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.

Paper Seven Citation: Bar-Zeev Y, Bonevski B, Bovill M, Gruppetta M, Oldmeadow C, Palazzi K, Atkins L, Reath J, ICAN QUIT in Pregnancy Pilot Group, Gould GS. 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.

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Bovill Michelle		13/08/2018
Gruppetta Maree		18/10/2018
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Co-authorship declaration- Paper Eight

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 develop the final study design and data collection tools, co-developing and conducting the webinar training, training the research facilitators at each research site, overseeing the day-to-day management of the study, leading the analysis plan, writing and preparing the manuscript for publication.

Paper Eight Citation: Bar-Zeev Y, Bovill M, Bonevski B, Gruppetta M, Oldmeadow C, Palazzi K, Atkins L, Reath J, 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.*

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