

**Aboriginal and Torres Strait
Islander women:
An examination of smoking
during pregnancy**

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I hereby certify that the work embodied in this Thesis is the result of original research and has not been submitted for a higher degree to any other University or Institution.

*Signed:*_____

Date: _____

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Abstract

After decades of discrimination and deprivation, Australia's Aboriginal and Torres Strait Islander population faces social circumstances and health status which resemble that of a third world population group. With a wide range of health risk factors and morbidities among this population, a logical place to begin tackling the health problems is at the beginning of life. With increasing recognition of the influence of the intrauterine environment upon health, not only during infancy but into adulthood, improving health during pregnancy offers substantial benefit for present and future generations.

The poor health of Aboriginal and Torres Strait Islander Australians is deeply ingrained in social deprivation, poor mental well-being, and an array of modifiable risk factors. Smoking is one risk factor at the centre of this complex web. Smoking is often accompanied by, or used as relief in, stressful situations associated with socio-economic status, mental health, illness, and other addictions.

In order to determine the most appropriate way to tackle the smoking issue among Aboriginal and Torres Strait Islander women, a series of studies were conducted. Initial literature reviews found limited evidence derived from methodologically rigorous studies in mainstream populations, and even less evidence for Aboriginal and Torres Strait Islander, or other Indigenous groups. Exploration of the knowledge and attitudes of these women in relation to antenatal smoking was conducted to identify the most appropriate targets for intervention.

The findings from extensive background studies were drawn upon to design an intervention which aimed to be culturally appropriate for Aboriginal and Torres Strait Islander women, providing intensive support to assist these women to quit smoking

during their pregnancy. Pilot data from the resulting intervention is presented in Chapter 8 of this Thesis.

The social network among Aboriginal and Torres Strait Islander communities appears to play a central role in the behaviour of individuals. With an array of risk factors and influences found not only in the individuals surrounding women, but in their socio-economic circumstances and overall environment, it may be that the most important approach for achieving health and behaviour change among this population is the mobilisation of social support and efforts to intervene with multiple elements of that environment.

List of Abbreviations

AC	Additional Care
ACCHS	Aboriginal Community Controlled Health Services
AHRQ	Agency for Healthcare Quality and Research
AIHW	Australian Institute of Health and Welfare
ANOVA	One way analysis of variance
APGAR	Activity, Pulse, Grimace, Appearance, and Respiration
BMI	Body Mass Index
CDC	Centres for Disease Control
EPOC	Effective Practice and Organisation of Care
ESRD	End Stage Renal Disease
ETS	Environmental Tobacco Smoke
FAS	Foetal Alcohol Syndrome
GP	General Practitioner
HIV/AIDS	Human Immunodeficiency Virus/Acquired-Immune Deficiency Syndrome
NCCAM	National Centre for Complementary and Alternative Medicine (United States)
NHMRC	National Health and Medical Research Council (Australia)
NNT	Number Needed to Treat
OECD	Organisation for Economic Cooperation and Development
RCT	Randomised Controlled Trial
SCBU	Special Care Baby Unit
SD	Standard Deviation
SGA	Small for Gestational Age
STATA	Statistical software package

STI	Sexually Transmitted Infection
TAIHS	Townsville Aboriginal and Islander Health Service
UK	United Kingdom
US	United States (of America)
USPSTF	US Preventive Services Task Force
WHO	World Health Organisation

CHAPTER 1

Indigenous health, social health, and the health of Australians

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Chapter 1

Indigenous health, social health, and the health of Australians

Introduction

Good health is central to wellbeing and quality of life for all people. Without health, the capacity for education, enjoyment and pleasure are compromised. In recent years there has been increasing recognition that while medical care is critical and can prolong survival after disease, it is the social conditions in which people live that play a more significant role in determining whether people get sick in the first place.¹ The impacts upon health have been described as involving surface issues such as health practices and stress, as well as structural issues such as those associated with economy, politics, law, culture, racism, resources, and access to medical care. It is recognised that changing the surface causes does not address the underlying structural causes.²

The World Health Organisation (WHO) has explored the social determinants of health and has identified ten key aspects of the social and economic environment that impact upon health:¹

1. The social gradient; people in lower social and economic circumstances run twice the risk of serious illness and premature death than those 'higher up the ladder';¹
2. Stress; social circumstances and deprivation can cause long-term stress which can then impact on physical health with effects such as depression, susceptibility to infection, and high blood pressure;³
3. Early life; early development, both in utero and after birth shapes a child's development and level of risk for poor health throughout childhood and adulthood;

4. Social exclusion; social exclusion is associated with poor psychological and physical health, and is common among minority groups such as the poor, and racial or ethnic minorities;¹
5. Work; a relationship is reported to exist between the level of control an individual has over their work, the level of demand at work, and rates of sickness and cardiovascular disease;⁴
6. Unemployment; stress associated with job insecurity and the financial pressures of unemployment can lead to adverse effects on health;
7. Social support; “*network[s] of communication and mutual obligation...have a powerful protective effect on health*”;(p22)¹ **
8. Addiction; a paradigm exists whereby those who are socially and economically disadvantaged often turn to alcohol, cigarettes or illicit drugs in response to their circumstances, but dependence can then lead to downward social mobility, with added financial pressure and poor physical and mental health;
9. Food; the ideal goal is to avoid the deficiency-associated malnutrition which is common in developing countries, without creating the malnutrition associated with excess consumption of low-cost foods which are high in fats and are highly processed, most common among the lower socio-economic classes in developed countries;
10. Transport; WHO recommend healthy forms of transport such as walking and cycling to encourage the integration of exercise into everyday life and minimize adverse effects of air pollution.¹

It is suggested that each of these factors is interrelated, with the cause of many adverse circumstances and health outcomes found either directly or indirectly, in the social and economic situation of an individual. Social and economic disadvantage may

** The candidate has used Italics for all quotes presented in all Chapters of this Thesis to ensure that they are easily distinguished from surrounding text.

take the form of limited assets, poor education, insecure employment or poor housing, with many disadvantages converging among the same people, and causing a cumulative effect on stress levels and health. The psychosocial environment is implicated in a link with health, with exposure to stressors more common among lower socio-economic groups with the vulnerability of these groups in turn, potentially compounding the effects of these stressors upon health.⁵ There is extensive evidence for the effect of these factors on health. Rates of disease and mortality are higher for those lower down the 'social ladder' and reflect material disadvantage and the associated levels of stress and anxiety.^{6 7} The scale of inequality of income in a society is also reported to be related to the overall level of health of the population.⁸ An example is the disparity in rates of survival from cancer in areas according to the level of affluence,⁹ and ethnicity.¹⁰ The social environment influences the behaviour of individuals by shaping norms, dictating the availability of opportunities, the level of stress and the capacity for individual choice.^{11 12} Individuals with higher levels of income and education are more likely to engage in healthy behaviours than those with lower income and education.¹¹

Indigenous populations throughout the world are in situations of poverty and poor health, with less access to education, health services, employment, and adequate housing than other parts of society.¹³ The nutritional ramifications of poverty are accompanied by health effects and social disruption associated with substance use. Shorter life expectancy, and high rates of mortality and morbidity in cardiovascular diseases, cancers, diabetes, and other illnesses are common to the Indigenous population groups of Australia, Canada, New Zealand, and the United States (US).^{13 14} Risk factors for disease are clustered among Indigenous groups, with disparities in smoking rates, levels of alcohol consumption, obesity, poor diet, and physical activity between Indigenous and non-Indigenous groups.¹⁴

Health disparities have been extensively studied and are now well described. The disparities associated with ethnicity are closely linked with those of education,¹⁵ income¹⁶ and geographical location,^{17 18} but introduce additional considerations associated with culture, which require different approaches to those adopted for health promotion and behaviour change in mainstream populations.¹⁴ Socio-cultural factors can influence an individual's attitude towards health and well-being,¹⁷ and receiving healthcare,¹⁸ as well as attitudes towards certain diseases^{21 22} and lifestyle factors such as exercise and diet, which directly impact upon health.¹⁹ In order to generate an understanding of the origins of these social disparities and the significance of the legacy of oppression on these populations, it is useful to consider the history of Indigenous health and the path which has led to the current state of affairs. Here, Australia's Aboriginal and Torres Strait Islander population is used to illustrate a pattern of deprivation, discrimination and social exclusion which have also occurred to some extent in the Indigenous populations of other developed countries.

Australia boasts a life expectancy at birth which ranks fourth highest among Organisation for Economic Co-operation and Development (OECD) countries,²⁰ and an all-cause mortality rate which ranks third (lowest) among these countries.²¹ When examined as a separate population, Indigenous Australians have an all-cause mortality rate more than two times higher than most other OECD countries.²¹ In 2004, the life expectancy of Aboriginal and Torres Strait Islander Australians was approximately 20 years less than for non-Indigenous Australians. The life expectancy gap between non-Indigenous and Indigenous populations in both Canada and the US was approximately seven years, and was 7.5 years between non-Indigenous New Zealanders and Maori.²² This translates to the lowest life expectancy of any first world Indigenous population.

While the poor health and social situation of Aboriginal and Torres Strait Islander Australians fits well into the WHO social determinants model, several authors have

identified additional factors as key determinants of health for Indigenous Australians.²

²⁷⁻²⁹ The social determinants of Indigenous health derived from the work of these authors and others are presented in the Beyond Band-aids publication.²³

- History and health; the change in diet from traditional hunting and gathering to processed foods and those provided in missions, as well as the introduction of European diseases led to a decline in the health of Aboriginal and Torres Strait Islander Australians. Further, the removal of access to traditional bush medicine and unequal treatment of Indigenous Australians by doctors confounded these problems. Drug addiction, mental illness, diabetes and hypertension soon arose in the Aboriginal and Torres Strait Islander population as a result;
- Racism and marginalisation; the process of colonisation led to the marginalisation of Indigenous Australians and created an attitude of racism which has persisted throughout history;
- Employment, education, and training; with limited training available to Aboriginal and Torres Strait Islander Australians until the 1970's, the work available to them was very limited. Traditionally, they were often employed in manual labor and other unskilled work. This work brought with it many difficulties including low wages, injuries from hard physical work, long hours, and the need to move around for seasonal or casual work, leading to the separation of families. Discontent with mainstream education systems led to poor attendance rates in schools and racism and community pressure often acted to discourage Aboriginal and Torres Strait Islander students from pursuing studies beyond the minimum requirements.
- Poverty, and social class; linked to the limitations of employment and education, Aboriginal and Torres Strait Islander Australians have long been trapped in a state of poverty, and are predominantly found in low positions on the social ladder.
- Individual control over health; for Aboriginal and Torres Strait Islander Australians, control over one's own health is of critical importance. This control was taken away

with the removal of access to bush tucker and traditional health practices, but has begun to be re-established with the development of Aboriginal Medical Services throughout the country.

- Powerlessness; this most explicitly relates to the situation in which the independence of Aboriginal and Torres Strait Islander people was taken away, and they forced to rely on the colonisers for survival, ultimately becoming dependent upon them.
- Incarceration and the justice system; there have been claims throughout history of racist and unfair treatment of Aboriginal and Torres Strait Islander people by police and the court system.²³ Today, Aboriginal and Torres Strait Islander people are highly over-represented in prisons and detention centres.²⁴
- Housing and Infrastructure; since being removed from their traditional land, Aboriginal Australians have been forced to live in mission or housing commission homes, or have built temporary dwellings from salvaged materials. Even in the present day, a large proportion of Aboriginal and Torres Strait Islander Australians rely on Housing Commission dwellings, and these are often over-crowded and poorly maintained. The housing provided is not in keeping with the traditional ways or cultural needs of these people and in many cases this has led to abandonment and damage of the houses provided.
- Family separation; Government policies and practices since white colonisation have led to the separation of families. The best known and most direct example is the removal of Aboriginal children which led to the 'Stolen Generation'.
- Land and Place; a connection with homelands is central to Aboriginal and Torres Strait Islander culture, with great importance given to sacred sites and natural spaces.
- Reconciliation; while this has become a point of political contention, the concept of reconciliation refers to the ability for Indigenous and non-Indigenous Australians to respect their differences, share stories, and heal past hurts. For Aboriginal and

Torres Strait Islander Australians this also involves the promotion of cultural survival and the recognition of Indigenous culture within Australian society.

These additional factors may go some way to explaining the extent of ill health and social problems experienced by Aboriginal and Torres Strait Islander Australians. If the co-existence of several of these factors has a cumulative impact on health, then it is little wonder that the life expectancy gap is so large. A study in New Zealand has reported steeper socio-economic mortality gradients among Maori groups, compared to those of Pacific, Asian or European origin.²⁵ These results suggest that Indigenous status carries a link to poor health, over and above the risk associated with low socio-economic status. The complex links between physical and mental health, and the social determinants of health which characterize the current health status of Aboriginal and Torres Strait Islander Australians are historically ingrained.

History and governance

It is estimated that prior to the occupation of Australia by Europeans, up to 900 000 Aboriginal and Torres Strait Islander people, comprising 500 tribal groups inhabited the country.²⁶ The population was nomadic and depended upon the land for food and shelter. Hunting and gathering created an active lifestyle, with a healthy, balanced diet of natural bush foods and meats. The population lived in harmony with the land and the environment, sustained by seasonally available foods for thousands of generations. The impact of the arrival of the British in Australia has been described as a three-pronged attack on the health and welfare of Aboriginal Australians. The three prongs, in addition to outright slaughter (which will be discussed later) are described as:

1. The introduction of diseases which were fatal either immediately or in the long term;

2. Claiming ancestral land which caused “*psychological illness and spiritual despair*”;
and
3. Placing Aboriginal people in small reserves and settlements in which their healthy lifestyles were replaced with “*conditions and diet poorer than those of the poorest newcomers*”.(p5)²⁷

While little is known about the life expectancy and diseases experienced by Aboriginal and Torres Strait Islander people prior to British settlement, it is generally accepted that overall health was good, and in fact better than that of the average Englishman at the time.²⁷ Since this time, the health of the white Australian and British populations has been ever-improving, whereas the Aboriginal population experienced a drastic decline, which has only recently begun to show any sign of turn-around.

With no written language in pre-colonial times, the history of Aboriginal and Torres Strait Islander people was passed on by the spoken word, rituals and recorded in the stories depicted in rock-art and traditional images. The earliest written history is that which was recorded by British explorers and pastoralists. As James Miller comments in his book ‘Koori: A Will to Win’, this is a history written by non-Indigenous people and interpreted in a ‘white man’s’ way.²⁸

The attitude stemming from white control over Aboriginal people is one which dominated the Governance of Australia for many years after white settlement, and which continues to plague attempts at reform today. Even before their arrival on Australia’s shores, Europeans were aware of the presence of “*Indians...in canoes....carrying spears*”.²⁹ Initially, relations between the Aboriginal inhabitants and white settlers were amicable, with Governor Phillip encouraging the trade of water, tools, and cloth: “*The Governor advanced by himself and layed down some presents for them....by noon we saw that our people and the Natives were mixed together*”.²⁹

Accounts of initial encounters appear to reflect a certain curiosity among both parties regarding the lifestyle and practices of one another.

As the colonies expanded and began to impact upon the land, some Aboriginal clans began to display some resistance. Even in the early encounters, the affinity of the Aboriginal people with the land and its resources was apparent. William Bradley, First Lieutenant on board HMS *Sirius* and a surveyor with the First Fleet, commented in his journal in 1788 that *"The Natives were well pleased with our people until they began clearing the ground, at which they were displeased and wanted them to be gone"*. In a later observation of the interaction between Aborigines and British upon a visit to shore to catch fish, Bradley remarked, *"When they saw the quantity of fish brought on shore at once were much astonished which they expressed by a loud and long shout"*.²⁹

In other parts of the country relations were characterised by conflict from the outset. The Swan River area in Western Australia was claimed by Europeans in 1829. Settlers developed three towns along the banks of the river and were attracted to resource-rich areas which they took by force in violent conflicts with the Aboriginal people. The Aboriginal population in the area was decimated by both conflict and disease. This situation was mirrored in Tasmania, Victoria, and other States, with some tribes completely destroyed. In addition to the toll of violent conflict, it is estimated that half of the Aboriginal population of Northern Australia may have died of tuberculosis, smallpox, typhoid, influenza and venereal disease between 1780 and 1870.³⁰ Aboriginal people had not previously been exposed to these diseases, and had no resistance to them.

It is difficult to determine that proportion of Aboriginal population decimation which is attributable to disease and that which is attributable to outright slaughter. While claims were made regarding an epidemic of smallpox sweeping inland ahead of British

settlers, a thorough examination of historical data by Berwick found no unequivocal evidence to this end. Squatters may have claimed that the Aboriginal population had been almost completely wiped out by disease before their arrival.²⁷

The Aboriginal people were generally viewed as primitive and unintelligent. Bowes Smyth, a First Fleet Record Keeper and Natural Historian commented in his 1788 journal: *"I presented many of them...with glass beads...trinkets...but they seemed altogether a most stupid, insensible...set of beings..."*, and later: *"Sometimes they feast upon the Kangaroo, but I believe them to be too stupid and indolent a set of people to be able to catch them"*.²⁹ It was perhaps this view of the Aboriginal Peoples that led to the declaration of the country as 'Terra Nullius', or 'of no owner' and settlement based on this premise. Colonisers justified the acquisition of the land with claims that the Aborigines were too primitive to be owners of the land, and had no Government with whom negotiations could be made.³¹

Many ongoing social and health problems experienced by Australian Aboriginal and Torres Strait Islander people have been attributed to the racial characterisations perceived by European observers, and their insensitivity to the culture, skills, and connection with land which truly characterise these groups. In an exploration of the underlying social determinants of health Anderson, Baum, and Bentley state:

*"For any people, the refusal to recognise occupation of land as a basic determinant of health would be crucial, but it is even more so for a people lived so closely to the land in a stable culture for hundreds of thousands of years".(page XI)*²³

This deep connection with the land and with nature is a recurring theme in any discussion of the current health status of Aboriginal Australians. Dispossession and dislocation may be blamed for many of the psychosocial and behavioural issues

experienced by Aboriginal and Torres Strait Islander Australians today. Traditionally, a view of health as indivisible from life itself was integral to the beliefs of early Aboriginal people. More recently, with advancing science and medicine, “...*what happens to people and their bodies is separate from social, economic, cultural, and community considerations*”.²³ These changes have paralleled the transition from a healthy, proud and independent people to a group which is disadvantaged, and in a position of helplessness to improve their social circumstances and health.

After a century of conflict and death from disease, the Colonial Governments began to pass protection acts. Having forcibly removed Aboriginal people from their land, colonists took away access to the foods upon which Aboriginal people had survived for thousands of years. Protection acts differed from State to State but generally controlled the employment opportunities and income of Aboriginal people, prevented them from owning property, and allowed the Government to remove Aboriginal children from their parents. Some States developed reserves in which they forced Aboriginal people to live, punishing them if they attempted to leave. When reserves and missions were established, Aboriginal people became reliant upon them for their food supplies and water. Reserves were set up to ‘look after’ Aboriginal people, but were administered by government departments and religious groups. Men were made to work on cattle stations or in other hard labor, and women were trained as house-keepers for the pastoralists building homes on the land. Wages for hard physical work were often paid in the form of food – modest rations of white flour, sugar, tobacco, and tea. Between 1910 and 1970 it is estimated that up to 100 000 Aboriginal children were forcibly removed from their parents to be raised in Church or State institutions. Most of these children were under five years old and many were exposed to physical and sexual abuse, inadequate nutrition and poor living conditions in the missions.³² The motive behind this was to assimilate Aboriginal children into European society over one or two generations, by denying or destroying their Aboriginality. Children were forbidden to

speak their native language or practice traditional ceremonies.³³ Over time these actions led to the breakdown of society and the emergence of social and health-related problems previously unknown among this population.

It is now recognised that much of the treatment of Aboriginal people in the early days of European settlement and even well into the 1900s does not accord with the fundamental principles later enshrined in the Universal Declaration of Human Rights (1948). Reassessment of Government responsibility for Indigenous needs is viewed as a late stage of colonisation. While the approach taken by the Australian State was labeled 'Protectionism', it was characterised by intrusion into the lives of Aboriginal and Torres Strait Islander people, creating dysfunction and dependency.³⁴ It was the general view of British colonisers that Aboriginal people were genetically inferior and would eventually die out. Unequal treatment, segregation and not allowing Aboriginal and Torres Strait Islander people from voting, buying land and accessing services, prevented these people from exercising their basic human rights. The impact of these violations on health and well being were articulated by Fran Baum, Michael Bentley, and Ian Anderson in their introduction to the Beyond Bandaid papers:

"It is not possible...to understand the persistent poor health status of the original custodians of Australia since the time of European arrival and invasion without situating this understanding within the history of dispossession, colonisation, failed attempts at assimilation, racism, and denial of citizenship rights".(page X)²³

Cultural genocide during European occupation sparked the sense of 'shame', which has become inherent in Aboriginal communities. The term 'shame' is used to describe the emotion felt when "something stupid or embarrassing has happened". With Aboriginal and Torres Strait Islander Australians trapped in a vicious cycle of poverty and powerlessness in an otherwise affluent nation, the resulting sense of hopelessness

is itself, a major health problem, with implications for both physical and mental wellbeing.³²

Australia finds a social conscience

Discrimination against Aborigines in Government policies and Federal documents gives an indication of their treatment since European Settlement. Even in the Constitution written prior to Federation in 1901, Aborigines were not included in the national census. This is particularly pertinent given that the number of cattle and sheep were considered worthy of inclusion.³⁵ This situation did not change until the 1967 referendum, when approximately 90% of voters elected to include Aborigines in the Australian census, and give the Commonwealth Government the right to make specific laws with respect to Aboriginal people. The result gave the Government a mandate to implement policies to benefit Aboriginal and Torres Strait Islander people, marking the beginning of what is known as the reconciliation movement in Australia. It was also at this time (1968) that the Council of Aboriginal Affairs was established. In 1972, the Whitlam Government upgraded the Council to a Department.³² The Terra Nullius legal concept was retained until 1992, when in what became known as The Mabo Judgement, the High Court ruled that the *“land title of the Indigenous Peoples, the Aborigines and Torres Strait Islanders, was recognised at common law”*. The case recognised the *“common law that the native inhabitants of any land have an incontrovertible right to their own soil”*⁸⁶ which was apparently ignored by early European settlers. This was a landmark case, giving *“through inheritance, the original occupants the right to possession of their traditional lands in accordance with their customs and lores”*, and leading the way for Australia’s native inhabitants to re-claim land across the country.³¹

Government approaches to Aboriginal Australians have not greatly improved the situation of poor health and poverty since earlier times. Efforts at governance for

Aboriginal Australians have been described as a “*paradox of innovation without change*”.³² The contrast between Indigenous and non-Indigenous styles of governance were not considered in early Government policy. As discussed by Patrick Sullivan and Katherine Oliver at the Social Determinants of Aboriginal Health workshop,³⁷ non-Indigenous interventions towards Aboriginal and Torres Strait Islander life will always be competing with a pre-existing system of governance. While this system may be informal, and may have changed since pre-colonisation, it will have a strong influence upon people’s lives and their relations with each other, as well as with non-Indigenous people and organisations. The approach of non-Indigenous Governments has attempted to “*codify, simplify, and rigidify*”(p182)³⁷ the traditional Aboriginal and Torres Strait Islander approach which is characterised by fluidity and a complex system of authority. The nature of Aboriginal and Torres Strait Islander culture, governance, and health issues do not lend themselves to simplistic analysis or presentation. Arguably, this complexity has limited the interest in addressing these issues, and led to an incremental approach to Aboriginal governance and health policy over several decades.³⁷

Discrimination in society, unequal pay, inadequate access to housing, and poor nutrition prevailed through various approaches to governance. Government approaches have moved through phases of protectionism, assimilation, and self-determinism, none of which have been successful in bringing about significant improvements in health outcomes. Many argue that even self-determination policies have in fact done more damage than good in the community, linking such approaches to the social breakdown which has occurred in many Aboriginal tribes and communities across the country.³⁸ Recent approaches such as Shared Responsibility Agreements and Regional Partnership Agreements have attempted to promote collaboration with Aboriginal communities to implement programs for health, housing, and employment, which take cultural differences and needs into consideration, giving communities a

certain level of control over their affairs.³⁹ These approaches have had a controversial reception, with suggestions that the agreements are a form of blackmail, and are designed for political gain rather than the true benefit of communities.⁴⁰

Informing health policy for Aboriginal and Torres Strait Islander

Australians

While the Government policy changed to allow for equal treatment of Aboriginal and Torres Strait Islander people, there is evidence of segregation and racism well into the 1960's. Examples of racial discrimination in public hospitals exist remained in the Northern Territory, New South Wales, and Queensland. In New South Wales in the 1960's, causing the (then) Minister for Health to issue a threat that hospitals practicing racial discrimination would lose their Government subsidy. This threat was met by a statement from the Chairman of the Board of Moree Hospital, that *"any order by the Government would be ignored, and any attempt to alter the current situation would 'lead to trouble'".*³² At this time, the Australian Government's assimilation policy stated that *"all persons of Aboriginal descent will choose to attain a similar manner of living to that of other Australians and live as members of a single Australian community".*³²

It was not until the 1960's that the scale of the Aboriginal and Torres Strait Islander health problems was fully realised. It was only the individual work of concerned medical practitioners and nurses which initially uncovered startling rates of infant mortality. A medical practitioner in Collarenebri in north-western New South Wales examined records of births and deaths in the town in 1957, and found that the Aboriginal infant mortality rate was 100 per 1000, compared to 20 per 1000 non-Indigenous infants. Similarly, a nurse in the Northern Territory noted in 1958 that her records indicated that one in every five Aboriginal babies did not live to adulthood.³² The first National Aboriginal Health Strategy was published in 1989 after a 1987 meeting of

Commonwealth, State, and Territory Ministers for Health and Aboriginal Affairs agreed to develop a coordinated national strategy to improve Aboriginal health services. It became apparent however, that the recommendations made in this strategy were not adequately resourced or implemented by the Government.

Other Government documents and reports on overall health since this time have frequently made reference to Aboriginal and Torres Strait Islander Australians as a population at high risk, and in need of specific attention. However, many such documents have fallen short of providing clear recommendations for action in Aboriginal and Torres Strait Islander health.⁴¹ In the last two decades, focus on Aboriginal and Torres Strait Islander health and efforts at improvement have gained momentum, with the establishment of various State and Commonwealth departments and groups focusing on Aboriginal and Torres Strait Islander specific issues. Each State and Territory health service has groups and positions designated to addressing Indigenous health issues, and each State has an affiliate group of the National Aboriginal Community Controlled Health Organisation, with designated health services treating Aboriginal and Torres Strait Islander people in a culturally appropriate environment. Despite these efforts however, and despite Aboriginal representation on health-related Steering Committees and Advisory Panels nationally, the gap remains. Aboriginal and Torres Strait Islander Australians continue to experience poorer health, and greater levels of absolute poverty than non-Indigenous Australians.

While the lack of progress in closing the gap between the health status of Aboriginal and Torres Strait Islander and non-Indigenous Australians is the source of a great deal of frustration for those who experience the consequences or who are working towards change, it is important to put this in the context of history. It should be acknowledged that these issues are the result of 200 years of marginalisation and damaging actions of European colonisers and Governments, but have only been receiving nationally

coordinated attention for the last 20 years. Acknowledgement of the need for culturally appropriate service provision and initiatives, and efforts tailored for specific communities is a young phenomenon in the Australian psyche. A problem so deeply ingrained over 200 years is likely to take some time to be rectified. Perhaps the current era of understanding and focused effort will go some way towards this goal.

Other more recent approaches to governance and policy

The importance of the connection with 'country' and natural resource management has gained recognition in recent times, with programs such as Indigenous Protected Areas aiming to promote the involvement of traditional land owners in natural resource management.⁴² An independent report in 2006 found that involvement in these programs led to benefits for communities which were far broader than the most obvious environmental outcomes. Communities involved in the programs reported substantial improvement in the rate of school engagement, substance abuse, and improvement in social cohesion and family functioning. It is perhaps the truly cooperative nature of such efforts which has made them more successful than other apparently 'mutually beneficial' approaches and efforts to promote self-determination. A major benefit of engaging Aboriginal and Torres Strait Islander people in environmental and cultural heritage management is the reliance upon their deep connection with the land and their cultural traditions, knowledge of which lies with them alone. This is one of the few areas of activity where Aboriginal and Torres Strait Islander people are confident and empowered, and represents an important starting point for building self-esteem and strengthening communities. It has been recognised that benefits for community health, group cohesion and social identity can be drawn from collaborative efforts in resource management.⁴³ It is important to consider the social impact, as well as the environmental impact of resource use and to engage the traditional owners of the land in these efforts.

Even today, as Governments attempt to address issues of poor health, sexual abuse and domestic violence, questions remain as to the level of commitment in working together for improvement. The Commonwealth Government was criticised by the Human Rights and Equal Opportunity Commission for their lack of consultation with communities involved, prior to their implementation of the radical Emergency Response Legislation in the Northern Territory (2007). Some spokespeople have described this legislation as a reversion back to an age thought to have been left behind; armed troops were sent into communities and medical practitioners sent with orders to perform child health checks on all Aboriginal children. While these actions may not in themselves be wrong, it is the lack of consultation and consideration for the consequences to communities, for which they have been criticised. Law enforcement may be necessary to break a cycle of drug use and criminal activity in communities, and child health checks may be needed to improve health of Aboriginal children. These actions cannot stand alone however. It may be argued that law enforcement should be done by engaging local police, as well as service providers to ensure that drug and associated mental health issues are treated, rather than being punished. There are suggestions that while child health checks are indeed an important aspect of health improvement for Aboriginal children, they should be performed by local doctors who have a rapport with families in the communities, and can follow-up on identified issues. These are just two examples of what has been cited as a potentially damaging approach taken by the Federal Government. The approach may have had the best of intentions, but has already been seen to have adverse effects within communities, with people running away for fear of their children being taken away by the authorities.⁴⁴

It is known that the concept of kinship was critical in Aboriginal culture prior to white settlement. Rich spirituality and social organisation, with families that were “*extended, dependent, and life giving to each other*”⁴⁵ forming the basis of society. Breakdown of

cultural ties and social structure accompanied the impacts on health associated with British interference and introduced diseases and substances of abuse. With the Aboriginal and Torres Strait Islander view of health as:

“...not just the physical well being of an individual but the social, emotional and cultural well being of the whole community in which each individual is able to achieve their full potential thereby bringing about the total well being of their community... a whole-of-life view...” ⁴⁶

...it is critical to consider the social structure of communities and to explore health of communities overall, including the complex interaction between health risk factors, behaviours, traditions and cultural factors.

Why does the gap remain?

Despite an increased consciousness and expenditure in Aboriginal and Torres Strait Islander health over the last decade or more, a considerable gap remains between the health of Indigenous and non-Indigenous Australians. Health expenditure per capita in 1998-99 was \$3065 for Aboriginal and Torres Strait Islander people and \$2518 for non-Indigenous people.⁴⁷ Even with these honourable Government intentions and massive expenditure, the gap still exists. While progress has been made in the development of the service delivery system and system infrastructure – both mainstream and Indigenous-specific, continued effort will be required to close the gap.

Health expenditure for Aboriginal and Torres Strait Islander Australians may be extensive, but a 2004 report on the Aboriginal and Torres Strait Islander Primary Health Care Review concluded that *“investment in comprehensive primary health care should be increased to a level between three and six times the national average per capita expenditure.”*(p78)⁴⁷ Per capita expenditure in itself is not a good measure for equity if

access to services, as it does not adjust for the different level of need. The report by Dwyer et al., (2004) also recommended that funding be allocated through both Indigenous-specific and mainstream funding programs, and to both Indigenous-specific and mainstream providers.

It seems that no single answer exists to explain the persistence of the gap. It is likely that the phenomenon is the result of a multiplicity of reasons, with several theoretical frameworks going some of the way towards an explanation.

Funding has been directed towards a range of programs in various sectors and areas of health. Such programs are planned and implemented separately from one another using different, often conflicting approaches, targeting slightly different parts of the population. An example is the Aboriginal Maternal and Infant Health Strategy (AMIHS) – a New South Wales Health Department initiative to improve birth outcomes for Aboriginal women. This program uses a midwife and Aboriginal Health Worker team who visit women in their homes as well as treating them in clinic settings. While these teams often work in partnership with Aboriginal Community Controlled Health Services (ACCHS) in each area, some cases exist in which a separate antenatal program operates through the ACCHS, leading to disjointed and non cost-effective service provision for this group.

In some cases, groups working on a particular health program are unaware of others working in a very similar field. In many cases, opportunity exists to collaborate and improve the cost effectiveness of programs and range of outcomes achieved.

Disjointed programs however, may ultimately prove counter-productive, causing the demarcation of closely related health issues or the approach to dealing with them. In the case of the AMIHS for example, child and maternal health are segmented, with the program funded to provide care up to 28 days post-natal only.⁴⁸ A woman who has

received intensive support and care from an AMIHS team throughout her pregnancy no longer has this support through some difficult stages of caring for a newborn, such as breastfeeding and immunisations. Separate programs such as Healthy for Life (Australian Government Department of Health and Ageing) offer support during this period but are not available in all areas, with specific sites funded to develop and undertake individual programs. The majority of funded sites are located in rural and regional areas, potentially creating a service gap in urban areas. Such disconnect between programs can occur as a result of separate Commonwealth and State Government funding and level of initiative. A more collaborative approach to health may alleviate these problems to some extent.

