­­ iSISTAQUIT (implementing Supporting Indigenous Smokers to Assist Quitting) Scale-Up in Indigenous populations of Australia

**Short title: iSISTAQUIT Scale-up**

**Version:** 3.0

**Date:** 27-11-2023

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***Resources:*** *GACD-NHMRC Funding 1.8 Million awarded. APP ID: 2009206*

***Abbreviations***

ABCD – A-ask/assess; B- brief advice; C- cessation; D- discuss psychosocial context (of smoking)

ACCHO – Aboriginal Community Controlled Health Organisation (an ACCHS)

ACCHS – Aboriginal Community Controlled Health Service

AHW – Aboriginal Health Worker

AMS- Aboriginal Medical Service

ANZCTR – Australia New Zealand Clinical Trial Registry

Baby/babies – offspring of the female participants (‘mothers’) born during participation in SISTAQUIT

Centre – an AMS, ACCHS/ACCHO or Mainstream service participating in iSISTAQUIT

Champion – research facilitator or key contact person for iSISTAQUIT scale-up at an AMS/ACCHS/Mainstream service

CI – Chief Investigator, person/s chiefly responsible for the study

CINSW – Cancer Institute NSW

CO – Carbon monoxide

COHb – Carboxyhaemoglobin, used to assess the amount of CO (carbon monoxide) in blood

cRCT- clustered Randomised Controlled Trial

Educational materials - the SISTAQUIT trial HP manual and participant flip chart and booklet

GP – general practitioner

HP – Health professional, e.g. general practitioner, nurse, midwife, Aboriginal Health Worker

HREC - Human Research Ethics Committee

ICAN QUIT in Pregnancy – Indigenous Counselling and Nicotine QUIT in Pregnancy

iSISTAQUIT - Implementation phase of the Supporting Indigenous Smokers To Assist Quitting project

Intervention – the SISTAQUIT health professional training in smoking cessation care + resources

Intervention group – centres randomised to receive the training + resources at the start of the trial

Intervention ‘later’ – centres randomised to the control group receive the Intervention at the end of the trial

LBW – low birth weight

Mothers – (pregnant) female participants enrolled in the SISTAQUIT trial

NACCHO – National Aboriginal Community Controlled Health Organisation

NBPU - National Best Practice Unit

NHMRC - National Health and Medical Research Council

NRT- nicotine replacement therapy

oNRT – oral NRT

OR – odds ratio, a measure of probability/likelihood

PBS – the Australian Pharmaceutical Benefits Scheme

Process Evaluation – an evaluation of the processes used to implement a new policy, action or method, such as the levels, rates of adoption and fidelity to a clinical intervention

RACGP – Royal Australian College of General Practitioners

RANZCOG – Royal Australian and New Zealand College of Obstetricians and Gynaecologists

RCT – randomised controlled trial

Resources – the SISTAQUIT trial HP manual and participant flip chart and booklet

SISTAQUIT® - Supporting Indigenous Smokers To Assist Quitting

Site – an AMS, ACCHS/ACCHO or Mainstream service participating in iSISTAQUIT

SCU – Southern Cross University

TIS NBPU- Tackling Indigenous Smoking National Best Practice Unit

Training – Usually refers to the iSISTAQUIT Intervention training (health professional training in culturally appropriate smoking cessation care for pregnant women)

UON- The University of Newcastle

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# Background

## History of the project

Present research builds on a multiphase research that started as community and expert panel consultations (Phase I) followed by a pilot study (ICAN QUIT in pregnancy) during Phase II. Results of phase II informed the **SISTAQUIT® (Supporting Indigenous Smokers to Assist Quitting)**1RCT (Phase III) and subsequently the iSISTAQUIT (iSQ) limited implementation project (Phase IV) on which the present study (iSISTAQUIT scale-up) is based.

Figure 1. Phase I and Phase II helped build the SISTAQUIT intervention which was tested in Phase III- the SISTAQUIT RCT.

In the **SISTAQUIT RCT**, the intervention group received the **SISTAQUIT intervention**, consisting of a) SISTAQUIT training (smoking cessation care training) for health professionals via pre-recorded webinars and PowerPoint slides delivered by an Indigenous team member,
b) an educational resource package consisting of a treatment manual and patient flipchart for health professionals, and a patient booklet for the pregnant women participants,
c) access to supplies of free oral nicotine replacement therapy (NRT) for recruited pregnant women, d) implementation support, and
e) study briefing (trial implementation training).

**SISTAQUIT®** 1 **intervention** is a sophisticated evidence-based intervention **co-designed with Indigenous communities** to improve health professionals’ provision of smoking cessation care in pregnancy. It has been shown to be a feasible, acceptable and effective intervention for Indigenous pregnant women and health professionals providing antenatal care in Aboriginal Medical Services (AMS) in multiple states in Australia.2 Control sites received usual care and resources including NRT through the Australian Government PBS and where relevant, close the gap scheme3 for Indigenous patients. Control services received the SISTAQUIT intervention and support after their last woman participant had given birth.

**iSISTAQUIT (iSQ)** was a multicentric, single armed, implementation phase of SISTAQUIT research implemented in around 40 health services. iSQ used an online version of the SISTAQUIT training. The full iSQ Intervention consisted of:

1. 14 eLearning modules that take approximately four hours to complete. The training is internet-enabled, self-paced and includes videos, text, and interactive elements,
2. Hardcopy resources i.e., a treatment manual and associated resources to aid smoking cessation care including a Patient Flipchart and patient (My Journey) booklet that includes augmented reality videos, and, NRT posters and ABCD (A—ask; B—brief advice; C—cessation; D—discuss the psychosocial context of smoking) mousepad for use within the health service,
3. Medical practice software templates based on the ABCD
4. CO breath monitors (smokerlyzers),

Services were also given the option to opt for a non-research version of iSQ (training only package), where they received only online training (14 eLearning modules) and hardcopy resources but did not have to take part in research i.e. they did not have to provide any health service or survey data. This approach was adopted to maximise the reach of iSQ training to time-poor health services.

**iSISTAQUIT scale-up** (present project) aims at doing a comprehensive scalability assessment of the iSQ intervention with the intention of scale up in around 50-100 health services Australia-wide.

