Improving Health Providers' Management of Smoking in Australian Indigenous Pregnant Women

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A thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy in Behavioural Science in Relation to Medicine

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School of Medicine and Public Health

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Declaration

I hereby certify that the work embodied in the thesis is my own work, conducted under normal supervision.

The thesis contains published scholarly work of which I am a co-author. For each such work a written statement, endorsed by the other authors, attesting to my contribution to the joint work has been included.

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 in the text. 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.

Yael Bar-Zeev

31 October 2018

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List of Abbreviations

ACCHS	Aboriginal Community Controlled Health Services
AH&MRC	Aboriginal Health and Medical Research Council
AMS	Aboriginal Medical Services
BCT	Behaviour Change Technique
BCW	Behaviour Change Wheel
EPOC	Effective Practice of Care
FCTC	Framework Convention for Tobacco Control
GPs	General Practitioners
ICAN QUIT in Pregnancy	Indigenous Counselling And Nicotine QUIT in Pregnancy
NHMRC	National Health and Medical Research Council
NRT	Nicotine Replacement Therapy
NSW	New South Wales
NT	Northern Territory
Qld	Queensland
QFNL	Quit for New Life
RACGP	Royal Australian College of General Practitioners
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCT	Randomised Controlled Trials
SCAAP	Stakeholder and Consumer Aboriginal Advisory Panel
SA	South Australia
TDF	Theoretical Domains Framework
WA	Western Australia
WHO	World Health Organization

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Paper Two

Bar-Zeev Y, Bonevski B, Gruppetta M, Twyman L, Atkins L, Palazzi K, Oldmeadow C, Gould GS. Clinician Factors Associated with Prescribing Nicotine Replacement Therapy in Pregnancy: A Cross-Sectional Survey of Australian Obstetricians and General Practitioners. *The Australian and New Zealand Journal of Obstetrics and Gynaecology.* 2018; 58(3):366-370. doi: 10.1111/ajo.12751.

Paper Three

Bar-Zeev Y, Skelton E, Bonevski B, Gruppetta M, Gould GS. Overcoming Challenges to Treating Smoking During Pregnancy – A Qualitative Analysis of Australian General Practitioners Barriers and Facilitators. *Under editorial review at Nicotine and Tobacco Research.*

Submitted version for thesis examination of: Bar-Zeev Y, Skelton E, Bonevski B, Gruppetta M, Gould GS. Overcoming Challenges to Treating Tobacco Use During Pregnancy – A Qualitative Study of Australian General Practitioners Barriers. *BMC Pregnancy and Childbirth* 2019; 19:61. doi: 10.1186/s12884-019-2208-8.

Paper Four

Bar-Zeev Y, Lim LL, Bonevski B, Gruppetta M, Gould GS. Nicotine Replacement Therapy for Smoking Cessation in Pregnancy – A Narrative Review. *The Medical Journal of Australia.* 2018; 208 (1): 46-51. doi: 10.5694/mja17.00446

Paper Five

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Paper Six

Bar-Zeev, Y., Bovill, M., Bonevski, B., Gruppetta, M., Reath, J., The ICAN QUIT in Pregnancy Pilot Group, Gould, GS. Assessing and Validating an Educational Resource Package for Health Professionals to Improve Smoking Cessation Care in Aboriginal and Torres Strait Islander Pregnant Women. *International Journal of Environmental Research and Public Health.* 2017, 14, 1148. doi: 10.3390/ijerph14101148.

Paper Seven

Bar-Zeev Y, Bonevski B, Bovill M, Gruppetta M, Oldmeadow C, Palazzi K, Atkins L, Reath J, Gould GS, The ICAN QUIT in Pregnancy Pilot Group. The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study Protocol: A Feasibility Step-Wedge Cluster Randomized Trial to Improve Health Providers Management of Smoking during Pregnancy. *BMJ Open.* 2017;7:e016095. doi: 10.1136/bmjopen-2017-016095.

Paper Eight

Bar-Zeev Y, Bovill M, Bonevski B, Gruppetta M, Oldmeadow C, Palazzi K, Atkins L, Reath J, ICAN QUIT in Pregnancy Pilot Group, Gould GS. Improving Smoking Cessation Care in Pregnancy at Aboriginal Medical Services: ICAN QUIT in Pregnancy Step-Wedge Cluster Randomized Pilot Study. *Under editorial review at BMJ Open.*

Synopsis

Globally, tobacco use is the leading cause of morbidity and mortality, causing an annual death rate of seven million people. In Australia, tobacco use is responsible for 9% of the total burden of disease. Smoking during pregnancy remains a significant public health problem for specific population groups, causing miscarriage, stillbirth, low birth weight and more. Psychosocial interventions such as behavioural counselling have been shown to be effective. Clinical guidelines in Australia recommend using the 5As approach: Ask about smoking status, Advise briefly to quit, Assess nicotine dependence and motivation to quit, Assist as needed (including behavioural counselling and nicotine replacement therapy [NRT] if required), and Arrange follow-up and referral to smoking cessation support services. NRT is recommended if the woman is unable to quit using only behavioural counselling, with oral NRT considered as first line.

Aboriginal and Torres Strait Islander pregnant women have the highest smoking rates in Australia at 43%, facing multiple barriers to quitting smoking, including lack of adequate support from health providers. Health providers also face many barriers to support pregnant women to quit smoking, on an individual and systematic organisational level. To date, very few interventions have tried to improve health providers' management of smoking with Aboriginal and Torres Strait Islander pregnant women. Those that have either did not use rigorous research methods or suffered from multiple implementation challenges.

The aim of this thesis was to explore health providers' practices regarding smoking cessation care during pregnancy, barriers to the provision of smoking cessation care and methods for improving health providers' care, and to test an evidence-based behaviour change intervention to improve health providers' provision of smoking cessation care to pregnant Aboriginal and Torres Strait Islander women.

Papers one to five explore health providers' provision of smoking cessation care during pregnancy in general. Some data for Aboriginal and Torres Strait Islander pregnant women who smoke is also presented. The results of the first five studies were used to refine the development of a multi-component pilot intervention: the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention for implementation in Aboriginal medical services. Papers six to eight explore the development of the intervention resources, the intervention protocol and the effect of this intervention on

health providers' smoking cessation care. Three related theoretical frameworks were drawn on throughout the research: the Theoretical Domains Framework (TDF), Behaviour Change Wheel (BCW) and the COM-B (Capability, Opportunity, Motivation–Behaviour) model for behaviour change.

Paper one, "Opportunities Missed: A Cross-Sectional Survey of the Provision of Smoking Cessation Care to Pregnant Women by Australian General Practitioners and Obstetricians", presents the results of a national cross-sectional survey of 378 general practitioners (GPs) and obstetricians about their knowledge, attitudes and practices providing smoking cessation care to pregnant women. Data from this survey revealed low levels of provision of several smoking cessation care components ("Assess", "Assist" and "Arrange"), with only 15.6% of GPs and obstetricians reporting "often and/or always" performing all of the recommended 5As. Specifically, GPs and obstetricians reported that they lacked time, resources and confidence in their ability to prescribe NRT during pregnancy, and lacked optimism that their intervention would be effective.

Paper two, "Clinician Factors Associated with Prescribing Nicotine Replacement Therapy in Pregnancy: A Cross-Sectional Survey of Australian Obstetricians and General Practitioners", reports the results from the same cross-sectional survey mentioned in paper one, exploring GPs' and obstetricians' NRT prescribing rates and factors that might influence this. Overall, 25% of GPs and obstetricians reported "never" prescribing NRT, with nearly 50% reporting they would "never" prescribe combination NRT (NRT patch plus an oral NRT). GPs had higher odds of prescribing NRT compared to obstetricians. Other factors that significantly increased the odds of NRT prescription were reading the Royal Australian College of General Practitioners (RACGP) guidelines, confidence in their ability to prescribe NRT and viewing NRT as safe, effective and with good patient adherence.

Paper three, "Overcoming Challenges to Treating Smoking during Pregnancy – A Qualitative Analysis of Australian General Practitioners' Barriers and Facilitators", reports on semi-structured qualitative interviews that were conducted with 19 GPs, aiming to explore their management of smoking during pregnancy in greater depth and what would enable them to improve their smoking cessation support to pregnant women. GPs were recruited from the cross-sectional survey participants and from those attending a national GP conference. Participants reported they lacked communication

skills to provide pregnant patients adequate support for quitting, focusing on providing information on smoking harms and discussing treatment options only with patients who reported an interest in quitting. Lack of time, NRT cost, previous negative experiences with NRT and safety concerns, being unfamiliar with the Quitline process and uncertainty over its suitability (specifically for Aboriginal and Torres Strait Islander peoples) were all perceived as additional challenges. Participants reported needing clear detailed guidelines, with visual resources they could use to discuss treatment options with patients.

Paper four, "Nicotine Replacement Therapy for Smoking Cessation in Pregnancy – A Narrative Review", provides an overview of the current guidelines regarding NRT use in pregnancy, while considering the existing evidence base on NRT safety, efficacy and effectiveness during pregnancy. Animal models show that nicotine is harmful to the foetus, especially for brain and lung development, but human studies have not found any harmful effects on foetal and pregnancy outcomes. Previous studies have used NRT doses that might have been too low and not have adequately accounted for the higher nicotine metabolism during pregnancy, and thus not sufficiently treating withdrawal symptoms. Nonetheless, studies of efficacy and effectiveness in the real world suggest that NRT use during pregnancy increases smoking cessation rates. Current national clinical guidelines from Australia, the United Kingdom, New Zealand and Canada recommend that if women are unable to quit smoking with behavioural interventions alone, they should be offered NRT in addition to behavioural counselling. The guidelines also impose many restrictions on NRT prescription during pregnancy and do not provide practical detailed guidance on when to initiate NRT and how to titrate the dosage. Pragmatic suggestions for clinical practice are made, including an approach for initiating and titrating NRT dosage during pregnancy and for discussing the risks versus benefits of using NRT in pregnancy with the pregnant patient and her partner.

Paper five, "Improving Health Providers' Smoking Cessation Care in Pregnancy: A Systematic Review and Meta-Analysis", reviews the data from all published interventions aimed to improve health providers' smoking cessation care during pregnancy. To be included, the intervention studies needed to collect data on the health providers' performance. Overall, 16 studies describing 14 interventions were included – 10 used a quasi-experimental design (pre–post), with only six studies using a randomised controlled trial (RCT) design. Using the Cochrane Effective Practice of

Care (EPOC) taxonomy of intervention components, the review found that the median number of intervention components reported by studies was two (range 1–6). The most common intervention components used were training (93%, n=13), educational resources (64%, n=9) and reminders (57%, n=8). Studies used a variety of outcome measures, with different data collection methods (such as self-report through survey, women's report on the health providers' care, audit of medical records or recordings of medical consultations), affecting the ability to synthesise the data. Specifically, the "Assist" or "Provide smoking cessation support" component of care was ill defined with vast variability between studies. Meta-analysis of the different smoking cessation care components (according to the 5As) showed a small significant increase in the provision of all smoking cessation care components. The review suggests that use of a behaviour change theory to guide intervention development, and inclusion of audit and feedback, increases the likelihood of intervention effectiveness in improving health providers' provision of certain smoking cessation care components.

Paper six, "Assessing and Validating an Educational Resource Package for Health Professionals to Improve Smoking Cessation Care in Aboriginal and Torres Strait Islander Pregnant Women", describes a multi-centre community-based participatory research study. This study aimed to assess a collaboratively developed educational resource package to aid health providers' smoking cessation care in pregnant Aboriginal and Torres Strait Islander women. A panel of eight experts with complementary expertise provided input and suggestions to aid simplicity and usefulness of the resources. Staff members from three Aboriginal medical services in New South Wales (NSW), Queensland (Qld) and South Australia (SA) scored each of the patients' resources using the "Suitability of Material" scoring method, finding that all received adequate or superior scoring. Average readability was grade 6.4 for patient resources (range 5.1–7.2; equivalent to ages 10–13 years) and 9.8 for health provider resources (range 8.5–10.6; equivalent to ages 13–16 years). Content analysis from focus groups with health providers from the three Aboriginal medical services revealed four themes including "Getting the message right", "Engaging with family", "Needing visual aids" and "Requiring practicality under a tight timeframe". Results were presented back to a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP), and resources were adjusted accordingly for inclusion in the ICAN QUIT in Pregnancy multi-component intervention.

Paper seven, "The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study Protocol: A Feasibility Step-Wedge Cluster Randomized Trial to Improve Health Providers' Management of Smoking during Pregnancy", describes the protocol of a step-wedge cluster randomised pilot study: the ICAN QUIT in Pregnancy intervention. This protocol described an intervention aiming to improve health providers' provision of evidence-based, culturally responsive smoking cessation care to pregnant Aboriginal and Torres Strait Islander smokers. Six Aboriginal medical services were randomised into three clusters for implementation. Clusters received the intervention staggered by one month. The intervention included a three-hour training webinar for health providers, educational resource packages for health providers and pregnant women, free oral NRT for pregnant women and audit and feedback on health providers' performance. Health providers would complete a cross-sectional survey pre training and post training. Health providers' outcomes would include changes in self-reported knowledge, attitudes and practices after receiving the intervention.

Paper eight, "Improving Smoking Cessation Care in Pregnancy at Aboriginal Medical Services: ICAN QUIT in Pregnancy Step-Wedge Cluster Randomized Pilot Study", presents the pilot study outcomes of changes in health providers' knowledge, attitudes and practices. Of 93 eligible health providers, 50 consented to the trial (54%), 45 completed the pre-intervention survey (90%) and 20 completed the post-intervention survey (40%). About 42% (n=39) of health providers participated in the webinar training. Health providers' knowledge was measured using two composite scores – one calculated using all 24 true/false statements and the other derived from 12 NRT-specific statements. Mean knowledge composite scores improved significantly from pre to post (78% vs 84% correct, p=0.011). The mean NRT-specific knowledge composite score also improved significantly (68% vs 79% correct, p=0.004). Self-assessment of 24 attitudes to providing smoking cessation care was measured using a 5-point Likert scale (Strongly Disagree to Strongly Agree). Two composite mean scores were calculated – one for 15 general smoking cessation care attitudes and the other for seven NRT-specific attitudes. The mean attitude composite score improved significantly (3.65 [SD 0.4] to 3.87 [SD 0.4]; p=0.017). The mean NRT-specific attitudes composite score also improved significantly (3.37 [SD 0.6] to 3.64 [SD 0.7]; p=0.005). Self-reported provision of smoking cessation care components was measured on a 5-point Likert scale

(Never to Always); none of the practices improved significantly, including the prescribing of NRT.

In summary, increasing health providers' provision of smoking cessation care to pregnant Aboriginal and Torres Strait Islander women is a significant priority in Australia. This body of work highlights that currently, health providers are lacking in their provision of smoking cessation care, specifically in their support for pregnant Aboriginal and Torres Strait Islander women to quit smoking. Particularly, the provision of the "Assist" smoking cessation component was low, including the prescription of NRT. Multiple barriers exist and include lack of knowledge, skills (especially communication skills), time, resources and lack of optimism. Guidelines do not provide clear guidance, including the optimal timing for initiating NRT and titrating the dosage. The pilot intervention tested within this thesis showed promising initial results, with health providers significantly improving their knowledge and attitudes, although this did not translate into improved practices. Several strategies might enhance the effectiveness of the intervention and should be tested in a larger and adequately powered trial. The complex nature of tobacco smoking, and considering its historical and social context in Aboriginal communities, suggests that wider and more intensive interventions are needed.

Preface

Terminology

There are several different terminologies used to describe Indigenous status in research. In consultation with several Aboriginal academics, I have decided to use the full term of "Aboriginal and Torres Strait Islander peoples" throughout my thesis in honour and recognition of their distinct cultures. The term "Indigenous" is used to refer to all Indigenous populations globally. Within the thesis chapters that contain published (or submitted) manuscripts, and due to editorial constraints imposed by academic journals, I have used the term "Aboriginal" to refer to both Aboriginal and Torres Strait Islander peoples, describing that this refers to both peoples in recognition of their separate cultures.

Personal Background

Within Aboriginal and Torres Strait Islander health research, it is considered imperative to situate oneself. It is important for me to state that I am not Australian and not Aboriginal and/or Torres Strait Islander. I was born as a Jew in Israel and have lived in Israel most of my childhood and adult life. As a child, my family temporarily relocated to the United States for two and a half years and to Canada for one year (due to my parent's sabbatical). My life as a Jew in Israel has provided me with personal insight that has contributed to my understanding of the challenges ethnic minorities face. On the one hand, the Jewish people have a history of racism, genocide, fight for recognition for their own land and restitution of their own language; my own grandparents' history is from Poland and Russia prior to and during World War II, immigration to Palestine and fighting for the foundation of the Israeli state. On the other hand, I am living as a privileged person, part of the majority ethnic group in Israel, from a high socioeconomic background, in a country that has other ethnic minority groups who experience bias and discrimination. This personal background and experience has helped me, in a small way, to understand Aboriginal and Torres Strait Islanders' spiritual and historical connection to their land and culture and their plea for recognition, equal rights and fight against racism and discrimination; but it has also helped me to understand the unintentional bias, and misconceptions, and privilege that majority groups may hold.

My professional background is in medicine, specialising in public health, with a special interest in health promotion, tobacco control and smoking cessation. During my years as a medical student, and later on as a young physician, I underwent training to become a tobacco treatment specialist and have since been supporting smokers to quit using group behavioural therapy combined with pharmacotherapy. Together with a few colleagues, I founded the Israeli Medical Association for Smoking Cessation (which I currently chair). In the last few years, I have realised that the treatment options available in Israel are not sufficient to address the needs of specific high-priority populations, such as those dealing with mental health issues and pregnant women who smoke. During this time, I was also working as the scientific coordinator for the Israeli Healthy Cities Network, funded by the Israeli Ministry of Health, helping cities develop evidence-based health promotion interventions. I constantly felt that data was missing as to what works where, with whom and how, which could help guide the development and implementation of these interventions. Both of these experiences led me to decide to pursue an academic career and focus on research.

Throughout my career so far, I have developed training courses for various health professionals in smoking cessation, including novel courses in Israel for tobacco treatment specialists working with mental health patients and those working with ultra-orthodox Jewish men who smoke. This led to my specific interest in implementation science and how we can improve the support currently provided to smokers by health professionals in various health care settings.

The opportunity to pursue a PhD focusing on improving health providers' smoking cessation care among a vulnerable population, and focusing on pregnancy in a country (Australia) that is known as one of the world leaders in tobacco control, led me to relocate to Australia for two years with my husband and four kids. We have now relocated back to Israel, where I hope I can translate my acquired research skills and knowledge to help further improve smoking cessation care in general and for vulnerable populations.

Co-Authorship Declarations

Co-authorship declaration- Paper One

I attest that Research Higher Degree candidate **Yael Bar-Zeev** has contributed substantially for the following publication for which I am a co-author. For this publication, Yael was responsible for the ethics amendments, survey data entry, data cleaning, development of the analysis plan and performing the analysis independently, writing the manuscript and preparing it for publication.

Paper One Citation: Bar-Zeev Y, Bonevski B, Twyman L, Watt K, Atkins L, Palazzi K, Oldmeadow C, Gould GS. Opportunities missed: A Cross-Sectional Survey of the Provision of Smoking Cessation Care to Pregnant Women by Australian General Practitioners and Obstetricians. *Nicotine and Tobacco Research.* 2017: 19 (5); 636-641. doi: 10.1093/ntr/ntw331

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Paper Two Citation: Bar-Zeev Y, Bonevski B, Gruppetta M, Twyman L, Atkins L, Palazzi K, Oldmeadow C, Gould GS. Clinician Factors Associated with Prescribing Nicotine Replacement Therapy in Pregnancy: A Cross-Sectional Survey of Australian Obstetricians and General Practitioners. *The Australian and New Zealand Journal of Obstetrics and Gynaecology*. 2018; 58(3):366-370. doi: 10.1111/ajo.12751.

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Paper Three Citation: Bar-Zeev Y, Skelton E, Bonevski B, Gruppetta M, Gould GS. Overcoming Challenges to Treating Smoking During Pregnancy - A Qualitative Analysis of Australian General Practitioners Barriers and Facilitators. *Under editorial review at Nicotine and Tobacco Research.*

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Paper Four Citation: Bar-Zeev Y, Lim LL, Bonevski B, Gruppetta M, Gould GS. Nicotine Replacement Therapy for Smoking Cessation in Pregnancy – A Narrative Review. *The Medical Journal of Australia.* 2018; 208 (1): 46-51

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Paper Five Citation: Bar-Zeev Y, Bonevski B, Lim LL, Twyman L, Skelton, E, Gruppetta M, Palazzi K, Oldmeadow C, Gould GS. Improving Health Providers Smoking Cessation Care in Pregnancy: A Systematic Review and Meta-Analysis. *Under editorial review at Addictive Behaviors.*

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Paper Six Citation: Bar-Zeev, Y., Bovill, M., Bonevski, B., Gruppetta, M., Reath, J., The ICAN QUIT in Pregnancy Pilot Group, Gould, GS. Assessing and Validating an Educational Resource Package for Health Professionals to Improve Smoking Cessation Care in Aboriginal and Torres Strait Islander Pregnant Women. *International Journal of Environmental Research and Public Health.* 2017, 14, 1148. doi: 10.3390/ijerph14101148.

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Co-authorship declaration- Paper Seven

I attest that Research Higher Degree candidate **Yael Bar-Zeev** has contributed substantially for the following publication for which I am a co-author. For this publication, Yael was responsible for managing the entire process of gaining ethics approval from six different HREC committees in three different states, working closely with Aboriginal Community Control Health Services staff, community members and investigators to collaboratively develop the final study design, data collection tools and analysis plan, writing and preparing the manuscript for publication.

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Introduction

Part 1: Burden of Tobacco Use

1.1 Global Burden of Tobacco Use

One fifth (20.2%) of the world's population uses tobacco, with an estimated 1.1 billion current smokers.[1] Each year, seven million people die worldwide due to tobacco-related diseases, with more than 800,000 deaths due to second hand smoke exposure.[2] Despite these alarming figures, smoking has decreased worldwide by 4.1% since 2005 when the World Health Organization (WHO) Framework Convention for Tobacco Control (FCTC) came into force.[1] The highest reductions were observed in high-income countries, whereas a net increase in the number of smokers was evident in low and middle income countries.[1]

1.2 Health Effects of Tobacco Use

Tobacco negatively impacts all organs and systems in the human body.[3] Extensive research over the last few decades has shown substantial negative health effects,[3] and new research discovering yet more negative health effects is emerging. Although all types of tobacco use are harmful, the most prominent form, causing most of the negative health effects, is smoking tobacco.

Mortality rates among smokers from any cause are approximately three times higher than among never smokers.[4] Smokers die on average 10 years younger compared to never smokers.[4] Most of the morbidity and mortality is due to cancer, cardiovascular disease and chronic lung diseases.[3,4]

Smoking is a known risk factor for several cancers, including those affecting the airways (such as the oropharynx, larynx, trachea, bronchi and lung), gastrointestinal system (i.e. oesophagus, stomach, liver, pancreas and colorectal cancer) and other internal organs (including kidney, ureter, cervix, bladder and acute myeloid leukaemia).[3]

Smoking also causes harm to the blood vessels, reducing endothelial function and elasticity, increasing the formation of atherosclerotic plaques, with narrowing of the vascular lumen, and creating a hypercoagulable state.[3] These physiological changes

increase the risk of coronary heart disease, stroke, aortic aneurysm, peripheral vascular disease and erectile disfunction.[3]

Smoking also damages the parenchyma of the lungs, causing both types of chronic obstructive pulmonary disease (chronic bronchitis and emphysema), increasing the risk of infectious lung diseases such as pneumonia and tuberculosis and increasing the severity of asthma.[3] Other health effects include an increased risk of diabetes, rheumatoid arthritis and overall immune function.[3]

Reproductive health effects of smoking on women and the foetus are described in section 3.2.

1.3 Prevalence of Tobacco Smoking in Australia

In Australia, tobacco use is the leading cause of morbidity and mortality, responsible for 9% of the total burden of disease.[5] Daily smoking rates have been decreasing slowly since 1991 (24%) but have been stable in the last three years: 12.8% in 2013 and 12.2% in 2016.[6] Overall, there are approximately three million smokers in Australia (14.9%) aged 14 years or older, with 2.4 million of them smoking daily (12.2%).[6] Smoking rates are highest in the Northern Territory (NT) (18.5% in 2016), and the lowest in the Australian Capital Territory (9.9% in 2016).[6]

1.4 Burden of Tobacco Use among Aboriginal and Torres Strait Islander Peoples of Australia

In 2014 to 2015, 42% of Aboriginal and Torres Strait Islander peoples aged 15 years or older were current smokers.[7] Of these, 39% were daily smokers and 3% smoked less than daily.[7] This represents a significant decrease from 49% daily smoking rates in 2002.[7] Most of the decrease has occurred in non-remote areas (37% in 2014–15 compared to 48% in 2002), rather than remote areas (47% in 2014–15, compared to 50% in 2002).[7]

Aboriginal and Torres Strait Islander peoples smoke at a rate 2.8 times higher than non-Indigenous Australians (age adjusted).[7] Furthermore, 60% of Aboriginal and Torres Strait Islander peoples live in a household with at least one member who smokes, therefore being exposed to second hand smoke.[7]

It is estimated that tobacco use is responsible for 20% of all deaths and 12% of the total burden of disease among Aboriginal and Torres Strait Islander peoples in

Australia.[5,8] The gap in life expectancy between Aboriginal and Torres Strait Islander peoples and the non-Indigenous population in Australia was estimated to be 10.6 years for males and 9.5 years for females for the period 2010 to 2012.[9] Smoking is considered one of the biggest contributors to this gap in life expectancy at 17%.[8] A government report from 2011 concluded that tobacco use was the biggest contributor (23%) to the health gap between the Aboriginal and Torres Strait Islander population and the non-Indigenous population in Australia.[5] Reducing tobacco use can help achieve two targets of the 2012 Council of Australian Government's "Closing the Gap" campaign for Aboriginal and Torres Strait Islander disadvantage: "Close the gap in life expectancy within a generation (by 2031)" and "Halve the gap in mortality rates for Aboriginal and Torres Strait Islander children under five within a decade (by 2018)".[9] The National Tobacco Strategy 2012–2018, as part of the Closing the Gap strategy, aims to halve Aboriginal and Torres Strait Islander smoking rates by 2018.[10] Although a significant reduction in smoking rates has been achieved, this target has not been met.[11]

The higher smoking rates in Aboriginal and Torres Strait Islander peoples have historical, cultural and social roots.[12,13] Aboriginal and Torres Strait Islander peoples have been chewing plants containing nicotine ("pituri") many years prior to colonisation[12-14]. Tobacco and smoking was introduced through trade with Indonesian fishermen and quickly became embedded in the social and ceremonial life.[13] Colonisation had a huge impact on smoking rates – tobacco was often used by European settlers in exchange for other goods, labour and services, later becoming a method of payment to Aboriginal and Torres Strait Islander peoples.[15]

In addition, due to the effects of colonisation and dispossession, Aboriginal and Torres Strait Islander peoples suffer from multiple and interrelated life stressors, all linked to higher smoking rates.[13] These include low income, lower levels of education, unemployment and housing problems.[16] Other factors that contribute to psychological stress and described in various studies specific to Aboriginal and Torres Strait Islander smokers include family and work responsibilities, relationship problems, domestic violence, discrimination and racism.[17] Being a member of the "Stolen Generation" (defined as children of Aboriginal and Torres Strait Islander descent who were removed from their families by the Australian Federal and State government agencies under acts of their respective parliaments) was also found to be a distinctive risk factor for tobacco use. In the 1994 national survey, 70% of males and 60% of females who

were taken away from their families as children were smokers, compared to 55% and 47%, respectively, of Aboriginal and Torres Strait Islander peoples who were not taken away.[18]

Smoking is also still considered a social norm among many Aboriginal and Torres Strait Islander communities.[19] Smoking is one way in which Aboriginal and Torres Strait Islander peoples preserve and reinforce family and broader relationships. It is also used as a method to improve the sense of belonging to the community. It is considered traditional to share cigarettes among friends and family. Studies have found that non-smokers reported feeling isolated for non-participation in this common social action.[19,20]

Other factors contributing to the higher smoking rates among Aboriginal and Torres Strait Islander peoples are difficulties in accessing culturally appropriate health services, including language barriers, lack of access in rural and remote areas and racism.[21,22]

Part 2: Tackling Tobacco Use

2.1 Tobacco Control Measures

The WHO FCTC is the first global treaty, signed by 161 countries and ratified by 181 countries.[23] The framework seeks "to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke".[23] The treaty includes a series of articles detailing required regulatory measures that can help reduce current tobacco use globally, among them price and tax measures; protection from exposure to tobacco smoke; regulation of the contents of tobacco products; packaging and labelling of tobacco products; raising public awareness to the harms of tobacco use; and restriction of tobacco advertising, promotion and sponsorship.[23] Article 14 of the FCTC "Demand reduction measures concerning tobacco dependence and cessation" requires parties to promote the cessation of tobacco use through effective programs, including in health care services.[23]

In 2008, the WHO introduced six measures to assist in the implementation of the FCTC.[24] These were the MPOWER: Monitor tobacco use and prevention policies; Protect people from tobacco smoke; Offer help to quit tobacco use; Warn about the

dangers of tobacco; Enforce bans on tobacco advertising, promotion and sponsorship; and Raise taxes on tobacco.

Therefore, helping people quit smoking, including the offer of support from health providers, is an essential part of the WHO plan to reduce the global tobacco burden of disease.[23,24]

2.2 Supporting People to Quit Smoking

The combination of behavioural counselling and pharmacotherapy has been shown to be the most effective treatment for the general population who smoke.[25,26] A meta-analysis from 52 studies, with over 19,000 participants, showed that this combination increased smoking cessation outcomes by 83% (RR 1.83, 95% CI 1.68–1.98).[26] Furthermore, interventions in health care settings had a larger effect compared to interventions in community settings (RR 1.97, 95% CI 1.79–2.18 compared to RR 1.53, 95% CI 1.33–1.76).[26]

Research assessing the effectiveness of culturally tailored interventions to support Indigenous peoples to quit smoking is sparse.[27] A Cochrane review from 2012, comprising only four studies, found a statistically significant effect in favour of the intervention (RR 1.43, 95% CI 1.03–1.98). A preliminary update of this review included an additional five studies (total of nine).[28] Five studies were from Australia with Aboriginal and Torres Strait Islander peoples, two from the United States with Native Americans and two from New Zealand with Māori people. Five studies used behavioural counselling, and the remaining four combined behavioural counselling with pharmacotherapy. Meta-analysis was possible only for seven studies (RR 1.43, 95 CI% 0.96–2.14). Removal of one study with methodological flaws showed a significant effect (RR 1.53, 95% CI 1.09–2.16).[28]

2.2.1 Behavioural therapy

Behavioural counselling is a broad term and can include different intervention components. These include cognitive behavioural therapy, problem-solving, motivational interviewing, relaxation techniques and others.[29,30] Different modes of delivery of behavioural counselling have been found to be effective, including individual, group and telephone counselling.[31-33]

Individual counselling (alone, not combined with pharmacotherapy) was more effective than brief advice or usual care (RR 1.57, 95% CI 1.40–1.77).[31] Intensive counselling was also superior to brief counselling (RR 1.29, 95% CI 1.09–1.53).[31]

Behavioural counselling, provided via telephone (i.e. Quitline) are also effective (RR 1.37, 95% CI 1.26–1.5), and there is some evidence that at least three calls are more effective than one to two calls.[32]

Similarly, group behavioural therapy was also found to be effective when compared to control (RR 2.6, 95% CI 1.8–3.76), providing self-help resources (RR 1.88, 95% CI 1.52–2.33) or brief support from a health provider (RR 1.22, 95% CI 1.03–1.43).[33] Group behavioural therapy appears to have the same benefit when compared to individual therapy of the same intensity (RR 0.99, 95% CI 0.76–1.26).[33]

2.2.2 Pharmacological therapy

There are several first-line pharmacotherapies for supporting smoking cessation, including Varenicline, Bupropion and NRT.[34-36]

Varenicline is a partial agonist of the α4β2nACh receptor in the brain. The medication works by binding to the receptor and preventing nicotine from other sources (such as a cigarette) to bind, while causing dopamine to be released at a lower dose. This combined mechanism reduces the enjoyment from the cigarette (the nicotine from the cigarette cannot induce dopamine release), while lowering withdrawal symptoms (due to the release of dopamine).[34] The most updated Cochrane review assessing Varenicline effectiveness compared to placebo included 27 RCT studies, with 12,625 participants, and found an RR of 2.24 (95% CI 2.06–2.43).[34]

Bupropion is an atypical antidepressant. The mechanism of action in smoking cessation is not completely understood, but the assumption is that it is an antagonist to the α4β2nACh brain receptor.[35] As it is also an antidepressant, it can also ameliorate the frequent mood changes that might be part of the quitting process.[35] A meta-analysis of 44 studies with over 13,000 participants showed Bupropion increased smoking cessation rates significantly (RR 1.62, 95% CI 1.49–1.76).[35] Data from four studies comparing Varenicline to Bupropion showed Bupropion had significantly lower cessation rates (RR 0.68, 95% CI 0.56–0.83).[35]

NRT acts by providing the brain the same nicotine as from the cigarette (therefore reducing withdrawal symptoms), yet due to the much slower and lower absorption rate,

it does not cause the same pleasure and reward that the nicotine from the cigarette achieves.[36] There are several different formulations of NRT, usually divided into long acting, that is, the NRT patch supplying nicotine through the dermis for 16 to 24 hours, and short acting, also known as oral NRT, with nicotine absorption occurring through the buccal mucosa.[36] Currently, in Australia there are five types of oral NRT, including the NRT gum, lozenge, mini-lozenge, inhaler and oral spray. A recent meta-analysis including RCTs with any form of NRT compared to control found that the RR for smoking abstinence was 1.55 (95% CI 1.49–1.61).[36]

2.2.3 Clinical guidelines

There are several optional clinical guidelines for the management of smoking. The most commonly used approach in Australia is the 5As that includes Ask about tobacco use, Advise briefly to quit, Assess motivation to quit and nicotine dependence, Assist with support and medication and Arrange follow-up.[25,37] This approach has also been adopted by the RACGP guidelines for smoking cessation.[38] A similar approach recommended in the New Zealand smoking cessation guidelines[39] is the ABC pathway (Ask about tobacco use, Brief advice to quit, Cessation support). A briefer approach is known as the AAR approach (Ask, Advise, Refer, i.e. to evidence-based cessation treatments such as a Quitline or group behavioural therapy).[40,41] A modified AAR approach – AAC – substitutes the "Refer" with "Connect", meaning that the provider needs to proactively help the patient make the connection with the service he is referring him to (for example, to make the first call together).[40,42] (See Table 1: Current optional guidelines for the management of smoking.)

Table 1: Current optional guidelines to the management of smoking during pregnancy

5As	ABC	AAR	AAC
• **Ask** about tobacco use • **Advise** briefly to quit • **Assess** motivation to quit and nicotine dependence • **Assist** • **Arrange** follow-up	• **Ask** about tobacco use • **Brief advice** to quit • **Cessation support**	• **Ask** about tobacco use • **Advise** briefly to quit • **Refer** to Quitline/ specialist cessation support	• **Ask** about tobacco use • **Advise** briefly to quit • **Connect** with Quitline/ specialist cessation support

The "Assist" component from the 5As and/or the "Cessation support" component from the ABC pathway should include brief behavioural counselling and pharmacotherapy.[25,37,39]

Part 3: Smoking During Pregnancy

3.1 Epidemiology

Globally, rates of smoking among pregnant women range from 0.2% to 38%, with higher rates of 30 to 50% across high-priority sub-populations.[43,44]

In Australia, in 2016, 9.9% of women who gave birth smoked at some point of their pregnancy.[45] Smoking rates during pregnancy are higher for specific vulnerable populations, such as those living in remote (19.5%) and very remote (34.6%) areas, living in the lowest socioeconomic status areas (17.4%) and young mothers under the age of 20 years old (30.5%).[45] Aboriginal and Torres Strait Islander women have the highest smoking rates during pregnancy (43%) and are more than three times more likely to smoke during pregnancy compared to non-Indigenous pregnant women.[45]

Similarly, smoking rates among Indigenous pregnant women in Canada, United States and New Zealand are higher compared to the non-Indigenous people in the same country.[46] In Canada, 47% of First Nations women and 56% of Inuit women smoke

during pregnancy compared to ≈12% of non-Indigenous women.[46] In New Zealand, ≈38% of pregnant Māori women smoke, compared to 14.8% in the general non-Indigenous population.[46]

In Australia, rates of smoking during pregnancy have been slowly decreasing. They have decreased by 7% for Aboriginal and Torres Strait Islander pregnant women (from 50% in 2009 to 43% in 2016) and by 4% for non-Indigenous pregnant women (16% in 2009 to 12% in 2016).[45]

Compared to non-Indigenous pregnant women, Aboriginal and Torres Strait Islander pregnant women are also more likely to live in remote areas (21% versus 1.5%) or low socioeconomic status areas (2.4 times more likely), or to be a teenage mother (14% versus 2%).[45] Aboriginal and Torres Strait Islander pregnant women also attend antenatal care later and at a lower rate compared to non-Indigenous mothers.[45]

Aboriginal and Torres Strait Islander women also quit smoking during pregnancy at a lower rate compared to the general population (13% of Aboriginal and Torres Strait Islander pregnant women reported smoking in the first 20 weeks of pregnancy and not smoking after 20 weeks, compared to 26% of non-Indigenous pregnant women, age-standardised).[45]

Many women who stop smoking in pregnancy relapse shortly after birth.[47-50] Relapse rates range from 47% to 63% six months after birth.[48,50] In a study with Aboriginal pregnant women from the NT, 35% of pregnant women who were non-smokers at the end of their pregnancy reported smoking by seven months postpartum.[49]

3.2 Health Impact of Smoking during Pregnancy

Tobacco smoking in pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes, including miscarriage, growth restriction, stillbirth and preterm birth.[3,45] Smoking during pregnancy also increases the risk of various chronic diseases in the long term such as asthma, diabetes and behavioural and learning problems.[17,51-53] Furthermore, smoking during pregnancy might be linked to increased likelihood of the baby smoking later in life,[54-56] although more recent research suggests this might be confounded by genetic and environmental factors.[57]

A recent Australian large retrospective cohort study with over 20,000 pregnant women (2000–2017), comparing the neonatal outcomes of babies of women who smoked during their pregnancy to those who did not smoke, showed consistent results:

Babies born to pregnant women who smoked had a higher rate of being preterm, having lower birth weight and more admissions to the neonatal intensive care unit.[58]

Table 2 details all the health consequences for the mother and baby both in the short and long term.

Aboriginal and Torres Strait Islander babies are more likely to be born preterm (14% compared to 6% for non-Indigenous babies), have low birth weight (11.6% compared to 6.3%) and are almost twice as likely to die in the perinatal period.[45]

A study in South Australia (SA) found that the population-attributable risks of smoking were significantly higher for Aboriginal births compared to non-Indigenous births, for small for gestational age (48% versus 21%), low birthweight (35% versus 23%) and preterm birth (20% versus 11%).[59]

Table 2: Health consequences of smoking in pregnancy on the mother and baby[3,60,61]

Effects on the Mother		Effects on the Foetus/Baby	
Short Term: Pregnancy Related	Long Term: In General	Short Term	Long Term
• Reduced fertility • Ectopic pregnancy • Preterm labour • Premature rupture of membranes • Placental abruption • Placenta praevia • Pre-eclampsia • Miscarriage • Stillbirth	• Cancer (including lung, breast, cervical, vulval, bladder, oropharyngeal) • Cardiovascular disease • Chronic respiratory disease • Osteoporosis • Premature menopause	• Low birth weight (less than 2500g at birth) • Growth restriction • Perinatal death • Birth defects (such as limb reduction defects, clubfoot, oral clefts)	• Sudden unexpected death in infancy • Respiratory disease (asthma, lower respiratory infection, decreased lung function, glue ears) • Nicotine dependence (higher risk of becoming a smoker) • Type 2 diabetes • Cognition (impaired academic performance and cognitive abilities) • Behaviour (conduct disorder, ADHD, antisocial behaviour)

3.3 Addressing Smoking during Pregnancy

3.3.1 Psychosocial approaches

Studies specific to pregnant women have also shown that psychosocial interventions such as behavioural counselling are effective.[43] These have the potential to reduce the population-attributable risk of neonatal intensive care unit admissions (by

22%) and low birthweight (by 17%), with approximately 63 interventions needed to prevent one infant being born with low birthweight.[43]

Behavioural counselling is effective compared to usual care (RR 1.44, 95% CI 1.19–1.73), but it is unclear whether it can also prevent smoking relapse postpartum among women who quit smoking during pregnancy. Feedback (i.e. interventions where the pregnant women are provided with an objective measurement of the effects of tobacco smoking, such as the level of carbon monoxide in expired air and the possible effect on the foetus health), were also effective when compared to usual care (RR 4.39, 95% CI 1.89–10.21), but this was based on only two studies. When compared to other less intensive interventions, the effect was not clear (RR 1.29, 95% CI 0.75–2.2).[43] Contingency-based incentives were also effective (RR 2.36, 95% CI 1.36–4.09);[43] however, it is not yet clear whether this would be socially acceptable among pregnant women, health providers and public in general.

A recent systematic review, focusing on digital psychosocial approaches for pregnant women (such as interventions delivered through a mobile telephone app), found these to be effective (12 papers, n=2970; OR 1.44, 95% CI 1.04–2.0), with the most effective interventions either computer based (OR = 3.06, 95% CI 1.28–7.33) or entailing text messages (OR 1.59, 95% CI 1.07–2.38).[62]

3.3.2 Pharmacological approaches

As mentioned previously, pharmacotherapy for smoking cessation in the general non-pregnant population includes three first-line treatments: Varenicline,[34] Bupropion[35] and NRT.[36] Varenicline and Bupropion have not been studied adequately in pregnancy and therefore are not recommended for smoking cessation in pregnant women.[38] The latest Cochrane review on pharmacotherapy for smoking cessation in pregnant women included eight trials of NRT enrolling 2,199 patients.[63] This meta-analysis found that compared to placebo and non-placebo controls, use of NRT increased smoking cessation rates by 40% (RR 1.41, 95% CI 1.03–1.93). It should be noted that an analysis of only placebo-controlled studies resulted in a lower non-significant smoking cessation rate (RR 1.28, 95% CI 0.99–1.66). There were no differences in NRT or control group regarding women's or babies' health outcomes. Adherence to NRT was low, and most participants did not finish their course of treatment. One suggestion from current trials is that NRT dosage needs to take into account the higher nicotine metabolism in pregnancy, and it is recommended that further trials with higher doses of NRT be

undertaken.[63,64] A recent Cochrane review on the effectiveness of NRT for smoking cessation in general[36] included a sub-analysis of six pregnancy-specific studies that had at least six months of follow-up, and found that NRT increased smoking cessation rates by 32% (RR 1.32, 95% CI 1.04–1.69).

Although the current evidence for the effectiveness and safety of NRT in pregnancy is not robust enough, and further research is warranted,[63] experts around the world agree that using NRT is safer than smoking, and if a woman is unable to quit without medication, she should be offered NRT.[65-68] Nonetheless, it is not clear if using NRT during pregnancy would be acceptable to the women themselves, as adherence was problematic in most trials,[63] and few studies have examined this directly with pregnant women.[69,70]

3.3.3 Current Australian guidelines for treating smoking during pregnancy

The 5As guidelines are also recommended for treating smoking during pregnancy.[38] The RACGP guidelines encourage health providers to support pregnant women to quit smoking first without pharmacotherapy, using behavioural counselling and referring to Quitline.[38] These guidelines also recommend that if a woman is unable to quit without using medication, she should be offered NRT after discussing the risks versus benefits. Ideally, oral short-acting NRT should be offered first, but if needed a patch can be added.[38] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) have a more conservative approach, stating that NRT is not recommended in pregnancy, but acknowledging that it may be needed by highly addicted woman that have been unable to quit without pharmacotherapy.[61]

In 2015, a pragmatic guideline for supporting Aboriginal and Torres Strait Islander Australian pregnant women to quit smoking was published. Structured similarly to the New Zealand ABC approach[39] (mentioned in section 2.2.3), these guidelines add an extra D component (Discuss the psychosocial context of smoking), and therefore follow an ABCD pathway.[71] As stated previously, the Aboriginal and Torres Strait Islander peoples in Australia are disadvantaged in many areas, all of which are linked to higher smoking rates[72] and add to the challenge of quitting. Therefore, discussing with the pregnant woman her family, social and cultural context for smoking is a vital component of providing smoking cessation care.[71] These guidelines also recommend using an expedited offer of NRT, not waiting more than one to two days of an unsuccessful quit attempt.[71]

3.4 Knowledge, Attitudes and Barriers to Smoking Cessation among Aboriginal and Torres Strait Islander Pregnant Smokers

Aboriginal and Torres Strait Islander pregnant smokers face multiple barriers to quitting smoking, at individual, community and systemic levels, and similar to barriers reported for all pregnant women who smoke, especially from other disadvantaged populations.[20,46,73-76]

A systematic review of Indigenous women's experiences of smoking, and needs to support them to quit, synthesised data from 13 qualitative studies from Australia (n=3), Canada (n=1), the United States (n=2) and New Zealand (n=7).[46] This systematic review reported on five main findings:

1. Indigenous mothers report pregnancy as a significant reason for altering their smoking behaviour (either due to wanting to protect their baby, social norms or feeling sick and not being able to smoke);

2. Knowledge regarding the harms was apparent, but it was not enough on its own to obtain abstinence;

3. Multiple barriers preventing abstinence, such as high nicotine dependence, stress, being surrounded by community and family members who smoke, lacking social support to qui, and being bored with nothing to do;

4. Needing ongoing, easily accessible smoking cessation support, with non-judgemental health providers;

5. Variable cessation needs and preferences, such as some viewing telephone support to be helpful, while others did not, and some wanting culturally tailored resources and others not viewing this as important.

Studies done in Australia with Aboriginal and Torres Strait Islander women show similar results. Although Aboriginal and Torres Strait Islander pregnant women who smoke express their will to protect their baby from harms of smoking, total absence is considered hard to achieve, and they often resort to reducing the amount they smoke[77,78] and protect new born babies from second hand smoke exposure in the house as an easier option.[20,73] Smoking is an integral part of many Aboriginal and Torres Strait Islander pregnant smokers' lives, used to deal with stress and boredom, and considered by some

to be an essential part of social interactions.[20,75] Although general knowledge of harm from smoking is quite high,[79] knowledge on more detailed or specific harmful effects is lower,[77,78] and health risks are sometimes perceived as an exaggeration, especially as many harms are not visible.[20,73] Aboriginal and Torres Strait Islander pregnant smokers place a great emphasis on personal choice and decision, while current messages against smoking are sometimes perceived as disturbing and not effective, potentially leading to avoidance.[20,73]

As stated earlier, smoking is still the social norm in many Aboriginal and Torres Strait Islander communities, leading to the pregnant woman being surrounded by other smokers at home (partner, other family members) and the wider community.[73-75] Women report feeling isolated from their social connections if they attempt to quit smoking. Lack of support for quitting from family and other community members is often mentioned, although others mention feeling shamed and guilty about continuing to smoke.[20,73]

Systemic and organisational barriers include the following:

a. Lack of access to oral NRT. As stated above, the RACGP clinical guidelines recommend using oral NRT as first-line treatment for pregnant women who are unable to quit smoking unaided.[38] Currently, oral forms of NRT are not subsidised through the Pharmaceutical Benefits Scheme, and only the NRT patch is available free of cost or subsidised.

b. Limited access to culturally appropriate medical services[80] and smoking cessation services.[74,81] Aboriginal and Torres Strait Islander pregnant women are more likely to attend antenatal care later in pregnancy, compared to non-Indigenous women.[45] On average, Aboriginal and Torres Strait Islander pregnant women attended one less antenatal visit compared to non-Indigenous women.[45] Only 86% of Aboriginal and Torres Strait Islander pregnant women attended five or more antenatal visits, compared to 94% of non-Indigenous pregnant women (age-standardised). The reasons for these gaps are complex but are due in part to the inadequate provision of culturally safe maternity care.[80] The provision of maternity care through Aboriginal Community Controlled Health Services (ACCHS) is one method of ensuring that women receive culturally safe care.[80] ACCHS are dedicated to healthcare delivery for Aboriginal and Torres Strait

Islander peoples and are run by the local Aboriginal community members and Elders for the local Aboriginal community.

c. Lack of support from health providers was cited as a shared and common barrier to smoking cessation in different vulnerable groups in general, including the Aboriginal and Torres Strait Islander peoples.[82] A cross-sectional survey of Aboriginal and Torres Strait Islander smokers in the reproductive age group revealed that most reported their perceived support from health providers during a quit attempt to be low.[83] Despite this, previously consulting a health provider on quitting was significantly associated with an intention to quit smoking (OR 3.82 95% CI 1.43–10.2),[83] emphasising once again the importance of the health provider's role in smoking cessation. A recent cross-sectional survey with Aboriginal and Torres Strait Islander pregnant women in NSW and the NT (n=261) found that most women were asked (90%) and advised to quit (81%), and 62% were offered support.[84] It was not clear from this study what type of support was offered, and the authors concluded that the "persisting high prevalence of smoking suggests that this support is insufficient".[84] A qualitative study with 20 Aboriginal women who were pregnant or recently gave birth, revealed that women were receiving inconsistent messages from health providers, emphasising reducing cigarette consumption rather than quitting, and fragmented advice on using NRT during pregnancy.[85]

Addressing the higher smoking rate in Aboriginal and Torres Strait Islander pregnant women, and increasing cessation success, may require a comprehensive "whole of picture" strategy, addressing the different levels of barriers that women face.[74,75,86]

3.5 Health Providers' Barriers to Providing Smoking Cessation Care during Pregnancy

A comprehensive review of the literature (2010) found that a high percentage of health providers are performing the Ask and Advise part of the 5As, but fewer than 50% Assess readiness to change, Assist in smoking cessation or Arrange follow-up appointments or referral.[87] Only up to a third of clinicians reported delivering all of the 5As.[87-89]

Another component of smoking cessation care, prescription of NRT to pregnant women who smoke, was also found to be relatively low and variable, ranging from 2% to 51% in studies.[87,88,90-94] A UK study found that the majority of surveyed GPs (n=240) reported that NRT in pregnancy was likely to be safer than smoking. However, GPs also reported low confidence in their ability to prescribe NRT in pregnancy.[91] The majority of obstetricians in a US-based survey (n=154) did not prescribe NRT because of a lack of confidence and lack of smoking cessation training.[90] In New Zealand, GPs and obstetricians in maternity care were reported as missing opportunities to intervene in smoking with pregnant women, with only half providing cessation advice and many being uncertain about the use of NRT.[95] In a 2008 New Zealand study, 70% of GPs were providing advice to pregnant smokers, but only 34% recommended NRT.[92]

There have been a few reviews addressing health providers' barriers to managing smoking during pregnancy.[87,96,97] None of these reviews were specific to health providers treating Indigenous populations (in Australia or globally).

Okoli et al.'s review identified three types of barriers to health providers' provision of smoking cessation care to pregnant women: (1) provider-specific barriers, (2) patient-specific barriers and (3) system-/organisational-specific barriers.[87]

1. **Provider-specific barriers** included lack of knowledge regarding patient counselling and referral to treatment, low confidence in personal intervention skills and low confidence in using NRT for pregnant women. Furthermore, the review identified perceptions that a health provider's advice cannot influence a patient's behaviour, tobacco dependence treatment is not the role of health providers working with pregnant women, smoking cessation interventions for pregnant smokers are ineffective and advising pregnant smokers to quit can be detrimental to the health provider's relationship with the patient.

2. **Patient-specific barriers** included health providers' perceptions that patients lacked interest in cessation, patients may have major stressors in their lives that smoking may help relieve, advising may make patients feel guilty and stop being honest with the health providers and patients do not expect advice about smoking cessation.

3. **System-/organisational-specific barriers** included a lack of time to engage in smoking cessation care with pregnant smokers, a lack of training, a lack of

materials, no reimbursement and no written protocol to document staff responsibility with smoking cessation.

This review also outlined health providers' perceptions of their needs to overcome these barriers: the need for training on how to provide recommended advice and support for pregnant smokers, information about which patient education materials to use, training in smoking cessation counselling, availability of specialist smoking cessation support services for patient referral, continuing education workshops, updates on evidence and research findings on smoking during pregnancy and clarification of the main smoking cessation messages that should be provided to pregnant women.[87]

Baxter et al.'s review, focusing on the factors relating to the uptake of smoking cessation care among pregnant women, outlined similar barriers among health providers, including fear that discussing smoking will have a negative impact on the relationship with the patient, a lack of knowledge, skills and confidence to counsel women, a lack of training, the perception of interventions being ineffective, pessimism and frustration, a lack of time and administrative support, a lack of good quality patient education resources and the perception of a lack of patient motivation to quit.[97]

Flemming et al.'s 2016 review was the only systematic review synthesising data from eight qualitative studies from high-income contries.[96] Only one of the studies was from Australia (2009) with only seven midwifes participating.[98] This review highlighted two main themes: the professional role of the health providers and the organisational context. It was evident that there was a need for health providers to find a way to discuss smoking without feeling that this will damage their relationship with the woman. Furthermore, it was recognised by the health providers that there is a need for this issue to also be addressed outside the healthcare system, in the broader social context and within community settings as well.[96]

In Australia, few studies have been done to explore health providers' barriers and facilitators to managing smoking during pregnancy, and most were done in the 1990s and only in antenatal clinics.[98-102] A recent qualitative study analysed interviews with 27 NSW maternity service managers, obstetricians and midwives, who reported similar barriers and enablers to those mentioned above (lack of knowledge, skills, training, time), lack of organisational support and fear that these conversations would be "difficult" and might damage their relationship with a woman.[102] Another study

surveyed antenatal health care providers (n=127) from NSW and the NT, caring specifically for Aboriginal women. This study included mainly nurses, midwifes and Aboriginal healthcare workers, and very few physicians.[103] In this study, 79% asked all their patients regarding their smoking status. Agreeing with statements such as "giving advice is not worth it given the low level of success", "I don't have the skills" and/or "I don't want to push women away from antenatal care by telling them to quit smoking" was associated with not asking about the women's smoking status.[103] In a different study with the same sample of health providers, under 50% considered referral to a Quitline to be helpful, and yet 74% thought providing free NRT would help.[104]

3.6 Previous Research to Improve Smoking Cessation Outcomes among Indigenous Pregnant Women

Currently, there have only been two published RCTs focused on smoking cessation among Indigenous pregnant women, one with Australian Aboriginal and Torres Strait Islander pregnant women[105] and the other with United States Alaska Native pregnant women.[106]

Eades' study (2012)[105] was conducted at three ACCHS in Qld and Western Australia (WA) and included 263 Aboriginal and Torres Strait Islander pregnant women who were randomised either to receive a brief intervention (usual care) (n=114) or an intensive tailored smoking cessation intervention (n=148). Health providers received training that included a video demonstration, role-plays and presentations of relevant research literature. They were also provided with a study manual and a one-page guide with scripted advice for each participant enrolment and intervention session. Results did not find a statistically significant difference between the control and intervention group (risk ratio for smoking in the intervention group relative to usual care group, 0.93 [95% CI, 0.86–1.08]; p=0.212). Physicians in the study adhered to the protocol in providing the intervention components in over 64% of consultations, but only 32% prescribed NRT at the third visit as recommended. Nurses and Aboriginal health workers adhered to the study protocol even less, providing the tailored cessation advice components in under 25% of consultations. This study also suffered from methodological and implementation problems, including a high (over 30%) loss to follow-up, high staff turnover, a lack of allocation concealment and the potential for contamination between groups.[105]

Patten's study (2010)[106] was a feasibility pilot study conducted in Western Alaska and included 35 Alaska Native women. In this study, the intervention focused solely on the pregnant women and did not include a component aimed at the health providers. The biochemically confirmed abstinence rate was not statistically different between the control (0%) and intervention (6%) groups. This study also suffered from implementation problems, mainly very low recruitment levels (12% of eligible women).[106] Reasons for not participating reported by women included lack of time, a lack of interest in quitting and logistic constraints preventing them from attending the study visits. The authors also attributed the low recruitment rates to the social stigma of smoking during pregnancy, causing women to not want to be seen entering the smoking cessation clinic.[106]

There have been two other studies focusing on smoking cessation among pregnant Australian Aboriginal women, using a less rigorous quasi-experimental design.[107,108]

Quit for New Life (QFNL) (2012–2015) is a NSW program that ran through Aboriginal Maternal and Infant Health Services, Building Strong Foundations for Aboriginal Children, Families and Communities services and other antenatal services. As part of this program, midwifes and Aboriginal health workers were trained to provide Aboriginal pregnant women who smoke with brief advice to quit, a referral to Quitline, free oral NRT and ongoing intensive follow-up support.[108] This program also offered support to quit for other household members who smoke, including free NRT.[108] The interim report for this program stated that the program faced many implementation issues, including challenges for practice change (such as interventions take time to be integrated into appointments in an environment that is already stretched), staff (such as resistance and low confidence to address smoking, and high turnover) and training (such as difficulties in staff travelling to attend). Despite this, many positive impressions from the program were reported by the health providers, including raised awareness, increased knowledge on using NRT during pregnancy and increased knowledge and confidence of staff. Among the women participating, uptake of the program components was low, with only 11% accepting an offer of NRT and 8.8% accepting a referral to Quitline.[108] However, there were issues about the accuracy and consistency of the data collection. Comparing the self-reported smoking cessation rate of Aboriginal women who attended these services pre and post implementation of the QFNL program showed no difference.[108]

The Stop Smoking in its Tracks program (2010–2012) was originally designed as an RCT with four Aboriginal Maternal and Infant Health Services (two intervention and two control). Due to staffing issues, two services dropped out of the study and the study was converted to a quasi-experimental trial with both services receiving the intervention. Midwifes and Aboriginal health workers from these services received a structured two-day training program with a detailed manual. The intervention included frequent support with individually tailored counselling (home visits twice weekly for three weeks, weekly for four weeks, then fortnightly until the birth), contingency-based incentives, free oral NRT, tailored educational resources, engagement with household members and the option of running a support group. Fifty-six percent (22/38) of eligible women enrolled and 86% (n=19) completed all the follow-up visits. Implementation of program components was variable, ranging from 21% to 100%. Staff viewed the implementation difficult for several components without additional team capacity, but advised that any additional worker would have to be integrated into the service and not separate. Forty-two percent (8/19) reported biochemically confirmed smoking abstinence at the end of pregnancy. Using an intention-to-treat approach, this would translate to a 36% smoking abstinence rate (8/22).

Part 4: Changing Health Providers' Behaviour – Theoretical Frameworks Used in this Thesis

4.1 Translating Evidence into Health Providers' Practice

Knowledge translation is "a dynamic and iterative process that includes the synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products and strengthen the healthcare system".[109] There are many other different terms used to describe knowledge translation, including implementation science and dissemination and diffusion.[109] As part of this process, it is not enough to disseminate evidence (i.e. through publications and reports), but requires actually changing what is being done in practice. For this to occur, and therefore an essential part of knowledge translation, health providers must change their behaviour.[110]

There is growing evidence to suggest that theory-based interventions to change health providers' behaviour are more effective than those that are based on researchers' perceptions.[111,112] There are numerous behaviour change theories and different

frameworks to design behaviour change interventions.[113,114] Recently developed is the Behaviour Change Wheel (BCW), synthesising knowledge from 19 different behaviour change frameworks that were identified in a systematic search.[115,116] It is used to practically identify and remediate barriers to achieving evidence-based care at the level of individual behaviour, interventions or policy.[115] The Theoretical Domains Framework (TDF) is linked to the BCW and can be integrated into it to assist in designing an intervention. The TDF is a validated and integrative theoretical framework developed for behaviour change research and cross-disciplinary implementation.

4.2 The Behaviour Change Wheel

At the centre of the BCW is the COM-B model (Figures 1 and 2).

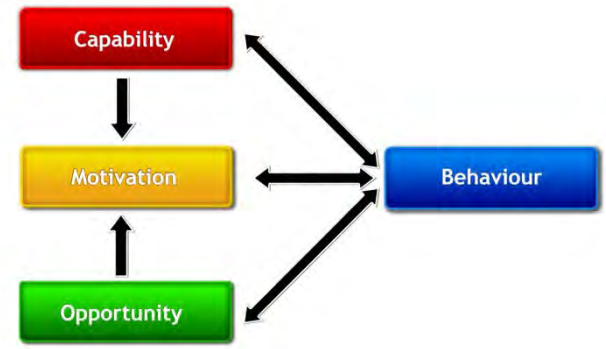

Figure 1: The COM-B behaviour change theory[115,116]

The COM-B articulates that behaviour is influenced by three components: capability, opportunity and motivation. These three components interact with one another and are influenced directly by the behaviour (Figure 1). Each one of these components is further divided into two sub-components:

1. Capability includes both psychological capability (knowledge and skills) and physical capability (physical strength or skill) to perform the behaviour.

2. Opportunity includes both social opportunity (interpersonal influences, social norm) and physical opportunity (for example, time, resources, cues), referring to influences on the individual from outside.

3. Motivation includes both automatic motivation and reflective motivation. Automatic motivation includes emotional reactions, desires (wants and needs),

impulses and inhibitions, whereas reflective motivation includes processes that are analytical and conscious.

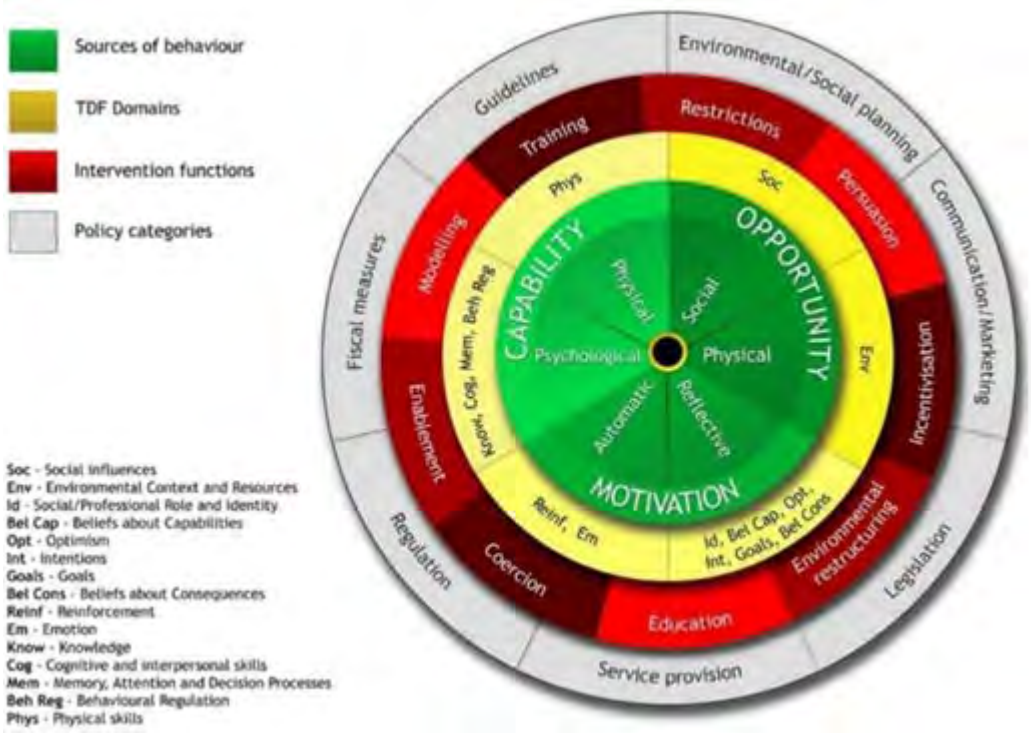

Figure 2: The Behaviour Change Wheel, linked with the Theoretical Domains Framework[115-117] (Reproduced with permission from Prof. Susan Michie)

The second layer in the BCW comprises the intervention functions (red layer in Figure 2), and the last outer layer contains the policy categories (grey layer, Figure 2). Both of these represent ways to bring about change in the relevant COM-B components. Different intervention functions can be used for the different COM-B components – for example, increasing reflective motivation can be done by using *"education"* and/or *"persuasion"* and/or *"incentivisation"* and/or *"coercion"*. Different policy categories can be used to deliver the intervention functions – for example, education could be delivered by using *"communication/marketing"* and/or *"guidelines"* and/or *"regulation"* and/or *"legislation"* and/or *"service provision"*. For example, if identifying a need to improve psychological capability (knowledge), this may be done used the intervention function "education" and the policy category "guidelines".

4.3 Theoretical Domains Framework

The TDF is a method of identifying the perceived factors that may influence the implementation of evidence-based behaviour by health professionals.[111,112,118,119] The

TDF covers a range of domains known to be relevant to professional behaviour change and has been applied across a wide range of clinical situations.[112] The TDF may be used in conjugation with the BCW to help identify the barriers and enablers influencing the behaviour (yellow inner layer, Figure 2).

The framework consists of 14 domains: knowledge; skills; memory, attention and decision processes; behavioural regulation; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; intentions; goals; reinforcement; emotion; environmental context and resources; and social influences.[112,120]

Each domain of the TDF is linked to a COM-B component. For example, physical opportunity is linked to the domain environmental context and resources; and psychological capability is linked to knowledge, cognitive and interpersonal skills, memory, attention and decision processes, and behavioural regulation.

4.4 Behaviour Change Techniques

Novel research in the last few years has emerged to try to specify the "active ingredients" that are part of behavioural therapy or interventions. Recently a taxonomy has been developed and validated to detail 93 specific behaviour change techniques (BCTs).[30,121,122] Each BCT is also linked directly with intervention functions (of the BCW), the COM-B sub-components and the TDF domains. For example, the BCT 6.2 "Social comparison" (defined as *drawing attention to others' performance to allow comparison with the person's own performance*) can be used as part of the intervention function "persuasion" to influence "social opportunity" (linked to the TDF domain "social influences"), and also "reflective motivation" (linked to the TDF domains "beliefs on capabilities" and "social/professional role and identity").[116]

Research has identified 43 specific BCTs for smoking cessation;[122] several of them have been found to be "evidence based" (included in at least two interventions found to be effective in randomised controlled studies)[123,124] and/or associated with biochemically validated quit outcomes.[125]

To date, only two studies have focused on BCTs for smoking cessation in pregnancy, identifying 23 different BCTs that were present in at least two effective interventions included in a Cochrane review on smoking cessation behavioural support in pregnancy.[123,126] Examples of BCTs that are considered as potentially effective for

smoking cessation during pregnancy include: provide rewards contingent on successfully stopping smoking, measure expired-air carbon monoxide, facilitate relapse prevention and coping, provide information on the consequences of smoking and smoking cessation, facilitate barrier identification and problem-solving, facilitate action planning/identify relapse triggers, facilitate goal setting and advise on/facilitate use of social support.

A recent review focused on digital interventions identified seven BCTs associated with smoking cessation during pregnancy: information about antecedents, action planning, problem-solving, goal setting (behaviour), review behaviour goals, social support (unspecified) and pros and cons. Data from this review indicates that using more BCTs in interventions is likely to yield the best results.[62]

4.5 The Effective Practice and Organisation of Care Taxonomy

The Effective Practice and Organisation of Care (EPOC) taxonomy is a framework characterising different intervention components that may be used to change health providers' behaviour.[127] This taxonomy includes several categories and subcategories encompassing a range of different intervention components in healthcare, on different levels. Under the category "Implementation Strategies" (defined as "Interventions designed to bring about changes in healthcare organisations, the behaviour of healthcare professionals or the use of health services by healthcare recipients"), they include 19 different subcategories under "Interventions targeted at health workers" (Table 3).[127]

Table 3: EPOC Taxonomy of Intervention targeted to change health providers behaviour[127]

Subcategory	Definition
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.
Clinical incident reporting	System for reporting critical incidents.
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.
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.

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.
Educational games	The use of games as an educational strategy to improve standards of care.
Educational materials	Distribution to individuals, or groups, of educational materials to support clinical care, i.e. any intervention in which knowledge is distributed. For example, this may be facilitated by the internet, learning critical appraisal skills; skills for electronic retrieval of information, diagnostic formulation; question formulation.
Educational meetings	Courses, workshops, conferences or other educational meetings.
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.
Clinical practice guidelines	Clinical guidelines are systematically developed statements to assist healthcare providers and patients to decide on appropriate healthcare for specific clinical circumstances.
Inter-professional education	Continuing education for health professionals that involves more than one profession in joint, interactive learning.
Local consensus processes	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.
Local opinion leaders	The identification and use of identifiable local opinion leaders to promote good clinical practice.
Managerial supervision	Routine supervision visits by health staff.
Patient-mediated interventions	The use of patients, for example, by providing patient outcomes to change professional practice.
Public release of performance data	Informing the public about healthcare providers by the release of performance data in written or electronic form.
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.
Routine patient-reported outcome measures	Routine administration and reporting of patient-reported outcome measures to providers and/or patients.
Tailored interventions	Interventions to change practice that are selected based on an assessment of barriers to change, for example, through interviews or surveys.

Note. Adapted with permission from https://epoc.cochrane.org/epoc-taxonomy.

There have been a few Cochrane reviews targeting specific intervention components, including audit and feedback,[128] printed educational materials,[129] computer-generated reminders,[130,131] external inspection,[132] local opinion leaders,[133] continued educational meetings[16] and educational outreach visits.[134] Most of these interventions show a modest effect on healthcare providers' performance, and it is not clear whether this correlates to a similar increase in patient outcomes.

An overview of systematic reviews on interventions to change health providers' behaviour, published in 2001, identified that currently, knowledge is lacking as to what works best for changing health providers' behaviour.[135] Active approaches are more likely to be effective than passive dissemination (such as providing educational material). Audit and feedback, the use of local opinion leaders, educational outreach and reminders were found to be moderately effective in general. Interventions that include more than one component were more likely to be effective.[135]

A more recent overview of systematic reviews[136] suggested that interventions that are based on action (such as audit and feedback, and reminders) and certain types of educational interventions (such as educational outreach) are more likely to work compared to interventions focused more on persuasion, such as local opinion leaders. Specifically, this review suggested that interventions focusing on changing health providers' behaviour are more likely to be effective if they included a method for the health providers to relate their own performance to their peers' expectations and norms.[136] Furthermore, a few reviews included in this overview specifically addressed the need to tailor interventions to pre-identified barriers.[137,138]

4.5 Previous Research on Improving Health Providers' Smoking Cessation Care

To date, there has been only one published Cochrane review (Carson et al.) which focused on training health providers to provide smoking cessation care.[139] Training has been shown to significantly increase health providers performance, including "asking patients to set a quit date", "arranging follow-up", "counselling" and "providing self-help material". Sub-group analysis showed that for the above-mentioned outcomes, ORs for training physicians were higher than ORs for other healthcare workers. Moreover, training health providers had an impact on patients' smoking cessation, both using point prevalence outcomes (OR 1.36, 95% CI 1.20–1.55, p= 0.004) and continuous abstinence (OR 1.60, 95% CI 1.26–2.03, p= 0.03). There was no evidence that training improved the provision of NRT.[139] None of the studies included in this review focused on smoking cessation during pregnancy.[139]

Part 5: Evidence Gap Summary and Research Aims

In summary, an evidence-practice gap exists in primary care approaches to providing evidence-based care to Aboriginal and Torres Strait Islander smokers during their pregnancy. More research is needed as to what are the best strategies to improve health providers' smoking cessation care for Aboriginal and/or Torres Strait Islander pregnant women. The research presented in this thesis aimed to enhance the current knowledge on this topic, while adhering to ethical guidelines, with utmost respect to Aboriginal and Torres Strait Islander peoples' cultural inheritance of past, current and future generations.

5.1 Research Aims

The overall aims of this thesis were to explore health providers' provision of smoking cessation care during pregnancy in general, specifically among Aboriginal and Torres Strait Islander pregnant women, and to test an evidence-based behaviour change intervention to improve health providers' provision of smoking cessation care to Aboriginal and Torres Strait Islander pregnant women. Health providers' practices regarding smoking cessation care during pregnancy, barriers to the provision of smoking cessation care to pregnant women and methods for improving health providers' care were explored. A multi-component pilot intervention was trialled with

health providers within six community controlled Aboriginal medical services in NSW, Qld and SA.

Specifically, this research aimed to

1. determine current self-reported knowledge, attitudes and practices of Australian GPs and obstetricians for smoking cessation care to pregnant women in general, and specifically to Aboriginal and Torres Strait Islander women (paper one);

2. explore current GPs' and obstetricians' self-reported prescription of NRT in pregnancy and what factors influence their prescription rates (paper two);

3. explore in depth the thoughts and attitudes of GPs actively engaged in treating pregnant women on the management of smoking in pregnancy and what would enable them to better manage smoking in pregnancy (paper three);

4. conduct a narrative review on the safety and effectiveness of NRT in pregnancy and what is recommended in national guidelines from high-income English-speaking countries, suggesting pragmatic clinical guidelines for health providers on the initiation and titration of NRT in pregnancy (paper four);

5. conduct a systematic review and meta-analysis of the effectiveness of interventions on health providers' provision of smoking cessation care during pregnancy and determine the impact of inclusion of different intervention components on the effectiveness (paper five);

6. develop and test the acceptability and usefulness of a tailored, culturally sensitive, educational resource package for health providers as an aid to the management of smoking in pregnant Aboriginal and Torres Strait Islander women (paper six);

7. describe the protocol for a tailored, culturally sensitive, behaviour change intervention on health providers' provision of smoking cessation care in Aboriginal medical services (paper seven);

8. describe the results of a tailored multi-component intervention on health providers' smoking cessation care for Aboriginal and Torres Strait Islander pregnant women (paper eight).

Part 6: Conducting Research in Collaboration with Aboriginal and Torres Strait Islander Peoples

6.1 National Health and Medical Research Council and Aboriginal Health and Medical Research Council guidelines for research with Aboriginal and Torres Strait Islander peoples

The National Health and Medical Research Council (NHMRC) guidelines for conducting research with Aboriginal and Torres Strait Islander peoples define six core values:[140]

1. Spirit and integrity;
2. Cultural continuity;
3. Equity;
4. Reciprocity;
5. Respect;
6. Responsibility.

The first core value, spirit and integrity, is the central core binding the other five core values.

In NSW, the Aboriginal Health and Medical Research Council's (AH&MRC) guidelines for ethical research with Aboriginal and Torres Strait Islander peoples define five key principles:[141]

1. Net benefits for Aboriginal people and communities;
2. Aboriginal community control of research;
3. Cultural sensitivity;
4. Reimbursement of costs;
5. Enhancing Aboriginal skills and knowledge.

6.2 The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy study

The research presented in this thesis is part of a larger study: the ICAN QUIT in Pregnancy study.

The overall aim of this study is to improve health providers' skills when offering smoking cessation care to Aboriginal and Torres Strait Islander pregnant women. The ICAN QUIT in Pregnancy study includes three phases. Part of the research presented in this thesis is included in phases 1 and 2 (as outlined below) and will inform phase 3 of the study (renamed later SISTAQUIT – Supporting Indigenous Smoking to Assist Quitting):

1. Phase 1 was a multi-centre community-based participatory research project and included an expert panel review. The aim of this phase was to assess the acceptability of a collaboratively developed, culturally tailored education package and a suite of resources to aid webinar training of health providers in the ICAN QUIT in Pregnancy guidelines and associated resources. These resources were previously developed with Aboriginal staff from two ACCHS. The resources were put through a stringent assessment process with an expert panel and health professionals and community members from three other ACCHS from three states (NSW, SA and Qld). Further information is outlined in paper six of this PhD.

2. Phase 2 was a single-arm multi-centred step-wedge pilot study. The overall aim of this study was to assess the feasibility, acceptability and usability of the targeted training program and resources to provide culturally competent management of smoking in Aboriginal and Torres Strait Islander pregnant women. This study was conducted in six ACCHS in the same three states. Further information is outlined in papers seven and eight of this PhD.

3. Phase 3 will be a cluster RCT, conducted in 30 Aboriginal medical services in NSW, Qld, SA, WA and the NT. The aim of this study will be to assess the effectiveness of a complex intervention, including webinar training and an educational resource package on health providers' smoking cessation care for pregnant smokers, NRT prescribing practices and women's quit rates compared to health providers using their standard practices. This phase will not be included as

part of this PhD. All papers in this thesis have informed the development and design of this larger trial.

6.3 Adhering to NHMRC and AH&MRC guidelines for research with Aboriginal and Torres Strait Islander peoples

Detailed below is how I, and the rest of the research team, adhered to the NHMRC and AH&MRC guidelines when working on the ICAN QUIT in Pregnancy study.

Spirit and integrity

The study adhered at all times to the ethical guidelines, acknowledging and respecting Aboriginal and Torres Strait Islander peoples' cultural inheritance of past, current and future generations and the links that bind the generations together. This is outlined and reflected upon in adhering to all other five core values.

Cultural continuity, including Aboriginal community control of research and cultural sensitivity

The study recognised the diversity of Aboriginal and Torres Strait Islander peoples by taking into account community variants, differences in individuals' attitudes and experiences about smoking and quitting in pregnancy. The research team included three Aboriginal Chief Investigators and three Aboriginal Associate Investigators, who were involved in all aspects of the project, including the design, implementation, data analysis and interpretation. A Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP) was formed and included members of the representative services and communities to ensure cultural appropriateness of the research and resources, as well as advising on the analysis and reporting. The SCAAP monitored the development of resources, dissemination of information and overall cultural advocacy and advice for the study. An Aboriginal Cultural Liaison position was maintained to ensure appropriate level of Aboriginal and Torres Strait Islander community control and consultation was upheld.

Equity, including reimbursement of costs

Effort was placed on establishing relationships with services and community members prior to participating in the study. Separate consultations were performed with each AMS community board to ensure the research was acceptable, feasible and

appropriate for their communities. This was done for each phase separately. For paper six, the study undertook Aboriginal and Torres Strait Islander community consultation in the form of focus groups engaging Aboriginal women, Elders and health professionals.

Reciprocity, including net benefits for Aboriginal people and communities and enhancing Aboriginal skills and knowledge

Aboriginal and Torres Strait Islander peoples experience a lower life expectancy than all Australians, with tobacco representing the largest preventable risk factor (17% of the health gap). Pregnancy is an important time to intervene with smoking as it is a "teachable moment", and Aboriginal and Torres Strait Islander women have strong protective attitudes toward their babies. This research project was of direct benefit to Aboriginal and Torres Strait Islander communities by helping tackle tobacco smoking in order to prevent chronic disease. The net benefit of this research is that it will assist to find better ways to reduce smoking prevalence in Aboriginal and Torres Strait Islander women in pregnancy and thus enhance the health and wellbeing of Aboriginal and Torres Strait Islander peoples.

Through involvement in the ICAN QUIT in Pregnancy project, the AMS staff received free webinar training, a treatment manual and supporting resources for implementing the ICAN QUIT in Pregnancy guidelines. Similarly, the members of the research team were open to receiving knowledge and guidance from the Aboriginal and Torres Strait Islander health staff to improve their skills and cultural sensitivity in Aboriginal and Torres Strait Islander research. A staff member was chosen by each service to act as the research facilitator, receiving training and ongoing support from the research team on conducting research, including gaining informed consent, data collection and data storage. Throughout the study, and whenever possible, Aboriginal research assistants were recruited and trained.

Respect and responsibility

Negotiation was performed with each AMS community board to achieve a research agreement, and an organisational consent form was signed usually by the medical service Chief Executive Officer or Chair of the Board. This was done separately for each phase of the study. Ongoing consultations were accomplished with monthly SCAAP meetings. Regular emails and newsletters were distributed, and active

communication with the research team was encouraged. Participation was voluntary, and informed consent was obtained from all participants and their right of withdrawal from the project outlined with no reason for withdrawal required. Participants were encouraged to take the necessary time to decide on their participation and consult with other family and community members if they wished. The individual and collective contribution of participants and services, and the SCAAP, was recognised and acknowledged on all reports, publications and presentations. Drafts of these were sent to services for feedback prior to publication. AH&MRC approval of publication was sought for each presentation and publication. A community newsletter, detailing the results of the study in plain language and using visuals where possible, was prepared and distributed after each phase to services, encouraging them to distribute these as they saw fit to other community members.

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Published and Submitted Papers

Paper One:
Opportunities Missed: A Cross-Sectional Survey of the Provision of Smoking Cessation Care to Pregnant Women by Australian General Practitioners and Obstetricians

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Associated appendices

Appendix 1: Survey related material

Appendix 1.1: Ethics approval

Appendix 1.2: Information sheet

Appendix 1.3: Survey

Appendix 5: Published manuscripts

Appendix 5.1: Paper one published manuscript

Abstract

Introduction: Similar to other high-income countries, smoking rates in pregnancy can be high in specific vulnerable groups in Australia. Several clinical guidelines exist, including the 5As (Ask, Advice, Assess, Assist, Arrange); ABCD (Ask; Brief advice; Cessation; Discuss), and AAR (Ask, Advice, Refer). There is lack of data on provision of smoking cessation care (SCC) of Australian General Practitioners (GPs) and Obstetricians.

Methods: A cross-sectional survey explored the provision of SCC, barriers and enablers using the Theoretical Domains Framework (TDF), and the associations between them. Two samples were invited: 1) GPs and Obstetricians from a college database (n=5,571); 2) GPs from a special interest group for Indigenous health (n=500). Dimension reduction for the TDF was achieved with factor analysis. Logistic regression was carried out for performing all the 5A's and the AAR.

Results: Performing all of the 5As, ABCD, and AAR 'often and always' was reported by 19.9%; 15.6%, and 49.2% respectively. 'Internal influences' (such as confidence in counselling) were associated with higher performance of the 5A's (Adjusted OR 2.69 (95% CI 1.5, 4.8), $p<0.001$), whereas 'External influences' (such as workplace routine) were associated with higher performance of AAR (Adjusted OR 1.7 (95% CI 1, 2.8), $p=0.035$).

Conclusions: Performance in providing SCC to pregnant women is low among Australian GPs and Obstetricians. Training clinicians should focus on improving internal influences such as confidence and optimism. The AAR may be easier to implement, and interventions at the service level should focus on ensuring easy, effective and acceptable referral mechanisms are in place.

Implications

Improving provision of the 5A's approach should focus on the individual level, including better training for GPs and Obstetricians, designed to improve specific 'internal' barriers such as confidence in counselling and optimism. The AAR may be easier to implement in view of the higher overall performance of this approach. Interventions on a more systemic level need to ensure easy, effective and acceptable referral mechanisms are in place. More research is needed specifically on the acceptability of the Quitline for pregnant women, both Indigenous and non-Indigenous.

Introduction

Rates of smoking in pregnancy have been declining in high-income countries, dropping from between 20-35% in 1980, to 10-20% in 2000[1]. In Australia, 12% of all pregnant women in 2013 were smokers, but higher rates are reported for Indigenous Australian mothers (47%)[2].

There are several clinical guidelines to addressing smoking during pregnancy, e.g. the 5A's (Ask about tobacco use; Advise briefly to quit; Assess dependence and motivation to quit; Assist with support and medication; Arrange follow-up)[3,4]. A similar approach is the ABC (Ask; Brief advice; Cessation support)[5], and adapted for Indigenous Australian pregnant women, the ABCD includes an extra D component (Discuss psychosocial context of smoking)[6]. A briefer approach is the AAR (Ask, Advise, Refer)[7,8].

International Studies have shown that health professionals perform the Ask and Advise components fairly routinely but seldom the other components[9-23]. Up to a third of clinicians report delivering all of the 5A's[9,10,16]. Few studies included both General Practitioners (GPs) and Obstetricians[16,19,24,25]: with either no difference in the provision of smoking cessation care (SCC) between the two physician groups[16,19], or findings suggesting that GPs perform better[24,25].

Clinicians report facing multiple barriers to providing SCC to pregnant women, including: lack of time and administrative support; lack of knowledge and training; low confidence in personal skills; and a perception that smoking cessation interventions are not effective[9,26]. There is no current data on the level of smoking cessation care delivered to pregnant women by GPs or Obstetrician's in Australia.

This study aimed to examine: 1) Self-reported provision of SCC to pregnant women by GPs and Obstetricians in Australia; 2) Barriers and enablers to SCC and 3) Associations between physician group (GP/Obstetrician), knowledge, attitudes and the performance of SCC.

We hypothesise that Australian GPs and Obstetricians surveyed are lacking in their SCC provision to pregnant women who smoke; and that Australian GPs will perform better compared to Obstetricians.

Methods

Design: A national cross-sectional survey. Two sampling methods were used: 1) A paper survey sent as an insert in the Royal Australian and New Zealand Collage of Obstetricians and Gynaecologists (RANZCOG) magazine (5571 Obstetricians and GPs with obstetric training); 2) An online survey emailed to a random sample of 500 members of the Royal Australian Collage of General Practitioners National Faculty of Aboriginal and Torres Strait Islander Health (RACGP NFATSIH) (with a special interest in Indigenous health).

The study was approved by the University of Newcastle Human Research Ethics Committee (18/03/2015: H-2015-0067).

Survey instrument: included professional and demographic characteristics, self-reported provision of SCC; and self-assessment of barriers and enablers (see on-line Supplementary File).

Self-reported Provision of SCC: was measured using 5-point Likert scales (Never (0%); Occasional (1-25%); Sometimes (26-50%); Often (51-75%); Always (76-100%)) on the various components included in the 5A's, ABCD and AAR. Performing all the 5A's, ABCD, or AAR 'often & always' was categorised as 'Yes' if the participant answered 'often' or 'always' to all relevant components. Other components of SCC such as prescription of NRT and involvement of family members were measured with the same 5-point Likert Scale.

Barriers and enablers to SCC: were measured using the Theoretical Domains Framework (TDF). This is a validated and integrative theoretical framework that covers a range of domains relevant to professional practices and behaviour change[27]. Six domains using a total of 9 statements were measured on a 5-point Likert Scale (strongly disagree to strongly agree) including: 'Beliefs about Capabilities' (Confidence in counselling and in prescribing NRT), 'Optimism', 'Beliefs about Consequences' (benefit relationship), Goals/Plans' (high priority), 'Environmental Context and Resources' (sufficient time, resources, and workplace routine), 'Emotions' (comfortable raising the issue). The Knowledge domain was measured with one question ("Have you read any of the following guidelines? with 5 named), and was re-categorised as 'reading any guideline' Yes/No.

Analysis: was performed with SPSS v24. We performed a descriptive analysis using counts and percentages for categorical measures. Univariate analysis was performed

using Pearson's Chi-square test for categorical measures (with post-hoc comparisons using Bonferroni correction).

Dimension reduction for TDF statements was achieved with factor analysis, using Maximum likelihood method with Promax rotation. Factor means were then computed using included statements.

Logistic regression was performed separately for performing all the 5A's 'often & always', and performing the AAR 'often & always'. We included clinically relevant variables – physician group; medical practice remoteness; reading any guideline; and TDF factors after reduction. Complete case analysis was performed.

Results

Sample characteristics: A total of 378 clinicians completed the survey (42 NFATSIH GPs, 157 RANZCOG GPs and 178 RANZCOG Obstetricians; response rate 6.2%). Participants came from all Australian states and territories. Sixty two percent (n=235) were female, 83% (n=313) never smoked, and 1.9% (n=7) were current smokers. Fifty five percent (n=210) had over 20 years of experience. Few (5.4%, n=20) worked in remote areas[28], 63% (n=234) in urban settings, and 31.5% (n=117) in regional. Only 7.8% (n=29) catered for a population that was over 30% Indigenous, more from the NFATIH GPs (28.9%, n=11), than from RANZCOG GPs (9.6%, n=15; p=0.006), or Obstetricians (1.7%, n=3; p<0.001).

Self-reported Provision of SCC: Over 75% reported 'always' performing the Ask and Advise components, and less than a third (33%) 'always' performing the rest of the components (Table 1). Less NFATSIH GPs reported 'always' referring their patients (7.1%, n=2) compared to RANZCOG GPs (21.1%, n=32; p=0.114); and Obstetricians (34.7%, n=61; p=0.003). Performing all the 5A's, ABCD, and AAR 'always' was stated by 1.6% (n=6), 1.4% (n=5), and 20.2% (n=76), respectively.

Performing all the 5A's 'often and always' was stated by 19.6% (n=74); 15.6% (n=59) for the ABCD; and 49.2% (n=186) for the AAR.

Table 1: Self-Reported Provision of Smoking Cessation Care, n(%)

Total sample (n=378) (missing n,%)	**Always (76-100% of the time)**	**Often (51-75%)**	**Sometimes (26-50%)**	**Occasional (1-25%)**	**Never (0%)**
Ask about smoking status (missing n=3, 0.8%)	290 (77.3%)	67 (17.9%)	14 (3.7%)	2 (0.5%)	2 (0.5%)
Give brief advise to quit if smoking (missing n=8, 2.1%)	276 (74.6%)	73 (19.7%)	13 (3.5%)	4 (1.1%)	4 (1.1%)
Assess nicotine dependence (missing n=6, 1.6%)	90 (24.2%)	89 (23.9%)	66 (17.7%)	47 (12.6%)	80 (21.5%)
Provide Cessation support to smokers (Assist) (missing n=6, 1.6%)	125 (33.6%)	112 (30.1%)	58 (15.6%)	43 (11.6%)	34 (90.1%)
Follow-up within 2 weeks (Arrange) (missing n=5, 1.3%)	26 (7%)	63 (16.9%)	104 (27.9%)	88 (23.6%)	92 (24.7%)
Prescribe/recommend NRT to assist quitting (missing n=7, 1.9%)	41 (11.1%)	76 (20.5%)	89 (24%)	72 (19.4%)	93 (25.1%)
Discuss their psychosocial context of smoking (missing n=6, 1.6%)	82 (22%)	106 (28.5%)	69 (18.5%)	57 (15.3%)	58 (15.6%)
Referral to Quitline/specialist service (missing n=21, 5.6%)	95 (26.6%)	99 (27.7%)	57 (16%)	47 (13.2%)	59 (16.5%)
Involving family members in counselling/tobacco management (missing n= 6, 1.6%)	15 (4%)	57 (15.3%)	87 (23.4%)	143 (38.4%)	70 (18.8%)

Barriers and enablers to SCC: Almost all clinicians (98%) reported that addressing smoking during pregnancy is a high priority, and that they feel comfortable raising the issue with a pregnant woman (95%). TDF statements receiving the lowest agreement (agree & strongly agree) were having sufficient time (41%), sufficient resources (47.5%) and optimism of intervention effectiveness (35%). Dimension reduction revealed two factors: 1) 'Internal influences' including confidence in counselling, confidence in prescribing NRT, optimism, sufficient time and resources; 2) 'External influences' including high priority, benefit relationship, workplace routine, and comfortable raising the issue.

Associations between knowledge and attitudes and performance of SCC: Table 2 details the crude and adjusted Odds Ratio (OR) for performing all the 5A's 'often & always' and performing the AAR 'often & always'. Compared to NFASTIH GPs, being an Obstetrician was associated with lower performance of all the 5A's (Adjusted OR 0.2 (95% CI 0.08, 0.5), $p<0.001$), but with a higher performance of AAR (Adjusted OR 39.43 (95% CI 8.6, 178.9), $p<0.001$). No difference was found between the performance of the RANZCOG GPs and Obstetricians. 'Internal influences' were associated with a higher performance of all the 5A's (Adjusted OR 2.69 (95% CI 1.5, 4.8), $p<0.001$), whereas 'External influences' were associated with a higher performance of AAR (Adjusted OR 1.7 (95% CI 1, 2.8), $p=0.035$).

Discussion

In this sample of GPs and Obstetricians in Australia, performance of SCC in pregnancy, aside from the Ask and Advise components, is low and variable, ranging from 4-33%. Internal influences (including high confidence in counselling and prescribing NRT, higher optimism, sufficient time and resources) were associated with a higher performance of all the 5A's, while External influences (high priority, workplace routine, benefit to relationship, and comfortable raising the issue) were associated with a higher performance of the AAR. Physician group was also associated with performance, with Obstetricians performing the AAR better, and the 5A's less well, compared to NFATSIH GPs.

Table 2: Crude and Adjusted Odds Ratio (OR) for performing all the 5A's and the AAR 'often & always'

*Internal barriers includes confidence in counselling, confidence in prescribing NRT, optimism in intervention effectiveness, sufficient time and resources

Variable	**Preforming all the 5As often or always** (n=340)					**Performing all the AAR often or always** (n=346)				
	Performing all the 5As often or always n (%)	**Crude**		**Adjusted**		**Performing all the ARR often or always n (%)**	**Crude**		**Adjusted**	
		Odds Ratio (95%)	**P-value**	**Odds Ratio (95%)**	**P-value**		**Odds Ratio (95%)**	**P-value**	**Odds Ratio (95%)**	**P-value**
Physician Group			<0.001		<0.001			<0.001		<0.001
RANZCOG OBS	23 (13.4%)	Ref.		Ref.		101 (57%)	Ref.		Ref.	
RANZCOG GPs	30 (19.5%)	1.567 (0.86, 2.83)	0.138	0.973 (0.18, 1.96)	0.938	82 (52.2%)	0.823 (0.53, 1.26)	0.376	0.635 (0.37, 1.08)	0.097
NFATSIH GPs	20 (50%)	**6.478 (3.03, 13.8)**	**<0.001**	**4.79 (1.95, 11.74)**	**0.001**	2 (4.8%)	**0.038 (0.009,0.1)**	**<0.001**	**0.025 (0.006, 0.1)**	**<0.001**
Medical Practice Remoteness			0.074		0.297			0.019		0.233
Urban	40 (17.8%)	Ref.		Ref.		126 (54%)	Ref.		Ref.	
Regional	31 (27%)	1.7 (0.99, 2.91)	0.05	1.12 (0.59, 2.12)	0.732	51 (43.6%)	0.65 (0.42, 1.0)	0.065	0.80 (0.47, 1.37)	0.422
Remote	2 (10%)	0.51 (0.11, 2.3)	0.384	0.27 (0.04, 1.6)	0.152	5 (25%)	0.28 (0.1, 0.8)	0.018	0.381 (0.11, 1.21)	0.104
Reading any guideline										
No	20 (12.8%)	Ref.		Ref.		65 (40.1%)	Ref.		Ref.	
Yes	54 (25.6%)	2.33 (1.33, 4.1)	0.003	**2.09 (1.08, 4.04)**	**0.027**	121 (56%)	1.92 (1.27, 2.9)	0.002	**2.73 (1.67, 4.45)**	**<0.001**
Internal barriers*	Mean(SD) Yes 3.7(0.6) No 3.3(0.6)	3.47 (2.16, 5.57)	<0.001	**2.69 (1.52, 4.78)**	**0.001**	Mean(SD) Yes 3.4(0.6) No 3.3(0.7)	1.18 (0.86, 1.62)	0.296	1.17 (0.76, 1.81)	0.465
External barriers[$]	Mean(SD) Yes 4.5(0.4) No 4.2(0.5)	3.275 (1.81, 5.91)	<0.001	1.989 (0.97, 4.06)	0.059	Mean(SD) Yes 4.3(0.5) No 4.2(0.6)	**1.57 (1.05, 2.33)**	**0.027**	**1.71 (1.03, 2.8)**	**0.035**

[$]External barriers includes high priority, benefit relationship, workplace routine, comfortable raising the issue

These findings are consistent with similar studies from other countries, with health providers providing Ask and Advise components more than with the other components of SCC[9-23]. The barriers reported in this study are very similar to those cited in a non-systematic review[9]: lack of time; low confidence in personal skills; and a perception that smoking cessation interventions are not effective[9,26]. Other studies have examined the associations of different barriers to the provision of the 5A's, showing that specific barriers such as lack of resources[16], or perceived impact of counselling[29], affect the overall performance of the 5A's. To the best of our knowledge, our research is the first to suggest which barriers influence the different approaches to SCC in pregnancy, such as the 5A's versus the AAR.

Performing all the required 5A's was done by less than 20% of participants and was associated with barriers that are internal such as low confidence and low optimism. These need to be addressed by specific behaviour change interventions at the physician level including more precise training, and providing adequate resources. Performance of the shorter, more practical, AAR was higher, with almost 50% performing this at least 'often'. This may suggest that the AAR approach could be easier to implement. External influences such as workplace routine and placing this topic as a high priority could be addressed through systematic interventions at the service level. Although perceived lack of time was grouped through the dimension reduction with the internal influences, this factor might be better addressed on a more systematic level, through adequate referral pathways.

The findings that NFASTIH GPs are performing the 5As better than Obstetricians or other GPs might reflect the importance of this topic in the population they treat. However, the low referral rates reported by this physician group require special attention. A Quitline is provided in Australia, with Aboriginal counsellors available. Currently there is no data on Indigenous pregnant women's views or utilization of this method. This is an area for further research.

Implication for policy and practice: Improving provision of the 5A's approach should focus on better training for GPs and Obstetricians, designed to improve confidence and optimism. Although the highest performance level was demonstrated by NFATSIH GPs, these levels are still low. The feasibility of training clinicians in the ABCD approach needs to be explored with those working with Indigenous pregnant mothers.