Funded programs are often episodic, with funding provided not only for very specific tasks, target groups and health issues, but also for very targeted and limited time periods. Gaps may be left in service provision when a funded program finishes, threatening the sustainability of any health improvements achieved. By leaving communities without particular services after the implementation of a program, there is in fact a danger of allowing the health status of that community to regress to a level worse than it was prior to the program or intervention.

It is also possible that the funding provided to address Aboriginal health issues is in fact not reaching the target group. A large proportion of research and program funding is spent on administration and absorbed at an organisational level, with only a limited amount filtering through to the community in need. Another aspect associated with reaching the target group is the cultural appropriateness of programs for Aboriginal and Torres Strait Islander Australians. In recent times, the concept of cultural appropriateness has become more widely accepted. Public health initiatives and research projects targeting Aboriginal and Torres Strait Islanders are now more frequently taking into consideration issues such as the importance of family and the

social environment for this group. A number of organisations have produced guidelines for appropriately working with Aboriginal people, and cultural audits for service providers. Such tools raise awareness of the issues which should be considered when working with Aboriginal and Torres Strait Islander clients, and give them an opportunity to address these issues.

Aboriginal Psychologist Dr Tracey Westerman¹ conducts cultural audits and training with non-Indigenous service providers, to ensure that they have the appropriate knowledge and understanding, and use appropriate language and approaches with Aboriginal and Torres Strait Islander clients. This work is based upon the concept of cultural competency – relating to the need for service providers to understand and have the capacity to address issues impacting upon Aboriginal and Torres Strait Islander people. For example in psychology, it is necessary to consider the very deep spiritual and cultural beliefs held by some very traditional individuals, which may drive their actions and impact upon their concept of right and wrong.

It may be that the limited improvement in Aboriginal and Torres Strait Islander health to date is associated with a lack of cultural awareness, or failure to tailor programs to the specific needs of these cultures. This concept relates to any group, and to any health intervention or program. For example, a program to improve nutrition in a Jewish community would not promote the consumption of pig products.

The need for evaluation

Several theories may be proposed to explain the minimal improvement in Aboriginal and Torres Strait Islander health, but with very limited evaluation of programs it is not

¹ Dr Tracey Westerman, Managing Director, Indigenous Psychological Services, Victoria Park, Western Australia.

possible to identify a single, clear reason for this phenomenon. Strategies should not be implemented into routine care without first assessing their efficacy and ensuring their cost effectiveness. Valuable resources would be wasted and opportunities lost in the adoption of potentially ineffective strategies. Thus, there is a clear need for critical review of the effectiveness of approaches to improve Aboriginal and Torres Strait Islander health, using methodologically strong designs. This will allow for cost-effective investment in those strategies with proven efficacy, and in turn, greater improvements in health to close the gap. Perceived barriers to evaluation include cost, a lack of skilled methodologists or researchers, methodological difficulties, and ethical dilemmas associated with randomisation.

Methodologically rigorous evaluation can be costly, with data collection and analysis requiring a great deal of staff time and often incurring additional costs associated with information technology, postage or statistical personnel. In order to conduct scientifically sound evaluations, large sample sizes are required and can add substantial cost to data collection processes. It may be argued however, that the substantial amount of funding in Aboriginal and Torres Strait Islander health programs should be sufficient to cover these components. Much of the funding in this area is channeled into clinical areas or primary health care sectors which lack skilled researchers or methodologists. Staff in such areas may also resist evaluation due to the perceived workload burden, or reluctance for their performance to be monitored.

Population health initiatives are notoriously problematic, with a number of barriers to conducting methodologically rigorous evaluation – particularly randomised controlled trials (RCTs). While the RCT may be able to accommodate population-based studies with methods such as cluster randomisation, issues such as obtaining sufficient sample size and achieving randomisation with minimal contamination represent complex obstacles to study design. Comparability of groups must be considered in order to

minimise the effects of adverse events on the internal and external validity of the study. The lack of independence among individuals within clusters reduces the effective sample size in such studies. This means that for the same statistical power and detectable difference, a larger sample size is required than for a non-cluster-randomised study.

Randomisation also raises an ethical dilemma whereby half of those who consent to participate will receive the potentially beneficial intervention, while the other half will not. While it can be argued that it is unethical to deliver an intervention or program which has not been proven to be effective, in situations where individuals or communities clearly need assistance, this can be difficult; particularly for the healthcare providers involved.

In the pilot study presented in Chapter 8 of this Thesis, the use of an RCT was carefully considered. With practicalities limiting the study to two sites, and a lack of comparable, reliable data collected at these sites prior to the study, alternatives such as multiple baseline and before-after designs were not feasible. Further, given that women were receiving what was deemed to be best-practice usual care prior to the study, it was not regarded as unethical to provide additional care to a limited number of participants.

The status of Australia's Aboriginal and Torres Strait Islander people today

Australia is home to approximately 460 000 Aboriginal and Torres Strait Islander people. This represents 2.4% of the country's population – a small but significant proportion. The Aboriginal and Torres Strait islander population is generally more widely dispersed across Australia, and less urbanised, than the non-Indigenous population. The 2001 census recorded that 26% of the Indigenous population lived in

rural areas, in small communities or 'on the land', compared with 12% of the non-Indigenous population. The majority (74%) of Aboriginal and Torres Strait Islander people however, lived in urban centres of more than 1,000 people, compared with 88% of the rest of the population.⁴⁹

This population is a severely disadvantaged minority according to many social and health indicators. The rates of employment (42%), reliance upon Government assistance, rented and over-crowded housing, access to critical infrastructure, and poor health are alarming indicators of the status of our Aboriginal and Torres Strait Islander population. According to the Australian Institute for Health and Welfare (AIHW) *"The life expectancy for Aboriginal and Torres Strait Islander males born in 1999-2001, is 56.3 years, almost 21 years less than the 77.0 years expected for all males. The expectation of life at birth of 62.8 years for Aboriginal and Torres Strait Islander females is almost 20 years less than the expectation of 82.4 years for all Australian females"*.⁵⁰

Households with Aboriginal and Torres Strait Islander persons are larger on average than other households, are more than twice as likely to be renting (including a larger proportion of rentals from Government agencies or community housing agencies as opposed to renting privately), and pay a median weekly rent that is two-thirds the median weekly rent paid by other households. Also, households with Aboriginal and Torres Strait Islander persons are almost three times more likely to report their home to be in high need of repair.⁵⁰ Inadequate housing and crowded living conditions are associated with the spread of infectious diseases such as skin infections, meningococcal, rheumatic fever, tuberculosis and respiratory infections.⁵¹

The leading cause of death for this population in 2002 was cardiovascular disease. This was followed by injuries, cancers, diseases of the respiratory system and

diabetes. With the exception of cancer, the standardised mortality ratio for each of these causes is substantially higher among the Aboriginal and Torres Strait Islander population than the non-Indigenous population.

Diabetes and renal disease

An epidemic of Type II diabetes mellitus is occurring worldwide.⁵² De Courten et al., (1998) report that 10-30% of Aboriginal and Torres Strait Islander people suffer from diabetes as a long-term health problem. This rate is two to four times the rate experienced by the non-Indigenous population.⁵⁰ Between 1999 and 2001 diabetes was the underlying cause of death for 18% of all deaths recorded as Indigenous.⁵⁰ The disease is brought about by a complex set of factors, including genetic susceptibility, poor diet (particularly early nutrition), exercise, obesity and psychosocial stress causing insulin resistance and pancreatic failure.^{61 62} A study in nine Torres Strait Islander communities between 1993 and 1997 found a very high prevalence of known cardiovascular risk factors for diabetes. Of 592 adults surveyed, 30% were overweight, 51% were obese, 70% had abdominal obesity, and 32% had hypertension.⁵³

Type II diabetes itself can be controlled with diet, but left uncontrolled, it can lead to serious complications including retinopathy and renal disease. A recent study of Aboriginal diabetic adults in the Katherine region of the Northern Territory reported that there is a lower overall incidence of retinopathy among Aboriginal diabetics compared to non-Indigenous diabetics, but that a significant proportion of retinopathy progressed to vision-threatening retinopathy and maculopathy in this population group.⁵⁴ This group has the highest reported incidence of vision threatening retinopathy in Australia and one of the highest incidences of clinically significant macula oedema in the world.⁵⁴

Diabetic nephropathy is responsible for 40% of cases of end-stage renal disease (ESRD).⁵⁵ Rates of ESRD among Aboriginal and Torres Strait Islander people are up to 30 times higher (particularly in remote areas) than among the non-Indigenous population.⁵⁰ The incidence of diabetes, ESRD, and cardiovascular disease among Aboriginal and Torres Strait Islander people are increasing at epidemic rates, and are interrelated, with these major diseases sharing many multi-factorial risks. Of all people registered on the Australian and New Zealand Dialysis and Transplant Registry, 6.2% were Aboriginal and Torres Strait Islander Australians.⁵⁰ One key issue contributing to the high prevalence of these diseases, is the rate of preventable risk factors such as central obesity, poor diet and nutrition, low levels of physical activity, smoking, and high risk alcohol consumption.⁵⁶

Circulatory System diseases

Circulatory system diseases are present in 19% of Indigenous Australians. The most common circulatory system disease is hypertension; the prevalence of which increases with age. In age groups over 25 years, the prevalence among Aboriginal and Torres Strait Islander people is similar to those experienced by non-Indigenous Australians who are 10 years older. Death rates for circulatory system diseases were 3.2 and 2.8 times higher than expected for males and females respectively.⁵⁰

Traditionally, Aboriginal people have been thought to have a lower prevalence of cardiovascular disease and ischaemic heart disease than non-Indigenous people. Social, economic, and cultural change over several decades has negatively affected this, with awareness and cultural change in mainstream populations not mirrored in Indigenous populations. Unlike mainstream populations, there has not been a decrease in cardiovascular disease-related deaths among Aboriginal and Torres Strait Islander

Australians, possibly the result of consistently high rates of cardiovascular risk factors such as smoking, high risk alcohol consumption, physical inactivity, and obesity.⁵⁷

Rheumatic Heart Disease is rare in most developed nations but continues to impact upon developing countries, and Indigenous populations in some developed countries. Aboriginal and Torres Strait islander Australians are 16 times more likely to die from Acute Rheumatic fever or Rheumatic Heart Disease than other Australians.⁵⁷

The rate of coronary heart disease is 1.7 times higher for Aboriginal and Torres Strait Islander people than non-Indigenous people.⁵⁰ It is also interesting to note that in a study involving 897 Aboriginal adults in the Northern Territory, the rate of coronary heart disease was five times higher among adults with diabetes, than those without. The risk of heart disease for women with diabetes was found to be significantly higher than that for men.⁵⁸

Infectious and Communicable Diseases

Infectious diseases, and in particular, skin infections and infestations are an important marker of poverty, hygiene and overall health status. Aboriginal and Torres Strait islander people suffer a much greater burden from infectious diseases than do non-Indigenous Australians.⁵⁰ The National Health and Medical Research Council (NHMRC) recommend extra vaccinations for Aboriginal and Torres Strait Islander people in the Australian Vaccination Schedule.

Scabies results from infestation of the skin with the mite *Sarcoptes scabiei*, and prevalence is high in areas where over-crowded living conditions and poverty exist.⁵⁹ The prevalence of scabies among primary school children in remote Aboriginal communities in the Northern Territory is up to 70%.⁶⁰ A Western Australian study

found a high burden of infectious diarrhoea among Aboriginal children and infants, with longer hospital stays and co-existing morbidities (including dehydration, sugar intolerance, failure to thrive, iron deficiency, anaemia, genitourinary infections, scabies or otitis media), than their non-Indigenous counterparts.

The prevalence of sexually transmitted infections (STIs) such as Syphilis, Gonorrhoea and Chlamydia are alarmingly high among the Aboriginal and Torres Strait Islander population relative to the non-Indigenous population. A study of STIs in North Queensland found positive associations with bacterial STIs and alcohol consumption, smoking, being female, and younger age.⁶¹ Alcohol, smoking, and drug use can lead to a compromised immune system and thus increased susceptibility to STIs. The link with age is possibly associated with risky behaviours and unsafe sexual activity. High rates of these infections may also facilitate HIV transmission. There has been a slower rate of decline of HIV/AIDS infection in the Aboriginal population, and a higher proportion of new HIV cases are female in the Indigenous population (27%) compared to the non-Indigenous population (11%).⁵⁰

Hepatitis C is a blood borne virus primarily contracted through shared injecting equipment or unsafe tattooing practices. This virus can lead to very serious health impacts including cirrhosis of the liver. Of all notifications of Hepatitis C in 2001, 19.6% identified as Indigenous. The rate was 19% for Hepatitis B, and 16.9% for Hepatitis A, 32.5% for Chlamydial infections, 91.3% of Donovanosis, and 64.6% of Gonococcal infection.⁵⁰ In discussion of infectious diseases it is interesting to note that high concentrations of C-reactive protein (CRP, a marker of inflammation) among adults in Aboriginal communities are associated with cardiovascular risk factors and renal disease.⁶² McDonald et al., (2005) have suggested that strong links exist between cardiovascular and renal disease, with shared backgrounds of infection or inflammation.⁶²

Mental Health

The Australian Mental Health Strategy defined mental health as “*the product of biological, psychological, and social environment (both past and present), healthcare and lifestyle*”.⁶³ Around the world, Indigenous people have experienced rapid culture change, marginalisation and absorption into a global economy that has little regard for their autonomy. Kirmayer et al., (2000) identified that “*cultural discontinuity has been linked to high rates of depression, alcoholism, suicide, and violence in many communities...*”.⁶⁴ A sense of hopelessness and dependence upon welfare and others can cause people to turn to alcohol and drugs for relief, and to try to overcome these emotions. A vicious cycle often emerges as people seek to repeat or prolong the effects of these substances, become addicted, and then face withdrawal and further social and health issues associated with this. Substance use and mental disorders often co-exist, and in many cases it is difficult to determine whether substances were used to bring relief from mental health issues, or whether in fact the mental health issues arose through over-use of substances.

Hospital separations for most types of mental and behavioural disorders were higher among Indigenous people in 2000-01, with rate ratios of 2.2 and 1.5 for males and females respectively. Hospitalisations for “*mental and behavioural disorders due to psychoactive substance use*”(p131)⁵⁰ were 4.8 times higher for Indigenous males, and 3.6 times higher for Indigenous females, than for non-Indigenous males and females.

Mental health is a very complex issue, with associations between mental and behavioural disorders and rates of assault, suicide, and incarceration. “*Indigenous mental illness and/or emotional distress may not only cause Indigenous Australians to*

come into contact with the criminal justice system, but incarceration may also be a risk factor for mental illness".(p131)⁵⁰

As discussed above, this relationship is common to other stressors, or risk factors for mental illness, such as alcohol and drug abuse, smoking, discrimination, and social circumstances. The link between physical health, health behaviours, and mental health is a strong, yet complex one (refer to Figure 1.1).

As a result of the Bringing Them Home Report on the inquiry into Separation of Aboriginal and Torres Strait Islander children from their families, the Australian Government now funds 106.5 counselors in 73 ACCHS sites across the country, to provide counseling to individuals, families, and communities affected by past practices regarding the forced removal of children from Aboriginal families.⁶⁵ The recognition of the impact of these policies on the social and emotional well-being of Aboriginal people is a positive step in reconciliation and health improvement. As is the case with many programs however, the 2007 evaluation of Bringing Them Home reported that the Government response to the report has been "*...insufficiently documented, poorly coordinated, and insufficiently targeted to meet the needs of the Stolen Generations*".(p27)⁶⁵ It is also interesting to note that this evaluation states that "*...the severity and incidence of the problems associated with the trans-generational impacts of the Stolen Generations experiences does not appear to be decreasing, and is unlikely to do so in the future*". This highlights the need for increased or more focused social and emotional well-being, and mental health services for Aboriginal and Torres Strait Islander Australians.

Figure 1.1: The link between physical health, health behaviours and mental health

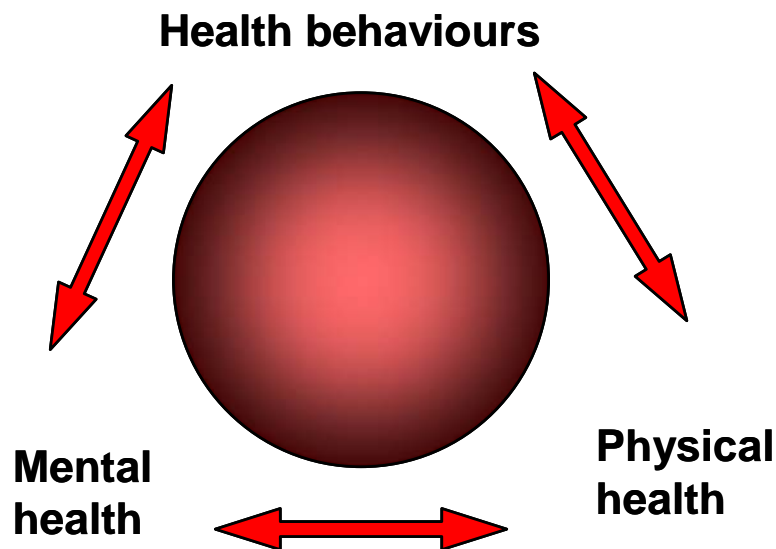


Figure adapted from NYC Vital Signs; A report from the New York City Community Health Survey⁶⁶

Addiction – tobacco, alcohol, and other drugs

Aboriginal and Torres Strait Islander Australians have a long history of tobacco use since it was introduced to those in Northern Australia by visiting fishermen from Indonesia and the Islands to the North of the country, and later used as payment for labour on farms and cattle stations. Since this time, the prevalence of tobacco consumption among Aboriginal and Torres Strait Islander Australians has risen to disturbing proportions, with this group smoking at a rate approximately twice as high as non-Indigenous Australians.⁵⁰ Tobacco consumption is a modifiable risk factor for many of the diseases which have become highly prevalent among this population, but efforts at increasing smoking cessation rates have proven difficult. Research in the area has increased in recent years, with extensive exploration of the tobacco issue

among Aboriginal and Torres Strait Islander's⁷⁸⁻⁸² and efforts to intervene in smoking behaviour.^{83 84}

Data regarding the prevalence of smoking among the population as a whole are complex. Trends suggesting a decrease in smoking in the late 1990s are blurred by tobacco consumption data which suggests that changes in the rate of use may have exceeded changes in the proportion of the population using tobacco. It is therefore possible that the proportion of smokers among the population has not decreased dramatically, but those individuals who continue to smoke may be smoking fewer cigarettes.⁸⁵⁻⁸⁷ Further, data from 2001 is suggestive of a widening differential in smoking rates between upper and lower socio-economic groups at that time,⁶⁷ which has continued further into this decade.⁶⁸ It has been hypothesised that this differential may be associated with increasing levels of education in recent years, with an inverse relationship between smoking prevalence and education levels having been demonstrated.⁸⁹⁻⁹¹

These patterns generate great concern regarding the smoking patterns among lower socio-economic and other disadvantaged groups. While a trend towards a reduction in the prevalence of smoking among the overall population has been observed since the 1970's,⁶⁹ disadvantaged groups are not improving as rapidly, and are potentially becoming more disadvantaged relative the whole population. White et al., (2003) reported trends in smoking prevalence which suggested a six-year lag in lower socio-economic groups achieving reductions in prevalence equivalent to that of higher groups.⁶⁷ If this is the case, it will take substantially more than six years for the prevalence of tobacco use among Aboriginal and Torres Strait Islander Australians to reach the rate among non-Indigenous people.

Alcohol and drug use has had a similarly damaging history among this population with Aboriginal and Torres Strait Islanders drinking at risky levels,^{59 92} and facing extremely high rates of abuse of substances such as kava and cannabis,⁹³⁻⁹⁷ as well as petrol sniffing.⁷⁰ These issues have gained widespread publicity in recent times, with the social and physical ramifications of these behaviours prompting substantial effort from Governments and communities.⁷¹ The roll-out of non-sniffable OPAL fuel in central Australia for example, increased awareness of the scale of this problem in the community.⁷² Substance abuse in Aboriginal communities has been linked with long-term social and health effects for users, their children, and those around them,⁷³ and has been associated with the breakdown of cultural values and traditions which has led to poverty and abuse.

In 2006, 20% of the total prisoner population of Australia was Aboriginal.²⁴ In New South Wales, 40% of juveniles in custody are Aboriginal. Up to one-quarter of Aboriginal men have direct involvement with correctional services each year. Like the complexity of risk factors for other diseases and for mental health issues, these incarceration rates and high rates of death in custody are likely to be an indirect result of dispossession and marginalisation. A cycle of poverty, drug taking and criminal activity, limited employment opportunities and poor physical and mental health makes it impossible to determine the most direct cause of the high incarceration rates. Poverty itself can cause people to incur a criminal record through behaviours such as failure to pay for travel transport or an inability to pay parking fines. Such behaviours are difficult to avoid when individuals must attend meetings with Centrelink[^] to meet social security requirements or attend clinics for chronic disease or methadone treatment. It then becomes difficult to emerge from the poverty cycle, as a criminal record leads to further difficulty in gaining employment and facilitating self-

[^] The Centrelink website (<http://www.centrelink.gov.au/>) describes the organisation as an Australian Government Statutory Agency, assisting people to become self-sufficient and supporting those in need.

improvement. Incarceration rates are also linked with Hepatitis C rates, as drug taking and tattooing often continues in prison with unsafe practices which lead to the spread of disease. In South Australia, close to 60% of metropolitan Aboriginal prisoners are positive for Hepatitis C.²⁴

Multiple risk factors

It is difficult to quantify the overall impact of a range of risk factors, but it is generally accepted that risk factors tend to co-exist, and be interactive in their effects. For example, an individual who is a smoker and is obese may have a greater risk of cardiovascular disease than a smoker who is not obese. In isolation, Indigenous adults are more likely than other Australian adults to be classified as obese, to smoke, to be classified as a high risk drinker and to report themselves to be sedentary or have low levels of activity. Further, Indigenous adults are more likely to be exposed to more than one of these risk factors – potentially increasing their overall risk of poor health.⁵⁰

Aboriginal and Torres Strait Islander children are born with greater risks of adverse health – they are born to parents who are poor, are more likely to smoke, consume alcohol, abuse drugs, and have limited employment options. These children are also more likely to be exposed to other risks throughout their lives – the socio-economic status of their family and a continued sense of dispossession and hopelessness increases their risk of mental health disorders, substance abuse, poor nutrition, and chronic disease. It is possible that without concerted and effective efforts to break this cycle, risk factors will accumulate and have an additive effect to worsen health, and in fact widen the gap between Aboriginal and Torres Strait Islander, and non-Indigenous Australians.

Where to start in bridging the gap

The influence of early life

With the emergence of the fetal origins theory of adult disease there is evidence to suggest that many health issues affecting adults could be prevented by improving the nutrition and overall health of mothers during pregnancy.^{101 102} The hypothesis proposes that adverse intrauterine events trigger adaptations which, in the face of adverse events, manifest as chronic conditions in adult life. The theory originally linked poor maternal diet with coronary heart disease,⁷⁴ and has since been extended to a number of adult diseases including hypertension,¹⁰⁴ type II diabetes mellitus,⁷⁵ hypercholesterolemia,⁷⁶ hypertension,⁷⁷ obesity in childhood,⁷⁸ and chronic obstructive pulmonary disease with non-fatal stroke⁷⁹ (reviewed in Khan et al., 2005).⁸⁰

A recent study in a remote Australian Aboriginal community examined the birth weight (obtained from health records), and current blood pressure of 456 adults. The study uncovered an inverse relationship between birth weight and blood pressure, which was amplified by high current weight.⁸¹ Similar relationships have been identified in various populations, occurring throughout development.⁸² Epidemiological data has recently been supported by animal studies demonstrating that rats fed low protein diets give birth to offspring that are small, develop hypertension, and have small kidneys relative to their body weight with small nephron numbers, compared to those fed normal diets.¹¹³⁻¹¹⁵ Small deficits in nephron numbers that are not detected at birth may induce long-term renal failure and increase the incidence of hypertension.^{116 117} Animal studies have also confirmed the impact of various other aspects of maternal nutrition on long-term health of offspring.⁸³

Highlighting the complexity of the relationship between social and economic factors and health is the well described gradient between family income and child health.¹¹⁹⁻¹²²

A positive relationship between income and child health has been described in the US¹²²⁻¹²⁴ and England,⁸⁴ with results from the US suggesting that the gradient becomes steeper as children get older.^{85 86} It is hypothesised that this pattern results from the accumulation of health disadvantages over time among children from low income families, meaning that these children enter adulthood with lower health status and more school absenteeism, potentially impacting on the income which they may earn, thus perpetuating the gradient.⁸⁵

An array of factors has been shown to impact upon both maternal and child health, with many of these factors also related to socio-economic status and income. Maternal education for example, is related to health behaviours such as smoking and alcohol consumption, and is also associated with socio-economic status, impacting upon the options for employment and level of attainable income. Various maternal factors such as smoking, alcohol consumption, exercise levels, and nutrition, which are known to be associated with infant birth outcomes,^{102 108 125-128} have been examined for their role in creating the relationship between maternal income and infant health. While factors associated with maternal health during and after pregnancy, and the quality of the intrauterine environment are clearly related to family income, they do not explain the relationship between income and child health.⁸⁷ These findings, reported by Dowd (2007)⁸⁷ serve to highlight the complexity of the interaction between social, and economic factors and the health of individuals, and the need for health promotion and intervention activities to take each of these components into consideration.⁸⁸

The earliest possible target for intervention

Improving the health of Australia's Aboriginal and Torres Strait Islander peoples is a public health priority. Considering the common set of risk factors associated with renal disease, cardiovascular disease and diabetes, as well as the potential link between

these morbidities and maternal health during pregnancy, a logical approach to the improvement of Aboriginal and Torres Strait Islander health is to tackle maternal health during pregnancy. While the co-existence of risk factors can increase the chance of developing disease over and above that of individual risks, the removal of all risks is likely to be necessary to have significant impacts upon improving health and ultimately closing the gap.

By improving maternal health during pregnancy and involving the social networks of mothers, we can potentially impact upon, not only the current generation of parents, but also future generations. Behavioural interventions to increase maternal health and nutrition potentially prevent a huge array of health issues for both mothers and their babies and lead to a reduction in the burden on the health system. An overall focus on health of Aboriginal and Torres Strait Islander mothers during pregnancy would be ideal for any improvement to the health of this population.

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CHAPTER 2

Antenatal health risk factors among women giving birth at Cairns Base Hospital

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Chapter 2

Antenatal health risk factors among women giving birth at Cairns Base Hospital

Introduction

Pregnancy is a particularly vulnerable period in the lives of women, with a wide range of factors – maternal and environmental – impacting upon pregnancy outcome. Links have been reported between birth outcome factors such as low birth-weight, small for gestational age (SGA), preterm delivery,¹⁻⁴ low Apgar (Activity, Pulse, Grimace, Appearance and Respiration) score,⁵ rate of assisted deliveries,⁶ length of hospital stay,⁵ and infant mortality,⁷⁻⁸ and a range of maternal factors such as socio-economic status,⁹ nutrition and body mass index (BMI),¹⁰ maternal age,¹¹ urinary tract and sexually transmitted infections,⁶⁻¹²⁻¹³ physical abuse,¹⁴⁻¹⁶ alcohol consumption,⁵ and smoking during pregnancy.¹⁷

Social and demographic predictors of birth outcome

Social and demographic factors are powerful determinants of birth outcome. Several studies have linked social and economic disadvantage with high infant mortality rates.⁹
¹⁸ Low socio-economic status is also often associated with, or identified as a predictor for, other risk factors such as smoking,¹⁸⁻²⁰ alcohol consumption,¹⁸ poor diet, and high body mass index (BMI).¹⁹ A study in Finland reported higher rates of SGA infants among unemployed women, and even higher rates among families in which both parents were unemployed.²⁴ In the United Kingdom (UK) a study found that the 84 gram difference in birth weight which was detected between the most and the least socially deprived mothers was reduced to 47 grams after adjusting for infant sex and

maternal smoking, height, weight gain, ethnicity, and parity.²⁰ Social inequalities in the rate of low birth weight detected in a population in Germany were partly explained by mediating factors which included smoking status, adequacy of prenatal care, and medical risks such as hypertension.²¹

Ethnicity

Studies in the US have examined disparities in birth outcomes between groups based on race, income and education, reporting that Black[♦] women experience health problems at rates which cannot be solely accounted for by socio-economic status.^{22 23} Disparities in health and pregnancy outcomes remain between Black and Caucasian women of similar, high levels of education,²⁴ and similar income.³⁰ Socio-economic indicators have “*complex joint effect patterns*”(p1)³¹ among different racial groups, possibly due to the differing implications of education and income status among groups.²⁸ The effect of smoking on the likelihood of preterm delivery has been reported to be stronger among African-American women than Caucasian women, and to act independently of socio-economic factors.²⁵ Ahern et al., (2003) have presented the following theoretical model of preterm birth: “*The social environment has a direct impact on preterm delivery by affecting susceptibility to disease, an indirect effect by shaping certain risk behaviours, and the effect of the social environment on preterm delivery may differ depending on individual characteristics and behaviours*”.(p606)²⁵ The difficulty in determining the contribution of individual risk factors to poor birth outcomes is further highlighted by a multitude of studies reporting clusters of risk factors associated with poor birth outcomes in certain groups. Poor housing conditions, maternal stress, and alcohol consumption are independent determinants of foetal growth, and are also associated with the partner’s smoking and alcohol consumption.²⁶

♦ “Black”, “Caucasian” and “African-American” are the terms used by the particular authors, and are repeated here by the candidate for correctness.

Australia's Aboriginal and Torres Strait Islander population has a lower overall socio-economic status compared with the mainstream population and suffers a higher rate of illness and poor birth outcomes. On average, Aboriginal and Torres Strait Islander women have more babies, and have them at a younger age than non-Indigenous women.²⁷ In 2002, total fertility rates were 2193 births per 1000 Aboriginal and Torres Strait Islander mothers, and 1752 births per 1000 non-Indigenous mothers. Fertility of Aboriginal and Torres Strait Islander teenagers (76 babies per 1000 women) was more than four times the fertility rate of all Australian teenage women (17 babies per 1000 women). Unfortunately, this contribution to Australia's population is not always a positive one of healthy mothers and babies. Of babies born to Aboriginal and Torres Strait Islander mothers from 1998 to 2000, 12.8% were of low birth weight (<2500 grams), compared with 6.5% of those born to other Australian mothers. Perinatal mortality rates for the Aboriginal and Torres Strait Islander population were twice those experienced by the non-Indigenous population (20.1 per 1000 total births for Aboriginal and Torres Strait Islanders, compared with 9.6 per 1000 for all births).^{27 28}

Place of residence

Linked with both socio-economic status and ethnicity, is place of residence and the urban/rural divide associated with health status and mortality.²⁹ These factors are particularly important considering the population distribution of Australia. A study in New South Wales examining associations between urban/rural place of residence, maternal factors and pregnancy outcomes among women giving birth between 1990 and 1997 reported different profiles among urban and rural mothers, consistent with socio-economic disadvantage.¹¹ This study is one example which highlights the complexity of factors associated with maternal health and birth outcomes.