## Need for the research and supporting evidence

Maternal smoking is a priority health issue for Indigenous women in Australia and a national priority under the Closing the Gap strategy.4-6 In June 2021, 46% of Indigenous regular clients who gave birth in the previous 12 months smoked at some point during pregnancy. Tobacco smoking is the leading risk factor for many cancers including: lung cancer in women (Indigenous women have double the rate of other women,7 and breast cancer from smoking during pregnancy (OR 2.7, 95% CI 1.1-6.3).8 Babies exposed in-utero to tobacco smoke are at increased risk of brain and nervous system cancers (neuroblastoma OR 1.22; 95% CI 1.04-1.44),9 childhood lymphomas (non-Hodgkin’s lymphoma OR 1.22, 95% CI = 1.03-1.45), 10 and acute lymphoblastic leukaemia (OR 1.10, 95% CI=1.02-1.19).11 Daughters are at risk from ovarian and breast cancer later in life.12 Second-hand smoke exposure in childhood increases risks of cancers of all types.13 Epigenetic mechanisms may be responsible for lifelong cancer risk of offspring, related to smoking by the mother during pregnancy.14 The first 2000 days of life sets a child’s life course on a positive or negative pathway. Over 75% of Indigenous women are motivated to quit smoking during pregnancy.15 Achieving a smoke-free pregnancy can reduce two people’s life-long cancer risks (mother and child) and have broader implications for the wider community. Economic evaluations suggest smoking cessation interventions in pregnancy offer value for money with a return on investment of 3:1 - every $1 invested saves $3 in downstream health-related costs.16, 17

Despite smoking being the critical factor that leads to a multitude of negative obstetric and birth outcomes in Indigenous babies, such as low birth weight, health services and health professionals seldom provide adequate resources and supports for smoking cessation.18 Many health professionals in Australia,18 and globally 19 still report not being sufficiently confident, optimistic or skilled to tackle the topic of smoking with all pregnant patients. GPs and obstetricians miss vital opportunities by not providing evidence based behaviour change techniques (BCTs), with only 13% prescribing Nicotine Replacement Therapy (NRT).19 System deficits have disproportionately affected Indigenous women due to multiple historical and social barriers.4 Additionally, only a small minority of AMS staff feel confident in motivating Indigenous women to quit smoking (19%) and fewer in suggesting NRT (15%).20

By health professionals supporting women to quit smoking in pregnancy, women can reduce their own risks of cancer and those of their offspring, thereby improving health and wellbeing of women, babies and helping to close the gap for future generations. Aboriginal community needs were expressed for culturally tailored resources that take into account the social and cultural determinants of health.21 Particularly in pregnancy, comprehensive smoking cessation approaches that utilize the psychological and cultural contexts of Indigenous women are required.22-24

This evidence-practice gap led us to co-develop the SISTAQUIT intervention. SISTAQUIT is one of a few Indigenous-targeted interventions to be developed to achieve scalable solutions on a national level. To our knowledge, this is the first study to examine optimal implementation and sustainability strategies and relevant means of evaluation for scale up for an Indigenous-targeted intervention. There is a great need to advance Indigenous implementation science by the use of innovative methodologies, recognising that meaningful strategies may need to take into account a collectivist worldview.

## Expected benefits of the study

This innovative research, using a multi-component intervention, aims to practically apply and integrate what is already known into a highly translatable approach in real-world primary care settings in AMS and Mainstream services. The research benefits Aboriginal women, babies and their family and community members through improved support for smoking cessation during pregnancy. Babies born to women who quit smoking have reduced complications and life-long benefits. Improvements to maternal and infant health through smoking cessation generate a relatively high return on investment realised through better quality of life, reduced toxic exposure, reduced morbidity and mortality, and increased family income.25 This study is low risk and has a high level of integrity. The intervention is based on accepted Australian and international smoking cessation guidelines, developed, and delivered in a culturally appropriate approach for Aboriginal communities. Benefits also extend to the staff participating in the research, through targeted training and support to implement this innovative approach.

# Aim and objectives

## Aim

To determine the best evidenced based co-designed and culturally appropriate implementation methods for iSISTAQUIT that is sustainable and cost-effective for national scale up.

## Objectives

* 1. To identify implementation and feasibility factors relating to all potential scale up aspects, including fidelity and adaptations, reach and acceptability, and implementation infrastructure and training. This will be done by conducting a comprehensive scalability assessment of iSISTAQUIT;
	2. Design three to five most appropriate context-relevant implementation and sustainability strategies and means of evaluation for iSISTAQUIT
	3. Implement iSQ intervention in health services using a preferential-adaptive trial design. This will be achieved by engaging/recruiting health services to adopt and implement iSISTAQUIT using the implementation strategies designed during objective 2 or their own implementation strategies
	4. Evaluate implementation strategies. Evaluation using RE-AIM framework to determine predictors of reach, effectiveness, adoption, implementation and maintenance.
	5. Assess the research impact of iSQ scale-up. Conduct a comprehensive mixed methods evaluation of the SISTAQUIT national scale-up using the Framework to Assess the Impact of Translational Research (FAIT) tool
	6. Identify and understand the broader context and factors related to implementation of iSQ. This will be achieved by retrospective analysis of the contextual factors associated with iSISTAQUIT scale-up success.

# Project design

## Project setting

The core project team will be based at the Southern Cross University, Coffs Harbour, New South Wales. Study will be conducted at 50-100 health services (henceforth referred to as sites) including Aboriginal Medical Services (AMS’s), General practitioners’(GP) practices, Public hospitals, dental practices, pharmacies and midwifery practices distributed across Australia. Majority of qualitative data collection (Interviews, focus groups, etc) will be conducted through an audio-visual telecommunication software like Zoom due COVID-19 impacts on face-to-face contact, geographic distance with the participants and to reduce carbon emissions generated during automobile and air travel.

## Methodology

### Stage 1: Conduct a comprehensive scalability assessment of SISTAQUIT

Stage 1 of iSQ scale-up aims to identify relevant factors for scale up, particularly the barriers and facilitators to design and, identify different iSQ implementation and quality improvement strategies that are most appropriate for different health systems and contexts in Australia for Aboriginal and Torres Strait Islander smoking cessation during pregnancy.

