

## 5 SISTAQUIT – Co-developing a smoking cessation intervention with Indigenous mothers in Australia

### Summary

Smoking remains the most common preventable cause of chronic diseases<sup>97</sup> and premature mortality.<sup>98</sup> Smoking during pregnancy increases the risk of non-communicable diseases (NCDs), such as obesity, hypertension, and some respiratory problems in children's early adulthood. Thus, pregnancy offers an important window of opportunity to prevent NCDs for Indigenous mothers and their babies. Globally, 53% of women who smoke daily continue to smoke during pregnancy.<sup>99</sup> Smoking prevalence among Indigenous pregnant women is four times the rate in non-Indigenous women.

The GACD project "Supporting Indigenous Smokers To Assist Quitting (SISTAQUIT)" was funded by a grant from the Australian National Health and Medical Research Council (NHMRC) (AUS \$1.8 million) from 2017 to 2020. The project aimed to increase the smoking cessation rates of Indigenous pregnant smokers. SISTAQUIT is led by Dr Gillian Gould, Associate Professor at the University of Newcastle, Australia, supported by a team which includes both Indigenous and non-Indigenous investigators and research staff. The study was implemented as a Phase 3 randomised controlled trial in Aboriginal Community Controlled Health Services or other Aboriginal Medical Services. SISTAQUIT is the first national trial providing smoking cessation care (SCC) for pregnant indigenous women and following the women and their baby postpartum.

The study builds on the success of the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention developed in earlier Phase 1 and 2 activities. This involved the **co-development and testing of smoking cessation care (SCC) resources with healthcare professionals and mothers from Indigenous communities using a participatory research approach**. Applying this approach ensured culturally appropriate and evidence-based SCC which was tailored to Indigenous mothers who smoke and was feasible for healthcare professionals to deliver, which is crucial for future adoption. Similarly, SISTAQUIT has recently established a Stakeholder and Consumer Aboriginal Advisory Panel, which comprises representatives from the study sites and is actively involved in providing feedback on the implementation of the research.

One of the key outcomes of the project is its **contribution to improved capacity of healthcare professionals to deliver effective SCC to patients**. The SISTAQUIT team is exploring opportunities to incorporate the training into undergraduate midwifery courses at universities and to integrate with smoking Quitline centres in Australia. The study team was awarded further funding from the Australian Government Department of Health for a Phase 4 study called iSISTAQUIT to recruit an additional 20 services in Australia and to develop a social media

<sup>97</sup>GBD 2016 Risk Factors Collaborators, Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet*. 2017;390(10100):1345-422.

<sup>98</sup>GBD 2015 Tobacco Collaborators, Smoking prevalence and attributable disease burden in 195 countries and territories, 1990-2015: a systematic analysis from the Global Burden of Disease Study 2015. *Lancet*. 2017;389(10082):1885-906.

<sup>99</sup> Lange S, et al. National, regional, and global prevalence of smoking during pregnancy in the general population: a systematic review and meta-analysis. *Lancet Glob Health* 2018;6:e769-76.

campaign. More recently, the study team was awarded a further GACD cancer call grant (\$1.8M, 2021) for a full national scale-up (Phase 5).

Among other activities, Dr Gould led an Australia-Canada Collaborative to explore the potential to adapt SISTAQUIT to the Canadian First Nations context, as well as foster collaborations in Alaska and New Zealand to help pregnant Indigenous women in other countries stop smoking. Dr Gould is also collaborating with researchers at the University of Newcastle, Australia to explore smoking cessation in pregnancy not specific to Indigenous peoples.

## 5.1 Background

Smoking remains the most common preventable cause of chronic diseases<sup>97</sup> and premature mortality.<sup>98</sup> Globally, 53% of women who smoked daily continued to smoke during pregnancy<sup>99</sup>. Tobacco smoking in pregnancy is the most important preventable risk factor for poor health outcomes in mothers and babies. Smoking during pregnancy increases the risk of non-communicable diseases (NCDs), such as obesity, hypertension, and some respiratory problems in children's early adulthood.<sup>100</sup> Smoking prevalence among Indigenous pregnant women is four times the rate in non-Indigenous women (45% vs.12%).<sup>101</sup> Almost one in two Aboriginal and Torres Strait Islander women smoke during pregnancy compared to one in eight non-Indigenous Australians. Indigenous women are also likely to be at higher risk of smoking-related respiratory and circulatory diseases and different types of cancers for which tobacco smoking is a major risk factor.<sup>102</sup>

Pregnancy offers an important window of opportunity to prevent NCDs for mothers and their babies. However, many factors need to be considered to effectively enable Indigenous mothers to quit smoking during pregnancy, such as their psychosocial contexts of smoking and life circumstances. An evidence-practice gap exists in primary care approaches for SCC. Furthermore, healthcare professionals often lack the confidence, skills, and training to help pregnant Indigenous women cease smoking. Provision of timely, evidence-based SCC thus has the potential to improve health outcomes for mothers and their babies.

