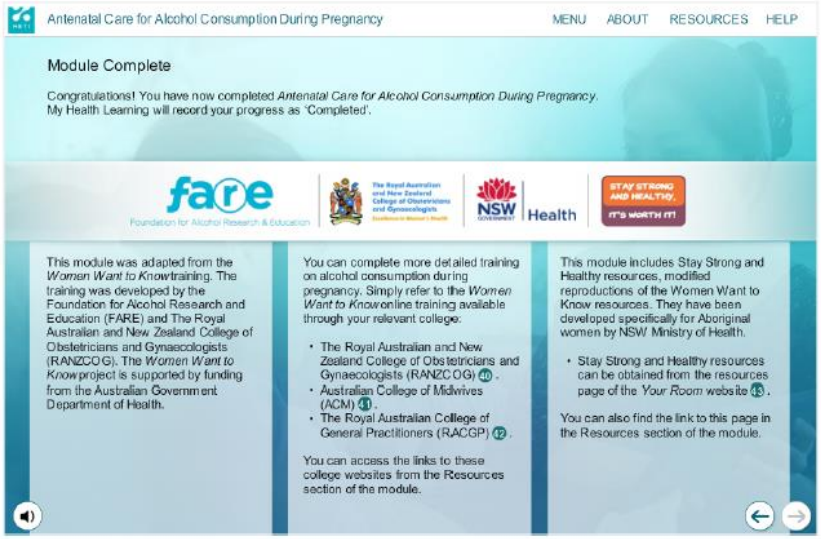

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 4 of 4
That's right.
All health professionals seeing women at the recommended assessment times should complete the AUDIT-C assessment and provide women with appropriate care.
Submit
Click the forward arrow to continue.

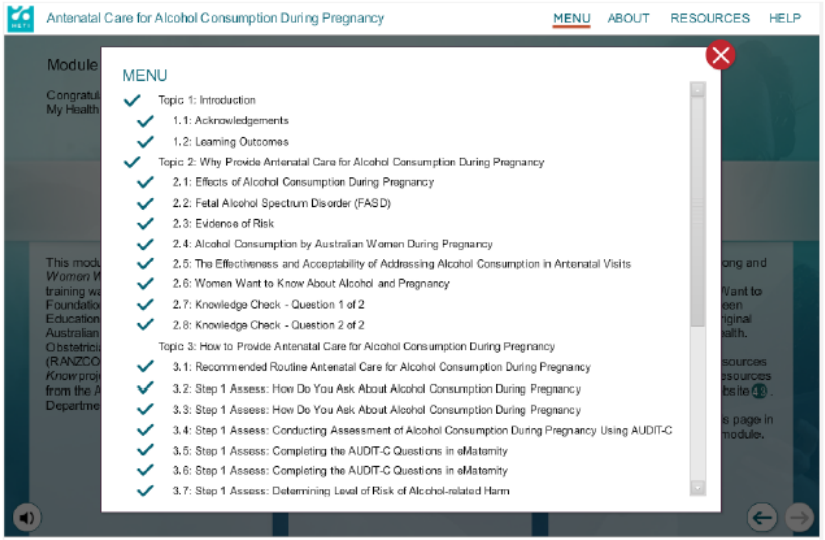

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Question 4 of 4
Incorrect.
All antenatal care providers seeing women at the recommended assessment times should complete the AUDIT-C assessment in eMaternity. They should provide women with appropriate care regardless of the client's model of care. Lucy feels that she isn't getting the same level of care that other women may get.
Submit
Click the forward arrow to continue.

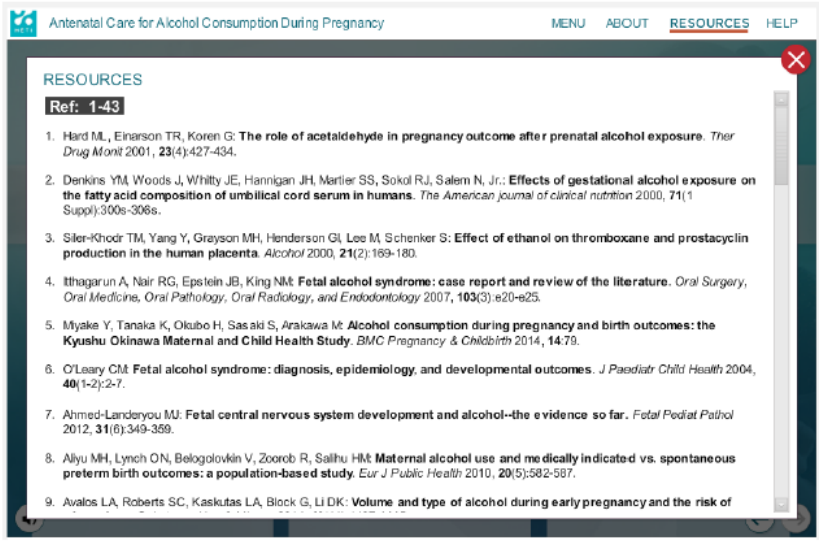

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Conclusion
Lucy is excited to let the doctor and AMIHS Aboriginal Health Worker know that she has stopped drinking. She has not drunk any alcohol since the last time she was asked about her alcohol consumption. The doctor and AMIHS Aboriginal Health Worker congratulate Lucy for making positive changes. They let her know that it is safest to continue not to drink. They ask Lucy how she is going with the support she is receiving from the Get Healthy in Pregnancy service. They also encourage her to continue with the service. Lucy is happy that she was able to make this positive change for her and her baby.

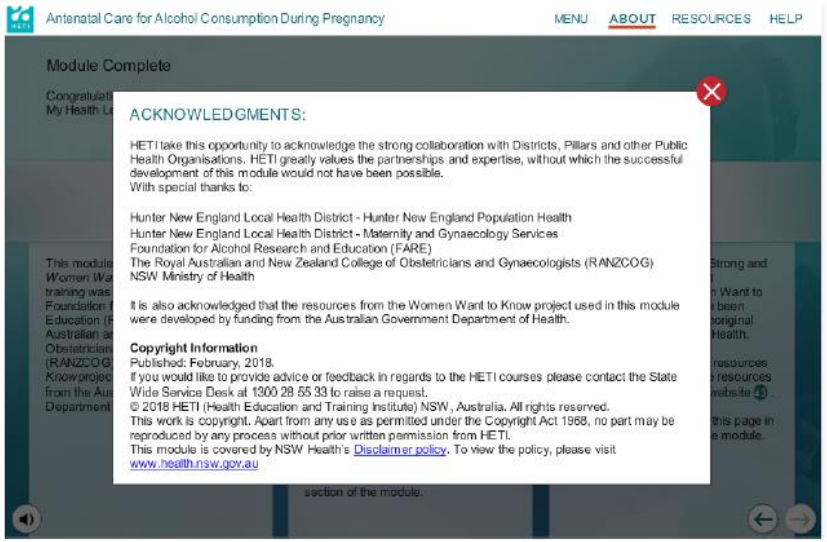

Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Advice for Women Planning to Breastfeed
When discussing alcohol consumption during antenatal care, take the opportunity to let women know the guidelines around alcohol and breastfeeding. Specifically, reference guideline four of the NHMRC Australian Guidelines to Reduce the Health Risks from Drinking Alcohol. It's recommended that for women who are breastfeeding, not drinking is the safest option 17.
Alcohol enters the breast milk and may stay there for several hours 31. Alcohol may affect milk production, and this can cause babies to eat and sleep less 31.
Take a look at some advice for women planning to breastfeed.
Click each image to learn more.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
DID YOU SKIP OVER SOME ACTIVITIES?
While you have reached the end of this module, it looks as though you may have skipped over some of the activities. This module will not be marked complete until these activities have been done. Please select the links below to revisit them. Note that as you complete each activity, you'll be brought back to this page to allow for easy navigation between unfinished activities.
Screen C: Welcome
2.2: Fetal Alcohol Spectrum Disorder (FASD)
2.3: Evidence of Risk
2.4: Alcohol Consumption by Australian Women During Pregnancy
2.6: Women Want to Know About Alcohol and Pregnancy
2.7: Knowledge Check - Question 1 of 2
2.8: Knowledge Check - Question 2 of 2
3.1: Recommended Routine Antenatal Care for Alcohol Consumption During Pregnancy
3.2: Step 1 Assess: How do you ask About Alcohol Consumption during Pregnancy
3.3: Step 1 Assess: How do you ask About Alcohol Consumption During Pregnancy
3.6: Step 1 Assess: Completing the AUDIT-C Questions in eMaternity
3.8: Step 1 Assess: Additional Points to Consider in Assessing Alcohol Consumption During Pregnancy
3.9: Step 2 Advise: Advise Women About Alcohol Consumption During Pregnancy
3.11: Step 2 Advise: Resources for Women to Take Away
3.12: Step 3 Refer: Referral Situations
3.13: Step 3 Refer: Knowing Whom to Refer to
3.14: Check Your Knowledge
3.15: Applying the Three Steps (Assess, Advise and Refer)
3.15.1: Applying the Three Steps (Assess, Advise and Refer) – Mel [Question 1 of 4]
3.15.1: Applying the Three Steps (Assess, Advise and Refer) – Mel [Question 2 of 4]
3.15.1: Applying the Three Steps (Assess, Advise and Refer) – Mel [Question 3 of 4]
3.15.1: Applying the Three Steps (Assess, Advise and Refer) – Mel [Question 4 of 4]
3.15.2: Applying the Three Steps (Assess, Advise and Refer) - Lucy [Question 1 of 4]
3.15.2: Applying the Three Steps (Assess, Advise and Refer) - Lucy [Question 2 of 4]
3.15.2: Applying the Three Steps (Assess, Advise and Refer) - Lucy [Question 3 of 4]
3.15.2: Applying the Three Steps (Assess, Advise and Refer) - Lucy [Question 4 of 4]
3.16: Advice for Women Planning to Breastfeed


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Module Complete
Congratulations! You have now completed Antenatal Care for Alcohol Consumption During Pregnancy.
My Health Learning will record your progress as 'Completed'.
fare
Foundation for Alcohol Research & Education
NSW Health
STAY STRONG AND HEALTHY, IT'S WORTH IT!
This module was adapted from the Women Want to Know training. The training was developed by the Foundation for Alcohol Research and Education (FARE) and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). The Women Want to Know project is supported by funding from the Australian Government Department of Health.
You can complete more detailed training on alcohol consumption during pregnancy. Simply refer to the Women Want to Know online training available through your relevant college:
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) 40.
Australian College of Midwives (ACM) 41.
The Royal Australian College of General Practitioners (RACGP) 42.
You can access the links to these college websites from the Resources section of the module.
This module includes Stay Strong and Healthy resources, modified reproductions of the Women Want to Know resources. They have been developed specifically for Aboriginal women by NSW Ministry of Health.
Stay Strong and Healthy resources can be obtained from the resources page of the Your Room website 43.
You can also find the link to this page in the Resources section of the module.