Improving the provision of the AAR approach might be easier to implement in view of the higher overall performance of this approach. It should be a priority to ensure easy, effective and acceptable referral mechanisms are in place. More research is needed specifically on the acceptability of the Quitline for pregnant women, both Indigenous and non-Indigenous. More explicit strategies could be put in place to ensure physicians refer women, and that the women are supported to use it. There may be a need to explore other referral options that are more intensive and individually tailored, such as to specialist cessation clinics. Studies have suggested that a more holistic approach that addresses the multiple stressors and challenges to quitting is needed, framing this more as a social matter that needs to be addressed in community settings, rather than just in the health sector[6,30,31]. This might be even more important in the Indigenous population, where medical services are often supplied through Aboriginal Community Controlled Health Services.

Limitations and Strengths: A limitation of this work is the low response rate, indicating this sample may not be generalizable to all Australian GPs and Obstetricians. In spite of this, these findings are consistent with other surveys globally[9-23], supporting the cautious assumption that this is a true or over-estimation of actual practices. The low response rate needs to be kept in mind when interpreting these findings, and these results need to be confirmed by a larger more representative sample. Another limitation is the lack of data regarding previous training. This needs to be addressed in further research. One strength of this study was that it was a national survey, covering all states, and different settings. Another strength is that we included a subsample of GPs that are involved in Indigenous Health. This was justified as Australian Indigenous women have the highest rates of smoking during pregnancy[2].

Conclusions: In summary, performance in 'Assess', Assist' and 'Follow-up' aspects of SCC is low. Training GPs and Obstetricians should focus on improving internal influences such as confidence and optimism. Interventions on the service level may lead to higher rates of referral, and improve the implementation of the AAR approach. Further research is needed in this area, specifically in the Indigenous population.

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Declaration of interests

Dr Bar Zeev has received fees for lectures in the past (years 2012-2015) from Novartis NCH (distributes NRT in Israel). She has not received any fees from pharmaceutical companies in Australia. No other co-authors have conflicts of interest.

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Introduction to Paper Two

Paper one described current practices, and barriers and facilitators, of providing smoking cessation care during pregnancy among GPs and obstetricians.

According to the 5As, only the first 2As ("Ask" and "Advise") were being reliably performed, with deficits in the implementation of the "Assess", "Assist" and "Arrange" components. The most commonly reported barriers were lack of time and resources, lack of optimism that their intervention would be effective and lack of confidence in prescribing NRT. A subset of GPs, members of the RACGP's National Faculty of Aboriginal and Torres Strait Islander Health (i.e. either working in Aboriginal and Torre Strait Islander health, identifying as Aboriginal and/or Torres Strait Islander themselves or having a special interest in Aboriginal and Torre Strait Islander health) performed better compared to RANZCOG's obstetricians and GP diplomates.

This paper quantitatively explored the factors that were associated with a higher performance of overall smoking cessation care, without delving into the influences of each smoking cessation component.

To gain a better understanding of what influences NRT prescription during pregnancy, this was examined specifically in paper two.

Paper Two:
Clinician Factors Associated with Prescribing Nicotine Replacement Therapy in Pregnancy: A Cross-Sectional Survey of Australian Obstetricians and General Practitioners

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Associated appendices

Abstract

The use of nicotine replacement therapy in pregnancy has been debated but evidence suggests that it is safer than smoking. A cross-sectional survey was conducted with: 1) general practitioners and obstetricians from a college database; 2) general practitioners with a special interest in Indigenous health. General practitioners had higher odds of prescribing compared to obstetricians. Reading guidelines, confidence, viewing nicotine replacement therapy as safe, effective, and with good adherence, also significantly increased the odds of prescription. Clear guidance regarding safety and efficacy, with practical clinical protocols, are required in order to reduce variation in prescribing rates across these clinicians.

Introduction

Smoking in pregnancy is an important risk factor for adverse pregnancy and foetal outcomes.[1] The use of nicotine replacement therapy (NRT) during pregnancy has been debated due to the potential harmful effects of nicotine on foetal development.[2-4] However, NRT provides a slower and lower absorption rate of nicotine, compared to smoking.[5] Due to the higher metabolism of nicotine in pregnancy,[6] pregnant women who smoke might need a higher NRT dose, than non-pregnant women.[1,2,6]

In the 2015 Cochrane review, NRT use during pregnancy increased cessation by 40% (relative risk 1.41, 95% CI 1.03-1.93), and was not associated with any harmful effects.[1] In UK stop smoking services,[7] combination NRT (oral NRT combined with a nicotine patch) was significantly associated with smoking cessation compared to pregnant women not receiving NRT (OR = 1.93, 95% CI 1.13–3.29), whereas using one form of NRT was not effective (odds ratio (OR) = 1.06, 95% CI 0.6-1.86).

The Royal Australian College of General Practitioners (RACGP)[8] guidelines recommend that pregnant women who are motivated to quit, and have been unsuccessful without medication, should be offered NRT after discussing the relative risks and benefits. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Statement[9] does not routinely recommend using NRT in pregnancy, yet acknowledges that NRT might be used with pregnant women who are highly dependent, and unable to quit.

International studies have found that NRT prescribing rates during pregnancy were relatively low, ranging from 7-55%[10-13]. Safety concerns and lack of training were mentioned as common barriers.[11-13]

Using NRT during pregnancy is recommended to be under the supervision of a health professional.[8] Nonetheless, NRT can be bought over the counter, and therefore for the purpose of this study, NRT prescription refers to either a prescription and/or a recommendation for NRT use.

This study aimed to examine: 1) self-reported NRT prescription rates during pregnancy; 2) the association between clinician-related factors, including attitudes, confidence and guidelines awareness, and NRT prescription rate, in Australian general practitioners (GPs) and obstetricians.

Material and Methods

Design: A national self-administered cross-sectional survey (July to November 2015).

Sample: Eligible participants were Australian obstetricians or GPs with or without obstetric training, who confirm pregnancy or consult with pregnant women.

Procedures: Two sampling methods were used: 1) a paper survey sent as an insert in The RANZCOG "O&G" magazine distributed to 5571 obstetricians and GPs with obstetric training, and 2) an online survey emailed to a random sample of 500 members of the RACGP National Faculty of Aboriginal and Torres Strait Islander Health (members are either working or have a special interest in Aboriginal and Torres Strait Islander health, and/or identify as Aboriginal and Torres Strait Islander). The first sample did not receive a reminder. The second sample received one reminder after two weeks. An Information Statement was provided with survey completion providing assumed consent. An incentive of a draw of one of two mini-tablet devices was offered. The University of Newcastle Human Research Ethics Committee approved the study (#H-2015-0067, 18/03/2015).

Survey: Included questions about participant's characteristics, self-reported provision of smoking cessation care, including NRT prescription; factors associated with prescribing NRT in pregnancy; and a self-assessment of barriers and enablers to providing smoking cessation care. The full survey description can be found elsewhere.[14] Results presented here include self-reported prescription of NRT and factors related to prescribing NRT in pregnancy.

Participant characteristics: included gender, years since medical qualification, smoking status, population their medical practice mostly caters for (general or Aboriginal and Torres Strait Islander), and work location postcode (for rural, remote and urban classification).[15]

Frequency of prescribing NRT: A 5-point Likert scale was used - Never (0%); Occasional (1-25%); Sometimes (26-50%); Often (51-75%); Always (76-100%). Another set of questions, with the same Likert Scale, asked specifically the prescription rates of a) oral forms, b) patches and c) combination NRT.

Clinician factors associated with prescribing NRT: Clinicians were asked to rate the following factors - perceived safety, effectiveness and women's adherence of NRT. Self-reported confidence (to prescribe) was measured using a 5-point Likert Scale

(strongly disagree to strongly agree). An additional question assessed reading the RACGP guidelines Yes/No.

Analysis: was performed with SPSS v24 (IBM, Armonk, NY, USA). A descriptive analysis used counts and percentages. Univariate analysis was performed using Pearson's Chi-square test for categorical measures (with post-hoc comparisons using Bonferroni correction), and Kruskal-Wallis for ordinal measures, to examine the association between all clinician factors (physician group – RACGP GPs, RANZCOG GPs, obstetricians; perceived NRT safety, effectiveness, and adherence; confidence; and reading the RACGP guidelines) and NRT prescription frequency.

Separate ordinal regressions were performed to examine the associations between each clinician factor listed above on NRT prescription frequency, adjusted for gender and years from medical qualification to account for possible confounding.

Results

Sample characteristics: 378 clinicians completed the survey (42 RACGP GPs, 157 RANZCOG GPs and 178 obstetricians, 1 missing the answer regarding specialty; response rate 6.2%), from all Australian states and territories. Most GPs (81.4% (n=162) had obstetric training, 97.5% (n=153) of RANZCOG GPs, and 21.4% (n=9) of RACGP GPs. A full description can be found elsewhere.[14]

Prescription of NRT and clinician factors associated with prescribing NRT

'Never' prescribing NRT was reported by 25.1% (n=93), more so by obstetricians (38.9%, n= 68) compared to RACGP GPs (12.2%, n=5, $p<0.001$), and RANZCOG GPs (13%, n=20, $p<0.001$). Nearly half (49.9%, n=181) reported 'never' prescribing combination NRT, fewer RACGP GPs (30%, n=12), compared to obstetricians (58.1%, n=100, $p<0.001$) and RANZCOG GPs (45.7%, n=69, $p=0.004$).

Clinician factors associated with NRT prescribing are presented in Table 1.

Table 1: Clinician factors association with NRT prescription to pregnant smokers according to physician group, n (%)

Variable	Total sample (n=378)	Online sample GP's from RACGP NATIFH (n=42)	Paper survey GP's from RANZCOG (n=157)	Paper survey OBS from RANZCOG (n=178)	Chi-Square/ Kruskal-Wallis test
NRT Safety (n=370, missing n=8)					
Very safe and Safer than smoking	165 (44.6%)	14 (34.1%)	75 (48.1%)	76 (43.9%)	$\chi2$=2.6, p=0.27
Safer than smoking but some concerns and Not safe	205 (55.4%)	27 (65.9%)	81 (51.9%)	97 (56.1%)	
NRT Effectiveness (n=372, missing n=6)					
Very effective and Moderately effective	247 (66.4%)	29 (70.7%)	113 (72.4%)	105 (60%)	$\chi2$=6.1, p=0.047
Low effectiveness and Not effective	125 (33.6%)	12 (29.3%)	43 (27.6%)	70 (40%)	
NRT Adherence (n=346, missing n=36)					
Most adhere to NRT well	29 (8.4)	2 (6.9)	20 (13.1)	7 (4.3)	$\chi2$=12.8, p=0.012
Equal numbers adhere well and poorly	179 (51.7)	12 (41.4)	84 (54.9)	83 (50.6)	
Most adhere to NRT poorly	138 (39.9)	15 (51.7)	49 (32)	74 (45.1)	
"I am confident that I can prescribe NRT for pregnant smokers" (n=370, missing n=8)					
Strongly agree	38 (10.3%)	5 (12.8%)	22 (14.2%)	11 (6.3%)	$\chi2$=29.4, p<0.001
Agree	163 (44.1%)	22 (56.4%)	78 (50.3%)	63 (35.8%)	
Neutral	91 (24.6%)	10 (25.6%)	36 (23.2%)	45 (25.6%)	
Disagree	61 (16.5%)	2 (5.1%)	17 (11%)	42 (23.9%)	
Strongly disagree	17 (4.6%)	0 (0%)	2 (1.3%)	15 (8.5%)	
Reading the RACGP guideline (n=359, missing n=19)					
Yes	150 (41.8%)	27 (64.3%)	90 (59.6%)	33 (19.9%)	$\chi2$=61.1, p<0.001
No	209 (58.2%)	15 (35.7%)	61 (40.4%)	133 (63.6%)	

GP, general practitioner; NATIFH, National Faculty of Aboriginal and Torres Strait Islander Health; NRT, nicotine replacement therapy; OBS, obstetricians; RACGP, Royal Australian College of General Practitioners; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

Table 2: Crude and adjusted† odds ratio for NRT prescription frequency from ordinal regression analyses

Variable	NRT Prescribing Frequency			
	Crude		Adjusted†	
	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)	P-value
Physician Group (n=370)				
RANZCOG OBS	Ref.		Ref.	
RANZCOG GPs	3.16 (2.12, 4.72)	<0.001	3.45 (2.3, 5.18)	<0.001
RACGP GPs	4.1 (2.2, 7.61)	<0.001	4.16 (2.23, 7.76)	<0.001
NRT safety (n=365)				
Concerns over safety	Ref.		Ref.	
Safer than smoking	3.26 (2.22, 4.78)	<0.001	3.24 (2.21, 4.77)	<0.001
NRT effectiveness (n=367)				
Not effective	Ref.		Ref.	
Effective	2.55 (1.71, 3.78)	<0.001	2.73 (1.82, 4.1)	<0.001
NRT adherence (n=342)				
Most adhere poorly	Ref.		Ref.	
Equal adhere well and poorly	1.86 (1.25, 2.79)	0.002	1.81 (1.21, 2.71)	0.004
Most adhere well	2.19 (1.07, 4.48)	0.032	2.19 (1.06, 4.51)	0.034
"I am confident that I can prescribe NRT for pregnant smokers" (n=366)				
Strongly disagree to neutral	Ref.		Ref.	
Strongly agree & agree	8.2 (5.39, 12.5)	<0.001	8.6 (5.64, 13.19)	<0.001
Reading the RACGP guidelines (n=354)				
No	Ref.		Ref.	
Yes	2.43 (1.27, 3.56)	<0.001	2.4 (1.65, 3.6)	<0.001

GP, general practitioner; NRT, nicotine replacement therapy; OBS, obstetricians; RACGP, Royal Australian College of General Practitioners; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists

†Adjusted for gender and years from medical qualification.

Associations between clinician factors and prescription of NRT:

Table 2 details the crude and adjusted ORs for prescribing NRT using ordinal regression analyses. RACGP GPs (adjusted OR 4.1, 95% CI 2.2-7.7, p<0.001) and RANZCOG GPs (adjusted OR 3.45, 95% CI 2.3-5.1, p<0.001) had higher odds of NRT prescription, compared to obstetricians. Reading the RACGP guidelines, confidence to prescribe NRT, viewing NRT as safe, effective, and with good adherence, were also significantly associated with higher odds of NRT prescription.

Discussion

Main findings: Twenty-five percent of participants reported 'never' prescribing NRT during pregnancy. Nearly half (49.9%) reported they 'never' prescribe combination NRT. Being an obstetrician, low confidence, and uncertainty over NRT safety, effectiveness and adherence, were all independently associated with lower odds of prescribing NRT.

Comparison with the literature: These findings are consistent with previous international studies showing low levels of NRT prescription and low levels of confidence, associated particularly with safety concerns.[11,13,16-19] The low frequency of NRT prescription could partly be explained by the lack of a strong evidence base on the effectiveness and safety of NRT in pregnancy.

Women may hold negative views regarding NRT use during pregnancy.[20] A clinician's low confidence might be partially attributable to their perceived ability to potentially address negative patient views.

Reading the RACGP guidelines was associated with higher odds of prescribing. As these guidelines are more "favourable" for NRT use in pregnancy, this highlights the need for clear practical up-to-date guidelines that can direct clinicians' decisions.

Implication for policy and practice:
Further research is needed to strengthen the evidence base regarding NRT safety and effectiveness in pregnancy, specifically in regard to using higher doses and combination NRT[1]. Specific training on the management of smoking during pregnancy is essential, in particular on 'when' and 'how' to use NRT, 'how' to consult on the risks versus benefit of using NRT during pregnancy, and 'how' to proactively address patient concerns about using NRT. Guidelines need to be updated regularly, and be more practical. . Pregnant women receive information from multiple health professionals as part of their prenatal care, and a consistent message is crucial for changing smoking behaviour.

A practical approach would be for clinicians to aid women to weigh up their relative risk versus benefit from using NRT in pregnancy. NRT provides lower levels of nicotine compared to smoking, and experts and guidelines agree that NRT is

comparatively safer. This may assist in all pregnant women who smoke being offered an informed option about NRT treatment in a timely manner.

Limitations and Strengths: Strengths of this study include national sampling, different geographical settings, and a subsample that are involved in Aboriginal and Torres Strait Islander Health. A limitation of the research was the low response rate, indicating that this sample may not represent all Australian GPs and obstetricians, and may reflect those more interested in tobacco related topics, suggesting that if anything, the results may over-estimate practices, and NRT prescribing rates may be lower. Another limitation is that the RANZCOG statement was not included as an option in the reading guidelines question, so we could not assess whether familiarity with this guideline impacted practice. The data presented here was part of a larger survey and only a few NRT specific questions were included. Further research should include a larger more representative sample, and a more in depth understanding of clinician's attitudes, and what they need in order to change their NRT prescription rates.

Conclusions: NRT prescription rates during pregnancy are low: more so among obstetricians than GPs. Concerns over safety and low confidence are associated with lower odds of prescribing NRT. Training and practical detailed protocols may help change clinicians' views on the 'harm versus benefit' of NRT.

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Introduction to Paper Three

Both papers one and two described the results from a cross-sectional study, using quantitative data analysis. Results from both these papers showed that among the survey participants, the provision of smoking cessation care during pregnancy was lacking. Specifically, GPs and obstetricians reported low rates of performing the "Assist" component of the 5As, including low rates of NRT prescription and low rates of referral to Quitline. Several factors were found to be associated with GPs' and obstetricians' low rates of smoking cessation care provision, including lack of time and resources, low optimism that their intervention would be effective and low confidence in their ability to counsel patients about smoking cessation during pregnancy. Higher levels of NRT prescription were associated with perceptions that NRT treatment during pregnancy is safe, effective and that pregnant patients adhere to the treatment, and with confidence in their ability to prescribe NRT. However, the cross-sectional survey design was not able to explore in depth the reasons behind these associations and what would enable GPs to provide a higher level of evidence-based smoking cessation care. Furthermore, to the best of my knowledge, a qualitative study has never been done in Australia with GPs to explore their provision of smoking cessation care during pregnancy.

In paper three, a qualitative exploration was undertaken to gain a deeper insight to the approach that GPs use in treating pregnant women who smoke and, more importantly, what they feel would help them to improve their support for smoking cessation during pregnancy and the prescription of NRT.

Paper Three:
Overcoming Challenges to Treating Smoking During Pregnancy – A Qualitative Analysis of Australian General Practitioners Barriers and Facilitators

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Associated appendices

Appendix 2: Qualitative study related material

Appendix 2.1: Ethics approval

Appendix 2.2: Information sheet

Appendix 2.3: Interview guide

Appendix 6: Confirmation emails of submitted manuscripts

Appendix 6.1: Paper three confirmation email of submission

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Abstract

Introduction

General Practitioners (GPs) can play an important role in addressing smoking among pregnant women but studies suggest they rarely do so. The aim of this study was to explore GPs perceptions about the management of smoking in pregnancy, and what would enable them to provide better care.

Methods

Qualitative semi-structured interviews were conducted with 19 Australian GPs recruited from a sample that participated in a national survey on managing smoking during pregnancy; and through a national GP conference. The interview and analysis were guided by the theoretical domains framework, exploring previously reported barriers and smoking cessation care components not often provided, such as nicotine replacement therapy (NRT).

Results

Participants reported lacking communication skills to provide pregnant patients adequate support for quitting, focusing on providing information on smoking harm, encouraging cutting down cigarettes smoked, following the 'Stages of Change' model and only providing treatment options to motivated patients. Lack of time, NRT cost and safety concerns, and being unfamiliar with the Quitline (particularly for Aboriginal and Torres Strait Islander pregnant smokers) were perceived as challenges. Participants reported needing clear detailed NRT guidelines, training, and visual resources they could use to discuss treatment options with patients.

Conclusions

Difficulty communicating with pregnant patients about smoking, using the 'Stages of Change' model to guide support provision and concerns regarding NRT safety are barriers to providing cessation support to pregnant patients for GPs. Training, clear guidance for NRT use, and practical visual patient education tools may facilitate smoking cessation care provision to pregnant women.

Implications

Smoking during pregnancy remains a significant health concern, yet, Australian general practitioners are not providing adequate smoking cessation support due to multiple barriers. This study suggests that to overcome the barriers, GPs require communication skills training, with practical detailed guidance on NRT prescription, and visual resources to support their discussions with their pregnant patients. General practitioners need to move beyond the 'stages of change' behaviour change model and provide every pregnant woman who smokes the current smoking cessation options, regardless of her reported motivation to quit.

Introduction

Smoking during pregnancy remains a global public health challenge[1,2], and is one of the most important risk factors for poor health outcomes.[3] Globally, rates of smoking among pregnant women range from 7% to 18%.[1] In Australia, in 2016, 9.9% of pregnant women reported smoking. Higher smoking rates are found in younger mothers under the age of 20 years (30.5%), living in the lowest socio-economic areas (17.4%) and Aboriginal and Torres Strait Islander women (42%) (hereafter referred to "Aboriginal" women with acknowledgement of the distinct cultures).[4]

Internationally recognised clinical guidelines recommend using the 5A's approach when treating pregnant women who smoke.[5] The Royal Australian Collage of General Practitioners (RACGP) also recommend using the 5A's[6] and structure the recommended counselling approach using the Trans-Theoretical theory, i.e. the 'stages of change' model.[7] According to this theory, smokers transition though a cycle of readiness to change their behaviour.[7] Hence RACGP guidelines recommend assessing the patients' motivation to quit, and tailoring advice accordingly.[6] However, evidence now suggests that this approach is outdated, and interventions based on stages of change have not shown to be more effective.[8]

Additionally, these guidelines recommend initially only behavioural counselling, but if this is unsuccessful, the pregnant woman should be offered nicotine replacement therapy (NRT) after weighing the risks versus benefits.[6] A meta-analysis of studies indicate that NRT might increase cessation rates by 40%.[9] Nicotine in itself has been found in animal studies to be harmful for the foetus brain and lung development[3,10], but studies in humans have not found any evidence of harm[9,11]. Therefore, expert opinion in Australia and other countries is that NRT is always safer than continuing smoking.[6,11-13] The RACGP guidelines recommend oral NRT as first line pharmacotherapy, then NRT patch followed by combination NRT (oral plus patch).[6]

Previous research has shown that globally health providers are not providing adequate smoking cessation care (SCC) during pregnancy. Studies report low rates of assisting pregnant women to quit, referring to other cessation support, including the Quitline, and prescribing NRT.[14-16] Multiple barriers have been identified in the past including lack of knowledge and skills, lack of confidence in ability to counsel and prescribe NRT, lack of time and resources, perceptions that patients do not want to be advised, and doing so would be detrimental to the provider-patient relationship.[14,15,17]

A recent Australian national cross-sectional survey with 378 general practitioners (GPs) and obstetricians, found similar results to other international studies.[18,19] A high proportion of clinicians reported always 'Asking' (77%) and 'Advising' to quit (75%), but lower proportions reported always doing the 'Assess' (24%), 'Assist' (33%), and 'Arrange' (7%) components.[18] Furthermore, 25% stated they would never prescribe NRT, and over 50% had some concerns regarding NRT safety.[19] Only 26% stated they always refer pregnant patients to the Quitline. The Theoretical Domains Framework (TDF) is a validated and integrative theoretical framework that covers a range of domains relevant to professional practices and behaviour change.[20] Using the TDF revealed that the most frequently reported barriers were lack of time and resources, lack of optimism, and lack of confidence in their ability to prescribe NRT.[18,19]

The purpose of this study was to further explore the perceptions and attitudes of GPs consulting with pregnant women who smoke, and what would enable them to better manage smoking in pregnancy. The study aims to describe their individual experiences with providing SCC to pregnant women who smoke and what would facilitate them to overcome known barriers.

Methods

Participants and Recruitment

Participating GPs (n= 19) were recruited from two samples:

1. 118 GPs were invited from a sample that took part in the national survey mentioned above[18,19,21] and gave consent to be further contacted. This database also provided the participants' socio-demographic data and self-reported knowledge, attitudes and actual practices.
2. During the 2016 National Australian GP conference, the study was advertised. Interested GPs were asked to contact the research team for further information (n=4 responded).

An email invitation was sent to all 122 GPs, and a reminder email was sent to those that didn't reply. Purposive sampling was conducted to try to sample GPs who had reported both high and low levels of SCC provision in the survey, however, no low level care providers were recruited. Recruitment was continued until saturation of themes, resulting in 16 GPs recruited through the survey database and 3 GPs recruited through the conference.

Procedure

Telephone interviews were conducted using a semi-structured interview guide (Supplemental file 1). The interview guide was structured using TDF[20] domains that were reported in the national survey as barriers [18,19]: Environmental Context and Resources (lack of time and resources); Beliefs about Capabilities (Confidence in prescribing NRT); and Optimism. Two components of SCC were specifically explored – NRT prescription, and Quitline referral.

Analysis

Transcription was completed by a professional service. Interviews were read repeatedly and then coded line by line using a general thematic approach[22], with NVivo software (version 11). Initially, a subset of the data (n=5 interviews) was independently coded by two researchers (YBZ and ES), and a coding manual developed. The coding manual was used by one researcher (YBZ) to code the remaining transcripts. If new themes were discovered, they were discussed and agreed upon with the second coder (ES). YBZ is a female Public Health Physician and Tobacco Treatment Specialist, with extensive experience in training physicians regarding smoking cessation. Prior to conducting this study, she received specific training on qualitative data collection and analysis. ES is a female health behaviour scientist with prior experience in qualitative analysis. In addition, field notes were kept during the data collection process, to capture the researcher's thoughts, opinions and feelings, and were reflected upon during the analysis. This process enabled researcher triangulation, reducing bias, and enhancing transferability and confirmability of the findings.

Ethics

This study was approved by the University of Newcastle Human Research Ethics Committee (H-2016-0063, 08/06/2016).

Results

Reporting was guided by the COREQ checklist.[23]

Participant's characteristics:

Participants came from all Australian states, except the Australian Capital Territory. Socio-demographic characteristics are detailed in Table 1. Interview length was, on average, 26 minutes (range 18-46). Data regarding self-reported practices and attitudes from the 16 survey participants are provided in Supplemental file 2.

Table 1: sociodemographic characteristics of participants and medical practice settings

Variable	N (%)
Gender - Female	16 (84.2%)
Age (missing n=4)	
Under 44	6 (42.9%)
45-60 years old	6 (42.9%)
Over 60 years	2 (14.3%)
Obstetric training (missing n=3)	13 (81.3%)
Years since medical qualification (missing n=3)	
<10 years	4 (25%)
10-19 years	5 (31.3%)
20 plus years	7 (43.8%)
Smoking status (missing n=3)	
Ex-smoker	2 (12.5%)
Never smoker	14 (87.5%)
Medical Practice	
Urban	6 (31.6%)
Regional	10 (52.6%)
Remote	3 (15.8%)
Population usually caters for (missing n=1)	
General population	10 (55.6%)
Over 30% Aboriginal and Torres Strait Islander	8 (44.4%)

Themes

'Needing clear and detailed information'

Participants' knowledge and confidence were high, most of the participants described their SCC concordant with RACGP guidelines. Nonetheless, when asked specific questions regarding NRT and the Quitline, it was evident that a lot of misinformation exists.

Most of the participants were comfortable prescribing NRT during pregnancy (also evident in their survey answers, supplemental file 2), and stated that NRT was safer than smoking. Despite this, some reported concerns "*I always feel a bit concerned about doing actually more harm than good insofar as you know these women that appear to not be smoking very much" (Female, 31-44, Northern Territory (NT)).* Several felt that not all pregnant women were addicted, smoking due to other reasons such as stress. They described NRT as only appropriate to consider in highly addicted smokers, and/or that combination treatment is not suitable *"it depends why she says*

she's smoking. If there's an element of addiction to it… I do suggest they go on patches" (Female, 31-44, Western Australia (WA).

Participants expressed a need for clear guidance on when it was appropriate to initiate NRT and how to determine the dose *"I suppose we need sort of like training modules… like an algorithm about 'This is what you use. This is how you start it. These are the benefits'."(Female, South Australia (SA), age unknown);* the lack of clear guidance impacted their confidence in discussing NRT "*I would have to look up doses…it might make me a little bit less happy to engage and have a longer consult because I just don't feel confident with my level of knowledge" (Female, SA, age unknown).*

'Viewing cutting down as adequate'

Most participants viewed the recommendation of "cutting down" consumption as an acceptable method for managing smoking during pregnancy *"for the person who says 'Well I'll just smoke the minimum and that's the best I can do', I accept that." (Male, 45-60 years, Victoria)*

'Needing better communication skills'

Participants expressed a need to learn 'how' to have conversations to support women in their quit journey. They wanted this shown to them explicitly (as opposed to just providing information): *"I don't feel like I know that very well because we don't really learn that in med school. We learn a lot of the medical issues with smoking, but we're not learning the psychology of smoking. It could even be just we watch a DVD and watch someone pattern a role model." (Female, 31-44 years, WA).*

It was important to them to maintain a positive relationship with the pregnant patient *"there's real caution in when to push it and when to slack off a little bit and don't say anything, but it just means you don't make the person feel guilty and they'll never want to see you again and you lose your influence altogether."(Male, Queensland, age unknown);* leading GPs to being wary of the way they were conveying the message "*I'm inclined to just kind of put my blinkers on, I sort of bite my tongue a little bit when I know that it's going to make the patient upset, or angry… it's a tough issue, really tricky." (Female, 31-44 years, NT);* and to try to provide information in a non-judgmental and supportive way *"it is a delicate conversation to be had with the*

patient because you are telling them that what they are doing is potentially harming their baby, people can get very defensive, you want to maintain that rapport and you don't want to be judgmental," (Female, 45-60 years, Queensland). Acceptance of 'cutting down' was related to wanting to maintain good rapport and being supportive *"I congratulate them on cutting down. She knows that she's not doing the best by her baby or by herself, so forcing the issue and making her feel more bad about herself than she already is, it's counter-productive"(Male, Queensland, age unknown).*

'Requiring visual resources'

Participants wanted resources to guide the conversation on NRT safety, helping them feel more confident to recommend it in pregnancy, and provide an objective portray for the women *"A very simple kind of handout or even if it's like a poster in the room… it's more just as a back-up thing. So, like, "Hey, it's not just me saying it" (Female, 45-60 years, Victoria).* Those working with Aboriginal women emphasized the need for a visual culturally responsive resource *"Handouts that are appropriate for my patients, Aboriginal and Torres Strait Islander women… as you're explaining it, you've got these visuals to point to." (Female, 31-44, New South Wales (NSW)).*

'Providing information on smoking harms'

Participants emphasized a strong focus on providing information on the harms of tobacco smoking: *"I don't want to be forceful like that, but I would say, "Did you know that smoking can make the placenta not work as well…, and then just make sure that they're aware of that" (Female, 31-44 years, NSW).*

'Providing treatment options only to those who are motivated to quit'

When asked about their approach to managing smoking, participants described using the "stages of change" approach[7] *"GP guidelines for quitting have got the whole 'stages of change'…." (Female, under 30, Tasmania).* Women who were perceived as 'not ready' were provided with information on smoking harms; whereas women who were perceived as 'ready' to quit, were offered options for support *"I give them the information that they needed in order to make a decision, so make sure they knew about the harmful effects of smoking and determine their level of motivation and confidence in quitting, and if they were ready to quit, then we talk about the different ways of doing so." (Female, 45-60 years, WA).* Participants also stated they would not mention the

Quitline if they felt patients were not ready to quit *"If people don't indicate to me that they're interested in a planned cessation or decreasing, I don't refer them to the Quitline." (Female, over 60, NSW)*

'Time as a challenge'

Time was perceived as problematic for some, usually in relation to other competing priorities. *"…something else would have to get cut out. There isn't really anything you can cut out is the problem…" (Female, 31-44, WA).* Others, especially those working within Aboriginal Medical Services, found this was not an issue *"Fortunately, we're not as time bound as a city general practice" (Female, over 60, NT).*

'NRT cost'

Those working with Aboriginal people (eligible to receive the patch for free as part of the Australian Government's Pharmaceuticals Benefit Scheme) viewed the patch as their only option due to the cost of oral NRT, with having the patch at the service for free a major facilitator *"…really important is having the stuff on hand to give to them, patches are pretty easy" (Female, 31-44 years, NSW); "in an Indigenous community, if anything costs money… that's almost out of the question." (Female, 31-44 years, NT)*

'Patients negative experiences and safety concerns guiding NRT treatment'

The common experience among participants was that most pregnant women simply did not want to use NRT *"There's quite a number of women who just aren't interested… even in spite of reassurances that nicotine replacement is preferable to smoking… will say 'No thanks. That's just not quite me." (Female, 41-60 years, Queensland).* This was related to safety concerns *"They feel that their baby would be better off if they were to smoke intermittently rather than have constant nicotine" (Male, 45-60 years, Victoria);* or to women's negative experiences from prior use *"Women are afraid about using patches and then the other half have used them before when they weren't pregnant and refused to use them again." (Female, 41-60 years, NSW)*

'Lack of familiarity with the Quitline'

Participants were aware of the Quitline and have referred pregnant women to it, but most remarked about not being familiar with its process *"it's sort of like an unknown…I don't know what happens when people call up to the Quitline, I don't know if they*

would get the same counsellor each time or whether they just call up and then get a random person" (Female, 31-44, NSW); feeling disconnected from the treatment their patients were receiving *".. I've been referring to the Quit Line, or giving the numbers to patients for the Quit Line for a long time. I've never received any information back and neither have I had any patients tell me that they've used it or found it effective." (Female, NSW, age unknown).*

'Questioning Quitline suitability'

Several participants, including those working with Aboriginal women, remarked on the Quitline not being suitable *"It wouldn't be something we'd jump into because of that kind of language and cultural barrier… It just means being the Aboriginal person thinking that the other person on the end of the line doesn't understand what they're doing in terms of Aboriginal people." (Female, over 60, NT);* preventing them from being more proactive *"I think it's pretty unlikely that a young remote Indigenous girl's going to call the Quitline. I wouldn't avoid talking about it, but I guess it's not usually sort of top of my list of things to talk to her about."(Female, 31-44 years, NT).*

When asked directly, participants working with Aboriginal people did not know that you can request an Aboriginal counsellor *"if you had an Aboriginal Quitline, they might be more likely to use that…. I've never actually rung them up and found out." (Female, over 60, NT).*

'Lack of optimism'

Participants demonstrated a mixture of feelings about optimism. Some were somewhat optimistic, mainly due to perceiving women as more receptive to change due to the pregnancy *"Probably optimistic because they do have that added incentive to quit, that sometimes it's a really good opportunity to get them to quit." (Female, under 30, Tasmania)*. Others were pessimistic, mainly due to recurring cases of continuing smoking, and related to all the other psychosocial issues that were out of their abilities to care for *"I suppose I feel defeated by the people's condition, too pessimistic about the people's condition. So much needs to change in terms of changing tobacco."(Female, over 60, NT); "I have had so many experiences where I feel like I've provided a lot of education and time I've spent invested in trying to help the pregnant woman understand how harmful smoking is and yet she continues to smoke. I think that's disheartening*

when you see the effects and you know you have tackled the problem and continue to address it, but that doesn't necessarily change the patient"(Female, Queensland, age unknown).

'This is not just a medical condition we can treat'

Participants viewed addressing smoking as an important part of their role, and viewed their relationship with the patient as imperative to reaching the patient *"there is benefit of having us there… as their regular health professional. I think it does make a huge difference to how much they're likely to listen to that advice and take it on board." (Female, Queensland, age unknown).* Nonetheless, it was evident that they felt that combating smoking in pregnancy is not just a medical condition they can treat, and would require other policy measures that address the psychosocial factors that also impact smoking, and make quitting more difficult *"when you've got overcrowding, domestic violence, you were abused as a kid, be it physically, emotionally or sexually, when there's flies crawling all around the floor, when everybody else in the house smokes, I just feel like it's just such a mountain." (Female, over 60, NT).*

Discussion

Main Findings

In this qualitative study with Australian GPs from diverse settings, participants reported focusing on providing information on smoking harms, and lacking practical communication skills. Their knowledge is out of date (through concordant with current Australian GP guidelines), still following the 'stages of change' model. Additional multiple challenges are present such as lack of time, patients' pervious NRT negative experiences and safety concerns, and not receiving feedback from the Quitline; and for participants caring for Aboriginal patients, also cost of Oral NRT, and Quitline suitability. Participants were pessimistic about whether they make any difference – their experience is that women continue to smoke despite their efforts to help. Subsequently, this causes participants to be passive, choosing sometimes to avoid the issue of smoking in fear of women's reaction, accepting if women only cut down, and offering treatment options only to those who they perceive as 'ready' to quit. In order to overcome these challenges, participants requested practical interactive 'role model' communication training, coupled with visual resources, and detailed clear guidelines on the initiation and dosage of NRT.

Comparison with the literature

Similar to this study, a recent systematic review, synthesizing data from eight qualitative studies from high income countries, highlighted that there is a need for health providers to find better ways to discuss smoking without feeling that this will damage their relationship with the women[24]. Additionally, it was recognized by the health providers that there is a need for this to also be addressed outside the healthcare system, in the broader social context.[24] This review included only one Australian study with only seven midwifes.[24] Another Australian qualitative study analysed interviews with 27 maternity service managers, obstetricians and midwives, and reported similar barriers and enablers to those found in our study (lack of knowledge, skills, training), including fear that these conversations would be "difficult" and might damage their relationship with the women.[25] This study did not include any GPs and only included participants from one Australian state (NSW).[25]

The uncertainty about the Quitline having Aboriginal counsellors was unexpected. In a small survey with 34 health providers working inside an Aboriginal health service, all of the participants knew this, and most of them found the Aboriginal Quitline counsellors helpful and appropriate.[26] However, this was a small study with most of the participants having received prior smoking cessation training.[26]

Concerns over safety of NRT use in pregnancy, and lack of confidence in prescribing it, have been found in numerous studies, from different countries.[27-30] However, all of these were cross-sectional surveys. To date, and to the best of our knowledge, only three qualitative studies explored this issue (from the UK and Canada), and their findings also emphasized the need for clear guidance on NRT safety and prescribing information.[17,31,32]

Strengths and Limitations

This is the first Australian study, as far as we are aware, to qualitatively explore GPs needs in overcoming barriers to providing SCC during pregnancy. Previous qualitative research did not include GPs.[24,25] As GPs are arguably one of the most influential health providers in primary care, it is important to understand their needs. This is especially true for GPs working with Aboriginal women, as they face additional barriers that need addressing. The fact that participating GPs were recruited from almost all Australian states, and from diverse clinical and geographical settings is an additional strength. The preponderance of female participants may have introduced a respondent bias.

Given that this sample was recruited mainly among participants from a national survey, the previous limitation of the surveys' low response rate apply to this study and impact the findings transferability. Despite purposely trying to sample low level care GPs, the recruited sample reflected GPs with potentially a higher performance level, and more positive attitudes, compared to the overall national survey results[18,19] (Supplemental file 2). This was a key limitation as we could not explore the needs for overcoming the challenges with those that perhaps have the highest need for improvement. None-the-less, even with these better performing (by self-report) GPs, there was still a necessity to improve their knowledge and skills. In fact, this study highlights that even the "best performing" GPs reported many barriers to overcome to provide evidence based SCC for pregnant women.

Implications for policy and practice

The trans-theoretical "stages of change" theory is one of the most well-known behaviour change theories.[33] Despite this, systematic reviews and meta-analyses of studies using staged-based approaches have not shown that interventions designed according to this theory have higher smoking cessation rates.[8,33,34] In fact, recent data suggests that the level of motivation to quit is highly variable, possible fluctuating by day to day.[35] This is also supported by the finding that 72% of quit attempts are reported as spontaneous.[35] This study reveals that all of the participating GPs use the 'stages of change' model to guide their intervention with pregnant women. Thus if women were perceived to be 'not ready', they may not receive valuable information on available smoking cessation support options or assistance to quit smoking. Simply knowing about these options and an offer of assistance might change their level of motivation to quit.[36] Specific training regarding the importance of offering all smokers current cessation options, regardless of their motivation or readiness to quit, is crucial. The New Zealand smoking cessation guidelines[37], recommend an ABC approach (Ask about smoking status, Brief advice to quit. Cessation support): this may be more suitable than the 5As currently used in Australia to highlight the need to offer support to all, regardless of their current motivation to quit.

Increasing GPs prescribing rates of NRT during pregnancy might increase smoking cessation rates.[9] GPs requested clear practical guidelines including how to make decisions on NRT dosage initiation and titration. Furthermore, patient material that clearly depicts that NRT is safer than smoking and can be used during pregnancy could help guide the doctor-patient discussion on the risk versus benefit. A recent narrative

review looking at national clinical guidelines from English-speaking high income countries, including Australia, show that guidelines pose many restrictions on NRT prescribing, and none offered practical details.[11] In an era of overwhelming volume of new data being published every day, clinical guidelines need to provide regularly updated and practical detailed recommendations.

On a higher organizational level, there is a need to find ways to provide GPs more time and skills for discussing behavioural issues with their patients. Integrating SCC into the patient journey within the health system, with a clear pathway of each health providers' role, and better communication between the different health providers, might reduce ineffective repetition, discordant health messages, and wasted time. GPs need to receive specific training to feel confident to provide brief behavioural counselling.

The specific barriers mentioned by GPs working with Aboriginal women, coupled with the higher smoking rates among this population, warrants separate considerations. Currently, the Australian federal government 'closing the gap' strategy[38], and as part of this, the "Tackling Indigenous Smoking" program is being implemented. The "yarning about quitting" resources were developed specifically to improve health providers' confidence in "how" to have a culturally appropriate conversation on smoking with pregnant Aboriginal women.[39] Data on the effectiveness of these initiatives are needed. Further cost-free treatment options that are culturally appropriate need to be explored, including providing the services with free oral NRT in addition to NRT patch.

Conclusion

Australian GPs report a lack of knowledge and communication skills for treating pregnant women who smoke. Focusing their time on providing information on the harms of smoking, while not offering and discussing treatment options, and providing support for smoking cessation with all pregnant patients who smoke, may be contributing to the low cessation rates, and pessimism. Specific training explicitly showing 'how to have this conversation', with clear detailed clinical protocols on using NRT during pregnancy, may help GPs to better support their pregnant patients in their smoking cessation journey. GPs treating Aboriginal pregnant women who smoke face additional barriers that need to be addressed, from multiple levels, including policy and community levels.

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Competing interests' statement

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Supplemental File 1

Interview Guide

Topics that should be covered (and an example of a question that can be used if not already covered)

a. Usual approach

i. What would you say is your usual approach to a pregnant woman who smokes?

ii. In your experience, what have been the outcomes from your management of smoking in pregnant women?

b. Enablers and Facilitators - General

iii. How do you feel about improving your management of smoking in pregnant women?

iv. In your opinion, what could help you improve your management of smoking in pregnant women?

v. What would help you remember to discuss this with pregnant women?

c. Knowledge

vi. What are your thoughts on your knowledge to address smoking properly in pregnant women?

vii. What would be the preferred way for you to improve your knowledge on this topic? What would be the most effective way for you?

d. Time

viii. What has been your experience concerning the time frame available to address smoking properly in pregnant women?

ix. How much time in your experience is needed for this issue? What do you think could help you incorporate this into your timeframe?

e. Optimism

x. Do you feel optimistic/pessimistic about your management of smoking in pregnant women? Could you describe why that is? What would help you feel more optimistic?

f. Confidence

xi. How would you describe your confidence on management of smoking in pregnant women? What would help you feel more confident?

g. NRT

xii. What has been your experience with prescribing Nicotine Replacement Therapy (NRT) in pregnant women who smoke? What do you think would help you subscribe NRT to pregnant women who smoke?

h. Referral

xiii. Could you tell me a little about your experience with referring women to cessation support (such as the quit-line or a local smoking cessation group)?

xiv. What would help you to routinely refer pregnant women to cessation support?

i. Follow up

xv. What has been your experience with following up on women in regard to their smoking?

xvi. What would facilitate you to follow up?

j. Discussing the psychosocial context

xvii. How do you feel about discussing with pregnant women the psychosocial context of smoking?

xviii. What can help you with this?

k. Subgroups

xix. Describe your experience with any subgroups of pregnant women for whom there may be additional challenges to treatment?

Supplemental File 2

Table 1: Self-Reported Provision of Smoking Cessation Care compared to the Overall National Survey Sample, n(%)

Smoking Cessation Care Component - Proportion reporting 'Often/Always' performing each component	**GPs participating in the qualitative interviews (n=16)**	**GPs and Obstetricians participating in the national sample (n=378)**
Ask about smoking status	16 (100%)	288 (77.2%)
Give brief advise to quit if smoking	16 (100%)	275 (74.7%)
Assess nicotine dependence	14 (87.5%)	89 (24.1%)
Provide Cessation support to smokers (Assist)	15 (92.8%)	124 (33.5%)
Follow-up within 2 weeks (Arrange)	6 (37.5%)	26 (7%)
Prescribe/recommend NRT to assist quitting	9 (56.3%)	40 (10.8%)
Discuss the psychosocial context of smoking	13 (81.3%)	82 (22.2%)
Refer to Quit line/specialist service	8 (50%)	95 (26.8%)
Involve family members in counselling/tobacco management	4 (25%)	15 (4.1%)

Table 2: Barriers and Enablers to Provision of Smoking Cessation Care to Pregnant Smokers, compared to the Overall National Survey Sample, n(%)

TDF domains –percentage answering 'Agree/Strongly Agree' n(%)	GPs participating in the qualitative interviews (n=16)	GPs and Obstetricians participating in the national sample (n=378)
I am confident that I can counsel women about their smoking during pregnancy	15 (93.8%)	299 (80.8%)
I am confident that I can prescribe NRT for pregnant smokers	13 (81.3%)	201 (54.5%)
I am optimistic my intervention for smoking during pregnancy is likely to be effective	6 (37.5%)	129 (35.1%)
Raising the issue of smoking with a client during pregnancy will benefit our relationship	9 (56.3%)	232 (65.2%)
Addressing smoking during pregnancy is a high priority	16 (100%)	351 (98.3%)
I am comfortable raising the issue of smoking with a pregnant woman	15 (93.8%)	338 (94.9%)
In my workplace, it is routine to help pregnant women to quit smoking during pregnancy	15 (93.8%)	271 (76.1%)
I have sufficient time to help pregnant women to quit smoking	10 (62.5%)	146 (41.1%)
I have sufficient resources to help pregnant women to quit smoking	9 (56.3%)	169 (47.5%)

Introduction to Paper Four

Papers two and three used quantitative and qualitative methods to study GPs' attitudes toward prescribing NRT in pregnancy. Despite NRT being recommended in the RACGP's guidelines for smoking cessation during pregnancy, results indicated that a high proportion of GPs do not consider this an appropriate option, mainly due to safety concerns and low confidence in their ability to prescribe it. Even GPs who reported prescribing NRT in pregnancy had several misconceptions, such as NRT being suitable only for highly addicted pregnant women and that combinations of different formulations (oral NRT combined with the nicotine patch) were not clinically recommended. Additionally, GPs wanted clear practical guidance on "when" and "how" to prescribe NRT, and visual resources that they could use as part of the discussion with the pregnant patient to support their recommendation that NRT is safer than smoking and can be used, if needed, during pregnancy.

To gain a better understanding of GPs' barriers to NRT prescription, paper four reviewed all current knowledge on the safety and effectiveness of using NRT during pregnancy and national guideline recommendations from English-speaking high-income countries. Paper four also suggests a practical clinical approach for NRT prescription, including a "harm versus benefit" discussion with a pregnant patient (and her partner) and ways to initiate and titrate the dosage of NRT, if needed.

Paper Four:
Nicotine Replacement Therapy for Smoking Cessation in Pregnancy – A Narrative Review

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Associated appendices

Appendix 5: Published manuscripts

Appendix 5.3: Paper four published manuscript

Summary

- Nicotine Replacement Therapy (NRT) is recommended in current Australian clinical guidelines for pregnant women who are unable to quit unassisted.
- Clinicians report low levels of prescribing NRT during pregnancy, due to safety concerns and low levels of confidence in ability to prescribe NRT.
- Animal models show that nicotine is harmful for the foetus, especially for brain and lung development; but human studies have not found any harmful effects on foetal and pregnancy outcomes.
- Studies of efficacy and effectiveness in the real world suggest NRT use during pregnancy increases cessation rates. Cessation rates may be hampered by the fact that studies so far have used an NRT dose that does not adequately account for the higher nicotine metabolism during pregnancy, and therefore does not adequately treat withdrawal symptoms.
- Further research is needed to assess the safety and efficacy of higher dosages of NRT in pregnancy, and specifically combination treatment using dual forms of NRT.
- As NRT is always safer than smoking, clinicians need to offer all pregnant women the option of receiving NRT. A practical guideline for initiating and tailoring the dose of NRT in pregnancy is suggested.

Background

Smoking during pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes. In 2014, 11% of women who gave birth in Australia smoked at some point of their pregnancy, and smoking rates during pregnancy were higher for specific vulnerable populations, such as Aboriginal and Torres Strait Islander women (45%).[1]

Behavioural counselling combined with medication is the most effective smoking cessation strategy.[2] In pregnant women who smoke, studies have shown counselling alone to be effective.[3] Medications such as varenicline and bupropion are not recommended during pregnancy,[4] and the use of nicotine replacement therapy (NRT), while well supported and safe for the general population,[5] remains controversial for use during pregnancy because nicotine crosses the placenta and may accumulate in the amniotic fluid.[6] Thus, it is important to gather evidence regarding the benefits and potential harms of NRT for pregnant women.

In a recent survey of Australian general practitioners and obstetricians, 25% of participants stated that they never prescribe NRT during pregnancy.[7] These findings mirror surveys from the United Kingdom,[8] New Zealand[9] and the United States.[10] The most frequently cited barriers are low confidence in the ability to prescribe NRT and safety concerns.[8,10]

The aim of this narrative review is to provide an overview of current guidelines regarding NRT use in pregnancy, considering the existing evidence base on safety, efficacy and effectiveness. In addition, we outline pragmatic suggestions for clinical practice and implications for policy and future research.

Method

For current guidelines, we performed online searches using Google and the keywords "smoking cessation", "guidelines" and "name of country". We included national guidelines from high income countries (eg, Australia, UK, US, Canada and New Zealand) published in English from the year 2010 onward.

We conducted MEDLINE searches on NRT safety, efficacy and effectiveness, using the Medical Subject Headings and keywords "nicotine", "nicotine replacement therapy", "fetal" and "pregnancy" — limited to the English language with no limit on the years.

Previous reviews were manually searched to identify further studies. We included both observational and interventional studies that aimed to specifically assess either the safety or efficacy of NRT during pregnancy. Studies that included NRT as part of a multicomponent intervention were excluded, as their design does not permit determining the effect of NRT alone.

To provide a full overview, we also include a short summary of findings previously published from animal models studying the effects of nicotine on fetal development.

Current Guidelines for the Use of Nicotine Replacement Therapy During Pregnancy

Although all clinical guidelines on the use of NRT during pregnancy acknowledge that there is insufficient evidence to firmly conclude whether NRT in pregnancy is safe or effective, national guidelines from Australia,[4] the UK,[11] New-Zealand[12] and Canada[13] recommend the use of NRT by pregnant women who have been unable to quit smoking without medication (Box 1). However, many of the guidelines impose caveats such as "only if women are motivated", "only give out 2 weeks supply" or "under close supervision".

In Australia, the Royal Australian College of General Practitioners has published the only comprehensive national guidelines on the use of NRT during pregnancy,[4] which recommend initiating NRT in pregnant women who are motivated to quit smoking and have been unsuccessful without medication. NRT should be offered after discussing the relative risks and benefits, and prescribed under supervision of the treating clinician. These guidelines recommend initiating treatment using oral forms of NRT, which are considered to deliver a lower total dose of nicotine compared with a patch.[4,5] In the event that the pregnant woman is still unsuccessful at quitting smoking, clinicians should consider adding a nicotine patch (ie, combination treatment).[4] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists has also issued recommendations regarding smoking cessation during pregnancy, and even though their statement takes a more conservative approach, it acknowledges that NRT may reduce the risk to the fetus in pregnant for women who continue to smoke heavily.[14]

1 Summary of current international guidelines for the use of nicotine replacement therapy (NRT) during pregnancy	
Organization, year updated	**Key points**
RACGP, 2014[4]	• NRT may be considered if quit attempts are unsuccessful and the woman is motivated to quit • The risks and benefits need to be explained to the woman • Oral NRT is the first line option, but larger doses or even combination NRT may be needed
RANZCOG, 2014[14]	• Insufficient evidence to routinely recommend NRT use in pregnancy • If the woman is a heavy smoker and unsuccessful in quitting with counselling alone, NRT may reduce the risk to the fetus
NICE, 2010 (update to be released March 2018)[11]	• Use NRT only in women who are unsuccessful in quitting smoking without medication • Only prescribe NRT once women stop smoking • Only prescribe 2 weeks of NRT • Only give subsequent prescription if the woman is still not smoking
New Zealand Ministry of Health, 2014[12]	• Trials have not shown NRT to be effective in pregnancy • NRT is safer than smoking • Women may use NRT in pregnancy once they have been advised of the risks and benefits
CAN-ADAPTT, 2011[13]	• Limited evidence that NRT is harmful in pregnancy • Some evidence that NRT may be effective • Benefits of NRT seem to outweigh potential risks • NRT should be considered if counselling has been ineffective • Oral NRT is preferred after a risk–benefit analysis
USPSTF, 2015[15]	• Current evidence is insufficient to assess the use of NRT in pregnancy
ACOG, 2015[16]	• NRT use in pregnancy has not been sufficiently evaluated to determine safety or efficacy • NRT should only be used under supervision, after a risk–benefit analysis, and only with a clear resolve of the woman to quit smoking
WHO, 2013[17]	• Cannot make a recommendation on NRT use during pregnancy

ACOG = American College of Obstetricians and Gynecologists. CAN-ADAPTT = Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment. NICE = National Institute for Health and Care Excellence. RACGP = Royal Australian College of General Practitioners. RANZCOG = Royal Australian and New Zealand College of Obstetricians and Gynaecologists. USPSTF = United States Preventive Services Task Force. WHO = World Health Organization.

Animal Models: Effects of Nicotine on Fetal Development

The most established evidence from animal models shows derangement in central nervous system and pulmonary development.[18] Nicotine binds to the nicotinic acetylcholine receptors located in the central nervous system.[19] Rat models indicate that prenatal nicotine exposure damages the developing brain by triggering apoptosis, reducing the number of neuronal cells and disturbing the genesis of axons and synapses. Chronic nicotine exposure in utero leads to changes in neuronal architecture, nicotinic acetylcholine receptor expression and the function of other neurotransmitter systems, including dopamine, noradrenaline and serotonin.[20,21]

Nicotine also causes developmental anomalies in the lungs in animal models; for example, non-human primates exposed to nicotine in utero have decreased lung size and volume.[22] Histopathological analysis has shown a reduced alveolar surface area, enlarged respiratory airspaces[23] and thickened alveolar walls.[24] These changes lead to impaired ability to adequately oxygenate blood.[25] Moreover, prenatal nicotine exposure also decreases pulmonary compliance and forced expiratory flow[26] and increases airway resistance.[27] It should be noted that most of these animal studies used a continuous form of nicotine delivery,[26,27] and it is not clear how directly transferable the findings from animal studies are to humans.[28]

Safety and Efficacy of Nicotine Replacement Therapy in Human Studies

The safety and efficacy of NRT during pregnancy has been studied in both observational and intervention studies (Appendix).

Observational studies

A UK population-based cohort study of 192 498 live births [29] examined the association between early pregnancy NRT exposure and major congenital anomalies; the study found no statistically significant increased risk for either the NRT group (*n* = 2677) *v* non-smokers (*n* =179 841) (odds ratio [OR], 1.12; 99% confidence interval [CI], 0.84–1.48) or the NRT group *v* smokers not receiving NRT (*n* =9980) (OR, 1.07; 99% CI, 0.78–1.47)". Examining system-specific anomalies, there were no significant increased risks except for respiratory anomalies, but the authors caution that this is based on small numbers of exposed cases.[29] A smaller Danish study[30] found similar results when restricting their analysis, comparing NRT users (*n* = 250) with non-smokers (*n* = 55 915), to major anomalies (OR, 1.13; 95% CI, 0.62–2.07); however, when

including minor anomalies, NRT use was significantly associated with a higher rate of anomalies (OR, 1.61; 95% CI, 1.01–2.58). A similar study from this cohort[31] did not find an association between using NRT and the rate of stillbirth (hazard ratio 0.57; 95% CI, 0.28–1.16).

Another Danish population-based cohort study[32] found that the use of NRT during the first 27 weeks of pregnancy was not significantly associated with changes in mean birth weight (mean change, 0.25 g per week of NRT use; 95% CI, -2.31 to 2.81). The use of more than one product in the same week was associated with a decrease in mean birth weight, but this was not statistically significant (mean change, -10.73 g per week of NRT use; 95% CI, -26.51 to 5.05).[32]

A UK cohort study,[33] including 3880 pregnant women who attended smoking cessation services, found that combination NRT (patch plus an oral form) was associated with significantly higher cessation rates (OR, 1.93; 95% CI, 1.13–3.29), but that the use of only one NRT form was not associated with an increased cessation rate (OR, 1.06; 95% CI, 0.60–1.86).

Randomised controlled studies

To date, there have been five double-blind placebo controlled studies[34-38] and three non-placebo controlled studies[39-41] on the safety and efficacy of NRT in pregnancy (Appendix). The most recent 2015 Cochrane meta-analysis,[42] which included all these eight studies (*n* = 2199 pregnant women), found that NRT use significantly increased the smoking cessation rate by 40% (relative risk [RR], 1.41; 95%CI, 1.03–1.93). Restricting the meta-analysis to only placebo controlled studies (five studies, n=1926) resulted in a lower, not significant cessation rate of 28% (RR, 1.28; 95% CI, 0.99–1.66).

No significant differences in health and safety outcomes were found in the Cochrane meta-analysis.[42] Data from four studies[34-36,40] were pooled together — with over 1700 women — showing no significant differences in the risk of miscarriage or spontaneous abortion (RR, 1.47; 95% CI, 0.45–4.77), stillbirth (RR, 1.24; 95% CI, 0.54–2.84), neonatal intensive care unit admissions (RR, 0.90; 95% CI, 0.64–1.27) and neonatal death (RR, 0.66; 95% CI, 0.17–2.62). Two studies[34,35] — with 1401 women — provided data for the pooled estimate of congenital anomalies and caesarean birth, showing no significant difference (RR, 0.73; 95% CI, 0.36–1.48; and RR, 1.18; 95% CI, 0.83–1.69,

respectively); and six studies[34-36,38-40] provided data for the pooled estimate of preterm birth (RR, 0.87; 95% CI, 0.67–1.14) with no significant difference.

The largest randomised placebo controlled trial[34] included 1050 pregnant women, of whom 521 were randomised to receive a 15 mg per 16 hours patch. This study found favourable results after one month of treatment (21.3% biochemically validated abstinence rate in the NRT group and 11.7% in the placebo group; adjusted OR, 2.1; 95% CI, 1.49–2.97), but these results were not sustained at delivery (9.4% NRT and 7.6% placebo; adjusted OR, 1.27; 95% CI, 0.82–1.98). Adherence was problematic, with few participants using NRT for more than 4 weeks, and there were no statistically significant differences in any pregnancy or birth safety outcomes.[34] This was the only study to follow infants for 2 years after delivery.[43] Infants born to mothers who received NRT had a significantly higher rate of unimpaired development, regardless of the mothers' smoking status (73% NRT group and 65% placebo group; OR, 1.4; 95% CI, 1.05–1.86). The results suggest a dose–response relation with no difference in impairment rates between women using one to ten patches during pregnancy and those not using patches, but they suggest a significant difference between women using 11–56 patches (OR, 1.72; 95% CI, 1.22–2.57).[43]

Almost all of the trials[34,37,38,41] (Appendix) used a fixed dosage regardless of the woman's smoking and tobacco dependence level. Taking into account the higher metabolism of nicotine in pregnancy,[44] this may have led to insufficient dosage to adequately treat withdrawal symptoms.[42,44] The most recent randomised placebo controlled study[35] adjusted the dosage of the patch according to the woman's baseline cotinine level (a metabolite of nicotine). Women in the NRT group in this study received on average a slightly higher mean daily dose (18 mg) compared to the 15 mg patch used in other studies — with 25% receiving 25–30 mg daily — for a longer duration (median prescription length, 105 days), and there was a high compliance rate (85%). Despite this, the validated abstinence rate at delivery was low and similar between the NRT (5.5%) and placebo groups (5.1%) (OR, 1.08; 95% CI, 0.45–2.6).[35] However, the conversion ratio used to determine the nicotine dose was not modified for pregnancy, and was based on studies with non-pregnant participants,[45] suggesting that participants did not receive an adequate dosage.[45]

Only one randomised placebo controlled study (n = 194) used 2 mg nicotine gum (and not a patch) in the intervention group (n = 100), allowing up to 20 doses of gum per

day.[36] Treatment was continued even if women had not quit smoking, with the gum being used to reduce the overall number of cigarettes smoked. This study did not find any significant treatment effect, with point prevalence abstinence rates similar between the two groups at 6 weeks after treatment (13% NRT group and 9.6% placebo group; $P = 0.45$) and at 32–34 weeks gestation (18% *v* 14.9%; $P = 0.56$).[36] However, birth weight (NRT group, 3287 gr; standard deviation [SD], 566 gr; placebo group, 2950 gr; SD, 653 gr; $P < 0.001$) and gestational age (NRT group, 38.9 weeks; SD, 1.7; placebo group, 38 weeks; SD, 3.3; $P = 0.014$) were significantly greater in the NRT group.[36] Moreover, rates of preterm birth (NRT group, 7.2%; placebo group, 18%; $P = 0.027$) and low birth weight (< 2500 gr) (NRT group, 2%; placebo group, 18%; $P < 0.001$) were both significantly higher in the placebo group.[36]

The limitations of many of the trials include low adherence to NRT, resulting in most women not receiving the intended dose, and NRT dosage not adjusted to the increased nicotine metabolism during pregnancy (Appendix). None of the studies assessed smoking withdrawal symptoms in order to adjust the dosage accordingly. The hypothesis that the dosage was not sufficient to treat withdrawal symptoms is supported by the findings from several trials that compared cotinine levels at baseline and during treatment with NRT patches.[37,41,46] These studies showed that cotinine levels were lower during treatment than at baseline (when women were still smoking).

Discussion

In summary, this narrative review found that in animal models, nicotine has been found to be harmful for the fetus, especially for brain and lung development. Human studies, however, did not find any harmful effects on fetal and pregnancy outcomes compared with placebo, but the evidence is limited due to the small numbers of participants in the meta-analysis.[42] In addition, efficacy studies suggest that NRT increased smoking cessation rates overall, but this effect is not statistically significant for the more rigorous placebo controlled trials. Nevertheless, one observational study using real world data shows promising results, specifically for NRT combination treatment, but studies so far have used an NRT dose that does not adequately account for the higher nicotine metabolism during pregnancy.

Pragmatic suggestions for clinical practice

Confidence in prescribing NRT and actual practices may be low due to the conflicting messages and different restrictions mentioned in the guidelines, particularly since they do not offer a detailed practical clinical protocol that includes clear instructions for NRT use in pregnant women.

Box 2 offers a practical detailed approach to initiating and managing NRT during pregnancy. As many pregnant women reduce, on their own, the number of cigarettes they smoke,[48] using measures that rely on number of cigarettes per day may be less effective. We suggest using the strength of urges to smoke (SUTS)[49] and the frequency of urges to smoke (FUTS) scales[50] as practical guides to the decision to initiate or increase the NRT dose:

SUTS — "in general, how strong have the urges to smoke been in the past 24 hours?" "Slight", "moderate", "strong", "very strong" or "extremely strong"; and

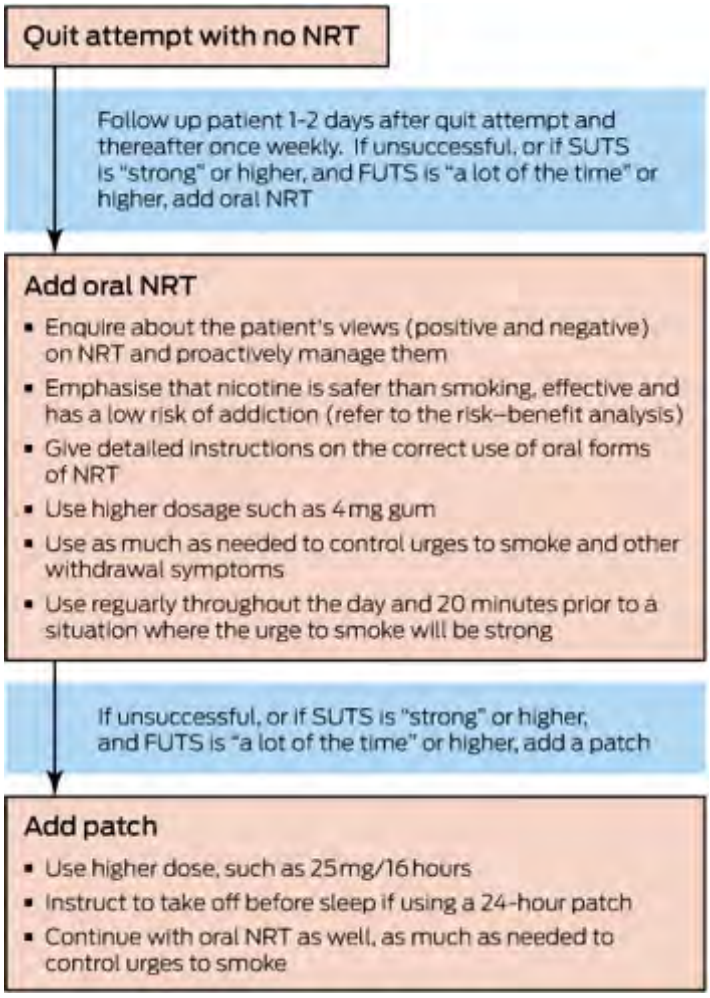
FUTS — "how much of the time have you felt an urge to smoke in the past 24 hours?" "Not at all", "a little of the time", "some of the time", "a lot of the time", "almost all of the time" and "all of the time".

If the women report experiencing strong or frequent ("a lot of the time") urges to smoke, this suggests the need for additional support.

The most important guidance for NRT in pregnancy is to use the lowest possible dose that is effective. However, to be effective, women should be instructed to use as much as needed to deal with cravings. Physicians should encourage using oral NRT regularly throughout the day to substitute for cigarettes; for example, a woman smoking ten cigarettes a day should be instructed to use one piece of gum every 1.5 hours regularly, even if she is not experiencing a strong craving at this time. In addition, physicians should encourage the use of oral NRT in anticipation of cravings; if a woman knows she is going to be in a situation where the urge to smoke will be strong (eg, going out with friends who smoke), doctors should encourage the use of oral NRT 20 minutes beforehand. Physicians should proactively review the SUTS and FUTS on a weekly basis and adjust dosage as needed. Further, women should be encouraged to use NRT for at least 12 weeks, or longer if required, in order not to relapse. This practical

approach is currently being tested as part of a multicomponent intervention in a pilot study.[51]

2 Suggested approach to initiating and managing nicotine replacement therapy (NRT) during pregnancy[47]



FUTS = frequency of urges to smoke. SUTS = strength of urges to smoke.

Risk versus benefit

Nicotine may not be completely safe for the pregnant mother and fetus, but it is always safer than smoking. A risk and benefit analysis needs to occur to help pregnant women (and their partners) judge whether to use a clean source of nicotine such as NRT, which might help cessation, and whether this is preferable to continuing exposure to the nicotine and other chemicals present in combustible cigarettes. The context of using NRT in pregnancy is always within a smoking cessation attempt, which means that it is used by women who are already exposed to higher levels of nicotine and other products

of combustion from smoking. Box 3 offers suggestions to aid the risk versus benefit analysis discussion.[47]

3 Suggested approach to a risk v benefit discussion with a pregnant woman who smokes[47]
Risks
Nicotine has been linked to harmful effects on the fetus in animal studies:[19] • low birth weight; • preterm birth; • still birth; • cognitive impairment; and • impaired lung development We do not know for sure how the data from animal studies can be transferred to humans[28] Studies with nicotine from NRT use in pregnant women (> 2000 women) have not shown NRT to cause any harm to the women or the baby[42]
Benefits
NRT has only nicotine in it, and none of the other 7000 chemicals also found in a cigarette (300 known to be toxic and harmful, 52 known to cause cancer)[5,42] By using NRT, you and your baby are not exposed to all of these other chemicals[42] Nicotine from NRT is absorbed at a slower and lower rate compared with nicotine from a cigarette. This means that if you use NRT, you are actually receiving less nicotine than when you smoke[5] NRT will increase your chances of quitting and remaining smoke-free by 40%[42] Every day that you do not smoke improves the health of you and your baby There is nothing better for you and your baby's health than to quit smoking Using NRT may help your baby's health, even if you do not quit smoking.[43] This is probably because of less overall exposure to chemicals

NRT = nicotine replacement therapy.

Implications for policy and future research

Reports from specialised smoking cessation services with trained counsellors in England[52] and Scotland[53] show that NRT is routinely prescribed during pregnancy — in England, 87% of smoking cessation services offer combination NRT in pregnancy.[52] Pregnant women are routinely referred to these services, highlighting not only the importance of additional training for health providers to increase their confidence and skills but also the question of whether the health system should be offering pregnant women access to specialised cessation support. The findings of Bar-Zeev and colleagues[7] provide further support for the importance of these services showing that referral is practised more frequently by Australian GPs and obstetricians than

prescribing NRT. Even though all Australian states and territories offer the Quitline service, it is still underutilised.[54] More research is needed on how to increase the the acceptability and usability of the Quitline and whether other options such as specialised smoking cessation clinics should be available.

Moreover, further research is needed to assess the safety and efficacy of higher dosages of NRT in pregnancy, specifically combination treatment, and also to evaluate the safety and efficacy of using NRT as a harm reduction strategy for women who are unmotivated to quit smoking, in order to reduce or eliminate exposure to cigarette smoke during pregnancy.

Conclusions

Ambiguous messages may be contributing to the low NRT prescribing rates and, therefore, it is important to provide a clear practical message to health practitioners and women. It is our duty as clinicians to interpret the evidence, deal with uncertainty and be able to provide pregnant women with information that will allow them to make an informed decision. Clinicians need to offer pregnant women the option of receiving NRT in a timely fashion if they cannot quit smoking on their own. In this review, we offered a practical guide on how the risks versus benefits of NRT use during pregnancy could be articulated, and how and when to decide whether to use or increase NRT during pregnancy. More education and training is required to improve clinicians' confidence and skills, and better referral pathways, including specialised smoking cessation services, need to be in place to help pregnant women to quit smoking.

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Supplemental File 1

Summary of Studies Addressing Safety and Efficacy of NRT in Pregnancy

Study	Year	Aims	Number of participants	Type and Dosage of NRT	Eligibility criteria	Efficacy outcomes	Health and Safety outcomes	Reported adherence
Observational studies – Population based cohorts:								
Dhalwani et al(35)	2015	To assess the relationship between early pregnancy exposure to NRT or smoking with major congenital anomalies (MCA) in offspring	192,498 live births (2001-2012), 2677 exposed to NRT, 9980 smokers, 179,841 control non-smokers	All types of NRT	Women age 15-49 from 570 general practices across the United Kingdom, (covering 6% of the population)	Not reported	OR for MCAs NRT group compared to non-smokers controls 1.12, 99%CI: 0.84–1.48, p=0.31. OR for MCAs NRT group compared to pregnant smokers not receiving NRT 1.07, 99% CI: 0.78–1.47, p=0.58. OR for Respiratory anomalies NRT group compared to non-smokers controls 4.65, 99% CI: 1.76–12.25, p<0.001. OR for Respiratory anomalies NRT group compared to pregnant smokers not receiving NRT 3.49, 99% CI: 1.05–11.62, p=0.07.	Not reported
Brose et al(39)	2013	To assess the association of single and combination NRT with	3880 pregnant women attending stop smoking	Any type	Pregnant smokers trying to stop with the	Using combination NRT (patch plus an oral form) was associated with a higher validated cessation rate (at 4 weeks) compared to not	Not reported	Not reported

		success of quit attempts of pregnant smokers	services (2009-2011), 1166 used single NRT, 2126 combination NRT, 588 no NRT		support of 49 English Stop Smoking Services (32% of all services)	using NRT, adjusted OR 1.93, 95%CI 1.13–3.29, p= 0.016. Using a single NRT was not associated with a higher cessation rate OR 1.06, 95%CI 0.60–1.86, p=0.84.		
Milidou et al(74)	2011	To investigate the associations between use of NRT and smoking during pregnancy and infantile colic	63,128 live births (1996-2002), 207 exposed to NRT, 15,016 smokers, 1245 to both smoking and NRT, 46600 control non-smokers	Patch/ gum/ Inhaler	Part of the Danish National Birth Cohort, completed two interviews during pregnancy, gave birth to a live singleton	Not reported	OR for infantile colic in NRT group compared to non-smokers 1.6 95%CI 1.0– 2.5, p=0.03. OR for infantile colic in smokers compared to non-smokers 1.3, 95% CI 1.2–1.4. No comparison reported between NRT group and smokers.	Not reported
Lassen et al(38)	2010	To estimate the association between the use of NRT during pregnancy and offspring birthweight	71,320 live births (1996-2002); 1753 used NRT, 15,796 smokers, 53,771 control non-smokers	Patch/ gum/ Inhaler	Part of the Danish National Birth Cohort, completed two interviews during pregnancy, gave birth to a live singleton	Not reported	Mean change in birth weight 0.25 g per week of NRT use 95%CI -2.31, 2.81. Mean change in birth weight when using more than one NRT product in the same week -10.73 g per week of NRT use, 95%CI -26.51-5.05.	Not reported

Strandberg-Larsen et al(37)	2008	To examine whether the use of NRT during pregnancy increases the risk of stillbirth	87,032 pregnancies (1996-2002), 1927 used NRT (of these, 1091 also smoked), 13266 smokers that did not use NRT, 71839 control non-smokers	Patch/ gum/ Inhaler	Part of the Danish National Birth Cohort, completed one interview during pregnancy, gave birth to a live singleton	Not reported	No significant differences were found in the risk of stillbirth for women using NRT during pregnancy compared to non-users, HR 0.57, 95%CI 0.28–1.16. Smoking during pregnancy was associated with an increased risk of stillbirth, HR 1.46, 95%CI 1.17–1.82 but Smoking and using NRT was not, HR 0.83, 95%CI 0.34–2.00 (compared with non-smoking women who did not use NRT).	Not reported
Morales et al(36)	2006	To examine whether maternal smoking and use of NRT during the first 12 weeks of pregnancy increased the prevalence of congenital malformations	76,768 live births (1997-2003), 250 used NRT, 16812 smoked, 55,915 control non-smokers	Patch/ gum/ Inhaler	Part of the Danish National Birth Cohort, completed one interview during pregnancy, gave birth to a live singleton	Not reported	NRT users had a significantly higher risk for congenital malformations compared to non-smokers; Specifically for musculoskeletal malformations OR 2.63, 95%CI 1.53– 4.52. Excluding minor malformations, the association was not significant For all MCA OR 1.13, 95%CI 0.62–2.07 For major musculoskeletal malformations OR 2.05, 95%CI 0.91– 4.63.	Not reported

Intervention studies:								
Randomized placebo controlled trials								
Coleman et al(40) Cooper et al(49)	2012 2014	To investigate the efficacy and safety of nicotine patches during pregnancy	1050 pregnant women, 521 randomized to NRT group, 529 to control with placebo patches (control)	15 mg/16 hour patch for 8 weeks	12-24 weeks gestation, ≥10 CPD prior to pregnancy, and currently ≥5 CPD, agreed to set a quit date	No difference in efficacy from quit date to delivery (9.4% validated abstinence rate in NRT group, 7.6% Placebo group; OR 1.27, 95% CI 0.82–1.98 After one month of treatment significant increase in validated abstinence; 21.3% NRT group, 11.7% Placebo; OR 2.1, 95%CI 1.49-2.97.	All pregnancy and birth outcomes including miscarriage, still birth, mean birth weight, rates of preterm birth, low birth weight, and congenital abnormalities similar in the two study groups. Significantly more deliveries by caesarean section in the NRT group (20.7%) than in the placebo group (15.3%) OR 1.45, 95%CI 1.05-2.01. Two years after delivery, infants born to mothers using NRT have a significant higher rate of absence of impairment; 73% in the NRT group, compared to 65% in the placebo group; OR 1.4, 95%CI 1.05-1.86, p=0.023.	7.2% in NRT group and 2.8% in Placebo group used patches for more than 1 month
Berlin et al(41)	2014	To determine the efficacy of nicotine patches among pregnant smokers, with the Dose individually adjusted	402 pregnant women, 203 randomized to the NRT group, 199 to placebo patches (control)	10-30 mg/16 hour patch, dose adjusted based on salvia cotinine level and	9-20 weeks gestation, ≥5 CPD, motivated to quit	No difference in efficacy from quit date to delivery (5.5% validated abstinence rate in NRT group, 5.1% Placebo group; OR 1.08, 95% CI 0.45–2.6.	Birth weight was not significantly different between the two groups (mean weight NRT group 3065gr (SE 44gr), placebo group 3015 gr (SE 44gr), p=0.41.	Median compliance rate in NRT group 85% (interquartile range 56-99%)

		according to saliva cotinine levels		maintained till delivery				
Oncken et al(42)	2008	To estimate the safety and efficacy of 2 mg nicotine gum for smoking cessation during pregnancy.	194 pregnant women, 100 randomized to the NRT group, 94 to placebo gum (control)	2 mg gum, up to 20 a day, substitute one piece for every cig, 6 weeks treatment and 6 weeks taper.	≤26 weeks gestation, ≥1 CPD, Did not have to agree to set a quit date	Point prevalence validated abstinence rates similar between the groups at 6 weeks post treatment (13% NRT group, 9.6% placebo group, p=0.45) and at 32-34 weeks gestation (18% vs 14.9%, p=0.56).	Higher birth weight and gestational age in the NRT group: Mean birth weight - NRT group 3287 gr (SD 566gr), placebo group 2950 gr (SD 653gr), p<0.0001. Gestational age - NRT group 38.9 weeks (SD 1.7), placebo 38 weeks (SD 3.3), p=0.14. Rates of preterm birth and very low birth weight (<2500 gr) were significantly higher in the placebo group compared to the NRT group: Preterm birth - NRT group 7.2%, placebo 18%, p=0.027. Low birth weight - NRT group 2%, placebo group 18%, p<0.001).	Average days of using the gum was 37.8 days, mean number of gum pieces a day 3.04
Kapur et al(43)	2001	to examine the efficacy of NRT in reducing smoking among pregnant women who were heavy smokers and who could not quit	30 pregnant women, 17 randomized to the NRT group, 13 to placebo patches (control)	15 mg/ 18 hour patch for 8 weeks, then 10 mg for 2 weeks, and 5 mg for last 2 weeks	12-24 weeks gestation, ≥15 CPD, motivated to quit	Abstinence at 12 week 23.3% in NRT group, 0% in placebo group (p=0.11).	Not reported	59% in NRT group discontinued treatment within first week

		smoking during their first trimester						
Wisborg et al(44)	2000	To assess the effect of nicotine patches on validated smoking cessation in pregnant women and the effect on birth weight and preterm delivery	250 pregnant women, 124 randomized to the NRT group, 126 placebo patches (control)	15 mg/ 16 hour patch for 8 weeks, then 10 mg for 3 weeks	≤22 weeks gestation, ≥10 CPD	Continuous validated abstinence from treatment to 4 weeks prior expected delivery date 21% NRT group, 19% placebo, RR 1.1 95%CI 0.7, 1.8.	Mean birth weight – NRT group 3457 gr placebo 3271 g; mean difference 186 gr, 95%CI 35-336 gr. Proportion of infants with low birth weight <2500 gr NRT group 3%; placebo group 9%, RR 0.4, 95%CI 0.1, 1.1. Preterm delivery - NRT group 8%, placebo 10%, RR 0.8, 95%CI 0.4, 1.7.	17% of NRT group participants used all 15 mg patches for 8 weeks
Randomized non-placebo controlled trials								
El-Mohandes et al(45)	2013		52 pregnant women, 26 randomized to NRT group plus behavioural counselling, 26 control group (behavioural counselling only)	Based on salivary cotinine levels Either 21 mg/2 wk; 14 mg/4 wk; and 7 mg/4 wk; Or 14 mg/6 wk; and 7 mg/4 wk	<30 weeks gestation, CO ≥8 ppm, or salivary cotinine ≥20 ng/ml, or urinary cotinine ≥100 ng/ml, motivated to quit	Point validated abstinence at end of study NRT group 19%, Control group 0%, p=0.05.	Higher gestational age and birth weight in the NRT group: Birth weight - NRT group 3203gr; control 2997gr, p=0.018. Gestational age - NRT group 39.4; Control 38.4 weeks, p=0.02. No difference in pre-term birth NRT group 4%, Control 8%; or low birth weight NRT group 12%, Control 16%.	Not reported
Pollak et al(46)	2007	To assess whether the addition of	181 pregnant women, 122 randomized	Choice between	Smoked >5 CPD	7-day point prevalence validated abstinence:	No difference in mean birth weight or gestational age	Use of a mean number of 23.4

		NRT to behavioural therapy resulted in improved smoking cessation rates	to NRT group plus behavioural counselling, 59 control group (behavioural counselling only)	patch/gum / Lozenge; Dosage of patch dependant on smoking level, ranging from 7-21 mg for 6 weeks. Number of gum or lozenge as number of CPD	Gestational age 13-25 weeks Agreed to set quit date	At 7 weeks post randomization – NRT group 24%, Control 8%, p=0.02. At 38 weeks gestation – NRT group 18%, Control 7%, p=0.04. For every 7 days of NRT use, women were 1.25 times, 95%CI 1.08-1.47, p=0.003 more likely to self-report 7-day point prevalent abstinence.	Birth weight – NRT group 3061 gr (SD=661 gr), Control 3132 gr (SD=688 gr), p=0.51. Gestational age – NRT group 37.9 weeks (SD=3.1), Control 38.6 weeks (SD=2.7), p=0.14. No difference in serious adverse events (after adjusting for previous pre-term labour) – NRT group 27%, Control 18%, Risk Difference=0.09, 95%CI 0.05–0.21, p=0.26.	patches; or using gum for a mean 8 days; or lozenge for a mean 4 days Secondary analysis published(75) 29% of women used patches for recommended 6 weeks
Hotham et al(47)	2006	To assess the feasibility of offering NRT patches to pregnant women in terms of acceptability and effects on cessation	40 pregnant women, 20 randomized to NRT group plus behavioural counselling, 20 control group (behavioural counselling only)	15 mg/16 hour patch for 12 weeks	Smoked ≥15 CPD, gestational age 12-28 weeks, Interested in quitting	Validated abstinence at delivery 15% NRT group, 0% Control group.	Not reported	50% NRT used for 6 weeks or less

Introduction to Paper Five

Papers one, two and three showed that GPs face multiple barriers to effectively treat pregnant women who smoke. These included lack of time and resources, low optimism that their intervention will be effective, lack of confidence and skills to perform behavioural counselling adequately, resulting in a focus on providing information on the harms of smoking rather than "assisting" women to quit, and fear that discussing smoking with the pregnant woman might affect their relationship with the patient, resulting in offering treatment to only pregnant women who state they are ready to quit. GPs also recognise their inability to treat tobacco dependence by themselves due to the other social determinants that impact smoking. This was especially evident for GPs treating Aboriginal and Torres Strait Islander pregnant women who smoke. In these settings, other barriers also exist such as lack of access to oral NRT and lack of culturally appropriate resources.

Specifically with regard to using NRT in pregnancy, papers two, three and four indicated that additional barriers are prominent. Barriers included concerns over NRT safety during pregnancy and lack of confidence in their ability to prescribe NRT, perpetrated by clinical guidelines giving ambiguous messages without providing a clear practical guide on how to use NRT in the context of pregnancy.

Paper five sets out to understand, from a global perspective, what interventions aimed at improving health providers' provision of smoking cessation care during pregnancy have been previously tested, what intervention components were used and in which setting and what was the impact of these interventions. This was conducted utilising a systematic review approach, with a narrative review of the data and a meta-analysis.

Paper Five:
Improving Health Providers Smoking Cessation Care in Pregnancy: A Systematic Review and Meta-Analysis

Authors

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Associated appendices

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Highlights

- Health providers are lacking in their provision of smoking cessation care during pregnancy.
- There is a lack of evidence of the effectiveness of interventions aimed specifically on improving health providers' provision of smoking cessation care during pregnancy, and if effective, does this correlate also with improved pregnant patients smoking rates?
- It is not clear which intervention components, or combination of, might be the most effective in improving health providers' smoking cessation care during pregnancy.
- Interventions designed to improve provision of smoking cessation care during pregnancy show a small increase in all care components, and may improve overall patients smoking abstinence rates.
- Audit and feedback and enhancing intervention design by using behaviour change theories may improve effectiveness.

Abstract

Introduction

Health providers are lacking in their provision of smoking cessation care during pregnancy. The aim of this study was to systematically review all available studies on the effectiveness of interventions in improving health providers' provision of smoking cessation care during pregnancy.

Methods

Five databases were searched, Inclusion criteria included all intervention study types. Two reviewers screened abstracts and full texts independently. Interventions were characterized according to the Effective Practice Of Care taxonomy. Random-effects meta-analyses examined intervention effects on smoking cessation care components based on the 5As. Estimates were number of participants reporting each outcome, or mean score, transformed into Cohen's d. Crude meta-regressions, and meta-analysis subgrouping, were performed to examine whether intervention effects for 'Ask', 'Advise' and 'Assist' differed by intervention components.

Results

Of 3165 manuscripts, 16 fulfilled inclusion criteria. Pooled analysis showed significant small to large intervention effects on the different care components (Cohen's d ranging from 0.47 for 'Ask' (95%CI 0.13-0.81) to 1.12 (95%CI 0.45-1.79) for 'Setting a quit date'). Crude meta-regression suggested that for 'Ask', having a theoretical basis may improve effectiveness (Cohen's d difference 0.62, 95% CI 0.12-1.1). Subgrouping the meta-analysis suggested that audit and feedback possibly increases intervention effectiveness for 'Advise' and 'Assist'.

Conclusion

Interventions designed to improve provision of smoking cessation care during pregnancy show a small increase in care components. Studies vary substantially in design, intervention components, and outcome measurement, impacting ability to synthesize available data. Audit and feedback and enhancing intervention design by using behaviour change theories may improve effectiveness.

Registration: PROSPERO CRD42016030143

Introduction

Smoking during pregnancy in one of the most important risk factors for poor maternal and infant health outcomes.[1] Guidelines on smoking cessation for health providers (HPs) recommend using a brief intervention such as the 5A's - Ask about tobacco use; Advise to quit; Assess motivation to quit; Assist with behavioural support and medication (such as nicotine replacement therapy (NRT)); and Arrange follow-up and referral. Previous reviews have identified numerous barriers to providing smoking cessation care (SCC) during pregnancy, including lack of time, resources, knowledge and skills.[2-4]

SCC during pregnancy has unique characteristics compared to the non-pregnant population. Firstly, pregnancy is a time-limited condition, therefore there is more urgency to act. The sooner cessation occurs, the bigger the health benefits are to the foetus.[5,6] Secondly, antenatal care is usually provided by a multi-disciplinary team through regular medical visits, thus allowing multiple opportunities for various HPs to intervene. Thirdly, in pregnancy guidelines recommend to first try smoking cessation unassisted by pharmacotherapy, due to safety concerns of nicotine administration using NRT.[7-11] Guidelines lack practical detailed information on when and how to use NRT during pregnancy.[7] Fourth, a high proportion of women who smoke spontaneously quit prior to, or in the early stages of, pregnancy.[12-14] Pregnant women who continue to smoke during pregnancy may have a higher nicotine dependence level,[15] and/or are a part of a disadvantaged minority population.[4,16] Thus, addressing smoking during pregnancy may require additional specific training and skills for HPs facing this challenge.

The Cochrane's Effective Practice and Organization of Care (EPOC), developed and published a taxonomy of interventions designed to improve HPs practice.[17] This taxonomy includes 19 different intervention components targeted at HPs including, but not limited to, educational material, educational meetings, audit and feedback, and reminders. There have been several Cochrane reviews targeting specific intervention components for HPs.[18-19] Most of these show a small effect on HPs performance, and it is not clear whether this correlates to a similar effect on patient's outcomes.

The aim of this study was to assess the effectiveness of interventions for improving HPs SCC during pregnancy, and explore which intervention components might be the most effective.

Methods

Data sources

Searches were carried out in Cochrane Central Register of Controlled Trials (CENTRAL); MEDLINE; EMBASE; PsycINFO and CINAHL. The search was conducted in December 2015 and alerts were kept until October 2018. Search terms included both Keywords and Medical Subject Headings (MESH) terms for 'Clinicians', 'Pregnancy', 'Tobacco' and 'Interventions' (Supplemental file 1: Full search strategy in Medline). Included papers were restricted to peer-reviewed journals, the English language, with no restriction on publication time.

Study selection

Studies were eligible for inclusion if they included any type of intervention study design and any comparison type. Intervention studies were excluded if they did not report outcomes at the HPs level.

Data extraction

One author (YBZ) conducted the search in each electronic database. Two authors (YBZ & LT) independently screened all titles and abstracts from the database search. Full texts of the abstracts that met the inclusion criteria were acquired for all potentially eligible studies. Two authors (YBZ & LL) independently screened all full texts. Discrepancies were resolved by discussion between the two reviewers, with a third reviewer (GG) acting as an adjudicator. Reference lists of included publications were checked for additional relevant studies.

A data extraction tool was used to record the following information: title, authors, year of publication, setting, aims, study design, theoretical framework used, intervention components (according to the EPOC taxonomy),[17] comparison groups, sample size, response rate, sample characteristics (type of health provider and age and sex distribution), data analysis, findings. One review author (YBZ) extracted the data from relevant full texts, and a second reviewer (ES) extracted a random 30% (n=5) to check for consistency.

Principal outcome measure: Changes in reported HPs behavior regarding any measures of SCC provision to pregnant women, including the 5As ("Ask", Advise", "Assess" motivation to quit and/or level of nicotine dependence, "Assist", Arrange follow up" and "Referral"). As "Assist" can include the provision of different elements such as setting a quit date ("Quit date"), education on health risks of smoking ("Education"), providing resources ("Resources"), and prescribing NRT ("NRT"), we included the changes in HPs provision of these elements when reported separately.

Secondary outcomes:

1. Smoking abstinence (point prevalence abstinence and/or continued abstinence; self-reported and/or biochemically validated) ("Quit rates")

2. Smoking reduction (numbers of women reducing smoking (any definition, self-reported > 50% reduction, and/or biochemically validated)

3. Post-partum relapse rates

Assessment of risk of bias

Quality of included studies was assessed using two separate tools according to the design of the studies. Studies using a quasi-experimental design were assessed with the Hawker Quality Assessment Tool,[20] rating 9 domains, and providing a total score between 9 (very poor) to 36 (good). Controlled studies were rated using the Cochrane Collaboration for assessing quality and risk of bias.[21]

Data synthesis

Data for each outcome was summarised separately and then synthesised together. A narrative synthesis followed Popay's Guidance on the Conduct of Narrative Synthesis in Systematic Reviews.[22]

Meta-analyses were performed when possible to examine the intervention effect for "Ask", "Advise", "Assess" motivation to quit, "Assist", "Arrange Follow-up", "Arrange Referral", "Education", "Resources", "Quit Date", and "Quit rates". Estimates were either number of participants reporting each outcome, or mean score for each outcome. These were extracted either as the post versus pre estimates for quasi-experimental designs, or as the intervention versus control estimates post intervention, for controlled studies. No adjustment was done for baseline estimates in controlled studies, as it was assumed that the randomization dealt with pre-intervention differences. Estimates were transformed into Cohen's d to allow pooling of findings.[23] One study (Chertok et al)[24] reported on median change in pre and post score, without the interquartile range, therefore we could not calculate the Cohen's d estimate. Thus, this study was not included in the pooled results. For "Quit rates", as only proportions

and not mean scores were recorded, odds ratio were pooled to examine overall treatment effect.

In studies where the same outcome was measured both through surveys of HPs, and through women's recall on the provision of the outcome – the HPs survey measure was used for the meta-analysis. Similarly, if the outcome was measured at more than one time point, the latest time point was used. This was done as changes in HPs behaviour tend to diminish over time, and this would be the most conservative treatment effect. For smoking abstinence ("Quit rates"), the most rigorous measure was selected, such as continuous abstinence rates, biochemically validated abstinence rates, and "Intention to treat" abstinence rates. Only one study reported abstinence rates 6 months postpartum, therefore only abstinence rates during pregnancy or immediately postpartum were included in the meta-analysis.

Stata program *Meta*n was used to pool Cohen's d estimates, and the results were displayed in a forest plot. Random effects modelling (DerSimonian and Laird's method) was used to account for between-study differences in underlying estimates, due to study population and design. Cohen's d pooled estimate were interpreted as follows: <0.2 very small effect; 0.2-0.5 small effect; 0.5-0.8 medium effect; 0.8-1.2 large effect; >1.2 very large effect.[25] Heterogeneity was reported using the I-squared measure. For meta-analysis with 10 or more studies,[26] Stata programs *Metafunnel* and *Metabias* were used to create funnel plots, and perform Egger's test of bias - these were used to examine publication or other bias.[27-29]

Meta-regression: For outcomes with more than eight studies ("Ask", "Advise" and "Assist"), a series of crude meta-regressions were performed to examine whether differences between studies could be explained by study factors. Factors that were included were year of publication; country (middle vs high income country); study

design (randomized controlled study (RCT) vs pre-post); study quality ("good" vs all others); time point measurement (≥12 months vs <12 months); number of intervention components (≥3 vs 1-2); whether the intervention included educational outreach, reminders, audit and feedback, an interactive component, systems change component, and a theoretical basis when developed (all yes vs no); and outcome measurement type (chart review vs HPs survey, and women's survey vs HPs survey). Additionally, the meta-analysis was grouped by the different intervention components to examine their effect on these outcomes.

All statistical analyses were programmed using Stata v14.1 (StataCorp LP, College Station,
TX, USA). Significance was set as α=0.05 a priori.

Registration: The review protocol was registered with PROSPERO International Prospective Register of Systematic Reviews (Identifier: CRD42016030143).

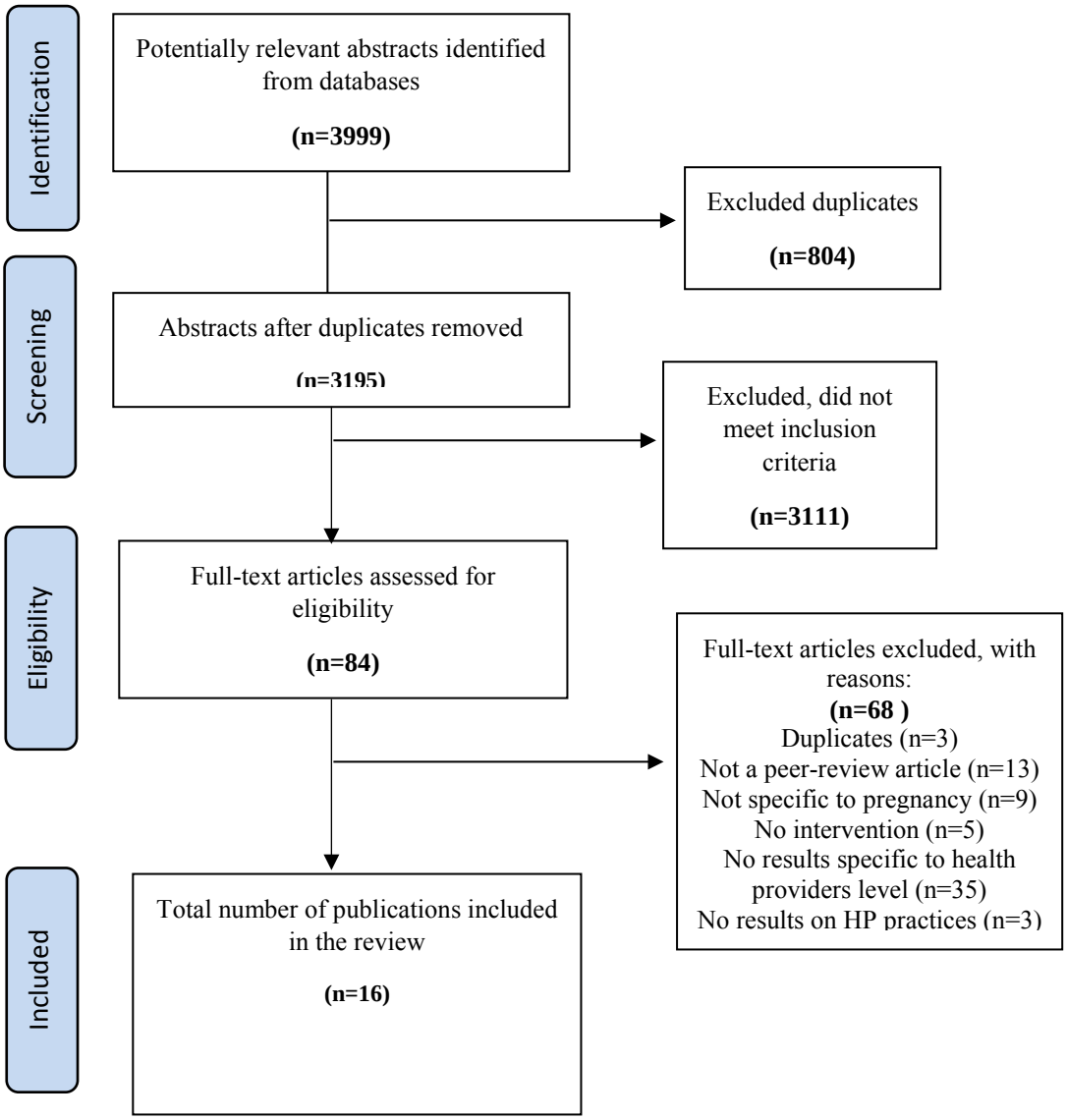
Results

In total 16 articles, describing 14 interventions, met the inclusion criteria and were included in this review (Figure 1: PRISMA diagram). Detailed information of each study, including the intervention description, and detailed outcome measurement for each study, is reported in Supplementary file 2.