## 5.2 The award

The "Supporting Indigenous Smokers To Assist Quitting (SISTAQUIT)" was a grant funded by the Australian National Health and Medical Research Council (NHMRC) (AUS \$1.8 million) from 2017 to 2020. The project aimed to increase the smoking cessation rates of Indigenous pregnant women who smoke. The study was implemented as a randomised controlled trial (RCT) in Aboriginal Community Controlled Health Services (ACCHS) or other Aboriginal Medical Services (AMS) in Australia.<sup>103</sup> The primary objective of the trial was to assess whether a multi-component intervention is more effective than standard measures taken to help pregnant women quit smoking. SISTAQUIT is led by Dr Gillian Gould, Associate Professor at the University Newcastle, and supported by a team which includes both Indigenous and non-Indigenous

<sup>100</sup> Australian Institute of Health and Welfare Australia's Mothers and Babies 2017 – In Brief. Canberra, Canada: AIHW; 2019

<sup>101</sup> Banderali G, et al. Short and long term health effects of parental tobacco smoking during pregnancy and lactation: a descriptive review. *J Transl Med.* 2015;13:327

<sup>102</sup> Burns J, et al. Overview of Aboriginal and Torres Strait Islander health status 2018. Perth, Australia: Australian Indigenous HealthInfoNet; 2019.

<sup>103</sup> Australian New Zealand Clinical Trials Registry: ACTRN12618000972224

investigators and research staff in Australia. SISTAQUIT is the first national trial providing SCC for pregnant indigenous women and following the women and their baby postpartum.

*Members of the original SISTAQUIT team*



Source: SISTAQUIT team

The SISTAQUIT intervention was developed by Dr Gould over many years of research.<sup>104</sup> It builds on the success of the Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention developed in earlier Phase 1 and 2 activities. This involved the co-development and testing of SCC resources with healthcare professionals and mothers from Indigenous communities using a participatory research approach. Applying this approach ensured culturally appropriate and evidenced based SCC which was tailored to Indigenous mothers who smoke and was feasible for healthcare professionals to deliver. This phase of activity was done in partnership with two ACCHS in New South Wales (NSW), Australia, before being piloted to test the feasibility and acceptability of the intervention in six ACCHS in three states (NSW, South Australia, and Queensland).<sup>105,106,107</sup>

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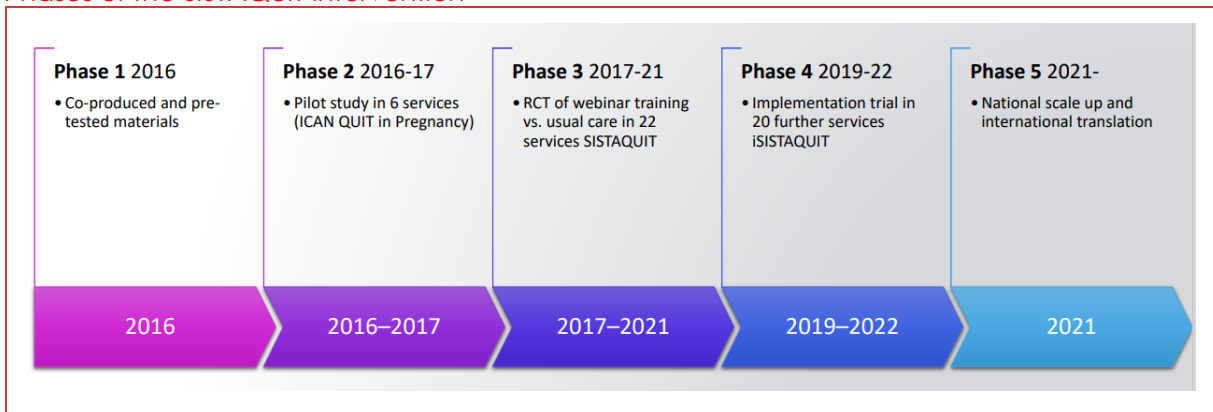
<sup>104</sup> Gould, Gillian. SISTAQUIT - Improving strategies to support pregnant Aboriginal women to quit smoking, NHMRC and Global Alliance for Chronic Disease. *Impact*. 2017. 6-8.

<sup>105</sup> Bovill M, et al. Collective and negotiated design for a clinical trial addressing smoking cessation supports for Aboriginal and Torres Strait Islander mothers in NSW, SA and Qld - developing a pilot study. *Aust J Prim Health*. 2017;23(6):497-503.