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
MENU
Topic 1: Introduction
1.1: Acknowledgements
1.2: Learning Outcomes
Topic 2: Why Provide Antenatal Care for Alcohol Consumption During Pregnancy
2.1: Effects of Alcohol Consumption During Pregnancy
2.2: Fetal Alcohol Spectrum Disorder (FASD)
2.3: Evidence of Risk
2.4: Alcohol Consumption by Australian Women During Pregnancy
2.5: The Effectiveness and Acceptability of Addressing Alcohol Consumption in Antenatal Visits
2.6: Women Want to Know About Alcohol and Pregnancy
2.7: Knowledge Check - Question 1 of 2
2.8: Knowledge Check - Question 2 of 2
Topic 3: How to Provide Antenatal Care for Alcohol Consumption During Pregnancy
3.1: Recommended Routine Antenatal Care for Alcohol Consumption During Pregnancy
3.2: Step 1 Assess: How Do You Ask About Alcohol Consumption During Pregnancy
3.3: Step 1 Assess: How Do You Ask About Alcohol Consumption During Pregnancy
3.4: Step 1 Assess: Conducting Assessment of Alcohol Consumption During Pregnancy Using AUDIT-C
3.5: Step 1 Assess: Completing the AUDIT-C Questions in eMaternity
3.6: Step 1 Assess: Completing the AUDIT-C Questions in eMaternity
3.7: Step 1 Assess: Determining Level of Risk of Alcohol-related Harm


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
RESOURCES
Ref: 1-43
1. Hard ML, Einarson TR, Koren G: The role of acetaldehyde in pregnancy outcome after prenatal alcohol exposure. Ther Drug Monit 2001, 23(4):427-434.
2. Denkins YM, Woods J, Whitty JE, Hannigan JH, Martier SS, Sokol RJ, Salem N, Jr.: Effects of gestational alcohol exposure on the fatty acid composition of umbilical cord serum in humans. The American journal of clinical nutrition 2000, 71(1 Suppl):300s-306s.
3. Siler-Khodr TM, Yang Y, Greyson MH, Henderson GI, Lee M, Schenker S: Effect of ethanol on thromboxane and prostacyclin production in the human placenta. Alcohol 2000, 21(2):169-180.
4. Ithagarun A, Nair RG, Epstein JB, King NM: Fetal alcohol syndrome: case report and review of the literature. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology 2007, 103(3):e20-e25.
5. Miyake Y, Tanaka K, Okubo H, Sasaki S, Arakawa M: Alcohol consumption during pregnancy and birth outcomes: the Kyushu Okinawa Maternal and Child Health Study. BMC Pregnancy & Childbirth 2014, 14:79.
6. O'Leary CM: Fetal alcohol syndrome: diagnosis, epidemiology, and developmental outcomes. J Paediatr Child Health 2004, 40(1-2):2-7.
7. Ahmed-Landeryou MJ: Fetal central nervous system development and alcohol--the evidence so far. Fetal Pediat Pathol 2012, 31(6):349-359.
8. Aliyu MH, Lynch ON, Belogolovkin V, Zoorob R, Salihu HM: Maternal alcohol use and medically indicated vs. spontaneous preterm birth outcomes: a population-based study. Eur J Public Health 2010, 20(5):582-587.
9. Avalos LA, Roberts SC, Kaskutas LA, Block G, Li DK: Volume and type of alcohol during early pregnancy and the risk of


Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Module Complete
ACKNOWLEDGMENTS:
HETI take this opportunity to acknowledge the strong collaboration with Districts, Pillars and other Public Health Organisations. HETI greatly values the partnerships and expertise, without which the successful development of this module would not have been possible.
With special thanks to:
Hunter New England Local Health District - Hunter New England Population Health
Hunter New England Local Health District - Maternity and Gynaecology Services
Foundation for Alcohol Research and Education (FARE)
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
NSW Ministry of Health
It is also acknowledged that the resources from the Women Want to Know project used in this module were developed by funding from the Australian Government Department of Health.
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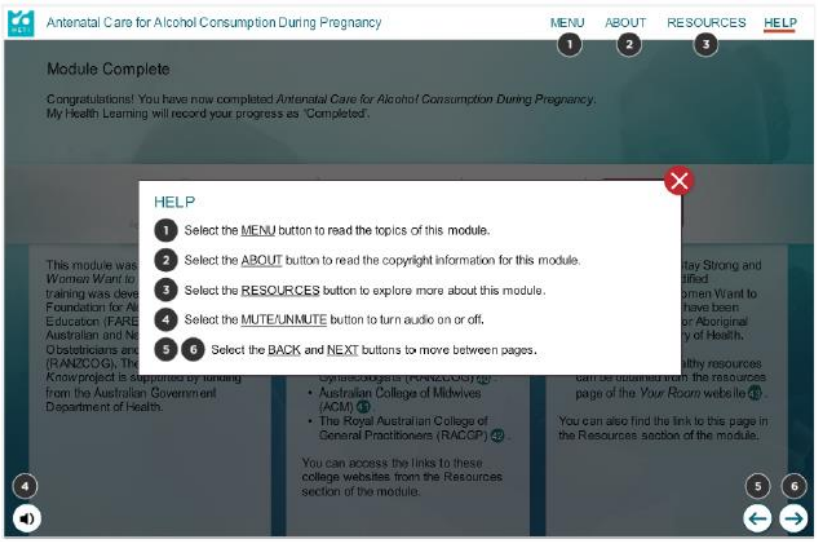
Antenatal Care for Alcohol Consumption During Pregnancy
MENU ABOUT RESOURCES HELP
Module Complete
Congratulations! You have now completed Antenatal Care for Alcohol Consumption During Pregnancy.
My Health Learning will record your progress as 'Completed'.
HELP
1 Select the MENU button to read the topics of this module.
2 Select the ABOUT button to read the copyright information for this module.
3 Select the RESOURCES button to explore more about this module.
4 Select the MUTE/UNMUTE button to turn audio on or off.
5 6 Select the BACK and NEXT buttons to move between pages.

First presentation delivered face-to-face by Clinical Midwife Educator

Screening and Management of Alcohol Consumption during Pregnancy

New Guideline and Procedure

Brendon Williams
Clinical Midwife Educator

Health
Hunter New England
Local Health District

Acknowledgement of Country

I would like to acknowledge the traditional owners of the land we are meeting on today and pay my respects to Elders, past, present, and future, and acknowledge any Aboriginal people in the room today

Today

- **New Guideline and Procedure:** Screening and management of alcohol consumption during pregnancy
  - Why we need it
  - What needs to be done
  - How you'll be supported

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Local Health District

WHY we need a Guideline & Procedure for Screening and Management of Alcohol Consumption in Pregnancy

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Local Health District

Effects of alcohol exposure

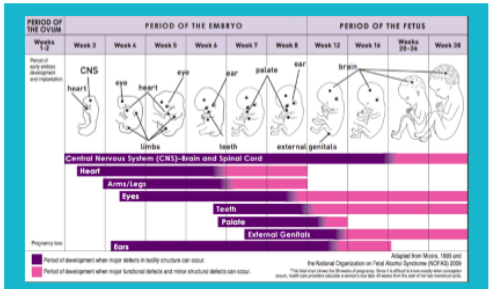

Image developed by the Centres for Disease Control and Prevention (CDC) and used with CDC permission.

Effects and Evidence of Risk

Adverse outcomes:
- Impaired placental/fetal blood flow leading to hypoxia
- Miscarriage
- Low birth weight, birth defects, premature birth, stillbirth
- Fetal Alcohol Spectrum Disorder (FASD)

Level of Harm
- Timing
- Frequency
- Quantity of alcohol consumed

Individual maternal and fetal characteristics:
- General health
- Nutritional status
- Genetic factors
- Other drug use

No safe threshold for alcohol consumption during pregnancy has been established

Woman's health and subsequent pregnancies

Additional benefits to not drinking alcohol during pregnancy include:

- Reduced risk of chronic disease and injury for the woman
- Benefit of subsequent pregnancies potentially not being exposed to alcohol

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Local Health District

National Alcohol Guidelines

- NHMRC Alcohol guidelines
  - **Not drinking is the safest option** if pregnant or planning pregnancy [10].
- However, NDSHS 2016 found:
  - 49% women consumed alcohol **prior to knowledge of their pregnancy**
  - 25% women **consumed alcohol after knowledge of their pregnancy [11].**

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Assess, Advise, Refer

- **All clinicians** provide routine antenatal care for alcohol consumption during pregnancy to **all women** using 3 steps:
  1. **Assess** – using a validated tool (AUDIT C)
  2. **Advise**
  3. **Refer**

These steps should be undertaken multiple times throughout pregnancy.

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Current antenatal care for alcohol consumption

Surveys of antenatal care providers in Australia show that:

- 47% **routinely assess** maternal alcohol consumption
- 12% **never ask**
- 25% provide **advice** about **alcohol intake** and potential **harms** to the unborn child [12, 13].

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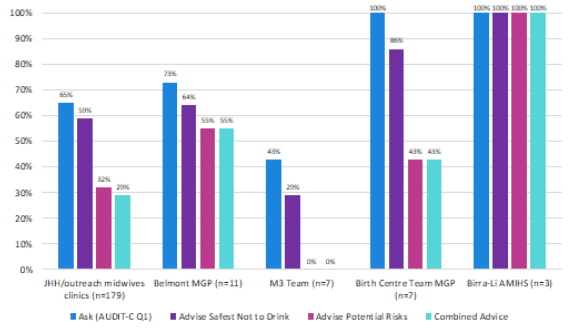
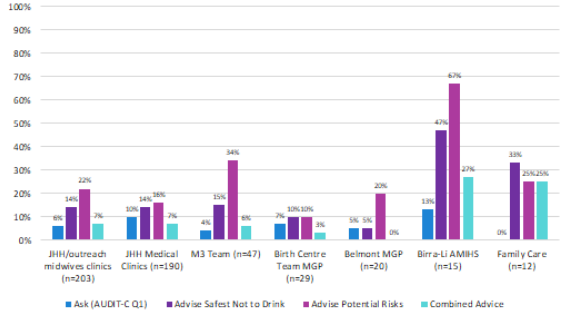
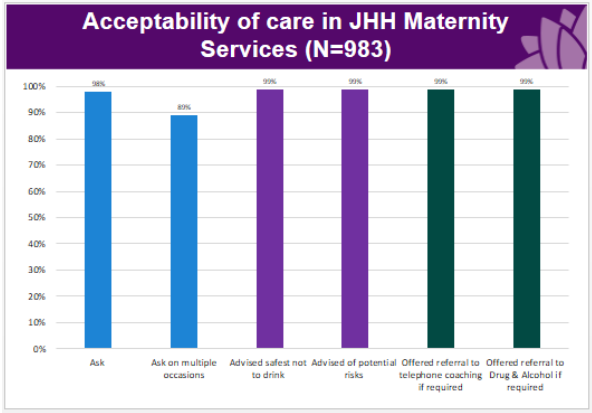
Local Health District

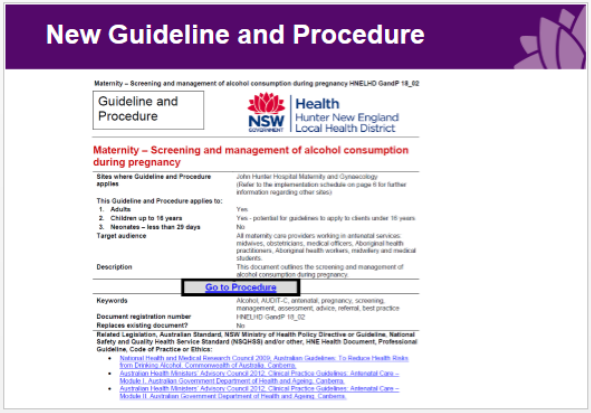
Current level of care provided in JHH Maternity Services – Booking In (N=207)

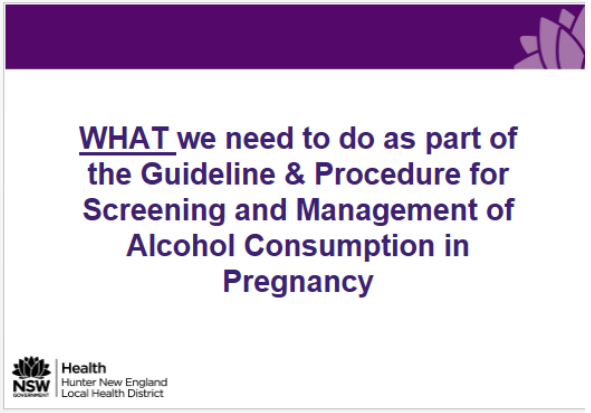


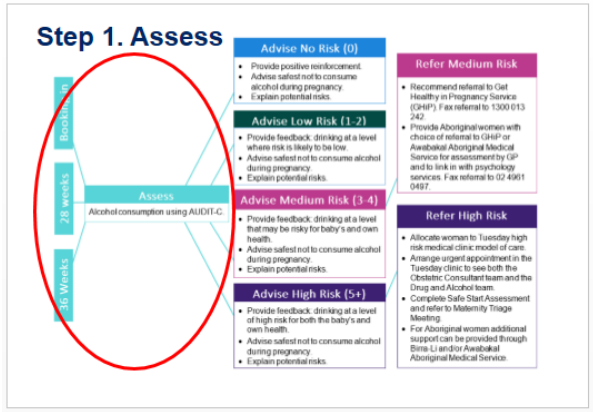
Current level of care provided in JHH Maternity Services – Subsequent visits (N=516)