Study Design

Ten studies used a pre-post design,[24,30-38] and six studies used an RCT design,[39-44] with one study (Altheba et al)[44] using a cluster RCT design.

Figure 1. PRISMA flow diagram of the systematic review process



One intervention used primarily a RCT design (Cooke M (b) et al[40] and Campbell et al[41]), but also reported on pre-post results - combining HPs intervention and control data for pre and post results (Cooke M (a) et al)[31]. These studies used the same intervention, but examined the effect of different dissemination methods – either through mail or face to face meetings. Therefore the RCT design studies tested the difference in effectiveness between the two dissemination methods, whereas the pre-post tested the effectiveness of

the intervention as a whole (combining both dissemination methods, and reporting pre and post effects).

Setting

Fifteen studies[24,30-43] were conducted in high-income countries. Only one cRCT study was conducted in middle-income countries – Argentina and Uruguay (Althabe et al)[44].

Participants

Twelve studies provided data on a mixture of providers – either a mixture of clinical HPs (ten studies)[31-33,35,36,38,40,41,43,44]; or a mixture that included clinical and non-clinical staff (two studies)[24,37]; Four studies provided data on one type of HPs – two on midwifes,[39,42] one on nurses,[34] and one on doctors.[30] RCTs included either only midwifes[39,42] or a mix of HPs.[40,41,44]

Sample size

Overall 1,411 HPs provided data for the pre-intervention or control arm; and 1,107 provided data for the post-intervention or intervention arm. In total, 11,505 pregnant women were recruited, 5,607 providing data for the pre-intervention or control arm; and 5,898 for the post-intervention or intervention arm.

Interventions

Intervention components according to the EPOC taxonomy[17]

Number of intervention components ranged from 1-6, with most interventions only including up to two components (n=9, 64%). The types of interventions components used included training (n=13, 93%; either through educational meetings or educational outreach visits); provision of educational materials to the HPs such as a flipchart (n=9, 64%); reminder tools such as prompts in medical records (n=8, 57%); audit and

feedback mechanisms to collect data on care provision and distribute results back to HPs (n = 3, 21%); and use of local opinion leaders such as the lead nurse to act as a champion (n=2, 14%). As part of the training provided, four studies (28%) described using an interactive learning component such as role-playing.

Intervention duration

Nine of the interventions only included 1-4 hours of training (average 2.2 hours), with one intervention training lasting 2 days. Four interventions did not mention the length of the intervention.

Theoretical models for behaviour change

Three interventions (21.4%) (Yusam et al[34], Althabe et al[44], Cooke et al[31,40], and Campbell et al[41]) were designed based on Roger's Diffusion of Innovations Theory.[45] Two studies mentioned other models that supported their intervention implementation. Carlson et al[35] used the Chronic Care Model of "Plan, Do, Study, Act"[46] as a framework for improvement at the organizational level; and Flenady et al[36] used the Australian National Institute of Clinical Studies guidelines based on the Cochrane EPOC.[17]

Quality of studies and risk of bias (Supplemental file 3)

Nine studies had an overall good quality score (≥28),[30,36,37,39-44] six studies a fair quality score, (19-27)[24,31-34,38] and one study a poor quality score (10-18).[35] All of the controlled interventions had a high or unclear bias regarding performance and detection bias, since blinding of HPs to the intervention is not possible. None of the studies reported on measures taken to effectively blind outcome measurement.

Effects of Interventions

Below we report the narrative synthesis, and meta-analysis results for the 5As and smoking abstinence. Results for other outcomes ('NRT', selected 'Assist' sub-components, smoking reduction and post-partum relapse rates) are presented in Supplemental file 4.

As mentioned previously, three studies provided data on the same intervention.[31,40,41] Whenever possible, we included the data provided in the pre-post design (Cooke M et al (a))[31] (as this represented measurement of the overall effectiveness of the intervention).

'Ask' about smoking

Thirteen studies (eleven interventions) provided data on changes in the performance of Ask.[24,31-35,37-42,44] Studies used a variety of measurements (Supplementary file 2 – Table of studies characteristics), with eight studies using HPs self-report,[24,31,33,34,38,40,42,44] six studies using women's report,[32,37,39,41,42,44] and two studies using chart review.[32,35] Two studies reported on both HPs and women's report,[42,44] and one study reported on both chart and women's report.[32] Ten studies showed a high performance of "Ask" at baseline (pre intervention/control group),[24,32-34,38-42] with the intervention either not changing this, or improving it slightly.

Pooled analysis of ten studies showed a small significant intervention effect on performance of "Ask" with high heterogeneity (Cohen's d=0.47, 95%CI 0.13-0.81, p=0.007, I^2=85.9%) (Figure 2). Funnel plot examination, and Eggers test indicates no asymmetry of the funnel plot (bias p=0.22), suggesting that publication bias is not present.

Crude meta-regressions found that having a theoretical basis for the intervention design significantly increased the intervention effect (Cohen's d difference=0.62, 95%CI 0.12-

1.1, p=0.022) and reduced heterogeneity (I^2=56.4%) (Supplemental file 5). This was evident also when running the meta-analysis sub-grouped by theoretical basis, showing a large pooled intervention effect for those studies (Figure 2). Inclusion of other study factors did not significantly impact intervention effect or reduce heterogeneity (Supplemental file 5). Subgrouping the outcome according to how it was measured (via HPs survey, women's survey, or chart review) shows a differential intervention effect (Figure 2). Those studies measuring documentation of smoking status (as opposed to reporting "Ask") showing a medium significant intervention effect. Similarly, grouping the meta-analysis by the different intervention components showed a medium intervention effect for including a systems change component, educational outreach, at least 3 intervention components, and audit and feedback; but no difference for including an interactive component, and a smaller intervention effect for those including reminders (Figure 2). Subgrouping the meta-analysis according to study design – quasi-experimental or controlled, showed no significant effect for the controlled studies (Figure 2).

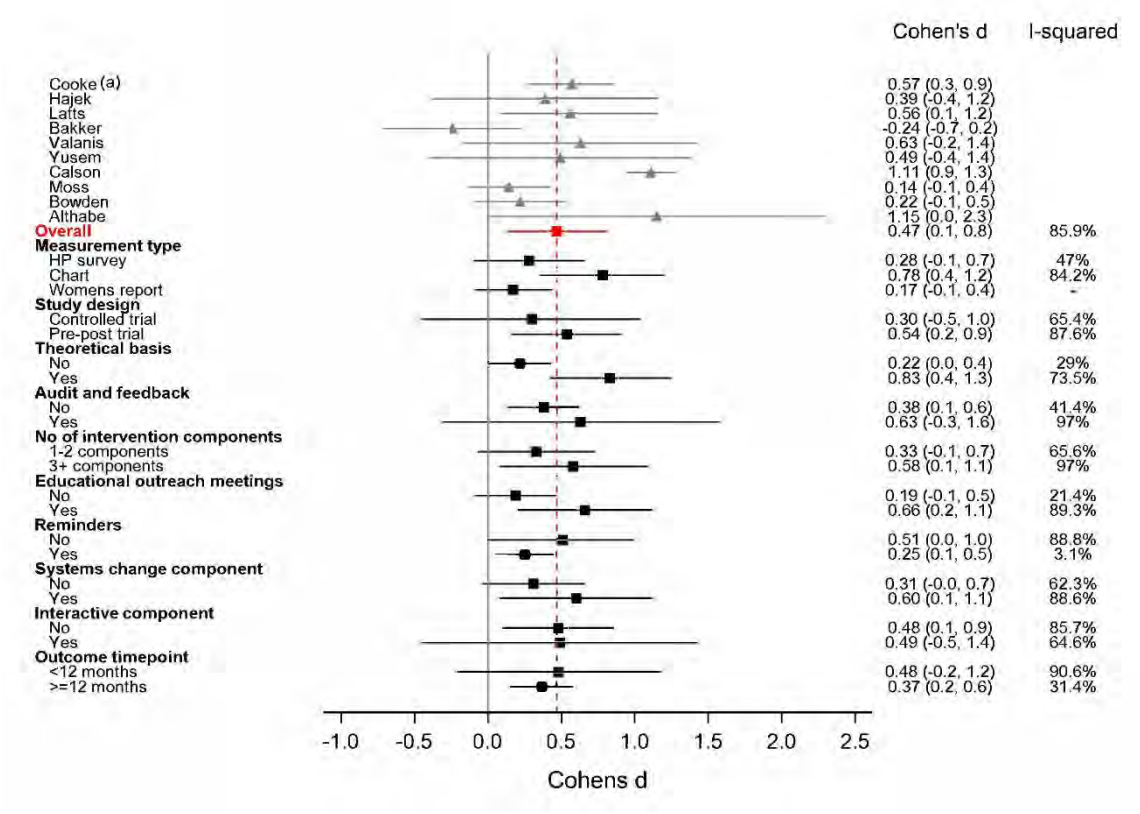


Figure 2: Meta-analysis for the provision of 'Ask' about smoking, overall and sub-grouped by different intervention components

'Advice' to quit

Fourteen studies (12 interventions) included data regarding changes in HPs performance of 'Advice' to quit.[24,31-37,39-44] Five of these used HPs self-report,[24,31,34,40,42] six used women's report,[36,37,39,41,43,44] one used chart review,[35] one reported on both chart review and women's recall,[32] and two measured both HPs and women's report.[33,44] Seven studies showed a significant improved in the provision of advice to quit,[33,35,36,39,42-44] and six showed no change.[24,31,34,37,40,41] Latts et al[32] found a decrease, both when using chart review (62% pre to 24% post) and women's survey (86% pre to 65% post). Four studies had high rates of provision of 'Advice' at the pre intervention/control arm.[24,34,37,42]

Eleven interventions provided data for the pooled analysis, showing a small significant intervention effect with high heterogeneity (Cohen's d=0.46, 95%CI 0.02-0.9, p=0.04,

I^2=91%) (Figure 3). Some indication was seen in the funnel plot that large effect sizes are not seen or not published in small studies. However, Egger's test indicates no significant asymmetry of the funnel plot (bias p=0.53).

No significant association was demonstrated between treatment effect and any of the studies factors in the crude meta-regressions (Supplemental file 5). Likewise, inclusion of the study factors did not reduce heterogeneity or between study variance.
Subgrouping the outcome according to the study design showed that combining only the controlled studies resulted in a significant medium effect (Cohen's d=0.66, 95%CI 0.1-1.3, I^2=76%) (Figure 3). Subgrouping according to the measurement approach displayed that only women's report showed a significant medium intervention effect (Figure 3). Grouping the meta-analysis by the different intervention components suggest that including audit and feedback favourably impacts on the intervention effect, but the rest of the factors had no influence (Figure 3). Additionally, the intervention effect seems to disappear when the intervention post measurement was done after 12 months or more.

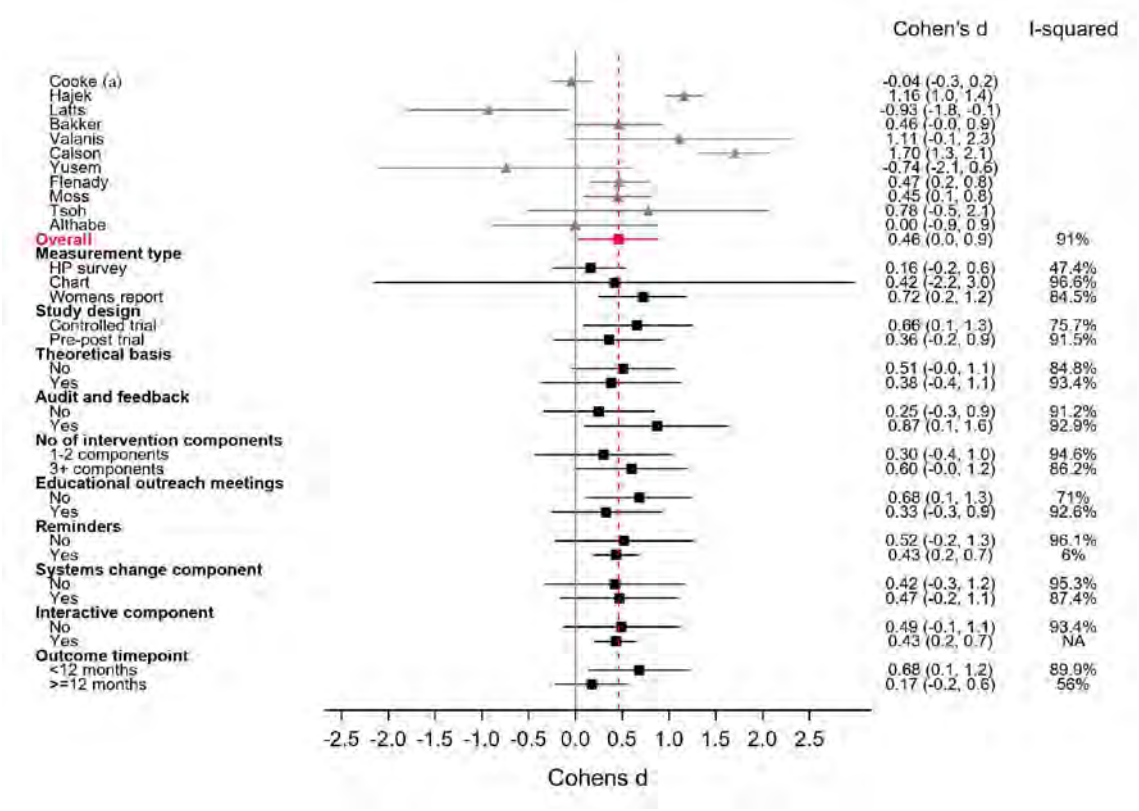


Figure 3: Meta-analysis for the provision of 'Advise' to quit, overall and sub-grouped by different intervention components

'Assess' motivation to quit

Six studies provided data on assessment of motivation to quit,[24,34-36,38,44] all expect one (Chertok et al),[24] showed a significant increase either in HPs self-report,[34,38] audit of charts,[35] or women's recall.[36,44] Five interventions provided data for the pooled analysis, showing a large significant intervention effect with high heterogeneity (Cohen's d=0.98, 95%CI 0.51-1.45, p<0.001, I^2=89%).

'Assist'

Eleven studies (nine interventions) included data on the provision of assistance to quit.[24,31,32,34-38,40,41,44] Cooke M et al (b)[40] and Campbell et al[41] found that although HPs self-report of providing assistance was higher in the group that received the intensive dissemination method,[40] women's recall did not differ between the intervention and

control group.[41] Most other studies found a significant improvement, either using HPs self-report,[31,34,38] chart review,[35] or women's report.[36,37,44] Latts et al[32] reported on 11% of women recalling being provided counselling at baseline, decreasing after the intervention (3%). Similarly Chertok et al[24] did not find a significant improvement in HPs self-report.

Eight interventions were included in the pooled analysis, finding a significant medium treatment effect with moderate heterogeneity (Cohen's d=0.65, 95%CI 0.46-0.83, $p<0.001$, $I^2=59.2\%$) (Figure 4).

Crude meta-regressions found no significant associations between treatment effect and any of the studies factors (Supplemental file 5). Nor did the inclusion of the study factors reduce heterogeneity or between study variance. Subgrouping the outcome according to the study design showed that combining only the controlled studies resulted in a significant medium effect (Cohen's d=0.66, 95%CI 0.1-1.3, $I^2=76\%$) (Figure 4). Subgrouping the meta-analysis by the intervention components shows that inclusion of audit and feedback, and having at least 3 intervention components, may have an impact on the intervention effect, while the rest of the factors had no influence (Figure 4).

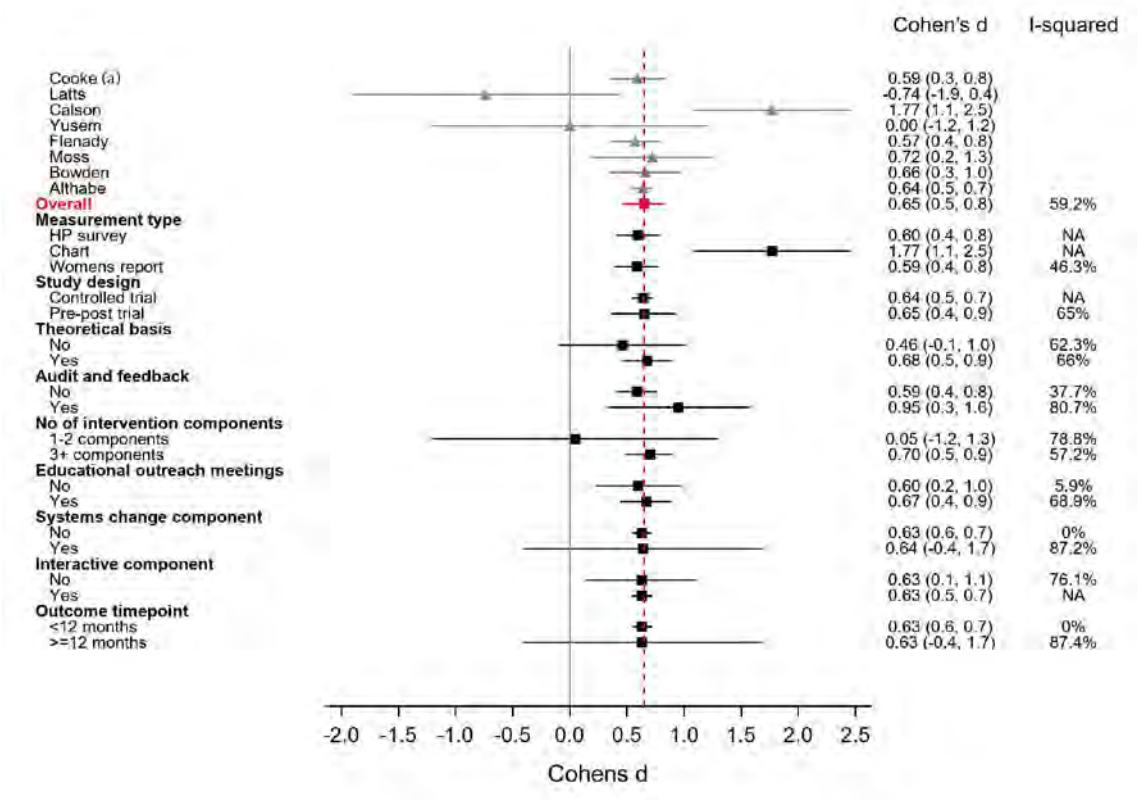


Figure 4: Meta-analysis for the provision of 'Assist' cessation, overall and sub-grouped by different intervention components

Arrange Follow up

Information regarding changes in HPs following up was included in seven studies[24,31,34,38,40,42,44] (six interventions). Five of these[31,34,38,42,44] were included in the pooled analysis showing a significant large treatment effect with high heterogeneity (Cohen's d=0.84, 95%CI 0.4-1.29, p<0.001, I^2=76.4%). Bowden et al[38] measured HPs self-report of arranging follow up grouped as part of 'Assist', therefore these results were included in both pooled analyses. Overall, studies show a small improvement in rates that were very low at baseline/control. Althabe et al[44] found no improvement with 0% and 2.7% of women recalling having an arrangement for follow-up in the control and intervention group respectively. Cooke et al (b)[40] also found no improvement

between the two dissemination methods, despite finding a slight improvement when studying the overall effect pre and post intervention (Cooke M et al (a)).[31]

Arrange referral

Seven studies[24,31,32,36,38,40,44] (six interventions) provided information on intervention effects regarding referral to other smoking cessation services. Three of these included information on referral to the Quitline,[24,36,38] three to any smoking cessation service,[24,32,44] and two studies (same intervention) included data of referral in general.[31,40] Chertok et al[36] reported on HPs rates of providing patients with the number of the Quit line; referral to online resources; and/or to resources in their county for smoking cessation; all not showing any differences pre and post. Bowden et al[38] measured self-report of referral to the Quit line only in the post intervention survey, with 3.48±0.9 on a 4-point Likert scale from never to always. Three studies found improvements in referral rates,[31,36,44] with one study (Latts et al[32]) reporting 0% of pregnant women recalling being referred with no improvement. Pooled analysis, with four interventions included,[31,32,36,44] found a significant large treatment effect with high heterogeneity (Cohen's d=0.99, 95%CI 0.2-1.79, p=0.014, I^2=91.3%).

Smoking abstinence

Seven studies[32,36,38,39,41,43,44] mentioned women's smoking outcomes. Only four studies,[39,41,43,44] all RCTs, reported on standardized quit rates and were included in the meta-analysis. Two studies used post intervention cross-sectional surveys. Campbell et al[41] measured women's report on quitting since their first visit to the clinic, with an expired air carbon monoxide (CO) ≤9 ppm. Althabe et al[20] measured self-reported smoking abstinence immediately after birth verified by salivary cotinine. The other two studies followed the same women throughout the study period. Hajek et al[39] measured

self-reported abstinence during the last 12 weeks of the pregnancy and up to the postnatal interview immediately after birth, with a CO reading of < 10 ppm. Tosh et al[32] measured self-reported 30 day abstinence at two months post intervention, but biochemical validation was not preformed. Both these studies used Intention-to-Treat analysis, with those missing for follow up considered as smokers. Meta-analysis showed a non-significant positive treatment effect (OR=1.37, 95%CI 0.94-2.01; p=0.105, I^2= 46.1%). The other three studies measured related smoking status outcomes. Bowden et al[38] recruited women only post intervention and followed them for up to 12 months, reporting a 7% point prevalence quit rate at one month, and a 3% rate of sustained quitting during the follow up. Flenady et al[36] measured self-reported continued smoking status during pregnancy at the 36 week pregnancy visit or immediately after birth, with pre-intervention continuous smoking rate of 19.5%, and post of 16.7%. Latts et al[32] surveyed women after delivery reporting a pre intervention smoking rate of 15% and a post intervention rate of 13%.

Discussion

Principal findings: Overall, studies show a small improvement in HPs provision of SCC, which might also impact pregnant women's abstinence rates. Studies vary substantially in design, intervention components, and outcome measurement, impacting our ability to interpret available synthesized data. Having a theoretical basis, inclusion of audit and feedback, and having at least 3 intervention components, may increase intervention effects on specific care components.

Strengths and weaknesses:

Including both RCT and quasi-experimental designs is both a strength and a limitation as it allowed us to look at all published data, but this also meant including studies with lower methodological quality and intrinsic risk for bias. Nonetheless, sub-grouping the

meta-analysis according to the study design, indicated that for 'Advise' and 'Assist', combining only the more rigorous controlled studies, showed a higher or similar effect size to the overall effect size. Another limitation was the high variability in the measurement/definition of outcomes. However, this was partially accommodated for by using an explorative analysis to investigate the impact of the different measurements on the effect size (both through meta-regression, and by meta-analysis sub-grouping). Nonetheless, the high heterogeneity seen supports the high variation in the studies included, and the meta-analysis results should be interpreted cautiously.

The limited number of studies that used intervention components other than educational meetings and educational materials did not allow us to ascertain which components might be more effective than others. However, the explorative sub-grouping of the meta-analysis results according to the different intervention factors, was able to provide suggestions as to those factors that might be more effective. We did not have enough data to test whether there is a difference in interventions effectiveness for different HPs, and/or different patient subpopulations.

We cannot exclude the possibility of publication bias, as due to the low numbers of studies for most of the outcomes, funnel plots and Eggers test were not feasible. Restricting the search to English only manuscripts may have also introduced a publication bias.

Comparison with literature:

Our findings are similar to other reviews studying the effect of intervention components on HPs behaviour change, showing a small effect, without a clear benefit to patient's outcomes. Despite previous research identifying that more active components such as audit and feedback, and having multiple components, were more effective[47,48], our

review shows that most interventions still rely on "traditional" methods of educational meetings and educational materials, and use only two components. A previous review (Carson et al)[49] targeted HPs provision of SCC in general (not centred on pregnancy), focused specifically on training and found a significant increase in HPs performance, and patients' abstinence. There was no evidence that training improved NRT provision.[49] To the best of our knowledge, our review is the first to focus specifically on interventions aimed at HPs treating pregnant patients.

Implications: Interventions that include a component focused on HPs performance are relatively inexpensive, and straightforward to implement. The small intervention effect on patients quit rates found in our review might be explained by the low number of studies measuring this (n=4). High-priority populations may need more intensive support options for pregnant women, such as designated smoking cessation services, and/or intensive personalized support through a tobacco treatment specialist. More extensive or costly tobacco control measures that target whole communities, and not just the medical services and the women themselves, can be justified by the fact that higher proportions of pregnant women who continue to smoke suffer from additional life stressors, and/or are part of disadvantaged minority populations.[4,16] The large intervention effect seen from pooled results of the few studies that provided specific data on setting a quit date, a behaviour change technique considered effective in pregnancy from previous research,[50] suggest this should be included as a specific SCC element taught to HPs. Our review also provides further support to previous research[47] showing 'audit and feedback' is an important and effective component that should be included as part of changing health providers behaviour. The lack of a theoretical background in designing many of the interventions was evident, and may partly explain the low effect size. This is not unique to the studies included in our review. A scoping

review of interventions aimed to improve guideline implementation among physicians found that only half of the interventions reported using a theoretical basis.[51] Research suggests that using behaviour change theory and frameworks to design interventions will lead to more effective and comprehensive interventions.[52,53] Our findings provide further support for this.

Only one study tested the intervention effectiveness in improving NRT prescription (Chertok et al).[24] Recent research has identified that health providers have specific barriers to recommending NRT during pregnancy, including lack of knowledge and confidence associated mainly with safety concerns.[54-57] Discussing medication use, including its risk versus benefit, is a natural part of the HPs clinical role. Addressing these barriers might improve the correct use of NRT, potentially having a significant impact on smoking cessation during pregnancy.

Future research: Researchers should consider moving beyond simply testing intervention effect to testing different interventions components within factorial RCTs, to allow better understanding of what might work to enhance intervention effectiveness overall. Interventions need to be described full detail, defining specific behaviour change techniques that were employed, to understand what works and what does not. Using a behaviour change technique taxonomy may aid this approach.[58,59] It is imperative to develop a global standardized measure for SCC, as was done for smoking abstinence rates, i.e. the Russel Standard.[60] This is especially true for 'Assist', which is currently ill-defined. It is not clear from current clinical guidelines what should be routinely included as part of behavioural counselling provided to pregnant women. Increasing NRT prescribing rates during pregnancy needs to be further explored, as they might lead to better smoking cessation outcomes.

Conclusions

Interventions designed to improve HPs provision of SCC during pregnancy show a modest increase in all of the care elements, and might improve smoking abstinence rates among pregnant women who smoke. Future research is warranted, focussing on understanding which specific intervention components can help improve intervention effects, with more rigorous standardized measures. Interventions designed on a theoretical basis, which also include an audit and feedback component, and have at least 3 components, are more likely to be effective.

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Statement 2: Contributors

YBZ designed the study, conducted the search, screening, full text extraction, narrative synthesis, oversaw the statistical analysis and wrote the manuscript. LT, ES and LLL assisted in conducting the screening and full text extraction. BB and MG advised on the methodology. KP and CO advised and conducted the statistical analysis. GSG contributed to the design of the study and oversaw the whole study. All authors critically reviewed and approved the final manuscript.

Statement 3: Conflict of Interest

Bar-Zeev Y has received fees for lectures in the past (years 2012–2015) from Novartis NCH (distributes Nicotine Replacement Therapy in Israel). No other authors declare any competing interests.

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Supplemental File 1

Full Search Strategy in Medline

Systemic Review of Interventions to Improve Health Provider Behaviour to better Manage Smoking in Pregnancy

1. "Attitude of Health Personnel"/
2. Health Knowledge, Attitudes, Practice/
3. health professional*.mp.
4. physicians/ or general practitioners/ or physicians, family/ or physicians, primary care/
5. exp General Practice/
6. general practitioners.mp.
7. dentist's practice patterns/ or nurse's practice patterns/ or physician's practice patterns/
8. physicians.mp.
9. allied health personnel/ or community health workers/ or licensed practical nurses/ or pharmacists' aides/ or physician assistants/
10. allied health professionals.mp.
11. doctors.mp.
12. specialists.mp.
13. medical practitioners.mp.
14. health personnel/ or exp dental staff/ or exp dentists/ or exp medical staff/ or nurses/ or nurse clinicians/ or nurse midwives/ or nurse practitioners/ or family nurse practitioners/ or nurses, community health/ or nurses, public health/ or exp nursing staff/ or personnel, hospital/ or dental staff, hospital/ or exp medical staff, hospital/ or nursing staff, hospital/ or pharmacists/
15. health personnel.mp.
16. dentist.mp.
17. exp Dental Auxiliaries/
18. dental hygienists.mp.
19. Dental Care/
20. dental setting.mp.
21. health services/ or community health services/ or community health nursing/ or exp maternal health services/ or exp dental health services/
22. oral health therapists.mp.
23. Pharmacists/
24. pharmacists.mp.

25. nursing/ or evidence-based nursing/ or maternal-child nursing/ or midwifery/ or obstetric nursing/
26. exp Role/
27. midw*.mp.
28. Gynecology/
29. gynecology.mp.
30. Obstetrics/ or obstetrics.mp.
31. maternity care providers.mp.
32. clinicians.mp.
33. exp General Practice/
34. nurse practitioners.mp.
35. nurse*.mp.
36. health care provider.mp.
37. obstetrician.mp.
38. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 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
39. Pregnancy/
40. Pregnancy Outcome/
41. peripartum period/ or exp postpartum period/ or exp pregnancy trimesters/
42. pregnancy.mp.
43. Pregnant Women/
44. pregnant.mp.
45. Maternal Behavior/
46. Maternal Exposure/
47. maternal.mp.
48. Mothers/
49. antenatal*.mp.
50. exp perinatal care/ or preconception care/ or prenatal care/
51. perinatal.mp.
52. perinatal care.mp.
53. prenatal.mp.
54. prenatal care.mp.
55. pre conception care.mp.
56. postpartum.mp.
57. Perinatology/
58. perinatology.mp.
59. postnatal.mp.

60. postnatal care.mp.
61. puerperium.mp.
62. peripartum period.mp.
63. postpartum period.mp.
64. 39 or 40 or 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 or 60 or 61 or 62 or 63
65. Tobacco/
66. exp tobacco products/ or "tobacco use cessation products"/
67. exp "Tobacco Use"/
68. "Tobacco Use Disorder"/
69. exp "Tobacco Use Cessation"/
70. tobacco.mp.
71. smoking.mp.
72. Nicotine/
73. smoking cessation.mp.
74. nicotine.mp.
75. tobacco dependence.mp.
76. nicotine dependence.mp.
77. "maternal tobacco smoking".mp.
78. smoking treatment.mp.
79. 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
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81. intervention studies.mp.
82. case-control studies/ or cohort studies/ or follow-up studies/ or longitudinal studies/ or prospective studies/ or controlled before-after studies/ or interrupted time series analysis/
83. prospective studies.mp.
84. experiment studies.mp.
85. epidemiologic research design/ or control groups/ or cross-over studies/ or double-blind method/ or random allocation/ or single-blind method/
86. double blind.mp.
87. single blind.mp.
88. triple blind.mp.
89. nonrandomized.mp.
90. nonrandomised.mp.
91. intervention.mp.
92. trial.mp.

93. program.mp.
94. evaluation studies as topic/ or program evaluation/
95. program evaluation.mp.
96. programme.mp.
97. randomized controlled trial.mp.
98. clinical trial.mp.
99. random allocation.mp.
100. controlled clinical trial.mp.
101. interrupted time series studies.mp.
102. 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101
103. 38 and 64 and 79 and 102

Supplemental File 2

Characteristics of Included Studies (n=16)

Author Year Country	Study design for intervention on HP	Population Setting Sample	Intervention	Outcome measures	Results
Secker-Walker, R. H.[30], 1992, USA	Pre-post	**Population:** Obstetric and Family Medicine medical residents, n= 35, 71.4% female, no data on age **Setting:** Community based prenatal care clinic	**Description:** Training included a small group 1 hour workshop with videotape demonstration and roleplay with corrective feedback; an additional 30 minute refresher was provided a few days prior to starting work in the clinic with roleplay and feedback; a prompt sheet was provided with instructions on actions to perform with pregnant women according to their trial group (intervention versus control). **Main focus of study intervention:** Women, with a system and health providers specific components. **Main focus on timing:** pregnancy **Theoretical background:** none mentioned	1. Rating of quality of smoking cessation care according to a predefined 7 point score, 2. time spent delivering smoking cessation care Both assessed through video recording with a simulated patient pre and immediately post training	1. Score pre training 2.15 ±0.88 post training 6.05 ±0.69 2. Time spend pre 3.14 ±1.21 min, post 3.09 ±0.82 min
Hajek, P.[39], 2001, UK	RCT	**Population:** Midwifes, n=178, average age 37, no data on sex Women recruited – 1121, Control 475 (440 smokers, 135 ex-smokers) Intervention 444 (431 smokers, 114 ex-smokers); **Setting:** Mixed – Hospital and Community based clinics	**Description:** **Intervention group:** 2 hour training **Control Group:** 1 hour on study procedures. Continue with usual care. **Main focus of study intervention:** Women, with a health providers specific component. **Main focus on timing:** pregnancy **Theoretical background:** none mentioned	1. Women's recall of interventions given by midwifes immediately after birth (6 months post intervention): ASK "discussed smoking"? Yes/No ADVISE "advised to set a date and stop abruptly" Yes/No ASSIST "advised on how to avoid relapsing"; "discussed coping with difficult situations" Yes/No RESOURCES "given a booklet to read" Yes/No	ASK: Intervention 99% Control 98.4% ADVISE: Intervention 55% Control 13% ASSIST: 1. Avoiding relapse Intervention 36.7% Control 10.4% 2. Coping with difficult situations Intervention 42.1% Control 14.3% RESOURCES: Intervention 90.4% Control 43.5%

				2. Continuous biochemically validated smoking abstinence rates immediately after birth and 6 months post-partum	RISK: Intervention 94.8% Control 80.2% QUIT RATES at birth Intervention 6% Control 7% 6 months postpartum Intervention 3% Control 3%
Cooke M[31], 2001a, Australia Note: Cooke M (2001a), Cooke M (2001b), and Campbell E all describe the same intervention study	Pre-post	**Population:** Clinical staff (doctors and midwifes), Pre n= 204, Post n=182. No data on age or sex. **Setting:** Antenatal clinics in public hospitals	**Description:** Training (either through a video or face to face) in a specific smoking cessation program, plus provision of educational materials (flipchart, quit kit, stickers and patient video) **Main focus of study intervention:** Women, with a health providers' specific component. **Main focus on timing:** pregnancy **Theoretical background:** Development of the Intensive dissemination intervention was guided by the Rogers theory of "Diffusion of Innovations" and by other frameworks proposed in preventive medicine.	Survey pre and post 18 months, reporting on use of different smoking cessation care components, including total # care components used out of maximum 13. ASK "use a smoking label" Yes/No ADVISE "give advice to quit" Yes/No ASSIST "counsel on quit methods" Yes/No RESOURCES "give self-help quit booklet" Yes/No FOLLOW UP "follow-up discussion" Yes/No REFERRAL "referral" Yes/No RISK " education about risk" Yes/No	ASK Pre 12.2% Post 27.5% ADVISE Pre 41.2% Post 39.5% ASSIST Pre 57.3% Post 79.7% RESOURCES Pre 29.9% Post 56% FOLLOW UP Pre 54.9% Post 69.8% REFER Pre 42.1% Post 55.5% RISK Pre 80% Post 92.3% Smoking cessation care total score Pre 4.9 ±3.1 Post 7.7 ±2.8
Cooke M[40], 2001b, Australia	RCT	**Population:** Clinical staff (doctors and midwifes), Control n=101 Intervention n=86 no data on age or sex **Setting:** Antenatal clinics in public hospitals	**Description:** Training in a specific smoking cessation program, plus provision of educational materials (flipchart, quit kit, stickers and patient video) **Intervention group:** Intensive dissemination – face to face training (average 1 hour), with additional support as needed, plus provision of educational material.	Survey of health providers, 18 months post intervention, reporting on proportions using different smoking cessation care components, including total # of care components used out of maximum 13 (Mean, SD)	ASK: Intervention 95% Control 97% ADVISE Intervention 46% Control 34% ASSIST 1. Methods to quit Intervention 86% Control 74%

			Control Group: Simple dissemination of program through mail with a training video (20 minutes), including provision of educational material. **Main focus of study intervention:** Women, with a health providers' specific component. **Main focus on timing:** pregnancy **Theoretical background:** Development of the Intensive dissemination intervention was guided by the Rogers theory of "Diffusion of Innovations" and by other frameworks proposed in preventive medicine.	ASK "assessment of smoking" Yes/No ADVISE "advice to quit" Yes/No ASSIST "methods to quit"; "negotiate quit data"; "encourage support person to assist" Yes/No FOLLOWUP "follow-up discussion" Yes/No REFER "referral" Yes/No RESOURCES "pamphlet on smoking effects" Yes/No RISK "education about risk" Yes/No	2. Negotiate quit data Intervention 47% Control 23% 3. Encourage support Intervention 62% Control 47% FOLLOW UP Intervention 70% Control 68% REFER Intervention 53% Control 55% RESOURCES Intervention 75% Control 78% RISK Intervention 93% Control 92% Smoking cessation care total score: Intervention 7.78 ±0.9 Control 7.16 ±1.3
Campbell, E.[41], 2006, Australia	RCT	**Population:** Women attending second or subsequent antenatal visit Control pre n=2374, post n=2302 Intervention pre n=3475, post n=2843 no data on age or sex **Setting:** Antenatal clinics in public hospitals	**Description:** Training in a specific smoking cessation program, plus provision of educational materials (flipchart, quit kit, stickers and patient video) **Intervention group:** Intensive dissemination – face to face training (average 1 hour), with additional support as needed, plus provision of educational material. **Control Group:** Simple dissemination of program through mail with a training video (20 minutes), including provision of educational material. **Main focus of study intervention:** Women, with a health providers specific component. **Main focus on timing:** pregnancy **Theoretical background:** Development of the Intensive dissemination intervention was guided by Rogers theory of "Diffusion of Innovations" and by other frameworks proposed in preventive medicine.	Survey with women's 18 months post intervention measuring: 1. recall of smoking cessation care components being done as part of antenatal visit ASK "discussed smoking at more than one visit" Yes/No ADVISE "advised to stop smoking completely" Yes/No ASSIST "staff discussed methods could use to quit"; "discussed a definite quit date" Yes/No RESOURCES "received written material about smoking" Yes/No	1. ASK: Intervention 92.9% Control 91.6% ADVISE Intervention 41.1% Control 38.7% ASSIST 1. Methods to quit Intervention 30% Control 24.8% 2. Negotiate quit data Intervention 5.8% Control 4.3% RESOURCES Intervention 33.8% Control 32.2% RISK Intervention 64.5% Control 63.8%

				RISK "Staff talked about risk of smoking in pregnancy" Yes/No 2. Proportion quitting since first visit biochemically validated 3. Proportion smoking biochemically validated	2. Quit rates Intervention 10.5% Control 6.4% 3. Smoking prevalence Intervention 24.8% Control 28.2%
Lattts, L.M.[32], 2002, USA	Pre-post	**Population** Clinical staff (Obstetricians, Family physicians, nurses, midwives). Pre n=66 Post n=51 Chart review Pre n=224, Post n=182 Women recruited Pre n=505, Post n=250 No data on age or sex **Setting** Community based clinics that provide antenatal care	**Description:** Training on site to a dedicated staff member, with 1-2 follow up phone calls and 1 follow up site visit. No mention how long the training was. Also resources (identification smoking status stickers, quitting kit for the women, and an incentive gift for women mid pregnancy and postpartum). In addition reimbursement for counselling. **Main focus of study intervention:** System with a component on health providers **Main focus on timing:** pregnancy **Theoretical background:** none mentioned	Measurement pre and up to 8 months post intervention 1. Chart review – documentation of smoking status, advise to quit ASK "smoking status identified" Yes/No ADVISE "documentation advice to quit" Yes/No 2. Women's survey – recall being asked, being given advice to quit, and counselling. ASK "recalling being asked" Yes/No ADVISE "advised to quit" Yes/No ASSIST "received smoking cessation counselling" Yes/No REFER "referred to smoking-cessation program" Yes/No	ASK 1. Chart Review Pre 90% Post 96% 2. Women's recall Pre 97% Post 90% ADVICE 1. Chart Review Pre 62% Post 24% 2. Women's recall Pre 86% Post 65% ASSIST (counselling) Women's recall Pre 11% Post 3% REFER Women's recall Pre 0% Post 0%
Valanis, B.[33], 2003, USA	Pre-post	**Population** Clinical staff (physicians, midwives, nurse practitioners, registered nurses and clinics assistants) Obstetric clinicians Pre n=32, Post n=31 Paediatric clinicians Pre n=36 Post n=22	**Intervention** 1.5-to 4-hour training sessions specific on brief motivational interviewing techniques and smoking cessation techniques according to the stage of change model. Provision of educational material including videos to show patients, prompts in medical records, "Champion" teams, consisting of a provider, the lead nurse, and a clinic assistant, were formed in each department to model the intervention, persuade their peers to	Survey assessing percentage of performing smoking cessation care components with over 75% of smoking patients. Measurement pre and 2 years post implementation:	ASK Obstetric Pre 75% Post 90% Paediatric Pre 35% Post 67% ADVISE Obstetric Pre 0% Post 17% Paediatric

		Setting Community based perinatal obstetric and postnatal paediatric clinics. Also in inpatient clinical settings.	try it, and find ways to adapt it to their clinical setting, continuous implementation support with feedback and tailoring to specific clinic needs. **Main focus of study intervention:** System with a component on health providers **Main focus on timing:** pregnancy and post-natal **Theoretical background:** None mentioned	ASK "with more than 75% of smoking patients asks patients whether they smoke" Yes/No ADVISE "with more than 75% of smoking patients advises patients to set a quit date" Yes/No RESOURCES "gives patients a booklet on how to stop smoking" Yes/No	Pre 0% Post 24% RESOURCES Obstetric Pre 12% Post 20% Paediatric Pre 0% Post 5%
Bakker, M.J.[42], 2003, The Netherlands	RCT Intervention versus Control	**Population** Midwifes Intervention n=37, Control n=32 Mean age Intervention 38.4 ±9.39 Control 36.7 ±8.16 Women recruited aggregated to the midwife level Control n=303 (51 midwifes) Intervention n=253 (44 midwifes) **Setting** Community based private antenatal practices	**Intervention** Provision of educational materials for midwifes (treatment manual and card) and for their patients (video, self-help guide, post-delivery booklet, and partner booklet), and an option to receive 3 hour training. **Main focus of study intervention:** Health providers **Main focus on timing:** pregnancy **Theoretical background:** None mentioned	**1.** Survey of health providers immediately and up to 1 month post intervention assessing performance of smoking cessation care components Likert scale from 1-5 (1 never, 5 always)- Mean (SD) "Did you discuss with your client" ASK "smoking behavior?" ADVISE ":the advice to quit smoking?" ASSIST "barriers to quitting?; quit date?" FOLLOWUP "aftercare"? RISK "consequences of smoking during pregnancy 2. Women's report of receiving smoking cessation care components 6 weeks post intervention on a scale from 0-1 (0-no 1 yes), aggregated to the midwife level "Did your midwife discuss" Yes/No ASK "smoking at intake" ADVISE "advice to quit"	ASK 1. Midwife survey Intervention 4.91 ±0.37 Control 5 2. Women's report Intervention 0.91 ±0.18 Control 0.72 ±0.29 ADVISE 1. Midwife survey Intervention 4.6 ±0.77 Control 4.19 ±1.03 2. Women's report Intervention 0.85 ±0.25 Control 0.64 ±0.36 ASSIST Discuss barriers to quitting 1. Midwife survey Intervention 3.49 ±1.12 Control 2.91 ±1.15 2. Women's report Intervention 0.38 ±0.29 Control 0.11 ±0.18 Set a quit data 1. Midwife survey Intervention 3.63 ±1.19 Control 1.63 ±1.1 2. Women's report Intervention 0.33 ±0.34 Control 0.03 ±0.16

				ASSIST "discuss barriers; Set a quit date"	FOLLOW UP Midwife survey Intervention 3.97 ±0.89 Control 2.84 ±0.99 RISK Midwife survey Intervention 4.31 ±0.99 Control 4.5 ±0.95
Yusem, S. H.[34], 2004, USA	Pre-Post	**Population** Public Health Nurses conducting home visits as part of a maternity case management with high risk pregnant women n=10 (full data set for both pre and post)) No data on age or sex **Setting** Community based	**Intervention:** Training in the 5A's model and motivational interviewing, with provision of educational materials (brochures, posters). Also incorporating system changes such as documentation of smoking status, a specific form to collect smoking data and act as a reminder, and a fax referral system to the quit line **Main focus of study intervention:** Health providers with a system component **Main focus on timing:** pregnancy **Theoretical background:** Rogers theory "Diffusion of Innovations"	Survey immediately before and at 12 and 24 months post intervention assessing performance of smoking cessation care components Likert scale from 1-5 (1 never, 5 always) Proportions representing those answering always. "when a pregnant woman enters case management" ASK "how often is she asked about her smoking status?" ADVISE "how often is she advised to quit smoking?" ASSESS "how often is her willingness to quit smoking in the next 30 days assessed?" ASSIST how often is a problem-solving approach used to counsel her?" FOLLOWUP "how often does a pregnant smoker who is willing to quit have a follow up contact arranged?"	ASK Pre 70% Post 12 months 90% Post 24 months 90% ADVISE Pre 80% Post 12 months 70% Post 24 months 70% ASSESS motivation to quit Pre 0% Post 12 months 40% Post 24 months 30% ASSIST Pre 10% Post 12 months 50% Post 24 months 10% FOLLOWUP Pre 10% Post 12 months 50% Post 24 months 30%
Carlson S.J.[35], 2005, USA	Pre-Post	**Population** HP working in 16 different practices – 5 family physician clinics, 3 Obstetrics, 5 residency and 3 tribal clinics. A mix of family physicians, Obstetricians, physician assistant, nurses and others. No data on age or sex	**Intervention:** Each site was assigned a "Practice Enhancement Assistant" that provided training, resources and performed the audit and feedback. In each site training to all health providers was provided, with provision of material. Furthermore, clinic meetings were done every 3 months to aid	Chart review performed at baseline and during one year of implementation (variable follow up between clinics from 3-9 months) – proportions of chart with documentation of	ASK Pre 33.9% Post 79.4% ADVISE Pre (n=106) 13.2%

		Audit of patient charts Pre n=522 Post n=379 **Setting** Community based clinics	system implementation tailored to the site needs. At each meeting – findings from chart reviews (audit) were presented as feedback. **Main focus of study intervention:** System with an health providers component **Main focus on timing:** pregnancy **Theoretical background:** Implementation based on the chronic care model. No theoretical background.	smoking cessation care components Except ASK all other components audited only from charts of current and/or former smokers ASK documentation of smoking status ADVISE documentation of advice to quit ASSESS documentation of willingness to quit ASSIST documentation of at least one strategy such as setting a quit data, identifying triggers, providing resources	Post (n=117) 76.9% ASSESS motivation to quit Pre (n=47) 14.89% Post ((n=78) 87.18% ASSIST Pre (n=47) 6.38% Post ((n=78) 62.8%
Flenady, V.[36], 2008, Australia	Pre-Post	**Population** Women attending the anta-natal clinic either on their 36 week visit or prior to discharge after birth, who are either smokers or recent quitters (quit in the past 12 months) Pre n=149 Post n=163 **Setting** Hospital based	**Intervention:** Development of clinical guidelines and implementing them through a process that included: 1. Project team staff from the antenatal clinic - clinical champions. 2. Four hour training session including a video showing examples of brief intervention and motivational interviewing and role play. 3. Adapting the computerized database to include a multiple-choice question on smoking status and partner smoking status 4. Insert inside record to remind and record smoking status 5. Chart audit and feedback to clinicians. **Main focus of study intervention:** System with an health providers component **Main focus on timing:** pregnancy **Theoretical background:** Implementation based on evidence summary by the National Institute of Clinical Studies. No theoretical background.	Survey, pre and up to 2 months post implementation, with women's recall of smoking cessation care interventions being done as part of antenatal visits during pregnancy ADVISE "you were advised to quit smoking?" Yes/No ASSESS "you were asked if you were interested in quitting smoking?" Yes/No ASSIST "you were offered support and advice about smoking in pregnancy?; you were encouraged to set a quit date?" Yes/No REFER "you were offered a phone number or referral to the Quitline?" Yes/No RESOURCES "you were given brochures about smoking in pregnancy?" Yes/No RISK "you were advised on the health risks of smoking"?	ADVISE Pre 50% Post 70% ASSESS motivation to quit Pre 40% Post 80% ASSIST 1. Offer support Pre 40% Post 65% 2. Set a quit date Pre 5% Post 30% REFER Pre 14% Post 67% RESOURCES Pre 35% Post 76% RISK

					Pre 55% Post 70%
Moss D.R.[37], 2009, USA	Pre-Post	**Population** Clinical and non-clinical staff (including doctors, nurses, nurse practitioner) Pregnant women recruited Pre n=122 Post n=129 **Setting** Hospital based obstetric outpatient clinic	**Intervention:** 2 hour training, 1 didactic, 1 interactive with practice of counselling skills through role playing, booster session 30-45 min twice a year, annual messages at holidays, smoking-as-a-vital-sign chart prompt to remind providers to ask about smoking, availability of patient/parent cessation handouts, on-site and telephonic referral sources, and regular performance feedback that included informal feedback - periodic e-mails reporting smoking rates among their patients, interim provider "Ask" rates, and the status of individual patients they referred, Structured feedback with global clinic performance rates once a year **Main focus of study intervention:** Health providers with a system component **Main focus on timing:** pregnancy **Theoretical background:** No theoretical background.	Survey of pregnant patients at exit visit from clinic, 12 months post intervention, assessing recall of being provided smoking cessation care components	ASK Pre 59% Post 65.1% ADVISE Pre 72% Post 85% ASSIST Pre 27.78% Post 61.76%
Bowden J.A.[38], 2010, Australia	Pre-Post	**Population** Clinical staff (including doctors and midwifes) Pre n=117 Post n=62 No data on age or sex **Setting** Hospital based	**Intervention:** 1 hour training, either in a group session or one on one. Provision of educational material including a designated form that was placed inside the medical records and served as a reminder. Also posters and postcards to remind staff. **Main focus of study intervention:** Health providers **Main focus on timing:** pregnancy **Theoretical background:** No theoretical background.	Survey of staff pre and post after 12 months, regarding the provision of smoking cessation care components Likert scale of 1-4 (1 never, 4 always) (Mean, SD) "Do you" ASK "ask about smoking" ASSESS "assess readiness to quit" ASSIST and FOLLOW UP "Assist those motivated to quit/arrange follow-up" RISK "advise about health effects of smoking"	ASK Pre 3.35 ±0.9 Post 3.54 ±0.8 ASSESS motivation to quit Pre 2.86 ± 0.9 Post 3.42 ± 0.9 ASSIST and FOLLOWUP Pre 2.71 ± 1.1 Post 3.39 ± 0.9 RISK Pre 3.29 ± 0.8 Post 3.70 ± 0.7

Tsoh, J.Y.[43], 2010, USA	RCT	**Population** Pregnant women who smoke attending their regular ante-natal visit Control n=19 Intervention n=23 Mean (SD) age Control 26.8 (5.3) Intervention 27.5 (6.7) **Setting** Community based prenatal clinics	**Intervention:** Providing a cueing sheet for health providers, which offered a summary of the patient's risk profile and suggested risk-reduction counselling statements. Providers received a brief orientation on how to use this. Women also received tailored specific messages through a multimedia interactive intervention delivered on a laptop computer. **Main focus of study intervention:** System with a component on health providers **Main focus on timing:** pregnancy **Theoretical background:** No theoretical background.	Survey of women pre and 1-2 months post intervention: 1. Receipt of advice from health providers in at least one visit Yes/No 2. Self-reported 30-day smoking abstinence	1. ADVISE Control 79% Intervention 96.5% 2. 30-day smoking abstinence Control 10.5% Intervention 26.1%
Chertok I.R.A.[24], 2014, USA	Pre-Post	**Population** Health providers and social care providers, including physicians (7.0%), nursing staff (32.0%), mid-level providers (14.1%), social workers (4.7%) , dieticians (3.1%), smoking cessation counsellors (2.3%), health counsellors (3.9%), community service providers such as resource coordinators, and pastors (32.8%). Pre n=120 Post n=76 Mean age 43±11.7; 96.2% female **Setting** Community based	**Intervention:** In person 1.5 hour training session - flexible meeting time including lunch and evening, included lectures, handouts, discussion of case-studies using an interdisciplinary team approach, and referral of participants to the online website with information, resources, and links (a presentation and a physician toolkit) **Main focus of study intervention:** Health providers **Main focus on timing:** pregnancy **Theoretical background:** No theoretical background.	Survey of staff pre and post 3 months regarding the provision of 25 SCC components Likert scale of 1-4 (not at all, less than half the time, more than half the time, and all of the time) (Median) ASK "I assess pregnant clients smoking" ADVISE "I advise pregnant smokers to quit" ASSESS "I ask pregnant smokers if they are willing to quit or cut down" ASSIST "if pregnant smokers are willing to quit, I provide support and assistance"; ":I advise pregnant women to set a quit date" NRT "I recommend use of nicotine gum unless contraindicated" FOLLOW UP "I follow up with pregnant smokers about smoking cessation at future visits"	ASK Pre 3 Post 1 z -0.361 ADVISE Pre 4 Post 4 z -0.573 ASSESS motivation to quit Pre 3 Post 4 z-0.918 ASSIST 1. General Pre 3 Post 4 z -1.508 2. Set a quit data Pre 1 Post 3 z -1.424 NRT Pre 1

				REFER "I provide the number for the toll-free Quitline	Post 1 z -0.604 FOLLOW UP Pre 1 Post 3 z -1.922 REFER Pre 3 Post 4 z -1.123
Althabe F.[44], 2016, Argentina and Uruguay	cRCT	**Population:** Clinical staff (including physicians, midwifes and nurses) working in ante-natal clinics. Pregnant women attending these clinics were also recruited. <u>Health Providers</u> Intervention Pre n=192 Post n=136 Control Pre n=166 Post n=136 Mean age ±SD; %Female ±SD Intervention Pre 44±3.1; 88.3%±7.4% Post 44.2±4; 85%±9% Control Pre 42.8±2.5; 74.9%±12.7% Post 40.7±5; 85.2%±9.8% <u>Pregnant women</u> Intervention Pre n=1562 Post n=1793 Control Pre n=1771 Post n=1732 **Setting** Hospital and Community based prenatal clinics	**Intervention:** 2 day training workshop, including roleplaying, devising a plan of implementation for their clinic, provision of printed pregnancy-specific self-help materials, posters and reminders; also visits and observation by research staff but no feedback given on performance **Main focus of study intervention:** Health Providers **Main focus on timing:** pregnancy **Theoretical background:** Diffusion of Innovation Theory	Measurement pre and post in both Intervention and Control arms: 1. Survey of women during visit at pre and 18-24 months post intervention (48 hours after birth) – recall of SCC components received ASK "ask about tobacco use (at more than one visit)" ADVISE "advice about tobacco use (at more than one visit)" ASSESS "assess late quitters and continuous smokers are ready to quit (at more than one visit)" ASSIST "assist late quitters and continuous smokers in the quitting process (at more than one visit)" FOLLOW UP "arrange follow-up with late quitters and smokers (at more than one visit" 2. Survey of health providers pre and 18	1. Women ASK Intervention Pre 43.1% Post 73.2% Control Pre 43.5% Post 48.9% ADVISE Intervention Pre 24.9% Post 55.4% Control Pre 22.6% Post 28.6% ASSESS motivation to quit Intervention Pre 8.3% Post 28.9% Control Pre 9.6% Post 14.7% ASSIST Intervention Pre 6.2% Post 31.7% Control

				months post regarding practices Likert scale of 1-4, % represent median rate ASK "ask always or frequently to their patients if they smoke at any prenatal visit" ADVISE "advise always or frequently to pregnant smokers to quit smoking" REFER "provide always or frequently referrals to other tobacco cessation services to pregnant smokers" RISK "discuss smoking and its harms always or frequently to patients who smoke during pregnancy" EDUCATION "provide always or frequently self-help materials to help pregnant smokers quit smoking" 3. Proportion quit during pregnancy biochemically verified	Pre 6.3% Post 12.7% FOLLOW UP Intervention Pre 0% Post 2.7% Control Pre 0.7% Post 0% ALL 5A Intervention Pre14% Post 33.6% Control Pre 10.8% Post 17% 2. HP ASK Intervention Pre 98.5% Post 100% Control Pre 90.2% Post 95% ADVISE Intervention Pre 98.5% Post 97.2% Control Pre 100% Post 97.6% REFER Intervention Pre 10.4% Post 37.5% Control

					Pre 1.9% Post 2.3% RISK Intervention Pre 89.4% Post 100% Control Pre 83.7% Post 88.6% EDUCATION Intervention Pre 10.4% Post 62.4% Control Pre 2% Post 10.6% 3. QUIT RATES Intervention 10.9% Control 8.1%

Supplemental File 3

Risk of Bias and Methodological Quality of Included Studies

Study	Cochrane tool for risk of bias assessment						Hawker assessment of quality									
	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (Performance bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Abstract and title	Intro and aims	Method and data	Sampling	Data analysis	Ethics and bias	Results	Transferability	Implications and usefulness	Total Score
Secker-Walker, R. H.[30], 1992	Not relevant						Fair	Fair	Good	Fair	Fair	Fair	Fair	Fair	Fair	28
Hajek, P.[39], 2001	Low	Low	High	Unclear	Unclear	Unclear	Fair	Fair	Fair	Good	Fair	Fair	Fair	Good	Good	30
Cooke M.[31], 2001 (a)	Not relevant						Fair	Fair	Fair	Fair	Poor	Fair	Fair	Fair	Fair	26
Cooke M.[40], 2001 (b)	Unclear	Unclear	Unclear	Unclear	High	Unclear	Good	Good	Fair	Fair	Fair	Fair	Fair	Fair	Fair	29
Campbell, E.[41], 2006	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Good	Fair	Fair	Poor	Good	Fair	Good	Poor	Good	29

Latts, LM.[32], 2002	Not relevant						Good	Poor	Poor	Poor	Fair	Very Poor	Poor	Poor	Fair	21
Valanis, B[33], 2003	Not relevant						Fair	Fair	Poor	Poor	Poor	Poor	Fair	Poor	Fair	22
Bakker, MJ[42], 2003	Low	High	Unclear	Unclear	Low	Unclear	Fair	Fair	Fair	Good	Fair	Poor	Good	Fair	Good	29
Yusem, S.H.[34], 2004	Not Relevant						Good	Fair	Fair	Fair	Fair	Very poor	Good	Fair	Fair	27
Carlson S.J.[35], 2005	Not Relevant						Very poor	Poor	Poor	Poor	Poor	Very poor	Fair	Poor	Poor	17
Flenady, V.[36], 2008	Not Relevant						Fair	Fair	Fair	Fair	Poor	Good	Fair	Fair	Good	28
Moss D.R.[37], 2009	Not Relevant						Good	Fair	Fair	Fair	Good	Fair	Good	Fair	Fair	30
Bowden J.A.[38], 2010	Not relevant						Fair	Fair	Fair	Very poor	Poor	Fair	Fair	Poor	Good	24
Tsoh, J.Y.[43], 2010	Low	Low	High	Unclear	Low	Unclear	Good	Fair	Fair	Good	Good	Fair	Fair	Fair	Good	31
Chertok, I.R.A.[24], 2014	Not relevant						Poor	Fair	Fair	Fair	Poor	Fair	Fair	Fair	Fair	25
Althabe F.[44], 2016	Low	High	High	High	Low	Low	Good	Fair	Fair	Good	Good	Fair	Good	Good	Good	33

Supplemental File 4

Narrative Synthesis and Meta-Analysis Results of Selected Behaviour Change Techniques and Other Secondary Outcomes

'NRT'

None of the interventions mentioned any components that were designed specifically to address NRT prescribing rates during pregnancy. Nor was there any mention of specific training or skill acquisition contents relating directly to NRT use in pregnancy. Only one study (Chertok et al)[24] measured changes in NRT prescribing rates, showing no difference in pre and post median frequency (4 point Likert scale, pre=1, post=1, z=-0.6, p=0.54).

'Quit date'

Five studies provided data on changes to setting a quit data with pregnant patients.[24,36,40-42] All the studies show a low pre or control arm use of this behaviour change technique (proportions ranging from 4% to 23%, mean of 1.6 or a median of 1 on a Likert scale of 1-4), improving with the intervention, except Campbell et al[41] with no change. Proportions of using this technique, despite improving, were still low following the intervention, ranging from 30% to 47%. Three studies were included in the pooled estimates,[36,40,42] showing a large significant intervention effect, with high heterogeneity (Cohen's d=1.12, 95%CI 0.45-1.79; p=0.001, I^2=83.7%).

'Resources'

Eight studies (6 interventions) include data on provision of resources,[24,31,33,36,39-41,44] six of these showed improvement following the intervention.[24,31,33,36,39,44] Cook M et al (b)[40] and Campbell et al[41], both tested changes when using different dissemination methods to the same intervention, not showing any differences. The pooled analysis from five studies[31,33,36,39,44] found a significant large sized pooled estimate of treatment effect with high heterogeneity (Cohen's d=1.0, 95%CI 0.61-1.4; p<0.001, I^2=87%).

'Education' about health risks

Nine studies (7 interventions) included data on the provision of education on the health risks of smoking.[24,31,36,38-42,44] Both Cook M et al (b)[40] and Campbell et al[41], showed no difference between dissemination methods, whereas the overall pre-post intervention showed an improvement (Cooke M et al (a)).[31] Almost all interventions found a

significant improvement, despite rates being high to begin with.[24,31,36,38,39] Six studies[31,36,38,39,42,44] were included in the pooled analysis showing a significant medium treatment effect (Cohen's d=0.52, 95%CI 0.22-0.82; p=0.001, I^2=71.6%).

Smoking reduction

Three studies reported on a reduction of number of cigarettes smoked by the women participants.[32,36,43] Flenady et al[36] reported 37.6% of women were smoking ≥10 cigarettes a day pre intervention, with 24.5% smoking ≥10 cigarettes a day post intervention. Tosh et al[43] found a mean decrease of 3.9 cigarettes a day in the intervention arm, compared to -0.1 in the control. Latts et al[32] reported that the average cigarettes a day was reduced from 13.9±9.2 to 7.4±8.3 post intervention.

Postpartum relapse rates

Two studies described postpartum relapse rates.[36,39] Flenady et al[36] reported that 62% of those quitting reported relapsing 12 months after birth. Hajek et al[39] reported on continuous abstinence until the 6-month post-birth interview, with an expired air CO<10 ppm, finding no difference between the intervention and control arm, both with 3% abstinence rate. Calculating the relapse rate (using point prevalence abstinence rates at birth) this translates to a 72% and a 70% relapse rate in the intervention and control arms respectively.

Supplemental File 5

Meta-Regressions for 'Ask', 'Advise, and 'Assist'

Table 1: Meta-regressions - association between study characteristic and treatment effect (Cohen's d) for performance of "Ask"

Study Characteristic	*Comparison*	*difference d (95%CI)*	*p-value*	*I^2*	*Tau^2*
Treatment effect "Ask"		*0.47 (0.14, 0.8)*	*0.01*	*85.9%*	*0.14*
Year	per 1 year increase	0.01 (-0.08, 0.09)	0.879	86.6%	0.16
Country	Argentina vs Other countries (ref)	0.72 (-0.92, 2.4)	0.342	87.3%	0.14
Study design	Controlled trial vs Pre-Post (ref)	-0.31 (-1.1, 0.48)	0.397	85.2%	0.13
# intervention components	3+ vs 1-2 (ref)	0.25 (-0.45, 0.94)	0.438	85.7%	0.15
Educational outreach	Yes vs No (ref)	0.42 (-0.2, 1.05)	0.159	81.2%	0.11
Reminders	Yes vs No (ref)	-0.13 (-0.82, 0.56)	0.674	80%	0.15
Audit/Feedback	Yes vs No (ref)	0.25 (-0.5, 1.0)	0.474	82.3%	0.14
System changes	Yes vs No (ref)	0.29 (-0.4, 0.95)	0.335	82.5%	0.13
Theoretical background	Yes vs No (ref)	0.62 (0.12, 1.1)	0.022	56.4%	0.05
Interactive component	Yes vs No (ref)	-0.08 (-0.99, 0.84)	0.852	84.5%	0.15
Measurement time point	≥12 months vs <12 months (ref)	-0.08 (-0.78, 0.63)	0.811	79.6%	0.15
Study Quality	Good vs Else (ref)	-0.44 (-1.1, 0.2)	0.136	78.1%	0.1
Outcome			0.155	67%	0.08
	Chart vs HP survey (ref)	0.51 (-0.12, 1.14)	0.095		
	Women vs HP survey (ref)	-0.06 (-0.8, 0.7)	0.867		

Table 2: Meta-regressions - association between study characteristic and treatment effect (Cohen's d) for performance of "Advise"

Study Characteristic	*Comparison*	*difference d (95%CI)*	*p-value*	I^2	Tau^2
Treatment effect "Advise"		*0.46 (-0.06, 0.98)*	*0.077*	*91%*	*0.46*
Year	per 1 year increase	-0.01 (-0.14, 0.12)	0.897	91.9%	0.52
Country	Argentina vs Other countries (ref)	-0.49 (-2.5, 1.5)	0.589	91.8%	0.49
Study design	Controlled trial vs Pre-Post (ref)	0.27 (-0.87, 1.4)	0.601	89.1%	0.51
# intervention components	3+ vs 1-2 (ref)	0.28 (-0.81, 1.37)	0.576	91.8%	0.5
Educational outreach	Yes vs No (ref)	-0.3 (-1.4, 0.81)	0.555	88.9%	0.5
Reminders	Yes vs No (ref)	-0.17 (-1.3, 0.93)	0.733	91.6%	0.51
Audit/Feedback	Yes vs No (ref)	0.61 (-0.49, 1.7)	0.24	91.7%	0.44
System changes	Yes vs No (ref)	0.05 (-1.08, 1.18)	0.923	91.9%	0.53
Theoretical background	Yes vs No (ref)	-0.11 (-1.2, 1.0)	0.824	90.4%	0.53
Interactive component	Yes vs No (ref)	-0.17 (-1.4, 1.04)	0.757	91.6%	0.52
Measurement time point	≥12 months vs <12 months (ref)	-0.5 (-1.6, 0.56)	0.313	84.6%	0.43
Study Quality	Good vs Else (ref)	0.26 (-0.8, 1.4)	0.606	90.5%	0.51
Outcome			0.620	85.8%	0.52
	Chart vs HP survey (ref)	0.38 (-.19, 1.94)	0.595		
	Women vs HP survey (ref)	0.54 (-0.7, 1.04)	0.351		

Table 3: Meta-regressions - association between study characteristic and treatment effect (Cohen's d) for performance of "Assist"

Study Characteristic	*Comparison*	*difference d (95%CI)*	*p-value*	I^2	Tau^2
Treatment effect "Assist"		*0.64 (-0.4, 0.88)*	*<0.001*	*59.2%*	*0.88*
Year	per 1 year increase	0.01 (-0.09, 0.12)	0.765	64.9%	0.19
Country	Argentina vs Other countries (ref)	0.009 (-1.4, 1.4)	0.988	65%	0.19
Study design	Controlled trial vs Pre-Post (ref)	0.009 (-1.4, 1.4)	0.988	65%	0.19
# intervention components	3+ vs 1-2 (ref)	0.47 (-0.6, 1.6)	0.338	63.4%	0.14
Educational outreach	Yes vs No (ref)	0.18 (-1.04, 1.4)	0.73	65%	0.15
Reminders	Yes vs No (ref)	-0.14 (-1.2, 0.9)	0.742	64.8%	0.11
Audit/Feedback	Yes vs No (ref)	0.45 (-0.5, 1.3)	0.268	64.3%	0.13
System changes	Yes vs No (ref)	0.17 (-1, 1.03)	0.969	65.1%	0.16
Theoretical background	Yes vs No (ref)	0.28 (-0.8, 1.3)	0.528	64.9%	0.16
Interactive component	Yes vs No (ref)	0.001 (-1, 1)	0.999	64.9%	0.16
Measurement time point	≥12 months vs <12 months (ref)	-0.13 (-1.2, 0.9)	0.771	65%	0.12
Study Quality	Good vs Poor (ref)	0.001 (-1, 1)	0.999	65%	0.16
Outcome			0.094	25%	0
	Chart vs HP survey (ref)	1.2 (0.08, 2.3)	0.040		
	Women vs HP survey (ref)	0.02 (-0.3, 0.3)	0.856		

Introduction to Paper Six

One of the barriers mentioned in both paper one and in paper three was the lack of adequate resources that are pregnancy specific. Paper three highlights that this barrier is also prominent specifically in regard to NRT prescription, with participating GPs expressing a need for visual resources that can be used to show patients that NRT is safer than continuing smoking, and detailed practical clinical guidelines on the initiation and titration of NRT. Furthermore, GPs working with Aboriginal and Torres Strait Islander pregnant women expressed a need for culturally appropriate visual resources.

The following papers will report the development, protocol and results of a targeted multi-component intervention aimed at improving health providers' management of smoking among Aboriginal and Torres Strait Islander pregnant women: ICAN QUIT in Pregnancy.

The ICAN QUIT in Pregnancy intervention was developed collaboratively with staff and female community members from two ACCHS (Biripi Aboriginal Corporation Medical Centre and Tobwabba Aboriginal medical service in the Hunter New England area of NSW. Phase one of this intervention included developing an educational resource package that would be useful for both health providers and pregnant patients. The development of these resources is justified by the findings in both papers one and three, as mentioned above.

Acknowledging the diversity of Aboriginal and Torres Strait Islander peoples, and to ensure this would be useful and acceptable to other Aboriginal communities, a community-based participatory action research process was used. This process and results, including additional changes that were made to the resources, is detailed in paper six. The educational resource package can be viewed in Appendix 7.

Paper Six:
Assessing and Validating an Educational Resource Package for Health Professionals to Improve Smoking Cessation Care in Aboriginal and Torres Strait Islander Pregnant Women

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Associated appendices

Appendix 7: Educational resource package

Appendix 7.1: Treatment manual

Appendix 7.2: Patient booklet

Appendix 7.3: Flipchart

Appendix 7.4: Mousepad

Appendix 7.5: Poster one

Appendix 7.6: Poster two

Abstract

Australian Aboriginal pregnant women have a high smoking prevalence (45%). Health professionals lack adequate educational resources to manage smoking. Resources need to be tailored to ensure saliency, cultural-sensitivity and account for diversity of Indigenous populations. As part of an intervention to improve health professionals' smoking cessation care in Aboriginal pregnant women, a resource package was developed collaboratively with two Aboriginal Medical Services. The purpose of this study was to assess and validate this resource package. A multi-centred community-based participatory 4-step process (with three Aboriginal Medical Services from three Australian states), included: (1) Scientific review by an expert panel (2) 'Suitability of Materials' scoring by two Aboriginal Health Workers (3) Readability scores (4) Focus groups with health professionals. Content was analysed using six pre-determined themes (attraction, comprehension, self-efficacy, graphics and layout, cultural acceptability, and persuasion), with further inductive analysis for emerging themes. Suitability of Material scoring was adequate or superior. Average readability was grade 6.4 for patient resources (range 5.1–7.2), and 9.8 for health provider resources (range 8.5–10.6). Emergent themes included 'Getting the message right'; 'Engaging with family'; 'Needing visual aids'; and 'Requiring practicality under a tight timeframe'. Results were presented back to a Stakeholder and Consumer Aboriginal Advisory Panel and resources were adjusted accordingly. This process ensured materials used for the intervention were culturally responsive, evidence-based and useful. This novel formative evaluation protocol could be adapted for other Indigenous and culturally diverse interventions. The added value of this time-consuming and costly process is yet to be justified in research, and might impact the potential adaption by other projects.

1. Introduction

Aboriginal and Torres Strait Islander pregnant women (hereafter referred to "Aboriginal" women with acknowledgement of the distinct cultures) have the highest smoking rate during pregnancy in Australia (45%) [1], and are three times more likely to smoke during pregnancy compared to non-Aboriginal pregnant women [2]. Smoking during pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes, including miscarriage, growth restriction, stillbirth and pre-term birth [3].

Lack of support from health professionals is a common barrier to smoking cessation in different vulnerable groups, including the Aboriginal population [4]. Aboriginal women report that they receive inconsistent messages from health professionals during pregnancy [5]. Health professionals also report many challenges to providing smoking cessation care in pregnancy [6,7], including insufficient topic knowledge, low confidence in counselling, shortage of time, and little optimism about the effectiveness of interventions. In a recent national cross-sectional survey of Australian General Practitioners (GPs) and Obstetricians, insufficient resources were reported as one of the main barriers to smoking cessation care in pregnant women [8]. A unique barrier in pregnancy is the lack of a strong evidence base on the safety and efficacy of nicotine replacement therapy (NRT), which might impact clinicians' confidence and skills to prescribe NRT [9]. These challenges were reported from studies conducted among the general population, and are not specific to the Aboriginal population.

Printed self-help materials have been shown to improve smoking cessation rates (RR 1.19, 95% CI 1.04–1.37) [10]. Similarly, printed educational materials intended for health professionals can also have a positive impact on their practice (median absolute risk difference in practice outcomes 0.02, range 0–0.11) [11]. When developing educational resources, many considerations need to be taken into account to ensure resources are actually useful and effective, including readability level, appearance and organization of the data [12].

1.1. Tailoring Educational Resources

Tailoring messages for a specific target population might improve their usefulness and effectiveness [13]. Previous systematic reviews exploring health promotion interventions that were adapted for ethnic minority populations have concluded that currently there is a lack of evidence for effectiveness of tailoring [14,15]. However, both

reviews agree that adapting interventions might increase salience, acceptability and uptake. Furthermore, none of these included studies with Indigenous populations. Research reveals that although generic (intended for the general population) messages impact Indigenous populations, there is a preference for culturally targeted messages [16]. Formative research ensures the development of targeted, culturally appropriate, health messages that work [17,18]. In the past few years, research done specifically with Aboriginal pregnant women has shed light on some of the myths and beliefs about smoking during pregnancy that are a barrier to quitting [19–22]. Additionally, in developing a suitable intervention, the challenge of designing appropriate anti-tobacco messages that account for the diversity of Aboriginal People has been outlined [19]. Conducting a pre-test of messages is associated with increased rigour in developing programs targeted to an Aboriginal population [23]. Daley et al. [24] describe in detail a rigorous assessment process of educational material they developed for a smoking cessation intervention for American Indians. These educational materials were then used as part of a randomized controlled study showing promising results in increasing smoking cessation rates [25].

This study comprised the first phase of the Indigenous Counselling and Nicotine (ICAN) Quit in Pregnancy trial [26]. The ICAN QUIT in Pregnancy intervention aimed to improve health professionals smoking cessation care with Aboriginal pregnant women who smoke and included three one-hour webinar training sessions for health professionals, an educational resource package, and free oral NRT [26]. Phase 1 of the ICAN QUIT in Pregnancy trial focuses on the development and pre-testing of the educational resources.

1.2. Aims

To assess the accuracy, readability, cultural acceptability and perceived usability of a collaboratively developed educational resource package to aid health professionals' smoking cessation care in pregnant Aboriginal women.

2. Materials and Methods

2.1. The Indigenous Counselling and Nicotine (ICAN) Quit in Pregnancy Trial

This intervention is based on the previously published ABCD guidelines (Ask about smoking; Brief advice to quit; Cessation support; Discuss the psychosocial context of smoking) with an expedited offer of NRT [27]. The authors worked collaboratively with two Aboriginal Medical Services [28] to develop this intervention.

A Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP) and a smaller Working Party (Aboriginal and non-Aboriginal staff from the two medical services, and Aboriginal female community members) guided the development of the educational resource package [28]. A whole-of-service approach was intended, to train all of the health professionals including GPs, midwives, Aboriginal Health Workers (AHW), and other allied health professionals. Thus, the educational resource package [29] needed to suit health professionals with different educational needs.

A main focus of the intervention was to address clinician's low confidence and skills to prescribe NRT [9]. The latest 2015 Cochrane review focusing on pharmacological interventions for smoking cessation during pregnancy found that NRT improved cessation rate by 40% (Relative Risk (RR) 1.43, 95% CI 1.03–1.93). However, when restricting the meta-analysis to only placebo controlled studies, a lower, not significant cessation rate of 28% (RR 1.28, 95% CI 0.99–1.66) was found [30]. Nicotine has been implicated in animal studies to affect foetal development; however, human studies have not found any harmful effects [9,30]. Therefore, experts and clinical guidelines recommend the use of NRT for pregnant women who smoke and have been unsuccessful quitting without medication [9].

Design: A multi-centre community based participatory research project.

Sample: Three participating sites, from three different states in Australia–South Australia (SA); New South Wales (NSW); and Queensland (Qld). All sites were Aboriginal Community Controlled Health Services (ACCHS), dedicated to healthcare delivery to Aboriginal communities, and overseen by an Aboriginal Community Board of Directors [31].

Materials to be assessed: The educational resource package [29] included resources intended for the health professionals, the pregnant women (patients), and both (Box 1).

Box 1. The educational resource package.

1. For the Health Professionals
(a) A detailed treatment manual covering the ABCD approach [27], including specific behaviour change techniques recommended for use to support pregnant women to quit smoking [32]; and detail practical guidelines on the use of Nicotine Replacement Therapy (NRT) in pregnancy.
(b) Desktop guide –to be used as a prompt to perform the ABCD, and included an NRT treatment algorithm.
2. For the Pregnant Women (Patients)
Brochures on three specific topics—'Quitting in Pregnancy', 'Triggers', and 'Smoke Free Homes' and also five information sheets on the different NRT products (Patches, Gum, Lozenge, Inhalator, and Oral Spray). To increase engagement and understanding in a population that may have low literacy skills [33], the brochures include short videos embedded into them that could be downloaded using a free App. Topics covered by these videos included: *'how smoke affects the baby when pregnant', 'myths of smoking when pregnant', 'explaining smoking triggers and how to address these'* and *'how to use the different NRT products'.*
3. For Both the Health Professionals and the Pregnant Women
A flipchart to be used by the health professional during the consultation with the pregnant woman. A visual side for the women with minimal text, and the reverse side for the health professional as a more detailed prompt on the topics to cover during the consultation. To increase engagement, the visual side for the women included photographs of Aboriginal women from a range of communities in Northern Territory, Victoria and New South Wales.

2.2. Procedures

The resources were assessed by a four step evaluation process, based on Daley et al. [24].

2.2.1. An Expert Scientific Panel

Eleven experts were invited to participate, with ten agreeing to review the resources. Feedback was provided by eight of these, from different areas of expertise (Tobacco Treatment Specialist specializing in maternity care; Tobacco Treatment Specialist experienced with providing training to physicians and allied health professionals in the area of smoking cessation; a member of the Royal Australia and New Zealand College of Obstetrics and Gynaecology—Indigenous Women's Group; An experienced international researcher in randomized controlled trials with NRT and pregnant women; a member of the Congress of Aboriginal and Torres Strait Islander Nurses and Midwives; a Torres Strait Islander General Practitioner; an appointed representative of the Aboriginal Health and Medical Research Council).

Invited experts received a digital and hardcopy of all the education resources. They were not provided with any structured feedback form, but rather asked via email to review the material and provide comments. Experts were instructed to provide the feedback in any way that they found acceptable–direct comments on the copies provided and/or separately in a word document or email. Any changes and/or comments that were made by the experts, for each separate resource, were coded by one researcher (YBZ) into one of six pre-determined themes—Attraction, Comprehension, Self-Efficacy, Graphics and Layout, Cultural acceptability, and Persuasion [34]. These themes have been previously identified as important when assessing health education material to be used specifically with populations with low literacy [34]. Thereafter, for each theme, a summary of the main recommendations was generated and distributed to all other researchers for feedback.

2.2.2. The Suitability of Materials (SAM) Assessment Method Score

The SAM score is a validated systematic process to objectively evaluate the suitability of health education material [34]. It includes 22 items covering 6 themes (Content; Literacy demand; Graphics; Layout and topography; Learning, stimulation, and motivation; Cultural appropriateness). For each item, a score between 0 (not suitable) to 2 (superior) is given. The total score is then calculated (0–39% not suitable material; 40–69% adequate; 70–100% superior).

The SAM was performed by 1–2 staff members from each participating site on a sample of the patient brochures. In total, four staff members participated—three AHW, and one non-Aboriginal Tobacco action worker. The service selected the staff member to perform the SAM rating. For each brochure, two separate SAM ratings (each from a different site) was performed. Mean scores for each brochure and an overall inter-rater agreement score (Kappa) were calculated.

2.2.3. Readability Testing

The text from all of the educational materials was entered into an online tool (Readable.io). Since the visual side of the Flipchart contained minimal wording, only the health professional side of the Flipchart was used for this analysis. The online tool utilizes five different readability measures (Flesch-Kincaid Grade Level, Gunning Fog Index, Coleman-Liau Index, SMOG Index, and Automated Readability Index). Each readability measure uses a different formula to provide a readability level equivalent to

a typical US school grade that would find it easy to read. An average readability school grade level is then calculated from all five measures. We aimed for an average readability score of grade five for the patient resources (meaning any patient who has finished at least grade five in school would find this easy to read), and grade nine for health professionals' resources (as recommended by the Working Party).

2.2.4. Focus Groups with Health Professionals

Were conducted at each site jointly by a female physician and Tobacco Treatment Specialist (YBZ) and a female Aboriginal research assistant (MB), both currently PhD candidates. MB has previous experience conducting qualitative interviews and focus groups among Aboriginal participants.

In total, three focus groups were conducted, with 7–9 participants in each group, and a total of 24 health professionals, until reaching data saturation, meaning that no new findings or themes were generated. Participants included three GPs, 6 midwives/nurses, 6 AHW; and 9 other allied health workers. Each focus group was approximately one hour in length, and included light refreshments. A semi-structured interview guide was developed across the same six themes used for the expert panel feedback analysis (Attraction, Comprehension, Self-Efficacy, Graphics and Layout, Cultural acceptability, and Persuasion) (Supplementary Materials: Appendix 1). The aim of the focus groups was to receive feedback on the draft version of the resources and suggest changes that would improve them. All of the health professionals treating pregnant women from the service were invited to attend. No information was collected on health professionals that chose not to attend the focus group from these services. Only the participants and researchers were present at the time of the focus group. In the NSW group, the medical director of the service, who also works at the service as a GP, participated.

Focus groups were audio-recorded and professionally transcribed. Transcribed data were coded using Nvivo 11 software. Analysis conducted by one researcher (YBZ) was checked by a second (MB) for the six pre-determined themes. Thematic analysis for emerging themes was conducted by both researchers (YBZ and MB) using a general inductive approach [35]. Coding was discussed until agreement was reached. This enabled researcher triangulation and helped ensure that the meaning of the analysis was the same between the two coders to enhance validity and reliability of the findings, and reduce personal bias.

2.2.5. Ethics

The study was approved by the University of Newcastle Human Research Ethics Committee (HREC) (Reference H-2015-0438); by AH&MRC Ethics Committee (Reference #1140/15); by AHREC Ethics Committee (Reference #04-16-652); and by the Far North Queensland Human Research Ethics Committee (HREC) (Reference #16/QCH/34-1040).

2.2.6. Reimbursement

The medical service/staff performing the SAM scoring received an $80 shopping voucher.

3. Results

3.1 An Expert Scientific Panel

A detailed summary of all the expert panel feedback is provided in Appendix 2 (Supplementary Materials). Overall, all experts agreed that the attraction and cultural acceptability of the resources were high. Some made specific recommendations on sensitive issues, such as ways to negotiate a smoke-free home with Elders; or suggestions for more acceptable and easily understandable wording for Aboriginal women. Minor suggestions were made about the graphic and layout to make the resources more practical and useful (e.g., highlighting certain information, and adding more visual references). Specific words were suggested to simplify the patient resources and additional information to aid self-efficacy and comprehension including electronic cigarettes; harm reduction; depression; family/household smoking; and women's perception on the use of NRT in pregnancy. Additional text was suggested to be consistent with a non-judgmental communication style.

3.2. The Suitability of Materials (SAM) Assessment Method Score

All of the patient brochures were scored as suitable by the staff members. Two brochures received a mean score above 70%, indicating a superior material (Table 1), and the rest of the brochures were perceived as adequate, with their mean score close to the cut point indicating a superior score. A consistent rating for the NRT brochures under 'Layout' was that the material looked "uninviting and discouragingly hard to read". The interrater reliability was found to be poor with Kappa = −0.75 ($p < 0.028$), 95% CI (−0.939, −0.177).

Table 1. Summary of Suitability of Resources (SAM) and Readability scores (before and after changes), and changes that were done to the educational resources package.

Resource	SAM Scores (Mean)	Readability Score-Average Grade Level (Range of Sub-Sections)	Summary of Changes to the Resource Materials	Readability Score after Changes-Average Grade Level
Training manual	Not relevant	10.4 (8–13.4)	Additional information was added as suggested: tabs were added; each section was given a different colour theme and prefaced with a colourful highlighted box summarizing the main points; an electronic version with hyperlinks was also provided	8.9
Flipchart	Not relevant	8.5 (4.7–31.4)	Additional information was added: two pages (from the women's side) were also transformed into A3 posters graphically illustrating the different NRT products, and the differences between using NRT and smoking a cigarette.	8.5
Desk top guide	Not relevant	10.6	Simplified to a three-step process; converted to a mouse pad.	7.1
Patient brochures:				
'Quitting in pregnancy'	86, 40 (63)	7.2	All brochures were aggregated into one A5 booklet; additional information was added as suggested to enable a shared discussion; Information regarding family member support was added; specific wording was simplified; layout regarding the different types of NRT products was improved, and pictures of pregnant women using NRT were added; blank 'quit plans' for the woman to fill out with the health professionals were added.	4.7 (booklet)
'Triggers'	43, 95 (69)	6.4		
'Smoke-free homes'	70, 100 (85)	6.5		
'NRT patch'	73, 43 (58)	6.1		
'NRT gum'	57, 93 (75)	6.6		
'NRT lozenge'	43, 91 (67)	6.3		
'NRT spray'	85, 50 (67.5)	5.1		
'NRT inhaler'	40, 86 (63)	7.1		

3.3. Readability Testing

The average readability score for the patient resources was 6.4 (range 5.1–7.2), and for the health professionals' resources, 9.8 (range 8.5–10.6) (Table 1).

2.3 Focus Groups with Health Professionals

2.3.1. Pre-Determined Themes

Two sets, each with two pre-determined themes, were closely related to one another with the same two themes coded to the same sentences. Therefore, each set was grouped together as one theme (1. Graphic and Layout impacting Attraction; 2. Self-efficacy and Persuasion), forming four distinct themes:

Graphic and Layout impacting Attraction

Overall the health professionals found the resources attractive, especially the pictures used for the flipchart *"The pictures are beautiful, absolutely. . . . They're gorgeous girls. . . no horror stories there. They're real" (SA).*

They suggested the treatment manual was too long and needed to include more visual devices such as graphs, boxes and tables.

> *"Reading a whole manual like this is not going to happen. . . . There's too much writing" (NSW); "I like more tables, graphs, pictures, because I don't have to go double. . . I don't like reading pages long. I'll just look at it and go 'Yeah, too much.'" (QLD).*

The desktop guide was perceived as too large and confusing, and was suggested to be converted to a mouse pad "*our desk is too small (NSW). . . Maybe if it was a mouse pad (Qld)"*. The layout of the NRT treatment algorithm was advised to be simplified, so that actions required by the health provider are described in boxes, and patient assessments in arrows between boxes "*It's not really clear to me how–what the categories are in each box." (NSW).*

Comprehension

Across the three states, health professionals had sound comprehension of the content within the resources, and agreed they were comprehensive *"Content wise it's pretty good" (SA) "The actual information is good" (QLD) "There's good stuff in here" (NSW).*

Self-Efficacy and Persuasion

Health professionals found the resources useful and helpful to engage in the conversation about smoking with the pregnant woman *". . . this little chart thing* (referring to a table describing the risks versus benefits of using NRT during pregnancy) *would be really, really good for the doctor to go through" (SA) ". . . some of my clients, I know what I'm going to address next time I see them, I'll probably go through this more myself" (NSW).*

They had various suggestions to increase the usefulness of the resources, including aggregating all of the brochures into one booklet "*people will nod very nicely and say "thank you very much" but if you go outside, they're in the bin. . . . as a book then she could look at the picture and I could run through this and discuss it with her" (NSW);* and having the videos available for them to show the woman *"I think it'd be more interactive if we had iPad in there also because then you could* (show them the videos*)" (NSW).*

Cultural Acceptability

Health professionals found the resources to be appropriate for the communities they treat, especially the use of photographs of Aboriginal women from diverse communities and backgrounds *"Because it's got different sorts of girls on it. . . " (SA); "see your own representation in the flip chart to relate to. Like 'That could be me" (QLD).*

The Qld focus group remarked on the absence of a Torres Strait Islander photograph *"I don't know if you've got any Torres Strait Islander women in there" (QLD).*

3.4.2. Emergent Themes

Four emergent themes arose from the data: 'Getting the message right'; 'Engaging with family'; 'Needing visual aids'; and 'Requiring practicality under a tight timeframe'.

Getting the Message Right

Health professionals were very cautious about using certain words or phrases. This was conveyed for two reasons: firstly, so not to upset the woman *". . . you can't really say that to a smoking mum. . . . (SA) She could turn around and say 'I smoked with my other kids, so you think there's something wrong with them?'"(Qld)*; and secondly, to make sure that the message was getting across *"if you go through things like increases the risk of stillbirth and cognitive impairment and impaired lung development, that's going to be more of a hitting home than 'small baby'" (SA).*

The NSW focus group focused on "how" to utilize the educational material to guide the conversation. Health professionals wanted resources that they can discuss jointly with the woman, *"I normally go through stuff and, okay, this says most people smoke at different times so what do you think is relevant to you, and you've got a picture to look at but you've also got the prompts" (NSW).*

Needing Visual Aids

Recommendations focused a lot on visual devices that could help both engage the woman in the conversation, but also help "getting the message right".

". . . with the community that we're looking after, it's about the visual" (NSW).

"I'd like these more as like posters around the counselling room even. . . . Because that would generate a conversation with me about all those things anyway." (SA).

Specific suggestions were made for posters that could be hung in consultation rooms. One idea was a poster to explain the different types of NRT products available, and a separate one visually showing the differences between NRT (delivering just nicotine) and smoking a cigarette (delivering thousands of different harmful chemicals in addition to the nicotine).

". . . the pictures of people actually using it (NRT), I think that would be really helpful." (NSW).

"I'd have, like, that big and then with nicotine and then that big with just nicotine because I like to say that to them. . . that's one of the messages I always try and say. . . " (NSW).

Engaging with Family

The importance of family and community within healthcare for Aboriginal people is an area health professionals were particularly aware of. Smoking among other family members was mentioned as a barrier *"the women are trying to quit but they live with a bloke who's still smoking in the same house" (NSW)*; *"That's a support (family) that women are often very concerned about when they try and quit smoking" (SA).*

Health professionals wanted the resources to address this more in depth and provide useful information to guide the discussion *". . . everybody's family and everybody's support network is very, very different, there could probably be a bit more of a focus on 'Okay, this is in specific how we could help you and how your family members could help you. . . " (SA).*

The importance of family and community was also requested to be integrated in the photography used in the resources, moving beyond pictures of only women and babies.

"at least include them so that visually you know that there are other people that would be smoking in the home." (Qld); "why is there not a picture of a father with a child and the baby, the mother and the father and the child?" (NSW).

Requiring Practicality under a Tight Timeframe

When discussing the graphic and layout of the resources, multiple suggestions were made to increase the practicality of the resources. Suggestions included making the resources easy to use and fast to find the exact information you need, i.e., adding tabs, having important key information highlighted in boxes, and offering an online version with hyperlinks in the table of contents.

"We have so many pieces of paper floating around, when you need them, you cannot find them. I need something simple, to the point that's easily done" (NSW); "I'd probably be want to be able to flip to it really quickly. . . tabs would probably be better for me" (SA).

Time was mentioned frequently as a barrier, both from the health professionals' point of view *". . . clinical time is so precious at the moment because of the amount of people you've got to access on that particular time . . . " (NSW),* as well as from the patients' perspective "*most of our pregnant clients have other kids that they didn't leave home . . . their ability to concentrate. . . is limited . . . And the partner's been dragged along and he doesn't necessarily want to be there for a whole lot of stuff or somebody else has been left in the car . . . Time is a challenge" (NSW).*

3.5. Summary of Changes to the Educational Resources Package

Following the above processes, results were summarized and presented to the SCAAP to discuss and agree on the changes that were required. Each medical service also received a community report to distribute to their community members, health professionals, and board for feedback. A summary of the changes that were made is detailed in Table 1. Readability scores improved (meaning they became more readable–i.e., scores were reduced) for all of the educational resources, both for the health professionals–average readability score of grade 8.1 (range 7.1–8.9), and patient booklet with an average readability score of grade 4.7. Unfortunately, due to time constraints, additional photographs with Torres Strait Islander women and/or family members were not feasible. This updated resource package is included as one of the components of the

ICAN QUIT in Pregnancy intervention, which in 2017 was pilot tested in six ACCHS across NSW, SA and QLD [26].

4. Discussion

4.1 Summary of Main Findings

A multi-level evaluation was conducted with an expert panel, a SAM assessment, readability testing, and focus groups with 24 health professionals in three Australian states. Multiple suggestions were made during this evaluation process to improve the usefulness and acceptability of the educational resource package:

- Additional information was required, such as how to deal with a family member who smoked in the house;
- Simplification of words was recommended to increase readability and comprehension;
- Increasing the practicality to allow faster access to information;
- Adding different visual aids to increase engagement and guide the consultation;
- Suggestions were made on how to improve wording to become more culturally responsive for Aboriginal women;
- Recommendations were made on how to facilitate health provider discussions on NRT use during pregnancy, which is a unique barrier for health professionals providing smoking cessation care during pregnancy.

4.2. Comparison with Other Literature

Previous research looking at the readability and suitability of educational resources for various health conditions have found that, in general, many are rated as non-suitable and with too high readability scores [36–40]. Many of these studies utilized readability and/or suitability measures, but without a participatory approach where end-users views on the health education material were assessed. In our study, the focus groups and expert panel provided the largest amount of information and recommendations for change.

A parallel analysis was conducted through focus groups with Aboriginal women on the patient-dedicated resources for this intervention (Bovill et al., unpublished data, 2017). Similar to the health professionals in our study, Aboriginal women were supportive of the cultural acceptability of the resources, suggested one booklet, and

wanted *'more information'* on specific harmful effects of smoking. They also requested that the resources would be *'more engaging'* including real stories of Aboriginal woman who quit smoking during pregnancy. Women also asked for information on non-NRT options to deal with cravings, illustrating that the use of NRT during pregnancy is a unique barrier for both health professionals and pregnant women. As mentioned previously, a similar process has been successfully used in the past for a culturally targeted smoking cessation program for American Indians [24]. Those pre-tested resources were subsequently used for a multi-component intervention in a randomized controlled study. The intervention showed promising results with self-reported 6 month intention to treat point prevalence abstinence rates significantly higher in the intervention group (20.1% compared to 12.0%, $p = 0.029$) [25].

Other smoking cessation interventions with Indigenous people [41] have described using a participatory approach in designing their intervention and resources [42,43], but only one study reported conducting a pre-test on their resources before rolling out the intervention [44]. This might be a contributing factor as to why these interventions did not show a higher smoking cessation rate compared to non-culturally tailored interventions [41,42]. An association has been found with conducting a pre-test and the reporting of cultural challenges by organisations developing tobacco control messages for Aboriginal Australians [45]. Programs not conducting a pre-test may be less aware of the requirements for cultural sensitivity.