<sup>106</sup> Bar-Zeev Y, et al. ICAN QUIT in Pregnancy Pilot Group. 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. *BMJ Open*. 2017;4:7(8).

<sup>107</sup> Bar-Zeev, et al. Assessing and Validating an Educational Resource Package for Health Professionals to Improve Smoking Cessation Care in Aboriginal and Torres Strait Islander Pregnant Women. *Int. J. Environ. Res. Public Health* 2017; 14, 1148.

### Phases of the SISTAQUIT intervention



The GACD project grant marked the start of a Phase 3 RCT called SISTAQUIT which aims to scale the implementation of the ICAN QUIT intervention to a further 20 to 30 ACCHS or other AMS nationally. Subsequently, the SISAQUIT team has secured further funding to scale the intervention further (see section 5.4).

The ICAN QUIT in Pregnancy intervention comprises of facilitated webinar-based training sessions and a treatment manual to improve the knowledge, skills and optimism of healthcare providers who deliver SCC. Healthcare providers to be trained included GPs, midwives, nurses, tobacco and Aboriginal Health Workers. Healthcare providers were also provided with free supplies of oral nicotine replacement therapy (NRT), educational resources for pregnant women, and carbon monoxide breath monitors and tools to measure the effectiveness of the intervention. Healthcare providers delivering SCC collected data on carbon monoxide validated smoking abstinence at four weeks. Secondary measures included abstinence to 6 months postpartum, birth outcomes, baby respiratory systems to 6 months, health providers attitudes/behaviours/practices for managing smoking in pregnancy, fidelity measures including audio recordings of smoking consultations, recruitment and retention rates, and NRT provision requests.

The trial had a recruitment target of 450 pregnant Indigenous who smoke. Enrolment of the services began in April 2017 and recruitment of participants was expected to run to June 2020. SISTAQUIT has recently established a Stakeholder and Consumer Aboriginal Advisory Panel, which comprises representatives from the study sites and is actively involved in providing feedback on the implementation of the research. Dr Gould explained: “The idea of this stakeholder meeting is so that [SISTAQUIT] is in the hands of the people and the sites”. The Panel has recommended several changes, which the team have been able to accommodate.

The implementation of the project was challenging in a number of ways. Challenges included lengthy community and expert consultations and longer than anticipated time to obtain ethics consent from different services. The project also had several service delivery challenges, including healthcare professionals not having access to the data required for reporting. Furthermore, due to their dual roles, healthcare professionals had limited time to allocate to work on SISTAQUIT and some moved on to new roles/work. This resulted in 40% of sites requiring re-training. Recruitment challenges included delays from COVID-19, bushfires, and floods affecting the research sites' recruitment and follow up of participants. The study team also had to temporarily stop the use of the carbon-monoxide monitors due to concerns about potential aerosolisation of COVID-19 virus particles during use. Lower than expected rates of pregnancy and pregnant women that smoke also affect the recruitment rate. SISTAQUIT was granted an extension to March 2022 to allow more time for recruitment and data collection. The sample

size target was also reduced from 450 women to 300 women. Mid-term interviews have recently been conducted by an Aboriginal research agency to enable implementation challenges to be better qualified. Learning from this study will be taken forward to other phases of the research.

### 5.3 Outputs, outcomes and impacts

The SISTAQUIT trial aimed to assess whether a multi-competent intervention is more effective than standard measures taken to help pregnant women quit smoking. To date, 20 sites have been recruited to the trial. The majority of sites are in rural and remote areas across five states/territories in Australia: Northern Territory, New South Wales, Queensland, Western Australian and Victoria. Collectively, these sites have recruited 90 women and 12 babies have been born.

Manuscripts describing the main findings of the study are yet to be published. The main outcome measure for the study will be quit smoking rates. The study will also provide insights on the challenges and barriers to implement this type of research in the Aboriginal health setting. Dr Marilyn Clarke (co-Investigator and obstetrician) explained: "There is a fear of disclosure of smoking and being seen as a bad mother and we need a new way [that is] sensitive and non-judgemental to engage women and help them to stop smoking". Dr Clarke is also part of the GACD Indigenous population working group which aims to produce a joint statement to share learnings from conducting implementation science projects in different indigenous populations and settings.

The study team has published a protocol paper on developing relevant and acceptable measures to report on respiratory illness and birth outcomes for use with Indigenous infants in the SISTAQUIT trial<sup>108</sup>. This initial protocol was developed in consultation with Indigenous multi-disciplinary experts using a modified Delphi approach. The study team also published a number of reviews including a systematic review and meta-analysis to evaluate the level of adherence to NRT and its impact on smoking cessation among participants of population-based studies and randomised clinical trials, and during pregnancy.<sup>109,110,111,112</sup> This review highlighted the strong association between the level of adherence to NRT and the success of a smoking cessation attempt. The findings will be used to inform policy makers and health care providers on the importance of addressing adherence to NRT to improve successful smoking cessation.