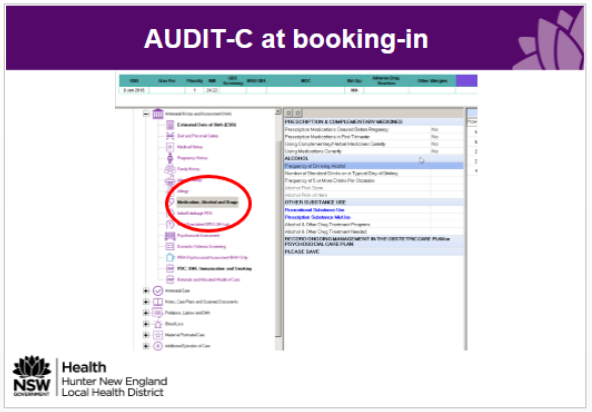


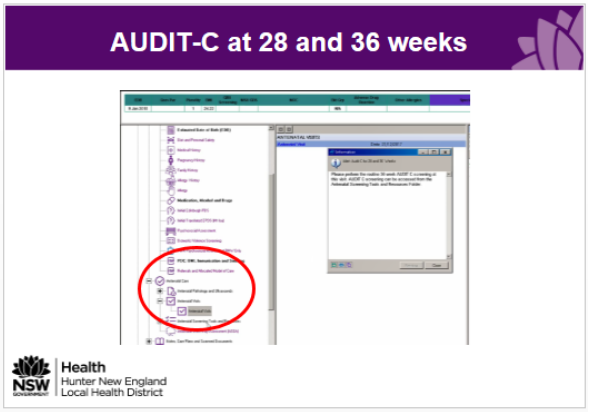

Acceptability of care in JHH Maternity Services (N=983)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
98%
89%
99%
99%
99%
99%
Ask
Ask on multiple occasions
Advised safest not to drink
Advised of potential risks
Offered referral to telephone coaching if required
Offered referral to Drug & Alcohol if required


New Guideline and Procedure
Guideline and Procedure
Health
Hunter New England
Local Health District
Maternity – Screening and management of alcohol consumption during pregnancy
Go to Procedure


WHAT we need to do as part of the Guideline & Procedure for Screening and Management of Alcohol Consumption in Pregnancy
Health
Hunter New England
Local Health District


Step 1. Assess
Booking
28 weeks
36 Weeks
Assess
Alcohol consumption using AUDIT-C
Advise No Risk (0)
Provide positive reinforcement.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise Low Risk (1-2)
Provide feedback: drinking at a level where risk is likely to be low.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise Medium Risk (3-4)
Provide feedback: drinking at a level that may be risky for baby's and own health.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise High Risk (5+)
Provide feedback: drinking at a level of high risk for both the baby's and own health.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Refer Medium Risk
Recommend referral to Get Healthy in Pregnancy Service (GHIP). Fax referral to 1300 013 242
Provide Aboriginal women with choice of referral to GHIP or Awabakal Aboriginal Medical Service for assessment by GP and to link in with psychology services. Fax referral to 02 4961 0497.
Refer High Risk
Allocate woman to Tuesday high risk medical clinic model of care.
Arrange urgent appointment in the Tuesday clinic to see both the Obstetric Consultant team and the Drug and Alcohol team.
Complete Safe Start Assessment and refer to Maternity Triage Meeting.
For Aboriginal women additional support can be provided through Bima-Li and/or Awabakal Aboriginal Medical Service.


AUDIT-C at booking-in
Health
Hunter New England
Local Health District


AUDIT-C at 28 and 36 weeks
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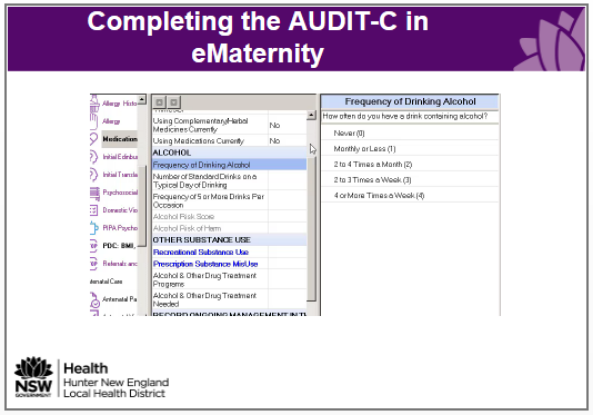
Completing the AUDIT-C in eMaternity
Frequency of Drinking Alcohol
How often do you have a drink containing alcohol?
Never (0)
Monthly or Less (1)
2 to 4 Times a Month (2)
2 to 3 Times a Week (3)
4 or More Times a Week (4)
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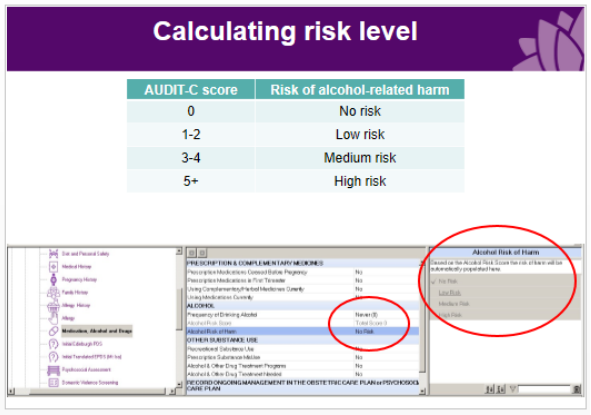
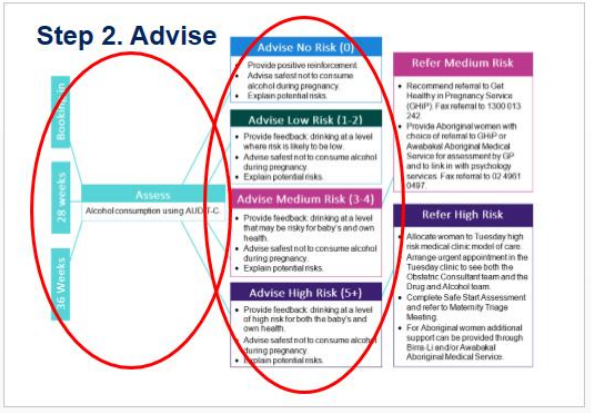
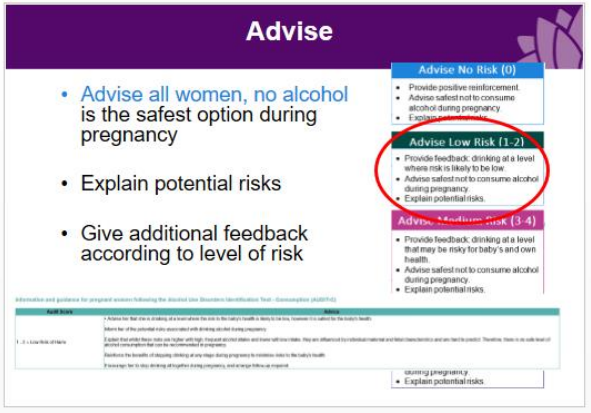
Standard Drinks Guide
Standard drinks guide
Health
Hunter New England
Local Health District


Calculating risk level
AUDIT-C score
Risk of alcohol-related harm
0
No risk
1-2
Low risk
3-4
Medium risk
5+
High risk


Step 2. Advise
Assess
Alcohol consumption using AUDIT-C
Advise No Risk (0)
Provide positive reinforcement.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise Low Risk (1-2)
Provide feedback: drinking at a level where risk is likely to be low.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise Medium Risk (3-4)
Provide feedback: drinking at a level that may be risky for baby's and own health.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise High Risk (5+)
Provide feedback: drinking at a level of high risk for both the baby's and own health.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Refer Medium Risk
Recommend referral to Get Healthy in Pregnancy Service (GHIP). Fax referral to 1300 013 242.
Provide Aboriginal women with choice of referral to GHIP or Awabakal Aboriginal Medical Service for assessment by GP and to link in with psychology services. Fax referral to 02 4961 0497.
Refer High Risk
Allocate woman to Tuesday high risk medical clinic model of care. Arrange urgent appointment in the Tuesday clinic to see both the Obstetric Consultant team and the Drug and Alcohol team.
Complete Safe Start Assessment and refer to Maternity Triage Meeting.
For Aboriginal women additional support can be provided through Birra-Li and/or Awabakal Aboriginal Medical Service.


Advise
Advise all women, no alcohol is the safest option during pregnancy
Explain potential risks
Give additional feedback according to level of risk
Advise No Risk (0)
Provide positive reinforcement.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise Low Risk (1-2)
Provide feedback: drinking at a level where risk is likely to be low.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.
Advise Medium Risk (3-4)
Provide feedback: drinking at a level that may be risky for baby's and own health.
Advise safest not to consume alcohol during pregnancy.
Explain potential risks.


Provide resources to women
STAY STRONG AND HEALTHY IT'S WORTH IT
No alcohol during pregnancy is the safest choice.
pregnancy & alcohol
Tips when out with friends
www.alcohol.gov.au
www.yourroom.com.au
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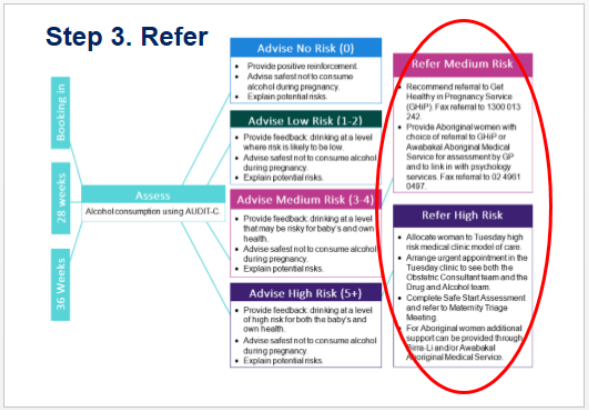

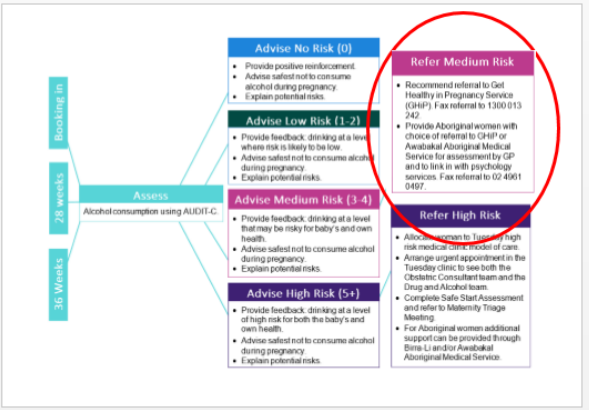

Get Healthy in Pregnancy

- Free telephone coaching service
- Goal = alcohol abstinence
- 10 individually tailored calls by qualified health coaches, tapered intensity
- If the woman is identified as Aboriginal origin on the referral form:

  A female Aboriginal Liaison Officer will explain the service & offer to attend the first call with the coach and the woman.

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Awabakal Medical Service

- For Aboriginal women give option of additional support through referral to the Awabakal Medical Service.
- Assessment by GP and to link in with Psychology service.

awabakal

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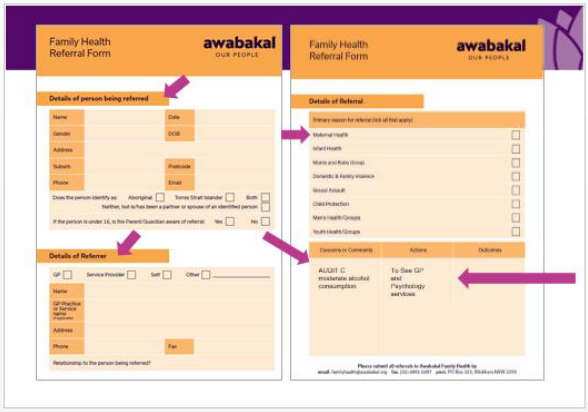

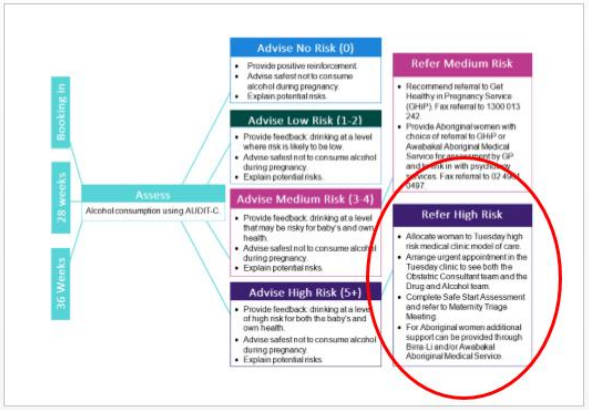
Booking in
28 weeks
36 Weeks
Assess
Alcohol consumption using AUDIT-C
Advise No Risk (0)
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Complete Safe Start Assessment and refer to Maternity Triage Meeting.
For Aboriginal women additional support can be provided through Birra-Li and/or Awabakal Aboriginal Medical Service.