The emergent themes from the health professionals' focus groups are consistent with previous research on barriers and facilitators to smoking cessation care during pregnancy [6,7]. Lack of time was mentioned as one of the most important barriers in a recent Australian cross-sectional survey of GPs and Obstetricians [8], and has also been mentioned in other surveys globally [6]. Health professionals report facing multiple high-priority issues that they need to address during a consultation, and therefore require the resources to aid them in a timely manner [7]. Smoking rates across Aboriginal communities are high, an average of 39% among adults [46]; therefore, smoking may be considered a norm in these communities [21] and has been shown to be an important barrier to quitting in pregnancy [20,21]. Health professionals require specific recommendations on how to address this topic. Visual devices have been shown to be imperative in Aboriginal communities and previous research has identified this need [47–49].

4.3. Strengths and Limitations

The major strength of this study was the community-based participatory research approach. The resources were developed collaboratively with a working party from two ACCHS including health professionals and community members, and then received input from numerous health professionals working in ACCHS, including Aboriginal Health Workers from those communities. AH&MRC ethical guidelines recommend community ownership: an important aspiration when working in Aboriginal research. Developing the educational materials collaboratively, and consulting with community members on these materials prior to commencement of the project, are factors that contribute to this ownership. Another strength was the multiple methods used to collect data, aiding in research and data triangulation. Readability was assessed both on objective scales, and with a more subjective evaluation (SAM), and comprehension was also assessed via input from health professionals.

There were several limitations that may have impacted on this study. Only three communities were included, and the results might only be representative of those communities. Despite this, the fact that these communities were diverse and from three different states, with similar results across the communities, suggests that these resources might be acceptable and useful for other ACCHS and communities. Another round of community input after the changes were done was not feasible. This is mitigated by the fact that the SCAAP gave constructive feedback on the revised resources. In 2017, a pilot study with six ACCHS across three states was conducted [26], using these resources as part of the intervention. Further feedback and data are being collected on the usefulness of these resources through surveys and interviews from the pilot participants. Due to logistic reasons, focus groups were held with all types of health professionals together. This raises the possibility of a power differential between doctors, nurses and AHW, which might have impacted the expression of their respective views, leading to an over representation of doctors' views compared to AHW or nurses. As midwifes and AHW are the main point of contact for a pregnant woman during her ante-natal care, under-representation of their respective views might have meant that not all of the issues were identified. As focus groups included a range of health care providers, we were unable to present the data according to the different types of health professionals. Focus groups were not conducted by an independent party, but by the co-authors of the resources. Furthermore, social desirability bias with the SAM

scoring and focus groups cannot be excluded, which might indicate that the resources are less acceptable and useful than perceived in this study. However, in the initial explanation about the study, the facilitators emphasized that the purpose was to receive as much feedback as possible to improve and change these resources and were eager to hear both negative and positive viewpoints.

Scores from the SAM differed greatly for the same material resulting in a low inter-rater reliability measure, and did not contribute much to the decision-making on the changes for the resources: The SAM may be thus more subjective and may require several assessments with different people.

4.4. Implication for Policy and Practice

These resources were drafted by a tobacco treatment specialist with years of experience in smoking cessation and training health professionals (YBZ), together with an Aboriginal cultural liaison and researcher (MB); and developed jointly with a working party that included health professionals and community members from two ACCHS. The whole process was overseen by a senior researcher who is also a tobacco treatment specialist and GP, and experienced in development of Aboriginal smoking cessation resources (GG). Despite this, many changes were needed to assure these resources were useful and appropriate. The findings from this study highlight why an evaluation process is important and justified and should be adapted as a requirement when developing educational resources, prior to rolling them out for practice. Despite educational resources being very common as part of behavioural change interventions, many of them lack a formal evaluation process, or this process is not included as part of the intervention description. The process described here is an example of what might be used in future interventions with diverse populations. However there are many other approaches to evaluation [50], such as the Cloze Test that assesses readability and comprehension together [51].

There are multiple educational resources being developed for various health conditions. In fact, most organizations and interventions develop their "own" branded resources. This is time consuming and potentially an uneconomical use of resources. Instead of multiple different resources, national peak organizations and/or the Department of Health should be focusing on developed targeted resources that are evidence based, cultural acceptable, useful, and shared nationally for free. These "template" validated resources could then be used by other organizations, projects and

interventions. The process described in this study was time consuming (over a year) and required funding (including travel costs, reimbursement, research assessment time, and transcribing) that might deter other projects from undertaking such a process. This supports having a well-developed regularly updated national "bank" of validated educational resources that can be used freely by anyone. Having a national bank as suggested might still require validated resources to be culturally tailored to the specific communities for which they are intended. The complexity of this, combined with the uncertain evidence regarding the added clinical benefit of tailored educational resources [15], makes this a complex issue that requires further research to better understand what would be the most time and cost-effective approach.

The current process has increased the likelihood that the updated resources would be acceptable, useful and culturally responsive among participants of these three communities. By implication, the resources might be suitable for other similarly located Aboriginal communities (in the same three states) and thus appropriate for the second phase of the ICAN QUIT in Pregnancy intervention [26]. However, for phase three of this intervention (a cluster randomized controlled trial), intended to include 30 communities across additional Australian states and territories, further input and changes may be needed to ensure acceptability, usability and cultural responsiveness across all of these diverse communities.

5. Conclusions

A structured 4-step evaluation process informed the development of a resource package to be used as part of a multi-component intervention, aimed at improving how health professionals manage smoking in Aboriginal and Torres Strait Islander pregnant women who smoke. The evaluation process elicited specific suggestions for needed changes and improvements to ensure these resources were acceptable, culturally responsive and useful. Health professionals require simple, practical, visual resources that engage pregnant women in a shared conversation on smoking during pregnancy. The generalizability of these findings might be limited and requires more research.

This novel formative evaluation protocol has never been done previously in Australia. If these resources prove effective, the methodology could be adapted for other Indigenous interventions, and culturally diverse programs. The added value of this time-consuming and costly process is yet to be justified in research, and might impact the potential adaption by other projects.

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Supplemental File 1

Interview Guide for Focus Groups—Health Professionals

Interview guide[1] for focus groups – Health Providers

Instructions for interviewers

Briefly introduce yourself and explain about the study.

Include main points outlined in the information sheet provided to participants.

Gain Informed consent.

Distribute each resource separately, for individuals to view before discussing with the group

Please allow all participants 5 minutes to review each resource (more if needed) before starting discussion

Encourage participants to refer to the resource in question throughout the session

Encourage participants to make notes as they go on the resources, make sure they understand you will be collecting these at the end.

Note – there are no right or wrong answers. Try not to prompt the participants. Try not to interrupt the responses.

List of resources to be discussed

1. Desk top Guide
2. Treatment Manual

[1] Doak C, Doak L, and Root J. *Teaching Patients with Low Literacy Skills*, 2nd Edition, Philadelphia: Lipincott 1996.
http://www.hsph.harvard.edu/healthliteracy/resources/teaching-patients-with-low-literacy-skills/

Ask the following questions.

1. **Attraction**
   Let's look at the cover. Would you want to read this?
   If not – could you tell me why?
   What catches your eye?
2. **Comprehension (understanding the content)**
   Could you tell me in your own words what this is all about?
   Anything else?
   Are there any words that you think might be hard to understand? Which ones?
   Do you have any suggestions for improvement as to the content?
   a. Should anything be added?
   b. Should anything be removed?
3. **Self-efficacy**
   Could you use this for treating pregnant patients?
   If not, what doesn't make sense? What doesn't seem useful?
   Would you need any other information in order to help them to quit smoking?
4. **Graphics and Layout**
   What catches your eye? What do the pictures tell you?
   Do the pictures help get the message across?
   What do you think of the colours?
   Do you have any suggestions for improvement as to the graphics?
   a. Should anything be added?
   b. Should anything be removed?
   c. Should any particular graphic be altered?
   Is the print big enough? Too big? Is there too much print/too little/just right
5. **Cultural Acceptability**
   a) Do you think this is OK to show to pregnant Aboriginal or Torres Strait Islander women?
   b) Is there anything in here that would make you uncomfortable?
   c) Do you find anything in this that is offensive to you?
   d) Are there any inappropriate parts (wording or graphics)?
6. **Persuasion**
   Do you think health providers would be willing to use this?

   Overall
   Overall, what is your opinion of this?
   Can you think of ways this could be improved?

Supplemental File 2

Summary of Feedback Provided by the Expert Panel

Resource Type	Summary of feedback (according to the themes – Attraction, Comprehension, Self-Efficacy, Graphics and Layout, Cultural acceptability, and Persuasion)
General	Self-efficacy: Add more on family/household smoke Attraction: High Cultural acceptability: High
Treatment Manual	Self-efficacy: • Add more information regarding harm reduction, e-cig, depression • Add more emphasis on asking women what they think about possibly using NRT and why with efforts being made to counter any strong erroneous views they hold. Add specific suggestions regarding how HP might counter incorrect ideas about NRT. • Add more detail regarding practical use of measures to guide decision • Suggested omitting HSI if doesn't affect treatment decision • Adding intro on purpose • Add additional resources available including YouTube videos. • Addition of information on differences between smokers, and their ability to quit (suggestion for an additional graph); • Additional information regarding breaking the habit (breaking the pairing) Graphics and layout: Specific recommendations on things that need to be made more clear, stand out Comprehension: • Minor editing suggestions • Suggesting reframing the Ask to the Ask-Provide-Ask method Cultural acceptability: • Suggested addition on issues regarding smoke free homes and sensitivity with how to communicate this to elders. • Revise the section on cultural competent care to be more in detail and comprehensive
Flipchart	Attraction: High Graphics and Layout: Minor changes to make more useful and understandable Organizing the pages differently Comprehension: Minor wording suggestions to clarify Self-efficacy:

	• Additional quotes to help clarify meaning of communication style recommended • Additional information on difference between harm from cigarette to harm from nicotine; differences between smokers, and their ability to quit (suggestion for an additional graph); cost of NRT; e-cig and chewing tobacco • Additional material as personal handouts, also laminated
Desktop Guide	Persuasion: Conflicting (some said helpful, others would not use)
Brochures – General	Attraction: High Comprehension: • Change specific wording to simplify • Check guidelines regarding timing in relation to food/drinks
Quitting in Pregnancy	Comprehension: Simplify wording
Triggers	Self-efficacy: Add ways specifically on stress management Comprehension: Simplify wording
Smoke Free Home	Self-efficacy: Add health benefits for children Comprehension: Simplify wording
NRT Brochures – General	
Patch	Comprehension: Simplify wording
Gum	Comprehension: Simplify wording
Lozenge	Comprehension: Simplify wording
Spray	Comprehension: Simplify wording
Inhaler	Comprehension: Simplify wording

Introduction to Paper Seven

Papers one, two and three provided valuable insight into specific barriers and enablers that GPs face when managing smoking during pregnancy, including several specific barriers and facilitators for GPs working with Aboriginal and Torres Strait Islander pregnant women. Paper four drew attention to an additional barrier to using NRT during pregnancy – the lack of a strong evidence base for NRT safety and efficacy in pregnancy, with guidelines including ambiguous messages regarding its use. Paper five highlighted that to date, no interventions have been conducted that aimed to improve NRT prescription rates during pregnancy, and that audit and feedback, with a strong theoretical basis, may augment intervention effectiveness.

These findings informed the development of a multi-component intervention, aiming to improve health providers' management of smoking with Aboriginal and Torres Strait Islander women: ICAN QUIT in Pregnancy. Further details regarding the development of this intervention, including the theoretical basis, can be found in Appendix 4.6.

Paper seven provides detail on the protocol for the ICAN QUIT in Pregnancy intervention and the study design aimed to assess the intervention's feasibility, acceptability and trend for effectiveness. The rest of the thesis reports only the health providers' results (paper eight), as health providers' provision of smoking cessation care is the main focus of this thesis. Other findings (feasibility, acceptability and pregnant women's results) are presented elsewhere.

Paper Seven:
The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study Protocol: A Feasibility Step-Wedge Cluster Randomized Trial to Improve Health Providers Management of Smoking during Pregnancy

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Associated appendices

Abstract

Introduction: Indigenous women have the highest smoking prevalence during pregnancy (47%) in Australia. Health professionals report lack of knowledge, skills and confidence to effectively manage smoking among pregnant women in general. We developed a behaviour change intervention aimed to improve health professional's management of smoking in Indigenous pregnant women – The Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy. This intervention includes webinar training for health professionals, an educational resources package for health professionals and pregnant women, free oral nicotine replacement therapy (NRT) for pregnant women, and audit and feedback on health professionals performance.
The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to improve health professional's provision of evidence-based culturally-responsive smoking cessation care to Australian Indigenous pregnant smokers.

Methods and analysis: This protocol describes the design of a step-wedge cluster randomized pilot study. Six Aboriginal Medical Services (AMSs) are randomized into three clusters. Clusters receive the intervention staggered by one month. Health professionals report on their knowledge and skills pre and post training and at the end of the study. Pregnant women are recruited and followed up for three months. The primary outcome is the recruitment rate of pregnant women. Secondary outcomes include feasibility of recruitment and follow up of participating women, and webinar training of health professionals, measured using a designated log; and measures of effectiveness outcomes, including quit rates and NRT prescription rates.

Ethics and dissemination: In accordance with Aboriginal Health and Medical Research Council guidelines, this study has been developed in collaboration with a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP). The SCAAP provides cultural consultation, advice and direction to ensure that implementation is acceptable and respectful to the Aboriginal communities involved. Results will be disseminated to AMSs, Aboriginal communities, and National Aboriginal bodies.
Registration details: This protocol (version 4, 14/10/2016) is registered with the Australian and New Zealand Clinical Trials Registry (Ref #: ACTRN12616001603404)

*The term Indigenous will be used in this document to refer to both Aboriginal and Torres Strait Islander peoples in Australia, but with recognition and respect of the autonomy of the two peoples.

Strengths and Limitations of this Study

- This is the first study in Australia to target specifically Indigenous smoking during pregnancy that covers three different states and different settings.
- This study is designed to overcome specific implementation issues identified in previous research, including ensuring community representation in governance of the research; participant recruitment by known health staff from the service; and adequate re-imbursement for time and effort of services and women.
- The intervention tested in this study was informed by theory and based on extensive formative research beforehand.
- This study is a pilot study aimed to assess feasibility and acceptability, and is not powered to assess the effectiveness of the intervention.
- This study covers health professionals treating Indigenous pregnant women who work at Aboriginal Medical Services only, and does not cover other general ante-natal care settings that Indigenous women may attend.

Introduction

Tobacco smoking in pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes. In 2013, 12% of women who gave birth in Australia smoked during pregnancy.[1] Indigenous Australian women have the highest smoking prevalence during pregnancy (47%).[1] Indigenous women also quit smoking during pregnancy at a lower rate compared to the general population (11% compared to 25%).[1] Smoking has been identified as an important contributor to the health and life expectancy gaps between the Indigenous and non-Indigenous people in Australia.[2]

Barriers to quitting

Australian Indigenous pregnant women face multiple barriers to quitting smoking.[3-6] These include social norms of smoking in some Indigenous communities, multiple life stressors, lack of prioritisation of smoking cessation, lack of support for cessation, lack of salience of anti-tobacco messages, and inadequate access to targeted programs.[4,5,7] Health professionals report they are ill-equipped to tackle the complexities of smoking cessation care for pregnant women, and lack resources and optimism.[8,9] First-line medications (oral nicotine replacement therapy (NRT)) are currently not subsidized in Australia,[3] disproportionally impacting lower socioeconomic populations, and Indigenous women.[10]

Evidence for smoking cessation care in pregnancy

The combination of behavioural counselling and pharmacotherapy has been shown to be the most effective treatment for smokers generally.[11] Studies specific to pregnant women have also shown that psychosocial interventions such as counselling are effective.[12] Recently a taxonomy was developed and validated to detail the specific "active ingredients" of behavioural counselling termed behaviour change techniques.[13-15] These include for example goal setting and identifying smoking triggers.[16]

Pharmacotherapy

In a Cochrane review on pharmacotherapy for smoking cessation in pregnancy, the use of NRT increased cessation rates by 40% (RR 1.41, 95% CI 1.03-1.93); The exclusion of non-placebo controlled trials resulted in a lower, non-significant increase in the cessation rate (RR 1.28, 95% CI 0.99-1.66).[17] The discrepancy between these findings, and the apparent effectiveness of NRT for the general population,[18] may be explained by the faster nicotine metabolism in pregnancy, requiring higher doses than those used in the included studies.[17,19,20] Importantly, The use of NRT was not associated with any

significant differences in pregnancy or birth outcomes.[17] Experts agree that NRT is always safer than smoking in pregnancy, and guidelines from several countries, including Australia, recommend the use of NRT, if a woman has been unsuccessful in quitting.[21-24] These guidelines recommend first using oral forms of NRT, and if the women is still unsuccessful quitting smoking, adding an NRT patch. This is done to ensure that the lowest effective dose is used.[22,25]

Need for health professionals training

Health professionals report that they lack the knowledge, skills and confidence to assist pregnant women to quit smoking. A recent national Australian cross-sectional survey[9] found that few General Practitioners (GPs) and Obstetricians routinely perform all of the required components of the clinical guidelines[11,26]. Furthermore, only 11% reported always prescribing NRT, 7% arranging follow-up, 22% discussing the psychosocial context of smoking, and 26% referring to a specialized cessation program (such as the national Quitline). Surveys with other antenatal health professionals in Australia (Aboriginal Health Workers, midwifes, nurses) report similar findings.[8]

These findings mirror surveys internationally,[25,27-39] portraying an evidence-practice gap in the way health professionals currently manage smoking in pregnant women. Addressing this gap is crucial, as it has been shown that advice from health professionals increases the chances of a quit attempt in the general population (RR 1.66, 95% CI 1.42, 1.92),[40] and is positively associated with intention to quit in Australian Indigenous smokers of reproductive age (OR 3.82, 95% CI 1.43, 10.2).[41] Training health professionals has been proven to increase rates of smoking cessation (OR= 1.60, 95% CI 1.26,2.03),[42] although this has not been studied specifically for Indigenous pregnant women.

Interventions for pregnant Indigenous smokers

Interventions developed to address smoking in Indigenous people have often lacked either rigorous evaluation, or deep cultural understanding.[43,44] Two Randomised Controlled Trials (RCTs) among Indigenous pregnant smokers have been conducted: one in Indigenous Australians, and the other in Alaska Native women.[45,46] Neither demonstrated any statistically significant differences between intervention and control groups, although the underpowered Eades' study found an assisted quit rate of 11% compared to a control rate of 5%.[45,46] Several implementation factors marred the outcomes of these studies, including low enrolment, high attrition, and possible

contamination between study arms.[45,46] Patten's study included NRT only through referral to a separate program;[46] Eades' study included an option for NRT at the third visit, after 7-10 days of unsuccessful quit attempts.[45]

The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention

In 2015, a pragmatic guide to the management of smoking cessation in Indigenous pregnant women was published.[47] These guidelines are structured on the ABC pathway (Ask about tobacco use; Brief advice to quit; Cessation support),[23] with the addition of a D component (Discuss the psychosocial context of smoking)[47] – the ABCD approach. A proactive approach is recommended – offering assistance to all pregnant smokers (regardless of readiness to quit, and smoking level), and an expedited offer of NRT after 1-2 days of an unsuccessful quit attempt.[47] These guidelines follow other Australian clinical guidelines, recommending the use of oral NRT as first line, higher doses of NRT due to the higher metabolism in pregnancy, and combination NRT if needed.[21,48]

On the basis of these ABCD guidelines,[47] we used the Theoretical Domains Framework,[49] the Behaviour Change Wheel,[50] and Behaviour Change Techniques recommended in pregnancy,[16] to develop a theory based behaviour change intervention aimed to improve health professionals management of smoking in Indigenous pregnant women – ICAN QUIT in Pregnancy. The Theoretical Domains Framework and Behaviour Change Wheel are used to identify barriers and facilitators to achieving evidence-based care to inform intervention design.[50]

The intervention was developed in collaboration and negotiation with two Aboriginal Medical Services (AMSs) in New South Wales (NSW). The Chief Executive Officers of those AMSs are Associate Investigators on the study and partnered with the research team to establish a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP), to advise on the design of the study. They also contributed to a Working Party including AMSs staff and community members that developed educational resources for the intervention. This collaborative process of intervention development has been described elsewhere.[51]

The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to increase health professionals provision of evidence-based, culturally-responsive smoking cessation care to Australian Indigenous pregnant smokers, positioning Aboriginal women and communities at the centre of the research with engagement and ownership upheld through the study.[51] This study will inform the final design and implementation of a clustered RCT (cRCT) aimed to study the

effectiveness of health professionals training on smoking cessation rates in pregnant Australian Indigenous smokers.

Methods and Analysis

Study overview

The overall objective is to reduce smoking in Aboriginal and/or Torres Strait Islander pregnant women.

Specific aims of this pilot are:

Primary aims: Assess feasibility and acceptability of a multi-component targeted intervention to train health professionals at AMSs in the culturally-responsive management of smoking in Australian Indigenous pregnant women.

Secondary aims:

1) Assess the effectiveness on NRT prescribing practices.
2) Evaluate the effectiveness on health professional's knowledge, attitudes and practices in managing smoking in pregnant Indigenous women.
3) Estimate the trends for quit attempts and biochemically verified smoking cessation rates in pregnant patients managed by trained health professionals.
4) Assess patient' perceived receipt and quality of smoking cessation care by the trained health professionals.
5) Evaluate changes in the perceived wellbeing of pregnant patients.
6) Evaluate behaviour change techniques use by the trained health professionals.

Study design

This is a step-wedge cluster randomized pilot study with six participating sites randomized to three clusters (each of two AMSs). Allocation of the sites to the clusters is based on geographical convenience. For each cluster, the period of treatment crossover was randomized using simple randomisation. Allocation concealment was not possible. All of the sites will receive the same intervention which will be sequentially delivered two months following commencement of the study, staggered by one month between clusters (the intervention is described below). Two cohorts, one of HPs and one of pregnant women, will provide data with repeated measures: from two months prior to receiving the intervention until 6 months following the intervention. See Figure 1 for a schematic illustration.

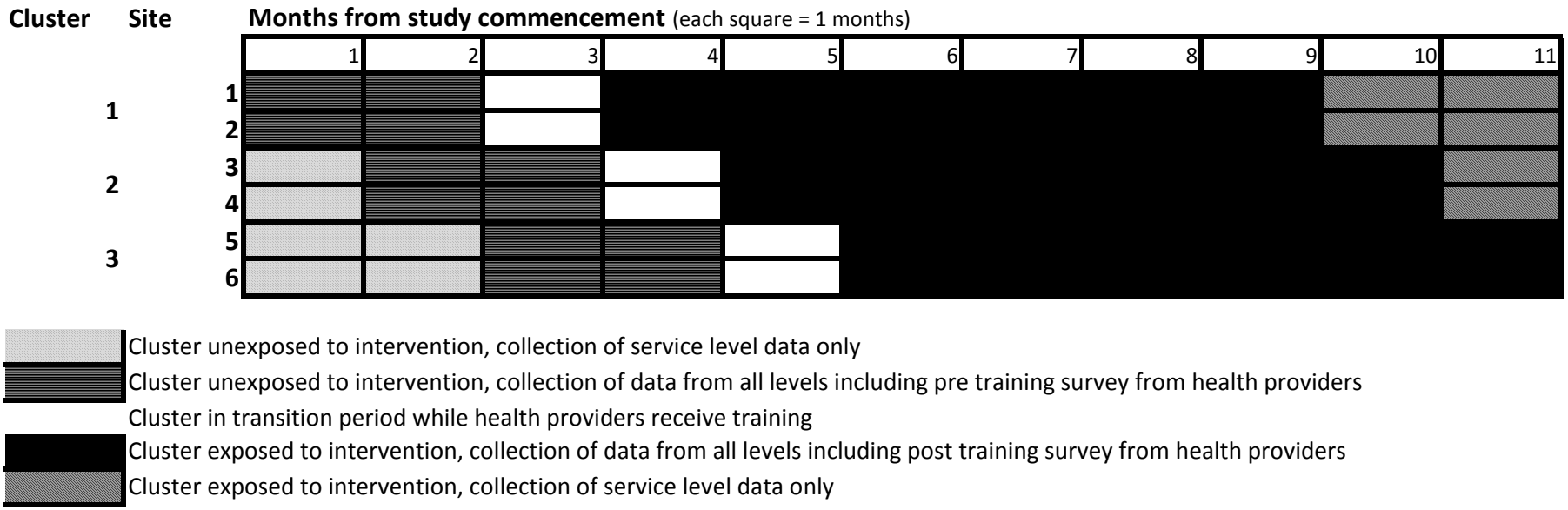

Figure 1: Schematic illustration of the step-wedge cluster study for the Indigenous Counselling And Nicotine (ICAN) QUIT in pregnancy Pilot Study

A step-wedge design was chosen since it allows the intervention to be delivered sequentially and therefore reduce the cost and burden of simultaneous implementation, while also providing some control of confounding factors through randomisation.[52] Furthermore, this design will ensure all sites receive the intervention which is important from an ethical view point. The cluster design was chosen to prevent contamination, a problem identified in the Eades' study.[45]

Timeline of study: November 2016-September 2017.

Setting: Urban and regional AMSs in NSW, Queensland, and South Australia. The AMS include Aboriginal Community Controlled Health Services which are non-government organisations operated by local Aboriginal and Torres Strait Islander communities, to deliver holistic, comprehensive, and culturally appropriate health care to the communities that control them through an elected board of management.[53]

Inclusion criteria

For participating services AMSs are included if they fulfil all of the following criteria:

1. Diagnose pregnancy or provide antenatal or routine care for pregnant Aboriginal or Torres Strait Islander women.
2. Employ at least one General Practitioner (GP).
3. Have contact with at least 20 pregnant women who smoke per year.
4. Are able to recruit and follow patients as required.

Participating health professionals are those who: consult with pregnant women either for confirmation of pregnancy, ante-natal care, and/or routine care.

Participating women will include those who fulfil all of the following criteria:

1. Pregnant, ≤28 week's gestation.
2. Aboriginal and/or Torres Strait Islander or expectant mothers of Aboriginal and/or Torres Strait Islander babies.
3. Aged ≥ 16 years old.
4. Smoke tobacco at any level of consumption, including those that only smoke occasionally.

Intervention components

The ICAN QUIT in Pregnancy intervention includes:

1. Training of health professionals in participating sites through webinar in three 60-minute weekly sessions. The training will be delivered by two experienced tobacco treatment specialists. Content will include background on smoking in

pregnancy including the Indigenous context; the ABCD approach, and the use of NRT in pregnancy (See supplemental file for full description of webinar content). As an incentive to complete the training, all health professionals will be offered continuing professional developments points (required as part of registration with the Australian Health Practitioner Regulation Agency).

2. An educational resources package, to be used by both health professionals and pregnant women, has been developed collaboratively and includes a training manual for health professionals, and flipchart, patient booklet and educational posters for engaging with the pregnant women. Resources were developed by a medical doctor and tobacco treatment specialist (YBZ) and Aboriginal researcher (MB) in consultation with AMSs. These have been rigorously pre-tested using a four step process, including review by an expert panel, assessment using a suitability of material score by two Aboriginal health workers, readability scores, and focus groups reviews with both health professionals, and female Aboriginal community members, in three states.[54]
3. Oral forms of NRT for the pregnant women will be supplied to the sites free of charge, as these are not currently subsidised in Australia. All available forms in Australia will be included (gum, lozenge, mini-lozenge, inhalator and spray). NRT will be dispensed through a voucher system. Sample packs will be provided directly to the sites to introduce patients to the selection available. If NRT patches are required, the GP at the service will write a government-subsidized prescription. NRT will be used according to product and Therapeutic Goods Administration instructions, as well as health professional's judgment on a patient-by-patient basis. No study-specific protocol to NRT dispensing will be followed. As nicotine has potential effects on the foetus,[55,56] a risk-benefit analysis will be undertaken with each woman when NRT is offered, as recommended in clinical guidelines.[21] A participant not using NRT can remain in the study with behavioural support only.
4. Audit and feedback regarding health professional's performance will be via aggregated, de-identified, service specific, monthly data collection, commencing in the pre-training phase and continuing through to study completion. Each service will receive feedback regarding their rate of NRT prescription to pregnant women who smoke compared to other study services.

Study implementation

A staff member will be nominated as a research facilitator by each service. The role of the research facilitator is to recruit patients, conduct surveys and evaluations, and collect feasibility data (table 1). The research facilitator will be trained by the research team in a face to face meeting and provided with supporting resources (detailed instructions and checklist) to assist them in their role. The research team will provide three site visits (before commencement, one month after commencement, and end of study) and weekly telephone calls as implementation support. Additional support will be provided as needed by the research facilitator.

Recruitment and Reimbursement

Services will be recruited through: a) written invitation to all AMSs in NSW asking for expressions of interest, and b) targeted invitations to services that worked previously with the researchers. The service will be reimbursed $6000 in instalments, for the involvement of their nominated research facilitator.

Service staff will aim to recruit all pregnant smokers under their care when they attend for any type of service including confirmation of pregnancy, antenatal, or routine care. The study will be advertised through posters at the service.

The research facilitator will complete a one-page eligibility checklist with women interested in the study, and if they are eligible, will gain informed consent. Consenting women will be assigned a unique code to link the data collected to the same participant. Pregnant women recruited to the study will be asked to attend three designated study visits (baseline at recruitment, 4 and 12 weeks post recruitment). At each study visit, the participating women will be asked to fill out 2-3 online surveys and perform a breath carbon monoxide test. We estimate that each study visit will take between 30-50 minutes. Women will receive reimbursement for their time in the form of a $20 shopping voucher for each visit (total $60 AUD). Women attending all three study visits will enter into a draw for one baby pack (value $50 AUD) per site.

Outcomes

Outcomes include feasibility and acceptability measures, and measures of effectiveness outcomes (detail description of all the outcomes are presented in Table 1 and 2). The primary outcome will be the recruitment rate of participating pregnant women defined as the number of eligible women who consented to participate in the study

Table 1: Feasibility and acceptability outcomes

Hierarchy of Measurement (Service, Health Professionals or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Recruitment rate (Primary outcome)	Research facilitator log	Number of woman recruited divided by number of woman approached for each site, overall sites and stratified by site.	End of Study
Service	Follow up rate	Participant survey	Percentage of women recruited who complete all follow-up surveys	4 weeks and 12 weeks
Service	Proportion of women's checklists completed	Women's checklist	Number of consultations with a completed checklist divided by the total number of consultation for each patient (designated and non-designated study visits)	End of study
Service	Provider training rate	Research facilitator log	Number of providers undergoing webinar training divided by the total number of providers, overall sites and stratified by site.	End of training
Service	Webinar completion rate	Research facilitator log	Number of webinar sessions each provider attended	End of training
Health professionals and pregnant women	Acceptability of intervention and implementation	Interviews with staff and patients	Thematic analysis	End of study

Table 2: Measures of effectiveness outcomes

Hierarchy of Measurement (Service, Health Professionals or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Proportion of pregnant smokers that were given nicotine replacement therapy (NRT)	Audit of de-identified grouped data	Pharmaceutical Benefit Scheme (PBS)* prescriptions or vouchers for NRT	Monthly
Health professionals	Self-reported knowledge, attitudes and practices about managing smoking in pregnancy	Health Professionals surveys	Changes in HPs knowledge, attitudes and practices comparing all time-points	Pretraining, post-training and end of study
Health professionals	Behaviour Change Techniques (BCT)	Audio recording of consultations	Analysis of transcripts by trained BCT coders	Pretraining and post training
Pregnant women	Self-reported smoking characteristics	Smoking characteristics survey	Changes in smoking characteristics	Baseline, 4 weeks and 12 weeks
Pregnant women	Woman's perception of receiving smoking cessation care	Woman's checklist	Composite scores on checklists	Exit from consultations with a Health Professional
Pregnant women	Self-reported quit rates	Smoking characteristics survey	7-day point prevalence and continuous abstinence[74]	Baseline, 4 weeks and 12 weeks
Pregnant women	Biochemically validated quit rates	Handheld CO meter	7-day point prevalence and continuous abstinence[74] using expired CO <6ppm as reference point	Baseline, 4 weeks and 12 weeks
Pregnant women	Self-report of adherence to NRT	Smoking characteristics survey	Changes in adherence to NRT	4 weeks and 12 weeks
Pregnant women	Self-reported knowledge, attitudes and smoking behaviours	Smoking characteristics survey	Changes in knowledge, attitudes and smoking behaviours	Baseline, 4 weeks and 12 weeks
Pregnant women	Growth and Empowerment	Growth and Empowerment survey	Changes in Growth and Empowerment domains	Baseline, 4 weeks and 12 weeks
Pregnant women	Critical success measures	Critical success survey	Descriptive analysis of the nine critical success factors	End of study

* Pharmaceutical Benefit Scheme (PBS) is the Australian government scheme for prescription subsidy

Data collection and instruments

Data will be collected at three levels – 1) Service 2) Health professionals and 3) Pregnant women (Table 1 and 2). Participant time lines are presented in Table 3 (Health professionals) and Table 4 (pregnant women).

1) Service Level

Research Facilitator log:

Feasibility data will be collected by the research facilitator using a designated log, including recruitment rate, follow up rate, proportion of participant surveys completed, and health professionals training rate. Reasons for non-participation or withdrawal will not be collected routinely as part of the research facilitator designated log, but will be discussed with the research facilitator on an ongoing basis in the weekly implementation phone calls and at the end of the study interview.

Aggregated computerized data:

De-identified aggregated monthly computerized data will be collected from study commencement (Figure 1), including: number of pregnant women attending the service; number of those that smoke; number referred to the Quitline, and number of NRT prescriptions (including oral NRT vouchers).

2) Health Professionals Level

Health professional's survey

A 102-item, 15 minute, self-administered online survey will include questions about health professionals demographic characteristics; self-reported knowledge, attitudes and provision of smoking cessation care; prescription of NRT; self-assessment of the barriers and enablers to providing smoking cessation care; and perceived usefulness of educational resources. This survey is based on a previous survey from a national study of 378 GPs and Obstetricians.[9] Survey will be sent pre and post-training, and at the end of the study (Table 3).

Health professionals demographic characteristics: include gender, age, years working as a health professional (less than 10 years; 10-19; 20 or more years), speciality (GP; Midwife; Nurse; Aboriginal health worker; other), smoking status (daily; occasionally, ex-smoker, never smoked); and average number of pregnant women who smoke seen per month (<5, 5-10, >10).

Table 3: Schedule of assessments for health professionals receiving training for Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study

Assessment	Performed by	Pre-training	Post training	End of study
		_ _/_ _/_ _ _ _ (dd/mm/yyyy)	_ _/_ _/_ _ _ _ (dd/mm/yyyy)	_ _/_ _/_ _ _ _ (dd/mm/yyyy)
Informed consent	Research facilitator	**X**		
Pretraining survey	Self-administered online	**X**		
Audio-recording of smoking consultations (optional)	Health professional	**X**	**X**	
Post-training survey	Self-administered online		**X**	**X**
Interview	Research team			**X**

Table 4: Schedule of assessments for pregnant women participating in Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study

Assessment	Performed by*	Day O	Any additional follow up*	4 weeks (+/- 3 days)	12 weeks (+/- 7 days)	End of study
		_ _/_ _/_ _ _ _ (dd/mm/yyyy)	_ _/_ _/_ _ _ _ (dd/mm/yyyy)	_ _/_ _/_ _ _ _ (dd/mm/yyyy)	_ _/_ _/_ _ _ _ (dd/mm/yyyy)	_ _/_ _/_ _ _ _ (dd/mm/yyyy)
Review eligibility for study	Health professional and/or Research facilitator	**X**				
Informed consent	Research facilitator	**X**				
Smoking characteristics survey	Research facilitator	**X**		**X**	**X**	
Growth and Empowerment survey	Research facilitator	**X**		**X**	**X**	
Critical Success Measures survey	Research facilitator				**X**	
Breath carbon monoxide test	Research facilitator	**X**		**X**	**X**	
Patient checklist	Research facilitator	**X**	**X**	**X**	**X**	
Audio-recording of smoking consultation (optional)	Health professional	**X**	**X**	**X**		
Interview	Research team					**X**

*Any additional follow up (not part of designated study visits) including all of her visits to the service for usual care.

Self-reported provision of smoking cessation care: will be measured using 5-point Likert scales (never (0%); occasional (1-25%); sometimes (26-50%); often (51-75%); always (76-100%)) on the various components of smoking cessation care ("How often do you provide the following types of cessation care with pregnant women?" ask; record smoking status; brief advice; assess nicotine dependence; measure carbon monoxide; cessation support; discuss psychosocial context; follow up; referral to Quitline; referral to other specialist cessation support; involve family members).
Prescription of NRT and attitudes towards prescribing NRT during pregnancy: NRT prescription will be measured with the 5-point Likert scale as for the other smoking cessation care components. Self-reported perceptions on NRT in pregnancy will include rating the safety for the foetus, effectiveness in aiding pregnant smokers to quit, and perceived adherence.
Barriers and enablers to smoking cessation care: (5-point Likert Scales - strongly disagree, to strongly agree). This will be measured using 22 statements covering 13 domains from the Theoretical Domains Framework,[50] including: knowledge, reinforcement, role/identity, beliefs about capabilities, optimism, beliefs about consequences, social influence/subjective norm, goals/priority, memory/attention, environmental context and resources, emotions/stress, intentions, behavioural regulation. Most domains include one question regarding smoking cessation care during pregnancy in general, and one question specifically regarding the prescription or recommendation of NRT.
The 'Knowledge' domain will also be measured with one question about guidelines ("Have you read any of the following smoking cessation guidelines? With a list of 3 different national guidelines, Yes/No); and 24 True/False statements that will be computed to form a composite score. The 'Skills' domain will be measured with one question ("Have you received any training in tobacco management related to pregnancy with list of 4 training types Yes/No).
Usefulness of educational resources: will be measured using 5-point Likert scales (Not useful at all to Very useful) for each webinar session, and each educational resource.

Interviews

At the conclusion of the study, one of each type of health professionals from each service (i.e. a midwife, a GP and an Aboriginal health worker), including also the manager and research facilitator, will be interviewed. Recruitment will continue until

saturation of themes. Estimated sample n=40. The objective of the interviews is to assess the feasibility of the intervention and the study, and gain valuable insights before commencing the cRCT. The semi-structured interview guide will include questions based on the Theoretical Domains Framework and Behaviour Change Wheel,[49,50] and include topics such as the challenges to implementing the study, and what could have been done to improve the study.

3) Pregnant Women Level

Smoking characteristics survey:

This 56-item, 15 minute, survey will incorporate questions from a previously tested survey in Aboriginal pregnant smokers.[57] Demographic and smoking characteristics will include: age, Aboriginal and Torres Strait Islander status, partner status, parity, number of children, any child living at home, smoking status, measures of nicotine dependence (Fagestrom Test of Nicotine Dependence,[58] Heaviness of Smoking Index,[59] Strength and Frequency of Urges to Smoke[60,61]), home smoking rules, intentions to quit smoking, number of previous quit attempts ≥24h, use of other smoking cessation resources (such as the Quitline), symptoms of nausea in pregnancy (morning sickness is a predictor of spontaneous quitting[62]), the Risk Behaviour Diagnosis Scale (previously validated in Aboriginal smokers, adapted here for pregnant smokers[63]), and attitudes to smoking and quitting. Adherence to NRT will be measured using a 5-item multi-choice question (did not take it all; used occasionally 1-2 times a week; used 3-4 times but not all doses; occasionally missed a dose; used most doses, every day).

At the 4 and 12 week follow up, the survey includes additional questions to determine 7-day point prevalence smoking abstinence and continuous abstinence rates.[64]

Growth and Empowerment Measure (GEM):

This survey has been previously validated with 184 Indigenous Australians, but has not been used specifically with Indigenous pregnant women65 and includes two components:

1. 14 item Emotional Empowerment Scale which comprises two domains: inner peace and self-capacity.
2. 12 Scenarios with two domains: healing and enabling growth and connection and purpose.

These are accompanied by the 6-item Kessler Psychological Distress Scale supplemented by two questions assessing frequency of happy and angry feelings. Estimated completion time is 15 minutes.

Critical Success Measure:

This measure was developed through analysis of six Indigenous youth social and emotional wellbeing programs[66] and was previously used in the evaluation of an urban art-based community health program with young Aboriginal and Torres Strait Islander parents.[67] This survey will be completed only once at the 12 week visit. This survey will measure 9 factors relevant to an empowerment-based program, including adopting full commitment to working from strengths; being patient to develop the relationship bond first; modelling reliability and being consistent; facilitating connection to culture; adopting a non-judgmental approach; setting rules and boundaries; modelling openness, honesty, hope and trust; maximising opportunity for choice making, self-motivation, feeling safe to try new things; celebrating small achievements and positive changes. For each factor, we will use 5-point Likert scales to measure woman's perception of the importance of the factor (from not at all to absolutely essential) and how well the intervention achieves this (from poorly to extremely well). Estimated completion time is 15 minutes.

Breath carbon monoxide. At the three study visits, a breath carbon monoxide test will be performed to validate smoking status, and estimate foetal carboxyhaemoglobin. Carbon monoxide level≥5 ppm=96% sensitivity and 99.6% specificity for agreement of carbon monoxide readings and self-report of smoking in Aboriginal communities.[68]

Women's checklist: At the end of any visit to the service, from recruitment to the end of follow up, including the designated study visits at 4 and 12 weeks, the patient will be asked to complete a 1 minute online checklist on a computer tablet. The survey will commence with a question regarding which health professional she saw on that occasion (GP/Midwife/Nurse/Aboriginal health worker /other). Eleven dichotomous questions (Yes/No) will be used to form a composite score representing quality of smoking cessation care. For example: *Did any of the health professionals you saw today give you the following care: Asked you about smoking? Gave you advice to quit…? Assisted you with making a quit plan? Explained how smoking affects…? Offered you NRT…? Measured your breath…? /Discussed with you…? Gave you support…? Made arrangements for follow-up appointments or referral? Gave you resources…?* Two

Likert Scales will be used to rate a) her perceived involvement in making a decision about quitting (no involvement to very much involved) and b) her overall satisfaction with the help she received (not satisfied at all to very satisfied).

Recording of consultations for behaviour change techniques analysis: A digital audio recording of provider-patient sessions relating to smoking cessation will be undertaken, including a mix of initial and follow-up consultations (i.e. pre-quit attempt, and during or post-quit attempt up to the 4-week follow-up point). A total estimate of 54 consultations will be recorded (nine consultations per service – three pregnant smokers from each service, for each woman, three consultations as outlined above).

Interviews

At the conclusion of the study, approximately three to four women from each service, will be interviewed to assess the feasibility of the intervention and related research in order to gain insights before the cRCT. Key topics to be discussed include their perceptions of the usefulness, acceptability and potential effectiveness of the support they received as part of the study, and what could have been done to improve this. Recruitment will continue until saturation of themes.

Sample size calculation:

Health professional's sample: expected sample size will be six services, training 5-10 per service, with total sample size of N=30-60 recruited health professionals. Expected completion of training is 80%.

Pregnant women's sample: expected recruitment is 10 eligible consenting women per service N=60 (range 50-80). Assuming a true recruitment rate of 50%, a sample of 200 eligible women will allow estimates of the true recruitment rate within a 7% margin of error.

Data Analysis Plan:

Recruitment rates (and other feasibility outcomes specified in Table 1) will be estimated as proportions (or percentages) with 95% CIs, SEs will be adjusted for the clustered design using the clustered jackknife.[69] All primary analysis will be according to the intention to treat principle, such that each site (and participants within) will be analysed according to the time at which the site crossed over to the intervention period.

Analysis of effectiveness outcome measures:

1) Changes in the proportion of eligible women that were prescribed NRT from pre to post training will be assessed using a logistic mixed effects regression model.

The model will include a categorical effect of time, an indicator of period (pre vs post intervention) and a random intercept for each site.

2) Changes in provider knowledge/attitudes relating to smoking cessation in pregnant mothers measured by self-administered survey: pre to post-training and end of study will be investigated using generalised linear mixed effects models, with random effects for the site and the health professionals, and fixed effects for time. If the fraction of missing data is less than 5% the primary method will be based of those with completed surveys from both time points. Otherwise we will use multiple imputation under the missing at random assumption, with a sensitivity analysis using pattern mixture models to explore the potential the data is missing not at random.
3) Trends in smoking characteristics and growth and empowerment; and factors associated with smoking characteristics and growth and empowerment, will be assessed using generalised linear mixed models.
4) Two certified behaviour change techniques coders will independently code the transcribed audio-recordings. Discrepancies will be resolved through discussion with a third coder. Coding will be based on the taxonomy of 44 smoking cessation behaviour change techniques.[15,16] Additionally, the two coders will independently code the training resources. Inter-rater agreement levels will be calculated. We will assess changes between behaviour change techniques present pre and post training; and the fidelity between the behaviour change techniques present in the training resources and those present in the post training recordings.
5) Interviews at the end of the study will be audio-recorded, transcribed, and analysed (using NVivo software) with a framework analysis[70] based on the Theoretical Domains Framework and Behaviour Change Wheel.[49,50] Two researchers will independently open code and index a 20% proportion of the transcripts line-by-line, using a predetermined coding matrix. After coming to consensus, one researcher will then complete the coding and indexing. If appropriate, inductive themes will be included after discussion between the two researchers.

Ethics and dissemination

We will follow Australian National Health and Medical Research Council ethical guidelines for research, including Aboriginal and Torres Strait Islander research, consistent with the Declaration of Helsinki.[71]

The Stakeholder and Aboriginal Community Advisory Panel (SCAAP) invites at least one member from each of the pilot study AMSs and will convene bimonthly. The role of the SCAAP will be to provide cultural consultation, advice and direction to ensure that the implementation of the ICAN QUIT in Pregnancy project pilot is acceptable and respectful to the Aboriginal communities involved. The SCAAP is instrumental in ensuring research practice, data collection and dissemination of findings is appropriate to each community. Members of the SCAAP will be included in the writing and publication of research results.

Furthermore, an Aboriginal cultural liaison position is maintained throughout the study to ensure appropriate level of cultural safety, Aboriginal community ownership and engagement is upheld. The research team includes three Aboriginal Chief Investigators and four Aboriginal Associate Investigators who are involved in various aspects of the project, including the design, implementation, data analysis and interpretation.

Pregnant smokers who are mature minors (aged over 16 but under 18 years) will be included if judged by the research facilitator able to give informed consent. Consent to the audio-recording is an additional option for both health professionals and participating pregnant women, which they can agree to or decline.

All of the data collected, at all levels, are de-identified. Pregnant women participating in the study are given a unique code by the research facilitator. Any data collected are only identified with this code. Health provider's survey are linked using the date of birth and the last three digits of their surname.

All serious adverse events, and study related adverse events considered severe in nature that do not otherwise fulfil the definition of a serious adverse event, will be reported immediately by sites during follow-up. For the purposes of this study those events that will be considered a severe study related adverse events include, but are not limited to, severe allergic reaction to the NRT, and clinical depression. A data monitoring committee will not be convened for this study and was not deemed necessary by the

human research ethics committee, as NRT will be used according to current clinical guidelines.

Study outcomes will be discussed with participating services. Sites will receive a lay summary of the study outcomes, to be distributed to their community and participants of the study as they see fit. A policy brief will be distributed to Aboriginal and Government peak bodies.

Significance of Study

The ICAN QUIT in Pregnancy intervention trial was designed to overcome implementation problems identified in previous research.[45,46,72,73,74] This includes ensuring community representation in governance of the research; participant recruitment by known health staff from the service; adequate re-imbursement for time and effort of the services and women participants. This pilot phase will enable us to test the feasibility and acceptability of the intervention, and make further adjustments as necessary, prior to the expense of a large cRCT. The ICAN QUIT in Pregnancy pilot trial will provide valuable information to advance the much needed reduction in smoking rates among pregnant Indigenous women.

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Collaborators Complete list of authors of the ICAN QUIT in Pregnancy pilot group is detailed in the acknowledgements.

Contributors YBZ wrote the manuscript and contributed to the design of the study. GG contributed to writing the manuscript, and designed and oversees the study. CO and KP advised on the study design, and statistical analysis. MB contributed to the design of the study and with MG advised on Aboriginal community consultations and adherence to ethical guidelines to research with Aboriginal communities. BB and JR advised on methodology and implementation of the research. LA advised on the design of the intervention using the Theoretical Domains Framework and Behavior Change Wheel. All authors critically reviewed the manuscript.

Competing interests None declared.

Patient consent Obtained.

Ethics approval University of Newcastle Human Research Ethics Committee (HREC) (REF #H-2015-0438). Aboriginal Health & Medical Research Council (AH&MRC) HREC (REF #1140/15). South Australia Aboriginal HREC (REF #04-16-652. Far North Queensland HREC (REF #16/QCH/34 – 1040). Note: The interviews at the end of the study were not included in the original ethics application and have recently been submitted as an amendment

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Supplementary File 1

Webinar Content

Session 1:

- Background on smoking in pregnancy and relevance to vulnerable subgroups including the Indigenous context.
- Non-confrontational history taking.
- Engagement of vulnerable pregnant smokers.
- Assessment of smoking in Indigenous and vulnerable women - nicotine dependence and motivation.
- Assessing socio-cultural aspects and environmental smoking.
- Culturally competent care - importance and content.
- Non-didactic counselling styles.
- Concept and benefit of 'teachable moments'.

Session 2:

- The ABCD approach – Ask-Brief advice-Cessation medications-Discuss psychosocial context.
- Behaviour change techniques (BCTs) successful in pregnancy, e.g. goal setting, setting a quit date, problems solving, and boosting self-efficacy.
- How to tailor advice to the client.
- Interventions of differing intensity - brief to intensive.
- Involving the family in smoking management and smoke-free environments.
- Supportive counselling and follow up.
- Psychosocial support.
- Use of optimised resources.
- Referral mechanisms.
- Ancillary resources available: Quitline, on-line and mobile phone apps.

Session 3:

- Using NRT in pregnancy:
    - Initiating NRT, and how to advise about NRT - NRT algorithm for pregnancy – step-wise titration.
    - Dosage management
    - Side-effects
    - Indications/contra-indications
    - Promoting adherence
- Use of the CO meter as a motivational tool, and for monitoring and validating abstinence.
- Advising re cannabis and e-cigarettes.

Introduction to Paper Eight

Paper seven described the protocol of the ICAN QUIT in Pregnancy pilot study. As mentioned previously, this study was informed by previous research findings – part of which was described in papers one, two, three, four and five – and a strong theoretical framework, the BCW and the TDF. The ICAN QUIT in Pregnancy intervention addressed the multiple barriers that health providers face described previously, and provided clear detailed guidance to health providers to improve their management of smoking with Aboriginal pregnant women. A specific focus was put on addressing the barriers to NRT prescribing during pregnancy.

The results of this intervention, relating to the health providers' level of data collection – as the main focus of this thesis – are presented in paper eight. This data included changes in health providers' knowledge, attitudes and practices following webinar training, provision of an educational resource package and free oral NRT dispensed as needed to pregnant women who smoke. Other outcomes from the ICAN QUIT in Pregnancy pilot study are described in detail elsewhere and are not included in this thesis.

Findings from this pilot intervention informed a larger trial, powered to test the effectiveness of the intervention to improve smoking cessation rates among Aboriginal and Torres Strait Islander women.

Paper Eight:
Improving Smoking Cessation Care in Pregnancy at Aboriginal Medical Services: ICAN QUIT in Pregnancy Step-Wedge Cluster Randomized Pilot Study

Authors

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Citation

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Associated appendices

Abstract

Objectives: This study aimed to examine the impact of the 'ICAN QUIT in Pregnancy' intervention on individual health providers (HPs) smoking cessation care (SCC) knowledge, attitudes, and practices, in general, and specifically regarding nicotine replacement therapy (NRT) prescription.

Design: Step-wedge clustered randomized controlled pilot study. HPs answered a pre and 1-6 months post intervention survey.

Setting: Six Aboriginal Medical Services in three states in Australia

Participants: All HPs were invited to participate. Of 93 eligible, 50 consented (54%), 45 completed the pre survey (90%) and 20 the post (40%).

Intervention: included three one-hour webinar sessions, educational resource package, and free oral NRT.

Outcomes: HPs knowledge was measured using two composite scores - one from all 24 true/false statements, and one from 12 NRT-specific statements. Self-assessment of 24 attitudes to providing SCC were measured using a 5-point Likert scale (Strongly Disagree-Strongly Agree). Two composite mean scores were calculated - one for 15 general SCC attitudes, and one for 7 NRT-specific attitudes. Self-reported provision of SCC components was measured on a 5-point Likert scale (Never-Always). Feasibility outcomes, and data collected on the service and patient level are reported elsewhere.

Results: Mean knowledge composite scores improved significantly from pre to post (78% vs 84% correct, p=0.011). Mean NRT-specific knowledge composite score also improved significantly (68% vs 79% correct, p=0.004). Mean attitude composite score improved significantly (3.65 (SD 0.4) to 3.87 (SD 0.4); p=0.017). Mean NRT-specific attitudes composite score also improved significantly (3.37 (SD 0.6) to 3.64 (SD 0.7); p=0.005). Self-reported practices were unchanged, including prescribing NRT.

Conclusions: A multi-component culturally sensitive intervention in Aboriginal Medical Services was feasible, and might improve HPs provision of SCC to pregnant Aboriginal women. Changes in NRT prescription rates may require additional intensive measures.

Trial registry: ACTRN 12616001603404

Strengths and Limitations of this Study

- The first study in Australia that specifically targeted health providers' care for pregnant Aboriginal and Torres Strait Islander women who smoke.
- The first intervention that had a major focus on improving prescription rates of Nicotine Replacement Therapy to support smoking cessation during pregnancy.
- The intervention, including the novel use of live interactive webinar training, was informed by theory and based on a solid foundation of prior formative research.
- This study was a pilot aimed to assess feasibility, and was not powered to assess the effectiveness of the intervention.
- This study included health providers who work at Aboriginal Medical Services only, and may not be generalised to other antenatal care settings that Aboriginal and Torres Strait Islander women might attend.

Introduction

Smoking during pregnancy remains a serious public health problem. Global rates range from 0.2% to 38%, with higher rates of 30-50%, across high-priority sub-populations.[1,2] In Australia, 10% of pregnant women smoke, with the highest rates across socially disadvantaged sub populations such as Aboriginal and Torres Strait Islander women (44%) (hereafter referred to "Aboriginal" women with acknowledgement of the distinct cultures).[3] The Aboriginal population compromise 3% of the total Australian population[4], but due to historical, cultural and social reasons have the highest smoking prevalence (42%)[5,6]. Tobacco was introduced to Aboriginal people through trade with Indonesian fisherman and quickly became embedded in the social and ceremonial life.[7] Colonization had a huge impact on smoking rates as tobacco was often used by European settlers as an accepted method of payment to Aboriginal people.[8]

Reducing smoking prevalence during pregnancy can lead to significant positive impacts on long term development of Aboriginal babies and help reduce the health gap between the Non-Aboriginal and the Aboriginal population.[9] Reducing tobacco use is considered to be one of the key areas for intervention to improve infant and maternal health outcomes, under the 2018 'Closing the Gap' governmental strategy for Aboriginal Australians.[10]

Pregnant Aboriginal women face many barriers to quitting smoking,[11-13] including multiple and inter-current life stressors, and living in communities with high smoking rates. A significant barrier, commonly cited, is lack of adequate support from health providers (HPs), with inconsistent health messages often provided.[13-15]

Effective interventions to increase rates of smoking cessation during pregnancy include behavioural counselling, incentives and feedback (i.e. when the pregnant woman is offered an objective measurement of the effects of tobacco smoking, such as the level of carbon monoxide in expired air) [1].

The most recent Cochrane review on using pharmacotherapy to aid smoking cessation is pregnancy concluded that nicotine replacement therapy (NRT) increased cessation

rates by 40%.[16] However, excluding non-placebo controlled studies resulted in non-significant changes. Therefore the evidence regarding the use of NRT in pregnancy is still not robust. Furthermore, adherence to NRT was identified as a problem.[16]

Australian smoking cessation guidelines recommend the use of NRT if a pregnant woman has not been able to quit smoking with counselling alone.[17] Despite this, 25% of Australian general practitioners and Obstetricians have reported they would "never" prescribe NRT during pregnancy, with 55% reporting safety concerns about NRT use in pregnancy.[18] A recent systematic review identified that HPs are not providing pregnant women adequate support to quit, specifically in regard to behavioural counselling, referral to specialist support (such as the Quit-line), and prescription of NRT.[19] Several reviews have outlined numerous barriers HPs face to providing smoking cessation care (SCC) during pregnancy, including lack of knowledge and skills, low confidence in ability to counsel, low optimism regarding the effectiveness of treatment, lack of time and lack of resources.[20,21] The same barriers were echoed recently in two Australian studies including HPs treating Aboriginal pregnant mothers.[22,23]

To date there have been two published studies focusing on smoking cessation in Australian Aboriginal pregnant women,[24,25] neither focused on the HPs provision of care, or on the use of NRT during pregnancy. Both implemented face to face smoking cessation training of HPs as part of the intervention. Despite an increase in webinar use as a mechanism for training HPs, very few studies have tested its effectiveness in regard to smoking cessation training[26,27]. A recent systematic review on interventions to improve HPs provision of SCC during pregnancy identified 14 different interventions, none of which included webinar training, and none included components aimed specifically at improving NRT prescription [Bar-Zeev et al, Improving health providers smoking cessation care in pregnancy: a systematic review and meta-analysis].

The Indigenous Counselling and Nicotine (ICAN) Quit in Pregnancy trial[28] was a pilot study with an overall aim of testing the feasibility and acceptability of a multi-component smoking cessation training intervention for HPs in Aboriginal Medical

Services (AMSs). The intervention included three hours of live interactive webinar training, an educational resource package and free oral NRT.[28] The intervention was developed collaboratively with two AMSs, with a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP) guiding the development and implementation of the intervention to ensure Aboriginal community ownership and cultural sensitivity. A full description of the development of this intervention is provided elsewhere.[29]

The results of this pilot study will inform the development and design of a larger cluster randomized controlled trail (SISTAQUIT – Supporting Indigenous Smokers To Assist Quitting).

This study examined the impact of 'ICAN QUIT in Pregnancy' on HPs' knowledge, attitudes and practices regarding SCC during pregnancy in general, and specifically on recommending NRT during pregnancy. The usefulness of the educational resources was also assessed.

Methods

Design: The 'ICAN QUIT in Pregnancy' study was a step-wedge clustered randomized trial (Figure 1). Full details of the study can be found in the protocol manuscript (Supplemental file 1).[28] In short, six AMSs were randomised into three clusters, with the intervention sequentially delivered to each cluster two months following study commencement, staggered by one month. The trial included data collection at the service and HPs levels, and from pregnant participants with the primary outcomes focused on feasibility.[28] In this manuscript, we report on the HPs secondary outcome data. The feasibility outcomes, service level and women's level data are reported elsewhere [Gould et al, Feasibility and acceptability of Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy multicomponent implementation intervention and study design for Australian Indigenous pregnant women: a pilot cluster randomised step-wedge trial; Bovill et al, Wingadhan Birrang (woman's journey) of smoking cessation during pregnancy: Aboriginal and Torres Strait Islander women participating in the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy pilot study]. All HPs in each service were invited to receive the training, and complete a survey pre and post training (Figure 1). Originally, HPs were to complete two post surveys – one

month after receiving the training and six months post training. Few HPs completed the post survey one month post training, and multiple reminders to complete the post survey were required over the follow up period. Therefore, only one post survey was collected from each HP (between one to six months post training).

Setting: Six AMSs – one urban and five regional - in three states in Australia - New South Wales, Queensland and South Australia. The AMSs were all Aboriginal Community Controlled Health Services which are non-government organisations operated by local Aboriginal and Torres Strait Islander communities, to deliver holistic, comprehensive and culturally appropriate healthcare to the communities that govern them through an elected board of management.[30]

Participants: All of the HPs from each service were invited to participate, as long as they consulted with pregnant women either for confirmation of pregnancy, antenatal care and/or routine care; These included General Practitioners, Midwifes, Aboriginal Health Workers, and other allied HPs. Aboriginal Health Workers are Aboriginal people who have undertaken specific training to work within primary care, either in non-clinical liaison or clinical roles.[31] Managers were also welcomed to attend the training as non-participants.

Randomisation and sample size: Randomisation occurred at the service level only, with allocation of the AMSs to the clusters based on geographical convenience. For each cluster, the period of treatment crossover was randomised using simple randomisation. Due to the step-wedge cluster design, HPs from each service received the training, and completed the surveys at different time points in the study, staggered by one month between each cluster (Figure 1). Sample size calculations for this study were guided by the primary outcome of pregnant women's recruitment rate[28], assuming that for each service the expected recruitment would be 10 eligible consenting women. This resulted in six services participating, with an expected 5-10 HPs eligible at each service (total 30-60 HPs).[28]

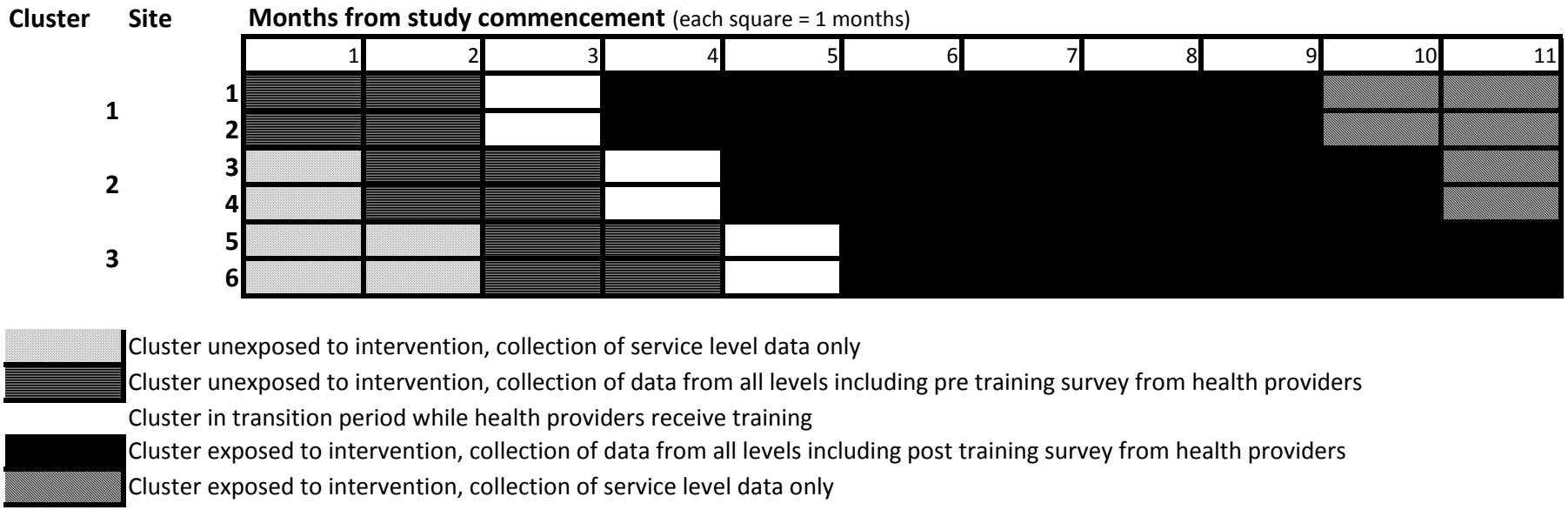


Figure 1: Schematic illustration of the step-wedge cluster study for the Indigenous Counselling And Nicotine (ICAN) QUIT in pregnancy Pilot Study

Intervention: included a) three one-hour sessions of live interactive webinar training for HPs, b) an educational resource package for both HPs and pregnant women, and c) free oral forms of NRT to be dispensed to women on-site.[28,32]

a) Webinar training was chosen to accommodate time and location constraints, important for future potential scaling of the intervention to other regional and remote AMSs. Webinars included PowerPoint presentations, embedded short videos and group discussions.[32] A full description of the webinar content can be found in Supplemental file 2. The webinars were recorded and supplied to each service. This enabled training for those HPs that could not attend the live webinar, and allowed HPs to view the webinar again if needed. Originally, the webinars were planned to be weekly, over three weeks, but all the services requested them to be in one three-hour time slot, due to HPs time limits.
b) The educational resource package included resources specifically for the HPs (a treatment manual, and a mousepad depicting the NRT treatment algorithm to act as a prompt), resources specifically for the women (patient booklet, posters showing different NRT options and the differences in chemical content between NRT and a cigarette), and resources for a joint discussion (a flipchart). Development and assessment of these resources, and full details regarding the intervention can be found elsewhere.[28,32,33] The educational resource package was provided to the services both in hard copies (one for each HP), and in a digital copy.
c) All forms of oral NRT were supplied to the services (gum, lozenge, spray, and inhalator) to be provided as needed free of charge to the women. Originally, oral NRT was to be supplied through a pharmacy voucher system, but all of the services requested that it would be dispensed directly at the service, to accommodate time and travel constraints for their patients. Due to the higher metabolism in pregnancy[34], it was advised to initiate treatment with the higher oral NRT dose (such as the 4 mg gum or 4 mg lozenge). Services were supplied with sample packs for each woman, and supplies to last for a three months

treatment period. NRT patches were available for free under the Australian government Pharmaceutical Benefits Scheme (PBS).[35] In Australia, NRT can be bought without a prescription at pharmacies, but in order to qualify for the PBS subsidisation, a script from a medical doctor is required.[35]

The original plan was to include audit and feedback through collection of monthly de-identified computerized data from each service regarding NRT prescription rates to pregnant women, providing each service with a monthly report on their prescription rates, compared to the other services in the study.[28] Unfortunately, audit and feedback was not feasible as services took a few months to organize the computerized data, and only four services were able to provide the data regarding NRT prescriptions to pregnant women [Gould et al, Feasibility and acceptability of Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy multicomponent implementation intervention and study design for Australian Indigenous pregnant women: a pilot cluster randomised step-wedge trial].

The HPs training followed the ABCD approach for brief behavioural counselling for Aboriginal pregnant women (Ask about smoking; Brief advice to quit; provide Cessation support; and Discuss the psychosocial context of smoking), together with an expedited offer of NRT if a woman is unable to quit without medication.[36] The training included specific guidance and resources focusing on improving knowledge and skills for recommending NRT during pregnancy.[28,32,33]

Development of the intervention was based on formative research,[13,18,37-41], and extensive consultation with Aboriginal stakeholders and communities.[29,33] Development was also informed by a rigorous theoretical analysis,[32] based on the Behaviour Change Wheel[42] and the linked Theoretical Domains Framework (TDF).[43] The Behaviour Change Wheel is a parsimonious model developed from an overarching synthesis of behaviour intervention frameworks.[42] The TDF is a validated and integrative theoretical framework developed for behaviour change research and cross-disciplinary implementation.[43,44] The TDF covers a range of domains known to be relevant to professional behaviour change and has been applied across a wide range of

clinical situations.[44] Both the Behaviour Change Wheel and the TDF are used to practically identify and remediate barriers to achieving evidence-based care.

Survey: A 102-item self-administered online or hard copy survey. Complete description of the survey measures can be found in Supplemental file 1[28].

The items reported in this paper are:

SCC Knowledge: was measured with a total composite score of 24 true/false statements. Of these, 12 statements were related to NRT use in pregnancy, so two additional separate knowledge composite scores were calculated – one specific to NRT (12 statements) and one general knowledge composite score (12 statements).

Attitudes to providing SCC: were measured using 5-point Likert scales (Strongly disagree (1), to Strongly agree (5); or Not often (1) to Very often (5)) for 15 statements covering 13 domains from the TDF[44] (knowledge, reinforcement, role/identity, beliefs about capabilities, optimism, beliefs about consequences, social influence/subjective norm, goals/ priority, memory/attention, environmental context and resources, emotions/stress, intentions, behavioural regulation). The Likert scales were dichotomised to 'Agree/Strongly agree' versus the rest; or 'Not often (1)/(2) versus rest. A mean composite score was created for all of the TDF domains. Seven domains from the TDF included an additional separate question regarding the prescription or recommendation of NRT (knowledge, role/identity, beliefs about capabilities, optimism, intentions, goals/ priority, memory/attention); measured and dichotomized as above. A mean composite score for all NRT-specific TDF statements was also created.

In addition, self-reported perceptions of using NRT in pregnancy were measured, rating the safety for the foetus (dichotomized to 'Very safe/Always safer than smoking' vs else), effectiveness in NRT as an aid to pregnant smokers to quit (dichotomized to 'Very/Moderately effective vs 'Low' effectiveness) and perceived adherence of pregnant smokers' use of NRT (dichotomized to 'Most adhere well' vs Equal numbers adhere well and poorly /Few adhere well).

Provision of SCC: was measured using 5-point Likert scales (Never to Always) on 12 different SCC components (Supplemental file 1). The Likert scales were dichotomised into 'Often/Always' versus the rest. NRT prescription was also measured in proportion reporting 'Never' prescribing NRT (dichotomized to 'Never' vs else). HPs assessment of exposure to other substances that include nicotine (such as electronic cigarette or second hand smoke, see Supplemental file 1) was measured and dichotomized as above.

Usefulness of educational resources: was measured using 5-point Likert scales (Not useful at all to Very useful) for each webinar session and for each educational resource.

Analysis: Demographic and patient or practice information are presented as means (standard deviations (SD)), or counts (%). Changes between the time points were examined using mixed modelling to account for repeated measures on some of the HPs. Outcomes with Likert scale answers were originally modelled using ordinal logistic mixed modelling, however, due to low numbers none of the models converged. Therefore, responses were dichotomised and logistic mixed modelling was used. Results are presented for each response, and the odds ratio for the dichotomised outcome (with 95% confidence interval; post compared to pre) was calculated. Mean composite scores were modelled using linear mixed modelling; crude mean scores for each time point and differences (beta) with 95% CI (post compared to pre) are presented. Model residuals were checked for heterogeneity and linearity and found to be acceptable for all models.

Sensitivity analysis of paired HPs responses: was performed using responses from HPs who completed both pre and post surveys; Wilcoxon signed rank test was used to compare ordinal responses, and paired t-test to compare composite means between the two time points.

Statistical analyses were programmed using SAS v9.4 (SAS Institute, Cary, North Carolina, USA). A priori, $p<0.05$ (two-tailed) was used to indicate statistical significance.

Registration: The study was registered with the Australian and New Zealand Clinical Trials Registry (Ref #: ACTRN12616001603404).

Ethics: Approval for this study was granted by the University of Newcastle Human Research Ethics Committee (HREC) (REF #H-2015-0438). Aboriginal Health & Medical Research Council (AH&MRC) HREC (REF #1140/15). South Australia Aboriginal HREC (REF #04-16-652. Far North Queensland HREC (REF #16/QCH/34 – 1040).

Patient (HPs) involvement: The study was designed in collaboration with two AMSs who also participated in the study.[29] A working party that consisted of various health providers (and female community members) met with the researchers to collaboratively develop the educational resource package, which was also tested through focus groups of HPs from three other AMSs participating in the study[33]. Each service employed one HPs (either an Aboriginal Health Worker or a Midwife) to act as the research facilitator. They were in charge of recruiting HPs and conduct of the study. At the end of the study, members of the research team visited each service and discussed study results. An infographic showing study results was sent to all services.

Results

Of 93 eligible HPs in the six services, 50 (54%) consented and filled out at least one survey – 45 (90%) completed the pre-training survey and 20 (40%) completed the post-training survey. Fifteen (30%) HPs completed both surveys (Table 1). Overall, 39 (42%) HPs participated in the webinar training. Figure 2 shows the breakdown of HPs for each service according to eligibility, training attendance and survey completion. HPs recruitment rate at the different AMSs ranged from 33% to 72%. All types of HPs were recruited, including 17 general practitioners, 17 nurses/midwives, 10 Aboriginal Health Workers, and 6 other (e.g. social worker). One service (#6) did not provide any post-training surveys. Post surveys were completed between 1-6 moths post intervention (range 29-182, mean 97.5 days SD 46.8).

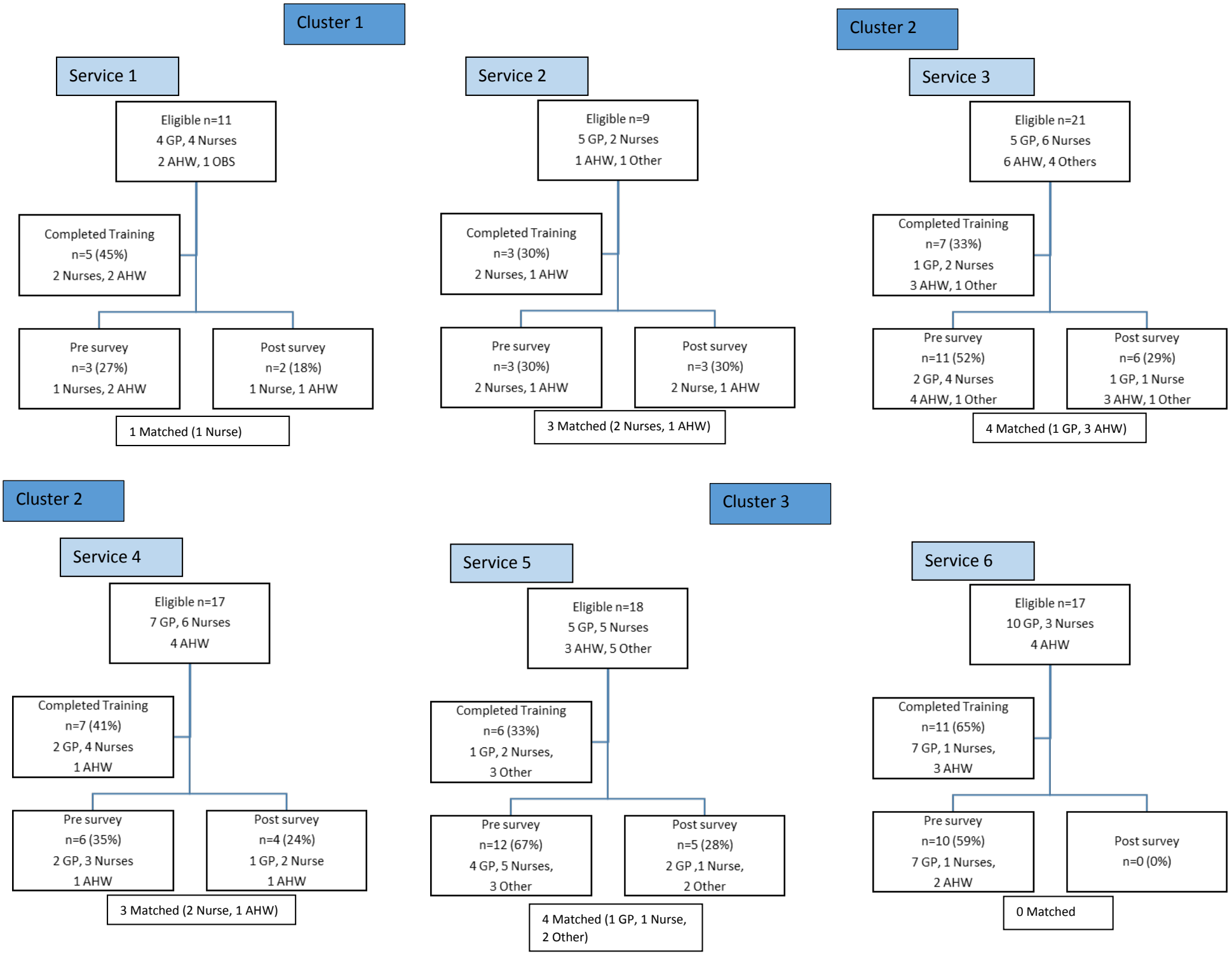


Figure 2: Health providers eligibility, recruitment and retention per service

Table 1: Demographic characteristics of participants (n=50), n(%)

Characteristic	Total n=50	Pre-training n=45	Post-training n=20
Age (mean, standard deviation)	43.8±10.6	43.7±11.07	45.6±10.04
Gender – Female	43 (86%)	39 (86.7%)	18 (90%)
Smoking Status			
Current smoker (daily and occasional)	5 (10%)	5 (11.1%)	2 (10%)
Ex-smoker	17 (34%)	13 (28.9%)	10 (50%)
Never smoker	28 (56%)	27 (60%)	8 (40%)
Profession			
General Practitioner	17 (34%)	15 (33.3%)	4 (20%)
Midwife/Nurse	16 (32%)	16 (35.6%)	6 (30%)
Aboriginal Health Worker	10 (20%)	9 (20%)	5 (25%)
Other*	7 (14%)	5 (11.1%)	5 (25%)
Work experience			
Less than 10 years	24 (48%)	20 (44.4%)	13 (65%)
10-19 years	10 (20%)	10 (22.2%)	1 (5%)
20 or more years	16 (32%)	15 (33.3%)	6 (30%)
Service			
1	4 (6%) (1 matched)	3 (6.7%)	2 (10%)
2	3 (6%) (3 matched)	3 (6.7%)	3 (15%)
3	13 (26%) (4 matched)	11 (24.4%)	6 (30%)
4	7 (14%) (3 matched)	6 (13.3%)	4 (20%)
5	13 (26%) (4 matched)	12 (26.7%)	5 (25%)
6	10 (20%) (0 matched)	10 (22.2%)	0 (0%)

*Other professions included all other allied health professionals including family strengthening worker, social worker, and psychologist

SCC Knowledge: Total knowledge mean composite score improved significantly from pre to post (77.9% vs 84% correct, beta (95%CI) 5.95 (1.57, 10.32), p=0.011). Breaking the total knowledge composite score into an NRT-specific and a non NRT-specific mean composite scores shows a significant improvement for NRT-specific score but not for

the non-NRT-specific score (78.8% vs 68.2% correct, beta (95%CI) 9.9 (3.66, 16.14), p=0.004; and 89.2% vs 88%, beta (95%CI) 1.89 (-3.46, 7.24), p=0.462); respectively).

Attitudes to providing SCC: Table 2 provides crude responses and logistic modelling odds ratio (OR) for all TDF domains. Seventy five percent of HPs reported 'Strongly agreeing/Agreeing' to having sufficient resources post intervention compared to 36.4% pre intervention (OR 5.66, 95%CI 1.44, 22.27, p=0.017). Optimism for effectiveness of their intervention with pregnant women who smoked showed a non-significant, but substantial effect size for improvement (60% post vs 31.8% pre, OR 3.3, 95% CI 0.95, 11.51, p=0.059). Similarly, a non-significant, but substantial effect size was seen for reporting 'Not often' forgetting to provide counselling (75% post vs 59.1% pre, OR 2.21 95%CI 0.55, 8.87, p=0.239). Five out of the seven TDF domains NRT-specific questions also showed a non-significant, but substantial effect size (knowledge about how to counsel on NRT, confidence in ability to recommend/prescribe NRT, optimism that NRT will be effective, intention to prescribe NRT, and less often forgetting to recommend/prescribe NRT, (Table 2)).

The total mean composite score for the general TDF domains improved significantly from 3.65 (SD 0.4) to 3.87 (SD 0.4) (Beta 0.23, 95%CI 0.05, 0.41, p=0.017). Mean composite NRT-specific TDF score was also significantly improved from 3.37 (0.6) to 3.64 (0.7) (Beta 0.36, 95% CI 0.13, 0.6, p=0.005).

Table 3 shows the responses for self-reported perceptions on NRT safety, effectiveness and adherence, all showing a non-significant but substantial effect size for improvement.

Table 2: Crude responses and logistic modelling for the odds of agreeing with the TDF statements pre and post intervention

Crude rates							Logistic mixed modelling (Strongly agree/Agree vs Rest)	
Theoretical Domains Framework Statement	**Time point**	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Odds Ratio (95% CI)**	**p-value**
I know how to counsel women about their smoking during pregnancy	Pre	0 (0%)	8 (18.2%)	10 (22.7%)	23 (52.3%)	3 (6.8%)	1.34 (0.36, 4.97)	0.637
	Post	0 (0%)	1 (5%)	6 (30%)	10 (50%)	3 (15%)		
I am sufficiently reimbursed financially to manage smoking during pregnancy	Pre	7 (16.3%)	10 (23.3%)	16 (37.2%)	7 (16.3%)	3 (7%)	2.84 (0.72, 11.18)	0.124
	Post	3 (15%)	3 (15%)	5 (25%)	8 (40%)	4 (20%)		
Counselling women about smoking during pregnancy is part of my work as a health provider	Pre	0 (0%)	1 (2.3%)	6 (13.6%)	15 (34.1%)	22 (50%)	1.76 (0.26, 12.06)	0.539
	Post	0 (0%)	0 (0%)	2 (10%)	7 (35%)	11 (55%)		
I am confident that I can counsel women about their smoking during pregnancy	Pre	1 (2.3%)	4 (9.3%)	8 (18.6%)	21 (48.8%)	9 (20.9%)	1.36 (0.34, 5.32)	0.647
	Post	0 (0%)	1 (5%)	4 (20%)	8 (40%)	7 (35%)		
I am optimistic my intervention for smoking during pregnancy is likely to be effective	Pre	1 (2.3%)	6 (13.6%)	23 (52.3%)	14 (31.8%)	0 (0%)	3.3 (0.95, 11.51)	0.059
	Post	0 (0%)	0 (0%)	8 (40%)	9 (45%)	3 (15%)		
In my workplace, it is routine to help women to quit smoking during pregnancy	Pre	0 (0%)	1 (2.3%)	8 (18.2%)	19 (43.2%)	16 (36.4%)	1.54 (0.30. 7.99)	0.584
	Post	0 (0%)	1 (5%)	2 (10%)	7 (35%)	10 (50%)		
I have sufficient time to help pregnant women to quit smoking	Pre	1 (2.3%)	12 (27.3%)	10 (22.7%)	13 (29.5%)	8 (18.2%)	1.14 (0.33, 3.92)	0.825
	Post	2 (10%)	3 (15%)	5 (25%)	10 (50%)	0 (0%)		
I have sufficient resources to help pregnant women to quit smoking	Pre	2 (4.5%)	13 (29.5%)	13 (29.5%)	10 (22.7%)	6 (13.6%)	5.66 (1.44, 22.27)	0.017
	Post	0 (0%)	4 (20%)	1 (5%)	9 (45%)	6 (30%)		
Raising the issue of smoking with a client during pregnancy will benefit our relationship	Pre	1 (2.3%)	2 (4.5%)	21 (47.7%)	15 (34.1%)	5 (11.4%)	1.24 (0.35, 4.39)	0.719
	Post	0 (0%)	1 (5%)	9 (45%)	6 (30%)	4 (20%)		
My colleagues would approve of me helping pregnant women quit smoking	Pre	0 (0%)	0 (0%)	3 (6.8%)	17 (38.6%)	24 (54.5%)	0.66 (0.08, 5.13)	0.669
	Post	0 (0%)	0 (0%)	2 (10%)	6 (30%)	12 (60%)		
I am comfortable raising the issue of smoking with a pregnant women	Pre	0 (0%)	1 (2.3%)	0 (0%)	17 (38.6%)	26 (59.1%)	Model did not converge; OR not shown	
	Post	0 (0%)	0 (0%)	0 (0%)	7 (35%)	13 (65%)		
I intend to provide smoking cessation support to all my pregnant patients who smoke	Pre	0 (0%)	1 (2.3%)	2 (4.5%)	23 (52.3%)	18 (40/9%)	0.77 (0.09, 6.9)	0.804
	Post	0 (0%)	0 (0%)	2 (10%)	7 (35%)	11 (55%)		
My workplace has a system in place to monitor whether I deliver cessation support to pregnant women	Pre	6 (13.6%)	7 (15.9%)	6 (13.6%)	16 (36.4%)	9 (20/5%)	1.47 (0.41, 5.27)	0.527
	Post	1 (5%)	1 (5%)	5 (25%)	3 (15%)	10 (50%)		

Theoretical Domains Framework Statement	Time point	Not Often	2	3	4	Very Often	Odds Ratio (95% CI)	p-value
Generally, when seeing pregnant women who smoke, how often is covering something else on your agenda a higher priority than counselling these women	Pre	5 (11.4%)	8 (18.2%)	11 (25%)	14 (31.8%)	6 (13.6%)	0.56 (0.13, 2.42)	0.406
	Post	2 (10%)	2 (10%)	5 (25%)	6 (30%)	5 (25%)		
How often do you forget to counsel women who come in to you who are smoking during pregnancy	Pre	16 (36.4%)	10 (22.7%)	10 (22.7%)	8 (18.2%)	0 (0%)	2.21 (0.55, 8.87)	0.239
	Post	7 (35%)	8 (40%)	3 (15%)	1 (5%)	1 (5%)		
NRT-specific Statements								
Theoretical Domains Framework Statement	**Time point**	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Odds Ratio (95% CI)**	**p-value**
I know how to counsel women about the use of NRT during pregnancy	Pre	3 (6.8%)	10 (22.7%)	9 (20.5%)	17 (38.6%)	5 (11.4%)	1.56 (0.44, 5.47)	0.46
	Post	0 (0%)	1 (5%)	7 (35%)	8 (40%)	4 (20%)		
Recommending/prescribing NRT for pregnant smokers is part of my work as a health provider	Pre	2 (4.5%)	2 (4.5%)	11 (25%)	21 (47.7%)	8 (18.2%)	1.26 (0.35, 4.49)	0.707
	Post	1 (5%)	0 (0%)	5 (25%)	7 (35%)	7 (35%)		
I am confident that I can recommend/prescribe NRT for pregnant smokers	Pre	3 (6.8%)	6 (13.6%)	10 (22.7%)	20 (45.5%)	5 (11.4%)	1.82 (0.47, 7.04)	0.36
	Post	1 (5%)	2 (10%)	3 (15%)	9 (45%)	5 (25%)		
I am optimistic that recommending/prescribing NRT for smoking cessation during pregnancy is likely to be effective	Pre	2 (4.5%)	5 (11.4%)	22 (50%)	15 (34.1%)	0 (0%)	2.37 (0.72, 7.75)	0.141
	Post	0 (0%)	1 (5%)	8 (40%)	10 (50%)	1 (5%)		
I intend to recommend NRT to my pregnant patients who smoke	Pre	1 (2.3%)	1 (2.3%)	14 (31.8%)	18 (40.9%)	10 (22.7%)	1.86 (0.48, 7.13)	0.341
	Post	0 (0%)	0 (0%)	5 (25%)	8 (40%)	7 (35%)		
Theoretical Domains Framework Statement	**Time point**	**Not Often**	**2**	**3**	**4**	**Very Often**	**Odds Ratio (95% CI)**	**p-value**
Generally, when seeing pregnant women who smoke, how often is covering something else on your agenda a higher priority than prescribing/recommending NRT for these women	Pre	4 (9.1%)	9 (20.5%)	7 (15.9%)	19 (43.2%)	5 (11.4%)	0.54 (0.13, 2.33)	0.383
	Post	1 (5%)	3 (15%)	6 (30%)	5 (25%)	5 (25%)		
How often do you forget to prescribe/recommend NRT for a pregnant woman who smokes?	Pre	13 (29.5%)	11 (25%)	8 (18.2%)	11 (25%)	1 (2.3%)	1.97 (0.55, 7.05)	0.274
	Post	8 (40%)	6 (30%)	3 (15%)	1 (5%)	2 (10%)		

Table 3: Crude responses and logistic mixed modelling for perceptions regarding NRT safety, efficacy and adherence

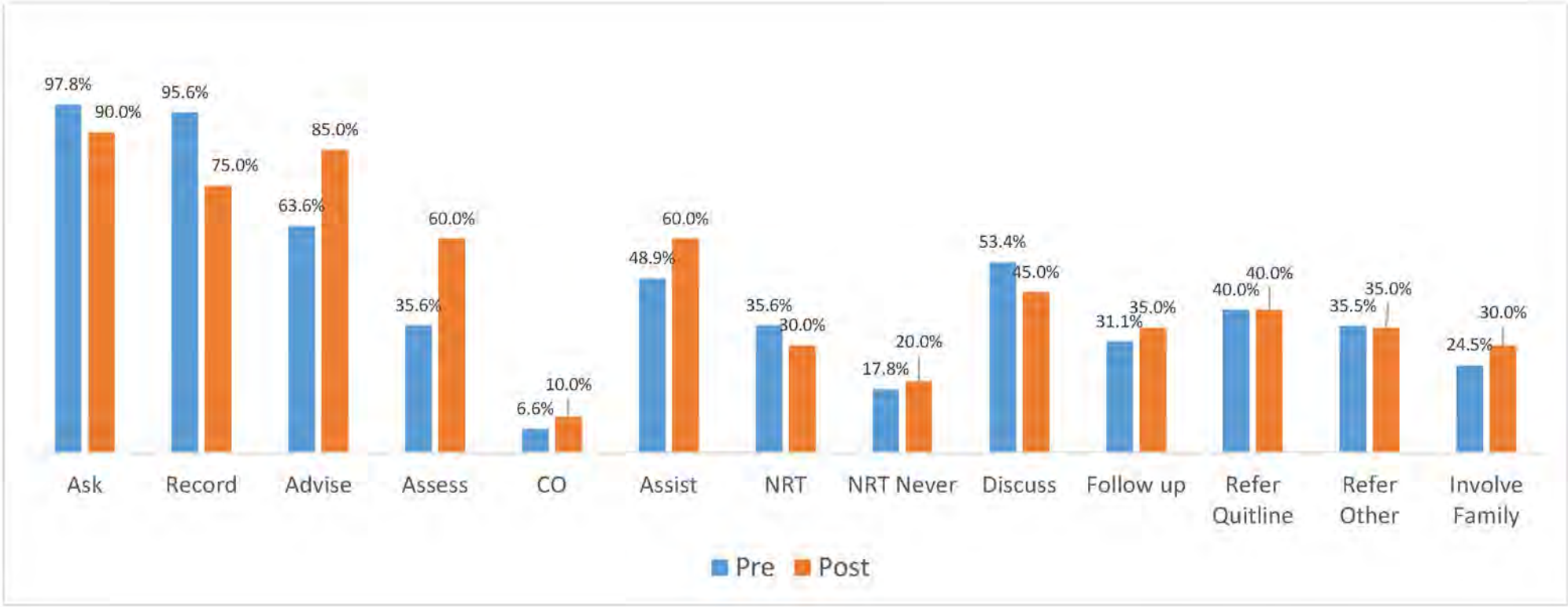
	Time point	Very safe	Always safer than smoking	Safer than smoking but some concerns	Not safe	Logistic mixed modelling	
						Odds Ratio (95% CI) (Very safe/Always safer vs rest)	p-value
NRT Safety	Pre	2 (4.5%)	20 (45.5%)	20 (45.5%)	2 (4.5%)	2.37 (0.66, 8.57)	0.171
	Post	2 (10%)	12 (60%)	6 (30%)	0(0%)		
	Time point	**Very effective**	**Moderately effective**	**Low effectiveness**	**Not effective**	**Very/Moderately effective vs rest**	**p-value**
NRT Effectiveness	Pre	6 (14%)	29 (67.4%)	8 (18.6%)	0 (0%)	4.32 (0.41, 46.1)	0.206
	Post	4 (20%)	15 (75%)	1 (5%)	0 (0%)		
	Time point	**Most adhere to NRT well**	**Equal numbers adhere well and poorly**	**Few adhere to NRT well**		**Adhere well vs rest**	**p-value**
NRT Adherence	Pre	4 (9.3%)	23 (53.5%)	16 (37.2%)		4.24 (0.9, 19.93)	0.065
	Post	6 (30%)	8 (40%)	6 (30%)			

Provision of SCC: is shown in figure 3 and Supplemental file 3. The odds of reporting on the provision of the different SCC components 'Often/Always' did not change significantly pre to post intervention, with the exception of 'Recording smoking status' in the medical file, which was significantly reduced (96% vs 75% for pre and post respectively, OR 0.14 95% CI 0.02, 0.97, p=0.047). 'Advise to quit smoking', 'Assess nicotine dependence' and 'Assist (provide cessation support)', showed a non-significant, but substantial effect size for improvement. No change was observed for self-report on NRT prescribing rate (neither an increase in reporting 'Often/Always' prescribing, or a decrease in 'Never' prescribing).

The odds of reporting 'Often/Always' assessing the use of cannabis were unchanged pre to post training (OR 1.00, 95%CI 0.24, 4.11, p=0.998). Assessing all other substances that expose the foetus to nicotine, showed a non-significant, but substantial effect size for improvement, including the use of electronic cigarettes with nicotine (OR 2.09, 95%CI 0.43, 10.17, p=0.2), chewing tobacco (OR 2.67, 95%CI 0.55, 13.01, p=0.2) and second hand smoke (OR 2.51, 95%CI 0.68, 9.31, p=0.15).

Usefulness of educational resources (n=20, post follow-up only): All of the resources except the mouse pad were rated as useful with a mean ranging from 3.89 (SD 1.1) for the patient flipchart to 4.17 (SD 0.9) for the different types of NRT poster (median 'useful (4)', mode 'very useful (5)' for all). The mouse pad was rated as somewhat useful, with a mean of 3.22 (SD 1.2) (both median and mode 'somewhat useful'). The webinar sessions were also rated as useful with a mean of 3.6 (SD 0.9), 3.8 (SD 1.0), and 3.9 (SD 1.0) for session 1, 2, and 3 respectively (with both median and mode 'useful', except for session 3 (dedicated to NRT) which had a mode of 'very useful'). Eighty per cent (n=16) of participants reported reading at least part of the treatment manual, but only four reported reading all of the manual from front to back.

Figure 3: Proportion of health providers self-reporting provision of SCC components 'Often/Always' vs else (and for NRT prescription also 'Never' vs else)



Sub-analysis of paired HPs responses: similar results were seen for the paired analysis, except for assessment of other substance use that did not show any improvement in the paired analysis (Supplemental file 4). As in the non-paired analysis, both mean knowledge composite score (post 5.8% higher than pre, p=0.015) and NRT-specific knowledge composite score (9.4% higher than pre, p=0.009) improved significantly; and the total mean composite score for the general TDF domains improved significantly from 3.65 (SD 0.4) to 3.91 (SD 0.4) (Beta 0.26, 95%CI 0.04, 0.47, p=0.021). Mean composite NRT-specific TDF score was also significantly improved from 3.4 (0.5) to 3.84 (0.5) (Beta 0.44, 95% CI 0.2, 0.67, p=0.001). Significant improvements were seen in self-reported attitudes including optimism (Wilcoxon signed rank, p=0.027); knowledge on NRT (p=0.031); perception that recommending/prescribing NRT is part of HPs work (p=0.045); and intention to prescribe NRT (p=0.045). 'Assessing' nicotine dependence also showed a significant improvement (p=0.04).

Discussion

Principal Results

'ICAN QUIT in Pregnancy' was a pilot multi-component intervention, including live interactive webinar training. Preliminary underpowered findings showed an improvement in HPs knowledge and attitudes towards providing SCC in pregnancy. Furthermore, a non-significant, but substantial effect size was observed for improvement in several practices ('Advise', 'Assess' and 'Assist'), and in assessment of overall exposures to tobacco and nicotine, including second-hand smoke and electronic cigarette use. NRT-specific knowledge and attitudes also improved, although no change was seen in self-reported NRT recommendation/prescription rates.

Limitations and Strengths

This study was a pilot study not powered to test effectiveness of changes in HPs knowledge, attitudes and practices. Our findings are suggestive that the intervention might improve knowledge, attitudes and some practices, but more conclusive results will require a larger trial. These results inform the design of SISTAQUIT®, which will include 30 AMSs nationally in Australia, and will be powered to test intervention effectiveness, inclusive of smoking cessation as an outcome for Aboriginal pregnant

women. A major limitation of the current study was the low retention rates of the HPs, resulting in only 40% providing a post-training survey, and only one follow-up survey (instead of the planned two). The variability around when the post survey was completed is another limitation, as changes in knowledge, attitudes and practices may change over time. The low retention rates and small sample size limits our ability to interpret the findings, and to generalize them to all HPs and services, while raising the question of a selection bias. Assuming those who chose to answer the post-training survey might be the ones that benefited most from the intervention, actual changes in HP attributes may in reality be lower than results reported. Participating HPs might have been those who had more interest in smoking cessation, thus representing better performing HPs. Despite this, to the best of our knowledge this is the most extensive study to date undertaken within Australian AMSs evaluating smoking cessation during pregnancy. Inclusion of six services, from three different states, aids the potential generalizability of these findings.

Comparison with Prior Work

A recent systematic review identified 16 interventions on smoking cessation during pregnancy, which included data on HPs [Bar-Zeev et al, Improving health providers smoking cessation care in pregnancy: a systematic review and meta-analysis]. This review found that interventions had a modest positive impact on the various SCC components. A few interventions also included data regarding knowledge and attitudes of HPs[45-49] also showing an overall positive increase. None of the interventions included in this review were tailored to HPs treatment in Indigenous populations, although a few were conducted with HP treating low socio-economic populations.[45,47,50-52] Our results are similar and provide further evidence that interventions can modestly increase HPs knowledge, attitudes and practices in supporting pregnant women to quit smoking; including in an Aboriginal context.