Maternal age

Young maternal age has been identified as a risk factor for low birth weight as well as foetal and neonatal mortality.^{30 31} This link may result from the fact that teenage mothers are themselves continuing to grow and thus they compete with the foetus for nutrients.³⁶⁻³⁸ Rates of poor birth outcomes among teenagers has also been associated with psychological factors such as the implications of unplanned or unwanted pregnancies, and socio-economic factors such as income and education.³⁶

In the US, Black teenage mothers have a lower incidence of low birth weight than Caucasian women in their twenties, but this is masked by the socio-economic risks of this group.³⁶ Women over 30 years of age were also at increased risk of delivering low birth weight babies. There are increasing racial disparities in birth outcomes and maternal health with increasing maternal age, suggesting that other health problems of older African-American women, such as obesity, high blood pressure and high cholesterol, may be responsible for differences in birth outcomes.³²

A recent study in South Australia found that Aboriginal teenagers in that State have a pregnancy rate more than twice that of non-Indigenous teenagers, with a smaller proportion of pregnancies being terminated. Aboriginal teenage mothers were younger, more likely to be single, to smoke, to have infections and anaemia, to give birth by caesarean section, and to give birth to small-for-gestational-age, preterm babies. These babies are more likely to have a congenital abnormality, to require intensive nursery care, and to stay longer in hospital.³³ A large study on births in New South Wales also reported that mothers giving birth in rural areas were more likely to be teenagers than their urban counterparts.⁹

Health and health risk behaviours associated with poor birth outcomes

Maternal nutrition

Low pre-pregnancy weight, low gestational weight gain, and at the opposite end of the scale, obesity, are linked with poor birth outcomes and infant health. Maternal weight and nutrition not only impact on foetal development and the size of the child, but have also been shown to influence long-term health and metabolic functioning. The foetal origins theory links maternal diet with chronic diseases such as coronary heart disease, hypertension and diabetes, in adulthood.^{44 45}

A study of 503 live-born singletons born to Aboriginal mothers at Royal Darwin Hospital (Northern Territory) between 1987 and 1990 found that infants born to mothers with a BMI less than 18.5kg/m² are at five times the risk of being low birth weight and 2.5 times the risk of intrauterine growth retardation, compared with those born to mothers with a higher BMI.³⁰ Other studies suggest that maternal diet, and in particular intake of protein and micronutrients, may be more important than pre-pregnancy BMI in influencing birth weight and intrauterine growth retardation.^{45 46}

Given the classification of 28% of Aboriginal and Torres Strait Islander women as obese (compared with 19% of other Australian women), it is also important to note that maternal over-nutrition may also retard foetal growth and increase foetal and neonatal mortality rates.³⁴ Consistent results have been obtained in both human epidemiological studies,³⁵ and animal studies.³⁴ Women with high BMI and excessive gestational weight gain are at increased risk of pregnancy complications such as urinary tract infection, thromboembolism, hypertension, and caesarean section.^{36 37} BMI and nutrient intake during pregnancy can be predicted, to some degree, by socio-economic status and level of education, with women of lower education and income less likely to

have an adequate intake of dietary fibre, folate, beta-carotene and calcium, and more likely to have a higher intake of fat.¹⁹

Alcohol consumption

In utero exposure to alcohol is associated with varying degrees of harm to the unborn child, from subtle developmental defects to foetal alcohol syndrome (FAS), characterised by physical abnormalities, growth retardation, neurological dysfunction, and developmental delay.³⁸ A study of alcohol consumption patterns among young Australian women reported that women who drank were more likely to be of low socio-economic status, live in rural or remote areas, be unmarried, be current or ex-smokers and have experienced a sexually transmitted infection.¹⁸ Recent data suggest that Aborigines and Torres Strait Islanders are less likely than non-Indigenous Australians to drink alcohol, but those who do so are more likely to drink at hazardous levels (as defined by NHMRC Australian Alcohol Guidelines).²⁸ While the rate of alcohol consumption during pregnancy has not been properly examined, a retrospective study in the Northern Territory found that the rate of FAS was 1.7 per 1000 live births among the non-Indigenous population, and 4.7 per 1000 live births among the Aboriginal and Torres Strait Islander births at Darwin hospital over a 10-year period.³⁹ The latter rate is alarming, represents a massive burden on the health system of Australia and is linked with a high rate of delinquency and criminality.⁴⁰

Smoking

Maternal smoking during pregnancy is hazardous to the developing foetus, and is an important factor leading to infant mortality and low birth weight.⁴¹⁻⁴³ A number of studies have demonstrated that reduction of smoking during pregnancy improves infant birth weight.^{44 45} Several determinants of intrauterine growth retardation have been

identified. In developed countries, cigarette smoking is the leading cause, followed by low gestational weight gain and low pre-pregnancy BMI.⁴⁶ The rates of smoking in pregnancy for Aboriginal and Torres Strait Islander women are unacceptably high^{10 47-49} with up to 65% smoking during pregnancy. In contrast only about 20% of other Australian women are reported to smoke during pregnancy.⁵⁰ Younger mothers, Aboriginal mothers, and those who first attend antenatal care late in their pregnancy are least likely to quit smoking during their pregnancy. Higher socio-economic status and early antenatal care attendance are associated with greater rates of smoking cessation during pregnancy.⁹

Physical abuse

Women who experience violence from their partners during pregnancy have been found to present more often with kidney infections, gain less weight during pregnancy, and be more likely to undergo operative delivery.¹⁶ An association has also been found between abuse during pregnancy and perinatal deaths, and preterm, low birthweight deliveries.¹⁵ A Canadian study reported that women who were abused during pregnancy were more likely to be younger, single, less educated and of lower socio-economic status than non-abused women.⁶³ The pregnancy outcomes resulting from abuse differ according to the body site injured, the timing of violence in the pregnancy and the number and severity of violent incidents.^{14 58 59} In Australia in 2000-01, rates of hospitalisation for assault were 28.3 times higher for Aboriginal and Torres Strait Islander females compared with non-Indigenous females.²⁷

Obstetric health

As many as 50% of spontaneous preterm births are associated with infection,⁵¹ and a significant proportion of adverse pregnancy outcomes have been attributed to

intrauterine infections and bacterial vaginosis.⁵² Urinary tract infections have also been linked with low birth weight, prematurity, and perinatal death.^{53 54} Sexually transmitted infections (STIs) are a particularly important category of infection, in both impact on pregnancy outcomes and prevalence among disadvantaged groups. Sexually transmitted infections have been associated with spontaneous abortion, stillbirth, premature delivery and low birth weight, as well as morbidities during infancy. The prevalence of STI is highest in the developing world,⁵⁵ but has risen recently in Australia, and is particularly high in remote communities and Aboriginal groups. A study in rural and remote Aboriginal communities in North Eastern Australia recently reported a rate of chlamydia and/or gonorrhoea of 23% among 15 to 19 year olds.⁵⁶

Study objectives

Each of the factors and influences mentioned above contributes to situations in which women are vulnerable to poor health and adverse health outcomes. It is hypothesised that the number of these factors experienced by women relates to their level of risk for adverse birth outcomes and their degree of vulnerability overall. Previous studies have reported on the individual risk factors for poor birth outcomes such as low birth weight,^{6 17 30 57 58} and many studies identify multiple risk factors and predictors for these outcomes.^{17 59 60} The relationships between social and demographic risk factors, health risk behaviours and obstetric health factors, have not been clearly characterised.

This study seeks to:

1. Explore the characteristics of vulnerable women who experience multiple risk factors during pregnancy, and
2. Identify appropriate target factors for intervening with these women.

It is hypothesised that by:

1. Clustering women who have similar levels of risk based on factors which have been demonstrated to be associated with adverse maternal and infant outcomes;
2. Examining the characteristics of women in each cluster to identify any cluster which appears to have increased vulnerability; and
3. Identifying the risk factors which are most prevalent in this cluster,

...it will be possible to establish a set of risk factors or characteristics which can be used to identify particularly vulnerable women and use those as targets for intervention. Demographic, social, and health characteristics of women will be used as the basis for clustering. Clusters will then be examined for the characteristics most likely to be associated with vulnerability, and to act as targets for intervention.

Ethical approval for this research was granted from the University of Newcastle Human Research Ethics Committee, The Cairns Base Hospital Human Research Ethics Committee and the Board of Mookai Rosie Bi Bayan. Refer to Appendix 2.1 for University Certificate of Approval, Appendix 2.2 for Cairns Base Hospital letter and Appendix 2.3 for in the Board letter respectively.[‡]

Methods

Study design

A cross-sectional study was performed, using an interviewer-administered questionnaire and medical record audit to examine factors associated with the health and lifestyle of women during pregnancy.

[‡] Copies of ethics approval letters are inserted into this Thesis as “pdf” or “jpg” files, and may therefore not appear as true A4 letter size. This applies to most Appendices throughout the Thesis.

Setting and recruitment

The study was conducted at the Women's Health Clinic at Cairns Base Hospital (CBH), Tropical North Queensland. The hospital serves a Health Service District which is home to approximately 144 300 people, and includes remote and very remote communities based on the Australian Standard Classification of Remoteness by Postcode.⁶¹ Approximately 9.5% of the Health Service District's population is Aboriginal or Torres Strait Islander. Approximately 2000 women give birth at the hospital annually, with women travelling from remote Cape York communities, as well as townships and remote areas to the south, north, and west of Cairns. Deliveries at CBH include all women within the region who are classified as at-high-risk during their pregnancies, as well as Cairns residents receiving public antenatal healthcare.

All women attending antenatal clinics at CBH for routine check-ups with midwives or Obstetricians at or after 36 weeks' gestation were invited to participate in the study. During screening or review consultations, eligible women were identified, given a brief information sheet explaining the research, and asked if they would be willing to speak to the researcher (PhD candidate) about the study. Those willing to participate, provided written informed consent (refer to Appendix 2.4 for the Information Statement and Consent Form). Women were excluded if they were less than 36 weeks gestation, less than 16 years of age, had a florid mental illness, or were being treated for any chemical dependency other than tobacco or alcohol (e.g. cannabis, heroin).

These criteria were developed to capture a broad sample of women, including those who were flown to Cairns from remote communities at 36 weeks' gestation for the final weeks of their pregnancy. Conducting interviews at 36 weeks' gestation or later enabled the collection of behaviour and lifestyle data depicting the experiences of

women for the majority of their pregnancies. By excluding women who were being treated for chemical dependencies, a sub-set of women who may be particularly resistant to smoking cessation, and who may already be experiencing traumatic withdrawals, were protected from the additional pressure of quitting smoking. Also, the intervention and process of quitting smoking may be influenced by the treatments and processes involved in eliminating other chemical dependencies.

Women who agreed to speak to the researcher were provided with more detailed information about the study and were invited to participate in a short interview, during which the PhD candidate asked a series of questions about their health, diet, alcohol consumption, cigarette smoking, lifestyle, living conditions and experience of domestic violence. The interview was conducted in a private section of the antenatal clinic waiting room or in a consultation room. Women were also asked to consent to access to their medical records for collection of birth outcome information after the birth of their babies.

Questionnaire design

The questionnaire (Appendix 2.5) was designed to collect information on a broad spectrum of items associated with increased risk of pregnancy complications and adverse birth outcomes. All items were based on previously used and validated instruments, and were tested for reliability during pilot testing and consultations with representative women. The questionnaire and participant information material were written for a reading age of grade six (Flesch readability level)⁶² and its interviewer-administered delivery enabled the PhD candidate to ensure that women understood and correctly interpreted each questionnaire item. Consultations were also held with Aboriginal and Torres Strait Islander health workers at the nearby Wuchopperen Health Service (an Aboriginal Community-controlled Health Service) and at Mookai-Rosie Bi

Bayan (an organisation which provides accommodation for women from remote communities who are flown to Cairns at 36 weeks gestation to deliver their babies). Staff at these organisations assisted with questionnaire development to ensure that the language was appropriate for Aboriginal and Torres Strait Islander participants, and that questions were culturally acceptable for this group. These consultations led to the removal of redundant items in the questionnaire. Minor changes were also made to the questionnaire during the first week of recruitment, adding options to some items based on the responses given by participants and the flow and logistics of the interview situation.

Demographic characteristics

Key demographic indicators were based on the format used in Australian Institute of Health and Welfare (AIHW) publications.²⁸ All demographic data were collected using options or categories for responses. Women were asked to identify their ethnic origin (non-Indigenous, Aboriginal, Torres Strait Islander, or both Aboriginal and Torres Strait Islander), marital status (never married, divorced, de facto, married), main source of income (full-time employment, part-time or casual employment, social security, supported by partner's work (full-time or part-time), supported by partner's social security payments, or supported by maintenance from another person), and level of education (highest year of school completed and any tertiary education). Income options were based on those used in a study of Aboriginal women in Western Australia.⁴⁷

Housing conditions

All questions were designed to capture the range of possible circumstances in which women live. Participants were asked to rate the maintenance or repairs in their home

as good, satisfactory, poor or bad. The presence of air-conditioning and fly screens in the home was recorded as present in most, some, or all rooms/windows. These items were relevant to the Tropical North Queensland area, where the hot climate and presence of potentially infectious mosquitoes and other insects call for some capacity for cooling without increasing exposure to mosquito-borne diseases.

Nutrition

Items regarding diet during pregnancy were based on the National Health and Medical Research Council (NHMRC) Dietary Guidelines for Australian Adults⁶³ which recommend that pregnant women consume four serves of fruit, five to six serves of vegetables, and one and a half serves of meat (or meat alternatives) each day. The NHMRC defines a serve of fruit as 150 grams of fresh fruit, equivalent to one medium-sized piece such as an apple or orange, two smaller pieces such as apricots, half a cup of fruit juice, or one metric cup of chopped or tinned fruit. A serving of vegetables is regarded as half a cup of cooked vegetables or legumes, one medium potato, or one cup of salad vegetables. A serve of meat or meat alternatives is classed as 65-100 grams of cooked red meat or chicken, 80-120 grams of cooked fish fillet, two small eggs, or a third of a cup of nuts or legumes. Images and descriptions of serving sizes were used to assist women in answering these questions (presented as the last page in Appendix 2.5).

Alcohol consumption

Questions regarding alcohol consumption were based on the NHMRC Australian Alcohol Guidelines⁶⁴ as well as advice from the National Drug and Alcohol Research

Centre.[^] The NHMRC recommends that during pregnancy, women should not consume more than seven standard drinks in one week, and should not have more than two standard drinks on any one day, spread over a minimum of two hours. For men, the recommendation is for an average of no more than four standard drinks a day, with one or two alcohol-free days per week, and never more than six standard drinks on any one day. The questionnaire, therefore, aimed to gauge the quantity and frequency of drinking, asking women to answer for both themselves and their partners (when partners were present during the interview, they were invited to take part and answer questions regarding their own alcohol consumption), how often they had a drink containing alcohol, with options ranging from “Every day”, to “One day a month”, and “Never”. The number of standard drinks normally consumed on a day when they were drinking was recorded, after women were shown images of standard drink volumes to assist with the accuracy of responses. For both women and their partners, the number of occasions in the previous month on which they consumed more than two standard drinks over a period of two hours, and more than five standard drinks on any one day, was also recorded.

Physical and verbal abuse

A series of questions concerned the level of verbal or physical abuse to which women were exposed. Women were notified that some questions were of a sensitive nature, and at all times they were free to refuse to answer any item (in particular when their partner was present during the discussions). Questions were based on the screening tool developed by Richard Tolman, Carla Parry, and Gabrielle Gruber for use in a working group session at the “Trapped by Poverty: Trapped by Abuse” conference held

[^] The National Drug and Alcohol Research Centre (NDARC) was established at the University of New South Wales in 1986 and officially opened in 1987. It is funded by the Australian Government as part of the National Drug Strategy. Website: <http://ndarc.med.unsw.edu.au> last accessed 1st February 2008.

on September 26, 1997. The questions are in use in a University of Michigan Research project on welfare, work and domestic violence.⁶⁵ Three levels of abuse were characterised by behaviours which were presented in three boxes in the questionnaire. The first box (A) contained low-level verbal behaviours: “Insult or swear”, “Sulk or refuse to talk”, “Storm out of the room”, or “Do or say something in spite”. The second box (B) was regarded as “medium severity” and included “Push, grab, or shove”, “Throw something” or “Slap”. The third box (C) contained severe physical violence: “Kick, bite, hit with fist”, “Hit or try to hit with something”, “Beat up”, “Choke”, or “Burn or scald”. Respondents were asked to indicate how often their partner did any of the things in each box when they had a disagreement, with options of “Often”, “Sometimes”, “Rarely”, or “Never”.

Obstetric and gynaecological history

Women were asked how many times they had been pregnant, followed by how many biological children they had. The PhD candidate found that it was not necessary to ask questions regarding any discrepancy in numbers between these two questions, as all women volunteering information regarding failed pregnancies or infant deaths of their own accord. This information was recorded, and due to relatively small numbers of these events, was classed as a voluntary termination or other failed pregnancy. Information related to illness or complications during pregnancy was obtained by self-report, with diarrhoea, urinary tract infections, gestational diabetes, high blood pressure, high cholesterol, and low iron listed as separate items. Women were invited to name any other illness or complication experienced during pregnancy.

Birth outcomes

Patient charts were searched for information about sexually transmitted infections and other recorded complications or illnesses, as well as the most recently recorded Haemoglobin level. Once each participant had delivered, the birth weight, birth length, gestation, method of delivery, APGAR scores, and other notes about infant and maternal health associated with the delivery or pregnancy complications were recorded from the charts.

Statistical analysis

All data were entered into a spreadsheet by the PhD candidate. Data-checking and data-cleaning prior to analysis involved examining the frequencies and distribution of variables. After initial data exploration, several variables were combined, collapsed, or categorised to eliminate disproportionately represented groups and simplify the data for analysis. Income was collapsed into three categories: own work, social security, or supported by partner or another person. Education was recoded to relate to number of years of education rather than school level. The items on living conditions were simplified, dividing responses into good/satisfactory or poor/bad. Air-conditioning and fly screen items were combined, classifying those women who have air-conditioning with or without fly screens as one group, those who do not have air conditioning but do have fly screens as another group, and those who have neither, as a third group.

The separate items related to nutrition were combined to indicate whether dietary guidelines were met. Each item was recorded as no consumption, sub-threshold consumption (one to three serves of fruit and vegetables, or less than six serves of meat or meat alternatives in a week), or meeting guidelines. Failure to meet any of the

guidelines was regarded as not meeting them overall, any sub-threshold consumption was regarded as sub-threshold overall, and women were only regarded as meeting all of the guidelines if each individual guideline was met.

Alcohol items were recoded and combined to create two variables measuring frequency and amount of alcohol consumption. Based on the data collected, responses were categorised as no alcohol, consumption of an alcoholic beverage once per month or less, or consumption ranging from 2-3 days per month to every day. Level of alcohol in the last month was classified as none to one drink, two to four drinks on any one occasion, or five or more drinks on any one day. Items related to physical and emotional abuse were collapsed into one variable to indicate level of violence. A response of “Never” for the items in box A was regarded as no violence, and a response of “Rarely”, “Sometimes”, or “Often” for these behaviours was regarded as low-level violence. Any occurrence (“Often”, “Sometimes”, or “Rarely”) of the behaviours in boxes B and C was regarded as medium and high severity respectively. Any injuries incurred as a result of violence during the current pregnancy were also recorded.

To investigate all potential response bias data for ethnicity, marital status, age group, and area of residence were compared between consenting participants and those who were eligible but declined to take part in the study using the Chi-square test (χ^2).

Exploratory data analysis was performed to examine the distribution of variables and the relationships among all possible pairs of variables. Correlation was performed to generate Pearson coefficients for comparison of continuous variables against each other, Chi-square analyses were performed for comparison of categorical variables, and one-way analysis of variance (ANOVA) was undertaken to compare continuous variables against categorical variables. Scheffe Post-Hoc comparisons (using SPSS)⁶⁶

were included in ANOVA to correct for the large number of comparisons being made. As a further control for the number of statistical tests performed on the data set, an alpha level of 0.01 was used as a minimum threshold of significance in initial explorations. Values between $p=0.01$ and $p=0.05$ were not regarded as significant.

The initial exploratory cluster analysis included all demographic, health risk, and obstetric variables. Variables for inclusion in secondary cluster analyses were chosen based on their importance in the initial analysis (i.e. highest ranking), as well as the associations and correlations detected between variables at the univariate level. In terms of pairs of items which related to the same or a similar risk factor and were statistically highly related, if it was deemed that the inclusion of both would not provide any benefit for the analysis, one variable only was chosen to represent the group or category.

Due to the potential importance and co-existence of a range of variables, a two-step cluster analysis procedure was used to reveal natural groupings within the sample population. Cluster analysis groups data based on the log-likelihood distance; a probability-based distance related to the decrease in log-likelihood as cases are combined together. The first step is a sub-cluster step which scans cases sequentially to determine whether an individual should be merged with a previously formed cluster or a new cluster started, based on the distance criterion for that case. Step two groups the sub-clusters into a final number of clusters based on the Bayesian Information Criterion (BIC); a conservative approach to assessing model fit.⁶⁷

Cluster analysis is based on the theory that the distribution of responses for any number of cases can be explained by a small number of mutually exclusive clusters.⁸¹

⁸² The process groups together participants on the basis of the similarity of their

characteristics, aiming to minimise variance within groups, and maximise variance between groups. The algorithm assumes that observations are independent, that categorical variables have a multinomial distribution, and that continuous ones have a normal distribution. Both categorical and continuous variables are entered into a model, which determines the most appropriate number of clusters to explain the variance between participants and variables.

Cluster analysis is a valuable data reduction tool, useful in uncovering groupings and identifying features among populations which may appear homogenous on the surface, and in simplifying large data sets. Factor analysis attempts to identify the variables or factors which explain a pattern of correlations or explain the variance observed in large sets of variables. Cluster analysis operates in a similar manner, but as well as identifying the key variables which describe or explain the variance within a large data set, this method also groups individuals on the basis of the similarities they possess. Clustering is an inherently useful organisational tool which has the capacity to increase the likelihood of identifying variables of importance. If individuals can be grouped with others sharing similar characteristics, the most important variables explaining the variance within that group are likely to be more highly associated with the members of that group, and are therefore likely to be more useful as targets for intervention or change. Cluster analysis is not only used in health research to examine the relationships between risk factors for certain conditions, or between several conditions,⁶⁸⁻⁷⁰ but is often used in fields such as marketing. This is a useful example of the value of cluster analysis, with the capacity to group consumers according to their demographic characteristics or purchasing history, identify the factors which are likely to impact upon these consumers and target marketing campaigns to the most appropriate groups. In this context, cluster analysis can save time and money on otherwise unsuccessful marketing efforts.⁷¹ Similarly, in health research, cluster

analysis offers the opportunity to avoid wasted effort and funding on treatments or intervention approaches which are not likely to be effective with certain groups.

A series of cluster analyses was run using the most important variables first (i.e. those ranked highest), and adding variables one by one to arrive at the model which captured the greatest proportion of the sample population (least exclusion from clusters) with the greatest number of variables included. The final structure was then used to define clusters which were examined and labelled according to their level of vulnerability.

Once clusters were obtained, the prevalence of all demographic, health and lifestyle, and obstetric risk factors was compared between clusters using Chi-square analysis. The assumptions for Chi-square analysis were checked, and where the expected count of any cell was less than five, non-parametric Chi-square analysis was employed, using Fisher's exact test.

Given that there are approximately 2000 births annually at CBH, it was estimated that approximately 158 (95% eligibility) would be eligible each month to participate in the study. Assuming a 70% consent rate, recruiting for a three to four month period would provide 442 participants, enabling reliable estimates of correlations (to within ± 0.06) among variables for generation of clusters, and, assuming three to four clusters, would allow detection of moderate difference in variables between clusters of about 15-20% for dichotomous variables and 0.35-0.4 of a standard deviation (SD) for continuous variables with 80% power and a 5% significance level.

Results

Questionnaire modifications

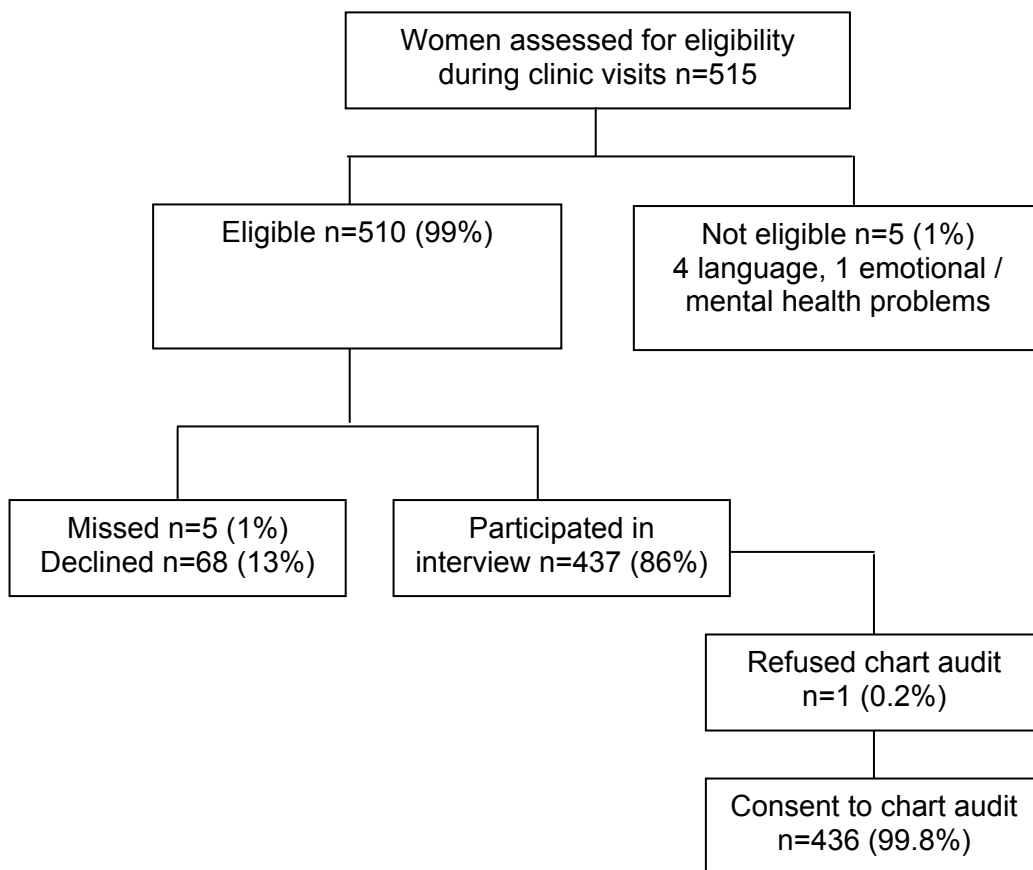
After initial consultations, the terms, “shed”, “tent”, and “donga”, were included in the caravan category for type of dwelling, and the responses, “boarding” and “work housing”, were added as options for the item related to dwelling status. An item on the presence of fly screens was added to the housing conditions questions on the suggestion of a participant and her partner. A set of questions related to women’s opinions of the care received at remote community health services was eliminated after it became apparent that it was difficult to ensure the women’s understanding of the questions without influencing their answers. The questions did not appear to be generating useful information, with most women answering in a very neutral fashion, perhaps due to a fear of the ramifications of any negative responses, or a lack of understanding. The options for cause of smoking cessation were modified throughout the study as a number of options which had not been previously listed appeared to be common. Several women, for example, stated that they had quit smoking for religious reasons and/or due to a death in the family, and many quit when they began breastfeeding a previous child.

Recruitment and participant characteristics

Five hundred and fifteen (n=515) women who attended the clinic between September and December 2006, on days during which the PhD candidate was present, were invited to participate. Of these women, four were excluded due to language or communication difficulties, and one was excluded due to emotional issues. Four hundred and thirty-seven women (n= 437, 85% of the original sample) participated in the interview, and 436 (84% of the original sample) gave consent to access their

medical records. An additional ten women consented to participate but were missed or could not complete the interview due to time constraints. Refer to Figure 2.1.

Figure 2.1: Eligibility and consent process



Comparison between participants and non-participants

Table 2.1 compares the demographic characteristics of participants and non-participants. Participants had a mean age of 29 years, and the majority of women (72%) were non-Indigenous. Thirteen percent of participants identified as Aboriginal, 11% as Torres Strait Islander, and 3% as both Aboriginal and Torres Strait Islander. Eighty-two percent of the women were married or in a de facto relationship and 90%

resided in the Cairns area, categorised as outer regional. Participants were older on average ($p<0.0001$), than non-participants, with a larger proportion aged over 30 ($p=0.023$). Non-participants were less likely to be married or in a de facto relationship ($p<0.0001$) than participants. Table 2.2 summarises key obstetric and health characteristics of the participant group.

Table 2.1: Comparison of participant and non-participant demographic characteristics

	Participants (n=437)		Non-participants (n=68)		χ^2	df	p-value
Ethnicity	n	%	n	%			
Non-Indigenous	315	72	43	64	4.503	3	0.212
Aboriginal	57	13	8	12			
Torres Strait Islander	50	11	10	16			
Both	15	3	6	9			
Marital status							
Never married	79	18	33	54	34.216	2	<0.0001*
De facto	182	42	12	20			
Married	174	40	16	26			
Age							
≤19	30	7	10	15	9.497	3	0.023*
20-24	90	21	21	31			
25-29	117	27	15	22			
≥30	200	46	22	32			
Region							
Outer regional	392	90	55	81	5.675	2	0.059
Remote	15	3	2	3			
Very remote	30	7	11	16			

**Statistically significant difference between groups at the $\alpha=0.05$ level.*

Table 2.2: Participant characteristics

	All participants (n=430)	
Demographics	n	%
Source of income		
Social security	110	25
Own work	255	58
Supported by partner or other	72	17
Housing status		
Privately rented	202	47
Housing Commission	65	15
Owned or being purchased	162	38
Education level		
Less than year 10	27	6
Year 10 to year 12	150	34
Tertiary education	260	60
Obstetric and gynaecological history		
Gravidity		
Primigravidas	147	33
2	115	26
≥3	175	40
Parity		
Primiparous	176	40
1	129	30
≥2	132	30
Health and lifestyle		
Dietary guidelines met		
Yes: meat, fruit and vegetables	14	3
Some: sub-threshold in one or more	411	94
No: none of three guidelines met	12	3
Smoking status		
Smoker	100	23
Ex-smoker	146	33
Never smoked	191	44
Usual alcohol consumption		
None	43	10
One day per month or less	54	12
2-3 days per month – every day	337	78

Table 2.2 continued

	All participants (n=430)	
Health and lifestyle (continued)		
Alcohol consumption in previous month (during pregnancy)		
None	414	95
2-4 drinks on some occasions	8	2
5 or more drinks on some occasions	15	3
Exposure to domestic violence during pregnancy		
None	138	34
Low severity	237	59
Medium severity	14	4
High severity	15	4

Birth outcome data were collected for 398 women (91%) who delivered during the data collection period. The mean gestation at delivery was 39 weeks (range 35-42, SD 1.3), mean birth weight was 3483g (range 1640-4990g, SD 479.3g) and birth length was 50.4cm (range 40-62cm, SD 2.4cm). APGAR scores ranged from 1-10, one minute after birth and from 4-10, five minutes after birth, averaging 8.2 and 9.3 respectively. Sixty-eight percent of women (n=272) delivered by normal vaginal birth, 7% (n=28) required forceps or vacuum extraction, 11% (n=44) elected to have caesarean sections, and 14% (n=57) had emergency caesarean sections. Sixty-three babies (14%) were admitted to the special care baby unit (SCBU) for treatment or monitoring after birth.

Cluster analysis

Exploratory analysis resulted in the elimination of some highly correlated variables thus producing a subset of variables for inclusion in the cluster analysis. For example, parity was highly correlated with the number of children in the house ($p<0.001$), maternal age ($p<0.001$), and BMI ($p<0.001$), leading to the exclusion of the latter three from the

analysis. Further justification for the exclusion of these variables was their correlation with several other variables including gravidity, years of school education, and the number of smokers in the house. The variables included in, and excluded from, the analysis are presented in Table 2.3. Those which were included were deemed to sufficiently represent the excluded variables and thus the data set. Continuous variables did not fit a normal distribution but the system used for analysis in SPSS includes an automatic standardisation of continuous variables, thus reducing the importance of the consideration of normality. The two-step cluster analysis procedure is expected to be robust to violations of distribution and independence.⁶⁶

Table 2.3: Variables included in, and excluded from, cluster analysis

Included	Excluded
Ethnicity Income Marital status Housing status Maintenance of home Years of education Region of residence Severity of domestic violence Normal alcohol consumption Level of consumption in the previous month Partner's normal alcohol consumption Partner's level of consumption in the previous month Cigarettes smoked per day by all women Smoking status of partner Parity The number of cohabitating smokers, Gestational diabetes Diarrhoea during pregnancy Infections during the current pregnancy	Number of adults in the household Number of Children in the household Gravidity BMI Age Number of quit attempts Years smoking Birth weight Birth length Gestation at birth Infant morbidities Infant AGPAR score Maternal low iron level Method of birth Pregnancy complications Infections in a previous pregnancy Transport to clinic Do other's smoke inside the house?

When all variables were included in the initial cluster analysis, 67% of participants were not able to be allocated to a cluster. This step gave an indication of the importance of each variable in grouping characteristics of women. The final cluster analysis structure included 19 variables: ethnicity, income, marital status, housing status, maintenance of home, years of education, region of residence, severity of domestic violence, normal alcohol consumption and level of consumption in the previous month for both women and their partners, cigarettes smoked per day by all women, with zero entered for non-smokers, the smoking status of partners, parity, the number of cohabitating smokers, gestational diabetes, diarrhoea during pregnancy and infections during the current pregnancy. The BIC was used to assess the appropriateness of the model and the fit to the data. Model fit was assessed for a range of cluster numbers from one to 15. The model fit indicated that the best number of clusters for the data under assessment was three. The three clusters included 300 participants (89% of the total), excluding 49 from the model. Cluster sizes were 194, 85, and 109 participants, accounting for 50%, 22%, and 28% of the included cases respectively.

Participants fell into three distinct clusters, separated on each level: demographic, health and lifestyle, and obstetric. The relatively small numbers and low incidence of low birth weight in the study group precluded meaningful statistical correlations being made between the risk factors studied and the birth outcomes recorded. The vast literature and evidence for each of the factors increasing the risk of poor birth outcomes validates the classification of women who experience a large number of risks as being “vulnerable”. The characteristics of each cluster are detailed in Table 2.4, Table 2.5 and Table 2.6. Based on overall characteristics, cluster two appears to be the most vulnerable group, with the lowest socio-economic status and highest concentration of known risks. Cluster one is the least vulnerable group, characterised by higher socio-economic status and fewer risks. Cluster three lies between these two in terms of the

level of vulnerability. For the remainder of this Chapter, cluster one will be referred to as the low vulnerability group, cluster two as the high vulnerability group, and cluster three as the moderate vulnerability group.

Table 2.4: Demographic characteristics of women within each cluster

Variable	Vulnerability clusters						χ^2 analyses		
	1 Low N=194		2 High N=85		3 Moderate N=109		χ^2	df	p-value
	n	%	n	%	n	%			
Indigenous	4	2	80	94	8	7	290.85	2	<0.0001
*Age									
≤ 19	3	2	7	8	11	10	37.02	6	<0.0001
20-24	23	12	25	29	28	26			
25-29	52	27	25	29	29	27			
≥ 30	116	60	28	33	41	38			
Marital status									
Never married	7	4	22	26	6	6	74.68	4	<0.0001
De facto	68	35	39	60	61	56			
Married	119	61	38	14	42	39			
*Level of education									
Less than year 10 (<11yrs)	4	2	7	8	7	6	22.85	4	<0.0001
Year 10-12 (11-13 yrs)	49	25	39	46	42	39			
Tertiary education	141	73	39	46	60	55			
Income									
Social security	4	2	63	74	11	10	202.72	6	<0.0001
Own work	151	78	21	25	67	62			
Supported by partner/other	39	20	1	1	31	28			
Housing status *									
Privately rented	69	36	26	31	82	75	196.66	6	<0.0001
Housing Commission	1	1	45	53	1	1			
Owned/being bought	119	61	12	14	25	23			
Boarding/work housing	5	3	2	2	1	1	35.51	2	<0.0001
Maintenance – poor/bad *	3	2	15	18	0	0			
Air-conditioning	167	86	38	45	89	82			
Fly screens but no air-con	23	12	34	40	16	15			
Neither air-con nor fly-screen	4	2	13	15	4	4	54.09	4	<0.0001
Region									
Outer regional	184	95	56	66	106	97	66.55	4	<0.0001
Remote	7	4	5	6	3	3			
Very remote	3	2	24	28	0	0			
Public transport to health service (as opposed to private)	5	3	21	25	5	16	34.05	2	<0.0001

Due to rounding, percentages may not add to 100 exactly.