HOW you will be support to undertake Screening and Management of Alcohol Consumption in Pregnancy
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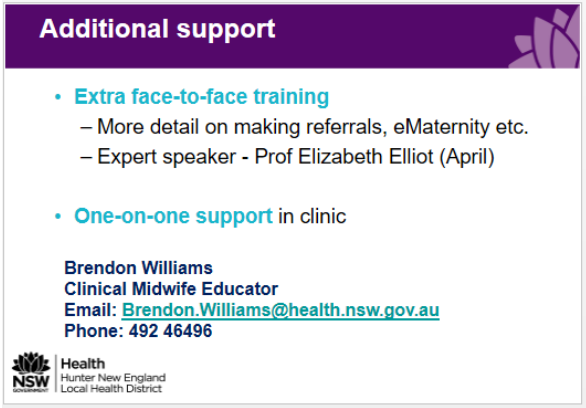
HETI
HEALTH EDUCATION & TRAINING
Antenatal Care for Alcohol Consumption During Pregnancy
START


Additional support
Extra face-to-face training
– More detail on making referrals, eMaternity etc.
– Expert speaker - Prof Elizabeth Elliot (April)
One-on-one support in clinic
Brendon Williams
Clinical Midwife Educator
Email: Brendon.Williams@health.nsw.gov.au
Phone: 492 46496
Health
Hunter New England
Local Health District


References
1. Hard ML, Einarson TR, Koren G: The role of acetaldehyde in pregnancy outcome after prenatal alcohol exposure. Ther Drug Monit 2001, 23(4):427-434.
2. Denkins YM, Woods J, Whitty JE, Hannigan JH, Martier SS, Sokol RJ, Salem N, Jr.: Effects of gestational alcohol exposure on the fatty acid composition of umbilical cord serum in humans. The American journal of clinical nutrition 2000, 71(1 Suppl):300s-306s.
3. Siler-Khodr TM, Yang Y, Grayson MH, Henderson GI, Lee M, Schenker S: Effect of ethanol on thromboxane and prostacyclin production in the human placenta. Alcohol 2000, 21(2):169-180.
4. Miyake Y, Tanaka K, Okubo H, Sasaki S, Arakawa M: Alcohol consumption during pregnancy and birth outcomes: the Kyushu Okinawa Maternal and Child Health Study. BMC Pregnancy & Childbirth 2014, 14:79.
5. O'Leary CM: Fetal alcohol syndrome: diagnosis, epidemiology, and developmental outcomes. J Paediatr Child Health 2004, 40(1-2):2-7.
6. Ahmed-Landeryou MJ: Fetal central nervous system development and alcohol--the evidence so far. Fetal Pediat Pathol 2012, 31(6):349-359.
7. Aliyu MH, Lynch ON, Belogolovkin V, Zoorob R, Salihu HM: Maternal alcohol use and medically indicated vs. spontaneous preterm birth outcomes: a population-based study. Eur J Public Health 2010, 20(5):582-587.
8. Avalos LA, Roberts SC, Kaskutas LA, Block G, Li DK: Volume and type of alcohol during early pregnancy and the risk of miscarriage. Substance Use & Misuse 2014, 49(11):1437-1445.
9. Donald KA, Roos A, Fouche JP, Koen N, Howells FM, Woods RP, Zar HJ, Narr KL, Stein DJ: A study of the effects of prenatal alcohol exposure on white matter microstructural integrity at birth. Acta Neuropsychiatr 2015, 27(4):197-205.
10. National Health and Medical Research Council: Australian Guidelines to Reduce Health Risks from Drinking Alcohol. In. Canberra: Commonwealth of Australia; 2009.
11. Australian Institute of Health and Welfare: National Drug Strategy Household Survey detailed report 2016. Drug statistics series no 31. Cat. no. PHE 214. In. Canberra, Australia: AIHW; 2017.
12. Payne JM, Elliott E, D'Antoine HA, al e: Health professionals' knowledge, practice and opinions about fetal alcohol syndrome and alcohol consumption in pregnancy. Aust NZ J Public Health 2005, 29:558-564.
13. Elliott E, Payne JM, Haan E, al e: Diagnosis of fetal alcohol syndrome and alcohol use in pregnancy: a survey of paediatricians' knowledge, attitudes and practice. J Paediatr Child Health 2006, 42:698-703.

Education presented by FASD subject matter expert

SCREENING FOR AND MANAGEMENT OF ALCOHOL CONSUMPTION DURING PREGNANCY

Elizabeth Elliott AM FAHMS
Professor of Paediatrics and Child Health, Sydney Medical School
Consultant Paediatrician, Sydney Children's Hospitals Network,
NHMRC MRFF Practitioner Fellow
Peel Sector, November 2018

Acknowledgement of Country

I acknowledge the *Kamilaroi* people - the traditional owners of the land on which we meet – and pay my respects to Elders, past and present and acknowledge any Aboriginal people in the room today

NHMRC Partnership Project, 2016-19
HNELHD, NSW Health, Uni Newcastle, Uni Syd, FARE
CIA John Wiggers, CIB Elizabeth Elliott

- **Aim:** Achieve health practice change
- **Method:** 3 pubic hospital antenatal services
- **Intervention:** evidence-based practice change strategy
  - Training staff, performance feedback
  - system prompts to HP to assess, advise about alcohol use, treat and refer *(e-maternity)*
- **Outcomes:**
  - HP best practice care related to alcohol
  - Are women asked, advised, referred?

Why participate in the Practice Change?

- Alcohol use in pregnancy is common
- Alcohol harms the woman, unborn child, offspring with lifelong consequences
- Women don't know about harms
- HP don't ask women about alcohol use, don't know how to ask
- HP unaware of harms, and don't know what to advise, where to refer
- Health care practice can be changed – interventions decrease alcohol consumption, increase abstinence

ALCOHOL USE IN PREGNANCY IS COMMON

Alcohol use is common in pregnancy

- **WHO: 10% drink in pregnancy**
- Up to 25% in Europe *(Popova, Lancet 2017)*
- **National household survey Australia (2016)**
  - 49% before, 25% after pregnancy awareness (↑2010)
  - Older women, higher SES & education continue

Alcohol use in pregnancy is common

- **High risk Aboriginal communities**
  - 55% high risk drinking *(Fitzpatrick, DAR 2015)*
- **NSW 2000-6: 417,464 pregnancies**
  - 0.1% had ≥ 1alcohol-related admission in pregnancy
  - 1/5 first presented on day of delivery
  - 0.8 urban vs. 1.8/1000births in regional/remote

(Burns, ACER 2011)

Assessing Alcohol intake

- Type
- Volume
- Timing
- Frequency
- Number of drinks on 'typical' occasion
- Estimated standard drink (10g alcohol) per occasion
- Occasions of >6 drinks

- **Audit-C to score 'risk'**

Fitzpatrick et al. Alcohol Drugs Review, 2014

Alcohol use in pregnancy is common

- **AQUA Victoria (n=1570 women)**
  - 59% drank in pregnancy
  - 18% 'binged' pre-aware, "special occasion" *(Muggli, BMCPH 2016)*
- **Triple B NSW, WA (n=1403) women**
  - 61% drank before pregnancy recognition *(McCormack, ACER 2017)*

ALCOHOL HARMS THE WOMAN, UNBORN CHILD AND OFFSPRING WITH LIFELONG CONSEQUENCES

Alcohol use in pregnancy: obstetric and neonatal outcomes

- Late booking >20 weeks (30% versus 10%)
- Not booked on delivery day (16% vs 3%)
- LSCS (70% vs 63%)
- Preterm (18% vs 6%)
- Small for Gestational Age (35% vs 9%)
- low 5m Apgar (6% vs 2%)
- Transfer NICU or special care (8% vs 2%)
- Maternal dependency/injury/poisoning *(Burns, 2011)*
- Stillbirth *(O'Leary, BJOG 2012)*
- SGA, Prematurity ≤32g/w *(Mamluk, BMJ Open 2017)*

Alcohol use in pregnancy: maternal outcomes

Risk of alcohol-related
- acute injury
- chronic disease
- Cancers
- General health, nutrition
- Mental ill-health

Benefit of
- treatment alcohol misuse/dependency
- Prevention of prenatal alcohol exposure in subsequent pregnancies

Alcohol in pregnancy: harm to the embryo & fetus

Maternal blood alcohol = fetal blood alcohol

Alcohol is Teratogenic
Harm depends on alcohol dose, frequency, timing, maternal and fetal factors; risk not predictable; no safe level; harm prior to pregnancy recognition

Effects of alcohol exposure

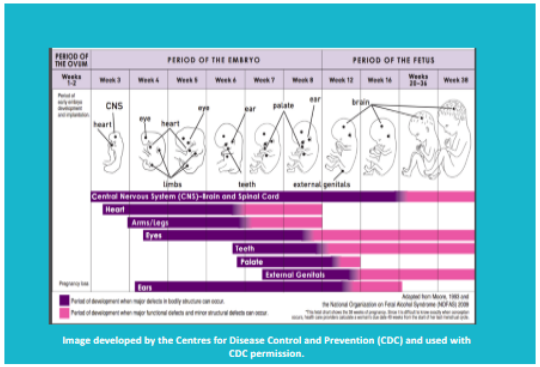


Image developed by the Centres for Disease Control and Prevention (CDC) and used with CDC permission.

Any child exposed prenatally to alcohol is potentially at risk of harm.....

.....we have a drinking culture, binge drinking in teens, unplanned pregnancy, alcohol use in pregnancy.....

Alcohol use in pregnancy: child outcomes

- Birth defects, Cerebral palsy, language delay, Intellectual disability, SIDS, somatic complaints, anxiety and depression *(O'Leary, WA)*
- Alcohol responsible for 1.3% of preventable disability in non-ATSI, 16% ATSI
- Microcephaly *(Jansen, 2017)*
- **Fetal Alcohol Spectrum Disorder**

Alcohol use in pregnancy: secondary outcomes in childhood

- Contact with child protection or justice system
- out of home care
- poor school attendance
- poor academic achievement
  (Hafekost, data linkage WA, 2017)

Alcohol use in pregnancy: harms to Others

- 22% of Australian children harmed as a result of someone else's drinking
- FASD is the ultimate harm

FETAL ALCOHOL SPECTRUM DISORDER

Fetal Alcohol Spectrum Disorder: an acquired brain injury with severe, pervasive ND impairment

FASD
ND impairment + 3 sentinel facial features (=FAS)
1st trimester (+/- birth defects)

FASD
Neurodevelopmental impairment <3 sentinel facial features (=pFAS, ARND, ND-AE)

+/- birth defects
+/- growth failure

Fetal Alcohol Spectrum Disorder

Alcohol exposure

- **CNS: Structural change**
- **CNS: Dysfunctional**
- **Growth failure**
- **Abnormal Face**
- **Other physical anomalies**
- **Behavioural problems**
- **Learning difficulties**
- **Developmental delay**

FASD (+/- 3 sentinal facial)

FASD: adverse lifelong outcomes

Adult outcomes: Mental illness, substance abuse, sexuality problems, unemployment, dependent living, contact with justice system *(Streissguth)*

Economic and social burden of FASD : disability, education, community, justice, health, child protection systems

Juvenille justice 33%
Banksia Detention Centre (Bower)
19x risk; 60% Canada

Mortality: Mean age at death 34 (31-37y); suicide, accidents, poisoning, drugs, organ systems. *(Thanh, 2016)*

FASD PREVALENCE

High global FASD prevalence

- 8 FASD cases/1000 pop.
- 635,000 cases FASD pa.
- Leading cause ID, birth defects

Popova, Lancet 2016; JAMA Pediatrics 2017.