None of the interventions included in this systematic review incorporated any components specifically addressing NRT prescription, and/or knowledge and attitudes regarding NRT prescription, with only one measuring changes in NRT prescription rates pre and post intervention, with no differences observed.[53] Our intervention was designed specifically to address low NRT prescription rates, and is the first to include

specific measures on knowledge, attitudes and practices of recommending/prescribing NRT during pregnancy.

None of the previous interventions focusing on HPs care during pregnancy used webinar as the training delivery method [Bar-Zeev et al, Improving health providers smoking cessation care in pregnancy: a systematic review and meta-analysis]. Lack of time, limited funding and lack of training are consistent barriers identified for health services and HPs to provide SCC during pregnancy[20,22,54]. Webinar is a novel approach and, if found to be effective in the SISTAQUIT® trial, might provide an effective measure to conduct training and skill development, reducing both costs and time for travel. Thus, webinar training may be suitable specifically within rural and remote medical services. To the best of our knowledge, this study was the first to use this training mode for improving SCC during pregnancy.

Implication for Policy and Future Research

As part of this intervention, oral NRT was supplied free within the service directly to the women throughout the study period. NRT patches were to be supplied as usual by providing women with a prescription, which they would fill at a pharmacy for a subsidized governmental rate. An analysis of actual provision of oral NRT [Gould et al, Feasibility and acceptability of Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy multicomponent implementation intervention and study design for Australian Indigenous pregnant women: a pilot cluster randomised step-wedge trial] throughout the study showed that 55% (12/22) of recruited women accepted an oral NRT offer, with 6/12 reporting using it at least occasionally. The data on NRT acceptance and usage might suggest that although HPs completing the post-survey did not report changing NRT practices, their improved NRT related knowledge and attitudes might have contributed to women's perception and NRT acceptance levels. Computerized data from four services showed that government prescriptions for the NRT patch did not change across three services, and improved in one service (from one women offered a prescription pre-training to four women post training). Having the oral NRT within the service, supplied 'on the spot' free of charge, may have had an impact on both HPs and women's practices, not reflected by the post-survey of HPs. Reducing cost and logistic barriers may be helpful to improving use of NRT in pregnancy.

Assessment of overall nicotine exposure of the foetus is important as nicotine in itself may be harmful, especially to the lung and brain development.[55,56] Previous research has shown that over 75% of Australian HPs ask about tobacco use during pregnancy,[22,57] yet the proportion asking about exposure to other nicotine-containing products is limited (9-38%).[58] Raising awareness of these exposures by training is important with the emergence of new nicotine-containing products, such as electronic cigarettes, and the uncertainties around the harm versus benefit of these alternate products in pregnancy. HPs should advise women that the best health benefits are seen with complete elimination of nicotine exposure in all forms. Future research needs to address whether, similar to NRT,[16,17] electronic cigarettes can offer a 'harm reduction' strategy for pregnant women as well.

We were unable to provide the audit and feedback component at a service level as planned [Gould et al, Feasibility and acceptability of Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy multicomponent implementation intervention and study design for Australian Indigenous pregnant women: a pilot cluster randomised step-wedge trial]. Audit and feedback has been found to be an important component in interventions aimed at changing HPs behaviour in general[59]. Future interventions should find ways to incorporate this as a feasible and acceptable method.

Changes to the future SISTAQUIT design

Results from this study have informed intervention development for the SISTAQUIT trial, including further incentives for HPs to participate (such as category one continuing professional development points and a prize-draw for survey completion). Surveys will be shortened, and training case study discussions will include videoed examples featuring the ABCD methods and how to conduct discussions about NRT with the pregnant woman. A full description of the recommended changes is described elsewhere [Gould et al, Feasibility and acceptability of Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy multicomponent implementation intervention and study design for Australian Indigenous pregnant women: a pilot cluster randomised step-wedge trial].

The 'ICAN QUIT in Pregnancy' pilot intervention was feasible with promising preliminary results. Strategies to increase HPs provision of NRT need to be improved, and the webinar training has been refined for the larger SISTAQUIT study. However,

even a small increase in smoking cessation rates can have significant positive health impacts, both for the mother and baby, and help close the health and life expectancy gap between the Aboriginal and non-Aboriginal Australian population.

Conclusions

Training HPs through live interactive webinar training and provision of educational resources was feasible, and might have a positive impact on HPs provision of SCC to pregnant Aboriginal women. Changes in NRT prescription rates may require additional intensive measures. The AMSs have a significant role in the Aboriginal community, therefore improving capacity to support pregnant Aboriginal women to quit is vital and should be part of a comprehensive approach to tackle Aboriginal smoking rates during pregnancy. Using webinar training may have the potential to save both time and funds, thus suitable especially for rural and remote medical services.

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Data sharing statement

No additional unpublished data is available

Competing Interests Statement

YBZ has received funds in the past (2012-2015) from Novartis NCH who used to distribute NRT in Israel. She has not received any funding from pharmaceutical companies in Australia. All other authors declare no conflict of interest.

Author Contributions

Gillian S. Gould, Yael Bar-Zeev and Michelle Bovill conceived and designed the study. Yael Bar-Zeev led the data collection and analysis plan, and wrote the manuscript. Michelle Bovill and Maree Gruppetta advised on Aboriginal community consultations and adherence to ethical guidelines to research with Aboriginal communities. Billie Bonevski and Jennifer Reath advised on methodology and implementation of the research. Kerrin Palazzi performed the statistical analysis, and Chris Oldmeadow oversaw the analysis and advised on methodology. Lou Atkins advised on the design and the analysis using the Theoretical Domains Framework and Behaviour Change Wheel. The 'ICAN QUIT in Pregnancy' Pilot Group advised on the research design and

implementation. Gillian S. Gould oversaw the entire study. All co-authors critically reviewed and approved the final manuscript.

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Supplemental File 2

Webinar Content

Session 1:

- Background on smoking in pregnancy and relevance to vulnerable subgroups including the Indigenous context.
- Non-confrontational history taking.
- Engagement of vulnerable pregnant smokers.
- Assessment of smoking in Indigenous and vulnerable women - nicotine dependence and motivation.
- Assessing socio-cultural aspects and environmental smoking.
- Culturally competent care - importance and content.
- Non-didactic counselling styles.
- Concept and benefit of 'teachable moments'.

Session 2:

- The ABCD approach – Ask-Brief advice-Cessation medications-Discuss psychosocial context.
- Behaviour change techniques (BCTs) successful in pregnancy, e.g. goal setting, setting a quit date, problems solving, and boosting self-efficacy.
- How to tailor advice to the client.
- Interventions of differing intensity - brief to intensive.
- Involving the family in smoking management and smoke-free environments.
- Supportive counselling and follow up.
- Psychosocial support.
- Use of optimised resources.
- Referral mechanisms.
- Ancillary resources available: Quitline, on-line and mobile phone apps.

Session 3:

- Using NRT in pregnancy:
    - Initiating NRT, and how to advise about NRT - NRT algorithm for pregnancy – step-wise titration.
    - Dosage management
    - Side-effects
    - Indications/contra-indications
    - Promoting adherence
- Use of the CO meter as a motivational tool, and for monitoring and validating abstinence.
- Advising re cannabis and e-cigarettes.

Supplemental File 3

Crude Responses and Logistic Modelling for the Odds of Responding 'Often/Always' for All Practices Post (n=20) vs Pre (n=45) Intervention

Practice	Time Point	Crude rates					Logistic Mixed Modeling (Often/Always vs rest)	
		Never	Occasional	Sometimes	Often	Always	OR (95% CI)	p-value
Ask about smoking status	Pre	0 (0%)	0 (0%)	1 (2.2%)	12 (26.7%)	32 (71.1%)	0.21 (0.01, 3.23)	0.241
	Post	2 (10%)	0 (0%)	0 (0%)	6 (30%)	12 (60%)		
Record smoking status in medical file	Pre	1 (2.2%)	0 (0%)	1 (2.2%)	13 (28.9%)	30 (66.7%)	0.14 (0.02, 0.97)	0.047
	Post	2 (10%)	1 (5%)	2 (10%)	5 (25%)	10 (50%)		
Give **brief advice** to quit if smoking	Pre	4 (9.1%)	1 (2.3%)	11 (25%)	7 (15.9%)	21 (47.7%)	3.26 (0.72, 14.84)	0.116
	Post	1 (5%)	1 (5%)	1 (5%)	10 (50%)	7 (35%)		
Assess nicotine dependence in smokers	Pre	12 (26.7%)	8 (17.8%)	9 (20%)	12 (26.7%)	4 (8.9%)	2.72 (0.82, 8.97)	0.094
	Post	3 (15%)	1 (5%)	4 (20%)	11 (55%)	1 (5%)		
Measure Carbon Monoxide (CO) in exhaled air	Pre	39 (86.7%)	2 (4.4%)	1 (2.2%)	2 (4.4%)	1 (2.2%)	1.57 (0.17, 14.06)	0.667
	Post	15 (75%)	1 (5%)	2 (10%)	2 (10%)	0 (0%)		
Assist (Provide cessation support to smokers?	Pre	5 (11.1%)	7 (15.6%)	11 (24.4%)	13 (28.9%)	9 (20%)	1.70 (0.47, 6.11)	0.392
	Post	2 (10%)	2 (10%)	4 (20%)	9 (45%)	3 (15%)		
Recommend/prescribe NRT to assist quitting (Always/Often)	Pre	8 (17.8%)	7 (15.6%)	14 (31.1%)	12 (26.7%)	4 (8.9%)	Often/Always vs rest 0.82 (0.23, 2.99)	0.751
	Post	4 (20%)	3 (15%)	7 (35%)	6 (30%)	0 (0%)	Never vs rest 1.16 (0.27, 4.99)	0.834
Discuss their psychosocial context of smoking	Pre	4 (8.9%)	8 (17.8%)	9 (20%)	12 (26.7%)	12 (26.7%)	0.72 (0.20, 2.61)	0.593
	Post	3 (15%)	3 (15%)	5 (25%)	7 (35%)	2 (10%)		
Follow-up within 2 weeks	Pre	11 (24.4%)	6 (13.3%)	14 (31.1%)	8 (17.8%)	6 (13.3%)	1.32 (0.36, 4.83)	0.658
	Post	3 (15%)	4 (20%)	6 (30%)	5 (25%)	2 (10%)		

Practice	Time Point	Crude rates					Logistic Mixed Modeling	
		Never	Occasional	Sometimes	Often	Always	OR (95% CI)	p-value
Refer to Quit line	Pre	11 (24.4%)	4 (8.9%)	12 (26.7%)	13 (28.9%)	5 (11.1%)	1.05 (0.30, 3.66)	0.935
	Post	3 (15%)	5 (25%)	4 (20%)	6 (30%)	2 (10%)		
Refer to other specialist smoking cessation service	Pre	8 (17.8%)	7 (15.6%)	14 (31.1%)	15 (33.3%)	1 (2.2%)	1.03 (0.29, 3.65)	0.957
	Post	3 (15%)	5 (25%)	5 (25%)	4 (20%)	3 (15%)		
Involve family members in counselling and tobacco management	Pre	11 (24.4%)	15 (33.3%)	8 (17.8%)	8 (17.8%)	3 (6.7%)	1.40 (0.34, 5.75)	0.613
	Post	3 (15%)	10 (50%)	1 (5%)	4 (20%)	2 (10%)		
Assess use of **Cannabis**	Pre	3 (7%)	2 (4.7%)	6 (14%)	10 (23.3%)	22 (51.2%)	1.00 (0.24, 4.11)	0.998
	Post	3 (15%)	0 (0%)	2 (10%)	5 (25%)	10 (50%)		
Assess use of **Cannabis mixed with tobacco**	Pre	9 (20.9%)	3 (7%)	11 (25.6%)	4 (9.3%)	16 (37.2%)	2.10 (0.60, 7.33)	0.225
	Post	4 (20%)	1 (5%)	2 (10%)	3 (15%)	10 (50%)		
Assess use of **e-cigarettes with nicotine**	Pre	24 (57.1%)	5 (11.9%)	7 (16.7%)	3 (7.1%)	3 (7.1%)	2.09 (0.43, 10.17)	0.337
	Post	11 (55%)	2 (10%)	2 (10%)	1 (5%)	4 (20%)		
Assess use of **chewing tobacco**	Pre	25 (58.1%)	4 (9.3%)	9 (20.9%)	2 (4.7%)	3 (7%)	2.67 (0.55, 13.01)	0.204
	Post	11 (55%)	3 (15%)	1 (5%)	1 (5%)	4 (20%)		
Assess use of **second-hand tobacco smoke**	Pre	8 (18.6%)	6 (14%)	12 (27.9%)	7 (16.3%)	10 (23.3%)	2.51 (0.68, 9.31)	0.155
	Post	1 (5%)	3 (15%)	4 (20%)	6 (30%)	6 (30%)		

Supplemental File 4

Sub-Analysis of Paired HP Responses (n=15)

1. **Crude responses and Wilcoxon signed rank test to compare ordinal responses for the TDF statements pre and post intervention, paired analysis**

Crude rates							Wilcoxon signed rank p-value
Theoretical Domains Framework Statement	**Time point**	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	
I know how to counsel women about their smoking during pregnancy	Pre	0 (0%)	5 (33.3%)	2 (13.3%)	7 (46.7%)	1 (6.7%)	0.156
	Post	0 (0%)	1 (6.7%)	5 (33.3%)	7 (46.7%)	2 (13.3%)	
I am sufficiently reimbursed financially to manage smoking during pregnancy	Pre	3 (20%)	3 (20%)	5 (33.3%)	3 (20%)	1 (6.7%)	0.422
	Post	3 (20%)	1 (6.7%)	4 (26.7%)	6 (40%)	1 (6.7%)	
Counselling women about smoking during pregnancy is part of my work as a health provider	Pre	0 (0%)	0 (0%)	2 (13.3%)	6 (40%)	7 (46.7%)	0.563
	Post	0 (0%)	0 (0%)	1 (6.7%)	5 (33.3%)	9 (60%)	
I am confident that I can counsel women about their smoking during pregnancy	Pre	1 (6.7%)	2 (13.3%)	2 (13.3%)	7 (46.7%)	3 (20%)	0.180
	Post	0 (0%)	1 (6.7%)	2 (13.3%)	7 (46.7%)	5 (33.3%)	
I am optimistic my intervention for smoking during pregnancy is likely to be effective	Pre	1 (6.7%)	3 (20%)	7 (46.7%)	4 (26.7%)	0 (0%)	0.027
	Post	0 (0%)	0 (0%)	7 (46.7%)	7 (46.7%)	1 (6.7%)	
In my workplace, it is routine to help women to quit smoking during pregnancy	Pre	0 (0%)	0 (0%)	4 (26.7%)	5 (33.3%)	6 (40%)	0.766
	Post	0 (0%)	1 (6.7%)	2 (13.3%)	4 (26.7%)	8 (53.3%)	
I have sufficient time to help pregnant women to quit smoking	Pre	1 (6.7%)	5 (33.3%)	2 (13.3%)	3 (20%)	4 (26.7%)	1.000
	Post	1 (6.7%)	3 (20%)	2 (13.3%)	9 (60%)	0 (0%)	
I have sufficient resources to help pregnant women to quit smoking	Pre	1 (6.7%)	5 (33.3%)	4 (26.7%)	2 (13.3%)	3 (20%)	0.059
	Post	0 (0%)	4 (26.7%)	0 (0%)	6 (40%)	5 (33.3%)	
Raising the issue of smoking with a client during pregnancy will benefit our relationship	Pre	0 (0%)	1 (6.7%)	8 (53.3%)	2 (13.3%)	4 (26.7%)	1.000
	Post	0 (0%)	1 (6.7%)	7 (46.7%)	4 (26.7%)	3 (20%)	
My colleagues would approve of me helping pregnant women quit smoking	Pre	0 (0%)	0 (0%)	1 (6.7%)	6 (40%)	8 (53.3%)	0.750
	Post	0 (0%)	0 (0%)	1 (6.7%)	4 (26.7%)	10 (66.7%)	
I am comfortable raising the issue of smoking with a pregnant women	Pre	0 (0%)	0 (0%)	0 (0%)	5 (33.3%)	10 (66.7%)	1.000
	Post	0 (0%)	0 (0%)	0 (0%)	5 (33.3%)	10 (66.7%)	
I intend to provide smoking cessation support to all my pregnant patients who smoke	Pre	0 (0%)	0 (0%)	2 (13.3%)	8 (53.3%)	5 (33.3%)	0.289
	Post	0 (0%)	0 (0%)	1 (6.7%)	6 (40%)	8 (53.3%)	
My workplace has a system in place to monitor whether I deliver cessation support to pregnant women	Pre	1 (6.7%)	4 (26.7%)	2 (13.3%)	4 (26.7%)	4 (26.7%)	0.090
	Post	1 (6.7%)	1 (6.7%)	3 (20%)	1 (6.7%)	9 (60%)	

Theoretical Domains Framework Statement	Time point	Not Often	2	3	4	Very Often	Wilcoxon signed rank p-value
Generally, when seeing pregnant women who smoke, how often is covering something else on your agenda a higher priority than counselling these women	Pre	3 (20%)	3 (20%)	3 (20%)	4 (26.7%)	2 (13.3%)	0.578
	Post	2 (13.3%)	2 (13.3%)	4 (26.7%)	5 (33.3%)	2 (13.3%)	
How often do you forget to counsel women who come in to you who are smoking during pregnancy	Pre	8 (53.3%)	1 (6.7%)	4 (26.7%)	2 (13.3%)	0 (0%)	0.727
	Post	6 (40%)	6 (40%)	2 (13.3%)	1 (6.7%)	0 (0%)	
NRT-specific Statements							
Theoretical Domains Framework Statement	**Time point**	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Wilcoxon signed rank p-value**
I know how to counsel women about the use of NRT during pregnancy	Pre	1 (6.7%)	4 (26.7%)	3 (20%)	6 (40%)	1 (6.7%)	0.031
	Post	0 (0%)	1 (6.7%)	5 (33.3%)	5 (33.3%)	4 (26.7%)	
Recommending/prescribing NRT for pregnant smokers is part of my work as a health provider	Pre	0 (0%)	0 (0%)	7 (46.7%)	7 (46.7%)	1 (6.7%)	0.045
	Post	0 (0%)	0 (0%)	3 (20%)	6 (40%)	6 (40%)	
I am confident that I can recommend/prescribe NRT for pregnant smokers	Pre	1 (6.7%)	1 (6.7%)	3 (20%)	9 (60%)	1 (6.7%)	0.109
	Post	0 (0%)	1 (6.7%)	2 (13.3%)	8 (53.3%)	4 (26.7%)	
I am optimistic that recommending/prescribing NRT for smoking cessation during pregnancy is likely to be effective	Pre	0 (0%)	3 (20%)	8 (53.3%)	4 (26.7%)	0 (0%)	0.072
	Post	0 (0%)	0 (0%)	7 (46.7%)	7 (46.7%)	1 (6.7%)	
I intend to recommend NRT to my pregnant patients who smoke	Pre	0 (0%)	1 (6.7%)	6 (40%)	5 (33.3%)	3 (20%)	0.045
	Post	0 (0%)	0 (0%)	2 (13.3%)	7 (46.7%)	6 (40%)	
Theoretical Domains Framework Statement	**Time point**	**Not Often**	**2**	**3**	**4**	**Very Often**	**Wilcoxon signed rank p-value**
Generally, when seeing pregnant women who smoke, how often is covering something else on your agenda a higher priority than prescribing/recommending NRT for these women	Pre	3 (20%)	4 (26.7%)	1 (6.7%)	6 (40%)	1 (6.7%)	0.219
	Post	1 (6.7%)	3 (20%)	5 (33.3%)	4 (26.7%)	2 (13.3%)	
How often do you forget to prescribe/recommend NRT for a pregnant woman who smokes?	Pre	6 (40%)	3 (20%)	2 (13.3%)	3 (20%)	1 (6.7%)	0.285
	Post	7 (46.7%)	5 (33.3%)	2 (13.3%)	1 (6.7%)	0 (0%)	

2. Crude responses and Wilcoxon signed rank test to compare ordinal responses regarding NRT safety, efficacy and adherence post vs pre intervention, paired analysis

	Time point	Very safe	Always safer than smoking	Safer than smoking but some concerns	Not safe	Wilcoxon signed rank p-value
NRT Safety	Pre	1 (6.7%)	7 (46.7%)	7 (46.7%)	0 (0%)	0.438
	Post	2 (13.3%)	9 (60%)	4 (26.7%)	0 (0%)	
	Time point	**Very effective**	**Moderately effective**	**Low effectiveness**	**Not effective**	**Wilcoxon signed rank p-value**
NRT Effectiveness	Pre	2 (13.3%)	11 (73.3%)	2 (13.3%)	0 (0%)	0.375
	Post	3 (20%)	12 (80%)	0 (0%)	0 (0%)	
	Time point	**Most adhere to NRT well**	**Equal numbers adhere well and poorly**	**Few adhere to NRT well**		**Wilcoxon signed rank p-value**
NRT Adherence	Pre	0 (0%)	9 (60%)	6 (40%)		0.172
	Post	5 (33.3%)	5 (33.3%)	5 (33.3%)		

3. Crude responses and Wilcoxon signed rank test to compare ordinal responses for all practices post vs pre intervention, paired analysis

Practice	Time Point	Crude rates					Wilcoxon signed rank p-value
		Never	Occasional	Sometimes	Often	Always	
Ask about smoking status	Pre	0 (0%)	0 (0%)	0 (0%)	4 (26.7%)	11 (73.3%)	1.000
	Post	0 (0%)	0 (0%)	0 (0%)	4 (26.7%)	11 (73.3%)	
Record smoking status in medical file	Pre	0 (0%)	0 (0%)	0 (0%)	5 (33.3%)	10 (66.7%)	0.531
	Post	0 (0%)	0 (0%)	2 (13.3%)	4 (26.7%)	9 (60%)	
Give **brief advice** to quit if smoking	Pre	1 (6.7%)	0 (0%)	4 (26.7%)	2 (13.3%)	8 (53.3%)	0.391
	Post	0 (0%)	0 (0%)	0 (0%)	8 (53.3%)	7 (46.7%)	
Assess nicotine dependence in smokers	Pre	4 (26.7%)	4 (26.7%)	1 (6.7%)	4 (26.7%)	2 (13.3%)	0.040
	Post	1 (6.7%)	0 (0%)	4 (26.7%)	9 (60%)	1 (6.7%)	
Measure Carbon Monoxide (CO) in exhaled air	Pre	12 (80%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0%)	0.125
	Post	10 (66.7%)	1 (6.7%)	2 (13.3%)	2 (13.3%)	0 (0%)	
Assist (Provide cessation support to smokers?	Pre	2 (13.3%)	0 (0%)	6 (40%)	4 (26.7%)	3 (20%)	0.480
	Post	1 (6.7%)	1 (6.7%)	3 (20%)	7 (46.7%)	3 (20%)	
Recommend/prescribe NRT to assist quitting	Pre	3 (20%)	2 (13.3%)	7 (46.7%)	2 (13.3%)	1 (6.7%)	0.344
	Post	1 (6.7%)	3 (20%)	6 (40%)	5 (33.3%)	0 (0%)	
Discuss their psychosocial context of smoking	Pre	1 (6.7%)	3 (20%)	3 (20%)	3 (20%)	5 (33.3%)	0.617
	Post	1 (6.7%)	2 (13.3%)	4 (26.7%)	7 (46.7%)	1 (6.7%)	
Follow-up within 2 weeks	Pre	4 (26.7%)	1 (6.7%)	8 (53.3%)	1 (6.7%)	1 (6.7%)	0.086
	Post	1 (6.7%)	3 (20%)	6 (40%)	3 (20%)	2 (13.3%)	

Practice	Time Point	Crude rates					Wilcoxon signed rank p-value
		Never	Occasional	Sometimes	Often	Always	
Refer to Quit line	Pre	4 (26.7%)	0 (0%)	6 (40%)	2 (13.3%)	3 (20%)	0.325
	Post	0 (0%)	4 (26.7%)	4 (26.7%)	5 (33.3%)	2 (13.3%)	
Refer to other specialist smoking cessation service	Pre	3 (20%)	2 (13.3%)	7 (46.7%)	3 (20%)	0 (0%)	0.704
	Post	2 (13.3%)	5 (33.3%)	3 (20%)	2 (13.3%)	3 (20%)	
Involve family members in counselling and tobacco management	Pre	6 (40%)	5 (33.3%)	1 (6.7%)	1 (6.7%)	2 (13.3%)	0.057
	Post	1 (6.7%)	8 (53.3%)	1 (6.7%)	3 (20%)	2 (13.3%)	
Assess use of **Cannabis**	Pre	1 (6.7%)	1 (6.7%)	1 (6.7%)	3 (20%)	9 (60%)	0.656
	Post	3 (20%)	0 (0%)	1 (6.7%)	3 (20%)	8 (53.3%)	
Assess use of **Cannabis mixed with tobacco**	Pre	3 (20%)	2 (13.3%)	2 (13.3%)	1 (6.7%)	7 (46.7%)	0.750
	Post	3 (20%)	1 (6.7%)	2 (13.3%)	1 (6.7%)	8 (53.3%)	
Assess use of **e-cigarettes with nicotine**	Pre	6 (40%)	2 (13.3%)	5 (33.3%)	0 (0%)	2 (13.3%)	1.000
	Post	8 (53.3%)	1 (6.7%)	2 (13.3%)	1 (6.7%)	3 (20%)	
Assess use of **chewing tobacco**	Pre	8 (53.3%)	2 (13.3%)	4 (26.7%)	0 (0%)	1 (6.7%)	0.531
	Post	9 (60%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	3 (20%)	
Assess use of **second-hand tobacco smoke**	Pre	2 (13.3%)	3 (20%)	5 (33.3%)	1 (6.7%)	4 (26.7%)	0.266
	Post	1 (6.7%)	2 (13.3%)	4 (26.7%)	4 (26.7%)	4 (26.7%)	

Discussion

Main Findings

This thesis contributes much needed data on health providers' knowledge, attitudes and practices on smoking cessation support for pregnant women, specifically in the Aboriginal healthcare setting. In particular, this thesis contributes new data regarding health providers' knowledge, attitudes and practices on NRT use during pregnancy.

Papers one and two suggested that current smoking cessation care provided to pregnant women who smoke is variable.[1,2] Assessing and recording smoking status and advising women who smoke to quit were found to be more consistently provided. However, health providers reported much lower levels of providing cessation support. Actions such as referral to Quitline, prescribing NRT, following up women and involving other family members were not often provided.[1,2]

Papers one, two and three described the challenges health providers might face when treating pregnant women who smoke, indicating that these mainly related to a lack of knowledge and skills.[1,2] Health providers interviewed were unsure of "how" to perform behavioural counselling (hence "how" to practically "assist" pregnant women to quit smoking), feeling they did not have enough time or resources to do this, and that talking about quitting smoking with their pregnant patients might negatively impact their relationship. As a result, heath providers reported focusing on what they do know and what is less threatening – that is, providing women with information on the harms of smoking to the mother and baby and accepting a reduction in number of cigarettes smoked during pregnancy. Using the 5As approach, based on the "stages of change" theory, health providers discuss treatment options only with pregnant patients who they consider "ready" to quit, thereby unintentionally denying support to some women.

In an effort to understand the reasons behind the low NRT prescription rates (as described in papers one and two), the picture that emerges from paper three is that health providers report safety concerns, lack of confidence, lack of skills and lack of knowledge about "when" and "how" to use NRT during pregnancy.[2] Paper four deepens our understanding of these perceptions, as it shows that currently, the evidence base to guide NRT prescription is mixed and ambiguous, and that guidelines in Australia and

other countries do not provide detailed information that can help the clinician.[3] Guidelines do not include instructions on how to communicate risk versus benefit of using NRT in pregnancy, and do not provide exact detail on when to initiate and how to titrate the dosage used in pregnancy.[3]

Paper five reviewed the evidence for the types of interventions that aimed to improve health providers' provision of smoking cessation care during pregnancy. Although overall health providers increased their provision of smoking cessation care components, the improvement was modest and did not show an improvement in patients' smoking cessation rates. It revealed that most of the interventions were not informed by theory to guide their design (as recommended for complex interventions), and none had any focus on improving NRT prescription rates. Furthermore, this review suggested that using theory to guide the design, and including audit and feedback, may improve intervention effectiveness. An important finding was the lack of a standard definition of "Assist" (or "cessation support"). Lack of an accepted valid and reliable measurement tool for health providers' smoking cessation care impacted the ability of this review to effectively synthesise the data.

One of the components of the ICAN QUIT in Pregnancy intervention is an educational resource package, which was developed collaboratively with health providers and community members from two Aboriginal medical services.[4,5] Findings from papers one and three reinforced the need for developing these resources, as they suggested that one of the barriers to effectively manage smoking during pregnancy for Aboriginal women is the lack of culturally appropriate visual resources.

Paper six examined the scientific validity, acceptability and usefulness of the ICAN QUIT in Pregnancy educational resource package, utilising a stringent four-step evaluation process. Health providers wanted resources that are easy and quick to provide the needed information, culturally appropriate, with visual data to engage and support their discussions with pregnant women. They also wanted more input on how to approach the high rates of smoking among other people in the pregnant women's lives (impacting their ability to quit) and specific resources to promote NRT use in pregnancy.[4] This study reinforced the importance of consumer and community consultation in health research, and Aboriginal community ownership, as a facilitator for implementation and uptake.

These resources were one part of a multi-component intervention designed to improve health providers' smoking cessation care with Aboriginal and Torres Strait Islander pregnant women, within community controlled Aboriginal medical services.[5-7] The COM-B model, TDF and BCW guided the development of this intervention, in collaboration with the SCAAP.[5,7] This intervention was tested in a pilot study with six Aboriginal medical services in three states as described in the research protocol in paper seven.[6] As evident by the data presented above, regarding specific barriers to prescribing NRT in pregnancy and suggested facilitators, a particular focus was put uniquely on improving health providers' knowledge, attitudes and practices on prescribing NRT during pregnancy.[6] Findings from paper five highlight the uniqueness of this approach, as none of the previous interventions conducted to date have focused on increasing NRT prescription rates.

Paper eight explored the effectiveness of the ICAN QUIT in Pregnancy intervention on health providers' knowledge, attitudes and practices in treating smoking among pregnant Aboriginal and Torres Strait Islander women. The results indicate that the intervention was successful in improving general smoking cessation care knowledge and NRT-specific knowledge. Composite scores of all attitudes toward treating tobacco dependence during pregnancy improved significantly, including all NRT-specific attitudes. The increased knowledge and positive attitudes did not lead to significant improvements in self-reported practices. Furthermore, despite participating women's data showing a high percentage being offered oral NRT, health providers did not report changing their NRT prescription rate.

Taken together, this body of work described current smoking cessation care provision and strategies for improving health providers' provision of evidence-based, culturally sensitive smoking cessation care to pregnant Aboriginal and Torres Strait Islander women who smoke.

Key Messages

1. Health providers' provision of smoking cessation care during pregnancy is suboptimal and needs to be improved

Multiple studies with different types of health providers, from different countries and different settings, have shown that health providers are lacking in their tobacco

dependence treatment for pregnant patients, with low levels of providing cessation support, following up, referring to other specialised smoking cessation support and prescribing NRT.[8-26] Previous studies in Australia had a small sample size[26,27] and were limited in their geographical area and/or setting.[26-28] The results presented in this thesis provide a larger national viewpoint, also pointing to low levels of smoking cessation care provision in the same areas. My findings on the barriers leading to the low levels of smoking cessation care provision are similar to those found previously.[8,9] This suggests that little has changed in recent years and patterns are similar across countries, health professional groups and health systems. Qualitative studies that provide a deeper insight to health providers' needs in order to overcome these barriers and improve their smoking cessation care are scarce, as evident by a recent systematic review.[29] In Australia, very few studies have explored health providers' barriers and enablers, with only one of these using qualitative methods.[26,28,30] Previous studies were conducted only in NSW and either included very few GPs or none at all.[26,28,30] Papers one, two and three complete the picture of health providers' barriers and facilitators to managing smoking during pregnancy, with both quantitative and qualitative data focusing on GPs (and obstetricians) from all states and territories in Australia.[1,2] Furthermore, the qualitative study recently conducted[30] only included three participants currently working in Aboriginal health services and did not separately report any qualitative findings specific to health providers working in this setting. Paper three, therefore, is the first qualitative study in Australia that also provides data on GPs caring for pregnant Aboriginal and Torres Strait Islander women. My findings suggest that health providers need specific training in communication skills on how to discuss smoking with their pregnant patients and visual pragmatic resources to aid their discussion with the patient.

2. Guidelines need to provide practical details on how to treat tobacco dependence in pregnancy

Paper three suggested that currently, clinical guidelines are misinterpreting the use of the "Stages of Change" theory, therefore recommending that health providers offer treatment approaches only to those who are "ready" to quit. These findings implicate that current guidelines need to change and include a more proactive approach. This has already been recognised by New Zealand authorities,[31] who have taken out the "assess motivation" component from their ABC smoking cessation guidelines and instead recommend providing cessation support to all smokers. Training health providers to

understand other factors that can also influence patient motivation to quit might prove to be effective. Improving health providers' knowledge to understand that patient motivation can also be increased indirectly, by increasing capability and opportunity, might increase their treatment effectiveness, persistence and optimism.

Research assessing health providers' capability to perform behavioural counselling has shown that in general, this is low, regardless of the topic in question (e.g. smoking cessation, healthy diet, physical activity).[32-34] Findings from this thesis support this, as they also show low levels of provision of the "Assist" component, with GPs reporting "not knowing how to have that conversation". The emergence of BCT taxonomies can aid this to some extent.[35,36] Instead of using a general overall term of behavioural counselling, studies have started to specify exactly which components as active ingredients should be included as part of counselling, for example, as part of smoking cessation counselling[35,37] or as part of counselling to increase physical activity.[38] BCTs are a novel development and have not yet been incorporated into mainstream, non-research, clinical guidelines in Australia. Neither has research begun to explore the acceptability and feasibility of different BCTs in different settings. So BCTs that might be effective and could be used as part of intensive smoking cessation counselling might be different to the ones used by health providers working in primary care settings, utilising a brief intervention approach.

3. Improving NRT prescription rates in pregnancy requires more comprehensive measures

An important finding of this thesis is that providing NRT at no charge could be a critical facilitator to improving NRT prescription. However, the lack of clear, detailed, practical guidelines was also evident regarding NRT prescription in pregnancy.[3] Good quality research underlining the low prescription rates of NRT in pregnancy is also sparse. Previous surveys aiming to explore health providers' provision of smoking cessation care during pregnancy only include data on rates of NRT prescription, and very few address health providers' knowledge of and/or attitudes to NRT prescription during pregnancy, and when this topic was addressed, data was limited.[12,17,22,27,39-47] Only four studies were published that focused on NRT prescription during pregnancy,[11,48-50] none from Australia, and all were conducted from 2000 to 2006. Qualitative studies on this topic are also limited, with only three studies published (2007, 2013, 2018) that include findings regarding health providers' attitudes to NRT

prescription during pregnancy, and none from Australia.[51-53] New evidence on the safety and effectiveness of NRT is still emerging, therefore studies conducted in the past decade might not represent current knowledge, attitudes and practices. The limited studies on this topic might be due to a high percentage of studies conducted in the United States,[11,12,19,22,39,41,43,46,50] where guidelines are more conservative regarding the use of NRT during pregnancy and do not recommend using it.[3,54] To improve NRT prescription rates, my findings suggest that health providers require detailed clinical guidelines, with clear messages regarding the safety of using NRT during pregnancy compared to continued smoking. The qualitative evidence from other countries also supports these recommendations.[51,52,55]

The barriers to prescribing NRT in pregnancy reported in this thesis are similar to those previously published.[11,48-50] This suggests that the emergence of additional studies on the safety and effectiveness of NRT have not yet changed health providers' perceptions, and safety concerns continue to be a major obstacle to NRT prescription. The ICAN QUIT in Pregnancy trial included clear, practical information about NRT, covering how to have a risk versus benefit discussion with the pregnant woman, how to clinically base the decision to initiate NRT and how to titrate the dosage if needed.[6,56] It also included visual resources emphasising NRT's safety compared to continuing smoking, and resources for a shared discussion around this issue with the pregnant woman.[6,56] In the small pilot sample that was included, these measures were successful in improving NRT knowledge and attitudes (which are considered as a precursor to changing practices), but not actual practices. This might be due to the short time frame of the study and follow-up, and/or lack of power; but this might also be an indication that changing actual NRT prescription rates would require more intensive and comprehensive strategies. Including as part of the training an actual demonstration of the discussion with pregnant women on using NRT (via video or face-to-face demonstration) might help. This BCT [6.1 Demonstration of the behaviour][36] has been shown to be important for other behaviour change, such as increasing physical activity,[57,58] and this was also mentioned as a possible facilitator by GPs themselves in paper three. Audit and feedback could have proven to be effective (as suggested by findings from paper five); however, it was not feasible the way it was planned in the ICAN QUIT in Pregnancy trial – which was at a service level rather than individual level [Gould et al, unpublished data]. Developing a shared decision tool to aid the

discussion of using NRT during pregnancy should also be explored. Shared decision tools are getting more and more attention in the latter years as an effective aid to discussions between health providers and patients.[59-62] They have been tested and proven effective in improving patients' knowledge and risk perceptions,[63] including for smoking cessation care.[64] Specifically, with Aboriginal and Torre Strait Islander peoples, it has been recognised that the ownership of the decision and journey is vital to the success – "It has to be their choice".[65,66]

4. Improving smoking cessation rates among Aboriginal and Torres Strait Islander women may require additional measures outside of the medical service

Many interventions that aim to increase smoking abstinence during pregnancy focus on the pregnant woman herself.[67-70] The only two randomised controlled studies previously undertaken in Indigenous settings also focused on changing the pregnant women's smoking behaviour.[71,72] However, Aboriginal and Torres Strait Islander pregnant women who smoke report that one of the major barriers to their quitting is the lack of support from health providers and inconsistent messages.[66,73,74] Therefore, there is a need to create novel interventions on how this can be effectively changed. Health providers in general, not only those specifically working with Indigenous populations, report facing many barriers (previously outlined) to treating pregnant women who smoke. Those treating Aboriginal and Torres Strait Islander pregnant women need to also consider specific barriers that women face in their journey to becoming smoke-free. The need to address these additional barriers was reflected in paper three ("Combating smoking in pregnancy is not just a medical condition they can treat") and also in paper six, where health providers from all three Aboriginal medical services discussed the need to engage also with the family and not only the woman.[4] Having other family members who smoke, especially the partner, is one of the most significant barriers to quitting smoking in general.[55,75,76] However, previous interventions that have focused on the partner and/or included the partner were not successful.[77-79] This type of intervention has not been explored in the Indigenous setting, but may be effective due to the vital part that family and community hold for Aboriginal people.[80]

The ICAN QUIT in Pregnancy showed promising results and is currently being tested as part of a larger cluster RCT, with 30 Aboriginal medical services in five states and territories. This larger study is powered to detect the impact of changing health

providers' behaviour via the complex intervention on women's quit rates compared to usual care. However, this intervention is focused on the medical service (as was the ICAN QUIT in Pregnancy intervention) and does not include intervention components directed at the community level. Changing smoking rates among pregnant Aboriginal and Torres Strait Islander women at a population level may require a more comprehensive "whole of community" approach. Future interventions need to go beyond the medical service and test whether including intervention components integrated into the community itself might have a higher impact. These might include interventions targeting the entire family (such as those that include the partner and other family members that smoke) or interventions that include Aboriginal Elders and Aunties. A pilot study with Māori Aunties in New Zealand showed this might be feasible.[81,82] The medical service, especially community controlled Aboriginal medical services, are a vital part of any strategy to reduce smoking, but they are not enough by themselves. This is highlighted not only by what GPs reported in paper three, but also by the modest effectiveness seen in other interventions reported in paper five and the results of the ICAN QUIT in Pregnancy intervention described in paper eight.

Limitations and Strengths

The limitations of each individual paper are described in detail in their corresponding discussion sections.

One limitation of this thesis is that the first five papers were not specific to health providers treating Aboriginal and Torres Strait Islander pregnant women, and included research about smoking in pregnancy more generally. This was done as the Aboriginal and Torres Strait Islander population comprises 3% of the total Australian population[83] and due to the lack of data on a national level, considering that many of the barriers health providers encounter might be general and not related only to the setting in which they work or related to the population they treat. Attempts were made to address this limitation in papers one, two and three by deliberately sampling a sub-population of health providers that were working in Aboriginal health settings, providing data also on health providers' barriers and facilitators in these specific settings. Nonetheless, due to the nature of these more general studies, and the national overview, there might have been specific barriers for health providers working in Aboriginal settings, which could have been overlooked or could have been studied more in depth.

Papers one, two and three focused on GPs and obstetricians only. These professions were selected due to the dearth of research, both internationally and in Australia, on GPs' treatment for smoking during pregnancy, but also as GPs were perceived to have a vital role to play in supporting pregnant women to quit in Aboriginal medical services, which were going to be the setting for the ICAN QUIT in Pregnancy intervention. However, findings from these papers highlighted the lack of time GPs face and the fact that other health providers, specifically midwifes and Aboriginal health workers, also play an intensive role in pregnant women's journey in these healthcare settings. This was reflected upon and accommodated by incorporating a "whole of service" approach that was undertaken for the ICAN QUIT intervention (papers six to eight). Thus, a limitation of this thesis is that no cross-sectional and/or qualitative studies were conducted with midwives and Aboriginal health workers to better understand their particular barriers and facilitators. However, studies focusing on Australian midwifes and Aboriginal health workers have been published by other researchers,[30] and several of these also informed the development and refinement of the ICAN QUIT in Pregnancy intervention.[26,28]

Another limitation is that all the research conducted used self-reported measurements, potentially leading to reporting bias. However, the results were consistent with those from similar studies with health providers from other countries, thereby strengthening the assumption that they represent true findings. Furthermore, the ICAN QUIT intervention study included multiple levels of data collection (at the service and participating women's levels), utilising both quantitative and qualitative methods, which support the health providers' survey results.[6] As part of the ICAN QUIT in Pregnancy study,[6] an objective measure of recording smoking cessation consultations, and coding these for the BCTs that were used, was trialled. Despite reasonable levels of health providers and pregnant women consenting to being recorded [Gould et al, unpublished data], in practice only two services provided a few recordings (n=7), all were recorded from the pre-intervention phase of the study, and none with GPs (Bar-Zeev et al, unpublished data). This may indicate that the services would need more support to set up the recordings for it to be a feasible method to objectively measure health providers' performance in this setting.

A major strength of this thesis is using rigorous methods throughout, specifically within Aboriginal medical services. To the best of my knowledge, to date, the ICAN

QUIT in Pregnancy intervention was the largest cluster randomised controlled study to be implemented in Aboriginal medical services (six services across three states). Previous research in this setting has highlighted the difficulties in conducting rigorous research in this context.[84] A smoking cessation study with pregnant Aboriginal women (conducted in three Aboriginal medical services across two states, WA and Qld) suffered from multiple methodological and implementation problems, including a high (over 30%) loss to follow-up, high staff turnover, lack of allocation concealment and the potential for contamination between groups.[71] A recent study, Stop Smoking in its Tracks, aiming to test a multi-component intervention that also includes contingent incentives, was originally designed as an RCT with four Aboriginal Maternal and Infant Health Services (two intervention and two control) in NSW only; but due to staffing issues in two services, the study was converted to a quasi-experiment with both remaining services receiving the intervention.[85] The ICAN QUIT in Pregnancy also suffered from several of the above-mentioned implementation issues, including staff turnover and low retention rates of health providers [Gould et al, unpublished data]. However, having services choose their own staff member as the research facilitator, with training and ongoing implementation support provided by the research team, proved to be beneficial to increase the service's ownership and engagement and might have been a major contributing factor to the ease of recruiting Aboriginal women to the study [Gould et al, unpublished data; Bovill et al, unpublished data].

Furthermore, the step-wedge design was found to be confusing to the AMS staff and managers [Gould et al, unpublished data]. Previous research has shown that a step-wedge design can be complex to implement, specifically when recruiting and collecting data on an individual basis.[86] To date, only 12 Australasian studies have used a cluster randomised step-wedge design.[87]

Future Research

The research presented as part of this thesis was overall conducted on smoking cessation care in pregnancy, and more specifically on prescribing NRT during pregnancy, as part of supporting pregnant women to quit. Other areas of "Assist" should be extensively explored, especially referral to Quitline. A referral to Quitline (or other smoking cessation support) is the cornerstone of the AAR approach to smoking cessation care.[88,89] This approach is mainly recommended where there are time

constraints. Findings from paper one also support this approach, as lack of time was the most frequent barrier reported, with the AAR reported to be practiced at a higher rate compared to the 5As.[1] Currently in Australia, Quitline is the only option of referral to a specialised smoking cessation service for most health providers. This form of treatment is underutilised in many countries,[90-93] including Australia,[94,95] and the reasons for this have not been extensively studied. Paper three provides initial data on this, suggesting that familiarisation of GPs with the Quitline process, and counsellors, including the presence of Aboriginal counsellors, might improve GPs' referral rates. It also highlights the paucity of smoking cessation support options that are perceived as suitable and useful and are readily available for referral in Australia. One study has recently been published,[96] which explores health providers' barriers to referring Aboriginal and Torres Strait Islander people in general to Quitline, but not specifically pregnant women.[96] This study had a small sample size (n=34) and only included participants from SA and the NT, most of whom had received prior training on this matter, impacting generaliability.[96] Further research should include qualitative studies with pregnant Aboriginal and Torres Strait Islander women to explore their knowledge and attitudes toward using Quitline. In addition, my research implies that health providers need to be educated regarding the Quitline process and the availability of Aboriginal counsellors.

Paper five highlighted the fact that currently, there is no acceptable valid and reliable measure to collect data on health providers' provision of smoking cessation care. Previous interventions used different methods (health providers' survey, women's report on health providers, audit of health records, recordings of visits) and different measures (yes/no questions, Likert scales – either never–always or never–all of the time). Developing a valid and reliable measurement tool to consistently collect data on health providers' provision of smoking cessation care should be investigated.

Regarding the "Assist" or "cessation support" component of treatment for smoking in pregnancy, it is not clear which exact components of care should be included as part of this component. Most interventions (including the ICAN QUIT in Pregnancy) utilise a general measurement without specifying what this entails (for example, "How often do you assist your patients to quit?"). Future research should focus on characterising exactly which BCTs should be included as part of "Assist", specifically in primary care settings, taking into account the lack of time and other competing demands (as opposed to a specialised smoking cessation service that can

include all BCTs recommended). The ICAN QUIT in Pregnancy treatment manual includes a detailed section on BCTs and includes specific BCTs for assistance, such as facilitating goal setting, restructuring the physical environment and facilitating barrier identification and problem-solving. However, this study was not able to collect data to attest to the feasibility and acceptability of each BCT in this setting, nor whether each BCT was actually practiced and/or improved after the intervention was implemented.

Significance

Tobacco use is the most significant risk factor for premature mortality and morbidity worldwide, including Australia.[97-99] Smoking during pregnancy has a major impact on future generations' health, negatively impacting the child's health from conception and throughout his or her adult life.[98] Due to historical and cultural reasons, Aboriginal and Torres Strait Islander women have the highest smoking rates during pregnancy compared with non-Indigenous pregnant women.[100,101] Thus, Aboriginal and Torres Strait Islander babies suffer early on from a major disadvantage, impacting their health. Smoking has been found to be the most important factor contributing to the health gap between Aboriginal and Torres Strait Islander peoples and non-Indigenous people in Australia.[99,102,103] Reducing smoking rates requires multiple strategies and cannot be achieved using only one or a few measures.[104,105] The WHO has outlined these measures as part of the Framework Convention for Tobacco Control[104] and the MPOWER actions.[105] Increasing smoking cessation rates is an important part of the complex multiple interventions needed to tackling tobacco use, with the healthcare system providing the cornerstone of cessation support. Thus, improving health providers' smoking cessation support needs to be included as an important pillar in all tobacco control policy.[105]

The Australian NHMRC Road Map 3 strategic framework for improving Aboriginal and Torres Strait Islander health through research (2018–2021)[106] states three important components that need to be achieved:

1. Focus on research that makes a difference – recognising this to include research that is focused on a particular life stage and that has the potential to address a significant burden of disease among Aboriginal and Torres Strait Islander communities;

2. Research excellence and integrity, ensuring that ethical guidelines to conducting research with Aboriginal and Torres Strait Islander communities are upheld at all times, while maintaining rigour;

3. Strong community engagement with Aboriginal and Torres Strait Islander communities at all stages of the research from development to study implementation and knowledge translation of the results.

This thesis has included all of these components as outlined previously, and contributes much needed data and knowledge that has informed the development and refinement of the largest national clustered RCT aimed to improve smoking cessation rates among Aboriginal and Torres Strait Islander pregnant women. A summary of the thesis recommendations for policy, practice and research is provided in Table 4.

Table 4: Recommendations for policy, practice and research

Recommendation	Evidence from papers
Policy and Practice	
1. Smoking cessation training for health providers should focus on improving communication skills – on "how" to discuss smoking with their pregnant patients.	Paper one – GPs reported low levels of providing smoking cessation support (the "Assist" component). Paper three – GPs reported a lack of communication skills with regard to discussing smoking cessation with pregnant patients.
2. Guidelines should adopt a more proactive approach by offering all pregnant women who smoke the recommended smoking cessation options, regardless of her perceived "readiness" to quit.	Paper one – Low rates of self-reported provision of "Assist" and "Referral" to Quitline. Paper three – GPs reported offering treatment options only to women who they perceived as "ready" to quit.
3. Guidelines need to include clear, detailed instructions on NRT initiation and dosage titration for pregnant women who smoke.	Paper two – GPs and obstetricians lack confidence in ability to prescribe NRT in pregnancy. Paper three – GPs requested detailed guidance on NRT initiation and dosage for pregnancy. Paper four – Current guidelines do not include detailed information as applied to the context of pregnancy. Paper eight – ICAN QUIT in Pregnancy treatment manual and webinar training was perceived as very useful; NRT-specific

	knowledge and attitudes significantly improved following the intervention.
3. Visual resources are needed that clearly express that NRT is safer than smoking in pregnancy and can be used by pregnant women who smoke.	Paper one and two – Safety concerns are a major concern leading to low NRT prescription rates. Paper three – GPs want visual resources for the patient that clearly state that NRT can be used in pregnancy and is safer than continued smoking. Paper six – Staff from Aboriginal medical services suggested posters showing that NRT is safer than smoking and modelling women using NRT while pregnant. Paper eight – ICAN QUIT in Pregnancy posters were perceived as very useful by health providers.
4. Oral NRT should be provided free of charge and distributed on site at Aboriginal medical services.	Paper three – For GPs working in Aboriginal medical services, having the NRT patch on site free of charge was considered a major facilitator; oral NRT cost and lack of availability at the service was reported as a barrier. Paper eight – All of the services participating in ICAN QUIT in Pregnancy requested the oral NRT (supplied free of charge) be provided directly at the service and not through a pharmacy voucher system.
Research	
5. The "Assist" component of smoking cessation care should be explicitly characterised and a valid and reliable measurement tool developed.	Paper five – Different studies used different measurement tools for the "Assist" component of smoking cessation care. Paper three – GPs were unsure "how" to support the pregnant women to quit.
6. Improving actual NRT prescription rates should be explored using other measures, such as a. training that includes the behaviour change technique "Demonstration of the behaviour"; b. audit and feedback on an individual health provider basis; c. developing a shared decision tool to aid the discussion of using NRT during pregnancy.	Paper three – GPs requested actual demonstration of how to have the conversation with a pregnant woman regarding smoking cessation. Paper five – Audit and feedback might enhance the effectiveness of interventions aimed to improve health providers' management of smoking during pregnancy. Paper eight – NRT-specific knowledge and attitudes improved, but not actual self-reported NRT prescription rates, implying further strategies are warranted.
7. Barriers and facilitators for utilising Quitline during pregnancy in general, and specifically for Aboriginal and Torres Strait Islander women should be explored	Paper one – Few GPs and obstetricians regularly refer to Quitline. Paper three – GPs questioned Quitline's suitability for their pregnant patients (especially Aboriginal and Torres Strait

	Islander pregnant women) and were unsure of the Quitline process. Paper eight – Levels of referral to Quitline did not improve after receiving the ICAN QUIT in Pregnancy intervention.
8. Interventions at a community level, such as those that include all family members and/or Elders and Aunties, should be explored to assess whether these interventions can improve smoking cessation rates among Aboriginal and Torres Strait Islander pregnant women	Paper three – GPs expressed a need for smoking cessation to be addressed on a more comprehensive, not just medical, level. Paper five – Meta-analysis of previous interventions show they can improve the provision of smoking cessation care in pregnancy, but this was only a modest improvement and did not correspond to an increase in a patient's smoking cessation rate. Paper eight – ICAN QUIT in Pregnancy pilot intervention found small non-significant increases in health providers' provision of several smoking cessation care components (with no change in other smoking cessation care components).

Conclusion

Increasing health providers' provision of smoking cessation care to Aboriginal and Torres Strait Islander pregnant women is a significant priority in Australia, recognised as part of the Closing the Gap strategy. This body of work highlights that currently, health providers are lacking in their provision of smoking cessation care, specifically in their support for Aboriginal and Torres Strait Islander pregnant women to quit smoking. The need for clear, practical, visual information to guide the clinical discussion with the woman is evident. A multi-component culturally tailored intervention can improve health providers' knowledge and attitudes and might also improve several practices for smoking cessation care during pregnancy. The complex nature of tobacco smoking, and consideration of its historical and social context in Aboriginal communities, suggests that wider, more intensive and comprehensive interventions are needed for pregnant Aboriginal women who smoke. Future research should focus on providing more insight to which BCTs need to be included as part of the "providing cessation support" or "Assist" in primary care, more effective ways to increase NRT use during pregnancy and other options explored for supporting Aboriginal and Torres Strait Islander pregnant women to quit, including Quitline.

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Appendices

Appendix 1: Cross-Sectional Survey of Knowledge, Attitudes and Practices Related Material (Paper One and Two)

Appendix 1.1: University of Newcastle Human Research Ethics Committee Approval

Appendix 1.2: Information Sheet

Appendix 1.3: Survey

HUMAN RESEARCH ETHICS COMMITTEE

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Doctor Gillian Gould**
Cc Co-investigators / Research Students:	**Associate Professor Billie Bonevski** **Miss Laura Twyman** **Dr Yael Bar Zeev**
Re Protocol:	**Exploration of the knowledge, attitudes and practices of clinicians in providing behaviour change counselling and prescribing NRT for women who smoke in pregnancy.**
Date:	**12-Dec-2015**
Reference No:	**H-2015-0067**

Thank you for your **Variation** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to a variation to the above protocol.

Variation to:

1. Add Yael Bar Zeev (PhD student) to the research team.

2. Send out a paper survey through the Royal Australian & New Zealand College Of Gynecologists (RANZCOG) magazine mail list. The paper survey will be attached to the magazine with the information sheet.

3. Phone and e-mail services directly (using contact details provided in the internet) with a request to answer the survey.

4. Delete a few questions from the online survey that are less relevant to the RANZCOG population and add a few questions to the survey - age of the participants, if they are an obstetric specialist, and how often they discuss the psycho-social context of smoking with their patients, and arrange for follow up.

4. Introduce a new version of the Information Statement to accompany the paper survey.

- Information Statement for Paper Survey (version submitted 30/10/2015)
- Paper Survey (submitted 30/10/2015)

Your submission was considered under **Expedited** review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is **Approved** effective **11-Dec-2015**.

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

For communications and enquiries:
Human Research Ethics Administration

Information Statement

Knowledge, attitudes and practices of clinicians caring for women who smoke in pregnancy

This research is led by Dr Gillian Gould, NHMRC Research Fellow, School of Medicine and Public Health, University of Newcastle. This paper survey has been sent to Australian members of RANZCOG database.

Why is the research being done?

- To understand the knowledge, attitudes, and practices of Australian GPs and Obstetricians about providing smoking cessation care in pregnancy.
- To generate evidence about effective strategies to decrease smoking rates in pregnant women.

Who can participate in the research?

- Clinicians consulting with pregnant women. You are eligible even if you only diagnose pregnancy.
- If you do not consult with pregnant women at all, you are not eligible to participate.

What would you be asked to do?

- Complete and return this paper survey in the addressed envelope (please provide a stamp) or fax to 02-403 35692.
- Answer questions about your type of medical practice, and knowledge, attitudes and practices in managing smoking in pregnancy, e.g counselling and using nicotine replacement therapy (NRT).

If you wish to go in a prize draw for one of two mini i-pads please supply contact details at the end of the survey. We will contact you again only if you win the draw, or if you indicate that you are interested in participating in future research projects.

What choice do you have?

Participation in this survey is entirely your choice. Completing the survey indicates your informed consent. Whether or not you decide to participate, your decision will not disadvantage you. You may withdraw from the project at any time without giving a reason, and withdraw any data that identifies you. If you discontinue part way through the survey, the incomplete survey will not be used for the research.

How much time will it take? The survey should take 10 minutes to complete.

***What are the risks and benefits of participating*?**

The study is low risk and should cause no discomfort to complete. The findings will benefit clinicians and pregnant women by informing a) practices and policies about evidence-based therapies for pregnant smokers; b) a future randomised controlled trial of clinician training in primary care.

How will your privacy be protected?

Any identifying information collected by the survey will be stored securely and only accessed by the researchers, unless you consent otherwise, except as required by law. Data will be retained for at least 5 years at the University of Newcastle in electronic form on a password protected computer and on the secure survey website (encrypted). Your name will be replaced with a numerical code prior to analysis and held in re-identifiable form. Any identifiable data will be kept confidential and you will not be named or identified in the research outcomes.

How will the information collected be used?

Data may be reported in journals, at conferences, reports to professional organisations and policy makers, and a lay report. Non-identifiable data may be shared with other parties to encourage scientific scrutiny, and to contribute to further research and public knowledge, or as required by law. You may request a summary of the results when available.

***What do you need to do to participate*?** Read and be sure you understand this Information Statement before participating.

Further information: Dr Gillian Gould NHMRC Research Fellow Tel: 0403615563 or Email: gillian.gould@newcastle.edu.au

The researchers gratefully acknowledge the RACGP Foundation and NHMRC for their support of this project.

Complaints about this research: University of Newcastle Human Research Ethics Committee Approval Number is H-2015-0067. If you have concerns about your rights as a research participant, or a complaint about the manner in which the research is conducted, contact the researcher, or, if an independent person is preferred, contact the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

Appendix 1.3: Paper One and Two Survey

Knowledge, attitudes and practices of clinicians caring for women who smoke in pregnancy

1. Please enter the postcode of your main work location_____

2. How would you best describe your specialty? (circle one)

a. GP (without obstetric training)	1
b. GP (with Diploma of Obstetrics/Certificate in Obstetrics)	2
c. GP Registrar	3
d. Obstetric specialist	4
e. Obstetric registrar	5
f. Other, please specify_____	6

3. In the main does your medical practice…..(circle one)

a. Cater mostly for the general population	1
b. Cater mostly for Aboriginal and/or Torres Strait Islander populations	2
c. Other, please specify_____	3

4. What is your gender? (circle one)

a. Male	1
b. Female	2

5. What is your age? (circle one)

a. Under 30 years	1
b. 31-44 years	2
c. 45-60 years	3
d. Over 60 years	4

6. When did you qualify for your medical degree? (circle one)

a. Less than 10 years ago	1
b. 10 to 19 years ago	2
c. 20 or more years ago	3

7. Do you currently smoke tobacco products? (circle one)

a. Yes daily	1
b. Yes occasionally	2
c. No I am an ex-smoker	3
d. No I have never smoked	4

8. On an average, how many pregnant women do you see per month? (circle one)

a. Less than 5	1
b. 5-10	2
c. More than 10	3

9. What proportion of these women are tobacco smokers? (circle one)

a. 0-20%	1
b. 21-40%	2
c. 41-60%	3
d. 61-80%	4
e. 81-100%	5

10. Have you read any of the following smoking cessation guidelines? (please answer all)

Guideline	**Yes**	**No**
a. Royal Australian College of General Practitioners Supporting smoking cessation: a guide for health professionals, Australia	1	2
b. Australian Health Ministers' Advisory Council. Clinical Practice Guidelines: Antenatal Care – Module 1 2012	1	2
c. Fiore et al: Smoking Cessation Clinical Practice Guidelines USA	1	2
d. National Institute for Health and Care Excellence (NICE) guidelines: Quitting smoking in pregnancy and following childbirth UK	1	2
e. South Australian Perinatal Practice Guidelines	1	2
f. Other, please specify_____	1	2

11. How often do you provide the following types of cessation care ***with pregnant women***: (please answer all)

	Never (0%)	**Occasional (1-25%)**	**Sometimes (26-50%)**	**Often (51-75%)**	**Always (76-100%)**
a. **Ask** about smoking status?	1	2	3	4	5
b. Give **brief advice** to quit if smoking?	1	2	3	4	5
c. **Assess nicotine dependence** in smokers?	1	2	3	4	5
d. **Provide cessation support** to smokers?	1	2	3	4	5
e. **Prescribe/recommend** nicotine replacement therapy (NRT) to assist quitting?	1	2	3	4	5
f. **Discuss their psychosocial** context of smoking?	1	2	3	4	5
g. **Follow-up** within 2 weeks?	1	2	3	4	5

12. In your current practice, how often do you prescribe/recommend the following cessation methods ***for pregnant women who smoke***? (please answer all)

	Never (0%)	**Occasionally (1-25%)**	**Sometimes (26-50%)**	**Often (51-75%)**	**Always (76-100%)**
a. Counselling	1	2	3	4	5
b. Cold turkey/quit unassisted by medication)	1	2	3	4	5
c. Reduce smoking gradually	1	2	3	4	5
d. Oral forms of NRT (e.g. lozenges, gum, inhalers, spray)	1	2	3	4	5
e. Nicotine patches	1	2	3	4	5
f. Combination of oral forms of NRT and nicotine patches	1	2	3	4	5
g. Hypnosis	1	2	3	4	5
h. Acupuncture	1	2	3	4	5
i. Referral to Quitline/specialist service	1	2	3	4	5
j. Other, please specify_____ _____	1	2	3	4	5

13. Please rate how **safe** you consider NRT is for the foetus when prescribed in pregnancy? (circle one)

a. Very safe	1
b. Always safer than smoking	2
c. Safer than smoking but some concerns	3
d. Not safe	4

14. How **effective** do you perceive NRT is in aiding pregnant smokers to quit? (circle one)

a. Very effective	1
b. Moderately effective	2
c. Low effectiveness	3
d. Not effective	4

15. In your view, how well do pregnant patients **adhere to/comply with** taking NRT if recommended? (circle one)

a. Most adhere to NRT well	1
b. Equal numbers adhere well and poorly	2
c. Most adhere to NRT poorly	3

16. How often do you involve **family members** in counselling/tobacco management when you see a pregnant smoker? (circle one)

a. Never (0%)	1
b. Occasionally (1-25%)	2
c. Sometimes (26-50%)	3
d. Often (51-75%)	4
e. Always (76-100%)	5

17. Have you have received any training in tobacco management ***related to pregnancy***? (answer all)

	Yes	**No**
a. Undergraduate training	1	2
b. Postgraduate training	1	2
c. In depth specialised course	1	2
d. Brief intervention course	1	2
e. Other, please specify_____ _____		

18. How much do you agree that the following system changes would improve the management of smoking in pregnant women? (please answer all)

	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
Subsidised oral forms of NRT on the PBS	1	2	3	4	5
Improved access to NRT patches (i.e. more courses available per year)	1	2	3	4	5
Health professional training	1	2	3	4	5
Medicare item number for smoking counselling	1	2	3	4	5
Other, please specify_____ _____	1	2	3	4	5

19. Please select an answer to represent your level of agreement with the following (please answer all)

Statements	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
1. I am confident that I can counsel women about their smoking during pregnancy	1	2	3	4	5
2. I am confident that I can prescribe NRT for pregnant smokers	1	2	3	4	5
3. I am optimistic my intervention for smoking during pregnancy is likely to be effective	1	2	3	4	5
4. Addressing smoking during pregnancy is a high priority	1	2	3	4	5
5. Raising the issue of smoking with a client during pregnancy will benefit our relationship	1	2	3	4	5
6. In my workplace, it is routine to help women to quit smoking during pregnancy	1	2	3	4	5
7. I have sufficient time to help pregnant women to quit smoking	1	2	3	4	5
8. I am comfortable raising the issue of smoking with a pregnant woman	1	2	3	4	5
9. I have sufficient resources to help pregnant women to quit smoking	1	2	3	4	5

20. How often do you ask a pregnant client about using these substances? (please answer all)

	Never	**Occasionally**	**Sometimes**	**Often**	**Always**
Cannabis	1	2	3	4	5
Cannabis mulled (mixed) with tobacco	1	2	3	4	5
E-cigarettes with nicotine	1	2	3	4	5
E-cigarettes without nicotine	1	2	3	4	5
Chewing tobacco	1	2	3	4	5
Second-hand tobacco smoke	1	2	3	4	5

21. Would you be interested to participate in a trial of clinician training for managing smoking in pregnant women in Indigenous or other vulnerable populations, at a future date? (tick one box)

- ☐ 1, Yes
- ☐ 2, No
- ☐ 3, Maybe

22. Would you like to go in the draw to receive one of two mini computer tablets? (tick one box)

- ☐ 1, Yes
- ☐ 2, No

IF you answered Yes/Maybe to Q21 or Yes to Q22 please provide name and contact details:

23. Please enter your name

24. What is your Practice Address?

25. What is your phone number?

26. What is your email?

Thank you for completing the survey.

Appendix 2: Qualitative Study Related Material (Paper Three)

Appendix 2.1: University of Newcastle Human Research Ethics Committee Approval

Appendix 2.2: Information Sheet

Appendix 2.3: Interview guide

HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Doctor Gillian Gould**
Cc Co-investigators / Research Students:	**Yael Bar Zeev** **Professor Billie Bonevski** **Associate Professor Maree Gruppetta**
Re Protocol:	**General Practitioners Barriers to Managing Smoking and Prescribing NRT in Pregnant Women – A Qualitative Research**
Date:	**08-Jun-2016**
Reference No:	**H-2016-0063**
Date of Initial Approval:	**08-Jun-2016**

Thank you for your **Response to Conditional Approval (minor amendments)** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under **Expedited** review by the Ethics Administrator.

I am pleased to advise that the decision on your submission is **Approved** effective **08-Jun-2016**.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. *If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.*

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2016-0063**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC 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 HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on this Approval Advice** to report adverse events.
2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at https://rims.newcastle.edu.au/login.asp) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at https://rims.newcastle.edu.au/login.asp). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

For communications and enquiries:
Human Research Ethics Administration

Research Services
Research Integrity Unit
NIER, Block C
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 17894
Human-Ethics@newcastle.edu.au

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

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Information Sheet for the Research project:

General Practitioners Barriers to Managing Smoking and Prescribing NRT in Pregnant Women – A Qualitative Research

Invitation: You are invited to take part in the research project identified above which is being conducted by Dr Gillian Gould from the Centre for Brain and Mental Health from the University of Newcastle.

The research is part of Dr Yael Bar-Zeev's PhD studies at the University of Newcastle, School of Medicine and Public Health, supervised by Dr Gillian Gould, A/Prof Billie Bonevski and A/Prof Maree Gruppetta.

Why is the research being done?

The purpose of this study is to explore in depth the thoughts and attitudes of General Practitioner's actively engaged in treating pregnant women on the management of smoking in pregnancy, and what would enable them to better manage smoking in pregnancy.

Tobacco smoking in pregnancy is the most preventable risk factor for poor maternal and infant health outcomes, including miscarriage, growth restriction, still birth and pre-term birth.

Who can participate in this research?

- We are seeking General Practitioners who consult with pregnant women. You are eligible to participate even if you only confirm pregnancy.
- If you do not consult with pregnant women at all, you are not eligible to participate.

What does participation involve?

- You would be asked to participate in a semi-structured one-on-one interview over the phone. Topics will be about the management of smoking in pregnancy, including (but not restricted to) prescription of Nicotine Replacement Therapy, following-up and referral to other cessation support.
- The interview will take 30-60 minutes of your time.
- The interview will be audio-recorded and transcribed for analysis. Your name and other details will not be recorded or transcribed. Any identifying details given throughout the interview will be erased before transcribing.

Will taking part in the study cost me anything, and will I be paid?

- There will be no cost to you other than giving up a small amount of your time.
- You will not be paid. However, you will be entered in a prize draw for 1 mini-ipad.

What are the risks and benefits of participating?

- There are no known risks from participating.
- The benefit of participating is that you will be contributing to the knowledge basis for informing a) practices and policies about evidence-based therapies for pregnant smokers; b) a future randomised controlled trial of clinician training in primary care.

How will my confidentiality be protected?

- Transcribing will be done either by the PhD candidate Dr Yael Bar Zeev, who will also be conducting the interviews or by a professional transcribing service bound by a confidentiality agreement. Any identified information will be deleted and not included in the transcription.
- You will receive a copy of your transcript, and will be given the opportunity to review and edit it if you wish before analysis.
- Any information collected is confidential and non-identified.
- Records will only be stored on University software with password protection. The data will be stored at the CBMH (Centre for Brain and Mental Health) at the University in a locked cabinet.
- Data will be stored for a minimum of five years. Only the researchers will have access to the de-identified data.
- This data might be used in the future for other research purposes (subject to further ethics approval)
- Your name will not be kept attached to your records or the other information you will give, nor used when we report the results.

What happens with the results of the research?

- Your information along with information from others will form the results of this research.
- These results will be used to inform a cluster Randomized Controlled Study aimed to improve provider's management of smoking in pregnancy.
- Results will also be used to write a report but you will not be identified in any way.
- We will e-mail you and other participants a copy of the final report from this study. We estimate the final report will be delivered to you by December 2017.

What if I don't want to take part in the research, or if I want to drop out later?

- It is your choice whether or not you choose to participate.
- Whether you participate, or not, will not affect your position in any way.
- If you choose to participate you can also drop out from the research without penalty at any stage of the interview.

What should I do if I want more information about the study before I decide to participate?

- You can ask any questions you like. Please talk to the following researchers:
  - **Dr Gillian Gould – 0403615563 Dr Yael Bar Zeev - 0478040759**

Complaints about this research:

This research has been approved by the University of Newcastle Ethics Committee, (Reference # H-2016-XXXX)

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 to the Senior Human Research Ethics Officer, University of Newcastle Ethics Committee (Senior Human Research Ethics Officer, The University of Newcastle, Callaghan NSW 2308, (02) 492 16333, E: Ruth.Gibbins@newcastle.edu.au)

Thank you for taking the time to consider this study.
Dr. Yael Bar-Zeev from the research team will follow up with a phone call in the next two weeks to ascertain your willingness to participate in this study.
This information sheet is for you to keep.

General Practitioners Barriers to Managing Smoking and Prescribing NRT in Pregnant Women – A Qualitative Research

Guide for qualitative interview

1. Setting up

a. Introduce yourself
b. Explain study, issues of confidentiality, anonymity and get informed consent
c. Explain and get permission for audio recording

2. Introducing the topic

I am interested in hearing your thoughts, ideas and personal experience with management of smoking in pregnant women. More specifically, I am interested to hear what you think can help you to improve your management of smoking in pregnancy.

I will ask you a few general questions as we go, but you are welcome to talk and share any experiences or thoughts on this matter. Anything you say will be confidential.

3. Topics that should be covered (and an example of a question that can be used if not already covered)

a. Usual approach

i. What would you say is your usual approach to a pregnant woman who smokes?
ii. In your experience, what have been the outcomes from your management of smoking in pregnant women?

b. Enablers and Facilitators - General

iii. How do you feel about improving your management of smoking in pregnant women?
iv. In your opinion, what could help you improve your management of smoking in pregnant women?
v. What would help you remember to discuss this with pregnant women?

c. Knowledge

vi. What are your thoughts on your knowledge to address smoking properly in pregnant women?
vii. What would be the preferred way for you to improve your knowledge on this topic? What would be the most effective way for you?

d. Time

viii. What has been your experience concerning the time frame available to address smoking properly in pregnant women?
ix. How much time in your experience is needed for this issue? What do you think could help you incorporate this into your timeframe?

e. Optimism

x. Do you feel optimistic/pessimistic about your management of smoking in pregnant women? Could you describe why that is? What would help you feel more optimistic?

f. Confidence

xi. How would you describe your confidence on management of smoking in pregnant women? What would help you feel more confident?

g. NRT

xii. What has been your experience with prescribing Nicotine Replacement Therapy (NRT) in pregnant women who smoke? What do you think would help you subscribe NRT to pregnant women who smoke?

h. Referral

xiii. Could you tell me a little about your experience with referring women to cessation support (such as the quit-line or a local smoking cessation group)?

xiv. What would help you to routinely refer pregnant women to cessation support?

i. Follow up

xv. What has been your experience with following up on women in regard to their smoking?

xvi. What would facilitate you to follow up?

j. Discussing the psychosocial context

xvii. How do you feel about discussing with pregnant women the psychosocial context of smoking?

xviii. What can help you with this?

k. Subgroups

xix. Describe your experience with any subgroups of pregnant women for whom there may be additional challenges to treatment?

4. Ending the interview

a. Thank participant for their time
b. Explain about transcribing the interview while removing all identifying details
c. Ask participant if they could recommend other potential participants

Appendix 3: Systematic Review Related Material (Paper Five)

Appendix 3.1: Prospero registration

Appendix 3.2: PRIZMA checklist

Appendix 3.3: Hawker quality assessment tool

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS National Institute for Health Research

PROSPERO International prospective register of systematic reviews

Review title and timescale

1 Review title
Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.
Systematic review of interventions to improve health professionals' provision of smoking cessation care in pregnancy from preconception to the postnatal period

2 Original language title
For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3 Anticipated or actual start date
Give the date when the systematic review commenced, or is expected to commence.
01/10/2015

4 Anticipated completion date
Give the date by which the review is expected to be completed.
31/12/2016

5 Stage of review at time of this submission
Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started ×

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

Review team details

6 Named contact
The named contact acts as the guarantor for the accuracy of the information presented in the register record.
Dr Bar Zeev

7 Named contact email
Enter the electronic mail address of the named contact.
yael.barzeev@uon.edu.au

8 Named contact address
Enter the full postal address for the named contact.
Level 5 McAuley Building Calvary Mater Hospital Centre for Brain and Mental Health Waratah 2298 New South Wales. Australia.

9 Named contact phone number
Enter the telephone number for the named contact, including international dialing code.
+61 0478040759

10 Organisational affiliation of the review
Full title of the organisational affiliations for this review, and website address if available. This field may be completed

as 'None' if the review is not affiliated to any organisation.
none

Website address:

11 Review team members and their organisational affiliations
Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation
Dr	Yael	Bar Zeev	University of Newcastle
Dr	Gillian	Gould	University of Newcastle
Miss	Laura	Twyman	University of Newcastle

12 Funding sources/sponsors
Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.
Hunter Cancer Research Alliance Implementation Science Flagship Program

13 Conflicts of interest
List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.
Are there any actual or potential conflicts of interest?
None known

14 Collaborators
Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details
Professor	Billie	Bonevski	University of Newcastle
Professor	Maree	Gruppetta	University of Newcastle

Review methods

15 Review question(s)
State the question(s) to be addressed / review objectives. Please complete a separate box for each question.
Identify the effectiveness of interventions for increasing health professionals provision of smoking cessation care in Pregnancy from Preconception to the Postnatal Period

Do interventions differ in effectiveness among subgroups of health professionals such as general practitioners, gynaecology and obstetric specialists, nurses and midwifes?

Do interventions differ in effectiveness for patients groups according to race/ethnicity, age-group, socio-economic status, and co-morbid conditions?

16 Searches
Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.
Searches will be carried out in Cochrane Central Register of Controlled Trials (CENTRAL); MEDLINE; EMBASE; PsycINFO; CINAHL; Reference lists of full text studies, and of similar reviews. Search terms will include Keywords and Mesh terms for Clinicians, Pregnancy, Tobacco and Interventions. Search terms were selected to provide broad return in identify papers that should be included. No restrictions on time. Included papers are restricted to English language.

17 URL to search strategy
If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available
No

18 Condition or domain being studied
Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.
Healthcare domain: Provision of smoking cessation care for pregnant women. Smoking cessation care will include (but not limited to) asking about smoking, assessing patient's motivation/interest in changing smoking behaviour, assessing nicotine dependence, advising about quitting, assisting to quit with e.g. counselling or pharmacotherapy, prescribing pharmacotherapy, discussing psychosocial contexts of smoking, following up patient, involving family members or partners in smoking cessation care or aiding family to quit, referrals, use of resources and self-help materials, advising about relapse, advise about smoke-free homes, use of Behavioural Change Techniques such as setting a quit date, increasing self-efficacy, monitoring carbon monoxide reading, validating abstinence. Knowledge includes objective measures of clinician knowledge about smoking cessation in pregnancy, knowledge of smoking cessation guidelines, and reported training. Attitudes include those about perceived skill level for counselling and prescribing pharmacotherapy, suitability/availability of cessation resources, optimism for treatment effectiveness, social/professional role, beliefs about capabilities, consequences, motivation and goals, memory, attention and decision processes, social influences, emotional and behavioural regulation.

19 Participants/population
Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.
Inclusion Criteria - All types of Health professionals (including allied health professionals) who treat women who smoke during ether pre-conception/postnatal care and/or pregnancy. Exclusion Criteria - Interventions that focus on the pregnant women (and not on the health professionals)

20 Intervention(s), exposure(s)
Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed
Inclusion Criteria: All type of intervention studies will be included – randomized controlled trials, pre-post study design, non-randomized controlled trials, Interrupted time-series studies, and quasi-experiments studies. Exclusion criteria: Intervention studies that report outcomes that focus solely on outcomes from the women (smokers) themselves and not providers. Descriptive studies with no intervention.

21 Comparator(s)/control
Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).
Inclusion Criteria: All comparison types (no comparison, usual care, less intensive, alternative) will be included. Exclusion Criteria: none

22 Types of study to be included initially
Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.
All type of intervention studies will be included – randomized controlled trials, pre-post study design, non-randomized controlled trials, Interrupted time-series studies, and quasi-experiments studies.

23 Context
Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.
Smoking cessation care by health professionals in any setting

24 Primary outcome(s)
Give the most important outcomes.
Intervention success rates (in changing provider behaviour) regarding any measures of provision of smoking cessation care to pregnant smoking women

Give information on timing and effect measures, as appropriate.

25 Secondary outcomes
List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.
1. Intervention success rates regarding any measures of knowledge and attitudes of health professionals

management of smoking in pregnant women 2. Smoking abstinence in late pregnancy (point prevalence abstinence and/or continued abstinence; self-reported and/or biochemically validated) 3. Smoking reduction from the first antenatal visit to late pregnancy (numbers of women reducing smoking (any definition, self-reported > 50% reduction , and/or biochemically validated) 4. Post-partum relapse rates

Give information on timing and effect measures, as appropriate.

26 Data extraction, (selection and coding)
Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.
Two researchers will complete study selection with a third acting as adjudicator. One researcher will complete data extraction with a second to data extract a random 20% of articles. Agreement over 90% will be sought.

27 Risk of bias (quality) assessment
State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.
Quality of included studies to be assessed by tools from Cochrane Collaboration for assessing quality and risk of bias, and Hawker et al. appraising the evidence: reviewing disparate data systematically. Qual Health Res. 2002; 12(9):1284-99.

28 Strategy for data synthesis
Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.
All data for each type of intervention will be summarised separately and then synthesised together. Narrative synthesis will follow Popay's Guidance on the Conduct of Narrative Synthesis in Systematic Reviews. A meta-analysis will be attempted if relevant to studies included.

29 Analysis of subgroups or subsets
Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.
Subgroup analysis will be conducted for: 1. Different health professionals subgroups (including general practitioners, obstetricians, nurses and midwifes) 2. Patients groups related to race/ethnicity, age-groups, socio-economic status and co-morbid conditions

Review general information

30 Type of review
Select the type of review from the drop down list.
Intervention

31 Language
Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.
English

Will a summary/abstract be made available in English?
Yes

32 Country
Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.
Australia

33 Other registration details
Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

34 Reference and/or URL for published protocol
Give the citation for the published protocol, if there is one.

Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available
Yes

35 Dissemination plans
Give brief details of plans for communicating essential messages from the review to the appropriate audiences.
Findings will be disseminated through a journal article and appropriate scientific conferences

Do you intend to publish the review on completion?
Yes

36 Keywords
Give words or phrases that best describe the review. (One word per box, create a new box for each term)
Smoking cessation

Pregnant

Health professionals

Intervention

37 Details of any existing review of the same topic by the same authors
Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38 Current review status
Review status should be updated when the review is completed and when it is published.
Ongoing

39 Any additional information
Provide any further information the review team consider relevant to the registration of the review.

40 Details of final report/publication(s)
This field should be left empty until details of the completed review are available.
Give the full citation for the final report or publication of the systematic review.
Give the URL where available.

Appendix 3.2: PRIZMA checklist

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4-5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4-5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplemental file 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5-6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	5-6
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	7
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8, figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Supplemental file 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Supplemental file 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Supplemental file 2
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	10-14, Figure 2-4, Supplementary file 4
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Supplemental file 3
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	11-14, Figure 2-4, Supplemental file 5
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	16
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	16-17
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17-19

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	20

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

Appendix 3.3: Hawker quality assessment tool

APPENDIX D

1. Abstract and title: Did they provide a clear description of the study?
   - Good: Structured abstract with full information and clear title.
   - Fair: Abstract with most of the information.
   - Poor: Inadequate abstract.
   - Very Poor: No abstract.
2. Introduction and aims: Was there a good background and clear statement of the aims of the research?
   - Good: Full but concise background to discussion/study containing up-to-date literature review and highlighting gaps in knowledge.
     Clear statement of aim AND objectives including research questions.
   - Fair: Some background and literature review.
     Research questions outlined.
   - Poor: Some background but no aim/objectives/questions, OR
     Aims/objectives but inadequate background.
   - Very Poor: No mention of aims/objectives.
     No background or literature review.
3. Method and data: Is the method appropriate and clearly explained?
   - Good: Method is appropriate and described clearly (e.g., questionnaires included).
     Clear details of the data collection and recording.
   - Fair: Method appropriate, description could be better.
     Data described.
   - Poor: Questionable whether method is appropriate.
     Method described inadequately.
     Little description of data.
   - Very Poor: No mention of method, AND/OR
     Method inappropriate, AND/OR
     No details of data.
4. Sampling: Was the sampling strategy appropriate to address the aims?
   - Good: Details (age/gender/race/context) of who was studied and how they were recruited.
     Why this group was targeted.
     The sample size was justified for the study.
     Response rates shown and explained.
   - Fair: Sample size justified.
     Most information given, but some missing.
   - Poor: Sampling mentioned but few descriptive details.
   - Very Poor: No details of sample.
5. Data analysis: Was the description of the data analysis sufficiently rigorous?
   - Good: Clear description of how analysis was done.
     Qualitative studies: Description of how themes derived/respondent validation or triangulation.
     Quantitative studies: Reasons for tests selected hypothesis driven/numbers add up/statistical significance discussed.
   - Fair: Qualitative: Descriptive discussion of analysis.
     Quantitative.
   - Poor: Minimal details about analysis.
   - Very Poor: No discussion of analysis.

6. Ethics and bias: Have ethical issues been addressed, and what has necessary ethical approval gained? Has the relationship between researchers and participants been adequately considered?

Good	Ethics: Where necessary issues of confidentiality, sensitivity, and consent were addressed. Bias: Researcher was reflexive and/or aware of own bias.
Fair	Lip service was paid to above (i.e., these issues were acknowledged).
Poor	Brief mention of issues.
Very Poor	No mention of issues.

7. Results: Is there a clear statement of the findings?

Good	Findings explicit, easy to understand, and in logical progression. Tables, if present, are explained in text. Results relate directly to aims. Sufficient data are presented to support findings.
Fair	Findings mentioned but more explanation could be given. Data presented relate directly to results.
Poor	Findings presented haphazardly, not explained, and do not progress logically from results.
Very Poor	Findings not mentioned or do not relate to aims.

8. Transferability or generalizability: Are the findings of this study transferable (generalizable) to a wider population?

Good	Context and setting of the study is described sufficiently to allow comparison with other contexts and settings, plus high score in Question 4 (sampling).
Fair	Some context and setting described, but more needed to replicate or compare the study with others, PLUS fair score or higher in Question 4.
Poor	Minimal description of context/setting.
Very Poor	No description of context/setting.

9. Implications and usefulness: How important are these findings to policy and practice?

Good	Contributes something new and/or different in terms of understanding/insight or perspective. Suggests ideas for further research. Suggests implications for policy and/or practice.
Fair	Two of the above (state what is missing in comments).
Poor	Only one of the above.
Very Poor	None of the above.

REFERENCES

Bond, S. (1993). Experimental research in nursing: Necessary but not sufficient. In A. Kitson (Ed.), *Nursing: Arts and science seminars* (pp. 94-112). Oxford: Chapman and Hall.

Critical Appraisal Skills Programme. (1998). *Critical Appraisal Skills Programme (CASP).* Retrieved September 17, 2002, from http:www.iphrp.salford.ac.uk/cochrane/diss_ex.htm#CASP

Chalmers, I., & Altman, D. G. (1995). *Systematic reviews*. London: BMJ Publishing.

Counsell, C. (1997). Formulating questions and locating primary studies for inclusion in systematic reviews. *Annals of Internal Medicine*, *127*, 380-387.

Appendix 4: ICAN QUIT in Pregnancy Study Related Material

Appendix 4.1: Ethics approval

Appendix 4.1.1: University of Newcastle HREC approval

Appendix 4.1.2: AH&MRC HREC approval

Appendix 4.1.3: AHREC HREC approval

Appendix 4.1.4: Far North Queensland HREC approval

Appendix 4.2: Information sheet

Appendix 4.3: Suitability of Material scoring

Appendix 4.4: Pilot study health professionals information sheet

Appendix 4.5: Pilot study health professionals survey

Appendix 4.6: Additional information regarding the development of the intervention

Appendix 4.1: Ethics Approval

Appendix 4.1.1: University of Newcastle HREC approval

HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Doctor Gillian Gould**
Cc Co-investigators / Research Students:	**Dr Marilyn Clarke** **Doctor Christopher Oldmeadow** **Assoicate Professor Alan Clough** **Ms Kristin Carson** **Professor Jennifer Reath** **Associate Professor Maree Gruppetta** **Professor Billie Bonevski** **Dr Peter O'Mara** **Professor Roger Smith** **Professor Yvonne Cadet-James** **Yael Bar Zeev** **Assoicate Professor Renee Bittoun** **Mrs Michelle Bovill** **Associate Professor Cheryl Oncken** **Dr Lou Atkins** **Brett Cowling** **Lisa Orcher**
Re Protocol:	**The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: a Cluster Randomised Control Trial to Improve Strategies for the Management of Smoking Cessation in Pregnant Aboriginal and/or Torres Strait Islander Women**
Date:	**19-Feb-2016**
Reference No:	**H-2015-0438**
Date of Initial Approval:	**19-Feb-2016**

Thank you for your **Response to Conditional Approval (minor amendments)** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under **Expedited** review by the Ethics Administrator.

I am pleased to advise that the decision on your submission is **Approved** effective **19-Feb-2016**.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. *If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.*

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2015-0438**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC 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 HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on this Approval Advice** to report adverse events.
2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at https://rims.newcastle.edu.au/login.asp) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at https://rims.newcastle.edu.au/login.asp). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of

recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

For communications and enquiries:
Human Research Ethics Administration

Research Services
Research Integrity Unit
The Chancellery
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 17894
F +61 2 492 17164
Human-Ethics@newcastle.edu.au

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
Cancer Institute NSW/Early Career Fellowship(**)	Improving strategies for the management of smoking cessation in NSW pregnant Aboriginal women: the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Trial	Gould, Gillian	G1500818

Aboriginal Health & Medical Research Council
of New South Wales

AH&MRC ETHICS COMMITTEE

5 February 2016

Dr Gillian Gould
Centre for Translational Neuroscience and Mental Health
University of Newcastle
CTNMH, PO Box 833
Newcastle NSW 2300

Dear Dr Gould,

1140/15 -The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: a Cluster Randomised Control Trial to Improve Strategies for the Management of Smoking Cessation in Pregnant Aboriginal and/or Torres Strait Islander Women

The Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee has considered your original application, received on 16 November 2015, for ethics approval.

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 **5 February 2016** until **5 February 2017** (12 months after), with extension subject to providing an Annual Progress Report on the research by **5 February 2017.**
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

ABORIGINAL HEALTH
RESEARCH ETHICS COMMITTEE

15 March 2016

Dr Gillian Gould
University of Newcastle,
CTNMH, PO Box 833
Newcastle NSW 2300
By Email: Gillian.gould@newcastle.edu.au , Yael.BarZeev@uon.edu.au

RE: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: a Cluster Randomised Control Trial to Improve Strategies for the Management of Smoking Cessation in Pregnant Aboriginal and/or Torres Strait Islander Women
Ref. No: 04-16-652

Dear Gillian,
Thank you for your submission requesting ethical review from the Aboriginal Health Research Ethics Committee (AHREC).

I am pleased to inform you that the study was reviewed at AHREC's meeting held on 10 March 2016 and met with support. The Committee recommended your application for approval. Whilst approved, please be advised that the Committee's approval is contingent upon the need for appropriate consultation to take place in order to ensure that the approached services actually fit the ACCHS inclusion criteria specified in your study. The Committee recommended that the study team should explore recruitment options through the Aboriginal Family Birthing Program in South Australia that has been implemented across various metropolitan and country local health networks. Please be advised of the following standard conditions:

- The duration of approval is from 15 March 2016 until the expected completion date of your project indicated as 1 June 2020.
- Data to be stored for at least 7 years instead of 5 years.
- In accordance with the NHMRC guidelines, AHREC requires annual reports from principal researcher(s). Please find the reporting template at: http://ahcsa.org.au/research-overview/ethical-review-ahrec/

We wish you well with the project and look forward to receiving your progress reports. If you require further information, please do not hesitate to contact the Executive Officer on 08 8273 7200 or email Gokhan.Ayturk@ahcsa.org.au .

Sincerely yours,
Dr Gokhan Ayturk on behalf of

Ms Kim Morey
Chairperson - AHREC

Queensland Government

Far North Queensland
Human Research Ethics Committee

HREC/16/QCH/34 – 1040
06.09 BS:jld
2nd Reply to queries reviewed-STUDY APPROVED
Telephone: *(07) 4226 5513*
Facsimile: *N/A*
Email: Cairns_Ethics@health.qld.gov.au

25 August 2016

Email: gillian.gould@newcastle.edu.au

Dr Gillian Gould
Centre for Brain & Mental Health
The University of Newcastle
Callaghan NSW 2308

Dear Gillian,

HREC Reference number: HREC/16/QCH/34 - 1040
Project title: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to Improve Strategies for the Management of Smoking Cessation in Pregnant Aboriginal and/or Torres Strait Islander Women

Thank you for submitting the above project which was first considered by the FNQ HREC on 21 April 2016 and again on 23 June 2016. Your response to the HREC's second request for further information dated 25 July 2016 has been reviewed by me out of formal session. I am pleased to advise that **ethical approval is granted** to your application.

You are reminded that this letter constitutes ethical approval only.

You must not commence this research project at *Queensland Health sites, utilize Queensland Health staff or Queensland Health resources* until separate authorisation from the Hospital and Health Service CE or Delegate of that site has been obtained. Should in the future, you wish to engage with Queensland health staff or sites, please contact the HREC Coordinator for advice.

The ethically approved documents are:

Document	*Document Version*	*Document Date*
NEAF (AU/1/272626)	2.2	17 May 2016
Original Cover Letter	*N/A*	16 March 2016
CV Gillian Gould	*N/A*	*Undated*
Letter of support from Debra Malthouse – Wuchopperen Health Service Limited	*N/A*	2 March 2016
Response to request for further information	*N/A*	26 May 2016
2nd Response to request for further information	*N/A*	25 July 2016
Protocol	3.0	11 July 2016

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HREC/16/QCH/34 – 1040
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Far North Queensland
Human Research Ethics Committee

Organisational Information Sheet for the Research project: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to I*mprove Strategies for the management of Smoking Cessation in Pregnant Aborignal and/or Torres Strait Islander Women ICAN QUIT in Pregnancy-phase I	5	11 July 2016
Organisational Information Sheet for the Research project: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to I*mprove Strategies for the management of Smoking Cessation in Pregnant Aborignal and/or Torres Strait Islander Women ICAN QUIT in Pregnancy-Pilot study (phase II)	5	11 July 2016
Focus Group Health Professional Information Sheet for the Research project: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to I*mprove Strategies for the management of Smoking Cessation in Pregnant Aborignal and/or Torres Strait Islander Women ICAN QUIT in Pregnancy-phase I	5	11 July 2016
Focus Group Consumer Information Sheet for the Research project: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to I*mprove Strategies for the management of Smoking Cessation in Pregnant Aborignal and/or Torres Strait Islander Women ICAN QUIT in Pregnancy-phase I	5	11 July 2016
Health Professional Survey Information Sheet for the Research project: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to I*mprove Strategies for the management of Smoking Cessation in Pregnant Aborignal and/or Torres Strait Islander Women ICAN QUIT in Pregnancy	5	11 July 2016
Participant Information Sheet for the Research project: The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to I*mprove Strategies for the management of Smoking Cessation in Pregnant Aborignal and/or Torres Strait Islander Women ICAN QUIT in Pregnancy-pilot study (phase II)	5	11 July 2016
Aboriginal Community Organisation Consent Form-Phase I	4	16 March 2016
Aboriginal Community Organisation Consent Form-Phase II	4	16 March 2016
Consent Form – Focus Group – ICAN QUIT in Pregnancy project phase I	5	11 July 2016
Consent Form – Phase II – Pilot Study	5	14 July 2016
Patient Survey-Recruitment	2	13 July 2016
Patient Survey-Follow up	2	13 July 2016
Interview guide for focus groups-Health Providers	1	13 November 2015

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Interview guide for focus groups – consumers and elders	1	13 November 2015
Poster – ICAN QUIT In Pregnancy	1	13 November 2015
Brochure - ICAN QUIT In Pregnancy	*N/A*	*Undated*
Poster ICAN QUIT In Pregnancy	*N/A*	*Undated*
Health Professional Survey	1	13 November 2015
Eligibility Form	2	16 March 2016
Draft partnership Terms of Reference-Stakeholder and Consumer Aboriginal Advisory Panel	1	13 November 2015
SAM Score	*N/A*	*Undated*
SAM Score Sheet	*N/A*	*Undated*
AH&MRC Ethics Committee Approval letter	*N/A*	5 February 2016
University of Newcastle Notification of Expedited Approval	*N/A*	19 February 2016
AH&MRC Letter from Kim Morey	*N/A*	15 March 2016
AH&MRC Letter from Sandra Bailey	*N/A*	19 January 2016
Letter of Support from Tom Calma, National Coordinator Tackling Indigenous Smoking	*N/A*	6 November 2015
Letter of Support from A/Prof Tony Proietto, Hunter New England Local health District	*N/A*	20 October 2015
Letter of Support from Professor Stephen Ackland, HCRA	*N/A*	21 October 2015
Letter of Support from Brett Cowling – Biripi Aboriginal Corporation Medical Centre	*N/A*	*Undated*
Letter of Support from Lisa Orcher, Tobwabba Aboriginal Medical Service	*N/A*	10 November 2015
Letter of Support from Dr Lucas de Toca, Miwatj Health Aborighinal Corporation	*N/A*	19 February 2016
Letter of Support from David Copley, Pangula Mannamurna Inc.	*N/A*	29 January 2016
Notice of Support from Dorothy Whyman, Riverina Medical & Dental	*N/A*	16 February 2016
Letter of Support from Erin Simmonds, Kids health, The Children's Hospital Westmead	*N/A*	16 November 2015

Ethically Approved study site as listed on Page 19 of the NEAF (AU/1/272626):

- WuChopperen Health Service Limited *(letter of support provided)*

A HREC Only Indemnity Form (template attached) needs to be signed by WuChopperen Health Service Limited prior to you commencing the study at that site. The HREC Only Indemnity Form covers the Far North Queensland Human Research Ethics Committee's ethical review of studies occurring at non-Queensland Health sites.

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HREC/16/QCH/34 – 1040
06.09 BS:jld
2nd Reply to queries reviewed-STUDY APPROVED
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Far North Queensland
Human Research Ethics Committee

Letters of support from the site are required to accompany the completed HREC Only Form of Indemnity template before the document can be presented to the Chief Executive of the Cairns and Hinterland Hospital and Health Service for signature.

All signatures are required on the Indemnity Form before you can commence your research at the listed non-Queensland Health sites.

Note: *For sites that are still to be determined, once these are known by the research team, an application in the form of a study amendment must be submitted to the FNQ HREC to add these sites.*

(If you are a student researcher you are obliged to advise your Supervisor/s as to the current status of your research application.)

Please note the following conditions of approval:

1. If relevant to your project, your attention is drawn to standards for clinical trials reporting as enunciated in the CONSORT statement *(hhpt://www.consort-statement.ort/?o=1001)* and a requirement by many journals for certain categories of clinical trials to be registered (see: *http://www.anzctr.org.au*/Support/HowToAdd.aspx).