** Non-parametric test used.*

Table 2.5: Health and lifestyle characteristics of women within each cluster

Variable	Vulnerability clusters						χ^2 analyses		
	1 Low N=194		2 High N=85		3 Moderate N=109		χ^2	df	p-value
	n	%	n	%	n	%			
Body mass index (kg/m ²)									
≤ 19 (underweight)	24	15	10	15	13	14	24.17	6	<0.001
20-25 (acceptable)	96	59	23	33	38	42			
26-30 (overweight)	27	17	14	20	25	28			
>30 (obese)	16	10	22	32	15	17			
Smoking status									
Current smoker	9	5	35	41	36	33	73.46	6	<0.001
Ex-smoker	69	36	20	24	38	35			
Never smoked	116	60	30	35	35	32			
Partner smoker	6	3	54	64	108	99	354.46	2	<0.0001
Alcohol consumption (normal)									
None	129	67	63	74	71	65	2.55	4	0.637
Once per month or less	28	14	8	9	17	17			
2-3 days per month or more	37	19	14	17	21	21			
Level of alcohol consumption (previous month – pregnancy)									
None	190	98	75	88	106	97	23.32	4	<0.001
2-4 drinks over 2 hours	4	2	1	1	1	1			
5 or more drinks in a day	0	0	9	11	2	2			
Partner alcohol consumption									
None	19	10	13	15	11	10	4.73	4	0.316
Once per month or less	22	11	15	18	17	16			
2-3 days per month or more	153	79	57	67	81	74			
Level of partner's alcohol consumption (previous month)									
None	65	34	22	26	28	26	25.62	4	<0.001
2-4 drinks over 2 hours	38	20	2	2	14	13			
5 or more drinks in a day	91	47	61	72	67	62			
*Severity of domestic violence									
None	81	42	23	27	30	28	41.77	6	<0.001
Low	111	57	45	53	74	68			
Medium	2	1	8	9	4	4			
High	0	0	9	11	1	1			
Other adults in the household (mean, SD)	2.2, 0.6		2.8, 1.4		2.3, 0.7		F=12.16	2, 385	<0.001
Children in the household (mean, SD)	0.9, 1.2		2.3, 1.8		1, 1.2		F=46.83	2, 385	<0.001
Smokers in the household (mean, SD)	0.1	0.3	1.1,	0.3	1.2	0.50	122.44	2, 385	<0.001
Other smokers smoke inside	3	27	9	17	14	13	1.56	2	0.458

F statistics provided for results of one-way ANOVA with continuous variables. Degrees of freedom are between groups, within groups.

Due to rounding, percentages may not add to 100 exactly.

** Non-parametric test used.*

Table 2.6: Obstetric and gynaecological characteristics of women within each cluster

Variable	Vulnerability clusters						χ^2 analyses		
	1 Low N=194		2 High N=85		3 Moderate N=109		χ^2	df	p-value
	n	%	n	%	n	%			
Gravidity									
Primigravidas	80	41	14	17	37	34	22.48	4	< 0.001
2	56	29	24	28	27	25			
≥3	58	30	47	55	45	41			
Parity									
Primiparous	89	46	16	19	54	50	42.73	4	< 0.001
1	69	36	24	28	23	21			
≥2	36	19	45	53	32	29			
Visits to a healthcare provider during pregnancy (mean, SD)	3.2, 0.8		2.7, 1.0		3.3, 0.8		F=10.65	2, 385	< 0.001
Sexually transmitted Infections during the current pregnancy	30	16	32	38	21	19	16.30	2	<0.001
Previous sexually transmitted infections	19	10	11	13	4	4	6.33	2	0.042
Illness during pregnancy*									
Gastric illness	49	25	14	17	38	35	8.65	2	0.013
Urinary tract infections	52	27	33	39	32	29	3.99	2	0.136
Gestational diabetes	14	7	14	17	9	8	5.50	2	0.064
High blood pressure	20	10	16	19	10	9	4.70	2	0.096
High cholesterol	4	2	0	0	1	1	3.11	2	0.211
Low iron levels	80	41	28	33	42	39	1.74	2	0.420
Admission to SCBU **	23	12	19	22	16	15	4.83	2	0.090
Pre-existing conditions	12	6	13	15	5	5	7.87	2	0.020
Social work or mental health referral	15	8	18	21	9	8	10.54	2	0.005
Method of birth									
Vaginal non-instrumental	107	60	55	72	73	70	8.23	6	0.222
Vacuum/forceps	16	9	2	3	9	9			
Elective Caesarean section	24	14	9	12	9	9			
Emergency Caesarean sect	31	1	10	13	13	13			
Previous failed pregnancies									
Termination	9	5	4	5	10	9	3.35	4	0.468
Other	30	16	14	17	20	18			
None	155	80	67	79	79	73			
Birth weight (g)	3474, 468.4		3546, 530.7		3469, 474.2		F=0.69	2, 352	0.504
Birth length (cm)	50, 2.4		50, 2.3		50, 2.5		F=0.01	2, 329	0.997
Gestation at delivery (weeks) (mean, SD)	39, 1.30		39, 1.51		39, 1.17		F=4.01	2, 354	0.019

* Self-reported ** SCBU: Special care baby unit

Due to rounding, percentages may not add to 100 exactly.

Characteristics of the cluster members

Low vulnerability group

The low vulnerability group is represented predominantly by non-Indigenous women (98%), 87% of whom were aged 25 or over, and 96% of whom were married (61%) or in a de facto relationship (35%). Seventy-three percent of these women had completed some tertiary education, 78% reported their own work as their main source of income, and 97% lived in homes that were privately rented, or which were owned or being purchased by themselves or their families. Eighty-six percent of these women had air-conditioning in their homes, and 95% lived in the Cairns urban (outer regional) area. Sixty percent of these women had never smoked, 36% were ex-smokers, 4% were smokers and 3% had smoking partners. None of the women reported having consumed five or more drinks on any one day during their pregnancy, with 98% not having consumed any alcohol in the month prior to their interview. None of these women reported having experienced high level domestic violence during their pregnancy. This group also had low rates of pre-existing conditions (6.2%), admission to the SCBU (12%) and referral to social work or mental health (7.7%). This group did, however, report a higher rate of low iron levels (41%) than members of the other two clusters.

High vulnerability group

Ninety-four percent of the women in cluster two were of Aboriginal or Torres Strait Islander origin, and 28% lived in areas classed as very remote. The women were younger on average than those in the low vulnerability group, with 8.2% aged 19 or less. Most of the women were in de facto relationships (60%), 14% were married and 26% had never been married. Fewer women (46%) in this group had completed tertiary education than women in the other groups, and 8.2% had not completed high school to

year ten level (less than 11 years of education). Seventy-four percent of the women reported social security as their main source of income, 53% lived in housing rented by a community council or the Housing Commission. Eighteen percent of the women claimed that the maintenance in their home was poor or bad and 15% had neither fly screens nor air-conditioning. Twenty-five percent of the women used public transport to travel to the clinic.

This group contained the highest proportion of women who failed to meet dietary guidelines (5.9%), the highest proportion of women classified as obese (32%), the highest proportion of smokers (41%), and the lowest proportion of ex-smokers (24%). While fewer women normally drank alcohol, those who did (26%) drank at high levels, with 11% having consumed five or more drinks on one day in the month prior to their interview. Similarly, fewer partners of these women drank at all compared to the other two clusters, but of those who did, 72% had consumed five or more drinks on any one day in the previous month. Domestic violence was more common in this group, with 9.4% reporting medium levels, and 11% reporting high levels of violence during their pregnancy. On average, these women lived with more adults (mean 2.8) and more children (mean 2.3) than women in either of the other groups. If the other adults in the home were smokers, more smoked inside the house on some occasions (17%).

Members of this cluster were more often multigravidas than women in either of the other clusters, with 55% in at least their third pregnancy, and were more often multiparous, with only 19% having no previous children. This group had made the least number of visits to the clinic during their pregnancy (mean 2.7), and had the highest rates of current and previous sexually transmitted infections (38% and 13% respectively), urinary tract infections (39%), high blood pressure during their pregnancy (19%), gestational diabetes (17%), and pre-existing conditions such as diabetes (15%)

of the three clusters. More of the babies born to members of this group were admitted to SCBU (22%), and more women were referred to social work or mental health services (21%).

Moderate vulnerability group

The rates of risk exposure and markers of low socio-economic status of members of the moderate vulnerability group generally fall between those of the other clusters. Seven percent of these women were of Aboriginal or Torres Strait Islander origin, 56% were in a de facto relationship, 39% were married, and 6% had never been married. A number of factors do not follow this trend however, with this group having a greater proportion of teenage mothers (10%), higher rate of partner smoking (99%), and larger number of smokers in the household (mean 1.2). Thirty-three percent of women in this group were smokers, 3% had consumed some alcohol in the previous month, and 4.6% failed to meet dietary guidelines. A higher proportion of these women were classed as overweight, with 28% having a BMI of 26-30kg/m², though fewer were classed as obese (17%) than in the high vulnerability cluster.

Women excluded from the clusters

Cases were excluded from cluster analysis if their individual profile did not fit clearly into any of the groups generated. Forty-nine women who were found not to share a clear pattern of characteristics were excluded from clusters in the final analysis. Chi-square analysis of this group against the women in clusters as a single group revealed that women in this group were significantly younger (18% ≤19 years, $\chi^2(3)=12.77$, $p=0.005$), had less education (6.2% less than year 10, $\chi^2(2)=13.53$, $p=0.001$), were more likely to live in Housing Commission properties (37%, $\chi^2(2)=25.53$, $p<0.0001$), were more likely to rely on social security as their main source of income (65%,

$\chi^2(3)=43.99$, $p<0.0001$), were less likely to be married (2%, $\chi^2(3)=159.51$, $p<0.0001$), and were more likely to be Indigenous (61%, $\chi^2(1)=28.59$, $p<0.0001$). Of the 49 women excluded, 19 were non-Indigenous, 14 were Aboriginal, 12 were Torres Strait Islander, and four identified as both Aboriginal and Torres Strait Islander. Partners of women in this group were less likely to have consumed alcohol in the previous month (86% had consumed no alcohol), or to have had more than two drinks, or more than five drinks on any occasion ($\chi^2(2)=61.94$, $p<0.0001$). Women were more likely to smoke (41%, $\chi^2(3)=19.02$, $p<0.0001$), and live with other smokers who smoked inside the house ($\chi^2(1)=5.87$, $p=0.015$). These women were more likely to be referred to social work or mental health services (25%, $\chi^2(1)=6.27$, $p=0.012$), experience high severity domestic violence (31%, $\chi^2(3)=16.27$, $p=0.001$), and report both current infections (41%, $\chi^2(1)=8.18$, $p=0.004$) and previous infections (27%, $\chi^2(1)=11.17$, $p=0.001$).

It appears that while the excluded cases experienced a high rate of many risk factors, lower or equivalent rates of factors such as obesity, risky alcohol consumption, smoking partners, parity and gravidity, prevent the grouping of these cases with the highly vulnerable women in cluster two, or moderately vulnerable women in cluster three. It may be that with the high proportion of Aboriginal and Torres Strait Islander women and the existence of markers of low socio-economic status among this group, these women are somewhat vulnerable to adverse health, but are not sufficiently similar to each other, or to any of the clusters, to be grouped together. To ensure that this group did not significantly influence the characterisation and comparison of clusters, all χ^2 analyses were re-run with the excluded cases included as a fourth cluster. This process did not result in any changes in outcomes.

Discussion

The results of the cluster analysis support the hypothesis that the factors which impart risk of poor health and adverse birth outcomes cluster together, with certain groups experiencing a greater number of risks than others. The study suggests that of the women receiving antenatal care at Cairns Base Hospital, those who are most vulnerable are of Aboriginal and Torres Strait Islander origin, cite social security as their main source of income, or live in housing rented by a community council or the Housing Commission. In the analysis these characteristics were found to be naturally grouped together in cluster two (high vulnerability). Ninety-four percent of all Aboriginal and Torres Strait Islander women, 81% of women whose main source of income was social security and 96% of those living in Housing Commission properties were clustered in this group.

The majority of members of the high vulnerability group fell into the above categories. These items had the greatest proportional difference in rate between clusters, suggesting that these factors carry a substantial proportion of the weight in defining cluster membership. The high vulnerability cluster is then characterised by other demographic, health, and obstetric factors. These are poor housing conditions, residence in remote or very remote areas and a high proportion of women who had never been married and were not in a de facto relationship during their pregnancy. While the present study does not have the capacity to quantify the associations between each factor and birth outcomes, substantial evidence exists in the literature about this relationship, supporting the classification of these women as vulnerable, based on the risk factors to which they are exposed.

The highly vulnerable women were not only regarded as such due to their socio-economic status, and younger age, but also due to their smoking status, risky alcohol consumption, relatively poor diet, rate of obesity, exposure to passive smoke, experience of domestic violence, rates of sexually transmitted infections, urinary tract infections, gestational diabetes, and other pre-existing conditions. Interestingly, most of the Aboriginal and Torres Strait Islander women who were not grouped in cluster two fell into cluster three, which is regarded as having a moderate level of vulnerability. This classification is largely the result of a high rate of smoking among women, and their partners, as well as moderate socio-economic status.

Patterns of alcohol consumption among the high vulnerability group are consistent with reports regarding Australia's Aboriginal and Torres Strait Islander population as a whole.²⁸ While a relatively low proportion of the women drink any alcohol, those who do drink, consume greater amounts and are more likely to drink at risky levels, than the other two groups. Eleven percent of women in this cluster reported having had five or more drinks on a given day in the previous month. The rate was 72% among the partners of women in this cluster, and 62% among those of the moderate vulnerability group, possibly reflecting a significant proportion of Aboriginal and Torres Strait Islander individuals within these groups. This is further reinforced by anecdotes given to the PhD candidate during interviews. Many women, predominantly from remote communities, can be quoted as saying that their partner "*doesn't drink much*". On further discussion, it was revealed that women were often referring to the frequency of their partner's alcohol consumption, rather than the quantity, with women frequently stating that their partner would "*have a case*" or "*drink all day*" when they did drink. Several women also stated that both they and their partners may only drink approximately once a month, but would "*share a case*" together on these occasions, suggesting that these social practices, and the behaviour of those around them have

significant influence upon their own behaviour. The rates of smoking and smoking among the partners in these groups are also substantial, further reflecting the impact of the social environment on the behaviour and health of individuals.

In a study in Canada, Aboriginal women and women receiving welfare in the study region were reported to be younger, smoke more, consume more alcohol, attended fewer antenatal visits, and had more preterm deliveries than other women in the same area.⁷² Interestingly, this study reported that fewer Aboriginal or welfare-supported women delivered low birth weight infants, but more gave birth to babies greater than 4000 grams. This is consistent with the impact of maternal BMI on pregnancy outcome, and the trends observed among Torres Strait Islander women in the present study. The validity of birth weight as a measure of health outcome for Torres Strait Islander babies has been questioned, with these women tending to have a larger build and higher BMI, with greater similarity to Pacific Islander people than to Aboriginal people. Torres Strait Islanders in Queensland have high rates of obesity and diabetes, which may explain the 2.5 fold increased rate of infant mortality compared with the non-Indigenous population, but appears to contradict an equivalent birth weight distribution.⁷³ In this population, maternal risk factors such as obesity and diabetes may lead to heavier, but not necessarily healthier babies.⁷³ In the high vulnerability cluster, 32% of women were classified as obese, and 20% as overweight. The moderate vulnerability cluster also had a substantial proportion of women classified as overweight or obese. This is not unexpected, as these groups contain the majority of Aboriginal and Torres Strait Islander participants.

Further, the rate at which women were classified as underweight did not differ significantly between the groups. While low maternal BMI is associated with low birth weight, the relatively small number of women falling into this category parallels the

small number of low birth weight infants born to mothers in the overall study population. This reinforces the importance of other measures of vulnerability, and the capacity for other factors to impact on health and birth outcomes, with the need for less emphasis on birth weight as the key indicator.

In the present population, 47% of Indigenous women identified as Aboriginal, 41% as Torres Strait Islander, and 13% as both. Equal numbers of Aboriginal and Torres Strait Islander women grouped into the high vulnerability cluster, but a larger proportion of Indigenous women in the moderate vulnerability cluster were Aboriginal. It is important to note several key physical and cultural differences between Aboriginal and Torres Strait Islander women which may have influenced their cluster grouping. As well as differences in BMI, key cultural differences exist between Aboriginal and Torres Strait Islander women. Torres Strait culture has remained very strong, with cohesive island communities and a strong sense of family contrasting in many ways with the social dislocation experienced by remote Aboriginal communities in Cape York. These family connections may take a great deal of pressure off young mothers, with an informal adoption system in place whereby a child may be looked after by an aunt or grandmother if the mother is unable to do so. These factors may decrease the vulnerability of Torres Strait Islander women relative to Aboriginal women, and explain their high rate of exclusion from the clusters.

Our findings of differential risk profiles for sub-groups based on place of residence and ethnic background are consistent with findings of studies in Canada and the United States. The Canadian Aboriginal population is made up of Inuit and Indian subgroups, which have differing levels of risk for preterm birth, SGA, sudden infant death syndrome and infection-related mortality.^{7 82 83} Different risk levels for poor birth outcomes have been reported according to the level of segregation or clustering

among African-American women in the United States. Women living in predominantly contiguous neighborhoods with other African-American women were reported to have more optimal birth outcomes than women who were less likely to encounter other African-American women in their neighborhood.⁷⁴ This may have implications for Australian Aboriginal and Torres Strait Islander peoples who live in urban areas and particularly those areas with small Aboriginal and Torres Strait Islander populations, compared with those in clusters, or discrete communities. As discussed above however, the effect of place may differ between the cohesive Torres Strait Islander communities, and the more fractured remote Aboriginal communities. Sixty-six percent of the women in the high vulnerability cluster live in the Cairns urban (outer regional) area. With the high proportion of Aboriginal and Torres Strait Islander women in this group, this suggests that many of these individuals are likely to be living in areas outside of clustered ethnic communities.

Limitations of the study

It is important to note the limitations which lead to the need for a degree of caution in interpreting these results. While the questionnaire was developed with valuable input from Aboriginal and Torres Strait Islander health workers, and was deemed to be culturally appropriate, responses to some topic areas may have been influenced by social pressures for both Aboriginal and Torres Strait Islander, and non-Indigenous women. Social stigma associated with issues such as nutrition, alcohol consumption and smoking during pregnancy, and domestic violence, may have led women to answer according to the most acceptable response, as opposed to the most accurate one.^{75 76} In some cases, partners chose to accompany women during the interview, potentially influencing the response to questions regarding domestic violence. The PhD candidate felt, however, that during interviews she was able to connect with women, and reassure them that no judgement was being made of them. Women frequently

joked regarding the response which they knew to be “correct” in terms of recommendations for nutrition, alcohol consumption or smoking, giving an honest answer which may not have matched such recommendations. In only a minority of cases were women relatively closed during the interview, answering questions with a sense of reluctance. In such cases, the accuracy of data collected may be questionable.

It is likely that the item relating to meeting dietary guidelines led to an overestimate of good nutrition. The nature in which questions were combined to result in an overall measure is likely to have been very generous. It should be noted however, that with the ready availability of fresh fruits in many parts of Far North Queensland including Cairns itself, and the Torres Strait Islands, it is likely that women do indeed consume large amounts of fresh fruits, thereby boosting their diet and their score in the questionnaire.

The interview-style questionnaire enabled the PhD candidate to ask questions using appropriate language, and ensure that women understood the questions being asked. In many cases, the interviewer was also able to build a rapport with women, often taking part in an extended conversation, in which women told stories and gave anecdotes regarding their lifestyle and experiences throughout their pregnancy, which were not able to be captured in the quantitative data collection. The rate of domestic violence occurring within the population is potentially underestimated by focusing on exposure during pregnancy only. Several women commented that while their current partner did not use any violent behaviours, a previous partner had indeed done so. A number of women stated that they had, in fact, left previous partners due to violence and associated issues. One woman described a spinal injury which she had incurred as a result of domestic violence in a previous relationship. Ten women described injuries such as bruises and cuts which they had received as a result of domestic

violence incidents during their pregnancies. One woman discussed having been hospitalised during her pregnancy as a result of domestic violence. At the time of the interview, this woman was sleeping on a mattress on the floor of her parent's bedroom in a house with six other adults, and was concerned as to what she would do when her baby was born. The cases of domestic violence recorded during interviews matched those recorded in patient medical records, derived from a routine Queensland Health screening tool.

The high consent rate (85%) which was consistent throughout the four-month study period suggests that the sample is representative of the overall population of women attending CBH for antenatal care. Recruitment was performed on each day that the clinic ran, and only ten women who attended on these days were recorded as being missed for recruitment. With approximately 2000 births at the hospital each year, the 515 invited to participate in the study are likely to represent the majority of women attending during the recruitment period. Women who delivered prematurely or failed to attend late pregnancy visits missed the assessment stage for eligibility and recruitment. However, this group is not likely to represent a significant proportion of the population. Recruitment at 36 weeks' gestation required a compromise between 1) consistency in gestational age and data collection, and ability to capture women from remote communities, and 2) the inclusion of women who deliver before this time. Due to the importance of including women from remote communities and achieving consistency in data collection, a decision was made to accept the loss of women who delivered prematurely from the potential study group.

Differences detected between participants and non-participants are not expected to impact on overall results. The higher rate of identification as both Aboriginal and Torres Strait Islander among the non-participant population is likely to relate to the younger

age and marital status of this group, with Aboriginal and Torres Strait Islander mothers younger on average and less often married than non-Indigenous mothers. Despite these differences, the non-participant population is a small proportion of the whole group, and is not likely to compromise how representative this group is compared to the study population.

The use of cluster analysis precluded the independent examination of specific risk factors. As an array of factors are known to increase risk of adverse birth outcomes, it is appropriate to construct a profile of risk based on the presence of such factors. While examination of the association between adverse outcomes and the presence of risks was considered, as was an assessment of the number of risks experienced by individuals, the cluster analysis approach offered additional capacity over these methods. Unlike the alternatives considered, the approach used here enabled identification of both the characteristics which indicate a woman's vulnerability, and the most appropriate targets for intervention. The assumptions associated with cluster analysis were largely irrelevant in the present study, and would be dealt with by the statistical program during analysis. In calculating likelihood distance measures, there is an assumption that the variables in the model are independent. In the present situation, however, the interdependence and complex interaction of the variables included were central to the aims and purpose of the study. Further, the final cluster was constructed to include the minimum number of variables, selecting only one item in cases where several items were correlated. With the robust nature of the analysis, it was therefore deemed appropriate to conduct the analysis and interpret its results despite assumptions being unobserved.

Value of the study

This study confirms suggestions and inferences which have emerged from previous research examining the risk factors for low birth weight and poor birth outcomes. The use of a cross-sectional population, comprising both Aboriginal and Torres Strait Islander and non-Indigenous women, as well as women from regional, remote, and very remote areas, enabled the study to expand on the findings of previous work which had been restricted to the examination of a limited number of risk factors, or conducted with limited populations such as Aboriginal or Torres Strait Islander women only, non-Indigenous women only, or women within certain regions. The cluster analysis highlights the interconnectedness of demographic and health risks, and the high concentration of these risks among Aboriginal and Torres Strait Islander women. It appears that key markers of vulnerability to adverse birth outcomes include being Aboriginal or Torres Strait Islander, and relying on Government support for income and housing. Using these markers, vulnerable women can be identified and targeted for public health interventions which focus on key risk factors such as alcohol, smoking and sexually transmitted infections.

Future directions

With the co-existence of multiple risk factors, efforts to improve birth outcomes for vulnerable women should ideally take into account the full spectrum of risks to which these women are exposed. It is possible however, that if one factor which clearly separates vulnerable women from others, and clearly co-exists with the wider array of risks can be identified, this factor can be used as a central target for interventions that may result in overall improvements in health. While screening for and treatment of infections and other health issues during pregnancy is vital, it appears that great

potential for reducing the vulnerability of women to adverse antenatal health and birth outcomes lies in tackling the issues of smoking and alcohol consumption. The results suggest that a greater proportion of women smoke during pregnancy overall, than drink. With this in mind, plus the fact that the two behaviours cluster together within a single group, interventions which target smoking have great capacity to impact on a wide range of risks, and to improve the chance of these women having healthy babies. This study provides useful information to direct future efforts to improve maternal health during pregnancy and infant birth outcomes.

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Appendix 2.1: University Certificate of Ethical Approval for study



The UNIVERSITY
of NEWCASTLE
AUSTRALIA

Form HE2:1/05

HUMAN RESEARCH ETHICS COMMITTEE

Certificate of Approval for a research project involving humans

Applicant	
Chief Investigator/Project Supervisor: (First named in application)	Professor Rob Sanson-Fisher
Co-Investigators/Research Students:	Professor Sandra Eades Dr Sam Scherman Ms Conor Gilligan
Project Title:	Health issues during pregnancy – A comparison of Aboriginal and Torres Strait Islander women with non-Indigenous women giving birth at Cairns Base Hospital

In approving this project, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the *National Statement on Ethical Conduct in Research Involving Humans*, 1999, and the requirements within this University relating to human research.

Details of Approval	
HREC Approval No: H-250-0706	Date of Approval: 19 July 2006
Approval valid for: 3 years, or until project ceases, whichever occurs first.	Progress reports due: Annually
<p>NOTE: Approval is granted subject to the requirements set out in the attached document <i>Approval to Conduct Human Research</i>, and any additional comments or conditions noted below:</p> <p>19 July 2006 The Committee ratified the approval granted by the Chair on 14 July 2006, which was subject to further amendments to the Information Statement and Consent Form, and receipt of written support from the Mookai Rosie Hostel.</p> <p>10 August 2006 Response received and accepted. Approval confirmed.</p>	

Signed for the Committee: _____

Ms Susan O'Connor
Human Research Ethics Officer

Appendix 2.2: Cairns Base Hospital letter of ethical approval for study



Queensland Health

Enquires: Ethics Committee
Direct Telephone: (07) 40 506 525
Direct Facsimile: (07) 40 506 696
Our Reference: JN/hp
Your Reference: 04:07: #433

PRIVATE & CONFIDENTIAL

Professor Rob Sanson-Fisher
Tenured Professor of Health Behaviour
Faculty of Medicine and Health Sciences
Room 267 David Madisson Building
Cnr King and Watt sts
Newcastle NSW 2300

Dear Professor Sanson-Fisher,

Re: Health issues During Pregnancy – A comparison of Aboriginal and Torres Strait Islander women with non-Indigenous women giving birth at Cairns Base Hospital.

I wish to advise that at the Ethics meeting held Thursday 6th July, 2006 the Ethics Committee has approved the above study.

The Cairns Base Hospital Ethics Committee is both duly constituted and operates in accordance with the National Statement on Ethical Conduct in Research Involving Humans and Supplementary Notes, (1999).

During the conduct of the study you are required to adhere to the following conditions:

- The National Statement on Ethical Conduct in Research Involving Humans requires a Human Research Ethics Committee to nominate a person to whom complaints from participants, researchers, or other interested person can be directed. The Cairns Base Hospital Ethics Committee has nominated The Chairperson Dr Jill Newland (Phone: 07- 40506525). This information must be included in the Information Sheet provided to participants.
- The reference number should be quoted on all correspondence relating to the application.
- You are required to provide a report on the outcome of the study at the completion of the study or annually if the study continues for more than 12 months.
- You must immediately report to the CBHREC any serious or unexpected adverse effects on participants, and any unforeseen events that might affect continued ethical acceptability of the project. In addition, the Investigator must provide a summary of the adverse events, in the

Office	Postal	Phone	Fax
Ethics Committee Secretary Cairns Base Hospital The Esplanade CAIRNS Q 4870	PO Box 902 CAIRNS Q 4870	(07) 40 506525	(07) 4050 6696

- specified format, including a comment as to suspected casualty and whether changes are required to the Patient Information and Consent Form.
- If any subsequent change/amendment is made to the protocol it will be necessary for you to obtain approval from the Cairns Base Ethics Committee. The amended documents must be accompanied by the letter, signed by the Principal Investigator, providing a brief description of the changes, the rationale for them and their implications for the ongoing conduct of the study. All amended documents must contain revised version numbers, version dates and page numbers. Changes must be highlighted using Microsoft Word "Track Changes" or similar.
- Copies of all publications resulting from the study should be submitted to the Cairns Base Hospital Ethics Committee. Please also ensure that a copy is also forwarded to the Cairns Base Hospital Medical Library.

Your reference number for the above application for all future correspondence is **433**

Yours sincerely



Helen Pharoah on behalf of
Dr Jill Newland
Chairperson
Cairns Base Hospital Ethics Committee

7 July, 2006

Office	Postal	Phone	Fax
Ethics Committee Secretary	PO Box 902	(07) 40 506525	(07) 4050 6696
Cairns Base Hospital	CAIRNS Q 4870		
The Esplanade			
CAIRNS Q 4870			

Appendix 2.3: Board of Mookai Rosie Bi Bayan letter of ethical approval
for the study



8 August 2006

MOOKAI ROSIE-BI-BAYAN

(ABORIGINAL AND TORRES STRAIT ISLANDERS CORPORATION)

P.O. BOX 306E, EARLVILLE, QLD 4870
105 BALACLAVA ROAD, EARLVILLE
PHONE: (07) 4033 2083
FACSIMILE: (07) 4054 6743

Susan O'Connor
Human Research Ethics Officer
Research Office
The University of Newcastle
University Drive, Callaghan NSW 2308

Dear Ms O'Connor,

**Re: Health Issues During pregnancy - A comparison of
Aboriginal and Torres Strait Islander women with non-
Indigenous women giving birth at Cairns Base Hospital.**

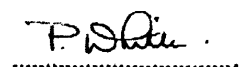
This letter is written to inform you that the above research project,
run by Professor Rob Sanson-Fisher, Professor Sandra Eades, Dr
Sam Scherman, and Conor Gilligan, will have the full support of the
Board of Directors of Mookai Rosie.

We are aware of the research proposal and recognize the potential
significance of this study. The Board appreciate that the
involvement of Mookai Rosie represents an attempt by the
researchers, to minimize any impact of the study upon our clients,
and to give women the opportunity to discuss the project with
people whom they trust, in an environment in which they feel
comfortable.

We look forward to being involved, and seeing the results of this
study.

Yours sincerely
Mookai Rosie-Bi-Bayan


.....
Ros Sultan
Chairperson


.....
Pat Whitta
Treasurer


.....
Margaret Simpson
Secretary

Appendix 2.4: Information statement and consent form



(Reading age 5.7)

Version #4. 24/7/2006

Researchers from the University of Newcastle are working with Cairns Base Hospital (CBH) and we need your help.

We are doing a research study about health issues during pregnancy. We would like you to help us by answering some questions about your health and lifestyle.

Why is this study being done?

We are interested in exploring the relationships between women's experiences during pregnancy, and the rate of low birthweight. We hope that this information will help us find ways to reduce the number of low birth weight babies in the future.

The results of this research may be used to help researcher Conor Gilligan to obtain her PhD.

Who can take part?

We are inviting all women aged 16 years and over who attend CBH for healthcare late in their pregnancy to take part. Women who have a mental illness or are being treated for addictions other than smoking or alcohol are not eligible.

What are we asking you to do?

If you agree to take part, you will be asked to speak to a research student (Conor) who will help you to answer some questions about your health and your lifestyle. The interview should take less than 20 minutes.

If you consent, we would also like to collect some information from your medical charts about your health and the birthweight of your baby. We will record your height and weight as well as information about any medical conditions you might have during your current pregnancy, such as infections, diabetes, anaemia, and any physical injuries. This information will be collected after your baby is born by one of the nurses looking after you.

You can choose to take part in one section only if you like.

Are there any risks?

There are no risks associated with taking part in this study.

What choices do I have?

- You do not have to take part in the research part if you do not want to.
- Your decision will not affect you having the best available health care.
- If you change your mind later about letting us access your medical records, you can withdraw your consent by signing the form attached to this information statement.

How will privacy be protected?

Your name will not be recorded on any information collected by the researchers.

How will information collected be used?

- All information collected in this study will be handled with respect.
- Data will be coded and stored securely at the Medical School of the University of Newcastle.
- Information about specific persons will not be revealed in any research reports arising from this project.
- The information from the study may be reported in a scientific journal.
- The full research reports, as well as a short summary of results will be available through the hospital, at the end of the study.

What do you need to do to participate?

- Please read this information statement and make sure you understand it before you consent to participate.
- If there is anything you don't understand or you have questions please ask the research student, or a nurse.
- If you would like to participate, please tell Conor so she can go through the questionnaire with you.
- You can also decide if you want to allow us to collect information from your medical records. If you consent, please sign the form on the next page.

Would you like more information?

- You can keep this information statement.
- If you would like more information, you can contact any of the researchers listed below

We thank you for considering taking part in this project.



Professor Rob Sanson-Fisher
Professor of Health Behaviour
University of Newcastle

Who are the researchers?