*Economic burden FASD (Popova, Canada)**

Health Care	$128.5 to $ 265 M
Diagnosis	$3.7 to $7.8 M
Speech Intervention	$77.1 to 153.3 M
Criminal Justice System	$394 M to 7.2 B
Youth in Foster care	$61.6 to 210.9 M
Special Education	$53.4 M
Loss of productivity	$556.1M to 2.4 B
Total	**$762 M to $10.5 B pa**

*FASD added to WHO Global Burden of Disease

FAS in Australia is under-recognised

Australian Paediatric Surveillance Unit: 2001- 4 (n=92)
Fetal Alcohol Spectrum Disorders 2014-

- 65% low birth weight; 36% preterm
- 53% microcephaly (26% at birth)
  - 7% diagnosed at birth
- 64% Indigenous;
- 60% out-of-home care
- 51% has an affected sibling
- 92% high risk exposure
- 75% exposed ≥ 1 drug plus alcohol

Elliott E, Payne J, Bower C, Haan E. Arch Dis Child 2007

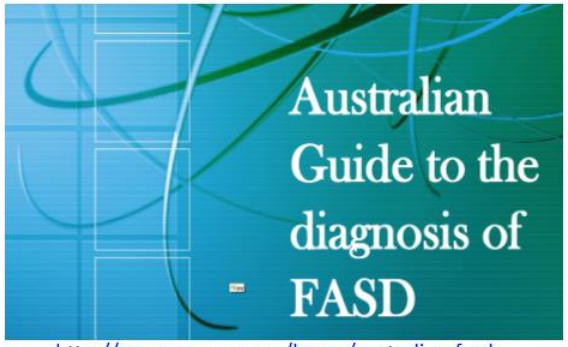
APSU FASD 2: 2014-17
Marcel Zimmet

- Epidemiology of full spectrum of FASD using new diagnostic guidelines
  - 302 case reports (258 met Dx criteria)
  - 36 paediatricians (70% from 4 clinics)
  - age Dx 6.3y
  - foster care 58%; both parents 20%
  - ATSI 56%
  - sibling affected 20%.
- Evaluate guidelines
- Ascertain cases for FASD register

The Lililwan study: population-based n=108, mean 8.7y, 7.4-9.6

High rates of:

- **FASD 1 in 5** **(19%)**
- FAS/pFAS (12%)
- ND-AE (7%)
- Physical problems
- Growth
- Behavioural problems
- Mental health
- IQ
- Memory
- Academic achievement
- Executive function
- speech and language
- Motor skills
- Mental health



http://www.apsu.org.au/home/australian-fasd-diagnostic-guidelines/
e-learning modules

2016

The CICADA Centre NSW: CHW 2015

Directors: Elizabeth Elliott, Sue Towns

Care and
Intervention for
Children
Adolescents affected by
Drugs
Alcohol

*Popi Iatrou

WOMEN DON'T KNOW ABOUT HARMS OF ALCOHOL

Women's knowledge and attitudes regarding alcohol use in pregnancy and FASD

- 1/3 unaware of the adverse effects
- 20% tolerant to alcohol use
- Drinking (35%) in pregnancy ***not*** associated with knowledge, education
- Drinking strongly associated with:
  - Neutral/tolerant **attitude** to alcohol in pregnancy
  - previous alcohol use in pregnancy
  - partner drinks
  - Smoking
  - currently drink at risky/harmful levels

Peadon, Payne, Bower, Elliott et al, 2008

Health Professionals' role

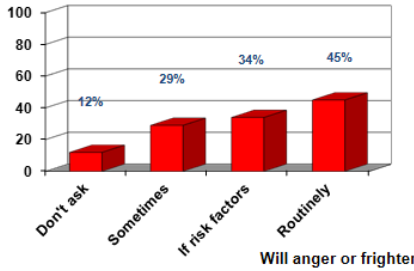
	Agree (%) (n=1103)
Health professionals should *ask* pregnant women about alcohol	96.9
Health professionals should *advise* women how many standard drinks are safe to drink during pregnancy	96.9
Health professionals should *advise women to give up drinking alcohol* during pregnancy	90.7

Peadon et al.

HEALTH PROFESSIONALS DON'T ASK ABOUT ALCOHOL USE, DON'T KNOW HOW TO ASK

HP don't ask/advise about alcohol use in pregnancy (n=659)

Contributes to under-diagnosis of FASD and missed opportunities for prevention



Payne, Elliott, Bower et al. ANZJPH 2005

Will anger or frighten 10%
"Easy" to ask 67%
25% information on harms

Why don't clinicians ask? CDU Perth

- Important to ask about alcohol use (82%)
- Confident to ask (42%)
- Questions
  - Judged, blamed, uncomfortable (64%)
  - impair relationship (46%)
  - no time (25%)
  - stressful (14%)
  - want a proven technique (86%)

Mutch R, Wray J, Bower C, 2012

DOH Funding 2017, 2018

https://www.fasdhub.org.au/

No FASD Australia

www.nofasd.org.au

Screening and management of maternal alcohol consumption in pregnancy HNE

All clinicians to undertake following for all women at booking visit, 28 weeks and 36 weeks:

1. **Assess:** alcohol use in pregnancy using AUDIT-C
2. **Advise:** not to consume alcohol throughout pregnancy and inform about risks of consuming
3. **Refer:** to further support based on risk level

Screening and management of maternal alcohol consumption in pregnancy HNE

- **HNELHD Guideline and Procedure:** for screening and management of alcohol consumption during pregnancy
- **eMaternity:** prompts for screening for alcohol consumption (AUDIT-C), brief advice and referral
- **Clinical support role:** Sophie Curtin (Clinical Midwife Educator) until April 2019.
- **Training:** online HETI module and face-to-face sessions
- **Resources:** laminated flowcharts in clinic rooms and pamphlets for women in booking in packs
- **Monitoring and feedback:** using eMaternity reports

Additional support

- **Extra face-to-face training**
  - Overview presentations (during November, December)
  - Additional upcoming sessions on making referrals, and using eMaternity (during January, February)
- **One-on-one support** in clinic

Sophie Curtin
Clinical Midwife Educator
Email: Sophie.Curtin@health.nsw.gov.au
Phone: 0436 018 454

NSW Health
Hunter New England
Local Health District

Interactive case study session facilitated by Clinical Midwife Educator

Screening and Management of Alcohol Consumption during Pregnancy

Assess, Advise, Refer and eMaternity

Brendon Williams
Clinical Midwife Educator

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Hunter New England
Local Health District

I would like to acknowledge the traditional owners of the land we are meeting on today and pay my respects to Elders, past, present, and future, and acknowledge any Aboriginal people in the room today

Scenario 1 – Ellen

Background
- 36 weeks gestation
- Previously reported no alcohol consumption

Today
- Routine appointment
- Currently drinking 1 bottle wine a night.
- Not coping and asking for help

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Local Health District

Assess

- eMaternity Walkthrough

Health
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Local Health District

Advise

- What advice would you give Ellen?

"Ideally you should not drink. But it is probably safe to have a few drinks a week at this stage. Just as long as you have an alcohol-free day occasionally."

"You are drinking at a level of high risk for both the baby's health and for your health. The risks to your baby's health increase with increasing amounts and frequency of alcohol consumption. These risks are often hard to predict as they are influenced by a woman's individual characteristics and those of her baby. Because of this, there is no safe level of alcohol consumption that can be recommended in pregnancy. Here is a leaflet about pregnancy and alcohol that you can take home to read later."

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Provide resources to women

Health
Hunter New England
Local Health District

Refer

- How would you refer Ellen?

Refer High Risk

- Allocate woman to Tuesday high risk medical clinic model of care.
- Arrange urgent appointment in the Tuesday clinic to see both the Obstetric Consultant team and the Drug and Alcohol team.
- Complete Safe Start Assessment and refer to Maternity Triage Meeting.
- For Aboriginal women additional support can be provided through Birra-Li and/or Awabakal Aboriginal Medical Service.

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Scenario 2 – Sandra

Background
- 28 weeks pregnant
- Reported no alcohol consumption at booking in

Today
- Drinking 1 glass of champagne a night
- Not concerned as its only one with dinner

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Hunter New England
Local Health District

Assess

- eMaternity Walkthrough

Health
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Local Health District

Advise

- What advice would you give Sandra?

"It is best not to drink any alcohol during pregnancy as we aren't able to say whether there is a safe level. Alcohol could affect your pregnancy, such as by bringing on early labour or effecting your baby's development. By stopping drinking at any stage during pregnancy you reduce risks to your baby's health. This Stay Strong and Healthy postcard provides some tips for saying no to alcohol when you are out with friends."

"You are a score of 3 on the AUDIT-C. This means you are classified as Medium risk."

Health
Hunter New England
Local Health District

Refer

- How would you refer Sandra?

Refer Medium Risk

- Recommend referral to Get Healthy in Pregnancy Service (GHiP). Fax referral to 1300 013 242.
- Provide Aboriginal women with choice of referral to GHiP or Awabakal Aboriginal Medical Service for assessment by GP and to link in with psychology services. Fax referral to 02 4961 0497.

awabakal
OUR PEOPLE

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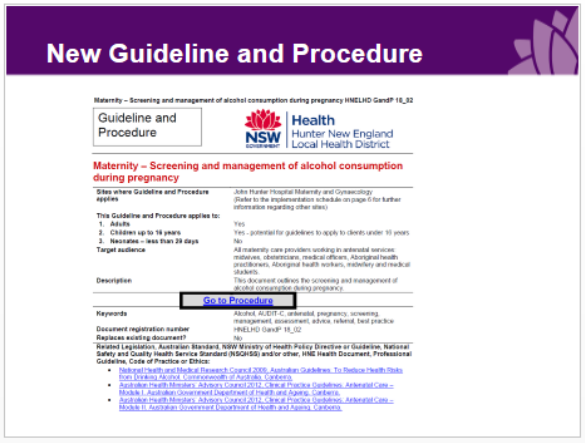
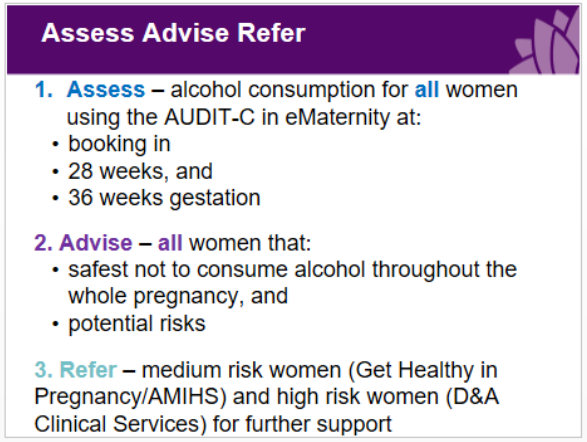
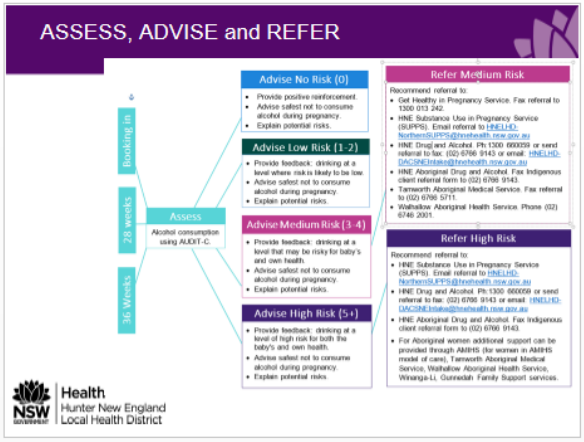
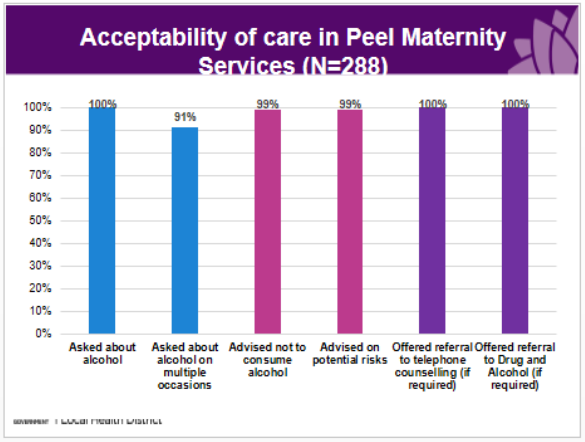
Local Health Distr

Final presentation delivered face-to-face by Clinical Midwife Educator









Ongoing training opportunities

- HETI online module - orange assigned learning pin

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Prompts/reminders to increase screening and care

Provide resources to women

www.alcohol.gov.au

www.yourroom.com.au

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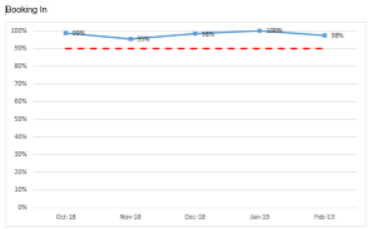
Current Progress since Guideline Change



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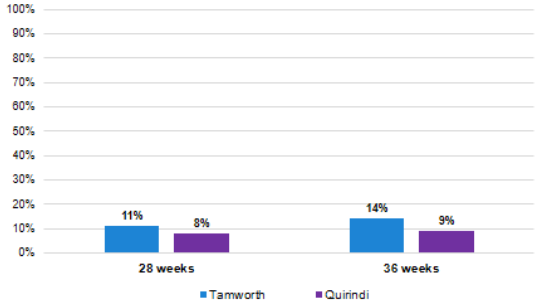
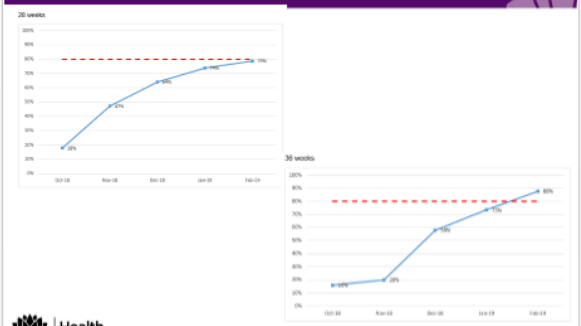
Initial level of assessment – Subsequent visits (Dec 17 – Sept 18)