2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

    a. Unforeseen events that might affect continued ethical acceptability of the project. Serious Adverse Events must be notified to the Committee as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

3. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from.

    http://www.health.qld.gov.au/cpic/documents/ethics/researcher_userguide.pdf

4. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).

5. Proposed amendments to the research project which may affect both the ethical acceptability

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Queensland Government

Far North Queensland
Human Research Ethics Committee

and site suitability of the project must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the RGO.

6. Amendments which do not affect either the ethical acceptability or site acceptability of the project(e.g. typographical errors) should be submitted in hard copy to the HREC coordinator. These should include a cover letter from the principal investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

7. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

8. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

9. The Health Service administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on hospital premises or claiming any association with the hospital; or which the Committee has approved if conducted outside of Queensland Health however within the jurisdiction of the Committee (Cairns, Cape & Torres Hospital & Health Services).

10. **If research is occurring in Aboriginal and Torres Strait Islander Communities please ensure that you provide progress reports and feedback to relevant Aboriginal and Torres Strait Islander Groups.**

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment III) and return to the office of the Human Research Ethics Committee.

HREC approval is valid for **three years** from the date of this letter.

The HREC wishes you every success in your research.

Yours sincerely

Dr Bernard Street – Acting Chair
Far North Queensland
Human Research Ethics Committee

William McCormack Place
Level 7 East, 5B Sheridan Street
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Dr Gillian S Gould
Centre for Translational Neuroscience & Mental Health
The University of Newcastle, Callaghan, 2308
Telephone: 0403 615563
Fax: 02 4033 5692
Email: gillian.gould@newcastle.edu.au

Focus Group Health Professional Information Sheet for the Research project:

The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to Improve Strategies for the Management of Smoking Cessation in Pregnant Aboriginal and/or Torres Strait Islander Women

ICAN QUIT in Pregnancy- phase I

The Research Team:

Dr Gillian Gould (Principle Researcher)

Associate Professor Billie Bonevski

Dr Peter O'Mara

Dr Yael Bar-Zeev

Invitation: You are invited to take part in the research project identified above which is being conducted by Dr Gillian Gould from the Centre for Translational Neuroscience and Mental Health from the University of Newcastle.

The research is part of Dr Yael Bar-Zeev's PhD studies at the University of Newcastle supervised by Dr Gillian Gould, A/Prof Billie Bonevski and A/Prof Maree Gruppetta.

Why is the research being done?

The purpose of the research is to improve the provision of evidence based smoking cessation care of expectant mothers of Aboriginal and/or Torres Strait Islander babies at Aboriginal Medical Services.
One in two Aboriginal women smoke during pregnancy.
Tobacco smoking in pregnancy can lead to a poor outcome of the pregnancy for the mother and for the baby, including miscarriage, low birth weight and pre-term delivery, and to other life-long diseases such as cancer and heart disease. Quitting smoking at any stage will help women and babies health.

Who can participate in this research?

We are seeking Health Professionals working in Aboriginal Medical Services or Aboriginal Community Controlled Health Services, and caring for pregnant smoking Aboriginal and/or Torres Strait Islander women.

What does participation involve?

- Participate in a group discussion
- Look at and read through educational resources developed for health professional use for the ICAN QUIT in Pregnancy project
- Give your honest opinion and feedback
- If you wish you can also write notes and comments for the research team

Dr Gillian S Gould
Centre for Translational Neuroscience & Mental Health
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- The group discussion will be recorded

Will taking part in the study cost me anything, and will I be paid?

- There will be no cost to you other than giving up a small amount of your time.

How will my confidentiality be protected?

- Any information collected about you during the focus group will be de-identified**.**
- Records will only be stored on University software with password protection.
- Your name will not be kept attached to your records or the other information you will give, nor used when we report the results.

What happens with the results of the research?

- Your information along with information from others will form the results of phase I of this research. We will modify and improve the educational resources based on yours and others input.
- These resources will be used in phase II (pilot study) and phase III (cluster randomised controlled trial) to evaluate the change in provider behaviour for supporting Aboriginal women quit smoking during pregnancy.
- Results will also be used to write a report but you will not be identified in any way.
- The results will be presented to Aboriginal communities and more widely though articles and at conferences.

What if I don't want to take part in the research, or if I want to drop out later?

- It is your choice whether or not you choose to participate.
- Whether you participate, or not, will not affect your position at the medical service in any way.
- If you choose to participate you can also later drop out from the research without any penalty.

What should I do if I want more information about the study before I decide to participate?

- You can ask any questions you like. Please talk to the following researchers:
  - **Dr Gillian Gould – 0403615563**
  -

Complaints about this research:

This research has been approved by the …….Ethics Committee, (Reference …….)

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 the Chairperson of the AH&MRC Ethics Committee (The Chairperson, AH&MRC Ethics Committee, P.O. Box 1565, Strawberry Hills NSW 2012, Telephone: 9212 4777) or The Chairperson of the University of Newcastle Ethics Committee (The Chairperson, University of Newcastle, Human Research Ethics Committee, human-ethics@newcastle.edu.au, (02) 4985 4269).

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

SAM Score
Suitability Assessment of Material Score Sheet

The SAM Suitability of Materials assessment method was developed by Doak, Doak and Root in 1993 and published in the book: *Teaching Patients with Low Literacy Skills,* Lippincott, Williams & Wilkins, 1996.

It offers a systemic method to objectively assess the suitability of health information materials.

The SAM score is composed of a rating in six areas:

- Content
- Literacy Demand
- Graphics
- Layout and Type
- Learning Stimulation and Motivation
- Cultural Appropriateness

Instructions:

1. Read through the SAM factor list and the evaluation criteria on the score sheet, below.
2. Read the material you want to evaluate
3. Determine its purpose(s) and key points.
4. Evaluate and score each of the 22 SAM factors using the evaluation criteria provided, and circle the appropriate score on the score sheet. The scoring system provides:
    - 2 points per factor for superior rating
    - 1 point per factor for adequate rating
    - 0 points per factor for not suitable rating.

5. As you evaluate each factor, you are likely to find wide variation in different parts of the material. For any one factor, some parts may rate high (superior), while other parts may rate low (unsuitable). Resolve this by giving most weight to the part of your material that includes the key points that you identified in step 3 above.

6. If the factor to be rated is not relevant, write N/A across the score column for that section.

7. Calculate the total suitability score. When you have evaluated all the factors and circled a score for each on the score sheet, add up the circled score to get the total score. The highest possible total score is 44 points.

   To account for SAM factors that may not apply to the material, revise your highest possible total score by subtracting 2 points for each N/A from the 44 total.

Interpretation of SAM percentage ratings:

70–100 per cent: superior material

40–69 per cent: adequate material

0–39 per cent: not suitable material.

SAM Score Sheet

SAM FACTOR TO BE RATED		EVALUATION CRITERIA	SCORE
1. Content	a. Purpose It is important that readers understand the purpose of the materials. If they don't they may miss the main point.	Purpose is explicitly stated in the title, cover illustration or introduction.	2
		Purpose is not explicit. It is implied or multiple purposes are stated.	1
		No purpose is stated in the title, illustration or introduction	0
	b. Content topics Adult learners usually want to solve their problem, rather than learn facts. The content of most interest and use is likely to be behaviour information to help solve their problem.	Thrust of material is application of knowledge/skills aimed at desirable reader behaviour rather than facts.	2
		At least 40 per cent of content topics focus on desirable behaviours or actions.	1
		Nearly all topics focus on non-behaviour facts.	0
	c. Scope Scope should be limited to the purpose/objectives of the material, and to what can reasonably be learned in the time typically allocated to reading the information.	Scope limited to essential information directly related to the purpose. Experience shows it can be learned in the time available.	2
		Scope expanded beyond the purpose of the document, but no more than 40% is non-essential information. Key points can be learned in the time available.	1
		Scope is far out of proportion to the purpose and time available.	0
	d. Summary/review A summary offers readers a chance to see the key points in other words or examples. They are important; readers often miss the key points when they first read them.	A summary is included and retells the key message in different words and examples.	2
		Some key ideas are reviewed.	1
		No summary or review is included.	0

SAM FACTOR TO BE RATED		EVALUATION CRITERIA	SCORE
2. Literacy demand	a. Reading Grade Level The text reading level will be an important factor in whether your target group understands your document. Reading formulas, like SMOG, provide a reasonably accurate measure of reading difficulty.	5th-grade or lower (5 years of schooling).	2
		6th – 8th- grade level (6 – 8 years of schooling).	1
		9th-grade level and above (9+ years of schooling).	0
	b. Writing style Conversational style and active voice lead to easy-to-understand text. E.g. *'Take your medicine every day'* (active voice) is more effective than *'Patients are advised to take their medicine every day'* (passive voice). Embedded information – long or multiple phrases included within a sentence – slows down the reading process and often makes comprehension harder.	Both of the following are present: • the text is mostly conversational style and active voice • simple sentences are used extensively • few sentences contain embedded information.	2
		About 50 per cent of the text uses conversational style and active voice. Less than half of the sentences have embedded information.	1
		Passive voice is used throughout. Over half the sentences have extensive embedded information.	0

	c. Vocabulary
	It's best to:
	• use common, explicit words, e.g. '*doctor*' rather than '*specialist*'/'*physician*'.
	• avoid words that express general terms:
	  • categories, e.g. '*a disability unit*' versus '*a unit that's specially designed for people with disabilities*'
	  • concepts, e.g. '*normal range*' versus '*15–70 metres*'
		All three of the following are present:
		• common words are used nearly all the time
		• technical, concept, category and value judgement words are explained by examples
		• imagery words are used as appropriate for content.
			2

		Common words are frequently used. Technical concept, category and value judgement words are sometimes explained by examples. Some jargon or math symbols are included.	1

	• value judgements, e.g. '*excessive pain*' versus '*pain that makes it hard to think about anything else*' • use words that create an image, e.g. '*brown bread*' versus '*dietary fibre*'; a '*runny nose*' versus '*excess mucus*'.	At least two of the following are present: • uncommon words are frequently used in lieu of common words • no examples are given for technical, concept, category and value judgement words • extensive jargon is used.	0
	d. Context We learn new facts/behaviours more quickly when told the context first. E.g. '*To find out what's wrong with you (*the context first*), the doctor will take a sample of your blood for testing in the lab.'*	The material consistently provides context before presenting new information.	2
		Provides context before new information about 50 per cent of the time.	1
		Context is provided last or no content is provided.	0
	e. Advanced organisers Headers or topic captions tell very briefly what's coming up next. These 'road signs' make the text look less formidable, and prepare the reader's thought process to expect the next topic.	Nearly all topics are preceded by an advance organiser (a statement that tells what is coming next).	2
		About 50 per cent of the topics are preceded by advance organisers	1
		Few/no advance organisers are used.	0
3. Graphics	a. Cover graphic People *do* judge a booklet by its cover. The cover image is often the deciding factor in a reader's attitude toward, and interest in, the information.	All three of the following are present: 1. The cover graphic is friendly 2. The cover graphic attracts attention 3. The cover graphic clearly portrays the purpose of the material	2
		The cover graphic has one or two of the superior criteria.	1
		The cover graphic has none of the superior criteria.	0

	b. Type of illustrations Simple line drawings can promote realism without including distracting details (photos often include extra details). Visuals are accepted and remembered better when they portray what is familiar and easily recognised.	Both of the following are present: 1. Simple, adult-appropriate line drawings/sketches 2. Illustrations are likely to be familiar to readers.	2
		One of the superior factors is missing.	1
		None of the superior factors are present.	0
	c. Relevance of illustrations Non-essential details such as room background, elaborate borders, unneeded colour can distract the reader, whose eyes may be 'captured' by these details. The illustrations should tell the key points visually.	Illustrations present key messages visually so the reader can grasp the key ideas from the illustrations alone. There are no distracting illustrations.	2
		Illustrations include some distractions and/or there are insufficient illustrations.	1
		There are confusing or technical illustrations (non-behaviour related), no illustrations or an overload of illustrations.	0
	d. List, tables, graphs, charts Many readers do not understand the purpose for lists, charts, and graphs. Explanations and directions are essential.	Step-by-step directions, with an example, are provided that will build comprehension and self-efficacy.	2
		'How-to' directions are too brief for reader to understand and use the graphic without additional counselling.	1
		Graphics are presented without explanation.	0

SAM FACTOR TO BE RATED		EVALUATION CRITERIA	SCORE
3. Graphics (continued)	e. Captions Captions can quickly tell the reader what the graphic is all about and where to focus within the graphic. A graphic without a caption is usually an inferior instruction and a missed learning opportunity.	Explanatory captions are provided with all or nearly all illustrations and graphics.	2
		Brief captions used for some illustrations and graphics.	1
		Captions are not used.	0
4. Layout and typography	a. Layout Layout has a substantial influence on the suitability of materials.	At least 5 of the following are present: 1. Illustrations are on the same page adjacent to the related text. 2. Layout and sequence of information is consistent, making it easy for the reader to predict the flow of information. 3. Visual cuing devices (shading, boxes, arrows) are used to direct attention to specific points or key content. 4. Adequate white space is used to reduce clutter. 5. Use of colour supports and is not distracting to the message. Viewers need not learn colour codes to understand and use the message. 6. Line length is 30–50 characters and spaces. 7. There is high contrast between type and paper. 8. Paper has non-gloss or low-gloss surface.	2
		Three+ superior factors are present.	1
		Two (or less) superior factors are present. The material looks uninviting or discouragingly hard to read.	0
	b. Typography Type size and fonts can make text easy or difficult for readers at all skill levels. For example text in ALL CAPS slows reading comprehension. Also, when too many (six or more)	The following four factors are present: 1. Text type is in uppercase and lower-case serif (best) or sans-serif. 2. Type size is at least 12 points. 3. Typographic cues (bold, size, colour) emphasise key points. 4. No ALL CAPS are used for long headings or running text.	2

	type fonts and sizes are used on a page, the appearance becomes confusing and the focus uncertain.	Two of the superior factors are present.	1
		One or none of the superior factors are present, or six or more type styles and sizes are used on a page.	0
4. Layout and typography (continued)	c. Subheadings ('chunking') Few people can remember more than seven independent items. For adults with low literacy skills, the limit may be three- to five-item lists. Longer lists need to be broken into smaller "chunks".	Lists are grouped under descriptive subheadings or "chunks". There are no more than five items presented without a subheading.	2
		No more than seven items are presented without a subheading.	1
		More than seven items are presented without a subheading.	0
5. Learning stimulation, motivation	a. Interaction When a reader responds to an instruction (i.e. does something in response) chemical changes take place in the brain that enhance retention in long-term memory. Readers should be asked to solve problems, to make choices, to demonstrate, etc.	Problems or questions are presented for reader responses.	2
		Question-and-answer format is used to present problems and solutions (passive interaction).	1
		No interactive learning stimulation provided.	0
	b. Modelling of behaviours People often learn more readily by observation, by doing something for themselves rather than by reading or being told, and when specific, familiar instances are used rather than the abstract or general.	Instruction models specific behaviours or skills, e.g. for nutrition instruction, emphasis is given to specific behaviours like reading produce labels.	2
		Information is a mix of technical and common language that the reader may not easily interpret in terms of daily living (for example, Starches: 80 calories per serve; High fibre: 1–4 grams of fibre per serve).	1

		Information is presented in non-specific or category terms such as food groups.	0
	c. Motivation People are more motivated to learn when they believe the tasks/behaviours are do-able by them.	Complex topics are subdivided into small parts so that readers may experience small successes in understanding or problem solving, leading to self-efficacy.	2
		Some topics are subdivided to improve the readers' self-efficacy.	1
		No partitioning is provided to create opportunities for small successes.	0
6. Cultural appropriateness	a. Cultural match A valid measure of cultural appropriateness of material is how well its logic, language, and experience (inherent in the instruction) match the logic, language and experience of the intended audience. For example a nutrition instruction is a poor cultural match when it tells readers to eat asparagus if asparagus is rarely eaten by people in that culture and is not sold	Central concepts/ideas of the material appear to be culturally similar to the logic, language and experience of the target culture.	2
		Significant match in the logic, language and experience for 50 per cent of the central concepts.	1
		Clearly a cultural mismatch in the logic, language and experience.	0
	b. Cultural image and examples To be accepted, an instruction must present cultural images and examples in realistic and positive ways.	Images and examples present the culture in positive ways.	
		There is neutral presentation of cultural images or foods.	
		Negative images are used, such as exaggerated or caricatured cultural characteristics, actions	
		Total SAM score	
		Total possible score	
		Per cent score	

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Health Professional Survey Information Sheet for the Research project:

The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy: A Cluster Randomised Control Trial to Improve Strategies for the Management of Smoking Cessation in Pregnant Aboriginal and/or Torres Strait Islander Women

ICAN QUIT in Pregnancy

Invitation: You are invited to take part in the research project identified above which is being conducted by Dr Gillian Gould from the Centre for Brian and Mental Health Research from the University of Newcastle.

The research is part of Dr Yael Bar-Zeev's and Michelle Bovill's PhD studies at the University of Newcastle, School of Medicine and Public Health, supervised by Dr Gillian Gould and A/Prof Maree Gruppetta. Dr Yael Bar Zeev is also supervised by Prof Billie Bonevski.

The research team (names and affiliations of all investigators) and sources of funding are detailed at the end.

Why is the research being done?

One in two Aboriginal women smoke during pregnancy.

Tobacco smoking in pregnancy can lead to a poor outcome of the pregnancy for the mother and for the baby, including miscarriage, low birth weight and pre-term delivery, and to other life-long diseases such as cancer and heart disease. Quitting smoking at any stage will help women and babies health.

The purpose of the research is to improve the management of smoking in pregnant mothers of Aboriginal & Torres Strait Islander babies at Aboriginal Medical Services.

Who can participate in this research?

We are seeking Health providers working in Aboriginal Medical Services or Aboriginal Community Controlled Health Services, and caring for pregnant smoking Aboriginal & Torres Strait Islander women.

What does participation involve?

- Answer 3 self-administered online surveys about your knowledge, attitudes and practices managing smoking in pregnant Aboriginal or Torres Strait Islander women.
- Audio record 2-3 of your smoking cessation consultations (with your consent and the participating women's consent). These will be shared with the researchers (with no identifying personal details).

Will taking part in the study cost me anything, and will I be paid?

- There will be no cost to you other than giving up a small amount of your time.
- You will not be paid

What are the risks and benefits of participating?

- The benefit of participating is that you will receive free three 1-hour webinar training sessions on the best evidence known for treatment of smoking in pregnant Aboriginal or Torres Strait Islander women. This will be done either at the beginning of the study and or at the end of the study, depending if your service is in the pilot study or is allocated to the intervention or control group in the randomised control trial.

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- There are no bad things likely to happen if you join in the study. You may find that answering the same questions on the surveys 3 times is a bit boring.

How will my confidentiality be protected?

- Any information collected is confidential**.** We will use your date of birth and last three letter of surname as a way of matching the surveys from the different time-points.
- Data will only be stored on University software with password protection. The data will be stored at the Centre for Brain and Mental Health Research at the University in a locked cabinet.
- Data will be stored for a minimum of five years. Only the researchers will have access to the de-identified data.
- This data might be used in the future for other research purposes (subject to further ethics approval)
- Your name will not be kept attached to your records or the other information you will give, nor used when we report the results.

What happens with the results of the research?

- Your information along with information from others will form the results of this research.
- These results will be used to evaluate the change in provider management of smoking in pregnant Aboriginal women.
- Results will also be used to write a report but you will not be identified in any way.
- The results will be presented to Aboriginal communities and more widely though articles and at conferences.

What if I don't want to take part in the research, or if I want to drop out later?

- It is your choice whether or not you choose to participate.
- Whether you participate, or not, will not affect your position held at the organisation.
- If you choose to participate you can also later drop out from the research without penalty.

What should I do if I want more information about the study before I decide to participate?

- You can ask any questions you like. Please talk to the following researchers:
  - **Dr Gillian Gould – 0403615563**

Complaints about this research:

This research has been approved by the University of Newcastle Ethics Committee, (Reference # H-2015-0438), by AH&MRC Ethics Committee (Reference #1140/15), by AHREC (Ref. No: 04-16-652), and by Far North Queensland Human Research Ethics Committee (HREC) (Reference #16/QCH/34 - 1040)

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 to the Senior Human Research Ethics Officer, University of Newcastle Ethics Committee (Senior Human Research Ethics Officer, The University of Newcastle, Callaghan NSW 2308, (02) 492 16333, E: human-ethics@newcastle.edu.au); or the Chairperson of the AH&MRC Ethics Committee (The Chairperson, AH&MRC Ethics Committee, P.O. Box 1565, Strawberry Hills NSW 2012, Telephone: 9212 4777); or to the Executive Officer, Aboriginal Health Research Ethics Committee (Aboriginal Health Council of South Australia Inc, 220 Franklin Street, Adelaide, SA, 500, Gokhan.Ayturk@ahcsa.org.au Ph: 08 8273 7200) or the District Executive Director of Nursing, Cairns & Hinterland Health Service District, Phone: 07 4226 5513 Email: cairns_ethics@health.qld.gov.au

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10. University College London, London, UK
11. Biripi Aboriginal Medical Service, Taree, NSW, Australia
11. Tobwabba Aboriginal Medical Service, Forster, NSW, Australia

This research is being funded by Hunter Cancer Research Alliance Implementation Flagship Program (phase II pilot study), NSW Ministry of Health (phase II pilot study) and Cancer Institute NSW (part of Dr Gillian Gould Early Career Fellowship project funding – phase III RCT study) and by National Health and Medical Research Council Early Career Fellowship (Dr. Gillian Gould)

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.

Knowledge, attitudes and practices of health providers caring for Aboriginal and/or Torres Strait Islander women who smoke in pregnancy

Date: _ _/ _ _/ _ _ _ _ **Medical Service: _____**

Date of Birth _ _/_ _/ _ _ _ **Last three letter of your surname: _____**

1) How would you best describe your position?
   - ☐ General Practitioner
   - ☐ Midwife
   - ☐ Nurse
   - ☐ Aboriginal Health Worker
   - ☐ Other, please state_____

2) How long have you been working as a health provider?
   - ☐ Less than 10 years
   - ☐ 10-19 years
   - ☐ 20 or more years

3) What is your gender?
   - ☐ Male
   - ☐ Female

4) What is your age in years _____

5) Do you currently smoke tobacco products?
   - ☐ Yes daily
   - ☐ Yes occasionally
   - ☐ No I am an ex-smoker
   - ☐ No I have never smoked

6) On an average, how many pregnant women who smoke do you see per month
   - ☐ <5
   - ☐ 5-10
   - ☐ >10

7) Have you read any of the following smoking cessation guidelines? (D 1 - Knowledge)

Guideline	Yes	No
a. Royal Australian College of General Practitioners Supporting smoking cessation: a guide for health professionals, Australia	1	0
b. South Australian Perinatal Practice Guidelines	1	0
c. NSW Ministry of Health Managing Nicotine Dependence – A Guide For NSW Health Staff	1	0
d. Other, please specify_____	1	0

8) How often do you provide the following types of cessation care ***with pregnant women***: (please answer all)

	Never (0%)	**Occasional (1-25%)**	**Sometimes (26-50%)**	**Often (51-75%)**	**Always (76-100%)**
a. **Ask** about smoking status?	1	2	3	4	5
b. Record smoking status in medical file	1	2	3	4	5
c. Give **brief advice** to quit if smoking?	1	2	3	4	5
d. **Assess nicotine dependence** in smokers?	1	2	3	4	5
e. Measure Carbon Monoxide (CO) in exhaled air?	1	2	3	4	5
f. **Provide cessation support** to smokers?	1	2	3	4	5
g. **Recommend/prescribe** nicotine replacement therapy (NRT) to assist quitting?	1	2	3	4	5
h. **Discuss their psychosocial** context of smoking?	1	2	3	4	5
i. **Follow-up** within 2 weeks?	1	2	3	4	5
j. Refer to Quitline?	1	2	3	4	5
k. Refer to other specialist smoking cessation service?	1	2	3	4	5
l. Involve Family members in counselling and tobacco management?	1	2	3	4	5

9) Please rank the order of your choice of cessation methods in pregnancy from 1 to 5 (1=top)

- ☐ Combination of oral form of NRT and nicotine patches
- ☐ Reduce smoking gradually
- ☐ Cold turkey/quit unassisted by medication
- ☐ Nicotine patches
- ☐ Oral forms of NRT such as lozenges, gum, inhalers, spray
- ☐ Other, please state_____

10) Please rate how **safe** you consider the use of NRT is for the foetus when prescribed for a pregnant women?

- ☐ Very safe
- ☐ Always safer than smoking
- ☐ Safer than smoking but some concerns
- ☐ Not safe

11) How **effective** do you perceive NRT is in aiding pregnant smokers to quit?

- ☐ Very effective
- ☐ Moderately effective
- ☐ Low effectiveness
- ☐ Not effective

12) In your view, how well do pregnant patients **adhere to/comply with** taking NRT if recommended?

- ☐ Most adhere to NRT well
- ☐ Equal numbers adhere well and poorly
- ☐ Few adhere to NRT well

13) How often do you ask a pregnant patient about using these substances? (please answer all)

	Never (0%)	**Occasional (1-25%)**	**Sometimes (26-50%)**	**Often (51-75%)**	**Always (76-100%)**
Cannabis	1	2	3	4	5
Cannabis mulled (mixed) with tobacco	1	2	3	4	5
E-cigarettes with nicotine	1	2	3	4	5
E-cigarettes without nicotine	1	2	3	4	5
Chewing tobacco	1	2	3	4	5
Second-hand tobacco smoke	1	2	3	4	5

14) Have you have received any training in tobacco management ***related specifically to pregnancy***? (Please answer all)

	Yes	**No**
a. Undergraduate training	1	0
b. Postgraduate training	1	0
c. In depth specialised course	1	0
d. Brief intervention course	1	0
e. Other, please specify_____		

15) How much do you agree that the following system changes would improve the management of smoking in pregnant women? (Please answer all)

	Strongly Disagree (1)	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly Agree (5)**
Subsidised oral forms of NRT on the PBS					
Improved access to NRT patches (i.e. more courses available per year)					
Health professional training					
Medicare item number for smoking counselling					
Training in cultural competence					

Part 2: Questions on the Theoretical Domains Framework

Please use one of the numbers in the right-hand column to represent your level of agreement with the following statements.

Statements	Strongly Disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly Agree (5)
1. I know how to counsel women about their smoking during pregnancy (D1-Knowledge)					
2. I know how to counsel women about the use of NRT during pregnancy (D1-Knowledge)					
3. I am sufficiently reimbursed financially to manage smoking during pregnancy (reinforcement)					
4. Counselling women about smoking during pregnancy is part of my work as a health provider (D3- Role/identity)					
5. Recommending/prescribing NRT for pregnant smokers is part of my work as a health provider (D3- Role/identity)					
6. I am confident that I can counsel women about their smoking during pregnancy (D4- belief capability)					
7. I am confident that I can recommend/prescribe NRT for pregnant smokers (D4-belief capability)					
8. I am optimistic my intervention for smoking during pregnancy is likely to be effective (D5-optimism)					
9. I am optimistic that recommending/prescribing NRT for smoking cessation during pregnancy is likely to be effective (D5-optimism)					
10. In my workplace, it is routine to help women to quit smoking during pregnancy (D11-Enviro context/resources)					
11. I have sufficient time to help pregnant women to quit smoking (D11-Enviro context/resources)					

12. I have sufficient resources to help pregnant women to quit smoking (D11-Enviro context/resources)					
13. Raising the issue of smoking with a client during pregnancy will benefit our relationship (D6-belief consequences)					
14. My colleagues would approve of me helping pregnant women quit smoking (D12-social influence/subjective norm)					
15. I am comfortable raising the issue of smoking with a pregnant women (D13-Emotion/stress)					
16. I intend to provide smoking cessation support to all my pregnant patients who smoke (Intentions)					
17. My workplace has a system in place to monitor whether I deliver cessation support to pregnant women (behavioural regulation)					
18. I intend to recommend NRT to my pregnant patients who smoke (intentions)					

Please use the numbers on the right columns to rate yours answers (on a sliding scale of 1-5) to the following questions.

Questions	1 (not often)	2	3	4	5 (very often)
19. Generally, when seeing pregnant women who smoke, how often is covering something else on your agenda a higher priority than counselling these women (D9-Goals -Priority)					
20. Generally, when seeing pregnant women who smoke, how often is covering something else on your agenda a higher priority than prescribing/recommending NRT for these women (D9-Goals - Priority)					
21. How often do you forget to counsel women who come in to you who are smoking during pregnancy? (D10-memory/attention)					
22. How often do you forget to prescribe/recommend NRT for a pregnant woman who smokes? (D10-memory/attention)					

Part 3: Questions on knowledge in smoking cessation care in pregnancy

Please tick True or False for each statement

Statements	True	False
1. Nicotine causes cancer.	❑	❑
2. Nicotine is the source of addiction to tobacco smoking.	❑	❑
3. Feeling anxious can be a symptom of nicotine withdrawal.	❑	❑
4. All smokers will experience severe withdrawal symptoms on quitting.	❑	❑
5. Dosage of nicotine replacement therapy should be guided by measures of nicotine dependence.	❑	❑
6. Nicotine replacement therapy is as addictive as cigarettes.	❑	❑
7. Using more than one form of nicotine replacement is unsafe.	❑	❑
8. Different types of nicotine replacement therapy release nicotine at different rates.	❑	❑
9. Pre-quit NRT increases the effectiveness of patches	❑	❑
10. There is a special way of chewing nicotine gum	❑	❑
11. Nicotine replacement therapy is just as harmful as smoking during pregnancy.	❑	❑
12. Pregnant woman may need higher doses of nicotine replacement therapy.	❑	❑
13. There are no absolute contra-indications to the use of Nicotine replacement therapy	❑	❑
14. Pregnant women may need additional intensive cessation support to quit	❑	❑

15. Reducing the number of cigarettes smoked per day in pregnancy is enough to prevent harm to the baby	❑	❑
16. Only quitting before the first three months of pregnancy is beneficial to the baby's health	❑	❑
17. Oral Nicotine replacement therapy may cause irritation to the mouth.	❑	❑
18. Some tobacco products are natural and therefore less harmful than manufactured products.	❑	❑
19. E-cigarettes have been proven to be safe and effective for smoking cessation	❑	❑
20. Cigarettes contain over 7000 chemicals	❑	❑
21. High risk situations for relapse include stress and depression	❑	❑
22. Just having one smoke is unlikely to make a person relapse	❑	❑
23. It may take several serious attempts before a person finally quits	❑	❑
24. Using a carbon monoxide breath monitor provides an objective measure of smoking status.	❑	❑

Part 4: Questions regarding usefulness of educational resources provided?

1. Have you seen any of the educational resources before (for example as part of a focus group)?
    0. No
    1. Yes

2. Please rate how useful you found the training provided as part of the ICAN QUIT in Pregnancy project?

Webinar session	1 (not useful at all)	2	3 (somewhat useful)	4	5 (very useful)
Session #1 (Background and Culturally sensitive care)					
Session #2 (The ABCD approach and behaviour change techniques)					
Session #3 (Using NRT in pregnancy)					

3. Have you read the training manual provided to you as part of the ICAN QUIT in Pregnancy?
    0. No
    1. Yes, all of it
    2. I read some parts of the training manual

4. Please rate how useful you found the educational material provided as part of the ICAN QUIT in Pregnancy project?

Patient resource	1 (not useful at all)	2	3 (somewhat useful)	4	5 (very useful)
Training manual					
Desktop guide					
Patient flipchart					
Patient Booklet					
Poster describing the different types of NRT in pregnancy					
Poster describing the difference between NRT and a cigarette					

5. Do you have any suggestions for changes or improvements to any of the resources?

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Thank you for completing the survey

Appendix 4.6: Additional information regarding the development of the intervention

For the development of the ICAN QUIT in Pregnancy intervention, a theoretical analysis using the Behaviour Change Wheel was performed, linked to the Theoretical Domains Framework (TDF) data that was collected. For each barrier, the corresponding TDF domain and COM-B model component was identified, then potential intervention functions and policy categories were recognized, and for each, specific behaviour change techniques were selected. In selecting the different intervention functions, the APPEASE criteria were used –Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, Equity).[1]

This process was done both from the health providers and the pregnant women's perspectives and was described in detail elsewhere (Gould et al, unpublished data).

For example, one of the **specific target behaviour identified** was that health providers ('who') working in Aboriginal Medical Services ('where') need to increase NRT prescription rates ('what') among pregnant Aboriginal and Torres Strait Islander women who smoke ('whom'). **A behavioural diagnosis** based on the data from papers one to three, showed that health providers lack – 1) **psychological capability** (Lack of knowledge regarding when to initiate NRT and how to titrate the dosage, and how to discuss the risk versus benefit); 2) **physical opportunity** (Oral NRT not subsidized on the PBS and not available in the services to dispense); and 3) **reflective motivation** (belief that women don't want to use NRT, lack of confidence in ability to prescribe NRT) (Table 5). Thereafter, and according to this behavioural diagnosis, intervention and implementation strategies were chosen, along with specific BCTs for each barrier (Table 5).

The process of designing this intervention was done collaboratively and in negotiation with the Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP). Guidance from the SCAAP on what would be appropriate and feasible for their staff and community members helped shape the finer details of the intervention and how it would be implemented in the services.

[1]Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. London: Silverback Publishing; 2014.

Table 5: Example of behavioural diagnosis and selection of intervention components as part of ICAN QUIT in Pregnancy

Target Behaviour: Increasing NRT prescriptions to Aboriginal and Torres Strait Islander pregnant women who smoke					
Barrier	**COM-B**	**TDF domain**	**Intervention functions**	**Selected BCTs**	**ICAN QUIT in Pregnancy component**
Lack of access to free oral NRT	Opportunity - physical	Environmental context and resources	Environmental restructuring	Adding objects to the environment	Free oral NRT samples in the services Free oral NRT through a voucher system
Lack of knowledge on NRT dosing, risk versus benefit	Capabilities – psychological	Knowledge Cognitive skills	Environmental restructuring Education Training	Prompts/Cues Instruction on how to perform a behaviour	Educational resource package including training manual, flipchart to guide discussion, mousepad as a reminder, and visual posters that show NRT safer than smoking) Webinar training
Lack of confidence in ability to prescribe NRT	Motivation - reflective	Belief about capabilities	Education Persuasion Modelling	Credible source Feedback on behaviour Social comparison	Two physicians who are also tobacco treatment specialists to perform webinar training

					Audit and feedback on NRT prescription on the service level
Belief that pregnant women do not want to use NRT	Motivation - reflective	Belief about consequences	Education Persuasion	Reduce negative emotions Information on health, social, emotional and environmental consequences	Webinar training including videos with Aboriginal women and health providers experiences

Appendix 5: Published Manuscripts

Appendix 5.1: Paper one published manuscript

Appendix 5.2: Paper two published manuscript

Appendix 5.3: Paper four published manuscript

Appendix 5.4: Paper six published manuscript

Appendix 5.5: Paper seven published manuscript

<u>Appendix 5.1:</u> Paper one published manuscript

This paper was removed for copyright reasons. The final version is available online:

Bar-Zeev Y, Bonevski B, Twyman L, Watt K, Atkins L, Palazzi K, Oldmeadow C, Gould GS. Opportunities missed: A Cross-Sectional Survey of the Provision of Smoking Cessation Care to Pregnant Women by Australian General Practitioners and Obstetricians. *Nicotine and Tobacco Research.* 2017: 19 (5); 636-641.

https://doi.org/10.1093/ntr/ntw331

<u>Appendix 5.2:</u> Paper two published manuscript

This paper was removed for copyright reasons. The final version is available online:

Bar-Zeev Y, Bonevski B, Gruppetta M, Twyman L, Atkins L, Palazzi K, Oldmeadow C, Gould GS. Clinician Factors Associated with Prescribing Nicotine Replacement Therapy in Pregnancy: A Cross-Sectional Survey of Australian Obstetricians and General Practitioners. *The Australian and New Zealand Journal of Obstetrics and Gynaecology.* 2018; 58(3):366-370.
https://doi.org/10.1111/ajo.12751

Narrative review

Nicotine replacement therapy for smoking cessation during pregnancy

Yael Bar-Zeev[1], Ling Li Lim[2], Billie Bonevski[2], Maree Gruppetta[2], Gillian S Gould[2,3]

Smoking during pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes. In 2014, 11% of women who gave birth in Australia smoked at some point of their pregnancy, and smoking rates during pregnancy were higher for specific vulnerable populations, such as Aboriginal and Torres Strait Islander women (45%).[1]

Behavioural counselling combined with medication is the most effective smoking cessation strategy.[2] In pregnant women who smoke, studies have shown counselling alone to be effective.[3] Medications such as varenicline and bupropion are not recommended during pregnancy,[4] and the use of nicotine replacement therapy (NRT), while well supported and safe for the general population,[5] remains controversial for use during pregnancy because nicotine crosses the placenta and may accumulate in the amniotic fluid.[6] Thus, it is important to gather evidence regarding the benefits and potential harms of NRT for pregnant women.

In a recent survey of Australian general practitioners and obstetricians, 25% of participants stated that they never prescribe NRT during pregnancy.[7] These findings mirror surveys from the United Kingdom,[8] New Zealand[9] and the United States.[10] The most frequently cited barriers are low confidence in the ability to prescribe NRT and safety concerns.[8,10]

The aim of this narrative review is to provide an overview of current guidelines regarding NRT use in pregnancy, considering the existing evidence base on safety, efficacy and effectiveness. In addition, we outline pragmatic suggestions for clinical practice and implications for policy and future research.

Method

For current guidelines, we performed online searches using Google and the keywords "smoking cessation", "guidelines" and "name of country". We included national guidelines from high income countries (eg, Australia, UK, US, Canada and New Zealand) published in English from the year 2010 onward.

We conducted MEDLINE searches on NRT safety, efficacy and effectiveness, using the Medical Subject Headings and keywords "nicotine", "nicotine replacement therapy", "fetal" and "pregnancy" — limited to the English language with no limit on the years. Previous reviews were manually searched to identify further studies. We included both observational and interventional studies that aimed to specifically assess either the safety or efficacy of NRT during pregnancy. Studies that included NRT as part of a multicomponent intervention were excluded, as their design does not permit determining the effect of NRT alone.

To provide a full overview, we also include a short summary of findings previously published from animal models studying the effects of nicotine on fetal development.

Summary

- Nicotine replacement therapy (NRT) is recommended in current Australian clinical guidelines for pregnant women who are unable to quit smoking unassisted.
- Clinicians report low levels of prescribing NRT during pregnancy, due to safety concerns and low levels of confidence in their ability to prescribe NRT.
- Animal models show that nicotine is harmful to the fetus, especially for brain and lung development, but human studies have not found any harmful effects on fetal and pregnancy outcomes.
- Studies of efficacy and effectiveness in the real world suggest that NRT use during pregnancy increases smoking cessation rates. These rates may be hampered by the fact that studies so far have used an NRT dose that does not adequately account for the higher nicotine metabolism during pregnancy and, therefore, does not adequately treat withdrawal symptoms.
- Further research is needed to assess the safety and efficacy of higher dosages of NRT in pregnancy, specifically of combination treatment using dual forms of NRT.
- As NRT is safer than smoking, clinicians need to offer this option to all pregnant women who smoke. A practical guide for initiating and tailoring the dose of NRT in pregnancy is suggested.

Current guidelines for the use of nicotine replacement therapy during pregnancy

Although all clinical guidelines on the use of NRT during pregnancy acknowledge that there is insufficient evidence to firmly conclude whether NRT in pregnancy is safe or effective, national guidelines from Australia,[4] the UK,[11] New Zealand[12] and Canada[13] recommend the use of NRT by pregnant women who have been unable to quit smoking without medication (Box 1). However, many of the guidelines impose caveats such as "only if women are motivated", "only give out 2 weeks' supply" or "under close supervision".

In Australia, the Royal Australian College of General Practitioners has published the only comprehensive national guidelines on the use of NRT during pregnancy,[4] which recommend initiating NRT in pregnant women who are motivated to quit smoking and have been unsuccessful without medication. NRT should be offered after discussing the relative risks and benefits, and prescribed under supervision of the treating clinician. These guidelines recommend initiating treatment using oral forms of NRT, which are considered to deliver a lower total dose of nicotine compared with a patch.[4,5] In the event that the pregnant woman is still unsuccessful at quitting smoking, clinicians should consider adding a nicotine patch (ie, combination treatment).[4] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists has also issued recommendations regarding smoking cessation during pregnancy, and even though their statement takes a

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1 Summary of current international guidelines for the use of nicotine replacement therapy (NRT) during pregnancy

Organisation, year updated	Key points
RACGP, 2014[4]	• NRT may be considered if quit attempts are unsuccessful and the woman is motivated to quit • The risks and benefits need to be explained to the woman • Oral NRT is the first line option, but larger doses or even combination NRT may be needed
RANZCOG, 2014[14]	• Insufficient evidence to routinely recommend NRT use in pregnancy • If the woman is a heavy smoker and unsuccessful in quitting with counselling alone, NRT may reduce the risk to the fetus
NICE, 2010 (update to be released March 2018)[11]	• Use NRT only in women who are unsuccessful in quitting smoking without medication • Only prescribe NRT once women stop smoking • Only prescribe 2 weeks of NRT • Only give subsequent prescription if the woman is still not smoking
New Zealand Ministry of Health, 2014[12]	• Trials have not shown NRT to be effective in pregnancy • NRT is safer than smoking • Women may use NRT in pregnancy once they have been advised of the risks and benefits
CAN-ADAPTT, 2011[13]	• Limited evidence that NRT is harmful in pregnancy • Some evidence that NRT may be effective • Benefits of NRT seem to outweigh potential risks • NRT should be considered if counselling has been ineffective • Oral NRT is preferred after a risk–benefit analysis
USPSTF, 2015[15]	• Current evidence is insufficient to assess the use of NRT in pregnancy
ACOG, 2015[16]	• NRT use in pregnancy has not been sufficiently evaluated to determine safety or efficacy • NRT should only be used under supervision, after a risk–benefit analysis, and only with a clear resolve of the woman to quit smoking
WHO, 2013[17]	• Cannot make a recommendation on NRT use during pregnancy

ACOG = American College of Obstetricians and Gynecologists. CAN-ADAPTT = Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment. NICE = National Institute for Health and Care Excellence. RACGP = Royal Australian College of General Practitioners. RANZCOG = Royal Australian and New Zealand College of Obstetricians and Gynaecologists. USPSTF = United States Preventive Services Task Force. WHO = World Health Organization. ◆

more conservative approach, it acknowledges that NRT may reduce the risk to the fetus in pregnant women who continue to smoke heavily.[14]

Animal models: effects of nicotine on fetal development

The most established evidence from animal models shows derangement in central nervous system and pulmonary development.[18] Nicotine binds to the nicotinic acetylcholine receptors located in the central nervous system.[19] Rat models indicate that prenatal nicotine exposure damages the developing brain by triggering apoptosis, reducing the number of neuronal cells and disturbing the genesis of axons and synapses. Chronic nicotine exposure in utero leads to changes in neuronal architecture, nicotinic acetylcholine receptor expression and the function of other neurotransmitter systems, including dopamine, noradrenaline and serotonin.[20,21]

Nicotine also causes developmental anomalies in the lungs in animal models; for example, non-human primates exposed to nicotine in utero have decreased lung size and volume.[22] Histopathological analysis has shown a reduced alveolar surface area, enlarged respiratory airspaces[23] and thickened alveolar walls.[24] These changes lead to impaired ability to adequately oxygenate blood.[25] Moreover, prenatal nicotine exposure also decreases pulmonary compliance and forced expiratory flow[26] and increases airway resistance.[27] It should be noted that most of these animal studies used a continuous form of nicotine delivery,[26,27] and it is not clear how directly transferable the findings from animal studies are to humans.[28]

Safety and efficacy of nicotine replacement therapy in human studies

The safety and efficacy of NRT during pregnancy has been studied in both observational and intervention studies (Appendix).

Observational studies

A UK population-based cohort study of 192 498 live births[29] examined the association between early pregnancy NRT exposure and major congenital anomalies; the study found no statistically significant increased risk for either the NRT group ($n = 2677$) *v* non-smokers ($n = 17\,9841$) (odds ratio [OR], 1.12; 99% confidence interval [CI], 0.84–1.48) or the NRT group *v* smokers not receiving NRT ($n = 9980$) (OR, 1.07; 99% CI, 0.78–1.47). Examining system-specific anomalies, there were no significant increased risks except for respiratory anomalies, but the authors caution that this is based on small numbers of exposed cases.[29] A smaller Danish study[30] found similar results when restricting their analysis, comparing NRT users ($n = 250$) with non-smokers ($n = 55\,915$), to major anomalies (OR, 1.13; 95% CI, 0.62–2.07); however, when including minor anomalies, NRT use was significantly associated with a higher rate of anomalies (OR, 1.61; 95% CI, 1.01–2.58). A similar study from this cohort[31] did not find an association between using NRT and the rate of stillbirth (hazard ratio, 0.57; 95% CI, 0.28–1.16).

Another Danish population-based cohort study[32] found that the use of NRT during the first 27 weeks of pregnancy was not

significantly associated with changes in mean birth weight (mean change, 0.25 g per week of NRT use; 95% CI, −2.31 to 2.81). The use of more than one product in the same week was associated with a decrease in mean birth weight, but this was not statistically significant (mean change, −10.73 g per week of NRT use; 95% CI, −26.51 to 5.05).[32]

A UK cohort study,[33] including 3880 pregnant women who attended smoking cessation services, found that combination NRT (patch plus an oral form) was associated with significantly higher cessation rates (OR, 1.93; 95% CI, 1.13−3.29), but that the use of only one NRT form was not associated with an increased cessation rate (OR, 1.06; 95% CI, 0.60−1.86).

Randomised controlled studies

To date, there have been five double-blind placebo-controlled studies[34-38] and three non-placebo-controlled studies[39-41] on the safety and efficacy of NRT in pregnancy (Appendix). The most recent 2015 Cochrane meta-analysis,[42] which included all these eight studies ($n = 2199$ pregnant women), found that NRT use significantly increased the smoking cessation rate by 40% (relative risk [RR], 1.41; 95% CI, 1.03−1.93). Restricting the meta-analysis to only placebo-controlled studies (five studies, $n = 1926$) resulted in a lower, not significant cessation rate of 28% (RR, 1.28; 95% CI, 0.99−1.66).

No significant differences in health and safety outcomes were found in the Cochrane meta-analysis.[42] Data from four studies[34-36,40] were pooled together — with over 1700 women — showing no significant differences in the risk of miscarriage or spontaneous abortion (RR, 1.47; 95% CI, 0.45−4.77), stillbirth (RR, 1.24; 95% CI, 0.54−2.84), neonatal intensive care unit admissions (RR, 0.90; 95% CI, 0.64−1.27) and neonatal death (RR, 0.66; 95% CI, 0.17−2.62). Two studies[34,35] — with 1401 women — provided data for the pooled estimate of congenital anomalies and caesarean delivery, showing no significant difference (RR, 0.73; 95% CI, 0.36−1.48; and RR, 1.18; 95% CI, 0.83−1.69, respectively); and six studies[34-36,38-40] provided data for the pooled estimate of preterm birth (RR, 0.87; 95% CI, 0.67−1.14) with no significant difference.

The largest randomised placebo-controlled trial[34] included 1050 pregnant women, of whom 521 were randomised to receive a 15 mg per 16 hours patch. This study found favourable results after one month of treatment (21.3% biochemically validated abstinence rate in the NRT group and 11.7% in the placebo group; adjusted OR, 2.1; 95% CI, 1.49−2.97), but these results were not sustained at delivery (9.4% NRT and 7.6% placebo; adjusted OR, 1.27; 95% CI, 0.82−1.98). Adherence was problematic, with few participants using NRT for more than 4 weeks, and there were no statistically significant differences in any pregnancy or birth safety outcomes.[34] This was the only study to follow infants for 2 years after delivery.[43] Infants born to mothers who received NRT had a significantly higher rate of unimpaired development, regardless of the mothers' smoking status (73% NRT group and 65% placebo group; OR, 1.4; 95% CI, 1.05−1.86). The results suggest a dose−response relation with no difference in impairment rates between women using one to ten patches during pregnancy and those not using patches, but they suggest a significant difference between women using 11−56 patches (OR, 1.72; 95% CI, 1.22−2.57).[43]

Almost all of the trials[34,37,38,41] (Appendix) used a fixed dosage regardless of the woman's smoking and tobacco dependence level. Taking into account the higher metabolism of nicotine in pregnancy,[44] this may have led to insufficient dosage to adequately treat withdrawal symptoms.[42,44] The most recent randomised placebo-controlled study[35] adjusted the dosage of the patch according to the woman's baseline cotinine level (a metabolite of nicotine). Women in the NRT group in this study received on average a slightly higher mean daily dose (18 mg) compared with the 15 mg patch used in other studies — with 25% receiving 25−30 mg daily — for a longer duration (median prescription length, 105 days), and there was a high compliance rate (85%). Despite this, the validated abstinence rate at delivery was low and similar between the NRT (5.5%) and placebo groups (5.1%) (OR, 1.08; 95% CI, 0.45−2.6).[35] However, the conversion ratio used to determine the nicotine dose was not modified for pregnancy, and was based on studies with non-pregnant participants,[45] suggesting that participants did not receive an adequate dosage.[45]

Only one randomised placebo-controlled study ($n = 194$) used 2 mg nicotine gum (and not a patch) in the intervention group ($n = 100$), allowing up to 20 doses of gum per day.[36] Treatment was continued even if the women had not quit smoking, with the gum being used to reduce the overall number of cigarettes smoked. This study did not find any significant treatment effect, with point prevalence abstinence rates similar between the two groups at 6 weeks after treatment (13% NRT group and 9.6% placebo group; $P = 0.45$) and at 32−34 weeks gestation (18% *v* 14.9%; $P = 0.56$).[36] However, birth weight (NRT group, 3287 g; standard deviation [SD], 566 g; placebo group, 2950 g; SD, 653 g; $P < 0.001$) and gestational age (NRT group, 38.9 weeks; SD, 1.7 weeks; placebo group, 38 weeks; SD, 3.3 weeks; $P = 0.014$) were significantly greater in the NRT group.[36] Moreover, rates of preterm birth (NRT group, 7.2%; placebo group, 18%; $P = 0.027$) and low birth weight (< 2500 g) (NRT group, 2%; placebo group, 18%; $P < 0.001$) were both significantly higher in the placebo group.[36]

The limitations of many of the trials include low adherence to NRT, resulting in most women not receiving the intended dose, and NRT dosage not adjusted to the increased nicotine metabolism during pregnancy (Appendix). None of the studies assessed smoking withdrawal symptoms in order to adjust the dosage accordingly. The hypothesis that the dosage was not sufficient to treat withdrawal symptoms is supported by the findings from several trials that compared cotinine levels at baseline and during treatment with NRT patches.[37,41,46] These studies showed that cotinine levels were lower during treatment than at baseline (when women were still smoking).

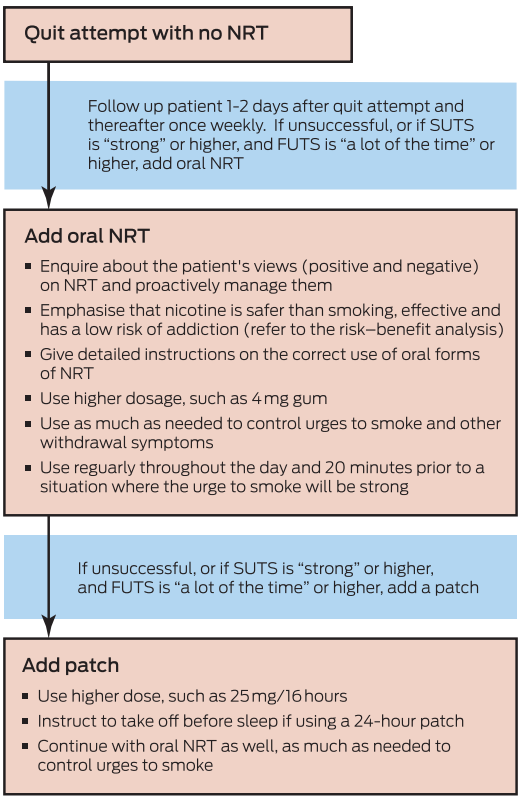
Discussion

In summary, this narrative review found that in animal models, nicotine has been found to be harmful for the fetus, especially for brain and lung development. Human studies, however, did not find any harmful effects on fetal and pregnancy outcomes compared with placebo, but the evidence is limited due to the small numbers of participants in the meta-analysis.[42] In addition, efficacy studies suggest that NRT increased smoking cessation rates overall, but this effect is not statistically significant for the more rigorous placebo-controlled trials. Nevertheless, one observational study using real world data shows promising results, specifically for NRT combination treatment, but studies so far have used an NRT dose that does not adequately account for the higher nicotine metabolism during pregnancy.

Pragmatic suggestions for clinical practice

Confidence in prescribing NRT and actual practices may be low due to the conflicting messages and different restrictions mentioned in the guidelines, particularly since they do not offer a detailed practical clinical protocol that includes clear instructions for NRT use in pregnant women.

2 Suggested approach to initiating and managing nicotine replacement therapy (NRT) during pregnancy[47]



FUTS = frequency of urges to smoke. SUTS = strength of urges to smoke. ◆

Box 2 offers a practical detailed approach to initiating and managing NRT during pregnancy. As many pregnant women reduce on their own the number of cigarettes they smoke,[48] using measures that rely on number of cigarettes per day may be less effective. We suggest using the strength of urges to smoke (SUTS)[49] and the frequency of urges to smoke (FUTS) scales[50] as practical guides to the decision to initiate or increase the NRT dose:

- SUTS — "in general, how strong have the urges to smoke been in the past 24 hours?" "Slight", "moderate", "strong", "very strong" or "extremely strong"; and
- FUTS — "how much of the time have you felt an urge to smoke in the past 24 hours?" "Not at all", "a little of the time", "some of the time", "a lot of the time", "almost all of the time" and "all of the time".

If the women report experiencing strong or frequent ("a lot of the time") urges to smoke, this suggests the need for additional support.

The most important guidance for NRT in pregnancy is to use the lowest possible dose that is effective. However, to be effective, women should be instructed to use as much as needed to deal with cravings. Physicians should encourage using oral NRT regularly throughout the day to substitute for cigarettes; for example, a woman smoking ten cigarettes a day should be instructed to use one piece of gum every 1.5 hours regularly, even if she is not experiencing a strong craving at this time. In addition, physicians should encourage the use of oral NRT in anticipation of cravings; if a woman knows she is going to be in a situation where the urge to smoke will be strong (eg, going out with friends who smoke), doctors should encourage the use of oral NRT 20 minutes beforehand. Physicians should proactively review the SUTS and FUTS on a weekly basis and adjust dosage as needed. Further, women should be encouraged to use NRT for at least 12 weeks, or longer if required, in order not to relapse. This practical approach is currently being tested as part of a multicomponent intervention in a pilot study.[51]

Risk versus benefit

Nicotine may not be completely safe for the pregnant mother and fetus, but it is always safer than smoking. A risk and benefit analysis needs to be done to help pregnant women (and their partners) judge whether to use a clean source of nicotine such as NRT, which might help cessation, and whether this is preferable to continuing exposure to the nicotine and other chemicals present in combustible cigarettes. The context of using NRT in pregnancy is always within a smoking cessation attempt, which means that it is used by women who are already exposed to higher levels of nicotine and other products of combustion from smoking. Box 3 offers suggestions to aid the risk versus benefit analysis discussion.[47]

3 Suggested approach to a risk *v* benefit discussion with a pregnant woman who smokes[47]

Risks

Nicotine has been linked to harmful effects on the fetus in animal studies:[19]

- low birth weight;
- preterm birth;
- still birth;
- cognitive impairment; and
- impaired lung development

We do not know for sure how the data from animal studies can be transferred to humans[28]

Studies with nicotine from NRT use in pregnant women (> 2000 women) have not shown NRT to cause any harm to the women or the baby[42]

Benefits

NRT has only nicotine in it, and none of the other 7000 chemicals also found in a cigarette (300 known to be toxic and harmful, 52 known to cause cancer)[5,42]

> By using NRT, you and your baby are not exposed to all of these other chemicals[42]

Nicotine from NRT is absorbed at a slower and lower rate compared with nicotine from a cigarette. This means that if you use NRT, you are actually receiving less nicotine than when you smoke[5]

NRT will increase your chances of quitting and remaining smoke free by 40%[42]

> Every day that you do not smoke improves the health of you and your baby
>
> There is nothing better for you and your baby's health than to quit smoking

Using NRT may help your baby's health, even if you do not quit smoking.[43] This is probably because of less overall exposure to chemicals

NRT = nicotine replacement therapy. ◆

Implications for policy and future research

Reports from specialised smoking cessation services with trained counsellors in England[52] and Scotland[53] show that NRT is routinely prescribed during pregnancy — in England, 87% of smoking cessation services offer combination NRT in pregnancy.[52] Pregnant women are routinely referred to these services, highlighting not only the importance of additional training for health providers to increase their confidence and skills but also the question of whether the health system should be offering pregnant women access to specialised cessation support. The findings of Bar-Zeev and colleagues[7] provide further support for the importance of these services showing that referral is practised more frequently by Australian GPs and obstetricians than prescribing NRT. Even though all Australian states and territories offer the Quitline service, it is still underutilised.[54] More research is needed on how to increase the acceptability and usability of the Quitline and whether other options such as specialised smoking cessation clinics should be available.

Moreover, further research is needed to assess the safety and efficacy of higher dosages of NRT in pregnancy, specifically combination treatment, and also to evaluate the safety and efficacy of using NRT as a harm reduction strategy for women who are unmotivated to quit smoking, in order to reduce or eliminate exposure to cigarette smoke during pregnancy.

Conclusions

Ambiguous messages may be contributing to the low NRT prescribing rates and, therefore, it is important to provide a clear practical message to health practitioners and women. It is our duty as clinicians to interpret the evidence, deal with uncertainty and be able to provide pregnant women with information that will allow them to make an informed decision. Clinicians need to offer pregnant women the option of receiving NRT in a timely fashion if they cannot quit smoking on their own. In this review, we offered a practical guide on how the risks versus benefits of NRT use during pregnancy could be articulated, and how and when to decide whether to use or increase NRT during pregnancy. More education and training is required to improve clinicians' confidence and skills, and better referral pathways, including specialised smoking cessation services, need to be in place to help pregnant women to quit smoking.

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Assessing and Validating an Educational Resource Package for Health Professionals to Improve Smoking Cessation Care in Aboriginal and Torres Strait Islander Pregnant Women

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Abstract: Australian Aboriginal pregnant women have a high smoking prevalence (45%). Health professionals lack adequate educational resources to manage smoking. Resources need to be tailored to ensure saliency, cultural-sensitivity and account for diversity of Indigenous populations. As part of an intervention to improve health professionals' smoking cessation care in Aboriginal pregnant women, a resource package was developed collaboratively with two Aboriginal Medical Services. The purpose of this study was to assess and validate this resource package. A multi-centred community-based participatory 4-step process (with three Aboriginal Medical Services from three Australian states), included: (1) Scientific review by an expert panel (2) 'Suitability of Materials' scoring by two Aboriginal Health Workers (3) Readability scores (4) Focus groups with health professionals. Content was analysed using six pre-determined themes (attraction, comprehension, self-efficacy, graphics and layout, cultural acceptability, and persuasion), with further inductive analysis for emerging themes. Suitability of Material scoring was adequate or superior. Average readability was grade 6.4 for patient resources (range 5.1–7.2), and 9.8 for health provider resources (range 8.5–10.6). Emergent themes included 'Getting the message right'; 'Engaging with family'; 'Needing visual aids'; and 'Requiring practicality under a tight timeframe'. Results were presented back to a Stakeholder and Consumer Aboriginal Advisory Panel and resources were adjusted accordingly. This process ensured materials used for the intervention were culturally responsive, evidence-based and useful. This novel formative evaluation protocol could be adapted for other Indigenous and culturally diverse interventions. The added value of this time-consuming and costly process is yet to be justified in research, and might impact the potential adaption by other projects.

Keywords: smoking cessation; indigenous health; health professionals; pregnancy

1. Introduction

Aboriginal and Torres Strait Islander pregnant women (hereafter referred to "Aboriginal" women with acknowledgement of the distinct cultures) have the highest smoking rate during pregnancy in Australia (45%) [1], and are three times more likely to smoke during pregnancy compared to non-Aboriginal pregnant women [2]. Smoking during pregnancy is the most important preventable

risk factor for poor maternal and infant health outcomes, including miscarriage, growth restriction, stillbirth and pre-term birth [3].

Lack of support from health professionals is a common barrier to smoking cessation in different vulnerable groups, including the Aboriginal population [4]. Aboriginal women report that they receive inconsistent messages from health professionals during pregnancy [5]. Health professionals also report many challenges to providing smoking cessation care in pregnancy [6,7], including insufficient topic knowledge, low confidence in counselling, shortage of time, and little optimism about the effectiveness of interventions. In a recent national cross-sectional survey of Australian General Practitioners (GPs) and Obstetricians, insufficient resources were reported as one of the main barriers to smoking cessation care in pregnant women [8]. A unique barrier in pregnancy is the lack of a strong evidence base on the safety and efficacy of nicotine replacement therapy (NRT), which might impact clinicians' confidence and skills to prescribe NRT [9]. These challenges were reported from studies conducted among the general population, and are not specific to the Aboriginal population.

Printed self-help materials have been shown to improve smoking cessation rates (RR 1.19, 95% CI 1.04–1.37) [10]. Similarly, printed educational materials intended for health professionals can also have a positive impact on their practice (median absolute risk difference in practice outcomes 0.02, range 0–0.11) [11]. When developing educational resources, many considerations need to be taken into account to ensure resources are actually useful and effective, including readability level, appearance and organization of the data [12].

1.1. Tailoring Educational Resources

Tailoring messages for a specific target population might improve their usefulness and effectiveness [13]. Previous systematic reviews exploring health promotion interventions that were adapted for ethnic minority populations have concluded that currently there is a lack of evidence for effectiveness of tailoring [14,15]. However, both reviews agree that adapting interventions might increase salience, acceptability and uptake. Furthermore, none of these included studies with Indigenous populations. Research reveals that although generic (intended for the general population) messages impact Indigenous populations, there is a preference for culturally targeted messages [16]. Formative research ensures the development of targeted, culturally appropriate, health messages that work [17,18]. In the past few years, research done specifically with Aboriginal pregnant women has shed light on some of the myths and beliefs about smoking during pregnancy that are a barrier to quitting [19–22]. Additionally, in developing a suitable intervention, the challenge of designing appropriate anti-tobacco messages that account for the diversity of Aboriginal People has been outlined [19]. Conducting a pre-test of messages is associated with increased rigour in developing programs targeted to an Aboriginal population [23]. Daley et al. [24] describe in detail a rigorous assessment process of educational material they developed for a smoking cessation intervention for American Indians. These educational materials were then used as part of a randomized controlled study showing promising results in increasing smoking cessation rates [25].

This study comprised the first phase of the Indigenous Counselling and Nicotine (ICAN) Quit in Pregnancy trial [26]. The ICAN QUIT in Pregnancy intervention aimed to improve health professionals smoking cessation care with Aboriginal pregnant women who smoke and included three one-hour webinar training sessions for health professionals, an educational resource package, and free oral NRT [26]. Phase 1 of the ICAN QUIT in Pregnancy trial focuses on the development and pre-testing of the educational resources.

1.2. Aims

To assess the accuracy, readability, cultural acceptability and perceived usability of a collaboratively developed educational resource package to aid health professionals' smoking cessation care in pregnant Aboriginal women.

2. Materials and Methods

2.1. The Indigenous Counselling and Nicotine (ICAN) Quit in Pregnancy Trial

This intervention is based on the previously published ABCD guidelines (Ask about smoking; Brief advice to quit; Cessation support; Discuss the psychosocial context of smoking) with an expedited offer of NRT [27]. The authors worked collaboratively with two Aboriginal Medical Services [28] to develop this intervention. A Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP) and a smaller Working Party (Aboriginal and non-Aboriginal staff from the two medical services, and Aboriginal female community members) guided the development of the educational resource package [28]. A whole-of-service approach was intended, to train all of the health professionals including GPs, midwives, Aboriginal Health Workers (AHW), and other allied health professionals. Thus, the educational resource package [29] needed to suit health professionals with different educational needs.

A main focus of the intervention was to address clinician's low confidence and skills to prescribe NRT [9]. The latest 2015 Cochrane review focusing on pharmacological interventions for smoking cessation during pregnancy found that NRT improved cessation rate by 40% (Relative Risk (RR) 1.43, 95% CI 1.03–1.93). However, when restricting the meta-analysis to only placebo controlled studies, a lower, not significant cessation rate of 28% (RR 1.28, 95% CI 0.99–1.66) was found [30]. Nicotine has been implicated in animal studies to affect foetal development; however, human studies have not found any harmful effects [9,30]. Therefore, experts and clinical guidelines recommend the use of NRT for pregnant women who smoke and have been unsuccessful quitting without medication [9].

Design: A multi-centre community based participatory research project.

Sample: Three participating sites, from three different states in Australia–South Australia (SA); New South Wales (NSW); and Queensland (Qld). All sites were Aboriginal Community Controlled Health Services (ACCHS), dedicated to healthcare delivery to Aboriginal communities, and overseen by an Aboriginal Community Board of Directors [31].

Materials to be assessed: The educational resource package [29] included resources intended for the health professionals, the pregnant women (patients), and both (Box 1).

Box 1. The educational resource package.

1. For the Health Professionals	
(a)	A detailed treatment manual covering the ABCD approach [27], including specific behaviour change techniques recommended for use to support pregnant women to quit smoking [32]; and detail practical guidelines on the use of Nicotine Replacement Therapy (NRT) in pregnancy.
(b)	Desktop guide –to be used as a prompt to perform the ABCD, and included an NRT treatment algorithm.
2. For the Pregnant Women (Patients)	
Brochures on three specific topics—'Quitting in Pregnancy', 'Triggers', and 'Smoke Free Homes' and also five information sheets on the different NRT products (Patches, Gum, Lozenge, Inhalator, and Oral Spray). To increase engagement and understanding in a population that may have low literacy skills [33], the brochures include short videos embedded into them that could be downloaded using a free App. Topics covered by these videos included: *'how smoke affects the baby when pregnant'*, *'myths of smoking when pregnant'*, *'explaining smoking triggers and how to address these'* and *'how to use the different NRT products'*.	
3. For Both the Health Professionals and the Pregnant Women	
A flipchart to be used by the health professional during the consultation with the pregnant woman. A visual side for the women with minimal text, and the reverse side for the health professional as a more detailed prompt on the topics to cover during the consultation. To increase engagement, the visual side for the women included photographs of Aboriginal women from a range of communities in Northern Territory, Victoria and New South Wales.	

2.2. Procedures

The resources were assessed by a four step evaluation process, based on Daley et al. [24].

2.2.1. An Expert Scientific Panel

Eleven experts were invited to participate, with ten agreeing to review the resources. Feedback was provided by eight of these, from different areas of expertise (Tobacco Treatment Specialist specializing in maternity care; Tobacco Treatment Specialist experienced with providing training to physicians and allied health professionals in the area of smoking cessation; a member of the Royal Australia and New Zealand College of Obstetrics and Gynaecology—Indigenous Women's Group; An experienced international researcher in randomized controlled trials with NRT and pregnant women; a member of the Congress of Aboriginal and Torres Strait Islander Nurses and Midwives; a Torres Strait Islander General Practitioner; an appointed representative of the Aboriginal Health and Medical Research Council).

Invited experts received a digital and hardcopy of all the education resources. They were not provided with any structured feedback form, but rather asked via email to review the material and provide comments. Experts were instructed to provide the feedback in any way that they found acceptable–direct comments on the copies provided and/or separately in a word document or email. Any changes and/or comments that were made by the experts, for each separate resource, were coded by one researcher (YBZ) into one of six pre-determined themes—Attraction, Comprehension, Self-Efficacy, Graphics and Layout, Cultural acceptability, and Persuasion [34]. These themes have been previously identified as important when assessing health education material to be used specifically with populations with low literacy [34]. Thereafter, for each theme, a summary of the main recommendations was generated and distributed to all other researchers for feedback.

2.2.2. The Suitability of Materials (SAM) Assessment Method Score

The SAM score is a validated systematic process to objectively evaluate the suitability of health education material [34]. It includes 22 items covering 6 themes (Content; Literacy demand; Graphics; Layout and topography; Learning, stimulation, and motivation; Cultural appropriateness). For each item, a score between 0 (not suitable) to 2 (superior) is given. The total score is then calculated (0–39% not suitable material; 40–69% adequate; 70–100% superior).

The SAM was performed by 1–2 staff members from each participating site on a sample of the patient brochures. In total, four staff members participated—three AHW, and one non-Aboriginal Tobacco action worker. The service selected the staff member to perform the SAM rating. For each brochure, two separate SAM ratings (each from a different site) was performed. Mean scores for each brochure and an overall inter-rater agreement score (Kappa) were calculated.

2.2.3. Readability Testing

The text from all of the educational materials was entered into an online tool (Readable.io). Since the visual side of the Flipchart contained minimal wording, only the health professional side of the Flipchart was used for this analysis. The online tool utilizes five different readability measures (Flesch-Kincaid Grade Level, Gunning Fog Index, Coleman-Liau Index, SMOG Index, and Automated Readability Index). Each readability measure uses a different formula to provide a readability level equivalent to a typical US school grade that would find it easy to read. An average readability school grade level is then calculated from all five measures. We aimed for an average readability score of grade five for the patient resources (meaning any patient who has finished at least grade five in school would find this easy to read), and grade nine for health professionals' resources (as recommended by the Working Party).

2.2.4. Focus Groups with Health Professionals

Were conducted at each site jointly by a female physician and Tobacco Treatment Specialist (YBZ) and a female Aboriginal research assistant (MB), both currently PhD candidates. MB has previous experience conducting qualitative interviews and focus groups among Aboriginal participants.

In total, three focus groups were conducted, with 7–9 participants in each group, and a total of 24 health professionals, until reaching data saturation, meaning that no new findings or themes were generated. Participants included three GPs, 6 midwives/nurses, 6 AHW; and 9 other allied health workers. Each focus group was approximately one hour in length, and included light refreshments. A semi-structured interview guide was developed across the same six themes used for the expert panel feedback analysis (Attraction, Comprehension, Self-Efficacy, Graphics and Layout, Cultural acceptability, and Persuasion) (Supplementary Materials: Appendix 1). The aim of the focus groups was to receive feedback on the draft version of the resources and suggest changes that would improve them. All of the health professionals treating pregnant women from the service were invited to attend. No information was collected on health professionals that chose not to attend the focus group from these services. Only the participants and researchers were present at the time of the focus group. In the NSW group, the medical director of the service, who also works at the service as a GP, participated.

Focus groups were audio-recorded and professionally transcribed. Transcribed data were coded using Nvivo 11 software. Analysis conducted by one researcher (YBZ) was checked by a second (MB) for the six pre-determined themes. Thematic analysis for emerging themes was conducted by both researchers (YBZ and MB) using a general inductive approach [35]. Coding was discussed until agreement was reached. This enabled researcher triangulation and helped ensure that the meaning of the analysis was the same between the two coders to enhance validity and reliability of the findings, and reduce personal bias.

2.2.5. Ethics

The study was approved by the University of Newcastle Human Research Ethics Committee (HREC) (Reference H-2015-0438); by AH&MRC Ethics Committee (Reference #1140/15); by AHREC Ethics Committee (Reference #04-16-652); and by the Far North Queensland Human Research Ethics Committee (HREC) (Reference #16/QCH/34-1040).

2.2.6. Reimbursement

The medical service/staff performing the SAM scoring received an $80 shopping voucher.

3. Results

3.1. An Expert Scientific Panel

A detailed summary of all the expert panel feedback is provided in Appendix 2 (Supplementary Materials). Overall, all experts agreed that the attraction and cultural acceptability of the resources were high. Some made specific recommendations on sensitive issues, such as ways to negotiate a smoke-free home with Elders; or suggestions for more acceptable and easily understandable wording for Aboriginal women. Minor suggestions were made about the graphic and layout to make the resources more practical and useful (e.g., highlighting certain information, and adding more visual references). Specific words were suggested to simplify the patient resources and additional information to aid self-efficacy and comprehension including electronic cigarettes; harm reduction; depression; family/household smoking; and women's perception on the use of NRT in pregnancy. Additional text was suggested to be consistent with a non-judgmental communication style.

3.2. The Suitability of Materials (SAM) Assessment Method Score

All of the patient brochures were scored as suitable by the staff members. Two brochures received a mean score above 70%, indicating a superior material (Table 1), and the rest of the brochures were perceived as adequate, with their mean score close to the cut point indicating a superior score. A consistent rating for the NRT brochures under 'Layout' was that the material looked "uninviting and discouragingly hard to read". The interrater reliability was found to be poor with Kappa = −0.75 ($p < 0.028$), 95% CI (−0.939, −0.177).

Table 1. Summary of Suitability of Resources (SAM) and Readability scores (before and after changes), and changes that were done to the educational resources package.

Resource	SAM Scores (Mean)	Readability Score-Average Grade Level (Range of Sub-Sections)	Summary of Changes to the Resource Materials	Readability Score after Changes-Average Grade Level
Training manual	Not relevant	10.4 (8–13.4)	Additional information was added as suggested: tabs were added; each section was given a different colour theme and prefaced with a colourful highlighted box summarizing the main points; an electronic version with hyperlinks was also provided	8.9
Flipchart	Not relevant	8.5 (4.7–31.4)	Additional information was added: two pages (from the women's side) were also transformed into A3 posters graphically illustrating the different NRT products, and the differences between using NRT and smoking a cigarette.	8.5
Desk top guide	Not relevant	10.6	Simplified to a three-step process; converted to a mouse pad.	7.1
			Patient brochures:	
'Quitting in pregnancy'	86, 40 (63)	7.2	All brochures were aggregated into one A5 booklet; additional information was added as suggested to enable a shared discussion; Information regarding family member support was added; specific wording was simplified; layout regarding the different types of NRT products was improved, and pictures of pregnant women using NRT were added; blank 'quit plans' for the woman to fill out with the health professionals were added.	4.7 (booklet)
'Triggers'	43, 95 (69)	6.4		
'Smoke-free homes'	70, 100 (85)	6.5		
'NRT patch'	73, 43 (58)	6.1		
'NRT gum'	57, 93 (75)	6.6		
'NRT lozenge'	43, 91 (67)	6.3		
'NRT spray'	85, 50 (67.5)	5.1		
'NRT inhaler'	40, 86 (63)	7.1		

3.3. Readability Testing

The average readability score for the patient resources was 6.4 (range 5.1–7.2), and for the health professionals' resources, 9.8 (range 8.5–10.6) (Table 1).

3.4. Focus Groups with Health Professionals

3.4.1. Pre-Determined Themes

Two sets, each with two pre-determined themes, were closely related to one another with the same two themes coded to the same sentences. Therefore, each set was grouped together as one theme (1. Graphic and Layout impacting Attraction; 2. Self-efficacy and Persuasion), forming four distinct themes:

Graphic and Layout impacting Attraction

Overall the health professionals found the resources attractive, especially the pictures used for the flipchart "The pictures are beautiful, absolutely.... They're gorgeous girls... no horror stories there. They're real" (*SA*).

They suggested the treatment manual was too long and needed to include more visual devices such as graphs, boxes and tables.

"Reading a whole manual like this is not going to happen.... There's too much writing" (NSW); "I like more tables, graphs, pictures, because I don't have to go double... I don't like reading pages long. I'll just look at it and go 'Yeah, too much.'" (QLD).

The desktop guide was perceived as too large and confusing, and was suggested to be converted to a mouse pad "*our desk is too small (NSW)... Maybe if it was a mouse pad (Qld)"*. The layout of the NRT treatment algorithm was advised to be simplified, so that actions required by the health provider are described in boxes, and patient assessments in arrows between boxes "*It's not really clear to me how–what the categories are in each box." (NSW).*

Comprehension

Across the three states, health professionals had sound comprehension of the content within the resources, and agreed they were comprehensive *"Content wise it's pretty good" (SA) "The actual information is good" (QLD) "There's good stuff in here" (NSW).*

Self-Efficacy and Persuasion

Health professionals found the resources useful and helpful to engage in the conversation about smoking with the pregnant woman *"...this little chart thing* (referring to a table describing the risks versus benefits of using NRT during pregnancy) *would be really, really good for the doctor to go through" (SA) "...some of my clients, I know what I'm going to address next time I see them, I'll probably go through this more myself" (NSW).*

They had various suggestions to increase the usefulness of the resources, including aggregating all of the brochures into one booklet "*people will nod very nicely and say "thank you very much" but if you go outside, they're in the bin.... as a book then she could look at the picture and I could run through this and discuss it with her" (NSW);* and having the videos available for them to show the woman *"I think it'd be more interactive if we had iPad in there also because then you could* (show them the videos)*" (NSW).*

Cultural Acceptability

Health professionals found the resources to be appropriate for the communities they treat, especially the use of photographs of Aboriginal women from diverse communities and backgrounds *"Because it's got different sorts of girls on it..." (SA); "see your own representation in the flip chart to relate to. Like 'That could be me" (QLD).*

The Qld focus group remarked on the absence of a Torres Strait Islander photograph *"I don't know if you've got any Torres Strait Islander women in there" (QLD).*

3.4.2. Emergent Themes

Four emergent themes arose from the data: 'Getting the message right'; 'Engaging with family'; 'Needing visual aids'; and 'Requiring practicality under a tight timeframe'.

Getting the Message Right

Health professionals were very cautious about using certain words or phrases. This was conveyed for two reasons: firstly, so not to upset the woman *"...you can't really say that to a smoking mum.... (SA) She could turn around and say 'I smoked with my other kids, so you think there's something wrong with them?'"(Qld)*; and secondly, to make sure that the message was getting across *"if you go through things like increases the risk of stillbirth and cognitive impairment and impaired lung development, that's going to be more of a hitting home than 'small baby'" (SA).*

The NSW focus group focused on "how" to utilize the educational material to guide the conversation. Health professionals wanted resources that they can discuss jointly with the woman, *"I normally go through stuff and, okay, this says most people smoke at different times so what do you think is relevant to you, and you've got a picture to look at but you've also got the prompts" (NSW).*

Needing Visual Aids

Recommendations focused a lot on visual devices that could help both engage the woman in the conversation, but also help "getting the message right".

> *"…with the community that we're looking after, it's about the visual" (NSW).*
>
> *"I'd like these more as like posters around the counselling room even…. Because that would generate a conversation with me about all those things anyway." (SA).*

Specific suggestions were made for posters that could be hung in consultation rooms. One idea was a poster to explain the different types of NRT products available, and a separate one visually showing the differences between NRT (delivering just nicotine) and smoking a cigarette (delivering thousands of different harmful chemicals in addition to the nicotine).

> *"…the pictures of people actually using it (NRT), I think that would be really helpful." (NSW).*
>
> *"I'd have, like, that big and then with nicotine and then that big with just nicotine because I like to say that to them… that's one of the messages I always try and say…" (NSW).*

Engaging with Family

The importance of family and community within healthcare for Aboriginal people is an area health professionals were particularly aware of. Smoking among other family members was mentioned as a barrier *"the women are trying to quit but they live with a bloke who's still smoking in the same house" (NSW)*; *"That's a support (family) that women are often very concerned about when they try and quit smoking" (SA).*

Health professionals wanted the resources to address this more in depth and provide useful information to guide the discussion *"…everybody's family and everybody's support network is very, very different, there could probably be a bit more of a focus on 'Okay, this is in specific how we could help you and how your family members could help you…" (SA).*

The importance of family and community was also requested to be integrated in the photography used in the resources, moving beyond pictures of only women and babies.

> *"at least include them so that visually you know that there are other people that would be smoking in the home." (Qld); "why is there not a picture of a father with a child and the baby, the mother and the father and the child?" (NSW).*

Requiring Practicality under a Tight Timeframe

When discussing the graphic and layout of the resources, multiple suggestions were made to increase the practicality of the resources. Suggestions included making the resources easy to use and fast to find the exact information you need, i.e., adding tabs, having important key information highlighted in boxes, and offering an online version with hyperlinks in the table of contents.

> *"We have so many pieces of paper floating around, when you need them, you cannot find them. I need something simple, to the point that's easily done" (NSW); "I'd probably be want to be able to flip to it really quickly… tabs would probably be better for me" (SA).*

Time was mentioned frequently as a barrier, both from the health professionals' point of view *"…clinical time is so precious at the moment because of the amount of people you've got to access on that particular time …" (NSW),* as well as from the patients' perspective "*most of our pregnant clients have other kids that they didn't leave home …their ability to concentrate… is limited … And the partner's been dragged along and he doesn't necessarily want to be there for a whole lot of stuff or somebody else has been left in the car …Time is a challenge" (NSW).*

3.5. Summary of Changes to the Educational Resources Package

Following the above processes, results were summarized and presented to the SCAAP to discuss and agree on the changes that were required. Each medical service also received a community report to distribute to their community members, health professionals, and board for feedback. A summary of the changes that were made is detailed in Table 1. Readability scores improved (meaning they became more readable–i.e., scores were reduced) for all of the educational resources, both for the health professionals–average readability score of grade 8.1 (range 7.1–8.9), and patient booklet with an average readability score of grade 4.7. Unfortunately, due to time constraints, additional photographs with Torres Strait Islander women and/or family members were not feasible. This updated resource package is included as one of the components of the ICAN QUIT in Pregnancy intervention, which in 2017 was pilot tested in six ACCHS across NSW, SA and QLD [26].

4. Discussion

4.1. Summary of Main Findings

A multi-level evaluation was conducted with an expert panel, a SAM assessment, readability testing, and focus groups with 24 health professionals in three Australian states. Multiple suggestions were made during this evaluation process to improve the usefulness and acceptability of the educational resource package:

- Additional information was required, such as how to deal with a family member who smoked in the house;
- Simplification of words was recommended to increase readability and comprehension;
- Increasing the practicality to allow faster access to information;
- Adding different visual aids to increase engagement and guide the consultation;
- Suggestions were made on how to improve wording to become more culturally responsive for Aboriginal women;
- Recommendations were made on how to facilitate health provider discussions on NRT use during pregnancy, which is a unique barrier for health professionals providing smoking cessation care during pregnancy.

4.2. Comparison with Other Literature

Previous research looking at the readability and suitability of educational resources for various health conditions have found that, in general, many are rated as non-suitable and with too high readability scores [36–40]. Many of these studies utilized readability and/or suitability measures, but without a participatory approach where end-users views on the health education material were assessed. In our study, the focus groups and expert panel provided the largest amount of information and recommendations for change.

A parallel analysis was conducted through focus groups with Aboriginal women on the patient-dedicated resources for this intervention (Bovill et al., unpublished data, 2017). Similar to the health professionals in our study, Aboriginal women were supportive of the cultural acceptability of the resources, suggested one booklet, and wanted *'more information'* on specific harmful effects of smoking. They also requested that the resources would be *'more engaging'* including real stories of Aboriginal woman who quit smoking during pregnancy. Women also asked for information on non-NRT options to deal with cravings, illustrating that the use of NRT during pregnancy is a unique barrier for both health professionals and pregnant women. As mentioned previously, a similar process has been successfully used in the past for a culturally targeted smoking cessation program for American Indians [24]. Those pre-tested resources were subsequently used for a multi-component intervention in a randomized controlled study. The intervention showed promising results with self-reported 6 month

intention to treat point prevalence abstinence rates significantly higher in the intervention group (20.1% compared to 12.0%, $p = 0.029$) [25].

Other smoking cessation interventions with Indigenous people [41] have described using a participatory approach in designing their intervention and resources [42,43], but only one study reported conducting a pre-test on their resources before rolling out the intervention [44]. This might be a contributing factor as to why these interventions did not show a higher smoking cessation rate compared to non-culturally tailored interventions [41,42]. An association has been found with conducting a pre-test and the reporting of cultural challenges by organisations developing tobacco control messages for Aboriginal Australians [45]. Programs not conducting a pre-test may be less aware of the requirements for cultural sensitivity.

The emergent themes from the health professionals' focus groups are consistent with previous research on barriers and facilitators to smoking cessation care during pregnancy [6,7]. Lack of time was mentioned as one of the most important barriers in a recent Australian cross-sectional survey of GPs and Obstetricians [8], and has also been mentioned in other surveys globally [6]. Health professionals report facing multiple high-priority issues that they need to address during a consultation, and therefore require the resources to aid them in a timely manner [7]. Smoking rates across Aboriginal communities are high, an average of 39% among adults [46]; therefore, smoking may be considered a norm in these communities [21] and has been shown to be an important barrier to quitting in pregnancy [20,21]. Health professionals require specific recommendations on how to address this topic. Visual devices have been shown to be imperative in Aboriginal communities and previous research has identified this need [47–49].

4.3. Strengths and Limitations

The major strength of this study was the community-based participatory research approach. The resources were developed collaboratively with a working party from two ACCHS including health professionals and community members, and then received input from numerous health professionals working in ACCHS, including Aboriginal Health Workers from those communities. AH&MRC ethical guidelines recommend community ownership: an important aspiration when working in Aboriginal research. Developing the educational materials collaboratively, and consulting with community members on these materials prior to commencement of the project, are factors that contribute to this ownership. Another strength was the multiple methods used to collect data, aiding in research and data triangulation. Readability was assessed both on objective scales, and with a more subjective evaluation (SAM), and comprehension was also assessed via input from health professionals.

There were several limitations that may have impacted on this study. Only three communities were included, and the results might only be representative of those communities. Despite this, the fact that these communities were diverse and from three different states, with similar results across the communities, suggests that these resources might be acceptable and useful for other ACCHS and communities. Another round of community input after the changes were done was not feasible. This is mitigated by the fact that the SCAAP gave constructive feedback on the revised resources. In 2017, a pilot study with six ACCHS across three states was conducted [26], using these resources as part of the intervention. Further feedback and data are being collected on the usefulness of these resources through surveys and interviews from the pilot participants. Due to logistic reasons, focus groups were held with all types of health professionals together. This raises the possibility of a power differential between doctors, nurses and AHW, which might have impacted the expression of their respective views, leading to an over representation of doctors' views compared to AHW or nurses. As midwifes and AHW are the main point of contact for a pregnant woman during her ante-natal care, under-representation of their respective views might have meant that not all of the issues were identified. As focus groups included a range of health care providers, we were unable to present the data according to the different types of health professionals. Focus groups were not conducted by an independent party, but by the co-authors of the resources. Furthermore, social desirability bias with

the SAM scoring and focus groups cannot be excluded, which might indicate that the resources are less acceptable and useful than perceived in this study. However, in the initial explanation about the study, the facilitators emphasized that the purpose was to receive as much feedback as possible to improve and change these resources and were eager to hear both negative and positive viewpoints.

Scores from the SAM differed greatly for the same material resulting in a low inter-rater reliability measure, and did not contribute much to the decision-making on the changes for the resources: The SAM may be thus more subjective and may require several assessments with different people.

4.4. Implication for Policy and Practice

These resources were drafted by a tobacco treatment specialist with years of experience in smoking cessation and training health professionals (YBZ), together with an Aboriginal cultural liaison and researcher (MB); and developed jointly with a working party that included health professionals and community members from two ACCHS. The whole process was overseen by a senior researcher who is also a tobacco treatment specialist and GP, and experienced in development of Aboriginal smoking cessation resources (GG). Despite this, many changes were needed to assure these resources were useful and appropriate. The findings from this study highlight why an evaluation process is important and justified and should be adapted as a requirement when developing educational resources, prior to rolling them out for practice. Despite educational resources being very common as part of behavioural change interventions, many of them lack a formal evaluation process, or this process is not included as part of the intervention description. The process described here is an example of what might be used in future interventions with diverse populations. However there are many other approaches to evaluation [50], such as the Cloze Test that assesses readability and comprehension together [51].

There are multiple educational resources being developed for various health conditions. In fact, most organizations and interventions develop their "own" branded resources. This is time consuming and potentially an uneconomical use of resources. Instead of multiple different resources, national peak organizations and/or the Department of Health should be focusing on developed targeted resources that are evidence based, cultural acceptable, useful, and shared nationally for free. These "template" validated resources could then be used by other organizations, projects and interventions. The process described in this study was time consuming (over a year) and required funding (including travel costs, reimbursement, research assessment time, and transcribing) that might deter other projects from undertaking such a process. This supports having a well-developed regularly updated national "bank" of validated educational resources that can be used freely by anyone. Having a national bank as suggested might still require validated resources to be culturally tailored to the specific communities for which they are intended. The complexity of this, combined with the uncertain evidence regarding the added clinical benefit of tailored educational resources [15], makes this a complex issue that requires further research to better understand what would be the most time and cost-effective approach.

The current process has increased the likelihood that the updated resources would be acceptable, useful and culturally responsive among participants of these three communities. By implication, the resources might be suitable for other similarly located Aboriginal communities (in the same three states) and thus appropriate for the second phase of the ICAN QUIT in Pregnancy intervention [26]. However, for phase three of this intervention (a cluster randomized controlled trial), intended to include 30 communities across additional Australian states and territories, further input and changes may be needed to ensure acceptability, usability and cultural responsiveness across all of these diverse communities.

5. Conclusions

A structured 4-step evaluation process informed the development of a resource package to be used as part of a multi-component intervention, aimed at improving how health professionals manage smoking in Aboriginal and Torres Strait Islander pregnant women who smoke. The evaluation process elicited specific suggestions for needed changes and improvements to ensure these resources were

acceptable, culturally responsive and useful. Health professionals require simple, practical, visual resources that engage pregnant women in a shared conversation on smoking during pregnancy. The generalizability of these findings might be limited and requires more research.

This novel formative evaluation protocol has never been done previously in Australia. If these resources prove effective, the methodology could be adapted for other Indigenous interventions, and culturally diverse programs. The added value of this time-consuming and costly process is yet to be justified in research, and might impact the potential adaption by other projects.

Supplementary Materials: The following are available online at www.mdpi.com/1660-4601/14/10/1148/s1, Appendix 1: Interview guide for focus groups—Health Professionals; Appendix 2: Summary of feedback provided by the expert panel.

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Open Access Protocol

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The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study protocol: a feasibility step-wedge cluster randomised trial to improve health providers' management of smoking during pregnancy

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ABSTRACT

Introduction Indigenous women have the highest smoking prevalence during pregnancy (47%) in Australia. Health professionals report lack of knowledge, skills and confidence to effectively manage smoking among pregnant women in general. We developed a behaviour change intervention aimed to improve health professionals' management of smoking in Indigenous pregnant women—the Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy. This intervention includes webinar training for health professionals, an educational resources package for health professionals and pregnant women, free oral nicotine replacement therapy (NRT) for pregnant women, and audit and feedback on health professionals' performance. The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to improve health professionals' provision of evidence-based culturally responsive smoking cessation care to Australian Indigenous pregnant smokers.

Methods and analysis This protocol describes the design of a step-wedge cluster randomised pilot study. Six Aboriginal Medical Services (AMSs) are randomised into three clusters. Clusters receive the intervention staggered by 1 month. Health professionals report on their knowledge and skills pretraining and post-training and at the end of the study. Pregnant women are recruited and followed up for 3 months. The primary outcome is the recruitment rate of pregnant women. Secondary outcomes include feasibility of recruitment and follow-up of participating women, and webinar training of health professionals, measured using a designated log; and measures of effectiveness outcomes, including quit rates and NRT prescription rates.

Ethics and dissemination In accordance with the Aboriginal Health and Medical Research Council guidelines, this study has been developed in collaboration with a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP). The SCAAP provides cultural consultation, advice and direction to ensure that implementation is acceptable and respectful to the Aboriginal communities involved. Results will be disseminated to AMSs, Aboriginal communities and national Aboriginal bodies.

Registration details This protocol (version 4, 14 October 2016) is registered with the Australian and New Zealand Clinical Trials Registry (Ref #: ACTRN12616001603404).

Strengths and limitations of this study

- This is the first study in Australia to target specifically Indigenous smoking during pregnancy that covers three different states and different settings.
- This study is designed to overcome specific implementation issues identified in previous research, including ensuring community representation in governance of the research; participant recruitment by known health staff from the service; and adequate reimbursement for time and effort of services and women.
- The intervention tested in this study was informed by theory and based on extensive formative research beforehand.
- This study is a pilot study aimed to assess feasibility and acceptability, and is not powered to assess the effectiveness of the intervention.
- This study covers health professionals treating Indigenous pregnant women who work at Aboriginal Medical Services only, and does not cover other general antenatal care settings that Indigenous women may attend.

INTRODUCTION

Tobacco smoking in pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes.

In 2013, 12% of women who gave birth in Australia smoked during pregnancy.[1] Indigenous Australian women have the highest

smoking prevalence during pregnancy (47%).[1] Indigenous women also quit smoking during pregnancy at a lower rate compared with the general population (11% compared with 25%).[1] Smoking has been identified as an important contributor to the health and life expectancy gaps between the Indigenous and non-Indigenous people in Australia.[2]

Barriers to quitting

Australian Indigenous pregnant women face multiple barriers to quitting smoking.[3–6] These include social norms of smoking in some Indigenous communities, multiple life stressors, lack of prioritisation of smoking cessation, lack of support for cessation, lack of salience of antitobacco messages and inadequate access to targeted programmes.[4 5 7] Health professionals report they are ill-equipped to tackle the complexities of smoking cessation care for pregnant women, and lack resources and optimism.[8 9] First-line medications (oral nicotine replacement therapy (NRT)) are currently not subsidised in Australia,[3] disproportionally impacting lower socioeconomic populations and Indigenous women.[10]

Evidence for smoking cessation care in pregnancy

The combination of behavioural counselling and pharmacotherapy has been shown to be the most effective treatment for smokers generally.[11] Studies specific to pregnant women have also shown that psychosocial interventions such as counselling are effective.[12] Recently a taxonomy was developed and validated to detail the specific 'active ingredients' of behavioural counselling termed behaviour change techniques.[13–15] These include, for example, goal setting and identifying smoking triggers.[16]

Pharmacotherapy

In a Cochrane review on pharmacotherapy for smoking cessation in pregnancy, the use of NRT increased cessation rates by 40% (RR 1.41, 95% CI 1.03 to 1.93); the exclusion of non-placebo controlled trials resulted in a lower, non-significant increase in the cessation rate (RR 1.28, 95% CI 0.99 to 1.66).[17] The discrepancy between these findings, and the apparent effectiveness of NRT for the general population,[18] may be explained by the faster nicotine metabolism in pregnancy, requiring higher doses than those used in the included studies.[17 19 20] Importantly, the use of NRT was not associated with any significant differences in pregnancy or birth outcomes.[17] Experts agree that NRT is always safer than smoking in pregnancy, and guidelines from several countries, including Australia, recommend the use of NRT, if a woman has been unsuccessful in quitting.[21–24] These guidelines recommend first using oral forms of NRT, and if the woman is still unsuccessful quitting smoking, adding an NRT patch. This is done to ensure that the lowest effective dose is used.[22 25]

Need for health professionals' training

Health professionals report that they lack the knowledge, skills and confidence to assist pregnant women to quit smoking. A recent national Australian cross-sectional survey[9] found that few general practitioners (GPs) and obstetricians routinely perform all of the required components of the clinical guidelines.[11 26] Furthermore, only 11% reported always prescribing NRT, 7% arranging follow-up, 22% discussing the psychosocial context of smoking and 26% referring to a specialised cessation programme (such as the national Quitline). Surveys with other antenatal health professionals in Australia (Aboriginal health workers, midwives, nurses) report similar findings.[8]

These findings mirror surveys internationally,[25 27–39] portraying an evidence-practice gap in the way health professionals currently manage smoking in pregnant women.

Addressing this gap is crucial, as it has been shown that advice from health professionals increases the chances of a quit attempt in the general population (RR 1.66, 95% CI 1.42 to 1.92),[40] and is positively associated with intention to quit in Australian Indigenous smokers of reproductive age (OR 3.82, 95% CI 1.43 to 10.2).[41] Training health professionals has been proven to increase rates of smoking cessation (OR=1.60, 95% CI 1.26 to 2.03),[42] although this has not been studied specifically for Indigenous pregnant women.