Professor Rob Sanson-Fisher	University of Newcastle	(02) 4923 6169
Professor Sandra Eades	Sax Institute	(02) 9514 5970
Dr Sam Scherman	Cairns Base Hospital	(07) 4050 8300
Conor Gilligan	University of Newcastle	0402 627 528

This project has been approved by the University of Newcastle, and Cairns Base Hospital Human Research Ethics Committees (Approval #'s H-250-0706/433) If you have any concerns about your rights as a participant, or if you have a complaint about the manner in which the study is conducted, you can advise the researcher or if an independent person is preferred, contact the human research ethics officer at the University of Newcastle: Research Office, The Chancellery, The University of Newcastle, University Drive Callaghan, NSW 2308
Phone: 02 49 216 333 Email: human-ethics@newcastle.edu.au or the Chairperson of the CBH Human Research Ethics Committee Dr Jill Newland; PO Box 902 Cairns, 4870, Phone: (07)40506525.

Participant Consent Form
Version #4. 24/7/2006



Health issues During Pregnancy – A comparison of Aboriginal and Torres Strait Islander women with non-Indigenous women giving birth at Cairns Base Hospital

I have read, or have had read to me, and I understand the Participant Information version 3 dated 20/7/2006.

I freely agree to participate in this project according to the conditions in the Participant Information.

I understand that I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to the researchers accessing my medical records relating to my current pregnancy for the purposes of recording information about:

- My height and weight
- Infections and other medical conditions
- Evidence of physical injury
- The birthweight and health of my baby.

I will be given a copy of the Participant Information and Consent Form to keep

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed)

Signature

Date

Name of Witness to Participant's Signature (printed)

Signature

Date

Researcher's Name (printed)

Signature

Date

Note: All parties signing the Consent Form must date their own signature.

Revocation of Consent Form

Version #3. 20/7/2006



Health issues During Pregnancy – A comparison of Aboriginal and Torres Strait Islander women with non-Indigenous women giving birth at Cairns Base Hospital

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with Cairns Base Hospital.

Participant's Name (printed)

Signature

Date

Appendix 2.5: Health and Risk Factors During Pregnancy Questionnaire

Health and Risk Factors During Pregnancy

Date ____/____/____

Patient # _____

Demographics

Marital Status

- ☐ 1 Never Married
☐ 2 Divorced
☐ 3 Defacto
☐ 4 Married
☐ 5 Not stated

DOB

1. Postcode OR Community/area: _____

2. Are you of Aboriginal or Torres Strait Islander Origin?

- ☐ 1 No
☐ 2 Yes Aboriginal
☐ 3 Yes Torres Strait Islander
☐ 4 Yes both Aboriginal and Torres Strait Islander

3. What is your main source of income?

Do you support yourself from:

- ☐ 1 Full-time employment
☐ 2 Part-time/casual employment
☐ 3 Social Security
☐ 4 Other (please describe) _____

Or are you supported by partner who is:

- ☐ 5 Employed full-time
☐ 6 Employed part-time/casual
☐ 7 On social security
☐ 8 Other (please describe) _____

Or are you supported:

- ☐ 9 From maintenance from another person

4. What was the highest year level you completed at school? (Please circle response)

5 6 7 8 9 10 11 12

5. Have you done any courses at TAFE or University?

- ☐ 1 Yes
☐ 2 No

Lifestyle and access to infrastructure

6. a. What sort of dwelling do you usually live in?

- ☐ 1 House
☐ 2 Flat/unit
☐ 3 Caravan, shed, tent, or donga
☐ 4 Other (please describe) _____

b. What is the current status of your dwelling?

- ☐ 1 Privately rented (by you/your partner or family)
☐ 2 Rented from government department (housing commission)
☐ 3 Owned or being purchased (by you/your partner or family)
☐ 4 Boarding
☐ 5 Work housing
☐ 6 Other (please describe) _____

7. How many adults usually live in the same house as you?

8. How many children usually live in the same house as you?

9. What is the maintenance like in your home? (Repairs)

- | | | |
|--------------------------|---|--------------|
| <input type="checkbox"/> | 1 | Good |
| <input type="checkbox"/> | 2 | Satisfactory |
| <input type="checkbox"/> | 3 | Poor |
| <input type="checkbox"/> | 4 | Bad |

10. a. Do you have air-conditioning in your home?

- | | | |
|--------------------------|---|------------------|
| <input type="checkbox"/> | 1 | Yes – most rooms |
| <input type="checkbox"/> | 2 | Yes – some rooms |
| <input type="checkbox"/> | 3 | No |

b. Do you have fly screens in your home?

- | | | |
|--------------------------|---|------------------|
| <input type="checkbox"/> | 1 | Yes – most rooms |
| <input type="checkbox"/> | 2 | Yes – some rooms |
| <input type="checkbox"/> | 3 | No |

Obstetric/Gynaecological History

11. How many weeks pregnant are you? *weeks*

12. How many times have you been pregnant? *times*

13. How many biological children do you have? *children*

14. How many times have you seen a doctor, health worker, or nurse about this pregnancy?

0 1 2 3 4 5 6 7 8 9 10

15. Has your doctor, health worker, or nurse asked you about smoking in this pregnancy?

- | | | |
|--------------------------|---|-----------------------------|
| <input type="checkbox"/> | 1 | Yes |
| <input type="checkbox"/> | 2 | No |
| <input type="checkbox"/> | 3 | I haven't seen a doctor yet |

16. How far away from your home is the nearest health service?

- | | | |
|--------------------------|---|-----------------------------|
| <input type="checkbox"/> | 1 | Easy walking distance |
| <input type="checkbox"/> | 2 | Less than 30 minutes drive |
| <input type="checkbox"/> | 3 | 30-60 minutes drive |
| <input type="checkbox"/> | 4 | 60-90 minutes drive |
| <input type="checkbox"/> | 5 | 90 minutes to 2 hours drive |
| <input type="checkbox"/> | 6 | More than 2 hours drive |

17. If your nearest health service is not within walking distance, how do you get there?

- | | | |
|--------------------------|---|--------------------------------------|
| <input type="checkbox"/> | 1 | Drive (own car) |
| <input type="checkbox"/> | 2 | Drive (borrowed car/partner's car) |
| <input type="checkbox"/> | 3 | Driven by friend or family member |
| <input type="checkbox"/> | 4 | Transport provided by health service |
| <input type="checkbox"/> | 5 | Other (specify) _____ |

Diet during pregnancy (Refer to Photographs for serving size)

18. How much did you weigh before your pregnancy? kilograms

19. How tall are you? Centimetres

20. How many serves of fruit do you normally have each day (during your pregnancy)?

- | | | |
|--------------------------|---|------------------|
| <input type="checkbox"/> | 1 | Do not eat fruit |
| <input type="checkbox"/> | 2 | 1 serve or less |
| <input type="checkbox"/> | 3 | 2-3 serves |
| <input type="checkbox"/> | 4 | 4-5 serves |
| <input type="checkbox"/> | 5 | 6 serves or more |

21. How many serves of vegetables do you normally have each day?

- | | | |
|--------------------------|---|-----------------------|
| <input type="checkbox"/> | 1 | Do not eat vegetables |
| <input type="checkbox"/> | 2 | 1 serve or less |
| <input type="checkbox"/> | 3 | 2-3 serves |
| <input type="checkbox"/> | 4 | 4-5 serves |
| <input type="checkbox"/> | 5 | 6 serves or more |

22. How many serves of red meat, fish, poultry, nuts, eggs or legumes do you normally have a week?

- | | | |
|--------------------------|---|--------------------------------|
| <input type="checkbox"/> | 1 | Do not eat meat or substitutes |
| <input type="checkbox"/> | 2 | 1 serve or less |
| <input type="checkbox"/> | 3 | 2-3 serves |
| <input type="checkbox"/> | 4 | 4-5 serves |
| <input type="checkbox"/> | 5 | 6 serves or more |

(please circle) Meat Fish Poultry Legumes Eggs

Smoking and passive smoke

23. Which statement best describes you?

- | | | |
|--------------------------|---|---|
| <input type="checkbox"/> | 1 | I'm a smoker, I smoke daily (go to question 29) |
| <input type="checkbox"/> | 2 | I'm a smoker, I smoke occasionally (Go to question 28) |
| <input type="checkbox"/> | 3 | I'm an ex-smoker, I never smoke now (go to question 34) |
| <input type="checkbox"/> | 4 | I'm a non-smoker, I have never smoked (go to question 37) |

24. Have you had a cigarette in the last 7 days?

- | | | |
|--------------------------|---|-----|
| <input type="checkbox"/> | 1 | Yes |
| <input type="checkbox"/> | 2 | No |

25. How many cigarettes do you usually smoke each day? Cigarettes

26. In the last five years, how many times have you tried to quit smoking?

27. What is the longest amount of time you have been able to quit smoking for?

(please circle units) a Days b Weeks c Months d Years

28. Have you changed your level of smoking since you found out you were pregnant?
(please circle the most appropriate response)

- | | | | | |
|--------------------|-----------------------|----------------|-----------------------|--------------------|
| Increased
a lot | Increased
a little | Stayed
Same | Decreased
a little | Decreased
a lot |
| 1 | 2 | 3 | 4 | 5 |

29. How old were you when you first started smoking?

Questions 34 to 36 are for ex-smokers only

30. When did you stop smoking cigarettes regularly? Year Month

31. How many times did you try before you finally gave up? times

32. What caused you to quit smoking?

- | | | |
|--------------------------|---|---|
| <input type="checkbox"/> | 1 | Pregnancy |
| <input type="checkbox"/> | 2 | Health Scare |
| <input type="checkbox"/> | 3 | Money Problems |
| <input type="checkbox"/> | 4 | Influence of doctor, nurse or health worker |
| <input type="checkbox"/> | 5 | Influence of partner or friends |
| <input type="checkbox"/> | 6 | Children in the house with asthma |
| <input type="checkbox"/> | 7 | Television |
| <input type="checkbox"/> | 8 | Other |

33. How many smokers other than yourself usually live with you? Smokers

34. Where do these people usually smoke?

- | | | |
|--------------------------|---|--------------------|
| <input type="checkbox"/> | 1 | Mostly outside |
| <input type="checkbox"/> | 2 | Mostly inside |
| <input type="checkbox"/> | 3 | Inside and outside |

35. In relation to your partner:

- | | | |
|--------------------------|---|---|
| <input type="checkbox"/> | 1 | My partner is a smoker |
| <input type="checkbox"/> | 2 | My partner doesn't smoke now, but used to smoke |
| <input type="checkbox"/> | 3 | My partner has never smoked |
| <input type="checkbox"/> | 4 | I don't have a partner at the moment |

Alcohol consumption (Refer to images for standard drink)

The next few questions are about your partner and how much he drinks. Do you mind answering a few questions about this? If the participant indicates that she does not wish to answer these questions, proceed to the next section.

36. How often do you have a drink containing alcohol?

- | | | |
|--------------------------|----|---------------------|
| <input type="checkbox"/> | 1 | Every day |
| <input type="checkbox"/> | 2 | 5-6 days a week |
| <input type="checkbox"/> | 3 | 4 days a week |
| <input type="checkbox"/> | 4 | 3 days a week |
| <input type="checkbox"/> | 5 | 2 days a week |
| <input type="checkbox"/> | 6 | 1 day a week |
| <input type="checkbox"/> | 7 | 2-3 days a month |
| <input type="checkbox"/> | 8 | About 1 day a month |
| <input type="checkbox"/> | 9 | Less Often |
| <input type="checkbox"/> | 10 | Never |

37. How many *standard drinks* (see picture below) do you typically have on a day when you are drinking?

38. In the last 30 days, how many times have you had more than 2 standard drinks in any one day (over a period of approximately 2 hours)?

Number of times _____

☐ Never (mark box for never)

39. In the last 30 days, how many times have you had 5 or more standard drinks on any one day?

Number of times _____

☐ Never (mark box for never)

The following questions relate to your partner's alcohol consumption. Please answer as best you can.

40. How often does your partner have a drink containing alcohol?

- | | | |
|--------------------------|----|---------------------|
| <input type="checkbox"/> | 1 | Every day |
| <input type="checkbox"/> | 2 | 5-6 days a week |
| <input type="checkbox"/> | 3 | 4 days a week |
| <input type="checkbox"/> | 4 | 3 days a week |
| <input type="checkbox"/> | 5 | 2 days a week |
| <input type="checkbox"/> | 6 | 1 day a week |
| <input type="checkbox"/> | 7 | 2-3 days a month |
| <input type="checkbox"/> | 8 | About 1 day a month |
| <input type="checkbox"/> | 9 | Less Often |
| <input type="checkbox"/> | 10 | Never |
| <input type="checkbox"/> | 11 | Don't know |

41. How many *standard drinks* (see picture below) would he typically have on a day when he is drinking?

42. In the last 30 days, how many times do you think he would have had more than 2 standard drinks in any one day (over a period of approximately 2 hours)?

Number of times _____

☐ Never
☐ Don't know

43. In the last 30 days, how many times do you think he would have had 5 or more standard drinks on any one day?

Number of times _____

☐ Never
☐ Don't know

Violence or abuse during pregnancy

The last few questions are about your experience of violence. Do you mind answering a few a questions about this? If the participant indicates that she does not wish to answer these questions, proceed to the end.

44. People handle disagreements in many different ways. Looking at box A, when you have a disagreement with your partner, how often does he do any of the things in the box?

- ☐ 1 Often
☐ 2 Sometimes
☐ 3 Rarely
☐ 4 Never

Box A

Insult or swear
 Sulk or refuse to talk
 Storm out of the room
 Do or say something in spite
 Threaten to hit

45. Looking at box B, when you have a disagreement with your partner, how often does he do any of the things in the box to you?

- ☐ 1 Often
☐ 2 Sometimes
☐ 3 Rarely
☐ 4 Never

Box B

Push, grab or shove
 Throw something
 Slap

46. Looking at box C, when you have a disagreement with your partner, how often does he do any of the things in the box to you?

- ☐ 1 Often
☐ 2 Sometimes
☐ 3 Rarely
☐ 4 Never

Box C

Kick, bite or hit with fist
 Hit or try to hit with something
 Beat up
 Choke
 Burn or scald

47. Have you had any injuries or pain as a result of violence from your partner during your pregnancy?

- ☐ 1 Yes (please provide details)
☐ 2 No

Number of occasions: _____

Body site injured: _____

Type of injury: _____

Overall health during pregnancy

48. Have you experienced or been told that you have any of the following during this pregnancy?
 (Tick more than one box if necessary)

	Yes	No	Don't know
a. Diarrhoea	1	2	3
b. Urinary tract infection	1	2	3
c. Gestational diabetes	1	2	3
d. High blood pressure	1	2	3
e. High cholesterol	1	2	3
f. Other illness (please describe)	1	2	3

Thankyou for helping us

Data collection from patient charts

Patient chart # _____

Maternal Information	
Height	
Weight	
BMI	
Infections (UTI, STI, parasitic, viral, etc)	
Gestational diabetes	
Blood pressure	
Haemoglobin levels (anaemia?) (If recorded in patient chart)	
Evidence of injuries	
Type of delivery	
Delivery complications	
Other comments on health of mother	
Infant Information	
Gestation at birth	
Birthweight	
Length	
APGAR scores	
Admission to Special Care Baby Unit	
Infant Morbidity	
Other comments on health of newborn	

What is a serve?

Vegetables and legumes (choose a variety)

Starchy vegetables

1 med potato/yam ½ medium sweet potato 1 medium parsnip

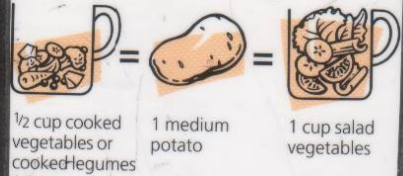
Dark green leafy vegetables

½ cup cabbage, spinach, silverbeet, broccoli, cauliflower or brussels sprouts

Legumes and other vegetables

1 cup lettuce or salad vegetables ½ cup broad beans, lentils, peas, green beans, zucchini, mushrooms, tomatoes, capsicum, cucumber, sweetcorn, turnips, swede, sprouts, celery, eggplant etc

One serve of VEGETABLES is 75 grams or:



Fruit

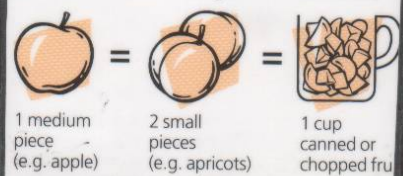
1 piece medium sized fruit eg apple, orange, mango, mandarin, banana, pear, etc

2 pieces of smaller fruit (apricots, kiwi, plum, figs) About 8 strawberries

About 20 grapes or cherries ½ cup fruit juice ¼ med melon (eg. rockmelon)

Dried fruit (4 dried apricots) 1½ tblspn sultanas 1 cup diced pieces/canned fruit

One serve of FRUIT is 150 grams of fresh fruit or:

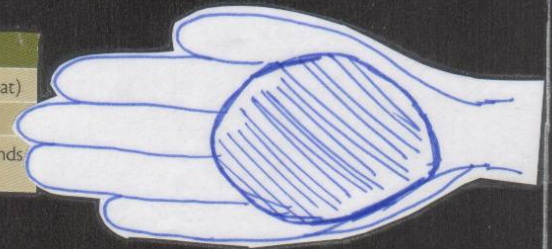


Meat, fish, poultry & alternatives

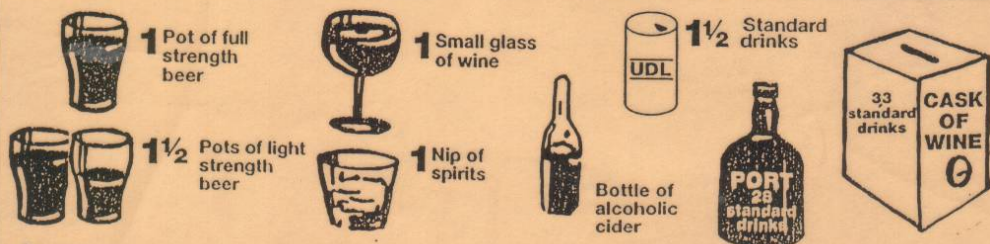
65-100gm cooked meat/chicken (eg ½ cup mince/2 small chops/2 slices roast meat)

80-120g cooked fish fillet, *or, as an alternative try:*

2 small eggs ½ cup cooked dried beans, lentils, chick peas, split peas or canned beans 1/3 cup peanuts/almonds



These are standard drinks



CHAPTER 3

Antenatal smoking in vulnerable population groups: An area of need

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The following paper has been published based on the findings of this Chapter:

Gilligan C, Sanson-Fisher R, Eades S and D'Este C. (2007) Antenatal smoking in vulnerable population groups: An area of need. Journal of Obstetrics and Gynaecology, 27:7, 664-671.

Chapter 3

Antenatal smoking in vulnerable population groups: An area of need

Introduction

Maternal smoking during pregnancy is hazardous to the developing foetus, and is an identified factor associated with infant mortality and low birth weight. The latter has been linked with health problems in childhood and adulthood.¹⁻³ Studies have demonstrated that reduction of smoking during pregnancy improves infant birth weight.^{4 5} Women who stop smoking in the first three to four months of pregnancy have been found to have infants of the same average birth weight as women who have never smoked.⁴ Exposure to environmental tobacco smoke is also a risk factor for childhood respiratory tract and middle-ear infections, sudden infant death syndrome, neurocognitive defects, and behavioural problems.⁵ The mortality rate for infants of smokers in the US in 2002 was 68% higher than the rate for infants of nonsmokers.⁶

Smoking rates during pregnancy are unacceptably high, and are particularly problematic in a number of vulnerable groups. Women giving birth in Public Hospitals,⁷ women of low socio-economic status,⁸ and Indigenous women smoke at higher rates than the overall population. Rates of antenatal smoking are substantively higher in the Indigenous populations of Australia, Canada, New Zealand and the US. Each of these nations has identified improving the health of Indigenous populations as a priority.^{4 9-16} Around 20% of non-Indigenous¹⁷ and 65% of Aboriginal and Torres Strait Islander¹⁸⁻²¹ Australian women are reported to smoke during pregnancy. In Canada, a smoking rate of 72% exists among the Inuit population, while the rate is 23% among non-Indigenous Canadians.¹⁴ In New Zealand, 57% of Maori women aged 15-44 were self-reported

smokers, as opposed to 26% of European women.¹⁰ In the US, the smoking rate is 24% among the overall population, and 41% among the American Indian/Alaskan Native population¹⁵ High smoking rates coincide with peak fertility rates, and the prime child-bearing years for women, as well as with elevated rates of infant mortality and low birth weight. The discrepant infant mortality rates among Indigenous and non-Indigenous populations of Australia, Canada, New Zealand and the US are shown in Table 3.1.

The consequences of smoking during pregnancy place continuing pressure on health services. Low birth weight babies have been found to be more prone to ill health in both childhood and adulthood.²³ Direct neonatal health care costs that were attributable to maternal smoking in the US in 1996 are estimated to be more than \$227 million. The burden imposed on the healthcare system by this behavioral pattern is preventable. Consequently, it would be expected that a substantive amount of research would be directed towards developing strategies to reduce the rate of antenatal smoking.

Table 3.1: Discrepancies in infant mortality rates between Indigenous and non-Indigenous groups

Country	Indigenous rates (deaths per 1000 live births)	Non-Indigenous rates (deaths per 1000 live births)
Australia ²²	20	9.1
Canada ¹¹	8.0	5.5
New Zealand ¹⁰	10	6.5
US ²³	14	7.0

A number of possible mechanisms exist by which research output in a particular field can be assessed²⁴ but no standardised system is in place. Translation of methodologically vigorous research results into developments in policy and practice or health status is possibly the most important indicator of research performance.²⁵ These markers are, however difficult to measure. Simpler and more commonly used measures include the amount of research resources allocated, the number of publications, the number of publications of certain types, and quality of research.²⁶

Given the increasing recognition of the adverse health risks of smoking, and the importance of evidence based clinical guidelines, we would expect that evidence in antenatal smoking cessation would also be increasing in line with these trends. Also, considering the health discrepancies between Indigenous and non-Indigenous populations, and the clear need for improvement in the former group, it would be expected that this increase in research output would be biased towards Indigenous groups.

This Chapter examines the differences across time (1984-86, 1994-96 and 2004-06) in the number and type of antenatal smoking publications for Indigenous and non-Indigenous populations in Australia, Canada, New Zealand and the United States. Two hypotheses were examined:

1. That the total number of publications focusing on antenatal smoking would increase over the time periods as a result of the importance of smoking as a health hazard for mother and child, and that publications relating to Indigenous women would increase to a greater extent, given the recognition of the relatively poor circumstances of these groups; and
2. That the proportion of all antenatal smoking publications which are intervention focused would increase over time, reflecting an effort to increase the evidence base

necessary to guide clinical behaviors that will decrease the prevalence of smoking in these vulnerable population groups.

Methods

Literature Searches

Literature searches were conducted to identify relevant antenatal smoking cessation publications. *Medline* and *PsycINFO*, were searched as these databases encompass many major journals publishing findings from the health field. Articles dated from January 1980 through to December 2006 were considered. While evidence for the impact of antenatal smoking on low birth weight was presented as early as 1964, the 1979 US Surgeon General's Report on Smoking and Health was the first to present an extensive literature review with "*abundant evidence that maternal smoking is a direct cause of a reduction in birth weight*" (p21) as well as evidence for links with fetal growth rate, pregnancy complications, fetal deaths and stillbirths, infant mortality, congenital malformations, and impaired development.²⁷ The study time period was therefore chosen to allow an opportunity for the research field to respond to this evidence, to allow ample time for change in research practices, and to capture current literature.

For pragmatic reasons, the first hypothesis was addressed using a broad search in Medline only. The second hypothesis also incorporated articles found in PsychINFO. Four searches were conducted in each database. The first search used the terms 'antenatal' AND 'smoking cessation', including any citation that contained in the title, article, abstract or MeSH heading the words or terms: 'antenatal', or 'pregnancy', or 'prenatal care' as well as 'smoking', 'smoking cessation', 'tobacco', or 'tobacco use cessation'. A further component was added in the second search, limiting the sample to citations that also contained the following terms in either the title, abstract, article or

MeSH heading: 'Aborigines' or 'Aboriginal'; 'Torres Strait Islander'; 'Maori'; 'American Indian'; 'North American Indian', 'North American'; 'Alaskan Native'; 'Hawaiian'; 'Native American'; 'American Samoan'; 'Eskimos', or 'Inuit'; 'Eskimos' or 'Aleut'; 'Metis'; 'Indigenous'. Two additional searches were performed using the terms 'low birth weight' and 'preterm birth' (also including premature birth) to enable comparison with the number of publications in a closely related field.

Classifications

Based on the title, abstract, keywords, and publication type listed in the citation, the publications were classified into the following groups:

i) Research studies

These articles reported new data or new analyses of existing data relating to antenatal smoking among Indigenous or non-Indigenous populations. Research studies were then sub-classified into one of the following categories:

a) Measurement research

This included studies in which the aim was to test a measure of smoking. This included research assessing the accuracy of self-reported smoking status, the qualities of a clinical screening or diagnostic tool, or the development and testing of questionnaires designed to measure outcomes or characteristics such as health risk behaviours or attitudes. Publications relating to the quality of care or the determination of the level of compliance by healthcare providers were also included in this category. Articles describing a new statistical method and using an antenatal smoking-related example were classed as not relevant.

b) Descriptive research

This included studies in which the aim was to describe health related variables or associations between variables. Epidemiological studies where the primary aim was to explore the frequency or patterns of disease, population groups at greater risk, or

socio-demographic factors that may be related to smoking and health such as knowledge, attitudes, or health care service utilization, at a community or population level were classed as descriptive. Also, studies performing *in vitro* scientific analysis of the effects of maternal smoking were included with a note to indicate their scientific nature.

c) Intervention research

This included studies where the aim was to test the effectiveness of a clinical or public health smoking cessation intervention with antenatal women (either Indigenous or non-Indigenous). If a publication focused on both descriptive and intervention research it was classified as intervention research.

ii) Systematic or critical reviews

These publications were defined as reviews in the literature database or referred to as reviews in the abstract or title.

iii) Descriptions of research or health programs with no data

This included publications where the primary aim was to describe the methods or processes being undertaken for a research project in the field of antenatal smoking. It incorporated papers where the primary aim was to describe an intervention or health initiative being applied, but where no program evaluations were reported. Interventions included clinical treatments or public health interventions.

iv) Discussion papers or commentaries

This included publications identified in the databases as comments or letters. It also included articles that did not present original data or describe a specific research project or intervention; for example, general articles on aspects of antenatal smoking and smoking among Indigenous populations, and recommendations of task forces or committees.

Articles were included for classification if they directly studied smoking, or examined smoking as a primary variable or risk factor for the health issue in question. Studies which controlled for smoking as a potentially confounding variable in their statistical analysis but did not directly assess or discuss smoking were classed as not relevant. Those studies in which smoking or pregnancy was mentioned as a secondary factor were included, but were noted as such. Studies in which pregnancy and smoking were both discussed but not in relation to each other were eliminated as not relevant. The publications arising from searches on low birthweight and preterm birth were not included in the classification process.

Country of origin was also recoded for articles on Indigenous antenatal smoking to enable between country comparisons of publication volume.

Statistical analysis

The numbers of publications addressing each topic are presented for each year from 1980 to 2006. Linear regression analyses were performed separately for each of the four groups of publications, for the number of publications versus year of publication to determine if there was an increasing trend in number of publications over time. The value of the test statistic and p-values for the test that the slope of the trend line is zero are reported.

For comparison of time periods, the number of articles published from January 1984-December 1986 were combined, and compared with those published between January 1994 and December 1996, as well as those published between January 2004 and December 2006 in the antenatal smoking cessation field in both the overall, and the Indigenous, search categories. A Chi-squared test of proportions was performed to assess the differences in proportion of publications in each classification.

Inter-rater Reliability

The candidate coded the publications into different classifications. In order to assess the reliability of the classification system, 10% of publications were randomly selected for independent classification by a second researcher at The University of Newcastle. The Kappa statistic, with 95% confidence interval was used to assess inter-rater agreement.

Statistical analyses were conducted in STATA²⁸ and a 5% level of significance used.

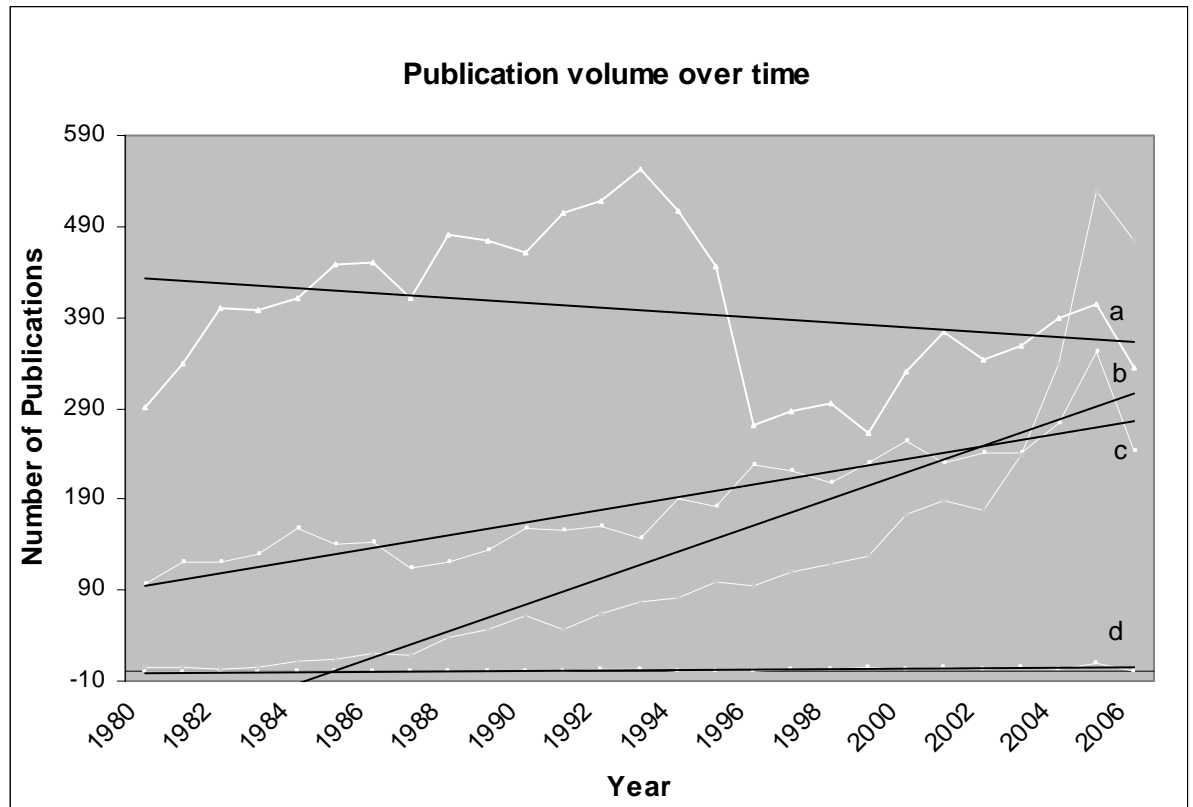
Results

For the assessment of publication volume since 1980, the results of a crude search of the Medline database were used. For reasons of practicality, no effort was made to assess the relevance of the papers, but as the search methods were the same for each topic, the proportion of relevant and unrelated papers was expected to be equivalent for each. A total of 6032 studies were included in the antenatal and smoking group, and 67 of these were retained in the Indigenous antenatal smoking group. An additional 13281 publications relating to low birth weight and 3497 relating to preterm birth were also included for comparison.

Figure 3.1 and Table 3.2 show the number of articles published each year from 1980 in the areas of antenatal smoking, Indigenous antenatal smoking, low birth weight and preterm birth. The publication volume increased significantly between 1980 and 2006 for three of the four categories, with low birth weight failing to achieve a significant increase after a drop in publication volume in the early 1990's. The number of publications increased significantly over time for publications focusing on antenatal

smoking cessation (t-test that slope of line=0: $t=11.01$, $df=1$, $p<0.001$). Indigenous antenatal smoking, (t-test that slope of line=0: $t=5.51$, $df=1$, $p<0.001$), and preterm birth (t-test that slope of line=0: $t=7.86$, $df=1$, $p<0.001$).