Current Progress since Guideline Change



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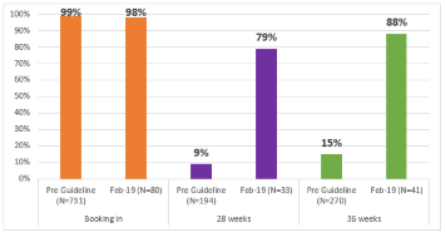
Progress Report Overview

AUDIT-C (eMaternity)



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Progress overview of Medical Staff

- 1st Audit – (11-14th Feb 1 week)
- 6 screened/ 29 eligible = 20% screening rate
- 2nd Audit – (18th Feb- 1st March 2wks)
- 10 screened / 50 Eligible = 20% screening rate
- 3rd Audit – (18th – 29th March 2 wks)
- 11 screened / 37 Eligible = 29%

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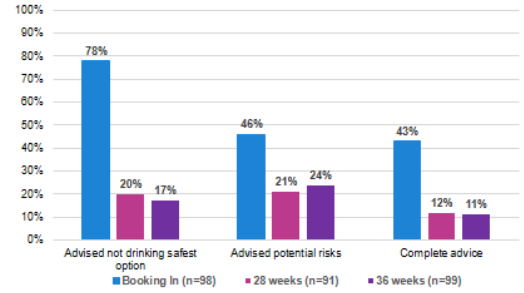
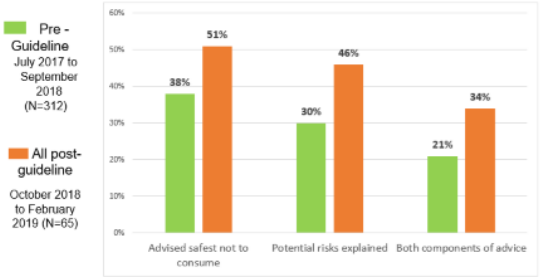
Level of advice (Jul 17 – Sept 18)



Improvement on Advice

Brief Advice (women's surveys)



Level of referral (June 17 – Sept 18)

	Number women identified at risk level	Referral/Care Pathway Documented & Accepted
Medium risk (AUDIT-C score 3-4)	13	1
High risk (AUDIT-C score 5 +)	5	0

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Current Level of Referral

Referrals (eMaternity October 2018 – February 2019)

- **Medium Risk** (AUDIT-C = 3-4)
  - Two women were identified as medium risk
  - Both women were offered a Get Healthy in Pregnancy referral
  - One woman accepted the referral.
- **High Risk** (AUDIT-C = 5+)
  - Four women identified as high risk
  - All of these women were offered Drug and Alcohol services
  - None of the women accepted the referral.

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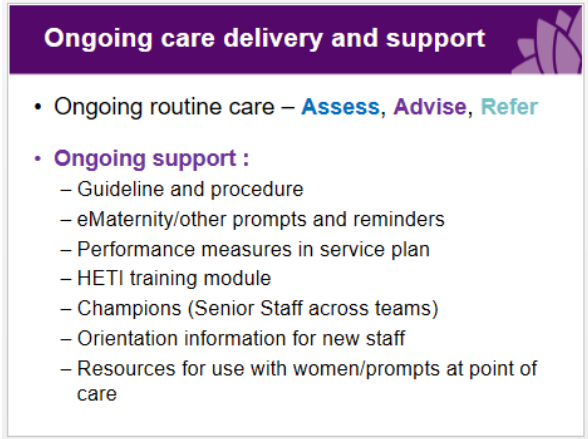
Ongoing care delivery and support
• Ongoing routine care – Assess, Advise, Refer
• Ongoing support :
– Guideline and procedure
– eMaternity/other prompts and reminders
– Performance measures in service plan
– HETI training module
– Champions (Senior Staff across teams)
– Orientation information for new staff
– Resources for use with women/prompts at point of care

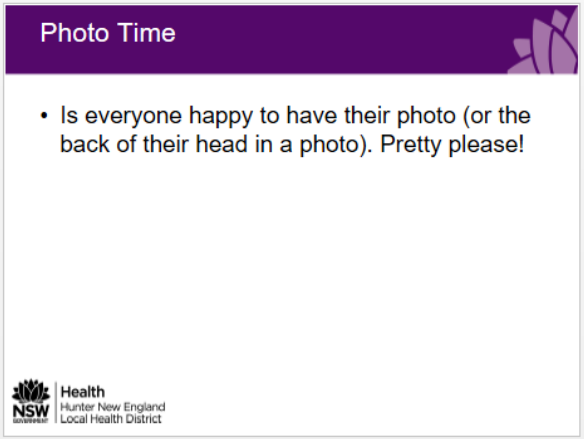
Photo Time
• Is everyone happy to have their photo (or the back of their head in a photo). Pretty please!
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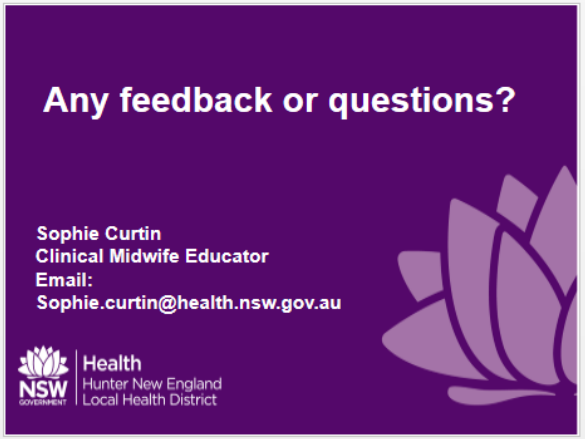
Any feedback or questions?
Sophie Curtin
Clinical Midwife Educator
Email:
Sophie.curtin@health.nsw.gov.au
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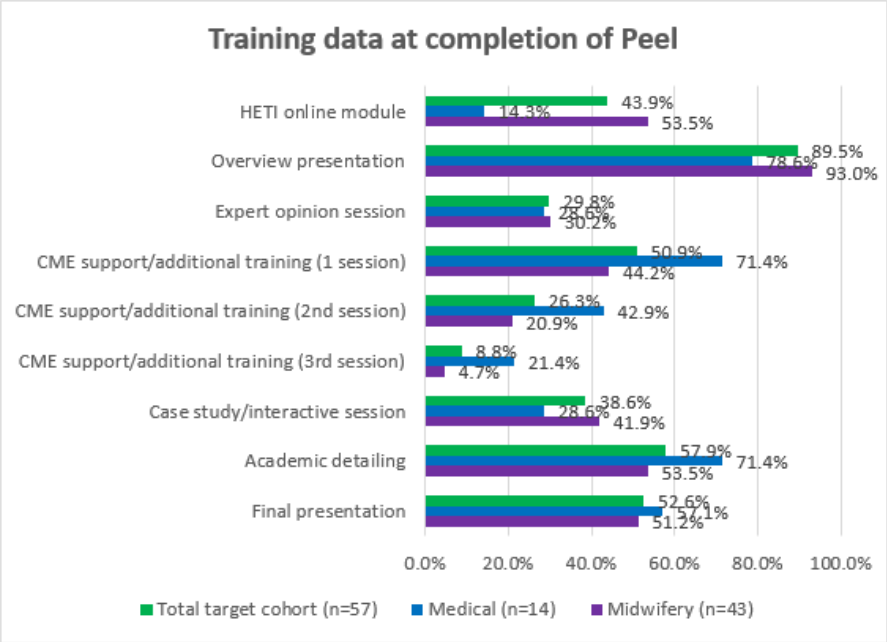
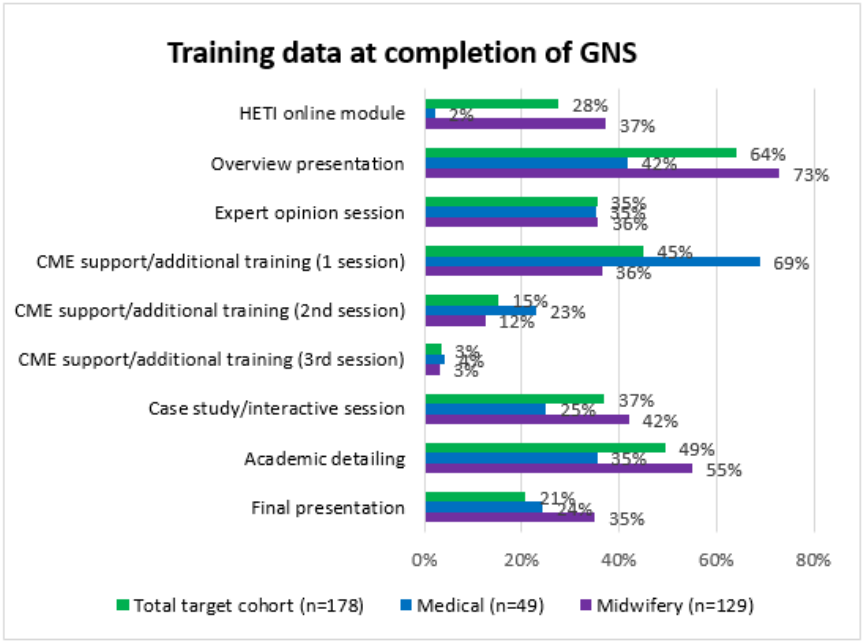
Example of report used to track completion of education by targeted maternity staff

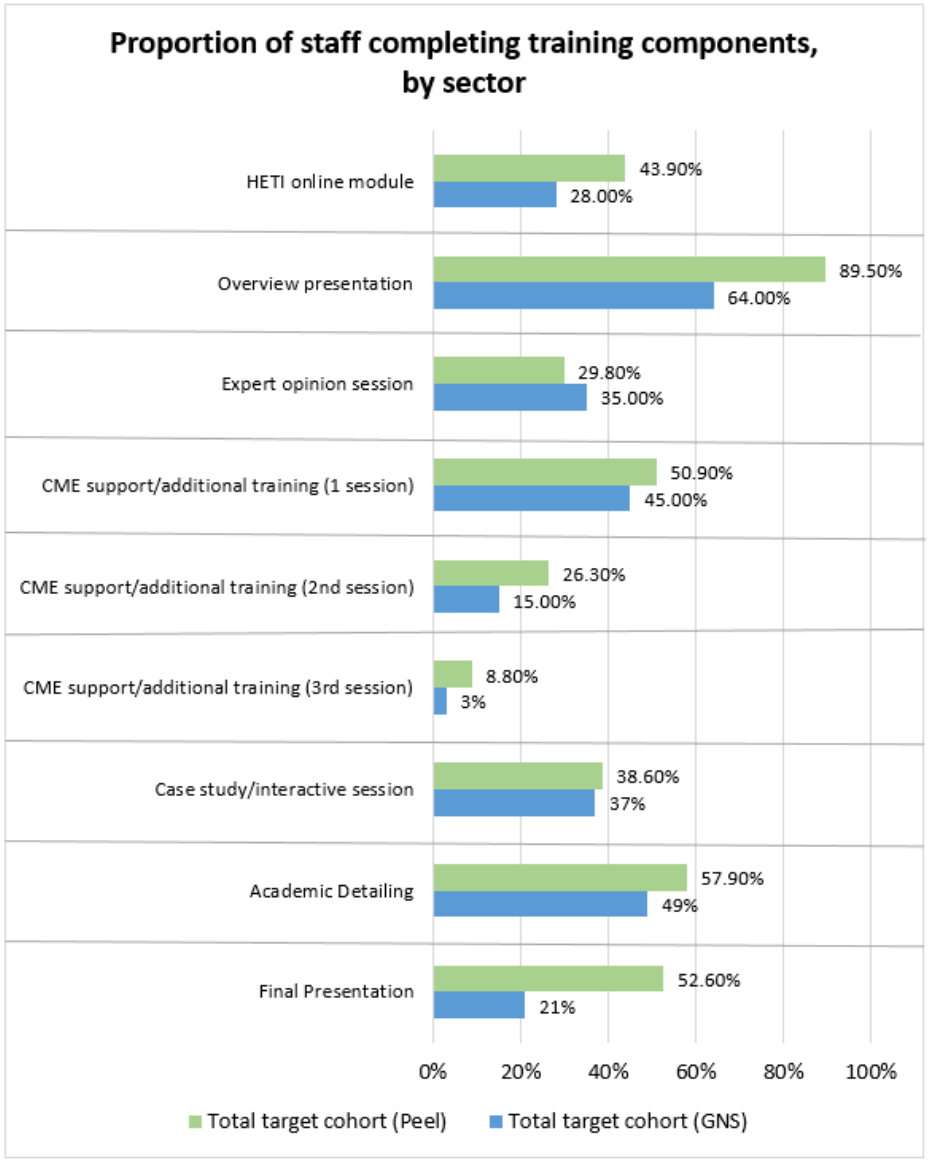
Screening and management of alcohol consumption in pregnancy: practice change initiative – Peel Sector