**Objectives of Stage 1:** This stage aims at exploring and obtaining in-depth knowledge about the following:

* + Organisational readiness to implement/scale up
	+ health service/professional learning needs
	+ community, political and managerial support, and administrative structures.
	+ Existing resources and resources needed
	+ Adaptations required to the implementation, intervention or the research
	+ Barriers and facilitators to health professionals completing iSISTAQUIT training and implementing it in their practice.
	+ Factors associated with sustainability and feasibility of providing iSISTAQUIT training through the Australian health system
	+ Comprehensive costing and factors associated with FAIT
	+ Feasibility and acceptability of health services and health professionals engaging in research
	+ Consensus on what constitutes feasible research process and minimum data for health service research within the Aboriginal health services.

**This stage will use data from 3 sub-studies and an existing dataset from iSISTAQUIT study:**

1. A systematic review
2. Delphi study
3. Qualitative interviews of stakeholders
4. Data collected during end of study interviews of iSISTAQUIT study (under another ethics application)
5. **Systematic review of research evidence** (i.e. a review of the literature of implementation strategies for successful adoption of public and primary health interventions and health services/professionals training in Indigenous settings)
Online scientific databases (such as Pubmed, CINAHL, Psychinfo, EMBASE, etc.) and grey literature will be searched for relevant literature related to implementation research in Indigenous contexts. Policy and government documents will also be retrieved through Google searches. Selection criteria will be decided a priori. Study selection will be done by at least two researchers. Data will be extracted and analysed followed by summarising of evidence.
6. **Delphi study** on achieving consensus for a feasible research process and minimum data set for health services. As the research is an integral part of the project, this project has an additional influence on low impact data collection, using a minimum data set, so that the research has a low likelihood of interfering with the implementation strategies. Delphi process will be used to develop a consensus on a minimum data set suitable for health services research related to smoking in pregnancy, and guidance for research methodologies suitable for implementation and continuous quality improvement in the relevant settings. Delphi techniques are structured group communication processes for complex issues where knowledge is uncertain and incomplete and are evaluated by experts using an iterative process. **Participants:** For this study, a diverse panel of 30-50 experts will be selected to achieve a broader perspective and generalization of consensus on research methodologies, minimum data set and implementation strategies.

Participants for the Delphi process will be derived from the following sampling frame of potential stakeholders:

* Health services representatives: Managers, team leaders, CEOs of health programs, e.g TIS
* iSISTAQUIT National Aboriginal and Torres Strait Islander Advisory Committee members, Academic and Social panels.
* Peak organisations representatives: CEOs/directors/chairpersons of NACCHO, Institute of Urban Indigenous Health, Tackling Indigenous Smoking (TIS), Queensland Aboriginal and Islander Health Council, AH&MRC, professional organisations such as NATSIAHW, RANZCOG and RACGP, etc. Other organisations will be included as and when opportunity arises.
* Health professionals: Health practitioners affiliated with Aboriginal Medical Services and mainstream services who have taken part in previous phases of the study and iSISTAQUIT, GP practitioners, dentists, pharmacists, midwives, obstetricians, nurse practitioners who work with pregnant Aboriginal women. Existing contacts with AMS’s and iSQ scale-up team members and CIs’ contacts will be utilized for recruitment. Health services/professionals may also be recruited through online channels such as social media announcements, newsletters and invites posted on iSISTAQUIT website.
* Researchers: Australian researchers working in the domain of smoking in pregnancy and Aboriginal People. Existing contacts and Google searches will be used to identify potential participants.
* Statisticians and health economists who have experience working in Aboriginal health.

**Data collection:** A two round Delphi process including an initial **qualitative round and a final quantitative survey** to establish consensus will be conducted. The qualitative round will consist of open-ended explorative interviews with the selected panel members (purposive sampling). Please see appendix for the semi-structured questionnaire. Interviews will be analysed with the aim to identify common themes among the expert opinions. These **results from the interview will inform a short survey** to calculate the proportion of experts who support each strategy identified during the first round.

1. **Qualitative study:**

We will interview a range of stakeholders including health professionals, health services staff members, managers, CEOs, and research team members involved in iSQ and SQ. Additionally we will interview health services that were interested in SQ and iSQ but did not participate, services making enquiries about future participation, policy makers (e.g. NACCHO, Cancer Councils, NHMRC), and community members. The qualitative study data collection will be done through an iterative process i.e., after collecting data from the first few participants, an interim analysis will be conducted, which will inform changes (if any) in the interview guide for any further data collection.

1. **Qualitative data from end of study interviews** of SQ and iSQ: We will utilise data from end of study interviews with end users (health services and health professionals) of iSQ, SQ and other Indigenous health network. The ethics for the SQ and iSQ end of study interviews are under ethics applications 2021/147 and 2021/133

**Stage 1 Recruitment, recruitment strategy and time frames:** Systematic review does not require any human participant recruitment. Recruitment for Delphi and qualitative study will be done through our existing networks of health services (existing and new services that have shown interest), iSQ Aboriginal advisory and academic committee members, relevant policy makers, community leaders, health professionals, health service staff members. Delphi will recruit 30-50 experts. Data from the qualitative study and the SQ/iSQ end of study interviews will be derived from a total of 100-120 stakeholders. The potential participants for Qualitative interviews and Delphi study will be contacted verbally, in person or via email to participate in the research. The interviews and consultations (for both Delphi and qualitative study) will be conducted in-person, phone or via videoconference such as Zoom.