Figure 3.1: Trends in publication volume



This figure provides a graphic representation of the publication volume presented in Table 3.1
Lines:

- (a) Low birth weight,*
- (b). Preterm birth,*
- (c) Antenatal smoking cessation,*
- (d) Indigenous smoking cessation*

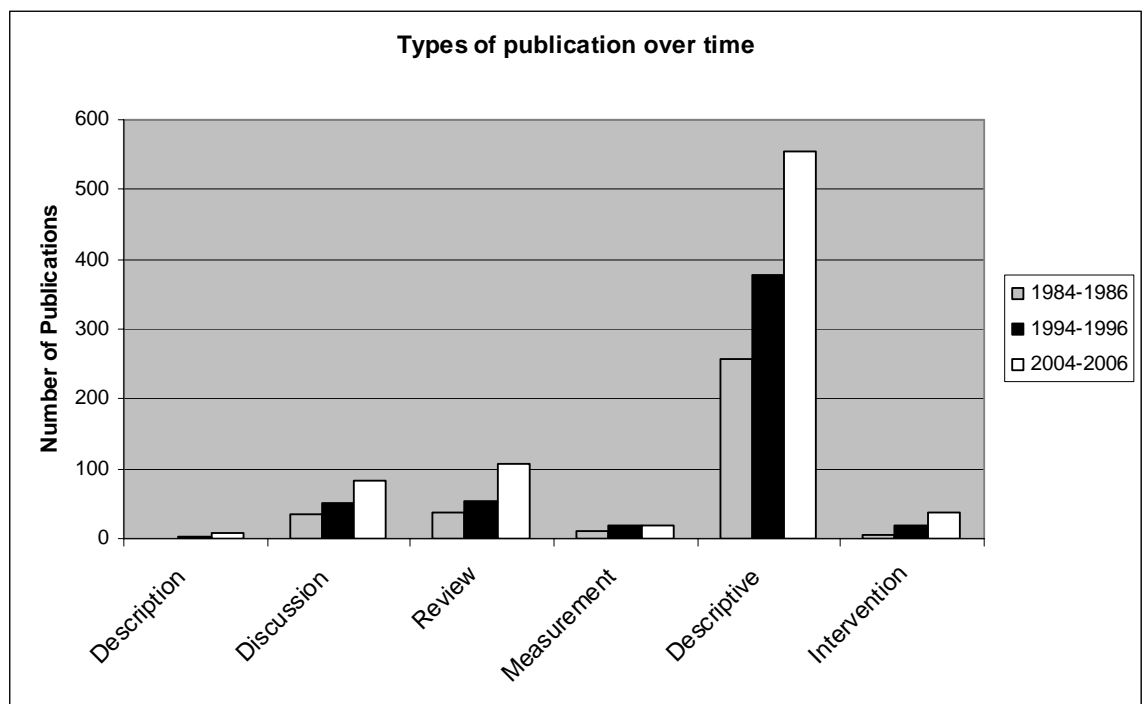
Table 3.2: Trends in publication volume

Year	Antenatal smoking	Indigenous antenatal smoking	Low birth weight	Preterm birth
1980	98	0	291	5
1981	120	0	339	6
1982	120	0	400	4
1983	130	0	398	6
1984	159	2	411	11
1985	140	1	449	14
1986	142	1	450	21
1987	115	1	412	18
1988	120	0	481	39
1989	135	1	474	46
1990	159	0	462	61
1991	155	1	505	46
1992	160	4	518	65
1993	147	3	554	78
1994	190	0	507	81
1995	182	0	447	100
1996	227	2	271	95
1997	222	4	286	111
1998	209	4	295	119
1999	230	5	262	127
2000	254	4	330	174
2001	229	5	375	189
2002	240	3	343	178
2003	240	5	358	239
2004	273	4	389	339
2005	353	9	405	529
2006	243	2	334	474
TOTAL	4992	61	10746	3175

This Table illustrates the number of publications identified each year from 1980 to 2006 in Medline. Additional publications on antenatal smoking derived from PsycINFO are not included here.

Figure 3.2 presents the allocation of all publications on antenatal smoking to the publication type classifications, across the three time periods (1984-86, 1994-96, and 2004-06). Comparison of the periods shows very little change in the allocation of publications to various categories. Chi-square analysis indicates that there was no significant change in proportional allocation to any publication type between the two time periods ($\chi^2=13.76$, $df=10$, $p=0.184$). In Indigenous antenatal smoking publications, all articles were classified as descriptive research, with no intervention or measurement research articles published in any time period, and no discussion papers, reviews or other descriptions relating to Indigenous populations.

Figure 3.2: Classification of publications



Classification of publications relating to antenatal smoking presented as percentages of the total.

After elimination of articles relating to minority ethnic groups other than Indigenous populations (e.g. Latin American), 26 articles were included in the Indigenous antenatal smoking category across the three time periods examined. Each of the articles was

classed as descriptive research, and five were noted as having smoking or antenatal smoking as a secondary topic. There were 11.5% (n=3) of articles that related to Australian Indigenous groups, 11.5% (n=3) to Canadian, 4% (n=1) to New Zealand, and 73% (n=19) to US populations. It is interesting to note that of the 19 articles published in the US, only seven related specifically to Indigenous groups, while the remainder mentioned these groups in comparison to the mainstream population and/or other minority groups. Two of the three Australian articles, and each of the Canadian articles were specifically focused on examining antenatal health of Indigenous groups. The only article which was based on New Zealand populations in this time frame was a comparison between Maori and non-Maori women in relation to maternal cigarette smoking as a risk factor for post-neonatal death and cot death.

Direct comparison of the coding allocated by each author for inter-rater reliability using a Kappa statistic revealed substantial agreement between the authors (observed agreement 93.1%, Kappa 0.9).

Discussion

The present study aimed to critically examine the publications and their potential contribution to the area of antenatal smoking in Indigenous and non-Indigenous women over the last ten years. Those publications identified should contribute knowledge to the evidence base for effective interventions and improvements in clinical practice.

Number of Publications

A statistically significant increase did occur in publication volume relating to antenatal smoking cessation overall. However, the publication volume remained substantially smaller than that of publications regarding low birth weight, and underwent a less

substantial increase than those regarding preterm birth. While an increase in publication volume is a positive indication of progress, the discrepancy in the number of publications relating to these topics compared to those regarding antenatal smoking is of concern. Antenatal smoking is a major risk factor for low birth weight and preterm birth and the levels of both of these outcomes are high among the Indigenous population of developed countries. These rates are not reflected in the publication volume relating to these Indigenous populations. It would not be unreasonable to expect that publication volume in the antenatal smoking field would be somewhat closer to that in low birthweight, and that increases in publication volume would occur in a similar pattern in all three areas.

As shown in Figure 3.1, low birth weight publications gradually increased in volume until 1996, when the volume dropped dramatically, causing an overall slight decrease. The volume of publications in this field was higher than for antenatal smoking. The publication volume in the antenatal smoking field escalated between 2004 and 2005, influencing the overall trend. Prior to this increase, the trend was a very gradual increase in volume occurring at a much slower rate than that for preterm birth. Relative to the other categories, the change in volume of Indigenous antenatal smoking publications was negligible.

In low-risk pregnancies, without the complication of diabetes or hypertension, one of the few factors which requires attention from healthcare providers, and which can be influenced by their advice, is smoking. Several studies have evaluated alternative antenatal care protocols with fewer visits, and found no difference in pregnancy outcome or patient satisfaction²⁹⁻³¹ While 'lack of time' is often cited as a limitation to smoking intervention delivery by usual care providers,^{32 33} this evidence suggests that a larger portion of time in routine visits could be dedicated to smoking cessation advice with no adverse effects on the pregnancy or its outcomes. If a reduction from 13 or 14

visits to nine visits during a pregnancy has no impact on outcome^{29 30} then in theory, the equivalent of up to five consultation periods could be allocated to the discussion of smoking cessation.

Reasons for the discrepancy in the volume of publications between antenatal smoking, low birth weight and preterm birth are speculative. It may be that the health professionals who are in contact with women giving birth before term or to low birth weight babies are more biomedically oriented. The research activity or publication volume which arises from this contact is not therefore likely to be based on health behaviour such as smoking. However, the World Health Organisation's recent report on Knowledge for Better Health and Strengthening Health Research Systems recommends that "*the culture and practice of health research be expanded beyond academic institutions and laboratories to include health service providers, policy-makers and civil society*".²⁴ The report highlights the need for research to consider diverse social, political, and health systems contexts to enable biomedical discoveries to be applied in such a way as to bring about improvements in health.

Type of published research

It might be expected that research development and progression would follow a logical process, with measurement research occurring first, followed by descriptive studies which allow the correlations and linkages between behaviours and other factors to be established. The findings of descriptive studies would then be used to develop programs for use in intervention studies, and ultimately translation into routine use in antenatal care settings, with the aide of dissemination research. This approach creates a circular flow of research and allows for development of a strong evidence base, and advancement in healthcare.³⁴ Examination of the volume of each type publication over

time acts as a marker of whether research efforts have progressed beyond descriptions of health issues to building an evidence base on approaches to facilitate change.

This review of antenatal publications found that the proportional allocation of measurement research publications decreased from 3.5% in 1984-86 to 2.5% in 2004-06. The proportional allocation of descriptive research publications also decreased slightly from 74% in 1984-86 to 68.5% in 2004-06. Intervention research increased slightly from 1.7% to 4.6%. None of these changes were statistically significant. All of the publications relating to antenatal smoking among Indigenous women across each of the time periods were classed as descriptive research.

Measurement research is essential for the establishment of accurate and reliable markers of a disease, disorder or behaviour. It is widely accepted that a significant level of mis-report occurs during questionnaire-based analysis of smoking behaviour. Several American and British studies have reported that up to 25% of pregnant smokers falsely declare themselves to be non-smokers due to social pressure or knowledge of adverse effects.^{36 37} Appropriate measures of smoking status must be developed for studies involving different participant groups, giving consideration to the different cultural and other values and influences upon the behaviour of groups such as pregnant women in general, and particularly, Indigenous groups.³⁵ The volume of measurement research publications identified in the present review does not reflect this need, and indicates the presence of a critical gap in the literature in this field.

Methodologically vigorous, descriptive research should employ established, accurate measures of smoking behavior in order to accurately describe the extent and characteristics of the problem. In the absence of measurement research to identify a reliable marker of cigarette smoking however, the results of descriptive research will

lack credibility. Similarly, any intervention studies conducted without requisite background data from measurement and descriptive research are potentially flawed.

The dissemination of research output and the uptake of interventions into routine care represent major barriers to the advancement of healthcare. Even after the establishment of a credible evidence base suggesting that healthcare providers should offer a certain intervention in routine care, the rate of compliance to such evidence is potentially low. Provider adherence was studied in an Australian antenatal smoking cessation trial, finding that only 26-38% of women in the intervention group were informed about risks relating to smoking during pregnancy.³⁶ Hunt and Lumley³⁷ report that advice about smoking cessation is rarely included in the recommendations routinely provided in antenatal care in 93 hospitals across Australia, with only 10% of antenatal care protocols including advice to quit smoking. Very little level one, high quality evidence is available to guide the development of recommendations for smoking cessation. More extensive evaluation of smoking cessation interventions is required to design systems that will be effective within communities, to increase smoking cessation rates over and above those influenced by medical practitioner advice alone, and to increase the rate at which healthcare providers deliver interventions.^{41 42}

The need for strong scientific evidence and stage-based research applies to the broad area of antenatal smoking, but is perhaps even more pertinent for Indigenous communities. It is recognised that Indigenous philosophy and cultural values can impact upon healthcare outcomes,³⁸ creating a need for approaches to be tailored to this population. Indigenous populations are often set apart from the mainstream population by markers of poor health and low socio-economic status.³⁹ Unique barriers also impact upon smoking cessation in these groups, such as Australia's Aboriginal and Torres Strait Islander population, with the high overall rate of smoking in the

community normalising this behavior for individuals.^{40 41} Low literacy levels, and high rates of abuse of other substances and of mental illness, all of which affect this population, are also associated with low rates of smoking cessation.⁴² It might be expected that health services and health promotion programs would therefore be designed specifically to meet the unique needs of this group. Increasingly, Indigenous people are requesting a balance between research efforts that define and measure health problems with those which explore clinical and public health interventions.⁴³

Limitations of the research methodology

The approach used in this study has limitations. Firstly, the use of only two major health publication databases limits the scope of publications identified. This factor was influenced by feasibility. However, no major restriction to the generalisability of the findings occurred, as the literature searches were expected to have captured a large proportion of the quality work in this field. Consequently, the findings are likely to accurately reflect the trends in publications in the field.

The use of online literature search engines may prove limited, as some of the work published in the Indigenous health may be published in the 'grey literature' and may not be accessed through scientific databases. This may have contributed to the relatively small proportion of publications identified in the Indigenous antenatal smoking category. Publishing in scientific journals is however, the most common means by which researchers disseminate their findings. Additionally, articles within such journals are most likely to have been peer reviewed and therefore, most likely to reflect the methodological scientific strengths of the published work.

Further, with differing levels of access to country-specific databases and grey literature sources, it was deemed most appropriate to maintain consistency and limit bias by restricting the searches to International, mainstream databases.

Conclusions

The relatively small volume of publications relating to antenatal smoking over time, in contrast to other areas such as low birth weight, should be considered by the research community. That descriptive publications dominate over three successive time frames limits the opportunity for deriving evidence that will guide interventions to reduce smoking in this vulnerable population group. The disproportional volume of descriptive research publications identified in this review might be the result of long-standing research culture. Descriptive research can potentially be performed and published more quickly and easily than intervention and measurement research, and is likely to be far less costly. The difficulties associated with performing intervention studies, and particularly those in Indigenous groups, may hinder many potential subjects, as well as researchers with a 'publish or perish' agenda. The small number of publications addressing the measurement of factors regarding antenatal smoking is also of concern. In a field such as smoking, the development of appropriate and reliable measures is critical for the reliability of descriptive and intervention research.

In an ideal world, the research community as a whole should be driven by the need to produce research output that translates into a benefit for the health of the population. This should be incentive enough to set aside personal agendas to make way for beneficial research. As is recognised by WHO, research efforts should focus on priority health problems, on health system challenges, and on managing opportunities for future growth and development.²⁴ In the case of antenatal smoking, there is a need for researchers to direct efforts towards vulnerable groups, with a need initially, for the

establishment of useful measures. Such measures would form a sound foundation for future energies in descriptive and in particular intervention studies. In the absence of experimental research, any anti-smoking intervention delivered by healthcare providers is potentially flawed and not ideal. A systematic review is currently being prepared to assess the quality of the interventions being conducted in this field.

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CHAPTER 4

Intervening to reduce antenatal smoking: What can we tell clinicians about the most effective strategies for intervening with antenatal smoking?

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Chapter 4

Intervening to reduce antenatal smoking: What can we tell clinicians about the most effective strategies for intervening with antenatal smoking?

Introduction

The adverse health effects of antenatal smoking upon mothers and infants, and the resulting burden on the healthcare system have been extensively described. Many women quit smoking when they are planning, or discover a pregnancy,¹ but a large percentage continues to smoke.^{2,3} There is evidence to suggest that interventions can reduce smoking rates, even among this resistant group.⁴ Particularly among Indigenous groups, rates of antenatal smoking have remained high, despite overall population drops in smoking. As discussed previously (Chapter Three), this issue places significant burden on the healthcare system, and represents an area in great need of intervention. Clinicians providing antenatal care are in an ideal position to identify smokers and to deliver the advice, support or tools necessary to help women quit. While evidence for the need to reduce smoking abounds, there is a gap in the literature regarding what is the most appropriate approach to bring about a reduction. The principle of evidence based medicine should be applied to every facet of healthcare. It would be unethical and not cost efficient to deliver interventions which have not been shown to be effective in methodologically rigorous evaluations.

Hunt and Lumley⁵ report that advice about smoking cessation is rarely included in routine antenatal care recommendations, with only 10% of the antenatal care protocols used in 93 hospitals across Australia including advice to quit smoking. Clinical practice

guidelines are established to encourage treatment that offers patients the maximum likelihood of benefit, and minimum likelihood of harm. Recommendations contained in guidelines should be based on the best possible evidence of the link between the intervention and the clinical outcomes of interest.⁶ In searching for evidence to guide informed recommendations regarding the most appropriate and potentially effective interventions that clinicians can deliver to antenatal smokers, it seems logical to turn to the published literature.

Looking to the published literature

A large body of literature has accumulated on the topic of antenatal smoking cessation. Numerous descriptive studies have explored predictors of smoking cessation during pregnancy and the key features of successful interventions.⁷⁻⁹ Various reviews have reported on the ingredients for 'success' of, and results obtained from antenatal smoking interventions with varying degrees of focus on the methodology behind the interventions. The most extensive review on this topic is the 2004 Cochrane review by Lumley et al.⁴ This assessed studies against a set of methodological criteria, as well as reporting on the overall results of the interventions.

Methodological approaches to intervention

Lumley et al., reported a 6% difference in smoking cessation rates between the intervention and control groups in pooled data from 48 trials. It is not possible from this review to draw clear messages regarding the intervention strategies which were associated with success. A wide range of intervention approaches and strategies were trialed in the studies included in this review. Several intervention approaches have gained popularity in the field of antenatal smoking cessation, with limited evidence for their effectiveness. The trans-theoretical model, for example has been widely used as

the basis for intervention in tobacco use^{10 11} but overall, has not been found to generate cessation rates significantly higher than usual care.¹² Motivational interviewing strategies have been demonstrated to be effective in various areas of behaviour change,¹³ but evidence for their effectiveness in antenatal smoking interventions is lacking. In another Cochrane review, Stead and Lancaster (2005) reported improved cessation rates with group behaviour counseling for tobacco, in comparison to self-help approaches, but were unable to identify particular components of the counseling which were associated with success.¹⁴

In the Cochrane review, the effects reported in those studies using cognitive behavioural strategies did not differ from the average effects of the whole group. Stages of change-based interventions were not effective, and those using nicotine replacement therapy were reported as having 'borderline' effectiveness. Studies using social support and rewards showed a significant positive effect compared with the overall pooled trials, but this group only comprised two studies. Further, no statistically significant differences were found between the overall results, and those achieved in studies of high intensity, high quality, or with biochemical validation.

How can the differences between studies be uncovered?

Meta-analyses such as the one conducted by Lumley et al., are based on an assumption that the interventions being assessed are relatively uniform, allowing for the combination of, and direct comparison between, results.¹⁵ This assumption is flawed in the context of such diverse approaches, but is often regarded as inevitable in most analyses. A measure of the heterogeneity between studies is made prior to meta-analysis to ensure that studies are sufficiently similar to be combined. Such a measure is based on an assessment of the magnitude of effect measured in each study, aiming to ensure that all studies are measuring the same underlying effect.¹⁵

Lumley et al., measured significant heterogeneity between studies but aimed only to assess the effects of the interventions, with no attempt made to explain the causes of this heterogeneity. The US National Centre for Complimentary and Alternative Medicine (NCCAM), and the Agency for Healthcare Research and Quality (AHRQ), recognising the importance of heterogeneity in meta-analysis, suggested that meta-analysts should not only measure heterogeneity, but attempt to identify and understand its sources. Meta-regression techniques consider the inevitable differences in design of individual studies, and attempt to identify the study-level covariates which account for heterogeneity. Such exploration potentially increases the scientific and clinical usefulness of the results of meta-analysis.¹⁶

The next step towards identifying successful intervention approaches

With the great heterogeneity observed between studies in Lumley's Cochrane review, it appears that in order to identify key elements of successful interventions, it is necessary to further explore the methodological and strategic aspects of studies. Development of evidence-based recommendations requires the identification of the elements that set successful interventions apart from unsuccessful ones. Comparison of interventions of equivalent methodological vigour might be expected to enable identification of such differentiating features.

The Cochrane Effective Practice and Organisation of Care (EPOC) Group have developed criteria for the Assessment of Methodological Quality, and The Centres for Disease Control (CDC) have published a Community Preventive Services Data Collection Instrument, which examines the potential effectiveness of intervention approaches and pragmatic issues associated with performing intervention research in primary healthcare settings. All trials included in traditional Cochrane reviews are

randomised controlled trials or quasi-randomised trials of smoking cessation programs. In recognition of the practical limitations associated with running randomised controlled trials, these groups have endorsed alternative research designs which meet standards of methodological vigour.

The present study expands on the review of antenatal smoking interventions performed by Lumley and colleagues to include a more timely set of studies published since 1995 which meet methodological criteria derived from the EPOC and CDC guidelines. By including methodologically rigorous studies which are not necessarily randomised controlled trials, this review has the capacity to examine more broadly the strategies used in interventions with pregnant women. The use of meta-regression techniques allows for the evaluation of these interventions, potential determination of what methods work in practice and are able to be replicated in routine healthcare settings. The slightly different selection of studies and extension of Lumley's analysis to include an exploration of the sources of heterogeneity may hold the key to the differential effectiveness of intervention strategies in practical settings. The present study aims to explore the (1) intervention strategies and (2) methodological quality of interventions in antenatal smoking, and to identify those components which are most likely to be associated with improved cessation rates.

Methods

Review of the literature

To identify papers published in English between 1995 and 2007 that report on relevant intervention studies, the following electronic databases were searched: *MEDLINE*, *CINAHL*, *EMBASE.com*, *CENTRAL*, *PSYCHLIT* and *AUSTHEALTH*. Searches in each database used the terms 'antenatal' OR 'pregnancy' AND 'smoking cessation' OR

‘smoking’, including any citation that contained these terms or related terms in the title, article, abstract or subject heading.

The Cochrane Tobacco Addiction Group’s trial register was also searched in March 2007. Consistent with recommendations for systematic public health reviews, the reference lists of included articles were hand-searched to identify any additional articles relevant to the review. Additional articles were sought which either published additional information on an already included intervention project, or separate studies not identified in the databases above.

Criteria for Inclusion of studies

Any study evaluating the effectiveness of clinical or public health interventions in which the aim was to reduce smoking rates among women during pregnancy with smoking cessation reported as a primary outcome were identified. Participants included pregnant women in any healthcare or community setting. For inclusion, studies were required to be defined as either randomised controlled trials, prospective cohort studies, time series studies, or cross-sectional studies (see definitions in Table 4.1), with interpretable data relating to smoking cessation presented or obtainable. The study design criteria are based on a combination of EPOC and CDC principles in order to capture studies which would assist in answering questions about the effectiveness of interventions. As well as those designs endorsed by EPOC, those which are regarded in the CDC criteria as having ‘moderate suitability to assess effectiveness’ were also incorporated. The EPOC assessment excludes studies which do not use concurrent data collection from intervention and control groups. CDC however, recognise as acceptable, studies which compare outcomes among a group exposed to the intervention versus outcomes in a historical group that was not exposed, or that was less exposed. Definitions of these study designs are summarised in Table 4.1.

Table 4.1: Minimum methodological criteria for inclusion of studies into the review

Feature	Definition
Study design	<p>(a) <u>Randomised controlled trials</u> – involving prospective, random allocation of units of analysis to treatment or control conditions.</p> <p>(b) <u>Prospective cohort studies</u> – several groups studied, defined by exposure to an intervention in a prospective manner, or assigned by non-random methods of allocation.</p> <p>(c) <u>Retrospective cohort studies</u> – several groups studied, defined by exposure to an intervention in retrospect. This may include studies which compare outcomes among a group exposed to an intervention versus outcomes in a historical group that was not exposed or was less exposed. This category is not used by EPOC, but is used by CDC.</p> <p>(d) <u>Controlled before and after studies</u> – pre- and post-intervention periods for the intervention and control groups are the same (concurrent data collection from intervention and control groups with comparable baseline characteristics)</p> <p>(e) <u>Time series studies</u> – multiple measurements made before, during, and after an intervention (minimum three data points before and three after the intervention, with a clear definition of the point at which the intervention occurred).</p> <p>(f) <u>Cross-sectional studies</u> – comparative studies in which exposure and outcomes are determined in the same population at the same time.</p> <p>Studies unable to be classified into one of the above categories were not included in the review for further analysis.</p>
Unit of allocation	<p>(a) Individual providers</p> <p>(b) Practice (Department or team within an institution)</p> <p>(c) Institution (e.g: hospital or clinic)</p> <p>(d) Individual patients</p> <p>(e) Communities</p> <p>(f) Other</p> <p>Where the unit of analysis did not fall into one of the categories (a) to (e), it was defined as “other”, and where it was not clearly defined it was labeled “NOT CLEAR”.</p>
Unit of randomisation	<p>(a) Individual</p> <p>(b) Cluster</p>
Biochemical validation	Was self-reported smoking status accompanied by a biochemical validation?
Possible bias	<p>(a) Was there adequate concealment of allocation, and randomisation?</p> <p>(b) Randomisation using alternation, record numbers, date of birth, weeks, or open list numbers are classed as inadequate (selection bias).</p> <p>(c) Was the usual healthcare provider blinded to the allocation? This was not possible (and therefore recorded as not applicable) where the usual provider delivered the intervention (performance bias).</p> <p>(d) Was a biochemical validation of self-report used? (detection bias).</p> <p>(e) Were power calculations performed? (sample size justification).</p> <p>(f) Were drop-outs treated as continuing smokers? (attrition bias).</p> <p>The risk of bias was classed as <u>low</u> if each of the criteria in (a) to (e) were performed adequately. Risk was <u>moderate</u> if 2 or more of the criteria were met, and was <u>high</u> if 2 or more of the criteria were not met.</p>

In addition to the study design criteria, papers were eliminated in a stepwise fashion in order to obtain studies of comparable, reasonable methodological quality for assessment of outcomes and approaches used. Studies were required to meet the following minimum methodological criteria. (1) Objective measurement of outcomes in a clinical situation. This refers to the need for validation of self-reported smoking status with a biochemical measure. (2) 'High' methodological quality, with a low to moderate risk of bias according to Lumley's criteria in Table 4.1. Studies focusing on smoking in the post-partum period, with no intervention during the pregnancy itself were excluded. The criteria used for the evaluation of these minimum methodological criteria are presented in Table 4.2.

The publications retained after assessment against minimum methodological criteria were evaluated to examine the features associated with the success of an intervention. The Cochrane Health Promotion and Public Health Field review group quality assessment tool,¹⁷ the Cochrane Handbook for Systematic Reviews of Interventions, the CDC Guide to Preventive Services Data Collection Instrument, as well as the criteria used by Lumley et al., in their 2004 Cochrane review⁴ were all drawn upon in the development of the assessment criteria detailed in Table 4.2. The features of the interventions and research design factors were explored, and all studies assessed against the detailed criteria.

The criteria were grouped into categories, with those relating to the components of the intervention itself, the intervention design and approach used, and the outcome measures used, based primarily on the criteria used by Lumley et al. Details of participant numbers, recruitment rates, and attrition were also collected, along with methodological features relating to study quality, based on the Cochrane and CDC tools, and details of the biochemical validation tests used.

Table 4.2: Criteria for assessment of included articles

<p>Intervention Features</p>	<p>1. Types of interventions were characterised according to the inclusion criteria used by Lumley et al., (2004)⁴</p> <ul style="list-style-type: none"> a. Information about the harmful effects of smoking on the fetus and infant, the mother herself or other family members (verbal, written or both). b. Advice by a health professional to 'stop smoking'. c. Supplementation of advice by reinforcement at subsequent antenatal visits. d. Supplementation of advice by group counselling. e. Supplementation of advice by the provision of peer support. f. Supplementation of advice by recording smoking status, or measuring by-products of smoking at other antenatal visits. g. Supplementation of advice by feedback of the effects of smoking on the fetus (fetal movements, fetal breathing, fetal heart rate). h. Supplementation of advice by positive information about the fetus and fetal development (for example, describing the ultrasound in detail). i. Individualised advice and support for smoking cessation based on 'stages of change'. j. Provision of pregnancy-specific self-help manual on strategies for quitting. k. Provision of the following as an adjunct to information and advice: <ul style="list-style-type: none"> - nicotine replacement therapy; - telephone follow up with reinforcement of advice and strategies for quitting; - rewards and incentives. l. Strategies to change the attitudes, knowledge and behaviour of healthcare providers with respect to smoking cessation. m. Other. <p>Additional fields were also added to specifically assess:</p> <ul style="list-style-type: none"> 2. Incentive offered 3. Quit date negotiated 4. Was motivational interviewing used? 5. Did the intervention involve personalised follow-up or individual counselling of clients?
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Table 4.2 continued

<p><i>Intervention approach</i></p>	<ol style="list-style-type: none"> 1. How much time was spent per client on the intervention? 2. How many contacts were made with each client? 3. How many written materials were provided to each client? 4. What was the intensity of the intervention? <ul style="list-style-type: none"> Intervention intensity was categorised according to the definitions used by Lumley et al. a. 0 = if undefined except as 'usual care', or limited to advice not to smoke; b. 1 = provision of written information on smoking (posters/pamphlets); c. 2 = personal advice to quit and written information; d. 3 = strategies for quitting (written or personal), personal advice and written information, and/or written follow up; e. 4 = personal follow up (telephone calls, counselling, peer support) and strategies to quit, personal advice to quit and written information. All studies categorised as four were defined as high intensity; studies categorised as three were defined as medium intensity, studies categorised as less than three were defined as low intensity. 5. How many providers were involved in delivering the intervention? 6. Were usual care providers or specific intervention staff responsible for the intervention delivery? 7. Were usual care providers or specific intervention staff responsible for recruitment? 7. What professions/disciplines were involved? 8. Did the GP provide intervention-related to women?
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Table 4.2 continued

<p><i>Outcome measures used</i></p>	<ol style="list-style-type: none"> 1. What were the main outcome measures? <ol style="list-style-type: none"> a. Smoking cessation in late pregnancy. b. Smoking reduction from the first antenatal visit to late pregnancy. c. Smoking cessation in the puerperium. d. Birth weight (mean birth weight, proportion less than 2500 g, less than 1500 g). e. Gestation at birth (proportion less than 37 weeks, less than 32 weeks, less than 30 weeks). f. Perinatal mortality (stillbirths, neonatal deaths, all perinatal deaths). g. Method of delivery. h. Proportion of women initiating breastfeeding; breastfeeding at three and six months after birth. i. Measures of anxiety, depression and maternal health status in late pregnancy and after birth. j. Participants' views of the interventions. k. Measures of family functioning in late pregnancy and postpartum. l. Measures of knowledge, attitudes and behaviour of health professionals (obstetricians, midwives and family physicians) with respect to facilitating smoking cessation in pregnancy. m. Other. 2. What was the timing within pregnancy of recruitment? 3. What was the timing within pregnancy of outcome measurement? 4. Was smoking abstinence measured as point prevalence or sustained?
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Table 4.2 continued

<i>Details of recruitment</i>	<ol style="list-style-type: none"> 1. What proportion of eligible participants agreed to participate? 2. How many pregnant women enrolled? 3. What was the attrition rate of participants who enrolled? 4. What were the exclusion/inclusion criteria? 5. Were 'recent quitters' included?
<i>Methodological quality measures</i>	<ol style="list-style-type: none"> 1. Blinding. Non self-report measures were assessed for blinding of the data collectors, to determine whether these individuals were likely to be influenced by the intervention status of patients. <ol style="list-style-type: none"> a. Blinded – if the authors explicitly stated that data collectors were blinded to the experimental involvement of the participants. b. Not blinded – data collectors were likely to be aware of the experimental involvement. c. Unclear – insufficient information was provided to make an assessment. d. Not applicable – data was self-reported. 2. Was there protection against contamination? This item refers to the likelihood that an unintended intervention effected results (e.g. concurrent government endorsed improvements), or that the control group received some of the intervention components or associated education. This may apply to studies with or without comparison groups. 3. Was a measure included to assess the level of provider adherence to the intervention protocol? If so, what level of adherence was reported (Good, moderate, poor, not clear)

Table 4.2 continued

<p>Methodological quality measures continued</p>	<p>4. Were the participants likely to be representative of the target population?</p> <ul style="list-style-type: none"> a. Likely – participants were randomly selected from the total target population, measures were obtained from all of the targeted population or the authors demonstrated that the demographic distribution of participants was similar to that of the target population. b. Not Likely – participants were a subsection of the target population, representatives volunteered, or control groups differed on confounding variables. c. Unclear – Insufficient information was provided to enable an assessment to be made. <p>5. Adequacy of description.</p> <p>Interventions were assessed according to their ability to be replicated.¹⁸ Based on the CDC guidelines, in order to have 'sufficient detail' to be replicated, authors were required to describe each of the following:</p> <ul style="list-style-type: none"> a. The setting – where the intervention was implemented, b. The agents or deliverers, c. The desired recipients (those towards whom the intervention was aimed) <p>6. Were clear definitions given for smokers/non-smokers/recent quitters?</p> <ul style="list-style-type: none"> a. Biochemical cut-point b. Self-report definitions <p>7. Did the intervention development include staff training?</p> <p>8. Were drop-outs treated as continuing smokers?</p> <p>9. Did the analysis control for differential intervention exposure.</p> <p>10. Was there a development phase for the intervention materials and methods?</p> <p style="padding-left: 40px;">If so, were the staff members involved in the intervention also involved in the development phase?</p> <p>11. Was there a process evaluation identifying the extent of implementation in terms of adherence to intervention protocol, its reach and the satisfaction of clients, consumers, and staff?</p> <p>12. Was there a relapse prevention component for those who stopped smoking before the first antenatal visit?</p>
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Statistical analysis

At the univariate level, relationships between the features and the relative risk of continued smoking reported in each of the studies, were assessed using Kruskal-Wallis analysis for comparison with categorical variables (including but not limited to; the use of motivational interviewing, stages of change, setting a quit date or a formal agreement, measurement of adherence, recruitment by GPs, intensity of the intervention, and the possible outcome measures used), and Spearman's coefficient of correlation for comparison with continuous variables (including the number of contacts with participants, the amount of time dedicated to intervention delivery, the number of written materials provided, the timing of follow-up, the number of participants).

Meta-analysis and meta-regression

A meta-analysis procedure (using the metan command in STATA 10)¹⁹ was carried out using random effects to obtain pooled estimates from the number of individuals who did/did not quit in each group. The meta-analysis procedure was also used to generate an estimate of the heterogeneity between studies. To assess sources of heterogeneity and identify possible predictors of intervention success, a meta-regression was used, analysing categories of criteria for their association with the treatment effect estimate (log relative risk) and its standard error. Assessment criteria which had greater than or equal to 10% variance were grouped into categories of intervention strategies, approach and logistics of intervention delivery, and research quality markers. These categories were assessed for their relationship to the relative risk of continued smoking. All statistical analyses were carried out using STATA 10.