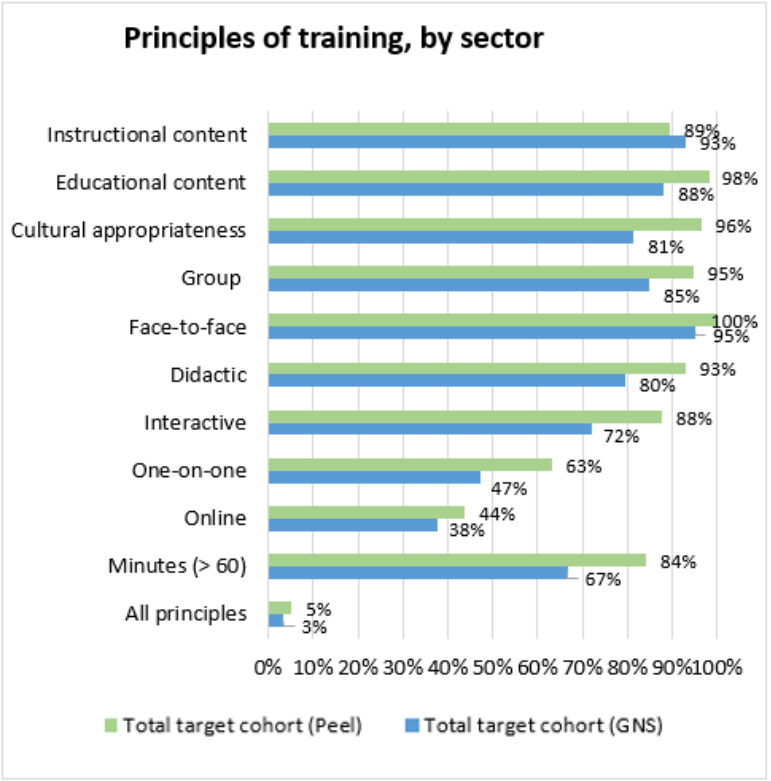
Training Tracking Report (03/05/2019)

The following graphs are based on a target cohort of **178 staff in the Greater Newcastle Sector** and **57 staff in the Peel Sector**:



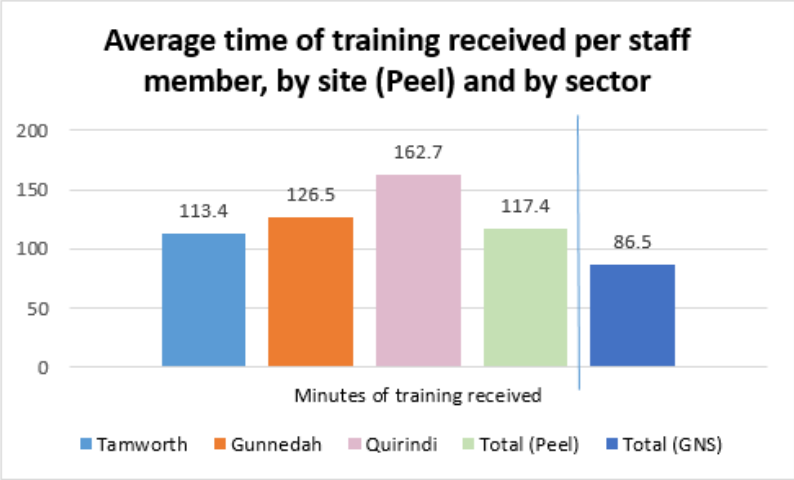


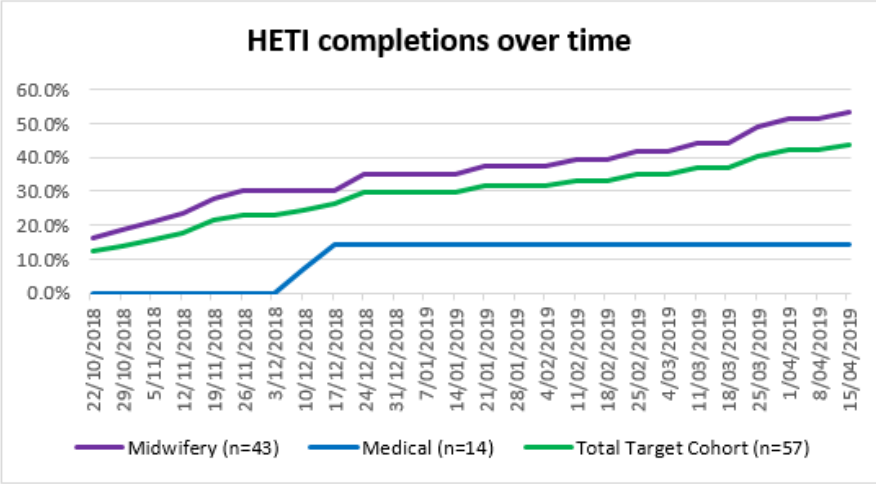

Proportion of staff completing training components, by sector
HETI online module
43.90%
28.00%
Overview presentation
89.50%
64.00%
Expert opinion session
29.80%
35.00%
CME support/additional training (1 session)
50.90%
45.00%
CME support/additional training (2nd session)
26.30%
15.00%
CME support/additional training (3rd session)
8.80%
3%
Case study/interactive session
38.60%
37%
Academic Detailing
57.90%
49%
Final Presentation
52.60%
21%
0%
20%
40%
60%
80%
100%
Total target cohort (Peel)
Total target cohort (GNS)


Principles of training, by sector
Instructional content
89%
93%
Educational content
98%
88%
Cultural appropriateness
96%
81%
Group
95%
85%
Face-to-face
100%
95%
Didactic
93%
80%
Interactive
88%
72%
One-on-one
63%
47%
Online
44%
38%
Minutes (> 60)
84%
67%
All principles
5%
3%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90%100%
Total target cohort (Peel)
Total target cohort (GNS)

2

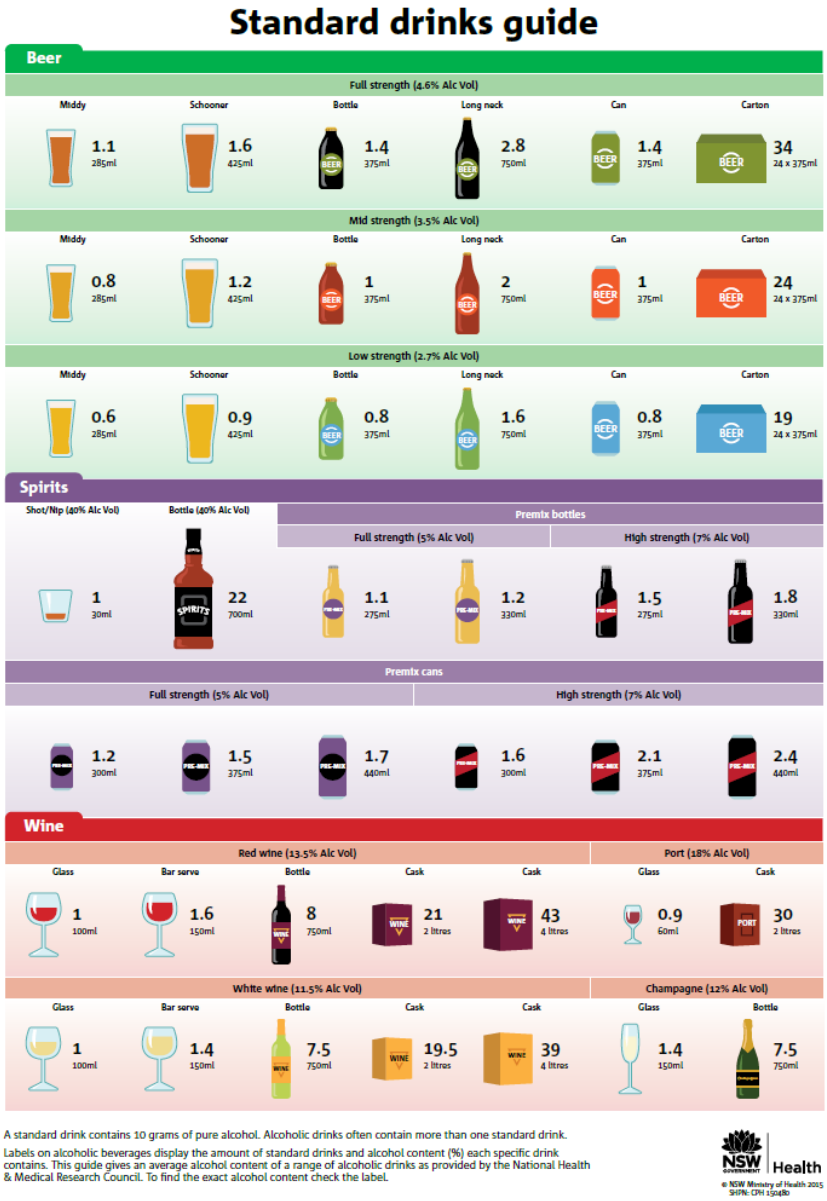
Peel target cohort (57 staff, 43 midwifery and 14 medical staff):

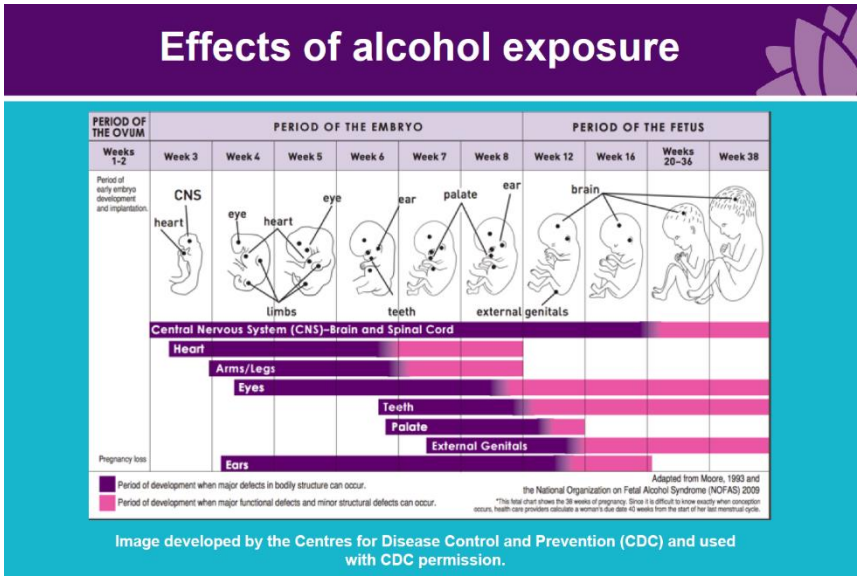


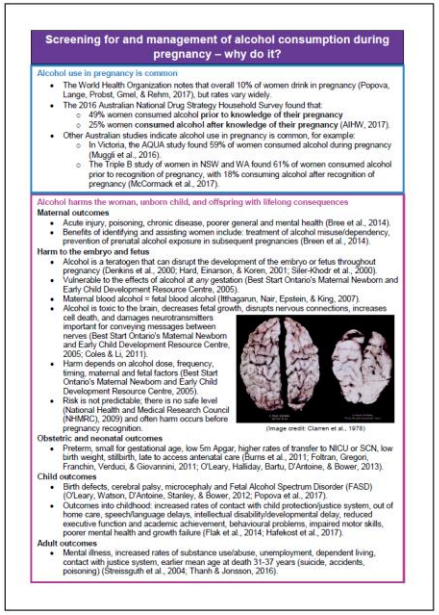


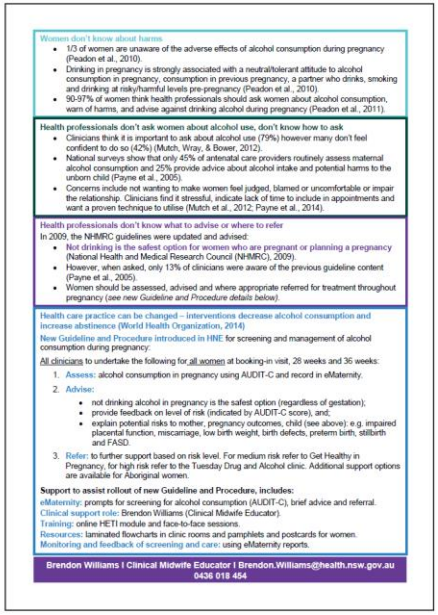
- Average length of training: 117.4 mins per individual clinician (range: 30 - Average length of training: 117.4 mins per individual clinician (range: 30 - 308 mins)
- **ALL staff** (n=57) have received at least 30 minutes of training.
- **84.2% of staff** (n=48) have received at least 60 minutes of training.
- 22 staff have completed the online HETI module (2 medical staff; 23 midwifery staff; 1 Gunnedah staff member; 1 Quirindi staff member; 23 Tamworth staff members).