**Time frames**: Data collection for Stage 1 is expected to be completed by July 2023.

### Stage 2: Design context-relevant implementation and sustainability strategies for iSISTAQUIT

This stage aims to identify and design iSQ implementation strategies informed by the results of Stage 1

**Methods:** The process of designing different implementation strategies will be informed by Stage 1 results. We will prioritise evidence based, highly context-relevant strategies for health professionals and services that are likely to improve project feasibility, local adoption into routine care, fidelity, sustainability, and maximize effectiveness.
The design process will chiefly be undertaken by the project design committee (Gillian Gould, Brian Oldenburg, Ratika Kumar, Rebecca Hyland, Chris Oldmeadow, Chris Doran) during two Zoom workshops. However, all iSQ CIs, iSQ team members, iSQ academic panel, iSQ Indigenous advisory panel members and willing participants of Stage 1 will be invited to these workshops and encouraged to take active part in brainstorming five different implementation strategies that are likely to be most successful when evaluated using the RE-AIM framework.
Workshop participants will first be presented with results obtained from stage 1 and five prototype implementation strategies designed by the iSISTAQUIT core team (Gillian Gould, Ratika Kumar, Rebecca Hyland). Workshop participants will then be invited to comment and discuss the prototypes. They will be free to accept, modify or totally reject a prototype. They will also be encouraged to introduce new ideas not presented by the team. Pros and cons of each strategy will be discussed. Ideas will be voted on by ballot and the 3-5 top strategies will be finalised to be used in Stage 3. Results of the Delphi process for the most suitable research process will also be presented and considered.

### Stage 3: Health service engagement and rolling out iSQ within a preferential-adaptive trial model Australia-wide

The main research activity conducted during this stage is engagement and recruitment of health services and health professionals in the project followed by implementation of the iSQ training in the recruited service. To this end, a three-phased approach to recruitment and implementation will be undertaken. Health services and practices will be considered eligible to participate if they provide health services to pregnant Aboriginal and Torres Strait Islander women.

**Phase 1: Health professional/service engagement:** Several engagement strategies will be utilised to recruit health services and health practitioners into the study.

**Indigenous sites** will be engaged and recruited through several approaches including online (such as social media, newsletters and iSISTAQUIT website, online dashboard) and offline channels. A list of all existing Aboriginal medical and health services will be prepared and approached by accessing search function on the National Aboriginal Community Controlled Health Organisation (NACCHO) website: [NACCHO Map - NACCHO](https://www.naccho.org.au/naccho-map/). We will also use our extensive network of Aboriginal Medical services created during the SISTAQUIT and iSISTAQUIT studies. Services that showed interest during the iSISTAQUIT study but were not recruited, will be contacted to gauge their interest in the scale-up.

**Mainstream sites -** we will ask our AMS/TIS networks to propose Mainstream sites that see a high volume of Indigenous pregnant women. We will also advertise in the media, and health professional newspapers and newsletters. To maximise engagement and recruitment, we will contact services and health professionals through our robust existing networks, including partnering professional colleges, professional societies and peak organisations e.g. APSAD, RANZCOG, Australian Medical Association, Australian Dental Association and our networks of chief and associate investigators to maximise recruitment and build on relationships.

For both type of recruitments, we will opportunistically promote the implementation via conferences, etc, for example the Lowitja Conference, NACCHO conference and GP20. We will also reach out to potential participants through community events like NAIDOC week, conferences, trade tables at events and conference and social media advertisements.

The scope of Mainstream services will include:

1. General Practices
2. Mainstream antenatal services (usually run by Local Health Districts or similar)
3. Aboriginal antenatal services
4. Obstetric practices
5. Dental practices
6. Pharmacies
7. Midwifery practices

The contact will be made via phone or email. Interested services will be followed up with PICF and agreements. Process may take several rounds of conversations with CEOs and management.

Health professionals will be recruited through the services as well as other online and offline approaches. For example, health practitioners recruited will include those affiliated with Aboriginal Medical Services and mainstream services, GP practitioners, dentists, pharmacists, midwives, obstetricians, nurse practitioners who work with pregnant Aboriginal women and other health professionals. Health practitioners may also be recruited through online channels such as social media announcements, newsletters and invites posted on iSISTAQUIT website. Inducements for undergoing training will include Professional Development points (PPD) and provision of unique iSISTAQUIT practice software apps and templates (if health service selects implementation option 2, Table 1).

Another strategy that will be explored will be short, lay language video explaining the aims, methods and role of the services in the scale-up designed in consultation with the iSQ national panel, CI’s and the social media panel. This video will be distributed among the target sampling frame i.e. Aboriginal and general health services including private practices (e.g. GPs, dentists, Obstetricians, midwives), public hospitals and pharmacies with the aim of inviting expressions of interest to participate in the research. It will be also available to the general public on the iSISTAQUIT website and via its social media platforms.
**Phase 2: Health professional/service consultation:** Services/HPs that express interest during Phase 1 will be sent more detailed information about the study via email and invited to a Zoom meeting with one or more of the core team members (Rebecca Hyland, Karen McFadyen, Gillian Gould, Nicole Ryan). The study process will be explained to the representatives/s in detail especially what the research requires of them in terms of time and personnel commitments, organisational consent and ethics processes. Services will be offered to take up the core intervention (iSISTAQUIT) and informed about different partnership packages/implementation strategies (Table 1 ) they can use to improve health professional engagement and adoption of iSISTAQUIT in their service. Implementation strategies are methods or actions that aim to overcome implementation barriers, increase the pace and effectiveness of implementation, and sustain interventions over time. Health services will be free to take up or reject the strategies offered. The core team can assist the services in finalising their implementation strategy.

An **interim analysis** about effectiveness of implementation strategies will be completed 2 years from the recruitment of first service. Implementation strategies that are ineffective in producing desired implementation of the iSQ training will no longer be offered to the services recruited subsequently (subsequent to results of the interim analysis). Please see Stage 4 for more details.

**Phase 3: Implementation:** The core intervention (Option 1: iSQ standard package, Table 1) will be made available to the health services along with implementation support as mutually decided upon by the health services and the research team.