Results

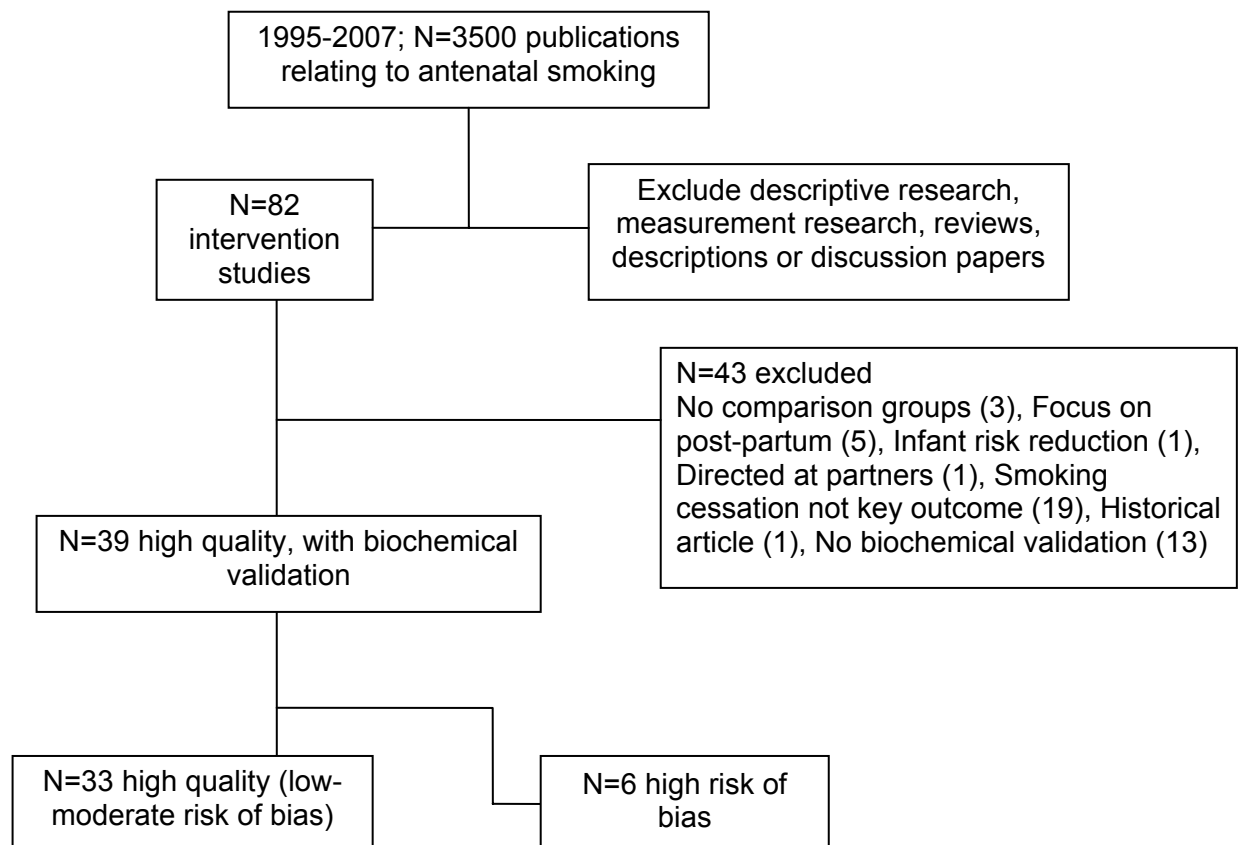
Broad literature searches indicated that approximately 3500 articles relating to antenatal smoking were published between 1995 and 2007. A total of 82 intervention articles aiming to increase antenatal smoking cessation rates were identified from this literature. Twenty-nine articles were excluded based on their study design (lack of control or comparison groups (n=3), focus on post-partum smoking cessation (n=5), focus on risk reduction for infants (n=1), direction at cessation for smoking partners (n=1), or lack of focus on smoking cessation as a key outcome (n=19)). One historical article, reporting on an intervention conducted in 1972 was also excluded, as our objective was to examine recent intervention efforts. A further 13 studies were excluded, as they did not include biochemical validation of self-reported smoking status. This resulted in 39 relevant articles.

To facilitate comparison of the approaches used and results obtained between studies, articles of relatively equivalent, reasonable methodological quality were sought. Studies were categorised according to their level of bias, those which could be classed as having a low or moderate risk of bias based on the criteria used by Lumley et al., detailed in Table 4.1 were regarded as high quality and were included in comparative analyses. This approach restricted the final sample to 33 studies.

Five studies which are included in the present review were not included by Lumley et al., due to their use of research designs other than randomised controlled trials or failure to control for clustered data. On the other hand, five studies which were included in the Lumley et al., review were excluded here, due the lack of biochemical validation of results, and two due to high risk of bias and consequent categorisation as low quality. Eight of the papers included in the final sample were published in the time since the earlier review. Figure 4.1 illustrates the volume of publications meeting

each component of the initial criteria. The final group of studies which were included in the analysis are listed in Appendix 4.1.

Figure 4.1: Number of papers regarding smoking cessation during pregnancy published since 1995 which met levels of methodological criteria



Heterogeneity

The meta-analysis found significant heterogeneity between the studies. Random effects estimation reported heterogeneity as a Chi-square of 111.12 on 32 degrees of freedom ($p < 0.001$). The level of heterogeneity can be observed in the Forrest plot in Figure 4.2.

Do the intervention strategies differentiate effective studies from ineffective ones?

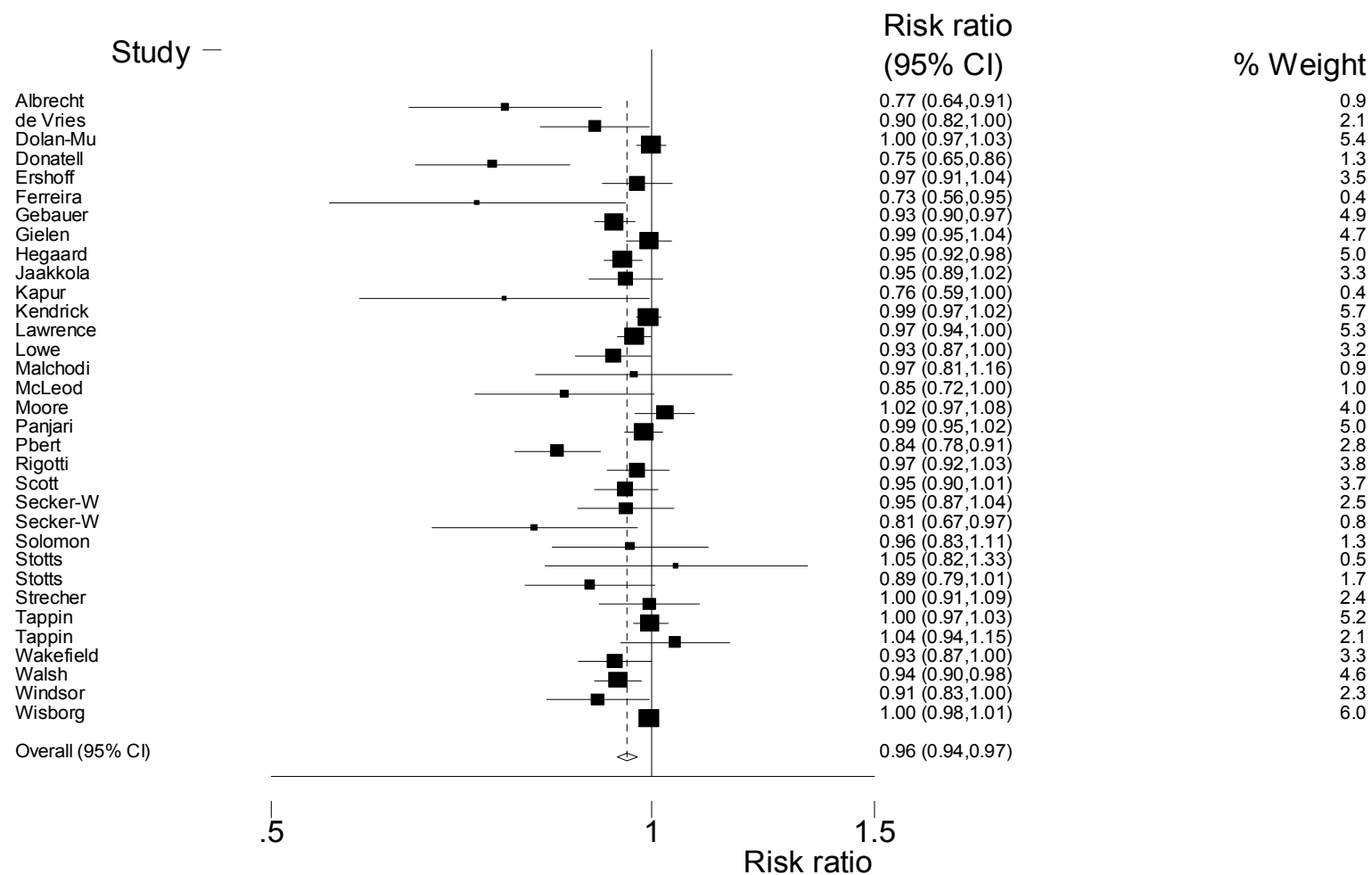
Intervention components

The examination of the intervention strategies used did not give a clear indication of the strategies which could be associated with success. The use of personalised follow-up was the only intervention strategy found to be significantly associated with the relative risk of continued smoking at the univariate level ($\chi^2(1)=6.091$, $p=0.14$). The meta-regression of intervention strategies (Table 4.3) included the use of motivational interviewing, personalised follow-up, negotiation of a quit date, delivery of clear advice to quit, delivery of information on the harms of smoking during pregnancy, inclusion of social support, use of the stages of change approach, use of a self-help manual, supplementation of advice at subsequent visits, offer of incentives for quitting and the use of nicotine replacement therapy. The use of group counselling, was not included due to a lack of variance with very few studies using this approach. No variables were found to be statistically significantly associated with the relative risk of continued smoking in the meta-regression (Table 4.3). Due to correlations between 'quit date' and 'offer of incentives' the meta-regression was repeated with these variables removed in turn. The only variable which became significant in these analyses was the use of personalised follow-up ($z=-2.53$, $p=0.011$; not shown).[†]

With limited significant relationships between intervention strategies and the measure of effect of the interventions, one may question whether it is in fact the intervention used which dictates 'success'. Motivational interviewing or other cognitive behavioural strategies were used in 46% of studies, and 46% also based interventions on the stages of change model.

[†] Z-statistic relates to the Fisher transformation derived from meta-regression.

Figure 4.2: Forrest plot of studies included in the meta-analysis



While these approaches are highly popular, no relationship was found between their use and the relative risk of continued smoking. The relatively small numbers, and lack of significant association between these features, and the effectiveness of studies, limits the capacity to link the approaches with the success of an intervention. Lumley et al., reported that the pooled results of the studies which used the stages of change theory and were included in their review indicated that the approach was not effective.

Table 4.3: Meta-regression analysis; intervention strategies used

Variable	Studies using technique N (%)	Z statistics	p-value
Motivational interviewing used	15 (46)	0.85	0.396
Personalised follow-up/counseling	14 (42)	-1.80	0.071
Social support included	11 (33)	0.17	0.864
Intervention based on stages of change	15 (46)	-1.02	0.307
Quit date set	6 (18)	1.75	0.081
Clear advice to quit	22 (67)	0.76	0.445
Information given regarding the harms of smoking during pregnancy	25 (76)	0.30	0.764
Supplementation of advice with reinforcement at subsequent visits	17 (52)	-0.68	0.498
Use of NRT	16 (49)	0.37	0.712
Offer of incentives	4 (12)	1.08	0.278
Use of self-help manual	16 (49)	-0.16	0.871

Approach and logistics of intervention delivery

The intervention was delivered by usual care providers in 17 (52%) of the studies, but recruitment was performed by study specific staff in 18 (60%). An intensity of three to four based on the system used by Lumley et al., was most common (27 studies,

84%). None of these logistical features reached significance in the association with success in terms of the relative risk of continued smoking in univariate analysis or in meta-regression (Table 4.4).

Table 4.4: Meta-regression analysis; logistical features of the intervention

Variable	Studies using technique; Number N (%)	Z statistic	p-value
Usual care providers deliver intervention	17 (52)	-.060	0.546
Recruitment performed by study staff/researchers (not usual care providers)*	18 (60)	-0.49	0.622
Average number of contacts with clients	4.7, range 1-18 Std dev 4.5	0.58	0.564
Intensity 0-2	5 (16)	-0.92	0.355
Intensity 3-4 (based on Lumley's system)	27 (84)	-0.82	0.414
Average number of written materials provided *	2.9, range 0-9, std dev 2.6		
Average time spent on intervention per client (minutes) *	104 mins, range 0-935, std dev 198		
Advice delivered by GP *	7 (22)		

Percentage based on valid cases in which assessment of each item was possible.

** Insufficient variance for inclusion in the meta-regression.*

Does the difference lie in the design or methodological quality of the research?

Rather than the intervention strategies, it is possible that the research methods and quality of studies are greater determinants of effectiveness. Study design features include the outcome measures assessed in each study, the number of participants in each study, as well as recruitment and attrition rates, and measures of research quality. The details of analyses used for biochemical validation were also assessed.

Outcome measures assessed

While comparison is made here with the primary outcome of smoking cessation in late pregnancy only, it is possible that the measurement of other outcomes acts as an indicator of the nature and quality of study design. At the univariate level, those studies which included a measure of smoking cessation in the puerperium ($\chi^2(1)=6.091$, $p=0.014$), birthweight ($\chi^2(1)=6.721$, $p=0.01$), and gestation at delivery ($\chi^2(1)=6.592$, $p=0.003$) were likely to report relative risks indicative of success. In meta-regression analyses, measurement of a reduction in smoking ($z=2.47$, $p=0.013$) was slightly related to the relative risk reported (Table 4.5).

Average participant numbers, attrition rates, and smoking cessation levels achieved in late pregnancy or very early after delivery are summarised in Table 4.6. Where differential recruitment or attrition rates were presented for different groups or outcome measurement points, an average was used for inclusion in the table. As variance was low for these variables, and no significant associations were detected in univariate analysis, meta-regression was not performed on this category.

Table 4.5: Meta-regression analysis; outcome measures and timing

Variable	Studies measuring outcome; Number N (%)	Z statistic (df=1)	p-value
Smoking reduction from first antenatal visit	15 (45)	2.47	0.013
Smoking cessation in the puerperium	18 (55)	-1.35	0.177
Birth weight	10 (30)	-1.54	0.125
Anxiety/depression, maternal health status in late pregnancy or after birth	2 (6)	0.90	0.371
Timing of late pregnancy outcome measure		0.00	0.999
Gestation at birth*	4 (12)		
Perinatal mortality*	3 (9)		
Breastfeeding*	2 (6)		
Participants views of intervention*	13 (39)		
Knowledge and attitudes of health professionals*	1 (3)		
Maximum gestation at recruitment (average, standard deviation)*	19, 6.7		
Gestation at late pregnancy outcome measurement (average, standard deviation)*	31, 6.9		

* Insufficient variance for inclusion in the meta-regression.
Intervention context and effectiveness

Table 4.6: Participant numbers, attrition and smoking cessation levels achieved, multiple linear regression

	Mean, standard deviation
Recruitment rate	74, 17
Total number of participants included	520, 961
Attrition rate (%)	21, 14
Statistically significant results (N, %)	13 (39)

Assessing methodological features of interventions

The methodological assessment criteria presented in Table 4.2 were used to examine the methodological quality of the studies. Even within the relatively small set of publications which met the methodological criteria, several key areas of weakness were observed. Of the 33 included studies, 27 (82%) were randomised controlled trials, two (6%) were prospective cohort studies, and four (12%) were retrospective cohort studies. While the majority of studies used individual randomisation (n=26, 79%), a total of six (18%) used cluster randomisation techniques, allocating midwives, clinics, or health service districts to intervention or control groups. This technique has the merit of reduced contamination in comparison to studies in which providers are expected to differentially treat women in intervention or control groups. Four of the six cluster randomised trials achieved statistically significant improvements in cessation rates.

Only thirteen studies (39%) reported taking measures to protect against contamination. Of these studies, two used geographically distinct samples which gave some degree of protection, and two others measured contamination but did not protect against it. This was not applicable in the four studies using historical comparison groups. Of those studies in which contamination was assessed, several indicated that the control group had received some intervention components.^{20 21}

Some form of process measure was performed in 24 studies (73%). Adherence to protocol by intervention agents was measured in 19 studies (58%), with 11 of these indicating that a good or reasonable level of adherence was achieved (58%). Importantly, several studies cited poor implementation as a potential explanation for

the small differences between intervention and control cessation rates,^{22 23} or noted that very low levels of adherence to intervention protocol had been achieved.²⁴

Twenty-four studies (73%) provided an adequate description of the intervention to enable replication. This required a description of the setting, the individuals responsible for intervention delivery, and the desired recipients.²⁵ While 32 of the 33 studies adequately defined their biochemical measures and cut-points, only 22 provided a sufficient description of the definitions of smoking and non-smoking used in self-report analyses. A total of 23 studies used intent-to-treat analysis, counting drop-outs as smokers. Table 4.7 summarises the methodological characteristics of the articles.

Table 4.7: Meta-regression analysis; methodological features

Criteria	Studies using technique N (%)	Z statistic	p-value
Blinding (among studies in which this is applicable)	5 (20)	-1.65	0.212
Protection against contamination	13 (39)	-0.94	0.348
Measure of adherence to protocol	19 (68)	-0.10	0.916
Representative sample	25 (76)	-1.73	0.083
Adequate description of intervention	24 (73)	-1.41	0.158
Definition of measures for self-report	22 (67)	1.25	0.211
Staff training involved	23 (70)	-0.33	0.738
Development phase	9 (27)	1.87	0.062
Process evaluation	24 (73)	0.22	0.824
High level of adherence to protocol reported (good-moderate adherence)*	11 (52)		
Control for differential intervention exposure*	7 (21)		

* *Insufficient variance for inclusion in the meta-regression.*

Chi-square analysis did not find any relationship between these methodological characteristics and the relative risk reported in each study. Meta-regression also failed to uncover any significant associations.

Biochemical validation used and accuracy of self-report

The methods used for biochemical validation may impact upon the accuracy of results. With a wide range of analysis techniques, biological samples, and cut-points used to distinguish smokers from non-smokers, it is possible that varying accuracy of these measures impacts upon the level of validated smoking cessation reported.

Twenty-nine of the studies used cotinine analysis in either saliva (n=12), serum (n=2), or urine (n=15) for biochemical validation of self-reported smoking cessation. The cut-points used for the different sample types are summarised in Table 4.8.

Table 4.8: Cut-points used to distinguish smokers from non-smokers in cotinine analysis

Sample	Mean (ng/mL)	Median (ng/mL)	Standard Deviation
Saliva	22.85	23.0	7.4
Serum	14.5	15	0.75
Urine	132.5	82.5	116.4

Of the 16 studies which named or described the analysis methods used, four used radioimmunoassay, seven used some chromatographic method, and five used other immunoassay methods. Five studies (two of which also assessed cotinine) used expired air carbon monoxide analysis, with a cut-point of 6-10ppm (mean 8, SD 1.4).

Two studies (one of which also assessed cotinine) measured thiocyanate levels. The wide variation in these methods and the cut-points presented in Table 4.8 raises the question of the accuracy of biochemical validation itself. No associations were found between the relative risk of continued smoking and the cotinine cut-point used, type of analysis, or biological sample used in univariate analysis. Variance was not sufficient to warrant meta-regression on this set of variables.

Discussion

Exploring the literature

While over 3000 articles were published on the topic of antenatal smoking cessation from 1995 to 2007, only 81 of these were classed as intervention studies. This is concerning given the importance of the antenatal smoking issue, and the need for effective interventions to facilitate reduction in smoking rates and improvements in birth outcomes and infant health.

It is interesting to note that despite the high levels of antenatal smoking and smoking-related poor birth outcomes and infant health issues amongst Indigenous populations, very few studies addressed antenatal smoking within these groups. Of the 53 initially assessed studies, only two were specifically targeted towards Indigenous groups.^{26 27} Twenty-seven studies included a proportion of Indigenous or ethnic minority women but did not specifically target these groups, and 24 made no mention of ethnicity. Only one of the studies, which included a majority of African-American women was of sufficient quality for inclusion in the final analysis.²⁷ This study did not achieve significant improvements in cessation rates. Thirteen studies specifically involved low income or under-insured women, and 25 others were

conducted in public healthcare settings. Only six studies were conducted in private clinics or other settings outside of routine antenatal care.

What features of study design or methodological quality are associated with effectiveness of interventions?

The extensive exploration of strategic and quality markers of interventions aiming to increase antenatal smoking cessation rates failed to identify a clear model of factors which dictate success in this endeavour. None of the approaches used could be definitively related to the success of an intervention. The results of meta-regression suggest that personalised follow-up or counseling after initial intervention delivery may potentially be associated with the intervention effect, but no other approaches or logistical considerations were significantly related. While significant associations were found with relative risk and the measurement of reduction in smoking, the importance of this relationship is questionable, given that the relative risk does not relate directly to these outcomes. The results of meta-regression procedures do not give a clear indication of the most important indicators of the success of interventions in decreasing smoking rates in late pregnancy.

Quality of the studies

Key areas of weakness in the studies overall, were the failure to blind data collectors or assessors, to the intervention status of participants, the failure to protect against contamination, and the failure to control for differential intervention exposure in analyses. Sources of bias and error in sample selection, contamination, and failure to measure adherence or account for differential intervention implementation have the capacity to alter the apparent effectiveness of an intervention, either underestimating or overestimating its effects.

Difference in quit rates between intervention and control groups may be influenced as much by study design, as by the effectiveness of the intervention itself. Failure to achieve statistically significant improvements may result from higher than expected quit rates in control groups, poor implementation of an intervention, or other methodological limitations.

The rate of smoking cessation achieved did not differ between studies which reported statistically significant improvements in quit rates based on an alpha level of 0.05, and those which did not. This suggests that the effectiveness of studies, when measured by statistical significance, relates more to the difference between groups and perhaps the resulting 'number needed to treat', than to the ability for the intervention to increase cessation rates.

The number needed to treat (NNT); in this case referring to the number of women who need to receive an intervention to lead to successful smoking cessation in one individual; is a useful statistical measure, and is often used to describe in real terms, the results of a study. NNT is the inverse of the absolute risk reduction, or in this case, the reduction in smoking rate between the intervention and control groups in late pregnancy. As such, NNT is strongly associated with the capacity of a study to reduce smoking rates differentially between the groups. When calculated based on the absolute risk reduction between intervention and control groups, the average NNT in the studies which achieved statistically significant results was 22, and in those reporting non-significant results, was 178. The average for all studies included in the review was 110. When calculated based on the actual cessation rate achieved in the intervention group, the average was seven in significant studies, 13 in non-significant studies, and 11 overall.

This is an important point, considering the emphasis placed upon the significance of results with respect to the difference between groups. This issue is associated with the complexity of confounding factors and sources of bias and contamination which have the capacity to influence the results of a study. It follows to raise the question of the statistical significance of results compared to their clinical significance, and whether studies which failed to reach statistical significance may in fact have achieved clinically important reductions in smoking cessation.

Only 68% of studies (n=19) measured adherence to the intervention protocol by providers or recipients, and of these 52% (n=11) achieved adequate levels of adherence. The lack of assessment of adherence to protocol, and actual uptake of the interventions raises questions as to the generalisability of results. Interventions with state-of-the-art, potentially successful designs may fail to generate positive results if providers do not adhere to intervention delivery protocol, or participants do not use self-help materials, or cannot be contacted for follow-up. Conversely, studies may claim that increased cessation rates result from an intervention which has not in fact been implemented thoroughly or does not differ substantially from usual care.

A measure of, or control for the quality and intensity of usual care is necessary to enable accurate assessment of the impact of an intervention. Such a measure is difficult, and is often not performed in situations in which the intervention is provided separately, or as an adjunct to routine antenatal care.^{23 28-33} Solomon et al., (2000) reported that the usual care provided by physicians and midwives in their study was likely to be more intensive than 'best practice' interventions provided in routine care.³⁴ This group suggests that this may be a flaw in their research which impeded their ability to measure the true impact of their intervention and achieve statistically significant results.

The participants recruited to a study, and the methods by which they are recruited can influence the possibility of success, and may limit the generalisability of results. Twenty-five studies appeared to involve a representative sample of participants, or used a design which should have recruited a representative sample. However, various barriers to recruitment were cited which may have introduced error in some studies. Slow recruitment rates led to altered proposals and power in many studies,²¹^{28 34 35} with some adding extra sites²¹ or offering a monetary incentive to providers for recruitment.²⁴

Interestingly, recruitment problems appeared to occur more often in studies in which usual care providers were responsible for recruitment. Walsh et al. (1997), suggested that their recruitment problems were likely to be the result of this pressure on usual care providers, and many studies which included feedback from providers reported that midwives and nurses responsible for recruitment cited time constraints^{20 36 37} or difficulty in approaching the smoking issue with women³⁸ as barriers to recruitment. Three studies assessing interventions delivered by usual care midwives, and relying on these midwives to recruit study participants, all reported that the midwives failed to invite all eligible women into the study, with invitation rates ranging from 65% to 88%.^{20 36 38}

Bias and error are also possible in studies in which recruitment rates were reported to be higher in intervention arms compared to control arms,³⁵ or where lower than expected eligibility rates suggest possible error due to self-report of eligibility criteria.³⁰ Panjari et al., (1999) suggest that the very low recruitment rate achieved in their study may indicate that women who agreed to participate had a greater desire to quit than might be expected in a random population sample.³⁹ Similarly, studies such as those assessing the efficacy of nicotine replacement therapy,³³ using volunteers as participants,³² or including a criteria for participants to be 'willing to

consider altering their smoking during pregnancy³⁴ are likely to have recruited a group of participants which does not represent the general population of pregnant smokers.

A total of forty articles met minimum methodological criteria of study design and presentation of data on smoking rates, as well as including a measure of biochemical validation. The need for biochemical validation of self-reported smoking status has been demonstrated for smoking cessation research in general, and in particular, for studies with pregnant women. The stigma associated with antenatal smoking is thought to be associated with high levels of mis-report of smoking status by women during pregnancy.^{40 41} Of 15 studies published since 1990, which assessed the validity of self-reported smoking status among pregnant women, ten presented results which were clearly in support of the need for biochemical validation,^{24 40 42-49} three did not present an argument either way,⁵⁰⁻⁵² one argued that cotinine is not appropriate for qualifying of the level of smoking during pregnancy,⁵³ and only one argued against the need for biochemical validation overall.⁵⁴ In these studies, as well as an additional 12 which presented data on the accuracy of self-report among pregnant women, the level of discrepancy between self-report and biochemical measures ranged from 0-52%, with an average mis-classification rate of 19%.

While the restriction of this review to those articles which included biochemical validation may have eliminated some potentially important studies, this is a critical factor in assessing the credibility of these research studies. Evidence for the effectiveness of antenatal smoking cessation intervention strategies must be derived from methodologically vigorous evaluation. It would be unethical to implement intervention strategies which have not been proven to be efficacious and cost-effective in scientifically sound evaluations. Lumley et al., also noted the high level of misclassification of smoking status based on self-report, and made a

recommendation that all future studies should include the biochemical validation of smoking status. This group state that only biochemically validated smoking cessation can be regarded as a reliable outcome measure.⁴

Limitations of the review

The results of meta-regression procedures should be interpreted with caution, due to inevitable limitations and low power in such analyses. With interventions conducted in similar settings and with potentially similar groups of participants, the dependent variables in the analysis are likely to be highly collinear. Ecological bias is also likely to exist in the analysis, as the assessment is conducted at the study level and fails to account for patient level variation. The extensive exploration of factors at the univariate level prior to regression procedures did not identify any factors which were likely to be clear markers of success. The agreement between univariate and multivariate analyses increases confidence in the interpretation of meta-regression outcomes.

This review was limited to a subset of studies examining smoking cessation as a key outcome. This approach was used to enable comparison between studies, but led to the exclusion of a small group of methodologically rigorous studies. While the strategies used in these studies and the methodological techniques adopted may have contributed useful information to the review, of the excluded studies, an equal number achieved and failed to achieve statistically significant improvements in smoking cessation rates. This increases confidence that the approach did not bias the outcomes of the review, and suggests that the overall trends observed can be broadly generalised within the field. While some studies examined relapse prevention, and outcomes such as smoking reduction, progression through stages of

change, and infant birth weight as secondary outcomes, these results were not scrutinised.

Implications of the review

The lack of obvious quality or intervention approach markers to predict the success of a study in improving cessation rates raises a question as to the clinical significance of treatment effects as opposed to their statistical significance. While the majority of studies did not achieve statistical significance, possibly due to the influence of contamination or bias, the impact of these interventions may in fact be substantial in the clinical setting.

Further to the issue of clinical significance is the applicability of interventions to various settings and target groups. Attempts to transfer intervention designs and materials from one setting to another may be ineffective if the settings and target groups differ in key cultural and social characteristics. An example of this is the Windsor self-help manual, which was originally developed and shown to be effective with low income, predominantly African-American women in Birmingham, US.^{55 56} The manual was less effective in Baltimore with a majority of African-American women, when delivered by minimally trained counsellors²⁷ and was received poorly by Australian women when used in a large public hospital in Brisbane.⁵⁷ During focus groups conducted to identify the reasons for women not using the booklet, discussions highlighted the differences in activities and approaches which were acceptable to US groups compared to Australian ones. Recent interventions have begun to recognise the associations between social inequalities and antenatal smoking, and the need for complex interventions which account for social and cultural circumstances.⁵⁸

The present review illustrates the difficulty in identifying with confidence, what the components are that should be included in interventions for assisting pregnant women to quit smoking. While a large body of literature exists on this important topic, conflicting results and the fact that only a small proportion of studies meet minimal methodological criteria, render it difficult to draw clear inferences from the findings.

Future studies should attempt to measure and control for the level of implementation of interventions and adherence to protocol, and should take measures to prevent contamination and eliminate bias. High quality, thorough, and well-designed research studies have the potential to generate quality evidence for interventions which may be generalised and transferred to other groups, in an effort to promote substantial improvement in antenatal smoking rates.

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CHAPTER 5

Knowledge and attitudes regarding smoking during pregnancy: A descriptive study of Aboriginal and Torres Strait Islander women to guide the design of an effective intervention

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Chapter 5

Knowledge and attitudes regarding smoking during pregnancy:

A descriptive study of Aboriginal and Torres Strait Islander women to guide the design of an effective intervention

Introduction

Indigenous philosophy and cultural values create a need for anti-smoking approaches to be tailored to this population.¹ Australia's Aboriginal and Torres Strait Islander population is set apart from the mainstream population by markers of poor health and low socio-economic status.² Unique barriers also impact upon smoking cessation in this population, with the high overall rate of smoking in the community normalising this behaviour for individuals.^{3 4} Low literacy levels, high rates of abuse of other substances and mental illness, all of which affect this population, are also associated with low rates of smoking cessation.⁵ Consequently, it seems logical that health services and health promotion programs should be designed specifically to meet the unique needs of this population group. In her 2004 evaluation of the applicability of evidence derived from systematic reviews on tobacco cessation interventions to an Australian Aboriginal population, Ivers suggested that an approach based on evidence derived from mainstream trials may not be the primary consideration in planning interventions for this group.⁶

In designing intervention programs to help Aboriginal and Torres Strait Islander women quit smoking during pregnancy, it is important to first identify the factors which shape smoking patterns and behaviours among this population.

While the influences upon, and predictors for smoking behaviour during pregnancy, have been extensively studied in other groups,⁷⁻¹⁰ limited studies have examined the knowledge and attitudes which support smoking among Aboriginal and Torres Strait Islander women. Identification of such knowledge and attitudes, and the self-exemptions associated with higher levels of smoking among this population group may provide targets for intervention in smoking behaviour. Interventions that are efficacious in non-Indigenous populations may or may not be appropriate for Aboriginal and Torres Strait Islander women who have different attitudes to, and motivations for smoking.

The Precede Proceed Model for health promotion, proposed by Green and Krueter,¹¹ has been used extensively in health research,^{12 13} policy,^{14 15} and analysis,^{16 17} and is a useful basis for the construction of steps in a process towards health promotion. Here, exploration of the predictors for, and knowledge and attitudes regarding, antenatal smoking is undertaken in order to identify the most appropriate targets and approaches for intervention with Aboriginal and Torres Strait islander women. Possible influences on smoking behaviour are identified, assessed, and analysed through an application of the Precede Proceed Model. In accordance with the Precede process, this study has identified smoking cessation among antenatal Aboriginal and Torres Strait Islander women as the desired outcome, and seeks to diagnose the factors which are likely to be important to this outcome. Failure to identify such factors before designing an intervention can lead to "*misdirected and ineffective intervention efforts*".(p26)¹¹

Having identified Aboriginal and Torres Strait Islander women as a vulnerable group, explored the societal and environmental influences upon this group, and recognised antenatal smoking as a potential target for health improvement, the initial phases of the Precede Proceed Model have been addressed (see Chapters 1 and 2). As was illustrated using the cluster analysis in Chapter 2, a plethora of factors may relate to smoking behaviour. In order to identify and focus on those factors which could be

employed in interventions to promote smoking cessation, the next phase of the Model is to group the factors as predisposing, enabling, or reinforcing factors based on the theoretical framework constructed by Green and Krueter.¹¹

Predisposing factors

Predisposing factors are those which hinder or promote an individual's motivation to change a certain behaviour. This predominantly refers to cognitive and personality factors associated with beliefs, values, knowledge, and self-confidence. On an individual level, the knowledge and attitudes regarding smoking during pregnancy may influence women's behaviour and willingness to change. A number of sources indicate that pregnant Aboriginal and Torres Strait Islander women may be highly motivated to quit, and often report making multiple quit attempts.¹⁸⁻²¹ Unfortunately these women often fail in their attempts, or relapse to smoking after the birth of their baby. The National Aboriginal Community Controlled Health Organisation (NACCHO) also report that many individuals are motivated to quit, but often lack the necessary confidence and knowledge regarding strategies for quitting.²¹

Perhaps unexpectedly, given the persistent high rates of smoking, knowledge in Aboriginal and Torres Strait Islander community members across Australia is generally good in relation to the health effects of smoking.^{19 21} This knowledge does not consistently translate into quitting however, with many individuals reporting that the diagnosis of serious health problems would not prompt them to quit.²¹ These attitudes appear discrepant with the number of people who report that they are trying to quit or have tried to quit,²¹ highlighting the complexity of the issue of smoking cessation in this population. It is possible that self-report of smoking habits and quit attempts is influenced by the social desirability of quitting smoking, leading to an over-estimation of these figures. Irrespective of the accuracy of these figures, it is apparent that

knowledge regarding the risks and adverse effects of smoking is necessary, but not sufficient to lead to successful smoking cessation.