APPENDIX 31. Educational materials strategy









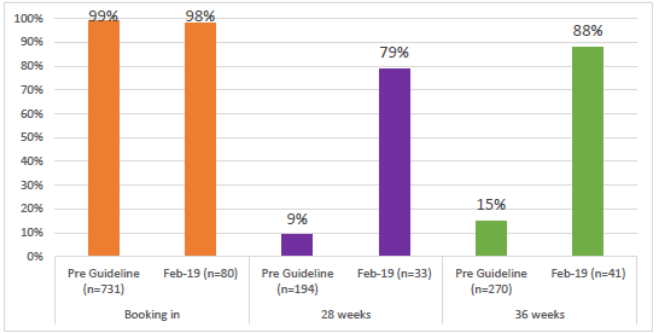
APPENDIX 32. Academic detailing, including audit and feedback, strategy

Screening and management of alcohol consumption during pregnancy
Guideline implementation feedback – Peel Sector

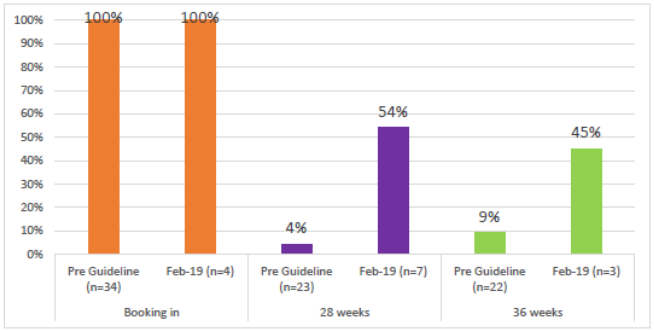
AUDIT-C (eMaternity)

Tamworth

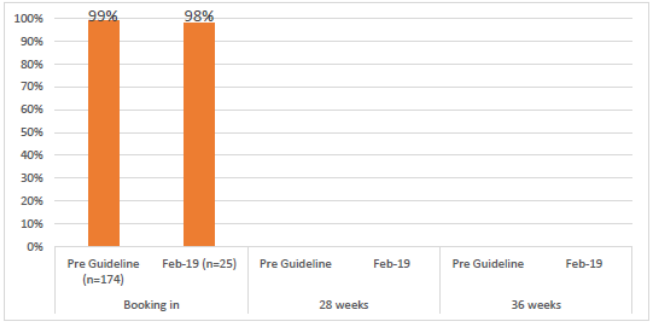
*Not all appointment at 28 and 36 weeks are recorded in eMaternity



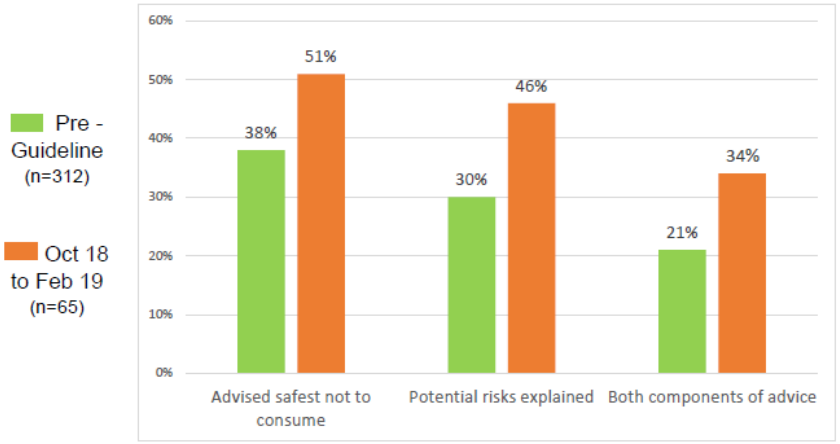
Quirindi



Gunnedah



Brief Advice (women's surveys)



Referrals (eMaternity. October 2018 – February 2019)

- **Medium Risk** (AUDIT-C = 3-4)
  - Two women were identified as medium risk (at booking in visits at Tamworth and Quirindi)
  - Both women were offered a Get Healthy in Pregnancy referral
  - One woman accepted the referral.

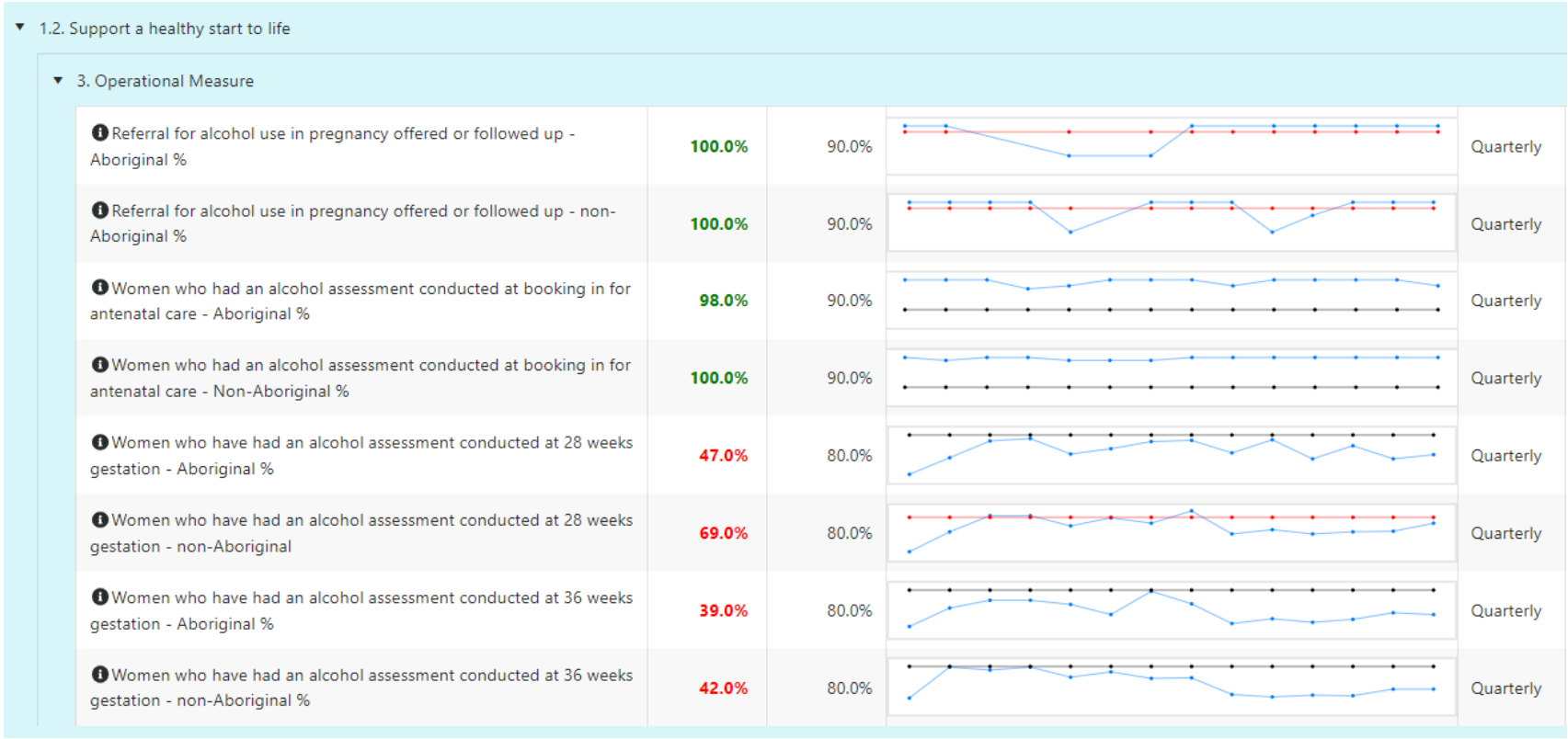
- **High Risk** (AUDIT-C = 5+)
  - Four women identified as high risk (three at booking in at Tamworth, one at Quirindi at 28 weeks gestation)
  - All of these women were offered Drug and Alcohol services
  - None of the women accepted the referral.

Name of Participant: All sessions summarised **Date: 13/08/2018**

MODEL OF CARE		BARRIER DISCUSSION	DISCUSSED ACTIONS
Model of care	**Model of care - characteristics**	**Potential barriers –** environment (eMaternity, resources, time, fitting into appointment type), knowledge/skills, confidence, motivations/beliefs/attitudes, management and peer support	**Feedback discussed** – discussed actions to improve quality of care and timeframe.
Assess	☐Booking In	Typically no barriers (single and group sessions) One instance where clinician noted 'abuse' – women don't like being asked about alcohol (1 comment) Time in clinic appointment not length of screening (all time points; 1 comment)	Typically no actions
	☐28 weeks	Difficult to complete/forgot to complete prior to upgrade (multiple comments) Pop up too early in appointment (1 comment) Lots of screening at 28 and 36 weeks so sometimes gets missed (1 comment) Late education due to being casual (1 comment) Remembering to screen (1 comment)	eMaternity upgrade resolved technical difficulties in completing AUDIT-C Belmont group session noted lack of clinician awareness that the error had been fixed. Stickers help and wheel also is user friendly. Clinician would like to see this changed to an appointment where less screening occurs Stickers help
	☐36 weeks	No barriers for self. Barrier for new staff only 1 day at orientation Lots of screening at 28 and 36 weeks so sometimes gets missed (1 comment) Patient upset about being asked/ embarrassed to disclose to Dr (1 comment)	Update orientation pack. Clinician would like to see this changed to an appointment where less screening occurs
Advise	☐Safest not to consume ☐Potential risks	Skill set more education around counselling women (group session). Only advising women who drink (3 comments). Given advise from GPs that small amounts of alcohol is ok and combating conflicting advice (1 comment). If time is a factor brief advice is the first to go. Time at 36 weeks, lots in this appointment (2 comment) Don't always tell women why (1 comment) Was unsure of referral pathway. Midwife does not feel qualified to counsel women on alcohol (1 comment) Difficulty delivering information without sounding judgemental (1 comment) Previous no education prior to this institute. Misinformation from previous education or old guidelines (1 comment) Confidence on potential risks (1 comment) Continuity might be first time have seen patient so less rapport built (1 comment)	Education by BW and referred to HETI. Education provide by BW to advise all women. Possible education to GPs? Education around myths

		Assumption that woman have already been told (1 comment)	
Refer	☐Get Healthy in Pregnancy ☐ Drug and Alcohol ☐ Awabakal	**GHiP** No feedback from referral as dont always get to follow (1 comment) Some distrust in the service (group session) Women prefer face to face (group session) Women don't have time to sit on the phone (1 comment) Women who drink at medium risk dont feel comfortable disclosing again to a third party (**GHiP**) however no barriers to **D&A** (1 comments). More information about the service and what is offered (multiple comments) Not as likely to offer GHiP because of client non compliance and distrust in service capability and patient motivation to access (1 comment). **D&A** Typically no barriers to referring to D&A (multiple comments) **All** Want for further education in what the services offer/referral pathways (multiple comments) Don't feel like have engaged skills to combat when women decline referral on where to go from that point (group session) No current referrals (1 comment) Sometimes women would like to self-refer and this is not followed through (1 comment) Women don't have time to sit on the phone (1 comment) Dont want to force referral as may damage relationship (1 comment)	Education by BW re: what the services offer and re: ability to refer to D&A if a woman prefers, importance of referral.

Appendix 33. Monitoring and accountability for performance strategy



▼ 1.2. Support a healthy start to life

▼ 3. Operational Measure

Referral for alcohol use in pregnancy offered or followed up - Aboriginal %	100.0%	90.0%		Quarterly
Referral for alcohol use in pregnancy offered or followed up - non-Aboriginal %	100.0%	90.0%		Quarterly
Women who had an alcohol assessment conducted at booking in for antenatal care - Aboriginal %	98.0%	90.0%		Quarterly
Women who had an alcohol assessment conducted at booking in for antenatal care - Non-Aboriginal %	100.0%	90.0%		Quarterly
Women who have had an alcohol assessment conducted at 28 weeks gestation - Aboriginal %	47.0%	80.0%		Quarterly
Women who have had an alcohol assessment conducted at 28 weeks gestation - non-Aboriginal	69.0%	80.0%		Quarterly
Women who have had an alcohol assessment conducted at 36 weeks gestation - Aboriginal %	39.0%	80.0%		Quarterly
Women who have had an alcohol assessment conducted at 36 weeks gestation - non-Aboriginal %	42.0%	80.0%		Quarterly