**iSQ standard package (core intervention)**: iSISTAQUIT training consists of 15 e-Learning modules which take approximately four hours to complete. The training is internet-enabled and self-paced and includes videos, text, and interactive elements, supported by hardcopy resources i.e., the treatment manual and patient flipchart for HP’s and the My Journey (patient booklet), which includes augmented reality videos to aid smoking cessation care and iSISTAQUIT mobile phone App for interactive weekly support of pregnant women. The iSISTAQUIT e-Learning is designed to use the Eight Aboriginal Ways of Learning, is self-paced and accredited for professional development points with several professional colleges. 26 The Eight Aboriginal Ways of Learning involves using an Aboriginal pedagogy (such as story sharing, community links and symbols and images) and is congruent with the Australian Health Practitioner Regulation Agency (AHPRA) framework for cultural safe practice by HP's.26, 27

All participating services will implement the iSISTAQUIT training package using implementation strategies that are most suitable to them (Table 1, Figure 2).

|  |
| --- |
| Table 1. Implementation strategy options |
| **Implementation Strategy:**  | **Option 1: Standard Package (online training with PDP + resources + support + networks)** |  | **Option 2: Standard Package + Adaption of resources to local context** | **Option 3: Standard Package + Hybrid Training model** |  |
| Health Service/HP commitments |
| Surveys to complete  | Pre- and immediate post-training HP surveys. 1- and 3-month implementation question |
| Data collection | 6 monthly health service nKPI’s |  | 6 monthly health service nKPI’s | 6 monthly health service nKPI’s |  |
| HP and other health service staff mid-study and end-study implementation interviews. |  | HP and other health service staff mid-study and end-study implementation interviews. | HP and other health service staff mid-study and end-study implementation interviews. |  |
| iSQ ABCD software template |  | iSQ ABCD software template | iSQ ABCD software template |  |
|  |  |  |  |  |  |
| Resources  | iSQ Treatment Manual, Patient Flipchart, ‘My Journey’ patient booklet, NRT and vaping posters, ABCD mousepad, social media package, iSISTAQUIT mobile phone App |
| Support and networks | iSQ Community of Practice (CoP) membership, iSQ newsletter, ongoing iSQ research team support. |

Figure 2. Partnership packages (implementation options) diagram

**Sample size calculation:** A minimum of 18 health services in each of the 3 implementation strategies, each with an average of 3 professionals per practice, with primary outcome success probabilities ranging between 40% and 70% will enable detection of the best implementation strategy with 80% probability (estimated through simulation). This is however a pragmatic adaptive trial and organically the best implementation strategy may be determined by health service preference for a particular implementation option.

### Stage 4: Evaluate scale-up using the RE-AIM framework.[[1]](#footnote-2)

The core outcome measures (the minimum data) will be broadly based on the RE-AIM Framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) and finalised during the Delphi process in Stage 1.  **The primary outcome measure will be Implementation.**

**Adoption** will be measured by cross-sectional audit at 6 monthly intervals from start of recruitment including once at the end of the project. It will comprise of a) participation rate of services and health professionals in the study AND b) completion of training by health professionals with respect to different implementation strategies.

**Reach** will be calculated at the end of the project by calculating the absolute number of the health services and health professionals who showed interest and participated in the present project.

**Effectiveness** will be measured by change in smoking cessation knowledge, attitudes and practice of the health professionals pre and immediately post training, as well as 6 months and 1-year post training.

**Implementation (primary outcome measure)** is defined as a composite outcome of the following three events:

1) Completion of training, AND

2) Participation in or receipt of the implementation strategy, AND

3) Intervention components being used by the health service on at least 50% of eligible occasions of service

Evidence of intervention components being used will comprise a) self-reported occasion of service offer about smoking cessation by the health professional to a pregnant woman and/or b) demonstration of use of the ABCD template and/or c) provision of the ‘My Journey Booklet’ to a pregnant woman and/or d) NRT supplied to a pregnant woman.

1. Periodic (every three months) check-in (via telephone and email) with health services to identify any barriers in implementing the training, kept in project implementation log. Documentary evidence from supportive outreach calls, emails and videoconferences with services will be analysed qualitatively at the end of the study.
2. Stakeholder feedback will be examined during stage 6 via the contextual factor analysis.
3. Percentage of health professionals using the iSISTAQUIT components and engaging women in smoking cessation care assessed through data extracted from the iSISTAQUIT ABCD software template (e.g. Pen CS or Communicare)
4. Service level data or national KPI’s on pre vs. post trends for pregnant women seen, number of women smoking and NRT scripts written and My Journey booklet
5. Cost of delivering interventions to sites

**Maintenance** will be measured at health professional and service levels, using qualitative methods. We will explore topics such as sites’ intent to maintain the program long term, and health professionals’ interest in using iSISTAQUIT study learnings and resources long term. The qualitative data will be collected during Stage 6 contextual factor analysis interviews.

**Additional measures:** Useability: User metrics data from the eLearning modules analysed for all modules completed, and scores of user assessment tasks. Fidelity measures via data related to the ABCD approach through the practice software templates.

**Statistical analysis:** A Bayesian framework will be used to determine which implementation strategy is the best to roll out. The posterior probability of the primary outcome success probability will be estimated as a Beta-Binomial distribution, with a binomial likelihood for the number of successful events under each strategy, and a Beta (1,1) prior distribution for the success probability (corresponding to an uninformative prior). The implementation strategy with the greatest mean posterior success probability will be chosen as the best.

**Interim analysis**

An interim analysis about the effectiveness of implementation strategies will be completed 2 years from the recruitment of the first service. Implementation strategies that are ineffective in producing desired adoption of the iSISTAQUIT training will no longer be offered to the services recruited subsequently (i.e. subsequent to results of the interim analysis). The posterior probability that the proportion of professionals successfully adopting iSISTAQUIT under that implementation strategy is greater than 0.5, if this is lower than 10% then the implementation strategy will be considered to be ceased for recruiting. The primary outcome measure of the interim analysis will be Implementation measures assessed via a practice domain of the health professional surveys. HPs from all services who have completed at least 3 months in the study at the time of interim analysis, will be included in this assessment. Included services will be sent a short survey consisting of only the practice domain of the 1- and 3- health professional survey. An acceptable implementation would be defined as 50% of health professionals in a service answering “Yes to the survey question/s on implementation.