Interventions for pregnant Indigenous smokers

Interventions developed to address smoking in Indigenous people have often lacked either rigorous evaluation or deep cultural understanding.[43 44] Two randomised controlled trials (RCTs) among Indigenous pregnant smokers have been conducted: one in Indigenous Australians, and the other in Alaska native women.[45 46] Neither demonstrated any statistically significant differences between intervention and control groups, although the underpowered Eades' study found an assisted quit rate of 11% compared with a control rate of 5%.[45 46] Several implementation factors marred the outcomes of these studies, including low enrolment, high attrition and possible contamination between study arms.[45 46] Patten's study included NRT only through referral to a separate programme;[46] Eades' study included an option for NRT at the third visit, after 7–10 days of unsuccessful quit attempts.[45]

The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention

In 2015, a pragmatic guide to the management of smoking cessation in Indigenous pregnant women was published.[47] These guidelines are structured on the ABC pathway (Ask about tobacco use; Brief advice to quit; Cessation support),[23] with the addition of a D component (Discuss the psychosocial context of smoking)[47] the ABCD approach. A proactive approach is recommended—offering assistance to all pregnant smokers (regardless of readiness to quit and smoking level) and an expedited offer of NRT after 1–2 days of an unsuccessful quit attempt.[47] These guidelines follow other Australian clinical guidelines, recommending the use of oral NRT as first line, higher doses of NRT due to the

higher metabolism in pregnancy and combination NRT if needed.[21,48,49]

On the basis of these ABCD guidelines,[47] we used the Theoretical Domains Framework,[49] the Behaviour Change Wheel[50] and Behaviour Change Techniques recommended in pregnancy,[16] to develop a theory-based behaviour change intervention aimed to improve health professionals management of smoking in Indigenous pregnant women—ICAN QUIT in Pregnancy. The Theoretical Domains Framework and Behaviour Change Wheel are used to identify barriers and facilitators to achieving evidence-based care to inform intervention design.[50]

The intervention was developed in collaboration and negotiation with two Aboriginal Medical Services (AMSs) in New South Wales (NSW). The chief executive officers of those AMSs are associate investigators on the study and partnered with the research team to establish a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP), to advise on the design of the study. They also contributed to a working party including AMSs staff and community members that developed educational resources for the intervention. This collaborative process of intervention development has been described elsewhere.[51]

The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to increase health professionals' provision of evidence-based, culturally responsive smoking cessation care to Australian Indigenous pregnant smokers, positioning Aboriginal women and communities at the centre of the research with engagement and ownership upheld through the study.[51] This study will inform the final design and implementation of a clustered RCT (cRCT) aimed to study the effectiveness of health professionals' training on smoking cessation rates in pregnant Australian Indigenous smokers.

METHODS AND ANALYSIS

Study overview

The overall objective is to reduce smoking in Aboriginal and/or Torres Strait Islander pregnant women.

Specific aims of this pilot are:

Primary aims

Assess feasibility and acceptability of a multicomponent targeted intervention to train health professionals at AMSs in the culturally responsive management of smoking in Australian Indigenous pregnant women.

Secondary aims

1. Assess the effectiveness on NRT prescribing practices.
2. Evaluate the effectiveness on health professionals' knowledge, attitudes and practices in managing smoking in pregnant Indigenous women.
3. Estimate the trends for quit attempts and biochemically verified smoking cessation rates in pregnant patients managed by trained health professionals.
4. Assess patients' perceived receipt and quality of smoking cessation care by the trained health professionals.
5. Evaluate changes in the perceived well-being of pregnant patients.
6. Evaluate behaviour change techniques use by the trained health professionals.

Study design

This is a step-wedge cluster randomised pilot study with six participating sites randomised to three clusters (each of two AMSs). Allocation of the sites to the clusters is based on geographical convenience. For each cluster, the period of treatment crossover was randomised using simple randomisation. Allocation concealment was not possible. All of the sites will receive the same intervention which will be sequentially delivered 2 months following commencement of the study, staggered by 1 month between clusters (the intervention is described below). Two cohorts, one of health professionals and one of pregnant women, will provide data with repeated measures: from 2 months prior to receiving the intervention until 6 months following the intervention. See figure 1 for a schematic illustration.

A step-wedge design was chosen since it allows the intervention to be delivered sequentially and therefore reduces the cost and burden of simultaneous implementation, while also providing some control of confounding factors through randomisation.[52] Furthermore, this

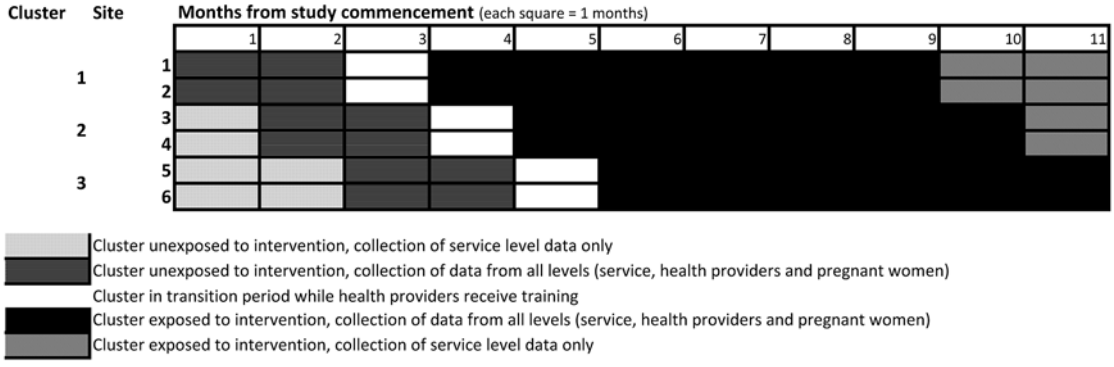

Figure 1 Schematic illustration of the step-wedge cluster study for the Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study.

design will ensure all sites receive the intervention which is important from an ethical viewpoint. The cluster design was chosen to prevent contamination, a problem identified in the Eades' study.[45]

Timeline of the study

November 2016 to September 2017.

Setting

Urban and regional AMSs in NSW, Queensland and South Australia. The AMSs include Aboriginal Community Controlled Health Services which are non-government organisations operated by local Aboriginal and Torres Strait Islander communities, to deliver holistic, comprehensive and culturally appropriate healthcare to the communities that control them through an elected board of management.[53]

Inclusion criteria

For participating services AMSs are included if they fulfil all of the following criteria:

1. Diagnose pregnancy or provide antenatal or routine care for pregnant Aboriginal or Torres Strait Islander women.
2. Employ at least one General Practitioner (GP).
3. Have contact with at least 20 pregnant women who smoke per year.
4. Are able to recruit and follow patients as required.

Participating health professionals are those who: consult with pregnant women either for confirmation of pregnancy, antenatal care and/or routine care.

Participating women will include those who fulfil all of the following criteria:

1. Pregnant, ≤28 weeks gestation.
2. Aboriginal and/or Torres Strait Islander or expectant mothers of Aboriginal and/or Torres Strait Islander babies.
3. Aged ≥16 years old.
4. Smoke tobacco at any level of consumption, including those that only smoke occasionally.

Intervention components

The ICAN QUIT in Pregnancy intervention includes:

- Training of health professionals in participating sites through webinar in three 60-min weekly sessions. The training will be delivered by two experienced tobacco treatment specialists. Content will include background on smoking in pregnancy including the Indigenous context; the ABCD approach, and the use of NRT in pregnancy (see online supplementary file for full description of webinar content). As an incentive to complete the training, all health professionals will be offered continuing professional development points (required as part of registration with the Australian Health Practitioner Regulation Agency).
- An educational resources package, to be used by both health professionals and pregnant women, has been developed collaboratively and includes a training manual for health professionals, and flip chart, patient booklet and educational posters for engaging with the pregnant women. Resources were developed by a medical doctor and tobacco treatment specialist (YBZ) and Aboriginal researcher (MB) in consultation with AMSs. These have been rigorously pretested using a four-step process, including review by an expert panel, assessment using a suitability of material score by two Aboriginal health workers, readability scores, and focus groups reviews with both health professionals, and female Aboriginal community members, in three states.[54]
- Oral forms of NRT for the pregnant women will be supplied to the sites free of charge, as these are not currently subsidised in Australia. All available forms in Australia will be included (gum, lozenge, mini lozenge, inhalator and spray). NRT will be dispensed through a voucher system. Sample packs will be provided directly to the sites to introduce patients to the selection available. If NRT patches are required, the GP at the service will write a government-subsidised prescription. NRT will be used according to product and Therapeutic Goods Administration instructions, as well as health professionals' judgement on a patient-by-patient basis. No study-specific protocol to NRT dispensing will be followed. As nicotine has potential effects on the fetus,[55 56] a risk-benefit analysis will be undertaken with each woman when NRT is offered, as recommended in clinical guidelines.[21] A participant not using NRT can remain in the study with behavioural support only.
- Audit and feedback regarding health professionals' performance will be via aggregated, deidentified, service-specific, monthly data collection, commencing in the pretraining phase and continuing through to study completion. Each service will receive feedback regarding their rate of NRT prescription to pregnant women who smoke compared with other study services.

Study implementation

A staff member will be nominated as a research facilitator by each service. The role of the research facilitator is to recruit patients, conduct surveys and evaluations, and collect feasibility data (table 1). The research facilitator will be trained by the research team in a face-to-face meeting and provided with supporting resources (detailed instructions and checklist) to assist them in their role. The research team will provide three site visits (before commencement, 1 month after commencement and end of study) and weekly telephone calls as implementation support. Additional support will be provided as needed by the research facilitator.

Recruitment and reimbursement

Services will be recruited through: (1) written invitation to all AMSs in NSW asking for expressions of interest, and (2) targeted invitations to services that worked previously with the researchers. The service will be reimbursed

Table 1 Feasibility and acceptability outcomes

Hierarchy of measurement (service, Health Professionals or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Recruitment rate (primary outcome)	Research facilitator log	Number of women recruited divided by number of women approached for each site, overall sites and stratified by site	End of study
Service	Follow-up rate	Participant survey	Percentage of women recruited who complete all follow-up surveys	4 weeks and 12 weeks
Service	Proportion of women's checklists completed	Women's checklist	Number of consultations with a completed checklist divided by the total number of consultations for each patient (designated and non-designated study visits)	End of study
Service	Provider training rate	Research facilitator log	Number of providers undergoing webinar training divided by the total number of providers, overall sites and stratified by site	End of training
Service	Webinar completion rate	Research facilitator log	Number of webinar sessions each provider attended	End of training
Health professionals and pregnant women	Acceptability of intervention and implementation	Interviews with staff and patients	Thematic analysis	End of study

$6000 in instalments, for the involvement of their nominated research facilitator.

Service staff will aim to recruit all pregnant smokers under their care when they attend for any type of service including confirmation of pregnancy, antenatal care or routine care. The study will be advertised through posters at the service.

The research facilitator will complete a one-page eligibility checklist with women interested in the study, and if they are eligible, will gain informed consent. Consenting women will be assigned a unique code to link the data collected to the same participant. Pregnant women recruited to the study will be asked to attend three designated study visits (baseline at recruitment, 4 weeks and 12 weeks postrecruitment). At each study visit, the participating women will be asked to fill out two to three online surveys and perform a breath carbon monoxide test. We estimate that each study visit will take between 30 min and 50 min.

Women will receive reimbursement for their time in the form of a $A20 shopping voucher for each visit (total $A60). Women attending all three study visits will enter into a draw for one baby pack (value $A50) per site.

Outcomes

Outcomes include feasibility and acceptability measures, and measures of effectiveness outcomes (detailed description of all the outcomes are presented in tables 1 and 2). The primary outcome will be the recruitment rate of participating pregnant women defined as the number of eligible women who consented to participate in the study.

Data collection and instruments

Data will be collected at three levels—(1) service (2) health professionals and (3) pregnant women (tables 1 and 2). Participant timelines are presented in table 3 (health professionals) and table 4 (pregnant women).

Service level

Research facilitator log

Feasibility data will be collected by the research facilitator using a designated log, including recruitment rate, follow-up rate, proportion of participant surveys completed and health professionals' training rate. Reasons for non-participation or withdrawal will not be collected routinely as part of the research facilitator designated log, but will be discussed with the research facilitator on an ongoing basis in the weekly implementation phone calls and at the end of the study interview.

Aggregated computerised data

Deidentified aggregated monthly computerised data will be collected from study commencement (figure 1), including: number of pregnant women attending the service; number of those that smoke; number referred to the Quitline and number of NRT prescriptions (including oral NRT vouchers).

Health professionals level

Health professionals' survey

A 102-item, 15 min, self-administered online survey will include questions about health professionals' demographic characteristics; self-reported knowledge, attitudes and provision of smoking cessation care; prescription

Table 2 Measures of effectiveness outcomes

Hierarchy of measurement (service, Health Professionals or pregnant women)	Outcome	Data collection method	Analysis	Time points
Service	Proportion of pregnant smokers that were given nicotine replacement therapy (NRT)	Audit of deidentified grouped data	Pharmaceutical Benefit Scheme (PBS)* prescriptions or vouchers for NRT	Monthly
Health professionals	Self-reported knowledge, attitudes and practices about managing smoking in pregnancy	Health Professionals surveys	Changes in knowledge, attitudes and practices comparing all time points	Pretraining, post-training and end of study
Health professionals	Behaviour change techniques (BCT)	Audio recording of consultations	Analysis of transcripts by trained BCT coders	Pretraining and post-training
Pregnant women	Self-reported smoking characteristics	Smoking characteristics survey	Changes in smoking characteristics	Baseline, 4 weeks and 12 weeks
Pregnant women	Women's perception of receiving smoking cessation care	Women's checklist	Composite scores on checklists	Exit from consultations with a Health Professional
Pregnant women	Self-reported quit rates	Smoking Characteristics Survey	7-day point prevalence and continuous abstinence[74]	Baseline, 4 weeks and 12 weeks
Pregnant women	Biochemically validated quit rates	Handheld CO metre	7-day point prevalence and continuous abstinence[74] using expired CO<6 ppm as reference point	Baseline, 4 weeks and 12 weeks
Pregnant women	Self-report of adherence to NRT	Smoking characteristics survey	Changes in adherence to NRT	4 weeks and 12 weeks
Pregnant women	Self-reported knowledge, attitudes and smoking behaviours	Smoking Characteristics Survey	Changes in knowledge, attitudes and smoking behaviours	Baseline, 4 weeks and 12 weeks
Pregnant women	Growth and empowerment	Growth and Empowerment Survey	Changes in growth and empowerment domains	Baseline, 4 weeks and 12 weeks
Pregnant women	Critical success measures	Critical Success Survey	Descriptive analysis of the nine critical success factors	End of study

*Pharmaceutical Benefit Scheme (PBS) is the Australian government scheme for prescription subsidy

Table 3 Schedule of assessments for health professionals receiving training for Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study

Assessment	Performed by	Pretraining _ _/_ _/_ _ _ _ (dd/mm/yyyy)	Post-training _ _/_ _/_ _ _ _ (dd/mm/yyyy)	End of study _ _/_ _/_ _ _ _ (dd/mm/yyyy)
Informed consent	Research facilitator	X		
Pretraining survey	Self-administered online	X		
Audio recording of smoking consultations (optional)	Health professional	X	X	
Post-training survey	Self-administered online		X	X
Interview	Research team			X

of NRT; self-assessment of the barriers and enablers to providing smoking cessation care; and perceived usefulness of educational resources. This survey is based on a previous survey from a national study of 378 GPs and obstetricians.[9] The survey will be sent pretraining and post-training, and at the end of the study (table 3).

Health professionals' demographic characteristics include: gender, age, years working as a health professional (less than 10 years; 10–19 years; 20 or more years), specialty (GP; midwife; nurse; Aboriginal health worker; other), smoking status (daily; occasionally, ex-smoker, never smoked) and average number of pregnant women who smoke seen per month (<5, 5–10,>10).

Self-reported provision of smoking cessation care: will be measured using 5-point Likert Scales (never (0%); occasional (1%–25%); sometimes (26%–50%); often (51%–75%); always (76%–100%)) on the various components of smoking cessation care ('How often do you provide the following types of cessation care with pregnant women?' ask; record smoking status; brief advice; assess nicotine dependence; measure carbon monoxide; cessation support; discuss psychosocial context; follow-up; referral to Quitline; referral to other specialist cessation support; involve family members).

Prescription of NRT and attitudes towards prescribing NRT during pregnancy: NRT prescription will be

Table 4 Schedule of assessments for pregnant women participating in Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study

Assessment	Performed by	Day 0 _ _/_ _/_ _ _ _ (dd/mm/yyyy)	Any additional follow-up* _ _/_ _/_ _ _ _ (dd/mm/yyyy)	4 weeks (+/−3 days) _ _/_ _/_ _ _ _ (dd/mm/yyyy)	12 weeks (+/−7 days) _ _/_ _/_ _ _ _ (dd/mm/yyyy)	End of study _ _/_ _/_ _ _ _ (dd/mm/yyyy)
Review eligibility for study	Health professional and/or research facilitator	X				
Informed consent	Research facilitator	X				
Smoking characteristics survey	Research facilitator	X		X	X	
Growth and Empowerment survey	Research facilitator	X		X	X	
Critical Success Measures survey	Research facilitator				X	
Breath carbon monoxide test	Research facilitator	X		X	X	
Patient checklist	Research facilitator	X	X	X	X	
Audio recording of smoking consultation (optional)	Health professional	X	X	X		
Interview	Research team					X

*Any additional follow-up (not part of designated study visits) including all of her visits to the service for usual care.

measured with the 5-point Likert Scale as for the other smoking cessation care components. Self-reported perceptions on NRT in pregnancy will include rating the safety for the fetus, effectiveness in aiding pregnant smokers to quit and perceived adherence.

Barriers and enablers to smoking cessation care: (5-point Likert Scales—strongly disagree, to strongly agree). This will be measured using 22 statements covering 13 domains from the Theoretical Domains Framework,[50] including: knowledge, reinforcement, role/identity, beliefs about capabilities, optimism, beliefs about consequences, social influence/subjective norm, goals/priority, memory/attention, environmental context and resources, emotions/stress, intentions, behavioural regulation. Most domains include one question regarding smoking cessation care during pregnancy in general, and one question specifically regarding the prescription or recommendation of NRT.

The 'Knowledge' domain will also be measured with one question about guidelines ('Have you read any of the following smoking cessation guidelines?' With a list of 3 different national guidelines, yes/no); and 24 true/false statements that will be computed to form a composite score. The 'Skills' domain will be measured with one question ('Have you received any training in tobacco management related to pregnancy? with a list of 4 training types' yes/no).

Usefulness of educational resources will be measured using 5-point Likert Scales (not useful at all to very useful) for each webinar session and each educational resource.

Interviews

At the conclusion of the study, one of each type of health professionals from each service (ie, a midwife, a GP and an Aboriginal health worker), including also the manager and research facilitator, will be interviewed. Recruitment will continue until saturation of themes. Estimated sample n=40. The objective of the interviews is to assess the feasibility of the intervention and the study, and gain valuable insights before commencing the cRCT. The semistructured interview guide will include questions based on the Theoretical Domains Framework and Behaviour Change Wheel,[49 50] and include topics such as the challenges to implementing the study, and what could have been done to improve the study.

Pregnant women level

Smoking characteristics survey

This 56-item, 15 min, survey will incorporate questions from a previously tested survey in Aboriginal pregnant smokers.[57] Demographic and smoking characteristics will include: age, Aboriginal and Torres Strait Islander status, partner status, parity, number of children, any child living at home, smoking status, measures of nicotine dependence (Fagerstrom Test of Nicotine Dependence,[58] Heaviness of Smoking Index,[59] strength and frequency of urges to smoke[60 61]), home smoking rules, intentions to quit smoking, number of previous quit attempts ≥24 hours, use of other smoking cessation resources (such as the Quitline), symptoms of nausea in pregnancy (morning sickness is a predictor of spontaneous quitting[62]), the Risk Behaviour Diagnosis Scale (previously validated in Aboriginal smokers, adapted here for pregnant smokers[63]), and attitudes to smoking and quitting. Adherence to NRT will be measured using a 5-item multichoice question (did not take it all; used occasionally 1–2 times a week; used 3–4 times but not all doses; occasionally missed a dose; used most doses, every day).

At the 4-week and 12-week follow-ups, the survey includes additional questions to determine 7-day point prevalence smoking abstinence and continuous abstinence rates.[64]

Growth and empowerment measure (GEM)

This survey has been previously validated with 184 Indigenous Australians, but has not been used specifically with Indigenous pregnant women[65] and includes two components:

1. 14-item Emotional Empowerment Scale which comprises two domains: inner peace and self-capacity.
2. 12 Scenarios with two domains: healing and enabling growth and connection and purpose.

These are accompanied by the 6-item Kessler Psychological Distress Scale supplemented by two questions assessing frequency of happy and angry feelings. Estimated completion time is 15 min.

Critical success measure

This measure was developed through analysis of six Indigenous youth social and emotional well-being programmes[66] and was previously used in the evaluation of an urban art-based community health programme with young Aboriginal and Torres Strait Islander parents.[67] This survey will be completed only once at the 12-week visit. This survey will measure nine factors relevant to an empowerment-based programme, including adopting full commitment to working from strengths; being patient to develop the relationship bond first; modelling reliability and being consistent; facilitating connection to culture; adopting a non-judgemental approach; setting rules and boundaries; modelling openness, honesty, hope and trust; maximising opportunity for choice making, self-motivation, feeling safe to try new things; celebrating small achievements and positive changes. For each factor, we will use 5-point Likert Scales to measure women's perception of the importance of the factor (from not at all to absolutely essential) and how well the intervention achieves this (from poorly to extremely well). Estimated completion time is 15 min.

Breath carbon monoxide

At the three study visits, a breath carbon monoxide test will be performed to validate smoking status, and estimate fetal carboxyhaemoglobin. Carbon monoxide level ≥5 ppm=96% sensitivity and 99.6% specificity for agreement of carbon monoxide readings and self-report of smoking in Aboriginal communities.[68]

Women's checklist

At the end of any visit to the service, from recruitment to the end of follow-up, including the designated study visits at 4 weeks and 12 weeks, the patient will be asked to complete a 1 min online checklist on a computer tablet. The survey will commence with a question regarding which health professional she saw on that occasion (GP/midwife/nurse/Aboriginal health worker/other). Eleven dichotomous questions (yes/no) will be used to form a composite score representing quality of smoking cessation care. For example: *Did any of the health professionals you saw today give you the following care: Asked you about smoking? Gave you advice to quit…? Assisted you with making a quit plan? Explained how smoking affects…? Offered you NRT…? Measured your breath…? /Discussed with you…? Gave you support…? Made arrangements for follow-up appointments or referral? Gave you resources…?* Two Likert Scales will be used to rate (1) her perceived involvement in making a decision about quitting (no involvement to very much involved) and (2) her overall satisfaction with the help she received (not satisfied at all to very satisfied).

Recording of consultations for behaviour change techniques analysis

A digital audio recording of provider-patient sessions relating to smoking cessation will be undertaken, including a mix of initial and follow-up consultations (ie, prequit attempt, and during or postquit attempt up to the 4-week follow-up point). A total estimate of 54 consultations will be recorded (nine consultations per service—three pregnant smokers from each service, for each woman, three consultations as outlined above).

Interviews

At the conclusion of the study, approximately three to four women from each service, will be interviewed to assess the feasibility of the intervention and related research in order to gain insights before the cRCT. Key topics to be discussed include their perceptions of the usefulness, acceptability and potential effectiveness of the support they received as part of the study, and what could have been done to improve this. Recruitment will continue until saturation of themes.

Sample size calculation

Health professionals' sample: expected sample size will be six services, training 5–10 per service, with total sample size of n=30–60 recruited health professionals. Expected completion of training is 80%.

Pregnant women's sample: expected recruitment is 10 eligible consenting women per service n=60 (range 50–80). Assuming a true recruitment rate of 50%, a sample of 200 eligible women will allow estimates of the true recruitment rate within a 7% margin of error.

Data analysis plan

Recruitment rates (and other feasibility outcomes specified in table 1) will be estimated as proportions (or percentages) with 95% CIs, SEs will be adjusted for the clustered design using the clustered jackknife.[69] All primary analysis will be according to the intention-to-treat principle, such that each site (and participants within) will be analysed according to the time at which the site crossed over to the intervention period.

Analysis of effectiveness outcome measures

1. Changes in the proportion of eligible women that were prescribed NRT from pretraining to post-training will be assessed using a logistic mixed effects regression model. The model will include a categorical effect of time, an indicator of period (pretraining vs postintervention) and a random intercept for each site.
2. Changes in provider knowledge/attitudes relating to smoking cessation in pregnant mothers measured by self-administered survey: pretraining to post-training and end of study will be investigated using generalised linear mixed effects models, with random effects for the site and the health professionals, and fixed effects for time. If the fraction of missing data is less than 5% the primary method will be based of those with completed surveys from both time points. Otherwise we will use multiple imputation under the missing at random assumption, with a sensitivity analysis using pattern mixture models to explore the potential that data is missing not at random.
3. Trends in smoking characteristics and growth and empowerment, and factors associated with smoking characteristics and growth and empowerment, will be assessed using generalised linear mixed models.
4. Two certified behaviour change techniques coders will independently code the transcribed audio recordings. Discrepancies will be resolved through discussion with a third coder. Coding will be based on the taxonomy of 44 smoking cessation behaviour change techniques.[15 16] Additionally, the two coders will independently code the training resources. Inter-rater agreement levels will be calculated. We will assess changes between behaviour change techniques present pretraining and post-training; and the fidelity between the behaviour change techniques present in the training resources and those present in the post-training recordings.
5. Interviews at the end of the study will be audio recorded, transcribed and analysed (using NVivo software) with a framework analysis[70] based on the Theoretical Domains Framework and Behaviour Change Wheel.[49 50] Two researchers will independently open code and index a 20% proportion of the transcripts line by line, using a predetermined coding matrix. After coming to consensus, one researcher will then complete the coding and indexing. If appropriate, inductive themes will be included after discussion between the two researchers.

Ethics and dissemination

We will follow Australian National Health and Medical Research Council ethical guidelines for research,

including Aboriginal and Torres Strait Islander research, consistent with the Declaration of Helsinki.[71]

The Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP) invites at least one member from each of the pilot study AMSs and will convene bimonthly. The role of the SCAAP will be to provide cultural consultation, advice and direction to ensure that the implementation of the ICAN QUIT in Pregnancy project pilot is acceptable and respectful to the Aboriginal communities involved. The SCAAP is instrumental in ensuring research practice, data collection and dissemination of findings is appropriate to each community. Members of SCAAP will be included in the writing and publication of research results.

Furthermore, an Aboriginal cultural liaison position is maintained throughout the study to ensure appropriate level of cultural safety, Aboriginal community ownership and engagement is upheld. The research team includes three Aboriginal chief investigators and four Aboriginal associate investigators who are involved in various aspects of the project, including the design, implementation, data analysis and interpretation.

Pregnant smokers who are mature minors (aged over 16 years but under 18 years) will be included if judged by the research facilitator able to give informed consent. Consent to the audio recording is an additional option for both health professionals and participating pregnant women, which they can agree to or decline.

All of the data collected, at all levels, are deidentified. Pregnant women participating in the study are given a unique code by the research facilitator. Any data collected are only identified with this code. Health professionals' surveys are linked using the date of birth and the last three digits of their surname.

All serious adverse events, and study related adverse events considered severe in nature that do not otherwise fulfil the definition of a serious adverse event, will be reported immediately by sites during follow-up. For the purposes of this study those events that will be considered severe study related adverse events include, but are not limited to, severe allergic reaction to NRT and clinical depression. A data monitoring committee will not be convened for this study and was not deemed necessary by the human research ethics committee, as NRT will be used according to current clinical guidelines.

Study outcomes will be discussed with participating services. Sites will receive a lay summary of the study outcomes, to be distributed to their community and participants of the study as they see fit. A policy brief will be distributed to Aboriginal and Government peak bodies.

Significance of the study

The ICAN QUIT in Pregnancy intervention trial was designed to overcome implementation problems identified in previous research.[45 46 72 73 74] This includes ensuring community representation in governance of the research; participant recruitment by known health staff from the service; adequate reimbursement for time and effort of the services and women participants. This pilot phase will enable us to test the feasibility and acceptability of the intervention, and make further adjustments as necessary, prior to the expense of a large cRCT. The ICAN QUIT in Pregnancy pilot trial will provide valuable information to advance the much needed reduction in smoking rates among pregnant Indigenous women.

Acknowledgements The authors thank the Aboriginal communities who have co-developed the ICAN QUIT in Pregnancy intervention. This includes staff and patients of Biripi Aboriginal Corporation, Taree NSW, and Tobwabba Aboriginal Medical Service, Forster NSW, and members of the Stakeholder and Consumer Aboriginal Advisory Panel for ICAN QUIT in Pregnancy. The following collaborators are in the ICAN QUIT in Pregnancy Pilot Group: Gillian S Gould, Billie Bonevski, Peter O'Mara, Marilyn Clarke, Chris Oldmeadow, Alan Clough, Kristin Carson, Jennifer Reath, Yael Bar-Zeev, Michelle Bovill, Katherine Boydell, Ling Li Lim, Maree Gruppetta, Roger Smith, Yvonne Cadet-James, Renee Bittoun, Lou Atkin, Brett Cowling, Lisa Orcher.

Collaborators Complete list of authors of the ICAN QUIT in Pregnancy pilot group is detailed in the acknowledgements.

Contributors YBZ wrote the manuscript and contributed to the design of the study. GG contributed to writing the manuscript, and designed and oversees the study. CO and KP advised on the study design, and statistical analysis. MB contributed to the design of the study and with MG advised on Aboriginal community consultations and adherence to ethical guidelines to research with Aboriginal communities. BB and JR advised on methodology and implementation of the research. LA advised on the design of the intervention using the Theoretical Domains Framework and Behavior Change Wheel. All authors critically reviewed the manuscript.

Competing interests None declared.

Patient consent Obtained.

Ethics approval University of Newcastle Human Research Ethics Committee (HREC) (REF #H-2015-0438). Aboriginal Health & Medical Research Council (AH&MRC) HREC (REF #1140/15). South Australia Aboriginal HREC (REF #04-16-652. Far North Queensland HREC (REF #16/QCH/34 – 1040). Note: The interviews at the end of the study were not included in the original ethics application and have recently been submitted as an amendment

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement This is a protocol manuscript therefore there is no additional unpublished data currently from this study.

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Appendix 6: Confirmation Emails of Submitted Manuscripts

Appendix 6.1: Paper three confirmation email of submission

Appendix 6.2: Paper five confirmation email of submission

Appendix 6.3: Paper eight confirmation email of submission

Appendix 6.1: Paper three confirmation email of submission

Nicotine & Tobacco Research - Manuscript ID NTR-2018-739

Nicotine & Tobacco Research <onbehalfof@manuscriptcentral.com>

Thu 27/09/2018 1:21 AM

To: Yael Bar Zeev <Yael.BarZeev@uon.edu.au>;

Cc: Yael Bar Zeev <Yael.BarZeev@uon.edu.au>; eliza.skelton@newcastle.edu.au <eliza.skelton@newcastle.edu.au>; billie.bonevski@newcastle.edu.au <billie.bonevski@newcastle.edu.au>; Maree Gruppetta <maree.gruppetta@newcastle.edu.au>; Gillian Gould <gillian.gould@newcastle.edu.au>; twilightfire1@bigpond.com <twilightfire1@bigpond.com>;

26-Sep-2018

Dear Dr Bar Zeev

Your manuscript entitled "Overcoming Challenges to Treating Tobacco use During Pregnancy - A Qualitative study of Australian General Practitioners Barriers and Facilitators" has been successfully submitted online and is presently being evaluated for consideration for publication in Nicotine & Tobacco Research.

If you have followed the author guidelines in preparing and submitting your manuscript, it will be forwarded to the editors for evaluation. If your manuscript does not comply with the guidelines, you will be asked to bring it into compliance before the manuscript is considered for review.

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Thank you for submitting your manuscript to Nicotine & Tobacco Research.

Yours sincerely,

Margaret Searle
Managing Editor, Nicotine & Tobacco Research
Email: ntr.editorialoffice@oup.com

Appendix 6.2: Paper five confirmation email of submission

Successfully received: submission Improving Health Providers Smoking Cessation Care in Pregnancy: A Systematic Review and Meta-Analysis for Addictive Behaviors

Addictive Behaviors <EviseSupport@elsevier.com>

Mon 22/10/2018 8:28 PM

To: Yael Bar Zeev <Yael.BarZeev@uon.edu.au>;

This message was sent automatically. Please do not reply.

Ref: ADDICTBEH_2018_907
Title: Improving Health Providers Smoking Cessation Care in Pregnancy: A Systematic Review and Meta-Analysis
Journal: Addictive Behaviors

Dear Dr. Bar Zeev,

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Appendix 6.3: Paper eight confirmation email of submission

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04-Oct-2018

Dear Dr. Bar Zeev:

Your manuscript entitled "Improving Smoking Cessation Care in Pregnancy at Aboriginal Medical Services: 'ICAN QUIT in Pregnancy' Step-Wedge Cluster Randomized Pilot Study" has been successfully submitted online and is presently being given full consideration for publication in BMJ Open.

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Appendix 7: Educational Resource Package

Appendix 7.1: Treatment manual

Appendix 7.2: Patient booklet

Appendix 7.3: Flipchart

Appendix 7.4: Mousepad

Appendix 7.5: Poster one

Appendix 7.6: Poster two

ICAN QUIT

In Pregnancy

Treatment Manual

The Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy educational resource package - a toolkit to aid the management of smoking with pregnant Aboriginal and Torres Strait Islander women.

Authors: Yael Bar-Zeev, Michelle Bovill, Gillian S Gould.

Photography and Film making: Ray Kelly

Suggested citation:

Bar-Zeev Y, Bovill M, Gould GS. (2016) Indigenous Counselling And Nicotine (ICAN) Quit in Pregnancy Educational Resource Package. University of Newcastle: Callaghan.

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Objective

This training manual is based on the "pragmatic guide for smoking cessation counselling and the initiation of nicotine replacement therapy for pregnant Aboriginal and Torres Strait Islander smokers" developed by Dr Gillian Gould, A/Prof Renee Bittoun, and Dr Marilyn Clarke[1].

It is designed for use by health providers who are trained in the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention. It is to be used in conjunction with the ICAN QUIT in Pregnancy Flipchart, Desktop Guide, Patient Booklet and Webinar training, as an education and information source.

This training manual should be read from cover to cover for full understanding of how to manage smoking during pregnancy and suggestions for action.

For easy and quick reference to specific topics, we have added a hyperlink option in the table of contents (online version); and tabs with different colours in the hard copy version.

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This treatment manual was written by Dr Yael Bar Zeev as part of her PhD candidature at the University of Newcastle

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Background on smoking in pregnancy

Epidemiology, health risks and benefits of cessation, relevance to vulnerable subgroups including the Indigenous context

Tobacco is considered to be the number 1 risk factor for morbidity and mortality around the world, killing around 6 million people each year[2]. Rates of smoking are higher among Indigenous populations, including Aboriginal and Torres Strait Islander people in Australia[3]. It is estimated that tobacco use is responsible for 20% of all deaths and 12% of the total burden of disease among Aboriginal and Torres Strait Islander people in Australia[4]. Life expectancy at birth was estimated, for the period 2005-2007, to be 67 years for Aboriginal and Torres Strait Islander males, and 73 years for females. This indicated a gap of 11.5 and 9.7 years respectively, compared to the general population in Australia[5]. Smoking was found to be the biggest contributor to this gap in life expectancy, at 17%[6].

In 2013, one in eight women (12%) smoked at some time during their pregnancy[7]. Smoking rates are higher for vulnerable populations in pregnancy, such as Aboriginal and Torres Strait Islander women (47%), women in low socio-economic postcodes (20%), and those living in remote geographic areas (21%) and very remote areas (37%)[7]. Aboriginal and Torres Strait Islander women also quit smoking during pregnancy at a lower rate compared to the general population (9.6% compared to 18.4% in 2010)[8].

Tobacco smoking in pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes, including miscarriage, growth restriction, stillbirth and preterm birth[7]. **Table 1** details all the health consequences to the mother and baby, in both the short and long term. Trans-generational effects from maternal and parental smoking include chronic diseases (cancer, heart and respiratory diseases, obesity and diabetes), and behavioral and learning problems. Epigenetics plays a role for these effects. A baby exposed in utero has >5-fold greater risk of early tobacco experimentation[9].

The relative risk of smoking for Aboriginal and Torres Strait Islander women, compared to non-Indigenous counterparts, has been increasing over the last two decades. In NSW for example the relative risk is currently (2014) six times, up from five times in 2012 and three times in 1997[10].

Indigenous women want to quit to protect their babies, but are hindered by psychosocial barriers: e.g. community norms, stressors, limited understanding of harms, lack of salience of media messages, and lack of support and efficacy for quitting[11]. Smoking is embedded in the life of Aboriginal women, and is used by them to deal with everyday stressors[11]. Furthermore, although most women understand that smoking in pregnancy is harmful, the effects are not fully understood, especially since these effects on the baby are usually not visible[11]. In addition, some women believe that quitting will not help as they are exposed to smoke anyway due to partner and other family and community members smoking around them[11]. Others believe that quitting smoking will cause a high level of stress that can also be harmful to the baby[11]. However, many women believe that education and advice on their own are insufficient, and women will need practical help and support with quitting[11]. Many of these areas remain under-researched, such as the way women may assess their risks for smoking and their level of efficacy for quitting [12, 13].

Comprehensive and often intensive interventions are recommended for pregnant Aboriginal and Torres Strait Islander women[14] but so far evidence to guide successful interventions by health practitioners and policy makers is sparse[15-17].

Table 1: Health consequences of smoking in pregnancy on the mother and baby

Effects on the mother		Effects on the foetus/baby	
Short term – pregnancy related	**Long term**	**Short term**	**Long term**
• Reduced fertility • Ectopic pregnancy • Preterm labour • Premature rupture of membranes • Placental abruption • Placenta praevia • Pre-eclampsia • Miscarriage • Stillbirth	• Cancer (including lung, breast, cervical, vulval cancer, bladder cancer, • oropharyngeal cancer) • Cardiovascular disease • Chronic respiratory disease • Osteoporosis • Premature menopause	• Foetal death • Perinatal death • Low birth weight (less than 2500g at birth) • Growth restriction • Birth defects • (such as limb reduction defects, clubfoot, oral clefts)	• Sudden unexpected death in infancy • Respiratory disease (asthma, lower respiratory • infection, decreased lung • function, glue ears) • Nicotine dependence (higher risk of becoming a smoker) • Type 2 diabetes • Cognition (impaired academic • performance and cognitive • abilities) • Behaviour (conduct disorder, ADHD, • antisocial behaviour)

Source: Adapted from Mendelsohn C, Gould GS, Oncken C. Management of smoking in pregnant women. *Aust Fam Physician.* 2014;43(1):46-51.[18]; RANZCOG *Women and Smoking.* 2014.[19]

Culturally safe care - importance and content

In this document, when referring to Aboriginal and Torres Strait Islander peoples' health, we use a holistic approach:

"Aboriginal health' means not just the physical well being of an individual but refers to the social, emotional and cultural wellbeing of the whole Community in which each individual is able to achieve their full potential as a human being, thereby bringing about the total wellbeing of their Community. It is a whole-of-life view and includes the cyclical concept of life-death-life"[20].

Practices should pay attention to cultural safety for Aboriginal and Torres Strait Islander clients, so women feel encouraged to attend for follow-up healthcare[21-24].

As opposed to the terms "Cultural Awareness" and "Cultural Sensitivity" that focus more on raising the awareness and knowledge of individuals about the experiences of cultures that are different from their own[24], the term 'Cultural Safety' includes "…a process of reflection (by the health provider) on his or her own cultural identity and will recognize the impact of his or her culture on his or her professional practice. Unsafe cultural practice comprises any action which diminishes, demeans or disempowers the cultural identity and well-being of an individual"[24].

The following are essential features of cultural safety[24]:

1. An understanding of one's own culture.
2. An acknowledgement of difference, and a requirement that caregivers are actively mindful and respectful of difference(s).
3. It is informed by the theory of power relations - any attempt to depoliticise cultural safety is to miss the point.
4. An appreciation of the historical context of colonization, the practices of racism at individual and institutional levels, and their impact on the lives and wellbeing of First Nations People, both in the past and the present.
5. Its presence or absence is determined by the experience of the recipient of care, it is not defined by the caregiver.

In terms of the clinical interactions between health providers and patients, specifically in regard to the power relationship between them, cultural safety calls for an honest partnership where the power is shared between the two parties, leading to a joint or shared decision making[22].

Non-didactic counselling styles

Main points:

1. **Smoking is an addiction, not a lifestyle choice or a habit**
2. **Each smoker is different. Some find it easy to quit, but most patients will need intensive support and medication**
3. **Offer support to all**
4. **Emphasize the woman's choice, and respect her choice**

All pregnant women should be routinely asked about their smoking in a non-threatening way, and be nicotine dependence assessed. Smoking may be under-reported in this population. Using a written multiple-choice format aids disclosure in the general population, but literacy issues may need to be taken into account in this population[25]. Using a conversational style of history taking has merit in the Aboriginal context, asking the woman to tell her smoking story. We also recommend a verbal version of the multi-choice format (see "A - Ask and record smoking status" on page 23)[1].

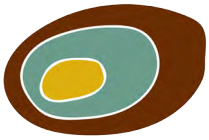
Midwifery approaches recommend a sensitive woman-centered dialogue building on trust and a long-term relationship[26].

Many health professionals in Aboriginal Medical Services are used to a more 'yarning' style of approach. None-the-less we remind health professionals to avoid insensitive and didactic communication styles with Indigenous pregnant women[27]. For example, do not tell the woman what she should do, or what is wrong with what she is currently doing. Instead, be non-judgmental, acknowledge her choice, discuss different options, and let her make an informed choice. For example:

"This is your choice. Quitting smoking is the best thing for you and your baby's health. We can discuss various options of what can help, so you can make a decision about what you want to do."

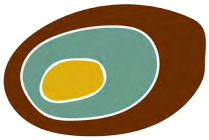
Delivering health education messages – the ASK-PROVIDE-ASK model

It can be hard to raise the issue of the health risks of smoking on the mother and baby. Fear-based messages often result in self-exempting beliefs (meaning the person may deny or refute the message, or think it does not apply to them). We also don't want to assume the woman knows nothing about the harms of smoking, and risk patronising her. A more respectful way of delivering health education is the Ask-Provide-Ask model.



ASK the woman: "What do you know about the health effects of smoking on you and your baby?"

Give her some time to tell you what she knows and then ask "would it be okay if I filled in a few gaps?" This allows you to **PROVIDE** some extra information which may influence her decision to quit smoking.



Then **ASK** the woman if she has any other questions about anything you've talked about.

It is common that Aboriginal and Torres Strait Islanders report not being given adequate assistance to quit smoking. Forty percent of Aboriginal smokers of reproductive age (male and female), in a community survey, gave very low ratings to the health professional assistance they received to quit smoking[28]. This is consistent with other reports that 38% of pregnant Indigenous smokers are offered no support[29].

These consumer perceptions tally with reports from health professionals themselves. In Australia, knowledge of smoking cessation strategies is low amongst antenatal health providers caring for Indigenous women (Aboriginal Health Workers (AHW), midwives, nurses, doctors). Those with better NRT knowledge were more likely to assess smoking status[30]. Despite 94% agreeing on the importance of the issue, not all these health providers considered it worthwhile to offer advice to Indigenous maternal smokers, due to low perceived success; >50% reported not having enough skills to advise[30]. Similar findings were found in a recent national survey of General Practitioners and Obstetricians in Australia, with 65% reporting not being optimistic that their intervention for smoking in pregnant patients would be effective[31].

It is important to understand that not all smokers are the same. Some smokers will find it very easy to quit and succeed without any additional support. This is not the case for most smokers – the success rate of quitting alone without

support or medication is around 5%. It's important to understand that smoking is an addiction (and NOT a personal lifestyle choice).

Most smokers (and a lot of health providers as well) expect themselves to be able to quit 'cold turkey' without any help, and may have a sense of pride to do so. When they are not successful, this sets them up to feel ashamed, guilty, and experience low self-esteem. It is important to remember to be non-judgmental and supportive – IT IS NOT THE SMOKER'S FAULT FOR NOT BEING ABLE TO QUIT.

For these reasons we are approaching Indigenous smoking in pregnancy through upskilling and training health professionals, in culturally competent evidence-based care. Thus, our aim is to provide Aboriginal and Torres Strait Islander women with the best chances of quitting in pregnancy.

Can smoking cessation support from health providers be effective?

Main points:

1. **Smokers may need multiple attempts to succeed**
2. **Counselling is effective**
3. **Smoking cessation support is one of the most cost-effective treatments you can do**
4. **The number of patients you need to treat (NNT = Number Needed to Treat) in order to achieve success with one woman quitting is much lower compared to other treatments. For example, NNT for smoking cessation is 16, compared to 847 for folate treatment in pregnancy**

A Cochrane review in 2012 showed that training health professionals improved their performance, and improved smoking cessation in their patients (continuous smoking abstinence, OR 1.60, 95% CI 1.26 to 2.03, p= 0.03)[32]. This meta-analysis included interventions on training a wide range of health professionals, among them physicians, nurse practitioners, physician assistants, psychologists, and pharmacists.

Specifically in pregnant patients, research has shown that counselling is effective and can increase the proportion of women quitting, and reduce harmful effects such as low birth weight and preterm birth[33].

Smokers sometimes need to make many attempts to finally quit[34], and it is not always predictable which attempt will be the final one. What we advocate in this intervention is to enable every pregnant woman who smokes to have the best chance of success with each quit attempt. If a health provider or service has not seen much success in their patients through quitting, it does not mean that pregnant women are not quitting successfully elsewhere. It may be unsatisfying to treat and provide smoking cessation counselling to many women and have only a few quit, but research has shown that smoking cessation is one of the most cost-effective treatments that a health professional can provide[35].

In fact, a Cochrane review indicated that a health professional would need to provide smoking cessation support to 16-17 pregnant women in order to achieve one successful quit attempt (number needed to treat – NNT)[36]. The number needed to be treated in order to prevent one baby born with low birth weight is 61; and the number needed to be treated in order to prevent one baby born preterm is 71[33]. **For comparison, you would need to counsel 847 pregnant women to take folate supplements in order to prevent 1 neural tube defect[37].**

In summary, health providers can confidently and optimistically assist pregnant women to quit smoking.

Approach to the management of smoking

There are several approaches to management of smoking in primary care. You might have heard of, or been trained in the past, with the 5A's[35] (Ask about smoking status; Advice to quit; Assess nicotine dependence and motivation to quit; Assist in quitting, including referral and prescribing medication as needed; Arrange follow up).

Recently, a pragmatic guide to the management of smoking in Aboriginal and Torres Strait Islander pregnant women has been developed and published[1]. These guidelines are based on the New Zealand smoking cessation guidelines for health professionals, the ABC[38] (Ask about smoking status, Brief Advice to quit, Cessation support including referral, prescription and follow up as necessary). This approach adds a fourth item to the ABC: D – Discuss the psychosocial context of smoking[1]. See Box 1 below for suggested approaches.

In this training, we suggest that the latter approach is more appropriate and ensures that the health professional does not omit key elements to smoking cessation, care of providing cessation support, and discussing the contexts that may be barriers to a woman quitting.

Box 1: Approach to the management of smoking

A – Ask about smoking – *"I hope you don't mind me asking, but does anyone at home smoke?"* Followed by *"Some women smoke more when pregnant, some smoke the same, or some smoke less – what's been your experience?"*

B – Brief advice to quit - *"The best way to help your baby and your own health is to quit smoking".*

Offer all pregnant smokers assistance with quitting. *"Have you had a time in this pregnancy or in the past when you tried to go a whole day without smoking? How did you go?"*

If appropriate suggest a trial of stopping smoking in the next few days for 1–3 days. Emphasise importance of taking one day at a time. Explain withdrawal effects and link with stress.

C – Cessation aids. *"One of the things we can really help you with is to quit smoking. If you cannot manage it alone, we can use nicotine replacement therapy (NRT) to help the cravings."* Introduce the idea of NRT, discuss previous experiences with NRT and address myths and personal views regarding the use of NRT. Explain risks and benefits. Measure CO reading and explain implications. If indicated offer samples of oral NRT for the current or following week, and follow-up in a few days to a week.

D – Discuss family, social and cultural context for smoking, and challenges for quitting. It may be helpful to find out what others in the family have said about smoking in pregnancy.

A - Ask and record smoking status

Main points:

1. **Ask every woman at every visit about smoking**
2. **Use a more conversational style of asking**
3. **Don't be judgmental – remember smoking is an addiction, not a choice!**

It is important to ask and document the woman's current smoking status at each visit. (For asking about other smoking exposure, see next section).

Many women quit or reduce the number of cigarettes they smoke per day when they find out they are pregnant. Furthermore, many of them do not disclose their smoking status accurately due to social stigma and shame[39,40].

Therefore, a simple "do you smoke?" yes/no and "how much a day?" are not enough and might not allow for a full understanding of their smoking status.

Studies have shown that a multiple choice question is better for this purpose, such as:[35,41]

"Which of the following statements best describes your cigarette smoking?

- *I smoke more since I have become pregnant.*
- *I smoke regularly now; about the same as before finding out I was pregnant.*
- *I smoke regularly now, but I've cut down since I found out I was pregnant.*
- *I smoke every once in a while.*
- *I have quit smoking since finding out I was pregnant.*
- *I wasn't smoking around the time I found out I was pregnant, and I don't currently smoke cigarettes."*

Using a more conversational style of asking about her smoking status might be more appropriate for Aboriginal and Torres Strait Islander women[1]:

"Some women smoke more when pregnant, some smoke the same, or some smoke less – what's been your experience?"

The health professional should be aware that women may smoke more once pregnant due to their increased metabolism, and that unless this is normalised and explained, women are unlikely to report smoking more due to the stigma of smoking[42].

If feasible within the timeframe, a full history should be taken that will include:[1]

- Age of starting smoking
- Number of cigarettes or amount of tobacco smoked per day
- What else they may smoke or use that may contain nicotine, e.g. cannabis mixed with tobacco, e-cigarettes, chewing tobacco
- Previous quit attempts, including in the current pregnancy
- Length of time of smoke-free episodes
- Whether cessation aids have been used previously e.g. nicotine replacement therapy (NRT), their effectiveness, and any side effects

The most important details are those concerning **previous quit attempts** during the current pregnancy, and **previous experience using NRT**, as these will guide the clinical decision regarding initiation of NRT in the current pregnancy.

It is important to remember to be non-judgmental, and not to confront the woman. Be understanding, accept the woman's choice, and give positive feedback for any effort she had made to reduce or quit:

"It can be hard to cut down on the number of cigarettes you smoke. That's great that you are willing to make that effort and have already succeeded cutting down. The best thing for you and your baby's health is to quit altogether."

A - Asking about other forms of tobacco or other forms of exposure to nicotine, and second-hand smoke exposure

Main points:

1. **Exposure to nicotine in any form will interfere with breaking the addiction**
2. **Exposure to other forms of tobacco, including second-hand smoke, also has negative health impact on the mother and baby**
3. **It is important to assess these exposures as part of the visit**

Although manufactured cigarettes are the most commonly-used form of exposure to tobacco,[43] a few women might use other forms of tobacco such as chewing tobacco, including "pituri" the traditional plant containing nicotine, depending on the geographic location[3]. Furthermore, many women might also be smoking cannabis ("yarndi" or "ganga") mulled with tobacco,[44] or using electronic cigarettes. Electronic cigarettes may or may not be used with the liquids that contain nicotine. At the time of publication, in Australia, nicotine for use in electronic cigarettes is supposed to be only imported with a doctor's prescription, but we have heard that there are loopholes to this rule, and some people do import nicotine liquid for electronic cigarette devices for their own use from the Internet. There is almost no research data on the pattern of use of other forms of tobacco, or electronic cigarettes in pregnant woman, and none in Australia.

Furthermore, many women are probably also exposed to second-hand smoke from their partners and family members living with them, and other community members. Research has shown that exposure to other forms of tobacco, including second hand smoke, also has a harmful effect on the mother and baby[45,46]. For example, babies born to mothers exposed to second-hand smoke had a higher risk of low birth weight compared to babies that were not exposed[45].

Since the main compound causing the addiction is nicotine[47] any exposure to nicotine in any other form will interfere with overcoming the addiction to tobacco. Therefore, it is important to ask and assess these exposures:

"Do you use any other forms of tobacco or products that might contain nicotine, such as, chewing tobacco/'pituri', and/or electronic cigarettes?" "If you smoke cannabis/yarndi, do you mix it with tobacco?"

If yes, follow up with: "Do you use them daily or occasional?"

"How much do you use during a day?"

It is important for pregnant women to quit smoking in any form. Explain to the woman the addictive nature of nicotine, and that all other products also have harmful effects to her and the baby, similar to the effects of 'regular' smoking.

Note:

If the woman is using cannabis on a daily basis, she should be referred to an addiction specialist

It is also important to ask about second-hand smoke exposure:

"I hope you don't mind me asking, but does anyone smoke at home? Where do people smoke at home – do you have any rules about that?"

When performing the other components of these guidelines (Brief Advice, Cessation support, and Discuss the psychosocial context of smoking), bear in mind the patient's possible exposure to other forms of tobacco or nicotine and address this as well (see other sections Pages 19 and 27 for further detail).

A- Assessing Nicotine Dependence

Main points:

1. **Understanding how strong and frequent the patient's urge to smoke is can help guide treatment decisions**
2. **If a woman is still scoring 3 or above on either the Strength of Urges To Smoke Score (SUTS) and/or the Frequency of Urges To Smoke Score (FUTS) she needs additional support**
3. **Additional support could be initiating NRT; or increasing the dosage of oral NRT; or adding a patch to oral NRT ("Fig 2: NRT treatment algorithm" on page 61)**

After establishing her smoking history and current smoking status, including using other forms of smoking products, it is important to get an understanding of the woman's level of physical dependence on nicotine (see "Box 2: What will assessing nicotine dependence add?" on page 28).

This makes it possible to anticipate in advance the strength of withdrawal symptoms she might encounter, and helps to guide the adjustments to the dosage of NRT (see "C - Cessation support - Nicotine Replacement Therapy (NRT) in Pregnancy" on page 49). This is also important as a baseline for comparison at follow-up visits, and will assist in explaining the importance of using NRT to aid the quit attempt.

Box 2: What will assessing nicotine dependence add?

What will assessing nicotine dependence add?

- Anticipate the level of withdrawal symptoms a woman might suffer from
- Inform your decision on the dosage of NRT (if needed)
- Used as a baseline for comparison at follow up
- Help you explain to the woman why she might need to use NRT to help her quit

Assessing a woman's nicotine dependence includes 2 measures:

1. Strength of Urges To Smoke Score (SUTS)
2. Frequency of Urges To Smoke Score (FUTS)

Strength of Urges Score (SUTS) and Frequency of Urges Score (FUTS)

Assessing nicotine dependency includes two simple questions (Table 2) measuring the Strength of Urges to Smoke score (SUTS)[48] and the Frequency of Urges to Smoke score (FUTS)[49]:

In general, how strong have the urges to smoke been **in the last 24 hours**?

How much of the time have you felt the urge to smoke **in the past 24 hours**?

These questions will help to assess how strong and frequent the woman's cravings are to smoke (both scales correlate with dependence), how she is coping with her quit attempt, and whether additional support is needed (such as initiating NRT/increasing the dosage of NRT already used/or using combination NRT). As a general rule, a score over 3 on either of these requires attention and suggests using additional NRT (see "Fig 2: NRT treatment algorithm" on page 61).

Table 2: SUTS and FUTS scores for nicotine dependence

SUTS Strength of Urges to Smoke score	FUTS Frequency of Urges to Smoke score
In general, how strong have the urges to smoke been in the last 24 hours? • Slight (1 point) • Moderate (2 points) • Strong (3 points) • Very strong (4 points) • Extremely strong (5 points) **Total SUTS Score:** _____	**How much of the time have you felt the urge to smoke in the past 24 hours?** • Not at all (0 point) • A little of the time (1 points) • Some of the time (2 points) • A lot of the time (3 points) • Almost all of the time (4 points) • All of the time (5 points) **Total FUTS Score:** _____

Carbon Monoxide (CO) in exhaled breath

Main points:

Measuring carbon monoxide (CO) levels is used as a visual aid to help explain the health effects of smoking, and to motivate patients to quit

In addition to these two scores, which rely on the woman's self-report, measuring the level of exhaled carbon monoxide can also assist in objectively assessing their active and passive exposure to smoking, and be used as a visual tool to motivate smoking cessation[48-50].

This is a very simple, non-invasive, inexpensive test that gives immediate results[49,51,52]

Carbon monoxide is a poisonous gas that has no odour, colour or taste[53]. It is produced any time combustion occurs (burning fire/ smoking anything/ running fuel engine)[53]. The CO has a higher affinity to the haemoglobin in the bloodstream than oxygen, and therefore binds to it strongly instead of oxygen, forming carboxyhaemoglobin (COHb)[53]. CO is the main reason smokers have higher levels of haemoglobin (Hb) and higher packed cell volume (Haematocrit) on their blood tests. These higher levels are a compensation method used by the body to try and provide more oxygen[54].

The CO monitor can be used to estimate the foetal carboxyhaemoglobin (FCOHb%) in the pregnant smoker (see "Box 3: How to use the piCO baby smokerlyser" on page 32). This measure can also help to educate the woman on the effects of smoking on her baby in a more visual way[1].

A simple way of explaining this to a patient would be to say…

"This carbon monoxide gas from tobacco smoke binds better and stronger than oxygen to our blood cells, blocking the oxygen from binding. Therefore when you smoke, your blood and the baby's blood have a lower level of oxygen than they should."

As a general rule, CO levels 6 parts per million (ppm) or over indicate that the woman has been smoking, or has been exposed otherwise to tobacco smoke[1,51]. CO levels ≥5 ppm have 96% sensitivity and 99.6% specificity for agreement with Aboriginal self-report[55], and highly correlate with higher risk of foetal growth restriction[56].

A patient's current level of exhaled CO will depend on the number of cigarettes she smokes per day, and the time elapsed from her last cigarette[57]. It also depends on the *topography* of smoking: this means the way a person inhales their smoke – if she inhales deeply and retains the smoke in her lungs for longer than usual, her CO is likely to be higher. CO quickly disappears from exhaled air (levels can drop by 50% after just 4 hours)[51]. Therefore low levels of cigarette smoking (CPD≤5) may not be detected, or may be indistinguishable from the pattern seen with passive smoking[51].

It is also crucial to remember that very high CO readings may be caused by other factors, such as exposure to traffic emissions, faulty furnaces, leaky gas appliances, or cannabis smoking (with or without tobacco)[51]. **In any case, if a woman has a CO reading >100 ppm (or COHb% higher than 10% in a smoker), she should be immediately referred to her GP to rule out CO poisoning[53].**

It is important to measure these scores - SUTS, FUTS and CO in exhaled air - **at every visit.** This will help monitor the woman's quit attempt, decide on initiating and adjusting NRT dosage as needed, and serve as a visual practical aid for discussing these issues with the patient.

Box 3: How to use the piCO baby smokerlyser

How to use the piCO Baby Smokerlyser

- Insert the plastic D-piece to the machine
- **Explain to the patient that when you tell her to, she should take a deep breath and hold all the air in. She will be expected to hold the air for 15 seconds. After 15 seconds, she will then blow the air slowly into the D-mouth piece.**
- Tell the patient to take a deep breath, and press the on button (located on the top of the machine).
- This will start the 15 seconds countdown (displayed on the screen). In the last 3 seconds you will hear three beeps to prepare the patient to blow the air in.
- After 15 seconds, the patient should blow all the air in her lungs **slowly** into the mouthpiece.
- The CO ppm score, the woman's %COHb and the baby's corresponding %FCOHb will show.
- A CO level over 6 ppm is considered to indicate a smoker.
- In addition the lights that flash relate to the level of CO: Orange and Red lights flash when levels are higher, and the faster the beeping noise the machine makes, the higher the levels.

COppm	%FCOHb
>20	5.66
19	5.38
18	5.09
17	4.81
16	4.53
15	4.25
14	3.96
13	3.68
12	3.40
11	3.11
10	2.83
9	2.55
8	2.26
7	1.98
6	1.70
5	1.42
4	1.13
3	0.85
2	0.57
1	0.28
0	0.00

*Adapted from Bedfont Scientific Ltd. Smokerlyser Chart, Issue 5- March 2016, Part No: LAB469 at http://www.bedfont.com

B - Brief Advice

Main points:

4. **Offer every woman, at every visit, support to quit smoking**
5. **Always aim for quitting, not cutting down**
6. **Cutting down can be used as a technique to aid women who aren't willing to try quitting at present**
7. **Remember – smoking is an addiction, not a habit - don't be judgmental – respect her choice.**

Offer all women, at every visit, clear advice that they should quit:

"The best way to help your baby and your own health is to quit smoking."

If the woman is using other forms of tobacco or nicotine containing products (such as electronic cigarettes), advise that the best way is to quit all forms of smoking together and at the same time.

Is cutting down enough?

No! Research has shown that simply reducing the amount of smoking has not been found to be associated with better health outcomes[58]. This is largely due to the fact that most people trying to reduce their amount of smoking compensate by taking deeper and longer inhalations from the cigarettes they do smoke, therefore leading to the same harmful exposure to all the toxins and chemicals in the cigarette smoke[58]. Also, some of the health effects, such as an increased risk of blood clotting (and therefore heart attack and stroke), occur from the very first cigarette that is smoked[59]

Cutting down can be used as a pathway to encourage and support women to quit[60], but the goal should always be quitting completely. It may be used as an interim measure while starting on NRT, since NRT use tends to help protect the woman from taking in more smoke through compensatory smoking.

It is important to encourage quitting rather than cutting down:

"It's great you have cut down (or thinking about cutting down), but the best thing would be to quit completely."; "There is nothing better for you and your baby's health than to quit smoking completely."

Offer all pregnant smokers assistance with quitting, but emphasize that it is her decision:

"If you choose to, I can help you quit. I know that quitting can be hard, but there are effective ways that I could support you with, and help you do it."

If appropriate, suggest a trial of stopping smoking in the next few days for 1–3 days.

"If you want, we could take it one day at a time, you might try and not smoke in the next few days then come back and tell me how you are going."

If a woman is reluctant to quit, suggest cutting down for now:

"I understand you prefer not to quit at this time. Do you think you might be able to just cut down for now?"

Suggest she comes back in a few days to see how it is going with the cutting down. Make sure to congratulate her for every effort and success (even the smallest). However, keep your praise realistic and do not go over the top with excitement for small changes, as it may seem insincere.

Ask her what helped her succeed to cut down. What were her strengths that helped her in the process?

Then suggest, again, a trial of quitting. Emphasise that she should take it one day at a time. Even if she manages to stay away from smoking for a short time, it will be beneficial for her baby.

Encourage quitting early in pregnancy. Quitting at any stage of pregnancy is beneficial to the mother and baby[61], but quitting as early as possible will have the greatest positive effect[62-64]. For example, quitting before the second trimester of pregnancy is associated with reduced risk for low birth weight and preterm birth, compared to women who smoked throughout the pregnancy[64-66].

Advice regarding e-cigarettes

If a woman reports using an e-cigarette to aid her quitting, explain that:

- E-cig. have never been studied in pregnant women
- E-cig. are basically an alternative **unregulated** device that may or may not provide nicotine
- NRT has been studied extensively in the general population and found to be safe and effective
- NRT has been studied in pregnancy and has been shown to help pregnant women quit, and hasn't caused damage to the mother or baby in these studies
- With NRT we can know and control the total amount of nicotine the woman and her baby will be receiving (this is unknown with e-cigarettes)
- NRT is the preferred first option before trying an e-cig

However, it is important to keep in mind that most experts agree that using an e-cigarette is less harmful than smoking cigarettes[67,68], and therefore it is better that she uses an e-cig, than resumes smoking conventional cigarettes.

Emphasize that although using e-cig. is better than smoking conventional "regular" cigarettes, the best thing for her own and the baby's health is to quit altogether.

Also explain that if she is continuing to receive nicotine from any other source (such as e-cig.) she is not breaking the addiction to nicotine in her brain.

"I'm not saying you should not use e-cigs if it is the only way you can stop smoking tobacco, but let's talk about trying NRT first, as it is a proven, safe option to quit."

C - Cessation support – Behaviour Change Techniques

Main points:

1. **Each smoker is different! It's important to discuss the woman's personal smoking pattern**
2. **Raise awareness of the woman's personal reasons for continuing to smoke and for quitting**
3. **Address any personal barriers she might have (fear of weight gain; mood changes; withdrawal symptoms)**
4. **Discuss her personal triggers and cues for a cigarette**
5. **Suggest using the STOP-THINK-DO or the 4D's to deal with an urge to smoke**
6. **Practice a breathing exercise together**
7. **Support the woman to prepare for her quit attempt – there are personal, social and environmental things she can do (Table 3)**
8. **Fill out a quit plan together**

Research has shown that the most effective method of quitting smoking includes a combination of behavioural support and pharmacotherapy[35,69,70].

Providing behavioural support involves using various different methods and techniques to aid the patient in the process of the behaviour change (called behaviour change techniques).

Many smokers, including pregnant women, will require additional or more intensive support, which can be provided through the Quitline and/or local support groups (see "Additional Support" on page 77)

However there are many things that can also be done in the setting of a primary care medical service.

1. Raise awareness about the patient's personal reasons for wanting and/or not wanting to stop smoking

This can be done with a simple discussion:

"Can you tell me why you want to stop smoking? What are your personal reasons for not wanting to quit?"

Or use a hand-out of a table of pros/cons for stopping smoking. For example:

Personal reasons to quit smoking	Personal reasons to NOT quit smoking
Afraid it will hurt my health	It relaxes me
Afraid it will hurt my baby's health	It's the only way I can get a few minutes to myself
Costs a lot of money	All my friends and partner smoke – what will I do when they smoke?
People give me a hard time for smoking with a big belly	I enjoy smoking

It's important to emphasize that the reasons should be **personal and relevant** to the patient.

Remember to not be judgmental or critical. Do not contradict what the patient says or thinks. Instead, focus on her reasons to quit and strengthen her motivation using these reasons.

For example, if a woman stated she wants to quit due to health risks for herself or the baby, ask her to elaborate in her own words

"Can you tell me a little bit more – what health risks are you concerned about?" Praise her reasons and confirm their relevance ***"Quitting smoking is the best thing you can do for you and your baby's health."***

If a woman states that one of the reasons is the high cost of cigarettes, you could help her to calculate the total amount she has spent so far in life on cigarettes and ask her to think of things she would do with that amount of money now. There are free online cost calculators you can use (or refer the women to), such as: http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/online-calculator

2. Address any personal barriers or concerns to quitting

There are many different concerns around quitting that may deter women from trying to quit. Common concerns are acute withdrawal symptoms, weight gain, and mood changes.

Acute withdrawal symptoms

As with any other addiction, when a woman stops smoking, her body and brain stop receiving the same amount of nicotine they are addicted to, and she might suffer from withdrawal symptoms.

Regarding the severity and length of withdrawal symptoms, these are experienced differently by each person. They can include headaches, hunger, constipation, tiredness, difficulty sleeping, feeling irritable or stressed, feeling depressed, and craving a smoke.

The severity and length of the symptoms are usually the highest during the first two weeks, and reduce with time.

Advise the woman that:

1. Withdrawal symptoms are usually the highest during the first few days after quitting and will get less as time goes by
2. She can reduce her withdrawal symptoms by using NRT (see "C - Cessation support - Nicotine Replacement Therapy (NRT) in Pregnancy" on page 49)

Weight gain

Many women fear weight gain as a result of quitting smoking.

Research has shown that the average weight gain is around 4-5 kg[71,72]. It should be emphasised that not everyone gains weight (≈15% don't)[72].

The reasons for gaining weight are multiple and include:

1. Reduction in the BMR (Basal Metabolic Rate) – the rate that we burn calories when we are resting
2. Enhanced taste and smell of food – after quitting our taste buds and sense of smell works better and therefore the food smells and tastes better
3. Need to occupy mouth and hands instead of using a cigarette

Mood changes

There is a strong association between smoking and mood disorders such as depression. People who smoke have a higher risk of depression, and people who suffer from depression are more likely to be smokers[73]. Quitting smoking can affect the mood and sometimes lead to actual depression[73].

It is important to explain to patients that a reduction in mood can happen, and over time a lot of cases will subside along with other withdrawal symptoms.

However, it is also important to monitor mood changes, and if severe or persistent to consider treatment.

3. Raise awareness to the patient's personal cues and triggers for smoking

There are a lot of common triggers for a smoke, for example, with a coffee, when bored, when stressed out, and after a meal. Each smoker has their own individual triggers that are the most important or strongest and will probably be the ones she will struggle with when quitting. It's important for the smoker to know what these are and to prepare in advance for how to handle these triggers.

This could be done again through discussion:

"In which situations do you feel like you need a smoke the most? When do you usually smoke?"

Alternatively, this could be done by using a smoking/urges "daily diary". If she is still smoking, ask her to record for one day all the cigarettes she smoked. For each cigarette she should record the time, the trigger/situation, and how strong the urge was from 1 (not strong at all) to 5 (the strongest). If she is trying to quit, she can record the urges she has

throughout the day (time of each urge, the trigger/situation, and how strong it was)

# of cigarette	Time	What was the trigger?	How strong was the urge to smoke it (1-5)
1	06:30	Just woke up	4
2	07:00	With morning coffee	2
3	07:45	The kids were driving me mad, needed a minute to myself outside	3
4			
5			

Ask her to suggest ways to remove certain cues, and/or deal with the triggers:

"What do you think you could do instead of having a smoke in these situations?"

It might be good to suggest that she asks for advice on how to deal with these triggers from other family members she trusts.

Being prepared for these situations helps in the quit attempt.

Discuss with the woman what her triggers are, and what can she do instead of a cigarette in these situations. Emphasize that anticipating an urge to smoke and planning ahead could help overcome the urge. When possible, avoiding known situations that will trigger an urge is recommended, specifically for the first few weeks after quitting.

For example, avoiding going to pubs, avoiding drinking alcohol (which will benefit the baby's health on its own), and substituting coffee for tea. When avoiding is not possible (as with many triggers), a practical plan of what to do when she has an urge to smoke can help deal with it. Discuss this with the woman and support her in coming up with her own plan of dealing with an urge (see below – 3. Help the woman set a plan how to deal with urges to smoke)

If a woman is considering using NRT (see "C - Cessation support - Nicotine Replacement Therapy (NRT) in Pregnancy" on page 49) suggest she uses

oral NRT in anticipation of these triggers, or at least have some on hand, perhaps in her handbag, so she can use as soon as possible if she gets a craving.

An important part of preparing to quit is to start separating triggers from the cigarettes (called "pairings") while the woman is still smoking.

For example, if the trigger is coffee, ask the woman to have the cigarette first, then wait 15 minutes before having the coffee, always in that order as satiation of nicotine seems to be more important than that of caffeine, and it avoids the likelihood of cheating (e.g. making it 10 minutes instead of 15).

If the trigger is driving, ask them in the preparatory phase to not smoke in the car, no matter what. Tell them they can smoke before getting in the car, and after getting out of the car, but for the journey itself, they are to put their cigarettes and lighter in the boot, and if they really want to smoke they have to stop (in a safe place) by the side of the road and have the cigarette there.

4. Help the woman set a plan for how to deal with urges to smoke

Emphasize that most urges last only a few minutes. Sometimes you just have to "ride" them out. Suggest not fighting the urge but more "flowing" with it. You could suggest to the woman to imagine that the urge is like a big wave – she could let it drown her, or **she could imagine herself surfing on the wave (urge), until it settles down.**

One way of dealing with an urge is **STOP – THINK – DO:**

Box 4: STOP-THINK-DO

STOP – what you are doing

THINK – about your reasons for quitting, think of all the days you have managed to stay smoke free

DO – something else!

You can also suggest the use of the **4D's**:

Box 5: The 4D's

Deep Breaths - breathe in and out slowly for a few minutes. Take deep breathes and try counting to ten while inhaling and exhaling. Repeat at least 3 times.

Drink Water – Drink a full cup of water. You could try and drink through a straw that also helps with the urge to put something in the mouth.

Distract – Do something else. For example: If you're sitting with friends, get up and go wash your face with cold water. If you are drinking coffee – throw it away and go outside for a few minutes. If you're upset or mad at someone – take a brisk walk or climb a few stairs fast.

Delay – Remind yourself that this will only last a few minutes… try the other D's.

Many women state that stress is a major barrier to quitting.[11] Breathing exercises can help cope with stressful moments, and should be encouraged.

It is important to proactively demonstrate how to do a relaxing breathing technique and practice this with the woman (see example in box 6).

Box 6: An example of a relaxing breathing technique

Abdominal Breathing Technique

- Sit comfortably with your back straight. Put one hand on your chest and the other on your stomach.
- Breathe in through your nose. The hand on your stomach should rise. The hand on your chest should move very little.
- Exhale through your mouth, pushing out as much air as you can while contracting your abdominal muscles. The hand on your stomach should move in as you exhale, but your other hand should move very little.
- Continue to breathe in through your nose and out through your mouth. Try to inhale enough so that your lower abdomen rises and falls. Count slowly as you exhale.

The goal: Six to 10 deep, slow breaths per minute for 10 minutes

5. Help the woman prepare for quitting

There are three separate levels of preparedness for quitting – personal, social and environmental **(table 3)**.

Table 3: Preparing for a quit date

Personal	Social	Environmental
• Decide on your quit plan (see "Box 7: An example of a quit plan" on page 47) • Decide whether you want to use NRT and if you do, then obtain NRT ahead of time • Prepare different items for mouth and hand activity such as toothpicks, straws, stress ball, rubber bands, carrot sticks to chew on. • Prepare regular gum or lollypops to help with cravings • Have a farewell ceremony from the cigarette – you could throw a party, write a song, bury your cigarettes – anything to acknowledge that this is your last smoke	• Notify all your family and friends that you are quitting • Post a status on Facebook/twitter/ other social media • Ask your friends and family to help you. Ask them not to offer you a cigarette or even a puff • Find a quit buddy, someone who will try and quit together with you, or even just someone that agrees in advance to be there for you whenever you have a craving and need support to talk on the phone • Ask your partner or a family member to quit with you	• Make your home and car smoke-free: • Get rid of all the ashtrays and cigarettes • Take the car to the carwash to get rid of the smell of smoke • Wash clothes/drapes/ furniture covers/sheets in order to get rid of the smell and chemicals from the smoke • Put up a 'smoke-free home/car' sticker in your car and at the entrance of your house • Establish where outside family members and visitors can smoke, this should be as far as possible from the windows and doors (at least 5 meters) • Notify all family members and friends and let them know where they can smoke when they come to visit

6. Help the woman to set a quit date and quit plan

It is important to help the woman to set a quit date, if she is willing to try and quit. It is also important to help her prepare for that date. Research has shown that people who prepare a plan for quitting have higher quitting rates[74,75].

The quit plan is basically an outline of everything already discussed with the patient, that she has decided on. It should include:

- ✓ What her quit date is
- ✓ How she is intending to quit (cold turkey/gradually)
- ✓ If she is intending to use any NRT to aid her, and if so, which type
- ✓ If she is intending to use other forms of support and if so, what it will be
- ✓ What are her triggers or challenges and what can she do to avoid them or deal with them or overcome them
- ✓ How she could reward herself for being smoke free. An example of a quit plan is detailed on the next page ("Box 7: An example of a quit plan" on page 47).

Box 7: An example of a quit plan

My Quit Plan

1. My quit date: __/__/____

2. My quit method:

- ☐ Cold turkey
- ☐ Reducing gradually
- ☑ With Nicotine Replacement Therapy. If so, with:
  - ○ Nicotine gum
  - ○ Nicotine lozenge
  - ○ Nicotine inhaler
  - ○ Nicotine spray
  - ◉ Nicotine patch

3. Other support I will use:

- ☐ Local quit group
- ☑ Quitline 137848
- ☑ Quit for You-Quit for Two app
- ☐ Quit coach website
- ☐ Quit Txt program
- ☐ Other: _____

4. My triggers and challenges and how I will deal with them

My triggers and challenges	**My solutions**
Drinking coffee	Avoid coffee for now, try drinking tea
When I'm stressed	Try deep breaths
Everyone around me is a smoker	Tell them I am trying to quit and ask for their help.
	Ask them not to smoke around me
	Make my home and car smoke free

5. My rewards for being smoke-free:

Time smoke free	**Reward**
1 week	Go out with friends
2 weeks	New shoes
1 month	A fun day with my partner

C - Cessation support - Nicotine Replacement Therapy (NRT) in Pregnancy

Main points:

1. **The level of nicotine absorbed from NRT is lower and slower compared to a cigarette**
2. **NRT only has nicotine in it and none of the other chemicals in a cigarette**
3. **Therefore, NRT is always safer than smoking**
4. **Addressing negative views and myths regarding NRT use in pregnancy is crucial to supporting the woman and ensuring correct and effective use**
5. **Higher doses of NRT are needed in pregnancy due to the mother's faster metabolism**
6. **Women should use as much NRT as they need to overcome withdrawal symptoms and urges to smoke**

Nicotine is the primary chemical causing the addiction to smoking, but most of the harmful effects of smoking are caused by the other 7000 chemicals that are present in cigarette smoke, such as tar and carbon monoxide[47,67,76].

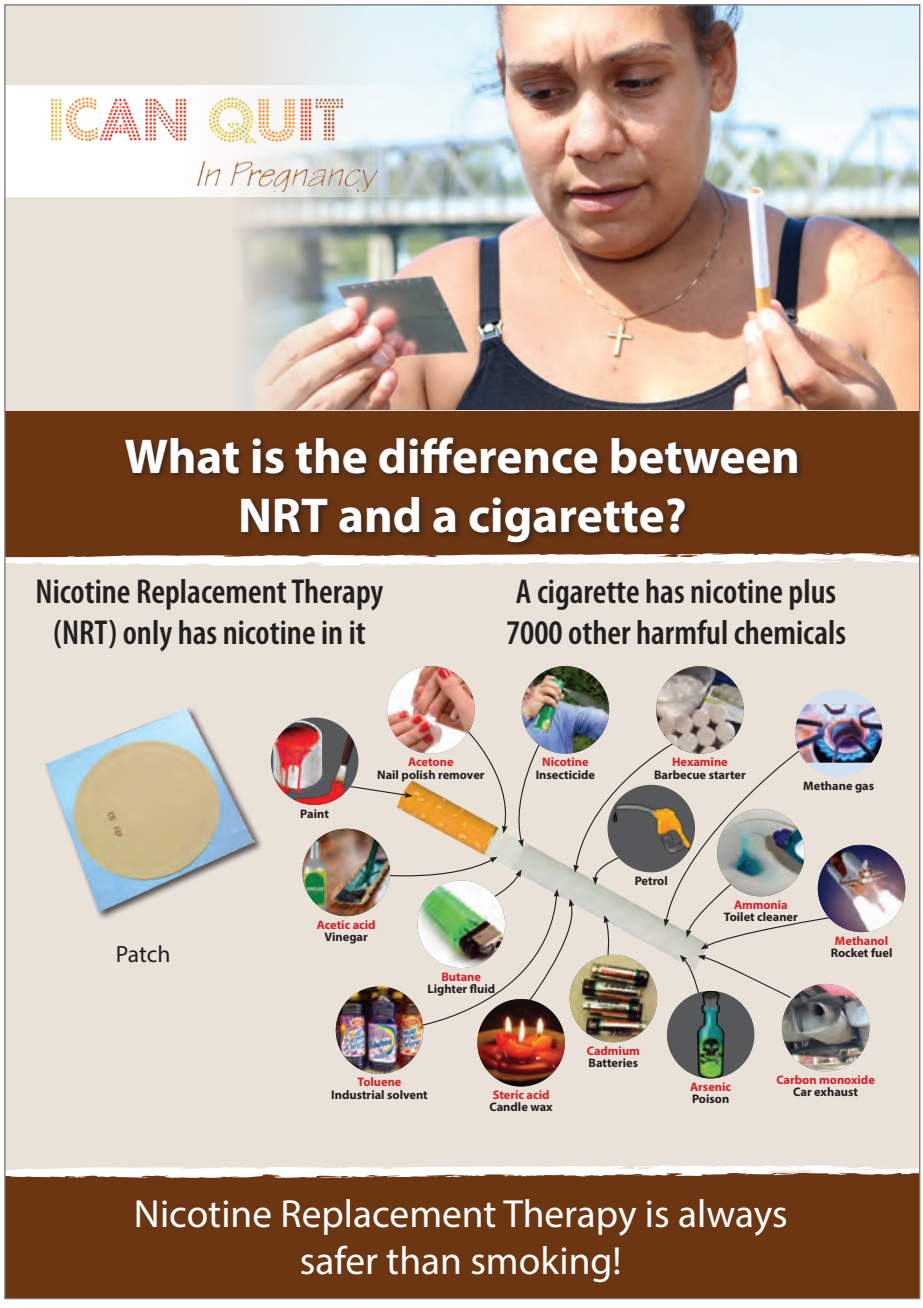
Nicotine in itself can be harmful to the foetus and plays a role in the increased risk for foetal growth retardation, preterm birth, stillbirth, cognitive impairment and impaired lung function[47,77].

Therefore, it is thought that pregnant women should first try to quit without NRT (or other medications)[1,38,51,67,78]. Bear in mind that some women have already tried to quit or reduce and have been unsuccessful; this demonstrates that they have already tried an unaided attempt, and can now be given NRT.

Nonetheless, experts around the world agree that NRT is safer than smoking for the mother and the foetus[38,51,77,78]. This is due to two main factors[67] :

1. NRT only supplies nicotine, while the cigarette exposes the woman and her foetus to nicotine plus an additional 7000 toxic chemicals, some of which are proven harmful toxins and carcinogens (Fig 1).
2. The level of nicotine absorbed from NRT is almost always lower than the level absorbed from the cigarette. None of the available forms of NRT (transdermal patch, gum, inhalator, lozenge, and mouth spray) offer the same rapid nicotine delivery of a cigarette. This is also one of the main reasons why NRT is not as addictive as cigarettes.

Fig 1: Harmful chemicals found in a cigarette



It is important to discuss the risks versus benefits of the use of NRT in pregnancy and explain these two factors above.

Emphasize to the woman that with NRT she is receiving less nicotine than from a cigarette, and not receiving any of the other harmful chemicals found in cigarette smoke (See table 4)

It should also be noted that there have been several studies involving thousands of women using NRT that have not shown any harmful effect on the mother's and baby's outcomes [79,80]. The latest Cochrane review did not find any differences between women receiving NRT and control groups in rates of miscarriage, stillbirth, premature birth, birthweight, low birthweight, admission to neonatal intensive care, caesarean section, congenital abnormalities or neonatal death[79].

Furthermore, in one study which followed up on the babies' outcomes two years after birth, the use of NRT during pregnancy (even if the mother did not quit) improved the babies' developmental outcomes[81].

Is NRT effective for smoking cessation?

The latest Cochrane review on pharmacotherapy for smoking cessation in pregnant women included 8 trials of NRT enrolling 2199 patients[79]. This analysis found that, compared to placebo and non-placebo controls, **use of NRT increased smoking cessation rates by 40%** (RR 1.41, 95% CI 1.03-1.93). It should be noted that an analysis of only placebo controlled studies resulted in a lower cessation rate (RR 1.28, 95% CI 0.99-1.66)[79].

In a non-randomised clinical trial of 3500 women in the UK, combination treatment (patch + oral NRT) doubled the quit rate at four weeks compared to no medication, or to using only one form of NRT (OR=1.93)[80].

Table 4: Risk versus Benefit of using NRT in pregnancy

RISK	BENEFIT
#1 Nicotine has been linked to harmful effects on the baby: • Low birth weight • Preterm birth • Stillbirth • Cognitive impairment • Impaired lung development	**#1 NRT has only nicotine in it, and none of the other 7000 chemicals** also found in a cigarette (300 known to be toxic and harmful, 52 known to be carcinogenic). You and your baby are not exposed to all of these other chemicals.
BUT Studies with **nicotine from NRT** in pregnant women (over 2000 women) have not shown NRT to cause harm to the women or the baby.	**#2 If you use NRT, you are receiving less nicotine than when you smoke.** Nicotine from NRT is absorbed not as efficiently or quickly as from a cigarette.
	#3 NRT will increase your chances of quitting and staying quit by 40%. Every day you don't smoke improves the health of you and your baby. There is nothing better for you and your baby's health than to quit smoking.
	#4 Using NRT may help your baby's health even if you don't quit smoking This is probably because of less overall exposure to all the other chemicals in smoke (see #1).

There are several forms of NRT available in Australia[67] (**Table 6**):

1. Oral forms:
    i. Gum
    ii. Inhalator/inhaler
    iii. Lozenge (also mini-lozenge)
    iv. Oral spray
2. Transdermal patches:
    1. 16-hour patches
    ii. 24-hour patches

In Australia, NRT is available over the counter in pharmacies, and some forms are available in supermarkets. Only patches are subsidised on the PBS at present[82]. Aboriginal or Torres Strait Islander qualify for PBS authority listing that provides up to two courses per year of nicotine patches, each to a maximum of 12 weeks[83]. Participation in a support and counselling program is recommended but not mandatory for Aboriginal patients. Access to nicotine patches can be facilitated through the Closing the Gap PBS co-payment measure[67]. A person registered for Close the Gap may not have to pay the script charge.

Dosage of NRT

Because of the potential harmful effects of nicotine, it is advisable to always use the lowest possible dose in pregnancy ***that would be effective.*** This does not mean being overcautious and not prescribing sufficient NRT, as we know that sometimes pregnant women need more NRT than non-pregnant due to their higher metabolism (see below). It is recommended to start with oral NRT. If the pregnant woman is experiencing nausea or vomiting, a patch may be more appropriate to start with[77].

If the woman is unable to achieve abstinence with the oral form alone, a patch may be used, but it should be removed overnight (16 hour use). If needed, combination pharmacotherapy can be used (patch + oral NRT)[1,67,80]. We recommend the use of the 16-hour patches in case the woman forgets to take the patch off overnight.

Refer to the NRT treatment algorithm for further details see "Fig 2: NRT treatment algorithm" on page 61.

Nicotine metabolism in pregnancy is much higher compared to non-pregnant woman. The clearance of nicotine is much faster in pregnancy (60% more)[42]. Therefore, it is expected that pregnant smoking women might need a higher dose of NRT (compared to a non-pregnant woman who has the same level of nicotine dependence)[1,18,42,67].

Due to the higher metabolism in pregnancy, if a woman is smoking ≥10 cig a day (or smoked this amount before finding out she was pregnant), and she is over 45 kg, it is advised to start with the higher dose of the Oral NRT (such as the 4 mg gum, 4 mg lozenge, or 4 mg mini-lozenge). If a patch is needed, start with the 25 mg/16 hour patch[1,84].

If the woman is unable to quit with the initial dosage provided to her, or if she quit but is still experiencing significant urges to smoke (measured by the Strength of Urges Score – SUTS ≥3; and/or the Frequency of Urges Score – FUTS ≥3), **dosage can be increased as needed.** (fig.2)

Patients generally do not use enough of the oral forms of NRT, and generally discontinue the medication too early[79,85]. Adherence to NRT was one of the key issues thought to contribute to low NRT effectiveness in the Cochrane review[79]. Health providers need to be very pro-active and ensure that the woman is receiving enough nicotine to deal with her cravings (Box 8), and take NRT for the 'whole course' of 12-weeks.

Explain in a simple way that her brain has receptors (or simply "specific areas") that the nicotine binds to and releases "feel-good chemicals" (i.e. Dopamine). Nicotine from a cigarette reaches the brain very fast (≈10-15 seconds) and this makes her feel good about smoking, and causes the addiction. Nicotine from NRT reaches the brain much slower (only after a few minutes) and therefore does not cause the same reaction of feeling good and the addiction. Quitting smoking causes these receptors to lower their amount and their ability to react to nicotine (i.e. down-regulation of nicotine receptors). This process takes time (a few weeks) and it is therefore important to continue the NRT for at least 8 weeks (and preferably 12 weeks)

Remember to explain that a whole course is needed to reduce the addiction levels, in a similar way to most people knowing these days that a whole course of antibiotics is needed if you have an infection warranting their use. If a woman does not receive enough nicotine this can lead to frustration, loss of motivation, discontinuation of the medication and, of course, to an unsuccessful quit attempt. In fact, the main reason for the low efficacy of clinical trials involving NRT in pregnancy is thought to be the fact that due to

the higher metabolism, pregnant woman need higher doses than used in the trials[79].

Box 8: Using NRT to deal with cravings

Women should be encouraged to use AS MUCH AS NEEDED to deal with cravings:

- **Encourage use of oral NRT in anticipation of cravings.** If a woman knows she is going to be in a situation where she would want to smoke (for example, family gathering with many smokers around) **encourage using the NRT 15-30 minutes before** this situation.
- **Encourage use of NRT regularly throughout the day to substitute for cigarettes.** If for example a woman smokes 10 cigarettes per day (an average of 1 cigarette per 1 ½ hours) **suggest she uses a piece of NRT every hour regularly** (even if she is not experiencing a strong craving at that time).

Women's views about NRT[86,87]

Furthermore, to promote adherence to NRT, health providers need to be pro-active about any myths or disinformation patients might have, such as that NRT is not safe, that it is addictive, or that it is not effective[85]. **Ask the patient what she thinks about NRT and if she has any concerns about using it.** She may know someone who used it who had problems, so explain that everyone is different, and this does not mean she cannot safely try it.

It is important to understand women's views on NRT in general[85], and specifically in regard to using them during pregnancy[86,87]. Addressing any negative views, or myths, could significantly help more pregnant women try NRT and use appropriate dosage and length of treatment (Table 5).

Table 5: Views and myths regarding NRT and suggested responses[85-87]

Views and Myths regarding NRT use during pregnancy	Suggested response and things to discuss
"NRT is not safe in pregnancy" "NRT can be harmful for the baby"	NRT is always safer than smoking. Nicotine levels from NRT are much lower than smoking. Nicotine does not cause cancer, lung disease or heart attacks. It is the other 7000 chemicals in tobacco smoke that cause most of the harmful health effects.
"NRT is addictive"	Cigarettes are far more addictive than NRT. You get less nicotine from NRT and it is delivered more slowly so the risk of becoming addicted is very small. It is always better for your health to use NRT than to smoke.
"It has side-effects" "Oral NRT doesn't taste good"	Most side effects are minor and settle with time. Make sure to explain the potential side effects to the patient, including specifically the possibility of nausea, and the taste and texture. Is the product being used correctly? Chew gum more slowly and try to avoid excessive swallowing of oral products. Remember to remove the patch at bedtime and rotate patch sites.
"I should be able to quit on my own" "Willpower should be enough"	Smoking is an addiction not a habit, or a lifestyle choice. Some people are more addicted than others because of their genetic makeup. Your body works faster in pregnancy making it harder to quit. It is not a question of willpower. Even if you use NRT it does not mean you are taking a short-cut, you can still be proud of quitting this way.

Views and Myths regarding NRT use during pregnancy	Suggested response and things to discuss
"NRT just doesn't work"	NRT is more effective when higher doses are used, especially in pregnancy because of the faster metabolism. Have more frequent doses of oral NRT, or add a patch. Do not drink or eat for 15 minutes before or while using so your mouth can absorb the nicotine. It is important to be followed up in case we need to adjust your dose. Suggest additional methods for support such as the Quitline.

Reproduced with permission from The Royal Australian College of General Practitioners from Mendelsohn C. Optimising nicotine replacement therapy in clinical practice. Aust Fam Physician 2013;42(5):305–09. Available at www.racgp.org.au/afp/2013/may/nicotine-replacement-therapy.

Length of treatment

It is recommended to continue treatment for at least 12 weeks, to allow for the down-regulation of the nicotine receptors and behavioural changes to be adopted.

Tapering of dosage is optional, although studies have not proven that this is more effective[88,89]. If it is decided to taper the dose, it is best to start lowering the initial dosage **only after 8 weeks**, and **only if the woman reports an improvement in her SUTS score**.

If needed, NRT treatment can be extended for more than 12 weeks. Studies in the general population did not show any negative health consequences from longer duration of NRT use[67,90]. **Remember – using NRT is always better than smoking.**

It is a common pattern for patients to discontinue the use of NRT before the recommended 12 weeks, usually about the 4-week point[79]. **Emphasize that quitting smoking is a process that takes time**, and even if she might not feel strong cravings anymore, **it is important to finish the course of the medication**. Relapse rates are highest during the first 3 months and that is one of the reasons she should continue to use NRT throughout the 12 weeks.

It is crucial to explain in detail the correct method for using oral NRT (see table 6), as incorrect use is common and often leads to early discontinuation[85].

Also explain that the products do not taste that nice: they are peppery since nicotine is the same plant group as the chilli family; she should regard the oral forms as 'medicine' and not something she would enjoy sucking or chewing. Many people get used to the taste in time and find it less unpleasant.

Ask the patient to explain back to you what she heard you say, and consider doing an actual demonstration to ensure full understanding.

Address any side-effects she might have from NRT use. Consider changing to a different form of NRT if the patient is experiencing side-effects that disturb them. Emphasize that most side-effects settle with time[85].

See Box 9 for a checklist for prescribing NRT to pregnant women
(Adapted from Mendelsohn, C. (2013). "Optimising nicotine replacement therapy in clinical practice." Australian Family Physician 42(5): 305-309[85])

Contraindications for NRT

As a rule, there are no complete contraindications for NRT. Since nicotine can increase blood pressure and heart rate, it should be used with caution in patients with:[88]

- **unstable** cardiovascular conditions, such as a recent (less than two weeks) heart attack, serious arrhythmias, or serious or worsening angina pectoris [88]
- **uncontrolled** hyperthyroidism

Specific precautions for each form of NRT are stated in their specific section in **table 6**.

Box 9: Checklist for prescribing NRT for pregnant woman

- ❑ Enquire what are her views (positive and negative) on NRT and proactively address these
- ❑ Explain why you think she should consider using NRT
- ❑ Emphasise that nicotine is safer than smoking, effective and has a low risk of addiction (Refer to the Risk vs Benefit analysis)
- ❑ Start with the higher dose of the Oral NRT (such as the 4 mg gum, 4 mg lozenge, or 4 mg mini-lozenge).
- ❑ If a patch is needed, start with the 25 mg/16 hour patch
- ❑ Give detailed instructions on the correct use of oral forms of NRT
- ❑ Emphasise the importance of using an adequate dose of oral forms – number of pieces, puffs or sprays per day. If in doubt, use more.
- ❑ Encourage use as much as needed to deal with cravings
- ❑ Discuss possible side effects
- ❑ Encourage a full course of treatment – at least 12 weeks

(Adapted from Mendelsohn, C. (2013). "Optimising nicotine replacement therapy in clinical practice." Australian Family Physician 42(5): 305-309 [70])

Fig 2: NRT treatment algorithm

Table 6: NRT

Product	Lozenges	Gum	Inhaler	Oral spray	Patches
Dosage	4mg	4mg	15 mg	1 mg	25mg 16hr patch
Method of Use	Place one piece in mouth and allow to dissolve slowly (20-30 minutes; for mini-lozenge 10 minutes). You might feel a warm tingling sensation. Rotate to different areas of the month to avoid irritation.	Chew a piece of gum slowly. When you feel a tingling sensation, park the gum at the side of the mouth. Resume chewing and parking until no more tingling occurs (approx. 30 minutes). Park in different areas of the month to avoid irritation.	Puff the inhaler continuously for 20 minutes. Inhale lightly into back of throat in short breaths. 1 cartridge provides 2 x 20 min puff sessions with 40 mins in between, over a 2 hour period	Press to release one spray into the side of the cheek or under the tongue.	Apply the patch to the skin. If needed, you can use adhesive tape to help the patch stay on (for example if sweating or during shower). Remove the patch before going to sleep Rotate the skin area each day to avoid skin irritation.

Product	Lozenges	Gum	Inhaler	Oral spray	Patches
Regime	Max 15 lozenges/day	Max 15 pieces/ day	1 cartridge per 1-2 hours. Maximum daily consumption is 6 cartridges.	1-2 sprays per hr, and up to 4 max per hr. Maximum daily 64 sprays	Prescribe if oral NRT alone is not achieving abstinence; and/ or nausea/vomiting prevents oral NRT use. Max 1 patch/day.
Advantages	Discreet, easy to adjust dose, helps prevent over-eating (occupies mouth), might delay weight gain,	Easy to adjust dose, helps prevent over-eating (occupies mouth), might delay weight gain	Keeps hands busy, hand to mouth action, fast acting	Easy to adjust dose, fast acting and good for break-through cravings that can't be anticipated	Discreet, easy to use, gives steady level of nicotine to avoid cravings
Product	**Lozenges**	**Gum**	**Inhaler**	**Oral spray**	**Patches**
Side Effects	Nausea, hiccups, cough, flatulence, heartburn, throat and mouth irritation	Mouth/jaw soreness, hiccups, heartburn, throat and mouth irritation	Rhinitis, hiccups, cough, heartburn, throat and mouth irritation	Hiccups, throat and mouth irritation	skin irritation – itching, erythema. Headache

Product	Lozenges	Gum	Inhaler	Oral spray	Patches
Precautions	None	Dentures, temporal-mandibular joint problems	Broncho-spastic disease (such as asthma)	None	Diffuse dermatologic conditions such as psoriasis, atopic dermatitis and diffuse eczema
Notes:	Need correct technique for use. Allow to dissolve in mouth, try not to produce too much saliva by sucking hard. No food or beverages 15 minutes prior to use and during. Do not chew or swallow.	Need correct technique for use. Do not use liquorice gum in pregnancy. No food or beverages 15 minutes prior to use and during. Gum is harder and tastes not as good as regular gum.	Need correct technique for use. Prime pump at beginning of day to avoid "spurts". Do not inhale into lungs like a cigarette. No food or beverages 15 minutes prior to use and during.	Need correct technique for use. Avoid the lips. Do not spray directly into the throat. Do not inhale while spraying. Don't swallow for a few seconds after spraying. Do not eat or drink for 15 minutes after spraying.	If patch not achieving abstinence, combination therapy is recommended under health professional advice

Adapted from *NHS Stop* Smoking in Pregnancy Treatment Guide – smokefree.nhs.uk; RACPG guidelines: Supporting smoking cessation: A guide for health professionals, 2014[67]; Prochaska, J.J. and N.L. Benowitz, The Past, Present, and Future of Nicotine Addiction Therapy. Annu Rev Med, 2016 [88] by Dr Yael Bar Zeev and Dr Gillian Gould

D - Discuss psychosocial context of smoking

Main points:

1. **Every smoker is different**
2. **Understand the woman's personal challenges to quitting**
3. **Discuss with the woman her personal challenges and find ways she thinks could help her overcome them**
4. **Remember – smoking is an addiction, not a habit – don't be judgmental, be supportive**

As outlined in the background section on page 11, the psychosocial context of smoking and quitting are important considerations in providing best practice to pregnant smokers[11]. Each pregnant woman's context and unique circumstances relating to smoking will differ. Some of the challenges and barriers to Aboriginal women quitting relate to the social determinants of health, such as education and income[91-95]. Others relate more to pregnancy such as parity (multiparous women are more likely to smoke) and age (young women are also more likely to smoke). Other factors relate to social norms of smoking (partners and family), and access to services and treatment[91,93].