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<sup>108</sup> Perkes S, et al. (2020) Respiratory, birth and health economic measures for use with Indigenous Australian infants in a research trial: A modified Delphi with an Indigenous panel. *BMC Pediatrics*. 2020;20(1).

<sup>109</sup> Mersha AG, Eftekhari P, Bovill M, Tollosa DN, Gould GS. (2020) Evaluating level of adherence to nicotine replacement therapy and its impact on smoking cessation: A Protocol for systematic review and meta-analysis. *BMJ Open*. 2020;10.

<sup>110</sup> Rahman T, et al., Socioecological Mapping of Barriers and Enablers to Smoking Cessation in Indigenous Australian Women During Pregnancy and Postpartum: A Systematic Review. *Nicotine Tob Res*. 2021 24;23(6):888-899.

<sup>111</sup> Mersha AG, et al., The effectiveness of technology-based interventions for smoking cessation: An umbrella review and quality assessment of systematic reviews. *Drug Alcohol Rev*. 2021.

<sup>112</sup> Mersha, Amanual Getnet et al., Barriers and Facilitators of Adherence to Nicotine Replacement Therapy: A Systematic Review and Analysis Using the Capability, Opportunity, Motivation, and Behaviour (COM-B) Model." *International journal of environmental research and public health* vol. 17,23 8895. 30 Nov. 2020

In addition, the study team has published a systematic review on the impact of active tobacco smoke and nicotine exposure during pregnancy on infant respiratory health.<sup>113</sup>

**One of the key outcomes of the project is improved capacity of healthcare professionals to deliver effective SCC to patients.** Recruited services have provided one or two existing staff to be trained as research facilitators (e.g. training in Good Clinical Practice and research ethics) to implement the SISTAQUIT intervention and collect data. The study team has run training sessions in Sydney, Brisbane and Newcastle and holds monthly supportive group videoconference meetings for research facilitators. Joley Foster (trial coordinator and cultural liaison) explained: “my role was to support and mentor them [research facilitators] from the beginning [...] because these women have never been involved in research”. This has resulted in 118 health providers being trained.



Research findings have been presented to the Australian Society of Behavioural Health and Medicine Conference. The study team regularly attend the National Aboriginal Community Controlled Health Organisation (NACCHO) conference and National Aborigines and the Islanders Day Observance Committee (NAIDOC) Week celebration, as well as promote the World No Tobacco Day. Engagement with these activities have been a key mechanism for communicating SISAQUIT aims and promoting engagement from the Aboriginal community. The study team won an Implementation Science best

poster award at the Hunter Cancer Research Symposium and the GACD annual conference. A unique feature of SISTAQUIT's dissemination of findings will be an arts-based activity, currently in design.

#### 5.4 Potential for future impact

The study team was awarded further funding (AUS \$3.89million, 2019) from the Australian Government Department of Health for a Phase 4 study called iSISTAQUIT to recruit an additional 20 services in Australia and to develop a social media campaign. The campaign will be an important mechanism for 'getting messages directly to women' and health providers to encourage engagement with the trial. **iSISTAQUIT is part of the National Tackling Indigenous Smoking programme which aims to improve the life expectancy among Aboriginal and Torres Strait Islander peoples by reducing tobacco use.**

The team has very recently been awarded a further GACD cancer call grant (\$1.8M) for a full national scale-up (Phase 5). The trial is innovative in its design as it applies an 'adaptive' methodology which is not often used in health settings. It involves testing several different implementation strategies and scaling up the most effective one. Dr Gould explains: "It's like a horse race [...] and backing the one that streaks ahead".

**Dr Gould led an Australia-Canada Collaborative to explore the potential to adapt SISTAQUIT internationally to the Canadian First Nations context, as well as foster collaborations in Alaska and New Zealand to help pregnant Indigenous women in other countries stop smoking.** Dr

<sup>113</sup> De Queiroz Andrade E, et al. Association between active tobacco use during pregnancy and infant respiratory health: a systematic review and meta-analysis. *BMJ Open* 2020;10.



Gould is also collaborating with researchers at the University of Newcastle, Australia to explore smoking cessation in pregnancy not specific to Indigenous peoples. The SISTAQUIT team is also exploring opportunities to integrate training from SISTAQUIT into midwifery undergraduate training courses in universities and integrating with smoking Quitline centres in Australia. SISTAQUIT “in time may be available to all Indigenous pregnant women in Australia, and it's really quite exciting” acknowledges Dr Gould.<sup>114</sup>

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<sup>114</sup> <https://www.newcastle.edu.au/profile/gillian-gould> (Accessed June 2021)