Implementation Strategy will be deemed to score poorly on the primary outcome measure of implementation i.e. if more than 50% of HPs in the service using that strategy answer “No” to the survey question/s on implementation. Poor performance on the survey will trigger a wider investigation into the implementation outcomes for that service via site logs, check-ins with service staff and implementation measures collected through practice software (if available). The implementation strategy used by that service will be discussed among the investigators and advisory board members and assessed holistically looking at the other outcome data related to that strategy and service. This will be followed by a ballot in favour or against the strategy. If the strategy is voted out, it will no longer be included in the list of implementation strategies offered to services. If a future service still wants to use the excluded strategy, they will be explained the shortcomings of the strategy and that we no longer provide support for implementing the strategy. The service would still be welcome to use the core iSQ intervention but without the implementation support from the iSQ team. For example, we will no longer provide support for audit and feedback (an implementation strategy) if it’s found to perform poorly on implementation measures. If none of the implementation strategies perform = or better than 50%, then the implementation strategies will be ranked and the 2 best performing strategies will be carried forward for future services enrolling.

### Stage 5: Impact assessment using Framework to Assess the Impact of Translational Research (FAIT)

An impact assessment will be undertaken using the Framework to Assess the Impact from Translational health research (FAIT). FAIT is a novel framework specifically developed by members of the project team to encourage research translation and measure and report on research impact in a multi-dimensional way. FAIT employs a combination of three integrated but separate proven impact assessment methods: quantified metrics (a modified form of Payback); economic assessment using a social return on investment (SROI); and narratives of the process as the research translates and generates impact. The assessment methods are underpinned by a modified program logic model.

**Modified program logic model**

The logic model identifies:

* the demand being addressed by the research program;
* the aims of the research program;
* the research activities being supplied to meet the ‘demand’;
* the expected research outputs;
* the stakeholders (including end users) of those research outputs;
* the anticipated intermediate and final impacts when end users use the research outputs.

The logic model emphasises the involvement of end users from the start and links in with planned stage 1-3 activities.

Figure 3: Program Logic Map for iSISTAQUIT Scale-Up



**Modified payback**: The modified payback framework is based on domains of benefit relevant to the research project such as advancement of knowledge, capacity building, clinical implementation, legislation and policy and economic benefit. Engagement with stakeholders will identify the relevant domains of benefit, metrics to measure change and appropriate outputs / outcomes. Table X below provides an initial consideration of potential impact indicators associated with each of these domains of benefit.

Table 2: Modified payback domains of benefit and metrics.

|  |  |
| --- | --- |
| Domains of benefit  | Metrics  |
| Advance knowledge | * Peer reviewed publications
* Minimum data set for a feasible research process in health services
 |
| Capacity building  | * Knowledge and capability of workforce
* Academic qualifications
 |
| Clinical implementation  | * Change in practice as a result of the intervention
* Change in patient behaviours
 |
| Engagement and networking  | Establishing dialogue with and recruitment of Aboriginal health services, public hospitals and GP practicesEngagement with stakeholders (service staff, health professionals, policy makers and community members) throughout the study Engagement with study advisory panelsSocial media engagement  |
| Economic impact  | * Health system savings
* New research funding
* Current and future income of staff associated with the project
 |
| Policy  | * Changes in policy at service, state and/ or national level.
 |

**Economic analysis:** Out of the suite of potential economic evaluation techniques, cost-benefit analysis (CBA) is the most appropriate tool for impact assessment. The reportable metric of CBA is a ratio of benefit per dollar of cost, or a ‘return on investment’. Where a CBA is not viable, a cost-consequence analysis may be used.

**Table 3:** Economic impact analysis

|  |  |  |
| --- | --- | --- |
| **Cost Benefit analysis**  | **Metric**  | **Output/outcome**  |
| Cost of resource use associated with intervention implementation  | Cost of implementation of each activity of intervention  | e.g. cost of training, cost of training per health professional, cost of materials / software, cost of NRTs  |
| Benefits converted to AUD | Economic benefit of deploying the intervention  | Monetary value of benefits / impacts of intervention  |

**Narratives**

The third aspect of FAIT is the use of narratives to provide the story behind the stats and in particular of how research impact has been generated during intervention implementation. The narratives will be collected during stage 6 of the research, supported by evidence from the modified payback and CBA. This Please refer to stage 6 for details.

### Stage 6: Contextual factor analysis

This stage will retrospectively analyse contextual factors related to the implementation and scale up of iSISTAQUIT. The aim of this stage is to gain an in-depth understanding of factors associated with successful implementation of the iSISTAQUIT intervention including those at individual, community, service, local and national or state levels. We will base the methodology of this research stage on a multi-layered context framework inspired by Taplin et al.,28 which was developed for implementation research involving cancer.



Contextual factor analysis will be informed by the rich data and knowledge acquired by the research team during the conduct of this research across all of its stages. The key researchers involved in the research will reflect on the qualitative and quantitative data (stages 1-4) collected during the study, notes from advisory meetings, call logs and health economic analysis, to map their learnings using a multilevel framework described by Taplin et al.28 The levels include:

* Individual/family level
* Community level
* healthcare setting level
* Local/district level
* National or state level

**Recruitment and data collection:** To clarify and confirm our concept map, triangulation of findings will be done via qualitative data collection in form of virtual or face to face interviews using a semi-structured interview guide (informed by the researcher reflections and data gaps hence identified) with embedded short survey/s. This data collection will also focus on assessing the impact of the research and explore FAIT domains of benefits such as advances in researcher and participant knowledge, effectiveness of implementation, extent of implementation and adoption, benefits to the community and perceptions about economic benefits. Data will be transcribed verbatim and analysed using framework analysis. The sample (n~30) would be derived from a sampling frame of representatives from families, Community members, healthcare personnel (service staff and health professionals and Local/district and National or state level policy makers.

### Communication of protocol amendments

Any protocol changes will be decided by consensus of the Chief Investigator and her Advisory Panels communicated to each of the health services through their CEOs, with explanations for the reasons the changes were needed. Any protocol changes will also be notified and authorised by all HRECs.

### Consent

Written informed consent will be obtained from all participants and organisations before recruiting them into the study. Any participant as well as any participating centre may withdraw from the study at any time. There will be a gap of at least 1 week between signing of consent form and the data collection. All participant information sheets (PIS) and consent forms will be submitted and approved by the ethics committees before being used in the study. All participants will be allowed as much time as they need to consider providing consent. All participating sites and participants will have access to researcher details along with contact details of the research team and ethics committee in case they need clarification on any aspect of the research.