The challenges related to smoking cessation should be addressed on an individual basis, but not necessarily all at the first visit. Some of these may emerge on follow up.

"What do you think will be some of the challenges for you at home with trying to quit smoking?"

Identify these challenges as part of 'making a quit plan' and help the client think through how she will tackle these challenges (see also "C - Cessation support – Behaviour Change Techniques" on page 37).

Assessing relevant psychosocial contexts can include:

Family and partner smoking – it is naturally hard to quit if everyone else or even one key person is smoking at home. When a pregnant mum is exposed to the smell of tobacco smoke, or witnessing others smoking, it can trigger her own cravings to smoke. Additionally women have reported feeling isolated if they have to keep away from their partner, friends or family when they are smoking, so as not to trigger their own cravings. Pregnancy is often a time when women need more (rather than less) support.

Smoking in the home (indoor smoking) – it is better for everyone to keep the indoor environment smoke free, and this also helps smokers to quit even if others are still smoking[96]. If others are smoking around her, a woman may not feel it worthwhile to quit herself.

Second-hand smoke and third-hand smoke does have harmful effects so also encourage smoke-free home and cars. To promote this, use the notion of preparing the environment for the baby as an additional rationale.

Emphasize to the woman that it is worthwhile to quit smoking, even if everyone around her continues to smoke. The most harmful effects to her health and the baby's health come from her own smoking.

Suggest that her partner and other family members visit the medical service to address their smoking. They could come with the patient, or separately – whatever she and they prefer.

It is important to address what could be done to lower the patient's exposure to other people smoking, both as a way to lower her exposure to second-hand smoke (and its harmful effects), and as a way to prevent and reduce cravings.

Furthermore, it has been proven that smoking outdoors (i.e. restricting smoking in the home and car) helps people be successful at quitting. Emphasize that a complete ban (no smoking at any time, not even when the woman or children are away) is better than a partial ban (smoking only on the veranda, or only when non-smokers are not around). Also highlight that if a complete ban is used, the smoking area needs to be as far as possible from all doors and windows, preferably at least 5 meters (**see Box 10**).

Be aware of cultural norms for Indigenous smokers. Many smokers will not feel comfortable to ask an elder not to smoke in the house and this will be further compounded if they live with older in-laws whose house it is.

Sometimes it is more appropriate to have a few "smoke-busters" stickers around the place. People trying to quit can then just point to the stickers and say "Hey Auntie…." or "Excuse me Uncle" without having to say the words "you can't smoke here"

Box 10: Partner and family members support

What could her partner or other family members do to support her quit attempt?

- ✓ The best thing would be to also for the partner/family to quit smoking. They could receive support and medication through the medical service.
- ✓ If they don't want to quit at the moment:
  - ❍ Don't smoke in the house or the car. The best is to make the house and car a 'smoke-free zone' always (even when the woman isn't present).
  - ❍ Don't leave any smoking products lying around in the house like cigarettes, tobacco pouches, ashtrays, and lighters.
  - ❍ Don't offer the woman a smoke, even when she is stressed, or saying that she wants a smoke. Instead talk her through the craving, and distract her.
  - ❍ Understand that the woman might be more irritable and anxious in the next few weeks. Understand and accept this, and be supportive.
  - ❍ Congratulate her for every smoke free day she achieves. Think of ways to reward her, for example buying her a small gift after a week smoke-free.
  - ❍ It is better not to nag at the person for smoking, but be supportive in a positive way.

Lack of support for quitting – do not assume that all family members will be supportive of the pregnant mum quitting. Our research shows that those close to her can sometimes undermine quitting attempts or challenge a woman's ability to quit[76]. If this is the case, work may need to be done to help the partner/family rally around her for support, or for the woman to seek support from her extended family (e.g. an auntie) or a friend outside of the family. In general, the support that women report receiving from family is better than what they report receiving from health professionals[28].

Ask specifically about family and partner smoking and their attitudes:

"What do you believe your family and partner think about your smoking in pregnancy? Do you think they will support you if you decide to quit?"

"Is there anyone else you need to speak to before making a decision about quitting?"

"Who will be the best people to support you among your family and friends?"

Stressful life circumstances – these need consideration, and their impact on quitting should be discussed.

An assessment may need to be made about whether the woman is suffering from depression and anxiety, and is facing serious life circumstances such as domestic violence, financial worries, housing issues, or homelessness. **If this is the case, appropriate referral options need to be considered, along with advocacy if required.**

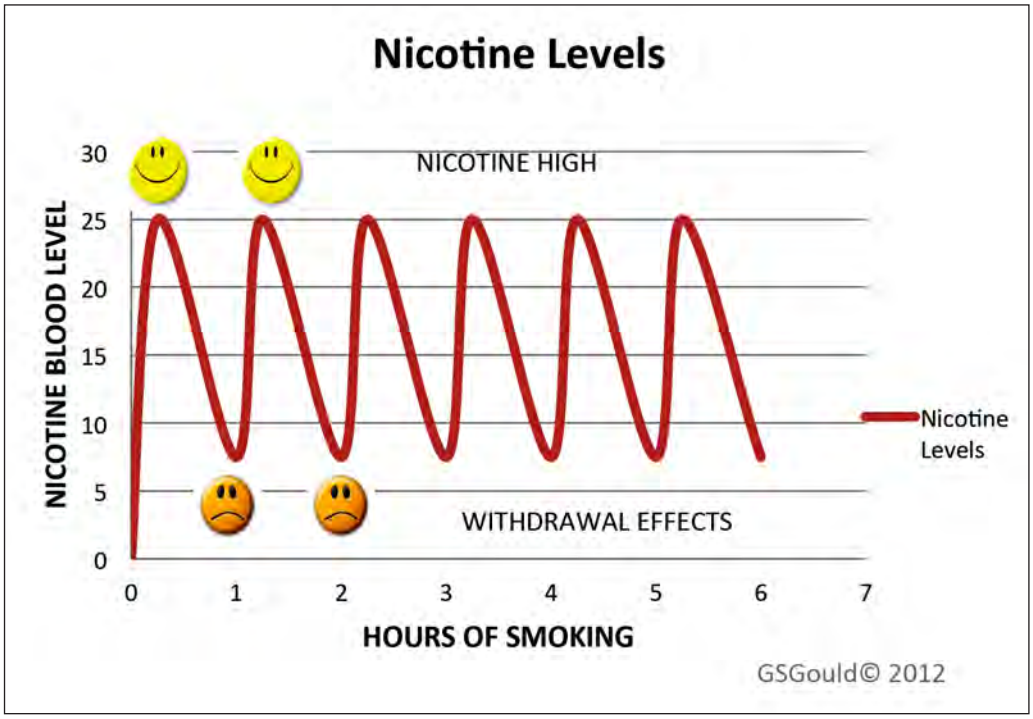
As time goes on, those who quit smoking generally become less stressed, depressed or anxious than those who continue to smoke[97-99]. It might be helpful to explain the link between quitting or cutting down, withdrawal effects, and the symptoms of 'stress'.

Explaining the link between stress symptoms and nicotine withdrawal

The following figure can be useful to explain about withdrawal symptoms from smoking, and to overlap it with symptoms commonly thought of as 'stress' or anxiety. Also, those who suffer from anxiety-related illnesses can be more sensitive to nicotine withdrawal.

Figure 3 shows in a simplistic way how nicotine levels go up with each cigarette smoked, and then go down in between cigarettes. This has a yo-yo effect all day on the feel-good chemicals (dopamine) and a smoker cycles in and out of withdrawal all day. These symptoms of withdrawal (such as irritability, annoyance, anxiety, and cravings for nicotine) are often perceived as 'stress'.

Fig 3: Nicotine levels, withdrawal and stress



Follow Up and Return Visits

Main points:

1. **Always follow up – this could be done by a different staff member**
2. **Follow up as soon as possible during a quit attempt**
3. **Review her SUTS, FUTS and CO and assess a need to adjust treatment and dosage ("Fig 2: NRT treatment algorithm" on page 61)**
4. **Every small step is a win – celebrate the small wins!**

Following up is an important part of smoking cessation care, but few clinicians 'always' follow up in this way. In a recent Australian study of 378 GPs and Obstetricians, only 11% 'always' followed up with women within two weeks[31]. The first two weeks of a quit attempt are crucial for success. This is the most challenging period for the smoker, as it is likely that relapse risks are at a maximum in this time frame[100].

In pregnancy, timing is more critical, as it is best for mother and foetus if quitting occurs as soon as possible in pregnancy[64]. By not arranging the follow up visits, it may send the signal to a woman that quitting is not important. Our own research shows women feel that if they were offered more intensive support they would have the ability to address their smoking and quit in pregnancy.

> *"The aids have got to be there, the support, more hands-on support from professionals would have been a lot better than say we'll give you this, we'll have someone call you, we'll provide all this…we need someone else to come in and have the one on one, the face to face and make sure they're going to be there to support them properly…" [Recently pregnant smoker aged 34 years]*[101]

Arrange follow-up within a few days if the client is having any sort of trial at quitting, or maximum of a week (**Box 11**). Ideally, someone would call them on Day 2 to see how Day 1 went. This could be with another health professional at the service if the GP is fully booked.

Box 11: Follow up

- **Ideally, see the patient 3-5 days after the first visit, then weekly, until the quit attempt is going smoothly.** Visits can be reduced to fortnightly, once the quit attempt is stabilised.
- **Encourage the pregnant smoker to return no matter how successful or unsuccessful the quit attempts have been.**
- **It's important to give positive feedback on any success the woman has managed.**
- **Check SUTS, FUTS, and CO measurement**
- **Review use of NRT:**
  - ❑ **correct method of usage**
  - ❑ **Side-effects?**
  - ❑ **Need for increasing dosage or adding a Patch?**
- **Review support at home. Suggest again using other forms of support (see "Additional Support" on page 77)**
- **Check if woman on any other medications that may be affected by quitting (see appendix 1)**

At each visit:

Check SUTS, FUTS and CO readings.

If the woman has been able to quit congratulate her, highlight the amount of time that has passed and the health benefits she has already provided for herself and the baby.

For example:

"That's great that you have succeeded quitting for XX days, well done! I know it's not easy, and you should feel proud of yourself. You and your baby are already breathing better and getting more oxygen"

Ask her what she did to help with cravings. Ask her if there are times she still finds it hard to cope and what she is doing at these times. Suggest exploring other strategies to deal with cravings.

If she is using NRT, review how she is using it, how much, and how often. Make sure she is using it in the correct way, and frequently enough. If the woman is still having many cravings, or very strong cravings, review the need to increase the dose or add a patch to any oral NRT she is using – see "Fig 2: NRT treatment algorithm" on page 61.

If the woman hasn't been able to quit, congratulate her on what she has managed to achieve, and ask what she thinks she could try differently to help her quit.

For example:

"I know it's hard to quit, and it's excellent that you are trying. It's great that you managed not to smoke for XX hours/days. What made you smoke the first cigarette/puff? What do you think you could do differently now to try again?"

If she hasn't been using NRT, suggest she try stopping smoking with NRT (see "C - Cessation support - Nicotine Replacement Therapy (NRT) in Pregnancy" on page 49). If she has, review what she is using, and how she has been using it, and how much. Make sure she is using it in the correct way, and enough times. Inquire about side effects. Review the need to increase the dose or add a patch to any intermittent NRT – see "Fig 2: NRT treatment algorithm" on page 61.

Support should be offered for at least 12 weeks, immediately pre-partum, and also post-partum.

Review support levels, and suggest again using also other forms of support such as the Quit-line. See "Additional Support" on page 77 for more detail.

Review if the woman is on any medications that might be affected by quitting (or reducing) smoking (see "Appendix 1: Interaction between Smoking and other medications" on page 83)[67]. Smoking increases the metabolism of certain medications primarily due to increased enzyme activity in the liver. When a person reduces the amount they smoke or quit, these enzymes return to their normal activity and this may result in increased levels of medications and a need to reduce dosage. There are no specific guidelines for each medication but more a general rule to review side effects and monitor drug levels (when available) and considering reducing the dosage as needed. Note that this interaction is not related to NRT but is a direct link between smoking and liver enzyme activity[67].

Relapse prevention

Main points:

1. **Relapse is the norm! Remember not to be judgmental or show disappointment**
2. **Discuss with the woman the advantages of staying smoke-free after her pregnancy, both for her and for her family**
3. **Review with her 'dangerous situations' that might lead to a lapse and make a plan on how to deal with them**
4. **Emphasise to continue using NRT in case of a lapse, so it doesn't become a full relapse back to her usual smoking**
5. **High risk times are just after the birth (as a reward or a relief) and when finishing breast-feeding – even one smoke at these times can lead to relapse**

Many women who stop smoking in pregnancy relapse shortly after birth[102-104]. Relapse rates range from 47%-63% six months after birth[103]. In a specific study with Aboriginal pregnant women from NT, 35% of pregnant women who were non-smokers at the end of their pregnancy reported smoking by 7 months post-partum[104].

Therefore, it is crucial to discuss with the woman closer to the birth (e.g. at 36 week visit) and at the first post-partum visit (by 4-6 weeks post-partum) the importance of staying smoke-free. Some women may not intend to stay quit after birth, others may intend to but find they lapse or relapse[102,105]. Just after the birth can be a risky time, even before leaving hospital. Women should be warned they may feel like 'just one' as a reward, but this can lead to relapse. Stopping breastfeeding can be another risk for relapsing[106].

There is very little evidence available about relapse prevention in pregnancy, and none in Indigenous women[107-110]. Only one study has shown a positive effect in the general population, and this was from educational materials provided throughout the pregnancy[110]. In the absence of evidence, we advise a pragmatic approach to raise awareness of the risk of relapse, and encourage a woman to plan ahead for a smoke-free post-partum period, emphasizing the positive benefits to her and her baby if she stays quit.

Aim to start building a relationship and open communication with the woman as soon as possible in pregnancy. As time goes on, start to raise the issue of potential relapse after she gives birth (**Box 12**).

Box 12: Relapse prevention

- ✓ Emphasize to her all the work she's done and the effort she put it and her success at quitting.
- ✓ Ask her what she thinks would be the health benefits to her and her baby if she can avoid smoking again post-partum.
- ✓ Explain that even one puff of a cigarette can trigger back the addiction to nicotine and she should avoid even one little puff.
- ✓ If she has lapsed, this is not a failure! This is normal. Emphasize that quitting smoking is a process that often takes time and repeat efforts.
- ✓ Emphasize not to stop the NRT use if a lapse occurs.
- ✓ Review with the woman what can be done differently now

It is important to understand that lapses are common in the process of quitting, and it is equally important to emphasize to the woman that if she has lapsed (smoked a puff, or one whole cigarette), it doesn't mean that she failed.

It just means she needs to find a better strategy to deal with the craving or situation that led to that lapse.

Emphasize that if she is using NRT, she should **not stop the NRT in case of a lapse.** Stopping the NRT will increase the chance that the lapse will evolve into a relapse (going back to smoking as usual).

Review with her what she could do differently the next time.

"I know it's hard. Many women who try quitting need to try a few times before they remain completely smoke free for good. This doesn't mean you can't do it. It just means we have to try again and try something differently this time. What helped you to deal with this situation in the past? What do you think you could do next time that might help?"

Discuss different challenges that might specifically arise after the birth (such as needing a minute to herself) that could trigger a lapse.

Ask the woman to make a list of "dangerous situations" that might trigger strong cravings and a lapse and write down different ways she could deal with these situations.

For example:

Dangerous Situations	Level of danger (1-10)	How am I going to deal with it?
Being with family and friends who smoke	8	Ask them not to smoke next to me, have an oral form of NRT with me.
After a fight with my partner	9	Breathing slowly and deeply for a few minutes, splashing water on my face, talking to a good friend on the phone.
When drinking alcohol	6	Ideally women when pregnant should not drink alcohol. Try to separate your drinking from smoking, and gradually cut down the alcohol, or avoid other drinkers.
When I need time to myself	4	Listening to my favourite music. Going for a walk.

Emphasise that the woman can continue to use the NRT for as long as she needs it. It is always better to use NRT than to smoke.

Rationalise that it is safe to breast-feed while using NRT and it is much better for the baby's health than breast-feeding while smoking. Explain to the woman that she can time the use of oral NRT to after the breastfeed in order to reduce the amount of nicotine that is absorbed.

Additional Support

Main points:

1. **Offer additional support to all women, at each visit**
2. **Discuss the different options and help the woman make a choice what suits her**
3. **The more support she gets, the better her chances of staying smoke-free**

Many women quit smoking alone, but most women will require help and support. Some women may quit just with your help and support, some may need the addition of NRT (see "C - Cessation support - Nicotine Replacement Therapy (NRT) in Pregnancy" on page 49) and some may need additional support from other sources.

"Quitting smoking is a process that is hard to do alone. Getting support and help from different places and people can increase your chances to become smoke-free."

Describe to the woman the different ways she could get additional support:

"There are many different ways to get more support. You know what is best for yourself and your baby, and which way suits you. It is your decision."

Box 13: Additional support

Emphasise that contacting another source of support is her choice:

- ✓ She doesn't have to give her name
- ✓ She doesn't have to commit to anything
- ✓ She doesn't have to quit
- ✓ She could use any (or all) of the sources just for getting more information, without any obligation.
- ✓ They are all FREE!

It is important to suggest and offer a referral to other sources of support **to all women**.

Sources of extra support that you could suggest:

1. Local quit groups

If available (The Quitline will know if any are available in your area).

2. (13QUIT or 137848) Quitline:

- ✓ This is a telephone service for smokers who want to quit
- ✓ The Quitline can be contacted by phone from anywhere in Australia, 7 days a week, 08:00 am to 08:00 pm
- ✓ Costs the same as a local call (normal charges apply if calling from a mobile)
- ✓ The Quitline is confidential – the woman doesn't have to give her name if she doesn't want to
- ✓ The Quitline has Aboriginal counsellors that are trained to support people. They know how hard it is and are never judgemental
- ✓ The woman can get a **free** Quit Pack from the Quitline (see below)
- ✓ Suggest you make the first call to the Quitline together while she is in the medical service, or use a faxed referral (see "Appendix 2: Smoking Cessation Referral Form to the Quitline" on page 84). The form can be downloaded from: http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/C267B0382618D7ECCA257A0D001F11DB/$File/smoking%20cessation%20form%20-%20Dec%202016.pdf

3. Quit Pack:

- ✓ Anyone can obtain a free Quit Pack by calling the Quitline on 13 7848 to order a Quit Pack over the phone.
- ✓ The Quit Pack has:
  - ➢ The Quit book – will help with planning and preparing to quit and provide tips and strategies for quitting successfully
  - ➢ Choosing the best way to quit – a guide to choosing the services and products which would best help you increase your chance of quitting successfully
  - ➢ Information on how you can speak to a Quit advisor

- A handy wallet card with tips to cope with cravings
- Information on ordering the Ten Steps to Quit for Good DVD/video and Ten Good Ways of Relaxing CD

4. Quit for You-Quit for Two

Mobile App:

- ✓ This mobile app was designed specifically to provide help and support for pregnant women to quit smoking
- ✓ NOTE: this app wasn't designed specifically for Aboriginal and Torres Strait Islander pregnant women
- ✓ The app provides information, practical tips and fun games to distract from cravings. It also has a calculator that keeps track of the money saved
- ✓ The app can be downloaded for Android smartphones or Apple smartphones: https://itunes.apple.com/au/app/quitforyouquitfortwo/id549772042

5. Quit Coach:

- ✓ This is a free web-based service that provides a personal quitting plan
- ✓ The program will ask the patient several questions on motivation, confidence and past attempts; and creates a specialised personal quit plan in a PDF format to print and read
- ✓ **Not suitable for women with low literacy and/or no computer at home.**
- ✓ It is recommended to revisit the web program when things change – the woman quit, the woman couldn't quit, and so on. It will ask further questions and adjust the quit plan
- ✓ Can be accessed on http://www.quitcoach.org.au/
- ✓ Works well with the QuitTxt program (see below)

6. QuitTxt:

- ✓ This service provides support through SMS messages
- ✓ The woman will be required to register and complete a brief survey
- ✓ The service will tailor the amount of messages she will get according to what she wants, and when she wants to receive them

- ✓ The service is free other than the costs of messages the woman might send
- ✓ It can work with the Quit Coach (they have the same log in username and password)

7. Blow Away The Smokes DVD

A guide to quitting cigarettes for Aboriginal & Torres Strait Islander smokers. Available from Quitline in NSW, South Australia, and Tasmania. It may be viewed online from: http://researchonline.jcu.edu.au/23707/1/index.html
Hard copies can also be ordered from the North Coast Primary Health Network, Uncle Terry Donovan tdonovan@ncphn.org.au, Tel 02 66591800

8. "Kick the Habit" Social Marketing Campaign

This campaign, developed and run by AH&MRC, includes the development of films and other resources to increase awareness of smoking cessation options and reduce the prevalence of smoking in Aboriginal communities. Access to all the resources, including YouTube videos: http://www.ahmrc.org.au/programs/2016-04-15-00-08-17/tobacco-resistance-control.html?id=384

9. ICAN QUIT website

This website provides information to guide patients in their quit attempt. The website provides the opportunity to join an online community and share with members any tips, stories or advice around quitting smoking or staying quit. https://www.icanquit.com.au/

10. My QuitBuddy mobile phone app

A personalized app to help the patient quit smoking. It is designed for the general population (not specific for pregnancy or for Aboriginal and/or Torres Strait Islander people). http://www.health.gov.au/internet/quitnow/publishing.nsf/Content/quit-buddy

11. "I QUIT BECAUSE" website

This website was developed by NSW Health in collaboration with 3 Aboriginal Medical Services. The site helps the smoker to find their reason to quit smoking through telling the stories of others who have succeeded.

The site includes access to short videos of Aboriginal people telling their story around smoking and quitting, including videos of women quitting during pregnancy, and women commenting on making their homes and cars smoke free. http://www.iquitbecause.org.au/

All of the videos can also be accessed through their Facebook page: https://www.facebook.com/IQuitBecause/app/212104595551052/

12 Quit For New Life program

(In NSW only) - provides counselling, free NRT, and cessation services for family members. This is delivered through specific ante-natal care services.

Extra resources for health providers:

1. *Blow Away The Smokes* DVD chaptered version on extras (hard copy only) can be used to lead a quit group, or group discussion.

2. *Yarning about Quitting* e-learning package and videos on how to talk with an Indigenous pregnant smoker and encourage quitting. https://nswhealth.seertechsolutions.com.au/public_content/HETICP/HETI/Yarning%20About%20Quitting/story.html

   http://www.health.nsw.gov.au/kidsfamilies/MCFhealth/Pages/yarning-about-quitting-videos.aspx

3. *Westmead Hospital* e-learning package from KidsQuit on quitting in pregnancy.

   https://kidshealth.schn.health.nsw.gov.au/kidsquit-smoking-cessation-brief-interventions

4. UK NCSCCT Brief intervention training.

   http://www.ncsct.co.uk/publication_pregnancy_and_the_post_partum_period.php
   http://www.ncsct.co.uk/shopdisp_midwifery_briefing.php

Appendix 1: Interaction between Smoking and other medications

Quitting smoking (or reducing the amount smoked substantially) can result in the ***opposite*** of the effects noted below. This is not an effect of going onto NRT, but a reduction in exposure to polycyclic aromatic hydrocarbons found in cigarette smoke

This is explained as follows in the Australian Prescriber: *"Cigarette smoking induces the activity of human cytochromes P450 (CYP) 1A2 and 2B6. These enzymes metabolise several clinically important drugs, including clozapine, olanzapine and methadone. Decreased CYP1A2 activity after smoking cessation increases the risk of adverse drug reactions, with reports of increased toxicity from clozapine and olanzapine. Predicting the required dose reduction of drugs metabolised by CYP1A2 after smoking cessation is challenging. Therapeutic drug monitoring should be used when possible. Nicotine replacement therapy does not influence CYP1A2 activity."*

See link for more information https://www.nps.org.au/australian-prescriber/articles/smoking-and-drug-interactions

Medication	Effect of smoking
Caffeine	Increased clearance (by 56%)
Chlorpromazine	Decreased serum concentrations (by 24%)
Clozapine	Decreased plasma concentrations (by 50%)
Olanzepine	Decreased plasma concentrations (by 30%)
Estradiol	Possibly anti-estrogenic effects
Flecainide	Increased clearance (by 61%)
Fluvoxamine	Decreased plasma concentrations (by 47%)
Haloperidol	Decreased serum concentrations (by 70%)
Heparin	Increased clearance
Imipramine	Decreased serum concentrations
Insulin	Decreased subcutaneous absorption due to poor peripheral blood flow
Lidocaine	Decreased oral bioavailability
Propranolol	Increased oral clearance (by 77%)
Theophylline	Increased metabolic clearance (by 58 to 100%)
Warfarin	Decreased plasma concentrations (by 13%). No effect on prothrombin time

Source: Zwar N, Richmond R, Borland R, et al. Supporting smoking cessation: a guide for health professionals Melbourne2011 [Updated July 2014][67].

Appendix 2: Smoking Cessation Referral Form to the Quitline

The form (opposite) can be downloaded from: http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/C267B0382618D7ECCA257A0D001F11DB/$File/smoking%20cessation%20form%20-%20June%202016.pdf

Smoking Cessation Referral Form

Last update June 2016

For use by health professionals to refer patients to Quitline

Fax Numbers:

ACT & NSW (02) 9698 2740 **NT** (07) 3837 5914 **Qld** (07) 3259 8217 **SA** (08) 8291 4280 **Tas** (03) 6242 8111 **Vic (03)** 9514 6804 **WA** (08) 8291 4

Referrer Details

From: _____

Address: _____

Phone: _____

Fax: _____

Health Professional: ☐ General practitioner ☐ Dentist ☐ Pharmacist ☐ Nurse ☐ Mental health worker ☐ Aboriginal health worker

☐ Other (please specify) .....

Privacy Warning: The information contained in this fax message is intended for Quitline Staff only. If you are not the intended recipient you must not copy, distribute, take any action reliant on, or disclose any details of the information in this fax to any other person or organisation.

Patient Information – CONFIDENTIAL

Name: _____ D.O.B __ __/__ __/__ __

Preferred Phone: (h) _____ (w) _____ ___ (m) _____

Email: _____

Is the patient of Aboriginal or Torres Strait Islander origin?

☐ No ☐ Yes, Aboriginal ☐ Yes, Torres Strait Islander

What is the best time and day for Quitline to call?

Monday-Friday ☐ 9am-1pm ☐ 1pm-5pm ☐ 5pm-8pm

Is it okay for Quitline to leave a messa

☐ Yes ☐ No

Smoking status

☐ Daily ☐ Weekly ☐ Less than weekly Number per day ☐

What stage is your patient at with quitting?

☐ Not ready (not currently thinking of quitting) ☐ Unsure (thinking about quitting within 6 months)

☐ Ready (planning to quit within 1 month) ☐ Recent quitter (within the last year)

Use of Medication?

☐ Currently using/ planning to use Bupropion Hydrochloride (Zyban®)

☐ Currently using/ planning to use Varenicline (Champix®)

☐ Currently using/ planning to use nicotine patches/ gum/ inhaler/ lozenge/ micotab

What are the patient's health issues relevant to Quitline counsellors?

☐ Heart/lung disease ☐ Respiratory disease ☐ Diabetes ☐ Depression ☐ Anx

☐ Psychosis ☐ Pregnancy ☐ Other – please specify _____

Please note

The interaction of chemicals in cigarettes and some medications e.g. Insulin, some antidepressants / antipsychotics, and the interplay betweer chemicals and some symptoms can mean some smokers need monitoring of drug levels and symptoms by their GP through the quitting proce

Health Professional is monitoring the above

☐ Yes

☐ No

I consent to this information being faxed to Quitline and for Quitline Staff to call me at a tim that I have suggested on this form. I understand that persons within the organisation with ac to the fax machine, who may not be Quitline staff, might view this form. I understand that in Queensland my telephone calls will be recorded for the purposes of quality monitoring and service improvement.

_____ Health Professional Signature

_____ Patient's Signature

__ __/__ __/__ _ Date

For use by Quitline staff

Quitline Confirmation of Action on Referral Date: __ __/__ __/__ __, your referral for _____ has been received by Quitline on __ __/__ __/__ __ , a call back time has been organised for __ __/__ __/__ __.

Referral feedback sent back to (referrer / GP name) on / /

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ICAN QUIT

In Pregnancy

Treatment Manual

ISBN: 978-0-9943652-8-6

Appendix 7.2: Patient booklet

ICAN QUIT
In Pregnancy

Patient Booklet

The Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy educational resource package - a toolkit to aid the management of smoking with pregnant Aboriginal and Torres Strait Islander women.

Authors: Yael Bar-Zeev, Michelle Bovill, Gillian S Gould.

Photography and Film making: Ray Kelly

Artwork for coloring-in by Saretta Fielding

Suggested citation:

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Corresponding Author: gillian.gould@newcastle..edu.au

ISBN: 978-0-9943652-8-6

This book has built in videos you can watch on your smart phone

Download the LAYAR app from the app store

OR

Scan the code to download the app

We will tell you which photos to scan to watch videos. Scan and enjoy!

Did you know?

Babies whose mums smoke are more likely to be:

- Smaller - they might not develop to their full potential
- Sicker - develop more breathing problems and more infections
- Can develop long term health problems such as:
- Asthma (wheezing)
    - » Ear infections
    - » Coughs and colds
    - » Learning difficulties
    - » Obesity and heart disease

Scan this photo to see Aboriginal OB/GYN Dr Marilyn Clarke answer common myths of smoking in pregnancy

Smoking is an addiction, not a lifestyle choice or habit

Over 95% of smokers need help to quit!

Will power is important but it is not enough!

Most smokers need to try multiple times before they quit smoking.

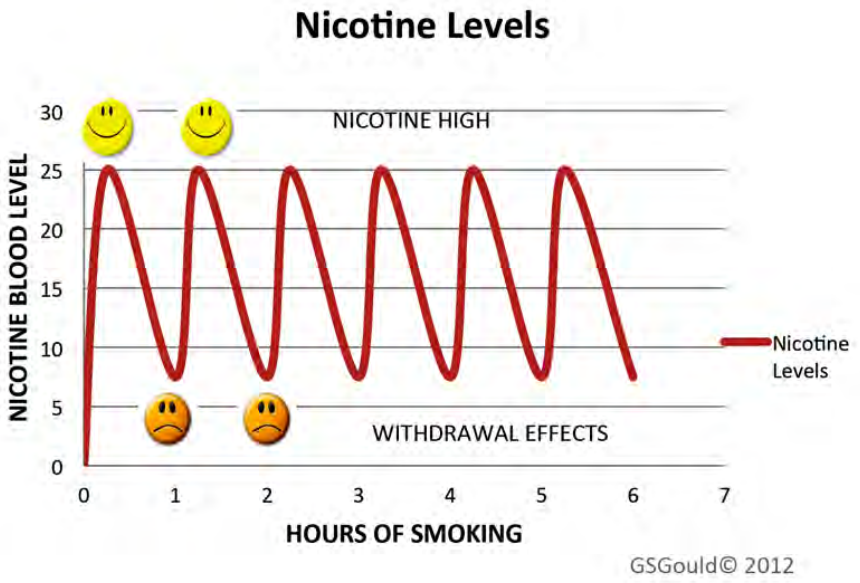
Smoking addiction has 2 parts to it:

1. **Behaviour part** – I need a cigarette when I drink coffee, when I'm bored, when I'm angry or "stressed" = triggers for smoking

2. **Physical part** – my body and brain want nicotine. If they don't get the nicotine, I feel anxious, stressed, irritable and I want a cigarette very much = withdrawal symptoms

   The nicotine helps the brain make feel-good chemicals, and the mind gets used to enjoying these.

   This physical addiction to nicotine happens because nicotine from a cigarette reaches the brain **very fast** (in seconds).

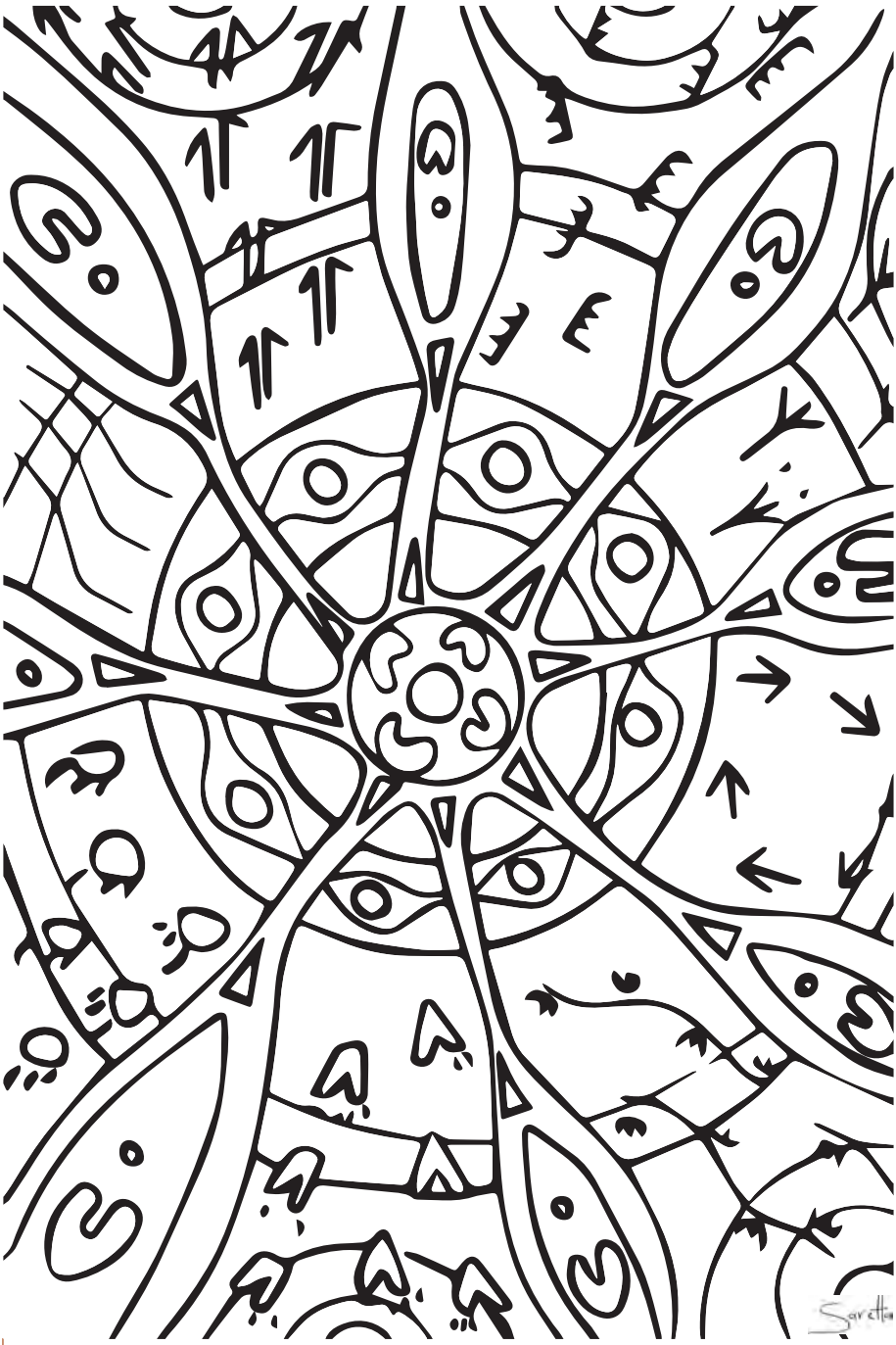


Nicotine levels go up with each cigarette smoked, and go down in between cigarettes.

This has a yo-yo effect all day on the feel-good chemicals in the brain, and a smoker is in and out of withdrawal all day.

These symptoms of withdrawal (such as feeling cranky, angry, anxious, and wanting a cigarette) are often felt as 'stress'.

Take a break and colour me in!



If you decide to quit, it is best to address both parts of the addiction – behaviour and physical:

Behaviour part:

- Know your triggers
- Prepare for your quit attempt
- Make a quit plan

Physical part:

If withdrawals symptoms (such as feeling cranky, angry, anxious, "stressed", low mood) are bothering you…

OR

Your urge for a cigarette is very strong or continues on and off during most of the day…then think about using Nicotine Replacement Therapy (NRT).

Know your triggers

Everyone has different triggers for smoking i.e. drinking coffee, yarning etc.

Did you know an urge for a cigarette usually lasts only one minute?

What can I do for one minute?

Finding out what your triggers are can help you quit.

My triggers:

Scan this image of Hannah to watch her talk about her smoking triggers

What can I do when I have a trigger?

Try the STOP-THINK-DO:

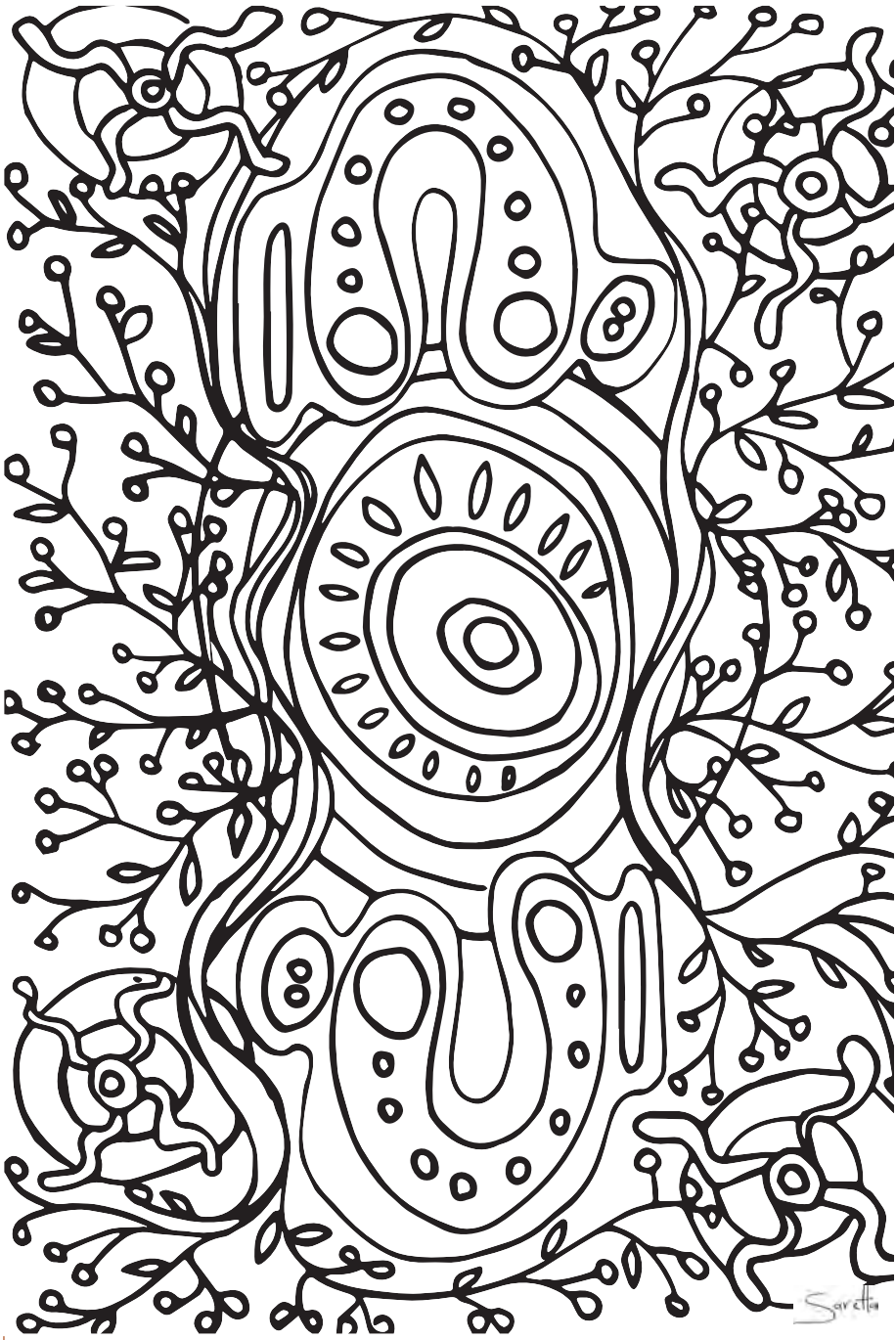
STOP – what you are doing

THINK – about your reasons for quitting; think of all the days you have managed to stay smoke free

DO – something else

Scan this image of Shayna to watch her talk about her smoking triggers

Take a break and colour me in!



Try the 4D's:

Deep Breaths - Breathe in and out slowly for a few minutes. Take deep breaths and try counting to ten while inhaling and exhaling. Repeat at least 3 times.

Drink Water – Drink a full glass of water. You could try and drink through a straw, because that also helps with wanting to put something in the mouth.

Distract – Do something else. For example: If you're sitting with friends, get up and go wash your face with cold water. If you are drinking coffee, throw it away and go outside for a few minutes. If you're upset or mad at someone, take a brisk walk or climb a few stairs fast.

Delay – Remind yourself that this will only last a few minutes… try the other D's.

Prepare for your quit attempt

There are three levels of preparing – Personal, Social, and Environmental

Personal

- Decide on your quit plan (see page 21)
- Decide whether you want to use NRT.
  If you do then get NRT ahead of time
- Prepare different items for mouth and hands such as toothpicks, straws, stress ball, rubber bands, or carrot sticks to chew on
- Prepare regular gum or lollypops to help with having something in your mouth
- Have a goodbye ceremony for the cigarette – you could throw a party, write a song, bury your cigarettes – anything to acknowledge that this is your last smoke

Social

- Tell all your family and friends that you are trying to quit
- Post a status on Facebook/twitter/other social media
- Ask your friends and family to help you – ask them not to offer you a cigarette or even a puff
- Find a quit buddy – someone that will try and quit together with you, or even just someone that agrees in advance to be there for you whenever you really want a cigarette and need support to talk to on the phone
- Ask your partner or a family member to quit with you

Did you know?

Chemicals in smoke stay in the air for several hours, and they can hang onto fabric long-term.

These chemicals are harmful to everyone, including babies, children and other adults that are not smoking.

Having a smoke-free home and car helps you quit smoking.

A smoke-free home and car means there is no smoking at all times, even if there is no one else around.

A smoke-free home reduces risks of serious diseases like cancer, heart disease and breathing problems.

A smoke free home also protects your children from the harmful effects of smoking.

Scan this photo to watch this video showing you how to make your home smoke-free

Environmental

- Make your home and car smoke-free:
- Get rid of all the ashtrays and cigarettes
- Take the car to the carwash to get rid of the smell of smoke
- Wash clothes/drapes/furniture covers/sheets in order to get rid of the smell and chemicals from the smoke
- Put up a 'smoke-free home/car' sticker in your car and at the entrance of your house
- Decide where outside family members and visitors can smoke. This should be as far as possible from the windows and doors, at least 5 meters.
- Tell all family members and friends your home is smoke-free, and let them know where they can smoke when they visit

Make a quit plan

There are blank Quit Plans at the end of this booklet.

My Quit Plan - Example

1. My quit date: __/__/____
2. My quit method:
   - ❑ Cold turkey
   - ❑ Reducing gradually
   - ❑ With Nicotine Replacement Therapy. If so, with:
     - ✓ ❍ Nicotine gum
     - ❍ Nicotine lozenge
     - ❍ Nicotine inhaler
     - ❍ Nicotine spray
     - ✓ ❍ Nicotine patch
3. Other support I will use:
   - ❑ Local quit group
   - ❑ Quitline 137848
   - ❑ Quit for You-Quit for Two app
   - ✓ ☐ Quit coach website
   - ✓ ☐ Quit Txt program
   - ❑ Other: _____
4. My triggers and challenges and how I will deal with them

My triggers and challenges	My solutions
Drinking coffee	Avoid coffee for now, try drinking tea
When I'm stressed	Try deep breaths
Everyone around me is a smoker	Tell them I am trying to quit and ask for their help Ask them not to smoke around me Make my home and car smoke free

5. My rewards for being smoke-free:

Time smoke free	Reward
1 week	Go out with friends
2 weeks	New shoes
1 month	A fun day with my partner

Try NRT

Remember most of the harm from the cigarette comes from the 7000 other chemicals, and NOT from nicotine!

Nicotine from NRT may be harmful to the baby but it will always be less harmful than smoking a cigarette!

This is because:

1. The level of nicotine from NRT is lower and slower compared to a cigarette

2. NRT only has nicotine in it and none of the other chemicals in a cigarette.

Remember: a cigarette has nicotine and an extra 7000 other nasty chemicals.

Take a break and colour me in!

NRT IS ALWAYS SAFER THAN SMOKING, and is much less addictive than a cigarette.

Pregnant women have fast metabolism (their body works faster compared to non-pregnant women). This means your body and brain may need bigger doses of nicotine and this means more NRT to deal with cravings.

Use as much NRT as you need to deal with withdrawal symptoms and urges to smoke.

Use NRT regularly throughout the day – don't limit yourself. Try and use a piece every time you would have had a cigarette.

Use NRT 15 minutes **BEFORE** you know a trigger is coming.

So for example if you are seeing a friend who smokes and you know you might want a cigarette – use NRT 15 minutes before meeting your friend.


We can help you quit,
you aren't alone
The best thing for you and
baby is to quit smoking

Summary

NRT is always safer than smoking

NRT is much less addictive than a cigarette

Most people (over 95%) need help to quit, will power is NOT enough – if you need it, use NRT

If you feel NRT is not helping – you probably need MORE NRT, discuss this with your GP/midwife/Aboriginal Health Worker

Scan this photo to see Torres Strait Islander GP, Dr Karen Nicholls explain how to use each form of NRT.


There is a range of NRT you can try to help during pregnancy
People that use NRT are 2-3 times more likely to have success quitting than people not using anything
nicorette
inhalator
15mg
4

Inhalator / Inhaler

Available dose - 15 mg cartridge

Usual dose is 1 cartridge per 1-2 hours. Top amount is 6 cartridges a day

The inhaler can be used whenever you feel you really want a cigarette (=urge to smoke or craving)

You can also use it BEFORE you are going to a place you will want a cigarette

Method of Use

1. Puff on the inhalator without stopping for 20 minutes
2. Do not inhale into the lungs like a cigarette
3. Instead, suck lightly into back of throat in short breaths
4. Do not eat or drink for 15 minutes before and during using the inhaler

Common side-effects

- Runny nose
- Hiccups
- Cough
- Heartburn
- Throat and mouth soreness

Precautions

Not recommended if you have asthma or other wheezing

Nicotine Gum

Dosage

Available in 2 mg or 4 mg dose.

Remember that 4 mg is recommended when pregnant, due to the body working faster in pregnancy.

Usual amount is 1-2 pieces per hour every day.

The gum can be used whenever you feel you really want a cigarette (=urge to smoke or craving).

You can also use it BEFORE you are going to a place you will want a cigarette

Top amount is 15 pieces a day for the 4 mg gum

Method of Use

1. Chew a piece of gum slowly.
   When you feel a tingling feeling, park the gum at the side of the mouth, between the cheek and gum. After a few minutes, start chewing again till tingling feeling. Park and chew until no more tingling occurs (usually 3 rounds of chew and park, about 30 minutes).

2. Park in different areas of the mouth to avoid soreness.

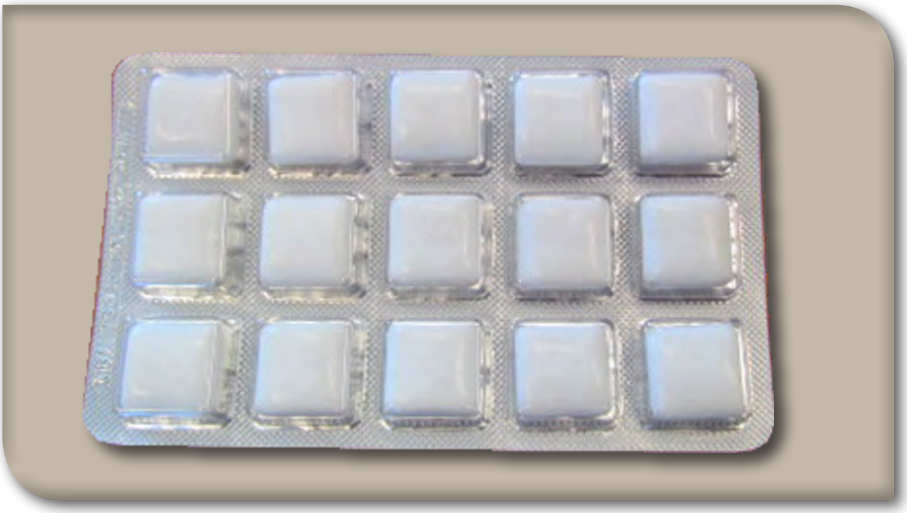
3. Do not eat or drink for 15 minutes before and during using the gum.

Common side-effects

- Mouth/jaw soreness
- Hiccups
- Heartburn
- Throat and mouth irritation

Precautions

Best to avoid if you have dentures (false teeth), and/or jaw joint problems.



Oral spray

Dosage

Available dose 1 mg.

Recommended dose 1-2 sprays per hour, and up to max 4 per hour

Top amount is 64 sprays per day

Can be used whenever you feel you really want a cigarette

Try it **BEFORE** you are going to a place you will want a cigarette

Method of use

For the first use (or if the spray hasn't been used in 2 days) - first prime the pump – point it away from you and press a few times until a mist appears.

1. Press to release one spray into the side of the cheek or under the tongue. Avoid the lips.
2. Do not spray directly into the throat.
3. Do not inhale while spraying.
4. Don't swallow for a few seconds after spraying.
5. Do not eat or drink for 15 minutes after spraying.

Common side effects

- Hiccups
- Throat and mouth soreness

Precautions

None

Lozenge/Mini Lozenge

Dosage

Both available in 2 mg or 4 mg dose.

Remember that 4 mg is recommended when pregnant, due to the body working faster in pregnancy.

Usual dose is 1 lozenge per hour every day. Top amount is 15 lozenges a day.

The lozenge can be used whenever you feel you really want a cigarette (=urge to smoke or craving).

You can also use it BEFORE you are going to a place you will want a cigarette

Method of Use

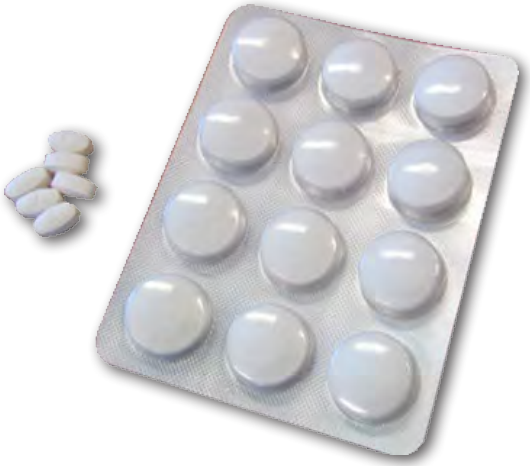
1. Place one lozenge in mouth and allow to melt slowly (20-30 minutes; or for mini lozenge 10 minutes). You might feel a warm tingling feeling.
2. Move to different areas of the mouth to avoid soreness.
3. Do not eat or drink for 15 minutes before and during using the lozenge.
4. Do not chew or swallow lozenge.

Common side-effects

- Feeling sick
- Hiccups
- Cough
- Gassiness
- Heartburn
- Throat and mouth soreness

Precautions

None



NRT Patch

Dosage

16 hour patches come in 10mg, 15mg, and 25mg strengths. We recommend that the 25mg patch is used as pregnant mums need a bit more NRT than others to help them quit, as their body works faster. 25mg ones are available on prescription. If you have a health care card they may be very cheap or free.

For pregnant women, there is only one brand of 16 hour patch called "Nicorette".

Method of use

1. Apply the patch to the skin. If needed, you can use tape to help the patch stay on (white tape is best).
2. Remove the patch just before going to sleep or after 16 hours.
3. Use one patch per day, unless advised by your GP or midwife to use more.
4. Move where you put the patch on the skin each day to avoid itchy or red skin.

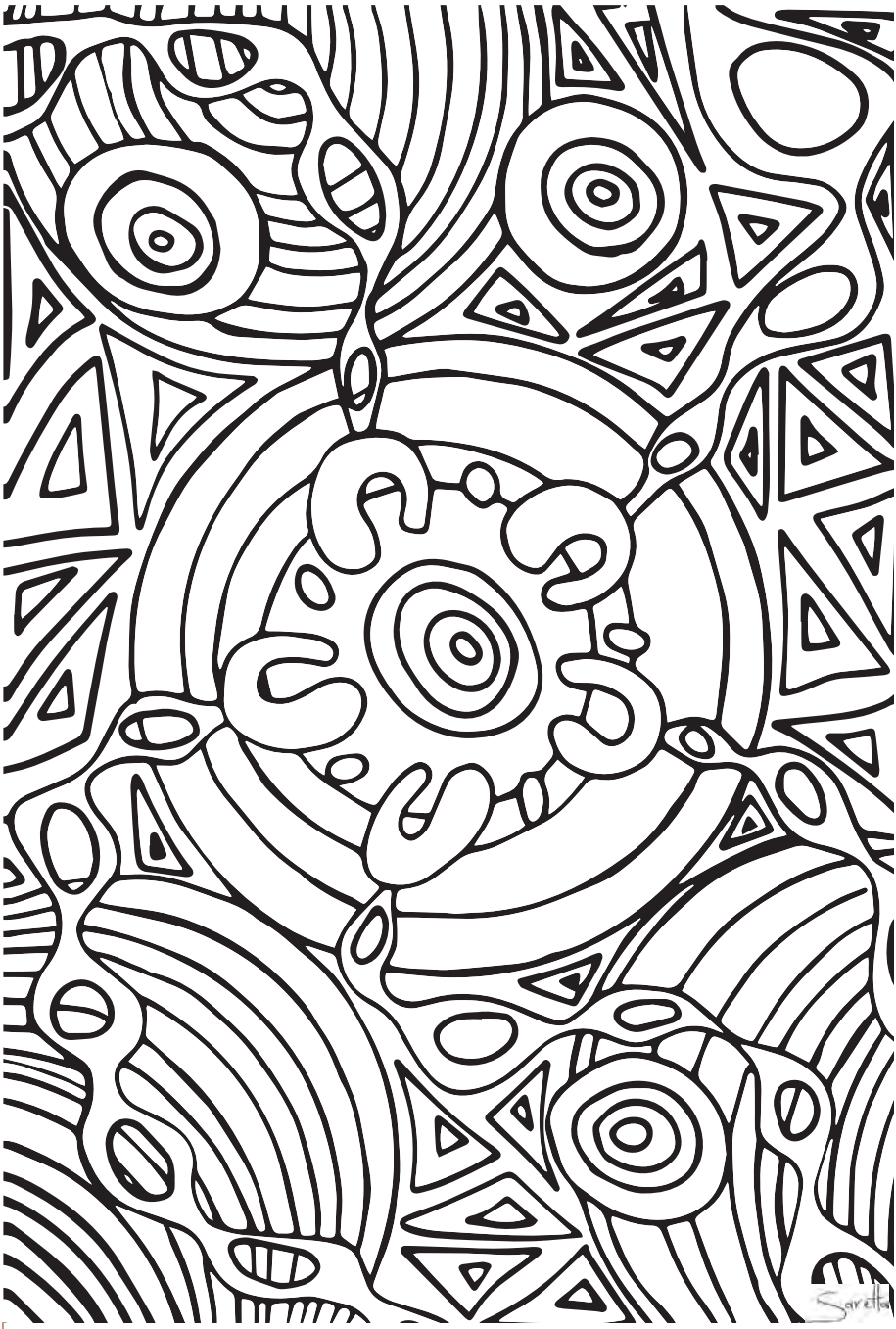
Potential side-effects

- Itching and redness of the skin
- Headache
- Trouble sleeping or vivid dreams (not common with the 16 hour patch)

Precautions

Not recommended if you have skin problems such as psoriasis, dermatitis and eczema (as there is an increased risk for bad skin irritation).

Take a break and colour me in!



Help for Quitting

You're not alone

Your Doctor, Midwife or Health Worker can help talk about the challenges and help you quit

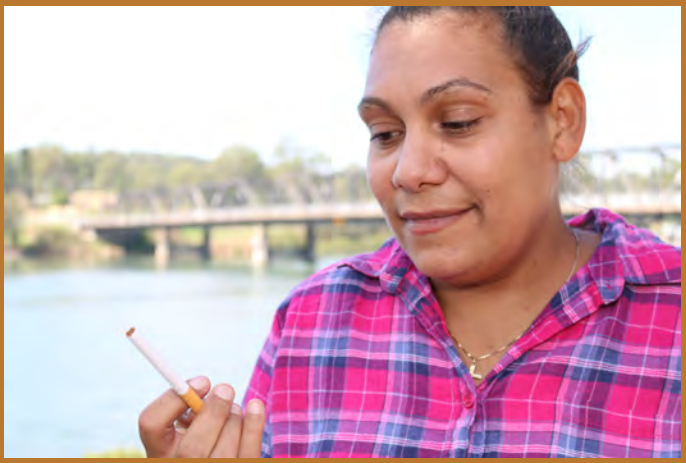
Make a quit plan

Look into using Nicotine Replacement Therapy (NRT)

Address triggers to smoking

If you can't quit straight away you can ease into it with NRT.

Scan this photo to see Aboriginal OB/GYN Dr Marilyn Clarke answer common myths of smoking in pregnancy



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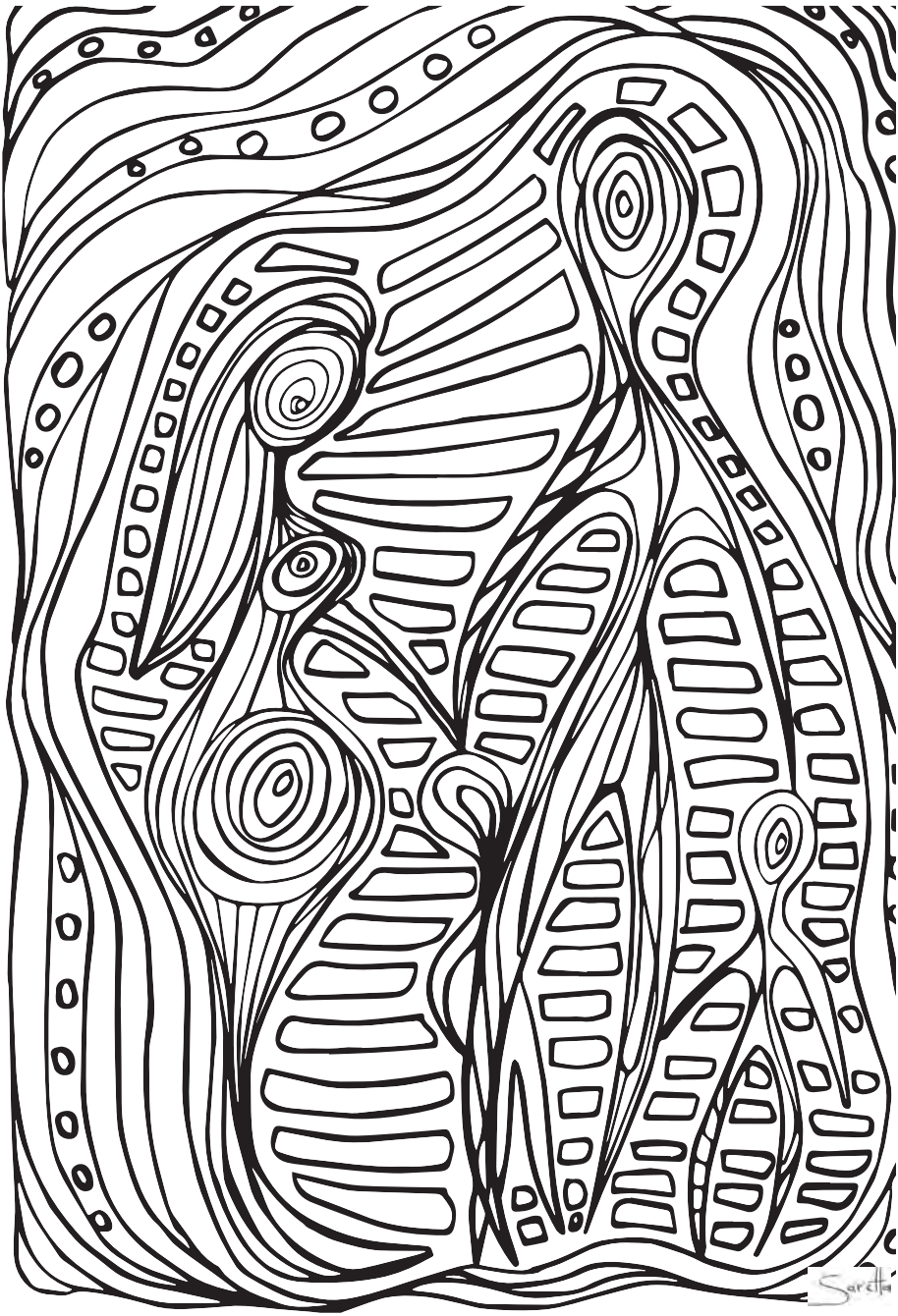

Support

Support from your partner and other family members can really help.

What can they do to help you?

- ✓ The best thing would be for your partner/family member to quit smoking with you. They could also get support and quit medicines through the medical service.
- ✓ If they don't want to quit at the moment:
  - » Suggest making the house and car "smoke-free" at all times, even when you or children are not around.
  - » Ask them not to leave any smoking products lying around in the house like cigarettes, tobacco pouches, ashtrays, and lighters.
  - » Ask them not to offer you a smoke, even when if you are stressed or saying that you really want a smoke. Instead ask them to talk to you through the urge, and help to distract you.
  - » Talk to them before and explain that you might be more cranky and anxious in the next few weeks. Ask them to be patient and help you get through this. It will get better in time.
  - » Ask them to congratulate you for every day/week that you manage not to smoke. If they can, a small present or reward is a great idea!
  - » Ask them not to nag you, but rather to support you.

What happens if I slip and have a smoke?

Slipping is NORMAL. A lot of people slip when trying to quit.

The important thing if you slip is to get back to trying as soon as possible.

Do not give up – continue trying to quit.

If you are using NRT – don't stop. Stopping the NRT will make it much harder to quit.

Think – what made you slip? What happened that made you take that smoke?

What can you do differently next time?

What can you try to avoid taking that smoke?

Think ahead – what are the triggers that might cause you to slip?

What are your "dangerous" situations? How would you rate each one from 1 (low) to 10 (high)?

How can you deal with them?

For example:

Dangerous Situations	Level of danger (1-10)	How am I going to deal with it?
Being with family and friends who smoke	8	Ask them not to smoke next to me, have an oral form of NRT with me.
After a fight with my partner	9	Breathe slowly and deeply for a few minutes, splash water on my face, talk to a good friend on the phone.
When drinking alcohol	6	Ideally pregnant women should not drink alcohol. Try to separate your drinking from smoking, and gradually cut down the alcohol, or avoid other drinkers for a while.
When I need time to myself	4	Listen to my favourite music. Go for a walk.

Now fill out some for yourself:

Dangerous Situations	Level of danger (1-10)	How am I going to deal with it?

Many women slip after birth or when they finish breast feeding.

It is always better for you and your baby if you are still not smoking after the birth.

Quitting smoking is hard. You can be proud of yourself. Think of all the time and energy you put into quitting during the pregnancy.

Remember: Smoking is an addiction, not a lifestyle choice or habit.

Take a break and colour me in!

Over 95% of smokers need help to quit!

Will power is important but not enough!

There is more support you can get and use

Try out different things to see what is best for you

Use as many types of support as you want – it is free!

The more support the better

Things you could try:

1. The Quitline – a free telephone service that will support you through your journey. The Quitline also has Aboriginal counsellors.
   Just call 13QUIT or 137848 or ask your GP/Midwife/Aboriginal Health Worker to refer you

2. Quit for You-Quit for Two mobile phone app:

   This mobile app was specially designed to give help and support for pregnant women to quit smoking.

   The app can be downloaded for Android smartphones or Apple smartphones.

3. Quit Coach and/or Quit text services
   Register for free at http://www.quitcoach.org.au/ for support through a website and/or text messages.

4. ICAN QUIT website: The website provides the opportunity to join an online community and share with members any tips, stories or advice around quitting smoking or staying quit.
   https://www.icanquit.com.au/

5. "I QUIT BECAUSE" website – this website was developed in collaboration with three Aboriginal Medical Services in NSW. The site helps the smoker to find their reasons to quit smoking through telling the stories of others who have succeeded. The site includes access to short videos of Aboriginal people telling their story about smoking and quitting, including videos of women quitting during pregnancy, and women yarning about making their homes and cars smoke free.
   http://www.iquitbecause.org.au/
   All of the videos can also be accessed through their Facebook page: https://www.facebook.com/IQuitBecause/app/212104595551052/

Write down your own reasons for wanting to quit smoking.

Also write why you don't want to quit. For example:

My reasons to quit smoking	My reasons to NOT quit smoking
Afraid it will hurt my health	It relaxes me
Afraid it will hurt my baby's health	It's the only way I can get a few minutes to myself
Costs a lot of money	My partner and all my friends smoke – what will I do when they smoke?
People give me a hard time for smoking with a big belly	I enjoy smoking

Now add some of your own:

My reasons to quit smoking	My reasons to NOT quit smoking

You may notice that the reasons you want to quit are more important in the long run – like better heath for you and baby and more money. The reasons not to quit may be short-term things that 'get you through the day'. How can you get through each day without smoking, so you can enjoy the longer term gains?

Notes to myself

My Quit Plan

1. My quit date: __/__/_____
2. My quit method:
   - ❑ Cold turkey
   - ❑ Reducing gradually
   - ❑ With Nicotine Replacement Therapy. If so, with:
     - ❍ Nicotine gum
     - ❍ Nicotine lozenge
     - ❍ Nicotine inhaler
     - ❍ Nicotine spray
     - ❍ Nicotine patch
3. Other support I will use:
   - ❑ Local quit group
   - ❑ Quitline 137848
   - ❑ Quit for You-Quit for Two app
   - ❑ Quit coach website
   - ❑ Quit Txt program
   - ❑ Other: _____
4. My triggers and challenges and how I will deal with them

My triggers and challenges	**My solutions**

5. My rewards for being smoke-free:

Time smoke free	**Reward**

My Quit Plan

1. My quit date: __/__/____
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My triggers and challenges	**My solutions**

5. My rewards for being smoke-free:

Time smoke free	**Reward**

ICAN QUIT

In Pregnancy

Patient Manual

ISBN: 978-0-9943652-8-6

ICAN QUIT

In Pregnancy

Patient Flip Chart

Smoking in Pregnancy - How to approach it?

Remember: Smoking is an addiction, not a lifestyle choice or habit

Not all smokers are the same. Most smokers need intensive support to be able to quit.

Develop your own non-judgmental way of introducing the topic of smoking

"Some things we can do to help you and baby have a healthy pregnancy, like regular check-ups; some things you can do yourself like eating well and resting, and some things we can do together, like helping reduce your and the baby's exposure to tobacco"

Ask an open ended question:

"What do you think/know about tobacco smoke and pregnancy?"

It's important to emphasize to the woman that the harmful effects of smoking on the baby are not always visible.

Key notes

- Almost half of all Aboriginal and Torres Strait Islander women smoke in pregnancy (47%). In the general population, 12% of women smoke during pregnancy.
- Under 10% of Aboriginal women stop smoking in pregnancy (compared to almost 20% in the general population).
- Smoking during pregnancy can cause: miscarriage, stillbirth, low birth weight, birth defects. A small baby does not mean an easy birth – it means a baby that wasn't developed to his or her full potential.
- The lower birth weight from smoking does not counteract the high birth weight from gestational diabetes: in fact smoking in pregnancy with gestational diabetes is very risky.
- Smoking during pregnancy, and exposure of the baby after birth to smoking, can cause:
  - » SUDIS (Sudden Unexplained Death in Infancy Syndrome)
  - » Respiratory or breathing problems e.g. asthma
  - » Glue ears/ middle ear infections
  - » Learning and behavioural problems such as learning disabilities and ADHD
  - » Children starting to smoke earlier

What do you know about smoking in pregnancy?

Quitting smoking at any stage of the pregnancy is good, both for the mother and for the baby. Quitting before 20 weeks is better, and can prevent low birth weight.

ASK and ASSESS

"I hope you don't mind me asking, but does anyone at home smoke?"

Then take a smoking history:

"Some women smoke more when pregnant, some smoke the same, or some smoke less – what's been your experience?"

Remember to be non-judgmental

Important pieces of information you want to hear and write down:

- Is the patient a current smoker? (even if she is only having a cigarette once in a while)
- How many cigarettes is she smoking each day on average?
- Has she cut down since she found out about the pregnancy?
- If so – congratulate her on her will and effort

"It can be hard to cut down on the number of cigarettes you smoke. That's great you're willing to make that effort and have already succeeded cutting down. ***The best thing for you and your baby's health is to quit altogether."***

- Has she ever tried to quit before? For how long?
- Has she used any cessation medication before? Which? Did they help her? Did they cause any side effects?
- Who else is smoking around her? Are they smoking inside the home? Inside the car?

Some women smoke more when pregnant, some the same, or some less. What has been your experience?

Assessment of Level of Dependence

These measures give an estimate of how dependent the patient is on nicotine, and help decide the dose of nicotine replacement therapy (NRT) needed.

SUTS Strength of Urges to Smoke score	FUTS Frequency of Urges to Smoke score
In general, how strong have the urges to smoke been in the last 24 hours? • Slight (1 point) • Moderate (2 points) • Strong (3 points) • Very strong (4 points) • Extremely strong (5 points) Total SUTS Score: _____	How much of the time have you felt the urge to smoke in the past 24 hours? • Not at all (0 point) • A little of the time (1 points) • Some of the time (2 points) • A lot of the time (3 points) • Almost all of the time (4 points) • All of the time (5 points) Total FUTS Score: _____

As a general rule – if a woman has a score equal or higher than 3 on one of these measures, she needs additional support. **Additional support could be initiating NRT; or increasing the dosage of oral NRT; or adding a patch to oral NRT.**


Can I ask a few questions about your smoking?
This will help us assess how dependant you are on nicotine

Measuring Carbon Monoxide (CO)

The 'piCO Baby smokerlyser' tests the mother's CO and also indicates the baby's levelof CO in their blood. *"The more you smoke the higher your CO reading will be. The reading can also tell how much CO is attached to the blood cells (%COHb - %Carboxyhaemoglobin). The amount in the baby's blood is called %FCOHb (% FoetalCarboxyhaemoglobin)."*

How to use the piCO Baby Smokerlyser

- Insert the plastic D-piece to the machine.
- **Explain to the patient that when you tell her to, she should take a deep breath and hold all the air in. She will be expected to hold the air for 15 seconds. After 15 seconds, she will then blow the air slowly into the D-mouth piece.**
- Tell the patient to take a deep breath, and press the on button (located on the top of the machine).
- This will start the 15 seconds countdown (displayed on the screen). In the last 3 seconds you will hear three beeps to prepare the patient to blow the air in.
- After 15 seconds, the patient should blow all the air in her lungs **slowly** into the mouthpiece.
- The CO ppm score, the woman's %COHb and the baby's corresponding %FCOHb will show.
- A CO level over 6 ppm is considered to indicate a smoker.
- In addition the lights that flash relate to the level of CO: Orange and Red lights flash when levels are higher, and the faster the beeping noise the machine makes, the higher the levels.

Key notes

- Carbon monoxide is a poisonous gas like that is produced in car exhaust fumes. It is also produced when a person smokes a cigarette.
- When smoke is inhaled from a cigarette, carbon monoxide gets into the blood stream through the lungs. The carbon monoxide stops the red blood cells carrying enough oxygen to the baby because it tags on to the same place that the oxygen should attach to.

COppm	%FCOHb
>20	5.66
19	5.38
18	5.09
17	4.81
16	4.53
15	4.25
14	3.96
13	3.68
12	3.40
11	3.11
10	2.83
9	2.55
8	2.26
7	1.98
6	1.70
5	1.42
4	1.13
3	0.85
2	0.57
1	0.28
0	0.00

Let's test your breath!

Take a deep breath
Hold it for 15 seconds
Breathe out slowly

Exposure to other forms of Nicotine

There are other forms of tobacco and/or nicotine that the woman and baby might be exposed to such as cannabis mulled with tobacco, chewing tobacco, or e-cigarettes.

It is important to ask and assess these exposures.

"Do you use any other forms of tobacco or products that might contain nicotine, such as, chewing tobacco/'pituri', and/or electronic cigarettes?"

"If you smoke cannabis/yarndi, do you mix it with tobacco?"

If yes, follow up with: *"Do you use them daily or occasional?*

"How much to do you use during a day?"

It is important for pregnant women to quit tobacco in any form.

Continual exposure to tobacco in other forms will mean the woman is still receiving harmful chemicals and not breaking the dependence on nicotine.

Note: If the woman is using cannabis daily you need to refer her to a drug and alcohol counsellor or an addiction specialist.

Do you use any of these?

Brief Advice

Offer *all women* clear advice that they should quit smoking or other tobacco use

- *"The best way to help your baby and your own health is to quit smoking."*
- *"Have you had a time in this pregnancy or in the past when you tried to go a whole day without smoking? How did you go?"*

Offer *all pregnant smokers* assistance with quitting:

- *"If you choose to, I can help you quit. There are effective ways that could support you to go smoke-free."*

If appropriate, suggest a trial of stopping smoking in the next few days for 1–3 days.

- *"If you want, we could take it one day at a time, you might try and not smoke in the next few days then come back and tell me how you are going."*

Key notes

Emphasize that cutting down is not enough because pregnant smokers who just cut down compensate by taking deeper breaths, smoking more from each cigarette and taking in the same amount of harmful chemicals.


We can help you quit,
you aren't alone
The best thing for you and
baby is to quit smoking

Cessation Aids

Introduce the idea of Nicotine Replacement Therapy (NRT)

"One of the things we can really help you with is to quit smoking. If you cannot manage it alone, we can use nicotine replacement therapy to help the cravings."

"As part of this program we offer NRT to every pregnant smoker to help her quit as soon as possible."

Key notes

- **Nicotine is the chemical in a cigarette that causes smoking to become addictive and makes it hard to quit smoking. It is not the most harmful part of smoking. The harm from cigarette smoking is caused by the various other 7000 chemicals found in a cigarette such as tar, which causes cancer. NICOTINE DOES NOT CAUSE CANCER.**
- The nicotine from the cigarette **quickly goes to the brain (in 10-15 seconds),** which then **releases dopamine**, which is a pleasure or 'feel-good' chemical. The smoker gets addicted to this feel-good chemical released by the nicotine receptors.
- When a person smokes the nicotine levels rise but this only lasts a short time before it wears off. The person starts to feel "withdrawal effects" and craves another cigarette to get the feel-good effect and stop the withdrawal symptoms or cravings. Some withdrawal symptoms are identical to stress-symptoms, like feeling anxious and irritable.
- Smokers have larger numbers of nicotine receptors in the brain. Over the years of smoking these nicotine receptors multiply, so more and more cigarettes are needed to satisfy the craving. It is like having thousands of 'hungry mouths to feed'! Once a person stops smoking the receptors eventually start to decrease – this happens more effectively when using Nicotine Replacement Therapy.

If you can't manage the cravings alone, we can give you nicotine replacement therapy to help

Risk Benefit Assessment of using NRT in pregnancy

RISK	BENEFIT
#1 Nicotine has been linked to harmful effects on the baby: • Low birth weight • Preterm birth • Stillbirth • Cognitive impairment • Impaired lung development	**#1 NRT has only nicotine in it, and none of the other 7000 chemicals** also found in a cigarette (300 known to be toxic and harmful, 52 known to be carcinogenic). You and your baby are not exposed to all of these other chemicals.
BUT Studies with **nicotine from NRT** in pregnant women (over 2000 women) have shown NRT to cause no harm to the mother or the baby.	**#2 If you use NRT, you are receiving less nicotine than when you smoke.** Nicotine from NRT is not absorbed as efficiently or quickly as from a cigarette
	#3 NRT will increase your chances of quitting and staying quit by 40%. Every day you don't smoke improves the health of you and your baby. There is nothing better for you and your baby's health than to quit smoking.
	#4 Using NRT may help your baby's health even if you don't quit smoking This is probably because of less overall exposure to all the other chemicals in cigarette smoke (see #1).

So what is the difference between a cigarette and nicotine replacement therapy?

VS

Nicotine Replacement Therapy

Explain the different forms of NRT available. Explain risks and benefits for pregnancy.

In pregnancy and when breastfeeding, an oral NRT (such as taking a lozenge or using a nicotine inhaler) is recommended to try first.

Nicotine patches can be used if these oral forms are unsuitable for the individual or if she cannot quit with using them. Oral and patches can be used together if needed, and can be more effective.

Oral NRT is not currently on prescription, but will supplied as part of this project. NRT patches are on prescription and so the price is subsidised or free in some cases.

NRT should be used for 8-12 weeks, even though the patient may feel fine before this, as it helps to reduce the numbers of 'nicotine receptors' in the brain. She can continue using NRT even longer as no long-term risks have been found.

NRT patches should be taken off at night by pregnant and breastfeeding women, but a 16hr patch will be provided to the patient if she needs it, and not a 24 hr patch (in case she forgets to remove it).

Key notes

Nicotine products help withdrawal symptoms and cravings associated with nicotine dependence during the early stages of a quit attempt. This allows the smoker to focus on the social aspects of quitting.

- The level of nicotine absorbed from NRT is lower and slower compared to a cigarette
- NRT has only nicotine in it and none of the other chemicals in a cigarette
- Therefore - NRT is always safer than smoking
- Addressing negative views and myths regarding NRT use in pregnancy is crucial to supporting the woman and ensuring correct and effective use
- Higher doses of NRT are needed in pregnancy due to the mother's faster metabolism
- Women should use **as much NRT as they need** to overcome withdrawal symptoms and urges to smoke


There is a range of NRT you can try to help during pregnancy
People that use NRT are 2-3 times more likely to have success quitting than people not using anything
nicorette inhalator
15mg

Myths and Suggested Responses

Views and Myths regarding NRT use during pregnancy	Suggested response and things to discuss
"NRT is not safe in pregnancy" "NRT can be harmful for the baby"	NRT is always safer than smoking. Nicotine levels from NRT are much lower than smoking. Nicotine does not cause cancer, lung disease or heart attacks. It is the other 7000 chemicals in tobacco smoke that cause most of the health effects of smoking.
"NRT is addictive"	Cigarettes are far more addictive than NRT. You get less nicotine from NRT and it is delivered more slowly so the risk of becoming addicted is very small. It is always better for your health to use NRT than to smoke.
"It has side-effects" "Oral NRT doesn't taste good"	Most side effects are minor and settle with time. Make sure to explain the potential side effects to the patient, including specifically the possibility of nausea, and the taste and texture. Is the product being used correctly? Chew gum more slowly and try to avoid excessive swallowing of oral products. Remember to remove the patch at bedtime and rotate patch sites.
"I should be able to quit on my own" "Willpower should be enough"	Smoking is an addiction and not a habit, or a lifestyle choice. Some people are more addicted than others because of their genetic makeup. Your metabolism in pregnancy is increased making it harder to quit. It is not a question of willpower. Even if you use NRT it does not mean you are taking a short-cut, you can still be proud of quitting this way.
"NRT just doesn't work"	NRT is more effective when higher doses are used, especially in pregnancy because of the faster metabolism. Have more frequent doses of oral NRT, or add a patch. Do not drink or eat for 15 minutes before or while using oral products so your mouth can absorb the nicotine. Suggest additional methods for support on top of NRT such as the Quitline. It is important to be followed up in case we need to adjust your dose.

Reproduced with permission from The Royal Australian College of General Practitioners from Mendelsohn C. Optimising nicotine replacement therapy in clinical practice. Aust Fam Physician 2013;42(5):305–09. Available at www.racgp.org.au/afp/2013/may/nicotine-replacement-therapy.


Do you have any questions about NRT?
nicorette
OUT OF REACH OF CHILDREN
Guidelines say pregnant women should try cold-turkey before NRT. Going cold-turkey may work for you if you can manage at least 1-2 days without smoking.

Checklist for prescribing NRT

- ❑ **Enquire what are her views (positive and negative) on NRT and proactively address these.**
- ❑ **Explain why you think she should consider using NRT .**
- ❑ **Emphasise that nicotine is safer than smoking, effective and has a low risk of addiction (Refer to the Risk vs Benefit analysis).**
- ❑ **Start with the higher dose of the Oral NRT (such as the 4 mg gum, 4 mg lozenge, or 4 mg mini-lozenge).**
- ❑ **If a patch is needed, start with the 25 mg/16 hour patch .**
- ❑ **Give detailed instructions on the correct use of oral forms of NRT.**
- ❑ **Emphasise the importance of using an adequate dose of oral forms – number of pieces, puffs or sprays per day. If in doubt, use more.**
- ❑ **Encourage use as much as needed to deal with cravings.**
- ❑ **Discuss possible side effects.**
- ❑ **Encourage a full course of treatment – at least 12 weeks.**

What do you think about NRT?

Triggers

Ask the patient to try and identify her own cues/triggers for smoking:

As much as time allows, the approach should be personalized. Helping the woman fill out her quit plan, and the section on challenges can aid this process (next page). Being prepared for these situations helps in the quit attempt.

"In which situations do you feel like you need a smoke? When do you usually smoke?"

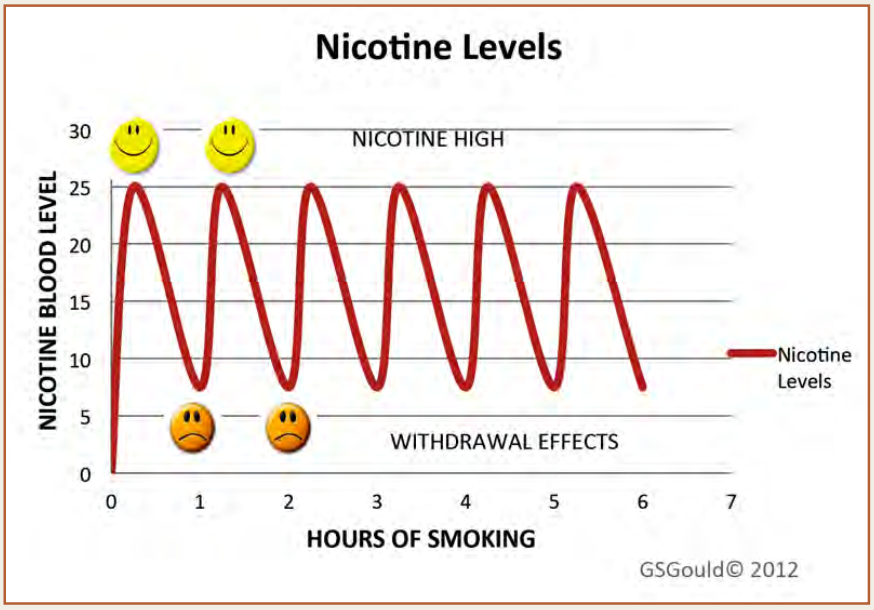
Ask her to suggest ways to remove certain cues, and/or deal with the triggers:

"What do you think you could do instead of having a smoke in these situations?"

Key notes

This patient-education figure can be used to explain about nicotine withdrawal symptoms, and the overlap with symptoms commonly thought of as 'stress' or anxiety. Turn this Flipchart around to show the figure.

'When you get up in the morning nicotine levels are low, so you crave a smoke. The nicotine goes to the brain quickly, and you produce feel-good chemicals (dopamine). Nicotine levels go down in between cigarettes. This has a yo-yo effect all day on the feel-good chemicals, and your mood. A smoker actually is in and out of withdrawal all day. Some symptoms of withdrawal feel the same as 'stress' - feeling irritable or anxious. They worsen when you try to cut down. They get less if you use with NRT to replace some of the nicotine. People who quit in time are much less 'stressed' than those who continue smoking.'



What are your smoking triggers?

I feel the urge to smoke when

_____

Discuss Family, Social and Cultural Context

1. This is a reminder for the importance of the pregnant woman's context and unique circumstances relating to smoking.

"What do you think will be some of the challenges for you at home (or work) with trying to quit smoking?"

2. Identify these challenges as part of 'making a quit plan' and help the client think through how she will tackle these challenges.
3. Psychosocial contexts that are relevant can include: family and partner smoking, smoking in the home (indoor smoking), friends that smoke, and social situations.
4. Triggers or environmental cues for smoking e.g. having a coffee, talking on the phone, stressful life circumstances.
5. Lack of support for quitting.
6. Ask specifically about family and partner smoking and attitudes.
7. Suggest that partners and family may attend with the patient (or separately) to get help for their own smoking earn how they can best support her.
8. **Emphasize to the woman that it is worthwhile to quit smoking, even if everyone around her continues to smoke. *The most harmful effects to her health and the baby's health come from her own smoking.***

Key notes

Second hand smoke does have harmful effects so also encourage smoke-free home and cars. You may promote the notion of preparing the environment for the baby as an additional rationale.

"What do you believe your family and partner think about your smoking in pregnancy?"

"Do you think they will support you if you decide to quit?"

"Is there anyone else you need to speak to before making a decision about quitting?"

"Who will be the best people to support you among your family and friends?"

What do you think will be some of the challenges for you trying to quit smoking?

What could her partner or other family members do to support her quit attempt?

- ✓ **The best thing would be for the partner/family to also quit smoking. They could receive support and medication through the medical service.**
- ✓ **If they don't want to quit at the moment:**
  - » **Don't smoke in the house or the car. The best is to make the house and car a 'smoke-free zone' always (even when the woman isn't present).**
  - » **Don't leave any smoking products lying around in the house like cigarettes, tobacco pouches, ashtrays, and lighters.**
  - » **Don't offer the woman a smoke, even when she is stressed, or saying that she wants a smoke. Instead talk her through the craving, and distract her.**
  - » **Understand that the woman might be more irritable and anxious in the next few weeks. Understand and accept this, and be supportive.**
  - » **Congratulate her for every smoke free day she achieves. Think of ways to reward her, for example buying her a small gift after a week smoke-free.**
  - » **It is better not to nag at the person for smoking, but be supportive in a positive way.**

It is important for your health
and the health of your baby
to make your home smoke-free

Smoke-free homes and cars

Chemicals in tobacco smoke linger in the air for several hours, and can cling to fabric long-term (this is termed third-hand smoke exposure). This means children and others are exposed to these chemicals, even if people try not to smoke while near them.

It is important to emphasize that **all children and adults** are affected by second-hand smoke and third-hand smoke, and not just newborns and young children.

It is therefore important to encourage a smoke-free home and car.

A smoke-free home means taking smoking completely outside, even if children are not present. Smokers need to stay at least 5 metres away from an open window or a doorway.

Having a smoke-free home also makes it easier to quit and stay quit.

Key notes

You may promote the notion of preparing the environment for the baby as an additional rationale. What steps are needed to make a smoke-free home?

- Make a "no smoking" rule indoors
- Put up smoke-free stickers
- Decide where people can smoke outside
- Stay 5 metres away from windows and doors when smoking outside
- Clear out ashtrays
- Notify family and friends who smoke that from now on your home is smoke-free!

A smoke-free car is mandatory in all the states when children are travelling with you, but it is recommended that the car becomes a **smoke-free zone at all times** because smoke particles can cling to the interior of the car and still affect children and adults.


Having a smoke-free home
makes it easier to quit
and stay quit.

My Quit Plan - Example

1. My quit date: __/__/____

2. My quit method:

- ☐ Cold turkey
- ☐ Reducing gradually
- ☑ With Nicotine Replacement Therapy. If so, with:
  - ○ Nicotine gum
  - ○ Nicotine lozenge
  - ○ Nicotine inhaler
  - ○ Nicotine spray
  - ◉ Nicotine patch

3. Other support I will use:

- ☐ Local quit group
- ☑ Quitline 137848
- ☑ Quit for You-Quit for Two app
- ☐ Quit coach website
- ☐ Quit Txt program
- ☐ Other: _____

4. My triggers and challenges and how I will deal with them

My triggers and challenges	**My solutions**
Drinking coffee	Avoid coffee for now, try drinking tea
When I'm stressed	Try deep breaths
Everyone around me is a smoker	Tell them I am trying to quit and ask for their help.
	Ask them not to smoke around me
	Make my home and car smoke free

5. My rewards for being smoke-free:

Time smoke free	**Reward**
1 week	Go out with friends
2 weeks	New shoes
1 month	A fun day with my partner

Let's make a plan!

Follow up

1. Encourage the pregnant smoker to return to see you, no matter how successful or unsuccessful the quit attempts have been.

2. Each visit, check FUTS, SUTS and CO readings, and assess a need to adjust treatment and NRT dosage. Go over her Quit Plan, and discuss how it went.

3. Arrange follow-up within a few days, or maximum of a week, if the client is having any sort of trial at quitting. This could be with another health professional at the service if the GP is fully booked.

It's important to give positive feedback on any success the woman has managed.

If the woman has been able to quit congratulate her, emphasize the time that has passed, and the health benefits she has already provided for herself and the baby.

"That's great that you have succeeded quitting for # days, well done! I know it's not easy, and you should be proud of yourself. You and your baby are already breathing better and getting more oxygen"

What she did to help with cravings?

When does she still find it hard to cope, and what is she doing at these times? Suggest exploring other strategies to deal with cravings.

If she is using NRT review what type, how is she using it, and how much? Check she is using NRT the correct way, and enough times. If having frequent cravings (FUTS scale ≥3), or very strong cravings (SUTS scale ≥3), review her need to increase the dose or add a patch to any intermittent NRT

If the woman hasn't been able to quit, congratulate her on what she has managed to achieve, and ask what does she think she could try differently to help her quit.

"I know it's hard to quit, and it's excellent that you are trying. It's great that you managed not to smoke for # hours/days. What made you smoke the first cigarette/puff? What do you think you could do differently now to try again?"

If she hasn't been using NRT, suggest she try with it (refer back to NRT pages). If she was using NRT, make sure she is using it the correct way, and enough times. Review the dose and if needed add a patch to any intermittent NRT.

Support should be offered for at least 12 weeks and postpartum.

Suggest again using also other forms of support such as the Quitline.

It's important that we meet again no matter how successful or unsuccessful your quit attempts was

Let's meet again in a few days!

Additional Cessation Aids

Offer all women a referral to additional support as available in your area.

- Local quit groups if available
- Quitline (13QUIT or 137848) – Aboriginal counselors are available
- Quit For New Life program in NSW (provides counselling, free NRT, and cessation services for family members)

It is recommended **to be proactive** in helping the woman link in with additional support (for example, suggest you or a health worker, make the first call to the Quitline together, or use a faxed referral)

Additional FREE online resources you can suggest (see treatment manual for a full list):

- Quit for You, Quit for Two phone App for maternal smoking https://itunes.apple.com/au/app/ quitforyouquitfortwo/id549772042
- "I QUIT BECAUSE" website – this website was developed by NSW Health in collaboration with 3 Aboriginal Medical Services. The site helps the smoker to find their reason to quit smoking through telling the stories of others who have succeeded. The site includes access to short videos of Aboriginal people telling their story around smoking and quitting, including videos of women quitting during pregnancy, and women commenting on making their homes and cars smoke free. http://www.iquitbecause.org.au/
- All of the videos can also be accessed through their Facebook page: https://www.facebook.com/IQuitBecause/app/212104595551052/

There are other supports out there...

Quitline 13QUIT even have Aboriginal counsellors available

Relapse prevention

Many women who stop smoking in pregnancy relapse shortly after birth. Some women may also relapse after they finish breastfeeding. Therefore, it is crucial to discuss with the woman closer to the birth (e.g. at 34-36 weeks) and at the first post-partum visit, the importance of staying smoke free:

- Emphasize all the work she's done and the effort she's put it, and her success
- Discuss health benefits to her and the baby post-partum
- Explain that even one puff of a cigarette can trigger the addiction to nicotine again, and she should avoid even one little puff
- It is important to understand that lapses are common and normal in the process of quitting, and it's important to stress to the woman that if she has lapsed (smoked a puff, or one whole cigarette), it doesn't mean that she failed.
- Discuss the importance of not stopping NRT treatment if she has lapsed
- Suggest you can help her find a better way to deal with the craving or situation that led to that lapse.

If she has relapsed, review with her what could she do differently the next time.

"I know it's hard. Many women who try quitting need to try a few times before they remain smoke free for good. This doesn't mean you can't do it. It just means we have to try again and try to do something differently this time."

"What helped you to deal with this situation in the past? What do you think you could do next time that might help?"

It is important to prepare for situations where you might relapse and smoke after bub is born. Let's work through some of these challenges and make a plan to keep you smoke-free

Relapse Prevention Challenges

Discuss challenges that might specifically arise after the birth (e.g. needing a minute to herself) that could trigger a lapse. Or the feeling that now the baby is born, he/she is less at risk from Mum smoking. Remember that some women may not intend to stay quit post-birth.

Help the woman make a list of "dangerous situations" that might trigger strong cravings and a lapse, and then write down different ways she could deal with these situations:

Dangerous situation	How am I going to deal with it?
Being with family and friends who smoke	Ask them not to smoke next to me, have an oral form of NRT with me.
After a fight with my partner	Breathing slowly and deeply for a few minutes, splashing water on my face, talking to a good friend on the phone.
When drinking alcohol	Ideally women when pregnant or breastfeeding should not drink alcohol. Try to separate your drinking from smoking, and gradually cut down the alcohol, or avoid other drinkers.
When I need time to myself	Listening to my favorite music. Going for a walk.

Key notes

She can continue to use the NRT for as long as she needs it. It's always better to use NRT than to smoke. Not much NRT absorbs into the baby from breast milk.

It is okay to breast-feed while using NRT and it is much better for the baby's health than breast- feeding while smoking. Explain to the woman that she can time the use of oral NRT to ***after the breast-feed*** to reduce the small amount of nicotine that is absorbed by the baby (very little is absorbed this way).


How are you going now bub is born?

Acknowledgements

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- New South Wales Ministry of Health
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- Faculty of Health and Medicine, The University of Newcastle
- Cancer Institute New South Wales

Objective

This Flipchart is designed for use by health providers who are trained in the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention. It is to be used in conjunction with the ICAN QUIT in Pregnancy Training Manual, Desktop Guide, Patient Booklet and Webinar training, as an education and information source.

This Flipchart will help to guide the conversation with a pregnant woman who smokes. One side of the flipchart is for the woman, and the other side is for the health provider. It is not intended to be used in just one consultation but rather that different pages be chosen, as needed, in ongoing consultations during antenatal or routine care.

The Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy educational resource package - a toolkit to aid the management of smoking with pregnant Aboriginal and Torres Strait Islander women.

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ICAN QUIT

In Pregnancy

Patient Flip Chart

ISBN: 978-0-9943652-8-6

Appendix 7.4: Mousepad

ICAN QUIT

In Pregnancy

A Ask about smoking

B Brief advice

C Cessation support

D Discuss family, social and cultural context for smoking

Quit attempt with no NRT

If unsuccessful or if SUTS/FUTS ≥ 3

Add oral NRT

If unsuccessful or if SUTS/FUTS ≥ 3

Add Patch

ISBN: 978-0-9943652-8-6

Appendix 7.5: Poster one

ICAN QUIT

In Pregnancy

Nicotine Replacement Therapy in Pregnancy

There are different forms of Nicotine Replacement Therapy (NRT) you can use:

Gum

Inhaler

Lozenge

Spray

Mini-Lozenge

Patch

Nicotine Replacement Therapy is always safer than smoking!

Appendix 7.6: Poster two

ICAN QUIT

In Pregnancy

What is the difference between NRT and a cigarette?

Nicotine Replacement Therapy (NRT) only has nicotine in it

Patch

A cigarette has nicotine plus 7000 other harmful chemicals

Nicotine Replacement Therapy is always safer than smoking!