Services, health professionals, stakeholders, experts and policy makers taking part in the Stage 1 and 6 qualitative study, will be contacted either by email or by phone in the first instance. They will be explained about the study in detail as well as what will be required of them during the data collection. The PIS and consent form will be preferably online via the iSISTAQUIT Dashboard or via email attachment for sign off and return.

Health services will be informed of the study design, time and resource commitments and other details about participation in the initial contacts which will include information sheets and group meetings as necessary. A health service/organisational consent will be available for sign-off through the Dashboard or sent to the services for signatures after receiving verbal consent from their representatives. Services will be free to withdraw from the study at any time.

Health professionals taking part in the iSISTAQUIT online training will be able to view the PIS and sign the consent form and/or click an Agree to consent tab through the online training platform (Moodle) after reading the PIS and definition of Agreeing before starting their training online. Associated statement for selecting the Agree tab will be: "By clicking on the Agree tab you are acknowledging that you have read the Participant Information Sheet (PIS) and Consent Form and are consenting to participate in the iSISTAQUIT Scale-Up study where you will complete pre- and post- training surveys associated with the iSISTAQUIT online training and the deidentified data from those surveys will be used for research purposes.”

If requested, we will provide a paper PIS and consent form.

**Reimbursements:** All participants taking part in the qualitative studies (Stage 1 and 6) will be paid $50 for their time.

Health professionals will not be paid for doing the training. They will be offered professional development points as an inducement for completing the training and surveys.

Services will be paid $2000 to help with any associated costs resulting from uptake of options 2 or 3 from the implementation/partnership packages.

Advisory panels consisting of Indigenous and non-Indigenous workforce, health practitioners and other stakeholders will be convened to advise on various stages of the project. This is an important gesture for reciprocity for their panel members’ time and intellectual investment. Honorarium will be paid to the members at the rate of $50 per meeting. We are expecting to have 10 members in this committee which will be convened at least 4 times each year.

# Data management

## Data storage

All participating study sites will be asked to nominate at least two staff members as champions or key contact persons. The champions will be responsible for entering information into the iSISTAQUIT Dashboard such as (list of participating HPs to enable membership to the Dashboard and access to weblinks for the training and iSISTAQUIT webpage, site nKPIs on smoking and baby birthweight, dispensed/prescribed NRT and ordering of resources such as the My Journey booklets)and communications with the iSISTAQUIT team. The Dashboard will be only accessible via password and associated data will be stored securely on the Southern Cross University iSISTAQUIT server. All on-line survey data (e.g. health professional surveys, surveys during Delphi) will also be stored in the password protected iSISTAQUIT server within the Southern Cross University network. Qualitative data collected during the study will be recorded and transcribed professionally. Data will be de-identified and stored in a password protected database. Only authorised personnel named on the ethics application will have access to the data. Only the AMS/Mainstream practice authorised staff will have access to identified data of pregnant women and their babies.

### Ethical issues relevant to data management

Australian National Health and Medical Research Council ethical guidelines for research, including Aboriginal and Torres Strait Islander research, will be followed, consistent with the Declaration of Helsinki. Appropriate community consultation is in-built in the study (stage 1).

The iSISTAQUIT- scale-up Aboriginal Advisory Panel will include members of the representative services and consumers. Organisational consent will be obtained from each service after full disclosure of the project plan through a detailed information sheet and group meetings as necessary.

Pregnant women will not be individually recruited to this study. De-identified grouped data will be collected via the software templates. nKPI data on smoking and baby birthweight as reported by health services to the Department of Health and Aged Care biannually will be requested and collected in the iSISTAQUIT Dashboard. Number of NRT prescriptions for same time period will also be entered by the health service nominated champion. A summary on the total number of outcomes per month (i.e. total number of women engaged, number of women followed up, number of women that quit smoking, among others) may also be collected by the nominated champion for reporting to iSISTAQUIT. It is likely that similar de-identified data will be picked up the PenCS iSISTAQUIT Topbar app or Communicare iSISTAQUIT clinical item quarterly reports.

The iSISTAQUIT Aboriginal Advisory Panel will advise on analyses of data and reporting of results to ensure these processes are culturally sensitive and align with the principles of reciprocity, respect, equality, responsibility, and survival and protection.

**Privacy**

The project will be conducted in accordance with applicable Privacy Acts and Regulations. All information regarding participants must be treated in strict confidence. Only aggregated data will be used in the publications. Only de-identified transcripts will be utilised during analysis of the interview-based data collected for the study. If identifying information is revealed during an interview or focus group, the identifying information will be removed prior to analysis and publication.

## Data analysis

Suitable qualitative and quantitative data analysis techniques will be used throughout the project. Please refer to the table below for the evaluation plan:

|  |  |  |
| --- | --- | --- |
|  | Study  | Analysis and outcome measures  |
| Stage 1 | Systematic review | Meta-analysis or synthesis/summarising of findings as appropriate. Outcomes: Most suitable implementation strategy/gies in Indigenous/Aboriginal healthcare settings. |
|  | Delphi -part 1-Qualitative  | Inductive and deductive approach for qualitative data. Outcome: With reference to the Aboriginal health settings, minimum dataset requirements, facilitators and barriers to collecting data and any other significant finding to inform the study aim.  |
|  | Delphi -part 2- Survey  | Descriptive and inferential statistical methods for quantitative dataOutcome: Consensus on what constitutes feasible research process and minimum data set for health service research related to smoking cessation within the Aboriginal health services. |
|  | Qualitative interviews/focus groups with health services, managers, policy makers, community members etc.  | Inductive and deductive analysis Outcomes: * + Organisational readiness to implement/scale up
	+ health professional learning and training needs
	+ community, political and managerial support, and administrative structures.
	+ Existing resources and resources needed
	+ Adaptations required to the implementation, intervention or the research
	+ Barriers and facilitators to health professionals completing iSISTAQUIT training and implementing it in their practice.
	+ Factors associated with sustainability and feasibility of providing iSISTAQUIT training through the Australian health system
 |
| Stage 2 | Core design committee workshop for designing of implementation strategies  | Discussion and ballot Outcome: Identification of top implementation strategies to be offered to health services  |
| Stage 3 | Recruitment and implementation of iSQ in the health services  | No analysis required  |
| Stage 4  | Evaluation  | **Reach: calculated at the end of the study** Descriptive analysis**Outcomes:** * Total number of health services who showed interest in participating but did not participate + total number of health services who participated in the project
* Total number of health professionals who started the training + total number of health professionals who completed the training
* Reasons for participating and not participating obtained through qualitative data collection in Stage 6 contextual factor analysis
 |
|  |  | **Effectiveness:****Descriptive and inferential statistics** will be used to calculate any changes in knowledge, attitude and practice domains as well as predictors of these changes with respect to health service and professional characteristics. **Outcomes:** * change in smoking cessation knowledge, attitudes and practice of the health professionals. A survey with questions about HP’s knowledge, attitude and practice related to smoking cessation practice will be administered to all health professionals who register to complete the training at baseline (before starting iSQ training). Same survey will be administered immediately after they complete the training and a one to two question implementation survey will be administered 1- and 3- months post training.
 |
|  |  | **Adoption:** (calculated every 6 months from start of recruitment and once at the end of the recruitment (July 2025) i.e. 6 months before end of funding.)**Descriptive and inferential statistics**Outcomes: * No. of services that sign on participation agreement ÷ Total services approached
* Number of health professionals who start the training ÷ total health professionals in the recruited services
* Number of health professionals who complete the training ÷ total health professionals who start the training
* Average amount of NRT dispensed by services
* Average number of My journey booklets dispensed by services
 |
|  |  | **Implementation:** Multidimensional assessment of how well an intervention was delivered, adaptations made, cost of delivery and stakeholder feedback on the process of implementation. **Outcomes:** * Practice domain of the health professional survey assessed at 1-, 3- months post recruitment. An interim analysis will be conducted 2 years post recruitment of the first service to assess if an implementation strategy is performing poorly and not producing desired implementation.
* Proportion of health professionals who answer “often” or “Always” to smoking cessation practice related questions
* Barriers and facilitators: Project staff will check in with services every 3 months from recruitment to provide support if needed and troubleshoot any difficulties experienced by the services in implementation. The interaction will be recorded in call logs and analysed qualitatively at the end of the study to identify common themes of barriers and facilitators for the study.
* Contextual factors: Stakeholder feedback about implementation: Contextual factor analysis during stage 6 would include interviews with services and health professionals about their experiences of implementation of the iSQ intervention. The interviews will be analysed inductively and deductively to identify themes of interest.
* Percentage of health professionals implementing iSQ training. This data will be obtained from the ABCD software templates or through site logs maintained by the services.
* Health professionals who use at least one component of ABCD template ÷ health professionals who complete the training x 100

Health professionals who use “A” component of the template ÷ health professionals who complete the training x 100* Health professionals who use “B” component of the template ÷ health professionals who complete the training x 100
* Health professionals who use “C” component of the template ÷ health professionals who complete the training x 100
* Health professionals who use “D” component of the template ÷ health professionals who complete the training x 100
* Health professionals who use all “ABCD” components of the template ÷ health professionals who complete the training x 100
* Pregnant women’s receipt of My journey booklet and NRT: This data will be obtained from site logs maintained by the services.
* Total number of My journey booklets given to the women ÷ total number of my Journey booklets sent to the service x 100
* Service level data on pre vs. post trends for pregnant women seen, number of women smoking and NRT scripts written. This data is subject to services agreeing to provide this data at the end of the participation.
* Cost of delivering intervention to sites: this calculation will be undertaken using appropriate health economics methods.
 |
|  |  | **Maintenance**: maintenance of an intervention occurs at two levels: maintenance of individual-level of effects of an intervention (i.e., long-term effectiveness), and maintenance of the intervention at the setting-level (i.e., long-term implementation)Maintenance will be measured at health professional and service levels, using qualitative methods. The qualitative data will be collected during Stage 6 contextual factor analysis interviews and regular call logs. Outcomes: We will explore topics such as sites’ intent to maintain the program long term, and health professionals’ interest in using iSQ study learnings and resources long term.  |
| Stage 5 | Impact assessment using Framework to Assess the Impact of Translational Research (FAIT) | A holistic impact assessment as detailed in Stage 4. The data collected during stages 1-4 and Stage 6 will inform the impact.  |
| Stage 6 | Contextual factor analysis  | Conceptual framework detailing the contextual factors associated with successful implementation of iSQ scale-up project. The main output would be a guideline/policy brief on conducting successful implementation research in Aboriginal settings in Australia.  |

# Knowledge translation and dissemination

Study results will be communicated to:

• Health Service Participants

• Communities

• The public

• Health professionals

• Scientific/medical community

• Policy makers

Research outputs will include:

1. **Publications:** This research will generate high quality publications for peer-reviewed journals. These will centre on the protocol and results from stages 1-6 of the study.
2. **Conferences:** The findings will be presented at State, National or International conferences.
3. **Lay Reports and Policy Briefs:** Newsletters and lay reports will be presented to participating communities as advised by the local contexts. A policy brief will be developed and disseminated to relevant peak and government organisations at end of project.
4. **Capacity Building:** Project aims to preferentially employIndigenous staff where available, and build capacity for project management and research in Indigenous staff, who will be mentored by Gould, other staff and advisors.To ensure maximum capacity-building we will endeavour to include an industry-funded Indigenous focused PhD scholarship. PhD candidates will be supervised by Gould, early career researchers on her team and invited Aboriginal academics.

**Newsletters:** A 6 monthly newsletter will be circulated to the recruited services to keep them abreast with the project activities and maintain their interest in implementing the training.

The outcomes will be presented to and reviewed by the consultation panels for the study before being disseminated, and also reviewed by the study's Aboriginal Cultural Liaison and Research Assistant prior to dissemination to ensure it is understandable and acceptable. Participating centres are also welcome to provide feedback and comment prior to distributing the results to their local participants and community. All publications will need to be reviewed and approved by AH&MRC NSW before publication.

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1. Please note that final evaluation measures will be decided during the Delphi study in consultation with stakeholders. This is a tentative list of outcome measures that we anticipate will be acceptable to the stakeholders and participants. [↑](#footnote-ref-2)