The only published study examining the knowledge of Aboriginal and Torres Strait Islander women regarding antenatal smoking or the associated risks, highlighted that the participating Aboriginal women had a lower level of knowledge about SIDS and safe sleeping positions than other women. Overall, very few women recognised smoking in pregnancy, or around infants, as risk factors for SIDS.²² These results are supported by the NACCHO report, and the findings reported by Ivers in her review of tobacco smoking. While general knowledge about the hazards of smoking is good, there is an ignorance or misconception among this population regarding specific health effects such as diabetes.^{19 21}

Enabling factors

Enabling factors are environmental or society-based factors which function as barriers to, or facilitators of, behaviour change. This includes living conditions which may act as barriers to taking action in behaviour change such as a lack of transport to access health care or inadequate income to access foods necessary for nutritional improvement. Enabling factors encompass the resources available to promote behaviour change, and the skills necessary for individuals to take action. In mainstream populations, several demographic factors have been reported to act as independent predictors of continued smoking during pregnancy. Younger mothers, those with less education, those who are unmarried and those with lower income are more likely to continue smoking.⁷ These factors are regarded as enabling factors as they are associated with the skill level of women and the environment in which they live, which may influence or enable behaviours. It is unclear whether these factors also predict antenatal smoking among the Aboriginal and Torres Strait Islander population. While

these factors are not modifiable by smoking-related interventions, they are useful in planning interventions and assessing the differential importance of certain factors among different groups. These factors may help to identify the intervention strategies which are most appropriate for certain groups.

There have been suggestions that availability of tobacco, and tobacco-sharing practices may have greater influence upon daily smoking levels than nicotine dependence or addiction.¹⁹ The culture and societal influences within Aboriginal and Torres Strait Islander groups act as enabling factors by providing or restricting access to tobacco in various circumstances. Unpublished data collected at Townsville Aboriginal and Islander Health Service (TAIHS) has indicated that the Fagerstrom Nicotine dependence Questionnaire,²³ which has been used widely to predict dependence and cessation in mainstream populations may not be an appropriate assessment for this population. It is suggested that the number of cigarettes smoked per day, while variable, may be a more accurate measure of smoking and addiction in this group.²⁰ This issue is likely to be relevant, not only to the Fagerstrom scale, but to many other nicotine dependence scales. The questionable relevance of nicotine dependence reinforces the need for these enabling factors to be considered in studies of smoking among these groups; patterns of smoking may differ markedly as a result of the cultural practices and tobacco resources available.

Reinforcing factors

Reinforcing factors are the elements of a woman's social environment, and the feedback from others within this environment which provide positive or negative reinforcement for a behaviour. Social or physical benefits or rewards provide positive reinforcement for a behaviour, while negative reinforcement occurs when a behaviour is strengthened by the consequence of stopping or avoiding a negative condition such

as stress or pain. The reactions and attitudes of peers or medical practitioners may encourage or discourage continued smoking or efforts towards quitting. With high overall rates of smoking in the Aboriginal and Torres Strait Islander community and high rates of cohabitation, individuals are often in the company of other smokers, and are exposed to high levels of passive smoking.²⁴ Such an environment and the feedback from peers within this environment is likely to impact upon a woman's resolve to change her smoking behaviour. Peer influences have been reported as significant predictors of smoking behaviour in mainstream populations.^{25 26}

The level of stress experienced by individuals within this population, and apparent relief associated with cigarette smoking may provide negative reinforcement for continued smoking. The actual mechanism behind this sensation is the anxiolytic effect of nicotine, meaning that an initial increase in anxiety occurs with abstinence.²⁷ Anxiety is in fact a symptom of withdrawal from nicotine,²⁷ with the relief gained from smoking giving many smokers the sensation that cigarettes relieve their stress, and leading to the claim that smokers 'need them to cope'.^{28 29} In a vulnerable population such as a group of pregnant Aboriginal and Torres Strait Islander women, financial pressures and those associated with overcrowded housing and responsibility for numerous children may lead to high rates of perceived stress which reinforce the desire for the 'stress-relieving' properties of cigarettes.

Exploring predictors, knowledge, and attitudes

After identifying the predisposing, enabling, and reinforcing factors for smoking cessation, the next step towards designing and developing effective interventions was to determine which of the factors were most likely to predict smoking behaviour, and act as targets in efforts to bring about change in this behaviour.

The three main aims of this study were to:

1. Determine the prevalence of smoking among a representative sample of pregnant Aboriginal and Torres Strait Islander women in Far North Queensland;
2. Identify the factors associated with antenatal smoking; and
3. Explore the characteristics of smoking behaviour among this population.

Ethical approval for this research was granted from the University of Newcastle Human Research Ethics Committee, and was endorsed by the Boards of Townsville Aboriginal and Islander Health Service and Wuchopperen Health Service. Refer to Appendix 5.1 for University Certificate of Approval, Appendix 5.2 for TAIHS endorsement letter and Appendix 5.3 for Wuchopperen endorsement letter.

Methods

Study Design

A cross-sectional study using data collected through interviewer-administered questionnaires was used to determine the prevalence of self-reported smoking, and to explore predictors and patterns of smoking in early pregnancy. The relationships between smoking behaviour and the prevalence of predisposing, enabling and reinforcing factors were examined, including women's knowledge about and attitudes towards, smoking and the risks involved.

Study Sample

Aboriginal and Torres Strait Islander women aged 16 years or over who attended Wuchopperen Health Service for antenatal care were eligible. Exclusion criteria were current treatment of chemical dependency other than tobacco or alcohol and florid mental illness. Recruitment was performed by a trained project officer, who provided a

detailed verbal and written explanation of the study, obtained written consent from those who were willing to participate, and interviewed women to complete a questionnaire relating to their lifestyle, smoking habits and history, knowledge, and attitudes regarding smoking during pregnancy (refer to Appendix 5.4 for participant information statement and consent form). Training for project officers was performed by the PhD candidate, with mock interviews to ensure that staff had a clear understanding of the questionnaire items and adequate interview skills. Project officers were skilled in healthcare roles and were experienced in patient interaction.

Questionnaire development and contents

Literature search

An extensive literature search was undertaken to identify factors likely to influence or predict the smoking behaviour of Aboriginal and Torres Strait Islander women. With very limited literature in this area relating specifically to Aboriginal and Torres Strait Islander populations³⁰ the questionnaire items were adapted from evidence derived from the mainstream population. The knowledge and attitude items were modeled on a similar set used by Walsh et al., with non-Indigenous women attending a public hospital antenatal clinic in New South Wales, Australia.^{7 31} The questionnaire items were designed to incorporate each of the categories of factors described in the Precede Proceed model, and to describe smoking habits and history.

Predisposing factors

Predisposing factors were addressed in 17 items relating to women's understanding of the potential effects of smoking during pregnancy, and their attitudes towards smoking during pregnancy. Women were presented with a list of adverse obstetric outcomes, an increased risk of which has been found to be associated with antenatal smoking. Women were asked to answer according to their belief that smoking during pregnancy may increase the risk of each of the outcomes.

Enabling factors

The questionnaire addressed 12 enabling factors with items regarding ethnicity, income, education level, stress, and obstetric history factors including gravidity and parity. Previous pregnancies and number of children are expected to impact upon a woman's attitude towards her pregnancy and health, as well as her confidence during the pregnancy. Women who have had successful pregnancies in the past, may be more relaxed and less inclined to alter their behaviours during their current pregnancy.^{25 32} These factors, as well as the financial and other pressures experienced by women, may influence their desire to quit smoking and their interest in their health. The level of daily 'hassles' and experience of a stressful event in the previous 12 months were also recorded to account for this possibility.

Reinforcing factors

The social environment in which women live was regarded as the most important reinforcing factor for continued smoking behaviour, or the ability to quit. Items relating to the number of other smokers with whom a woman lived, and the smoking status and ethnicity of her partner, were included in this category.

Smoking Patterns

Extending the exploration of potential predictors of smoking behaviour, the questionnaire collected information regarding smoking patterns and experience of ex-smokers. The number of cigarettes smoked per day, number of quit attempts made in the previous five years, longest smoke-free period and any change in smoking level during pregnancy were collected from all women who were self-reported daily or occasional smokers. In order to gauge the impact of pregnancy on the women, and the level of nicotine dependence, ex-smokers were asked when they quit smoking (to determine whether it was prior to, or associated with, the pregnancy), how many quit

attempts they made before successfully quitting, and the reason for which they quit smoking.

Negotiations and piloting

The questionnaire was examined for acceptability with a representative sample of antenatal Aboriginal and Torres Strait Islander women and staff members at two ACCHS sites in Far North Queensland (TAIHS and Wuchopperen) before commencement of the study. It was essential to clearly and concisely communicate the research concepts, reasons for the study, and the questions being asked of women. Initial discussions with staff regarding the language used and questions asked, led to minor changes to enhance cultural appropriateness and acceptability. The modified questionnaire was then tested for suitability with ten antenatal women (four smokers and six non-smokers). The questionnaire was designed for a reading age of grade five³³ to ensure that the majority of participants could read and understand the material easily without causing distress or discomfort which may be associated with the presentation of complicated material and the use of complex language. The interview-style delivery of the questionnaire also aided understanding and ensured that all women interpreted the questions correctly. A copy of the final 28-numbered item questionnaire is located in Appendix 5.5.

Statistical analysis

Review of continuous variables led to the decision to categorise variables for analyses. Continuous variables including age, years of school education, parity and gravidity were recoded as categorical variables. The number of smokers living with women was collected as a continuous variable before being recoded into categories of none, one to three, or more than four other smokers. The skewed distribution of continuous

variables and the fact that a linear relationship with the log odds was unlikely meant that more meaningful analysis and ease of interpretation could be achieved with categorical data. Categorisation enhanced the capacity to find a clearer relationship between variables in logistic regression. Use of this method led to decreased power to detect relationships between smoking cessation and the variables studied, but the benefit for analysis and capacity for the interpretation of results outweighs this negative ramification. The smoking status, gestation at recruitment, and date of birth, were recorded for all antenatal women. Women were presented with the following options and were asked to select the one which best described them; “I’m a smoker, I smoke daily”, “I’m a smoker, I smoke occasionally”, “I’m an ex-smoker, I never smoke now”, or “I’m a non-smoker, I have never smoked”. Categories were collapsed to classify women reporting daily or occasional smoking as smokers, and ex- or never-smokers as non-smokers.

The responses to knowledge items were explored as proportions of participants answering ‘yes’, ‘maybe’, ‘no’ or ‘don’t know’ for each item. The overall score of questions answered ‘yes’ or ‘maybe’ out of the total 12 items was calculated as the score of correct responses for each participant. The scores were also categorised into three groups; those answering 0-5 items correctly (low knowledge), those answering 6-9 items correctly (medium knowledge), and those answering 10-12 items correctly (good knowledge). Responses to attitudes items were examined according to the proportion of participants who agreed or disagreed with each statement. The four valid attitudes items were assessed to generate an overall indicator of women’s attitude. A woman was scored as having an accepting attitude towards smoking behaviours if she answered any of the items on the negative end of the scale, as un-accepting if she answered all of the questions on the positive end of the scale, and as neutral, or unknown, if she responded ‘don’t know’ to any of the items. The validity of responses to the item ‘it is highly unlikely that my baby will be unhealthy’ are questionable, as reports

from health workers conducting the interviews suggested that the wording of the item may have been confusing to themselves, as well as some participants. It is expected that the item was often misinterpreted. This item was therefore not included in the analysis.

Chi-square tests were used to compare the characteristics of participants and non-participants. The prevalence of smoking among the study sample was calculated based on the self-reported status as daily or occasional smokers and 95% confidence intervals obtained using the normal approximation to the binomial distribution (aim 1). In order to investigate the predisposing, enabling, and reinforcing factors which may be associated with smoking behaviour during pregnancy (aim 2), characteristics of smokers and non-smokers were compared using the Chi-square test for categorical variables (as all explanatory variables were categorical). Backwards stepwise logistic regression was used to determine which factors were associated with antenatal smoking when adjusting for confounders and other variables in the model. Variables which were associated with smoking behaviour, as indicated by a p-value of less than 0.25 in the initial univariate Chi-square tests (presented in Appendix 5.6) were initially entered into the regression equation and were removed in a stepwise fashion if they had a p-value of less than 0.1 on likelihood ratio tests. For aim 3, summary statistics such as mean or median, or frequency distributions as appropriate were used to describe the characteristics of self-reported smokers.

All statistical analyses were carried out in SPSS.³⁴

Sample size

Sample size was based on the sufficient numbers required for the continuing randomised controlled trial as well as this study. It was expected that approximately 300 women at any stage of a pregnancy would attend Wuchopperen over a 12-month

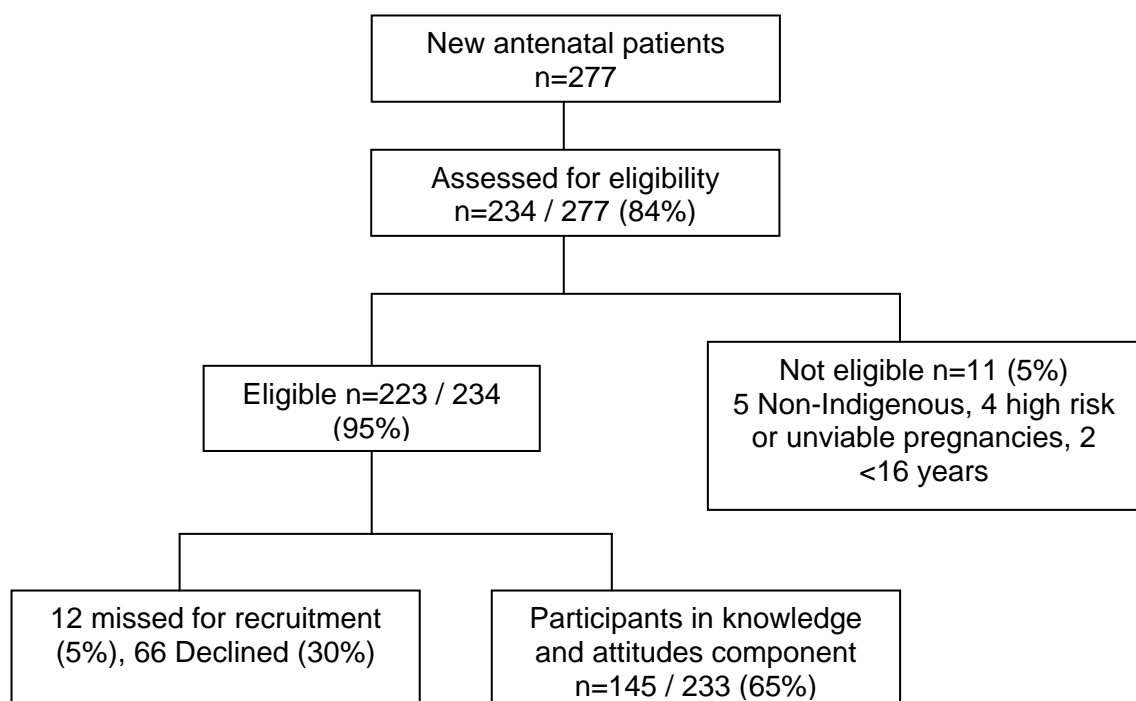
period. Therefore, with recruitment occurring over a 14-month period from November 2005 to December 2006, 350 pregnant women were expected to attend the clinic. Based on an eligibility rate for these women of 90%, and a consent rate of 60% it was expected that 190 women would take part in the study. A sample of 190 women allowed the estimation of the prevalence of smoking with 95% confidence intervals within $\pm 7\%$. Based on findings reported in the literature, it was assumed that approximately 50% of women would be smokers, and thus the study would have 80% power, using a 5% significance level, to detect differences in characteristics between smokers and non-smokers of 20%.

Results

Recruitment

Eligibility and recruitment numbers are detailed in Figure 5.1.

Figure 5.1: Summary of eligibility and recruitment numbers



Of 277 women attending for antenatal care, 234 (84%) were assessed for eligibility (n=43 were missed as they left the clinic before being screened), and 223 (81%) were identified as eligible for participation. From the 234, four women were ineligible due to high risk or unviable pregnancies making recruitment inappropriate, two were less than 16 years of age, and five were non-Indigenous. Of the 223 eligible women, 145 (65%) consented to participate, and completed the full questionnaire, 12 of the remaining 78 were missed and 66 declined. The demographic characteristics of participant and non-participant groups are presented in Table 5.1.

Comparisons were made to assess differences between women who participated in the study with those who were eligible but were missed for recruitment or declined the invitation. Age and ethnicity were similar for participants and non-participants. There were some indications that participants were at an earlier stage of pregnancy than non-participants, but this was not statistically significant (although power for these analyses is low). There were a statistically significantly smaller proportion of smokers among the participant group relative to non-participants. Table 5.1 details the results obtained for each variable differentially for participants and non-participants.

Prevalence of smoking

Forty-one percent of responders (n=60 women) reported being daily or occasional smokers (95%CI 33-50). Twenty-three percent of women (n=33) claimed to be ex-smokers.

Table 5.1: Characteristics of participants and non-participants

	Participants (N=145)		Non-participants (N=74)		χ^2	df	p-value
	n	%	n	%			
Age							
<=19	25	17	10	14	0.578	3	0.901
20-24	43	30	24	32			
25-29	45	31	23	31			
>=30	32	22	17	23			
Gestational age							
1 st trimester (wks 1-12)	64	44	29	39	5.229	2	0.073
2 nd trimester (wks 13-27)	65	45	28	38			
3 rd trimester (wks 28-40)	16	11	17	23			
Smoking status							
Smokers	60	41	34	46	27.911	2	<0.0001
Non-smokers	85	59	29	40			
Ethnicity							
Aboriginal	49	34	28	40	2.804	2	0.246
Torres Strait Is.	77	54	38	54			
Both	18	13	4	6			

Data is missing for 11 non-participants, as smoking status was not identified.

Comparison of smokers and non-smokers

While slightly more smokers than non-smokers were of Aboriginal origin, were on social security, failed to complete year 10 of high school, were in the second or third trimester of pregnancy at recruitment, and were pregnant for the third time or more, none of these differences reached statistical significance. The only significant differences between smokers and non smokers were the number of smokers in the home ($p=0.007$, fewer smokers do not live with other smokers), the number of women whose partners smoked ($p<0.001$, non-smokers were less likely to have a smoking partner), and the level of daily stress experienced ($p<0.001$, fewer smokers than non-smokers cite low stress levels, and more cite high stress levels).

Predisposing factors

Knowledge of adverse effects of smoking in pregnancy

Results are presented for the responses to each of the knowledge and attitudes items separately (Table 5.2 and Table 5.3).

Table 5.2: Responses to knowledge items

	Smokers (N=60)		Non-smokers (N=85)		χ^2	df	p-value
	n	%	n	%			
Damage to the placenta (the sac that provides air and food the baby when it is growing inside you)	47	80	69	81	3.360	3	0.339
Spontaneous abortion or miscarriage (losing the baby)	43	73	63	75	2.870	3	0.412
Having a caesarean section	27	46	40	47	0.814	3	0.846
Baby being born too soon (premature birth)	53	90	78	92	0.716	3	0.869
Low birth weight	54	91	78	92	2.225	3	0.527
Slower physical and mental growth of the baby	52	88	71	84	2.136	3	0.545
Breathing problems and sickness in infant	58	99	81	95	2.280	3	0.516
Lower intelligence when baby grows up	46	78	64	75	1.901	3	0.593
Problems with breastfeeding	40	68	69	81	4.306	3	0.230
Cot death (sudden infant death syndrome – SIDS)	40	68	56	60	0.802	3	0.849
Mother getting diabetes	40	68	44	52	4.702	3	0.195
Mother having high blood pressure and increased heart rate	53	90	73	86	1.136	3	0.769

Percentage of women who believe that smoking in pregnancy could increase the risk of each adverse outcome. No, maybe, and don't know responses for each group are detailed in Appendix 5.7.

Table 5.3: Responses to attitude items

	Smokers (N=60)		Non-smokers (N=85)		χ^2	df	p-value
	n	%	n	%			
It's good to have a smaller baby	1	2	4	5	2.674	2	0.263
It's highly unlikely that my baby will be unhealthy	26	45	32	38	3.825	3	0.281
Light smoking does not cause harm to unborn babies	10	17	13	15	11.988	3	0.007*
Stopping smoking increases the chance of having a healthy baby	57	97	82	97	6.218	3	0.101
If you are exposed to a lot of smoke from other people you might as well keep smoking yourself	21	36	13	15	14.591	3	0.002*

Proportion of women who agree with the statements. No, maybe, and don't know responses for each group are detailed in Appendix 5.8.

** Significant difference between smokers and non-smokers at the $p < 0.05$ level*

The average number of adverse outcomes which women thought could be increased by smoking was 9.2 (standard deviation 2.7). Further exploration failed to identify significant associations between the knowledge level or categorical knowledge score and the enabling factors, reinforcing factors, or smoking patterns examined. Non-parametric analyses were carried out for all demographic and characteristic variables. Chi-square analysis of the categorised knowledge score with all potential predictors, identified an association between a higher score and the completion of tertiary education ($\chi^2 (11)=19.83$, $p=0.048$). Lower score was associated with others smoking inside the house ($\chi^2 (11)=24.70$, $p=0.010$).

Attitudes regarding smoking during pregnancy

Responses to each statement presented in the 'attitudes' section are given in Table 5.3. Each item was compared with enabling factors, reinforcing factors, and smoking

patterns individually using Chi-square. Chi-square analyses revealed significant correlations between a lower knowledge score and the belief that having a small baby is a good thing, or responding 'don't know' to this item ($\chi^2 (4)=11.025$, $p=0.026$), as well as the belief that light smoking will not cause harm to an unborn baby ($\chi^2 (6)=15.665$, $p=0.016$). A higher knowledge score was associated with the belief that stopping smoking would be healthy for the baby ($\chi^2 (6)=14.586$, $p=0.024$). The likelihood of believing that light smoking is okay was higher among smokers ($\chi^2 (3)=11.988$, $p=0.007$). Agreeing with the statement 'if you are exposed to a lot of smoke from other people you may as well keep smoking yourself' was more common among Aboriginal participants ($\chi^2 (6)=15.885$, $p=0.014$), and among smokers ($\chi^2 (3)=14.59$, $p=0.002$). Women who reported having been asked about smoking by a healthcare provider were more likely to disagree with this statement ($\chi^2 (3)=10.896$, $p=0.012$).

Enabling factors

No relationships were found between the enabling factors and the smoking status of women. The participant group had a mean age of 25 years, and 34% were of Aboriginal origin. The majority of the group received social security payments as their main source of income (77%) and had completed an average of 12 years of school education (to grade 11). Fifty-four percent of participants stated that they had completed some form of tertiary education such as Technical and Further Education (TAFE) or university courses. Women had an average of two other children. Enabling factors experienced by smokers and non-smokers are presented in Table 5.4.

Table 5.4: Enabling factors

	Smokers (N=60)		Non-smokers (N=85)		χ^2	df	p-value
	n	%	n	%			
Ethnicity							
Aboriginal	20	41	29	59	3.491	2	0.175
Torres Strait Is.	29	37	48	63			
Both	11	19	7	8			
Age							
<=19	12	20	13	15	0.393	3	0.942
20-24	9	15	13	15			
25-29	27	45	39	46			
>=30	12	20	20	24			
Source of Income							
Social security	49	82	63	74	1.303	2	0.521
Own work/partner's work	11	19	22	26			
Education level							
Less than year 10	8	13	4	5	4.412	2	0.110
Year 10 to year 12	25	42	30	35			
Tertiary education	27	45	49	58			
Gestational age at recruitment							
1 st trimester (wks 1-12)	23	38	41	48	1.672	2	0.433
2 nd trimester (wks 13-27)	31	52	34	40			
3 rd trimester (wks 28-40)	6	10	10	12			
Gravidity							
Primigravidas	13	22	27	32	1.757	2	0.415
2	13	22	18	21			
>= 3	33	56	40	47			
Parity							
Primiparous	14	23	29	33	1.896	2	0.388
1	14	23	20	24			
>=2	32	53	27	44			

Column percentages may not total 100% due to rounding.

Reinforcing factors

Women lived with an average of 1.6 other smokers, and of those women with a current partner, 54% reported that their partner was a smoker. Fourteen percent of women reported that their partner was non-Indigenous, 22% had Aboriginal partners, 47%

Torres Strait Islander and 14% both Aboriginal and Torres Strait Islander. At the univariate level, the number of smokers in the household ($p=0.010$) and having a smoking partner ($p<0.001$) were significant predictors of continued smoking (Table 5.5).

Table 5.5: Reinforcing factors

	Smokers (N=60)		Non-smokers (N=85)		χ^2	df	p-value
	n	%	n	%			
Number of smokers in home							
0	10	17	34	40	12.592	3	0.006 [†]
1-3	40	67	44	52			
4-6	8	13	4	5			
>6	1	2	2	2			
Others smoke inside the house at any time	20	39	12	24	2.497	1	0.114
Others smoke in car	15	30	11	23	0.633	1	0.426
Partner smoker (of women with current partner) **	36	75	31	41	15.618	1	<0.0001*
Ethnicity of partner							
Non-Indigenous	7	12	13	15	6.578	3	0.087
Aboriginal	19	32	13	15			
Torres Strait Islander	25	42	39	46			
Both	6	10	20	24			
Stress							
Level of daily stress							
Low/very low	10	17	34	40	19.450	4	0.001*
Moderate	26	43	39	46			
High/very high	32	53	12	14			
Distressing event in previous 12 months	51	85	63	74	2.752	1	0.097

* Significant difference between smokers and non-smokers at the $p<0.001$ level

[†] Significant difference between smokers and non-smokers at the $p<0.05$ level

** 22 women did not report having a current partner

Stress levels

Smoking status was not related to women having experienced a stressful event in the previous 12 months (Odds Ratio [OR]=0.43, 95%CI 0.17-1.08, $p=0.073$) but was associated with the level of daily stress reported. Smokers were significantly more likely to report high levels of daily stress or 'hassles' (OR=12.67, 95%CI 2.09-76.7, $p=0.003$). In Chi-square analysis, the disparity in stress levels between smokers and non-smokers was also clear, with 40% of non-smokers reporting very low or low levels, as opposed to 17% of smokers, and 14% of non-smokers reporting high or very high levels, as opposed to 41% of smokers ($\chi^2 (4)=19.65$, $p=0.001$). The stressful events reported by the 114 women who stated that they had experienced one of the listed events in the previous 12 months are presented in Table 5.6.

Table 5.6: Stressful events experienced in previous 12 months

Event	Smokers (N=50)		Non-smokers (N=64)	
	n	%	n	%
Pregnancy complications	0		7	11
Depression/anxiety	9	18	15	23
Moving house	11	22	21	33
Loss of job	2	4	5	8
Financial problems	10	20	13	20
Illness in close family	2	4	4	6
Death in close family	13	26	15	23
Problems with immediate family	23	46	18	28
Problems with current partner	16	32	12	19
Problems with previous partner	5	10	12	19
Partner away	10	20	10	16
Partner in jail	4	8	2	3

Only women who reported having experienced any stressful events (n=114) are shown, percentages are given only for those women.

Items associated with continued smoking among all factors

A positive attitude towards smoking was only slightly predictive of the behaviour itself ($\chi^2(2)=3.95$, $p=0.139$), as was leaving high school prior to the completion of year 10 (11 years of education; $\chi^2(2)=1.17$, $p=0.558$) and cohabitating with four or more other smokers ($\chi^2(2)=1.37$, $p=0.504$). Those women who reported having experienced a stressful event in the previous 12 months were also slightly more likely to be smokers ($\chi^2(1)=0.036$, $p=0.850$). In backwards stepwise logistic regression variables whose p-value for the likelihood ratio test was greater than 0.10 were removed, resulting in a final model of three predictors of smoking. The Hosmer Lemeshow goodness of fit statistic indicated that the final model was a good fit for the data ($\chi^2(8)=6.988$, $p=0.538$). The final model is presented in Table 5.7.

Table 5.7: Final logistic regression model for predictors of continued smoking during pregnancy

Variable	N	%S	Odds ratio	SE	95%CI	Likelihood ratio test χ^2 df p-value		
Partner Smoker	66	53	4.75	0.21	0.09-0.48	15.62	1	<0.0001
Partner non-smoker	55	20						
Ethnicity of father								
Non-Indigenous	20	35	0.99	0.69	0.19-5.20			
Aboriginal	32	59	0.18	0.76	0.04-0.82			
Torres Strait Islander	68	31	0.94	0.84	0.24-3.64			
Both	21	38	*			11.73	3	0.008
Level of daily stress								
Very low	34	23	*			4.82	2	0.090
Moderate	64	39	0.49	0.56	0.17-1.46			
High	36	67	0.26	0.63	0.08-0.89			

* Reference group

%S=refers to the percentage of women within each response category who are smokers

The only variable which could be identified as an independent predictor of smoking status, with a statistically significant likelihood ratio, was having a smoking partner. Having an Aboriginal partner also approached significant, as did a high level of daily stress.

Patterns of smoking behaviour

Forty percent (n=60) of the women responding to the knowledge and attitudes items identified themselves as daily or occasional smokers. Of the 41 smokers who reported having made a quit attempt in the previous five years, the average number of attempts was 2.7, with attempts lasting for an average of six months. This average is higher than might be expected due to the influence of a small number of individuals who abstained for up to five years before returning to smoking. The majority of women were able to quit for substantially shorter periods of weeks or months. The number of cigarettes per day ranged from 1-50, with an average of 8.8 cigarettes smoked. Thirty-seven women claimed to have decreased their level of smoking since discovering their pregnancy, 17 maintained the same level, and six women reported having increased their level of smoking. The characteristics of those women who increased smoking were examined in order to identify any trends which may be associated with this behaviour. Each of the women reported having experienced a stressful event in the previous 12 months, and all reported that their level of daily 'hassles' ranged from moderate to very high. Four of the five women with a current partner reported that their partner was a smoker, and all lived with other smokers. Five of the women who increased smoking were Aboriginal, and one was both Aboriginal and Torres Strait Islander.

The 33 women who reported being ex-smokers had made an average of two quit attempts before successfully quitting, and 58% quit during or immediately before their current pregnancy. Pregnancies, the influence of a partner or friends, or a health scare,

were most commonly cited as the motivation for smoking cessation among successful quitters, with 79% of ex-smokers having quit for the current, or a previous, pregnancy.

Table 5.8 summarises the smoking behaviours of participants.

Table 5.8: Patterns of smoking behaviour

	N	%
Smokers (n=60)		
Cigarette in last 7 days (occasional smokers)	18	86
Cigarettes per day		
<10	36	61
10-20	21	36
>20	2	3
Mean, med, std dev	8.2, 6, 8.9	
Quit attempts in previous 5 years	Mean 2.7, median 2, range 0-12, SD 2.8 (n=41)	
Longest smoke free period	Median 6-months, median 55 days, std dev 324 days	
Changed level during pregnancy		
Increased a lot	2	4
Increased a little	4	7
Stayed same	16	20
Decreased a little	10	19
Decreased a lot	28	50
Ex-smokers (n=33)		
Quit prior to study/pregnancy	14 (42)	
Quit attempts before successful	Mean 2, median 2, range 0-8, SD 2.3	
Reason for cessation*		
Pregnancy	26	79
Health scare	6	18
Money problems	3	9
Influence of health professional	1	3
Influence of partner or friends	8	24
Children in house	7	21
Television	4	12
Other	10	30

* Respondents were able to provide more than one reason for cessation

Discussion

Prevalence of smoking

Forty percent of the participants were self-reported daily or occasional smokers. While this is a smaller proportion than the rate reported in other studies, it is expected that the results are influenced by the large number of Torres Strait Islander women in the study population, who report smoking at a lower rate than the Aboriginal women. Studies with Aboriginal groups in Western Australia indicate rates of smoking of up to 65% in this group.³⁵ Data are not available on the rate of antenatal smoking specifically for Torres Strait Islander women. Among the population studied in Chapter 2, the rate of smoking was 51% among Aboriginal women, and 18% among Torres Strait Islanders.

The ratio of smokers to non-smokers enables this study to identify characteristics which differentiate between the two groups. By combining daily and occasional smokers as one group, and ex- or never-smokers as a separate group, the analysis focuses on the characteristics of women who continue to smoke at any level, relative to those who have never smoked or who have quit for their pregnancy.

Predictors of continued smoking during pregnancy

The present results are consistent with a hypothesis that shifted population norms among Aboriginal and Torres Strait Islanders are accompanied by a shift in the markers which can effectively differentiate between smokers and non-smokers within this population. The examination of the characteristics of this population has revealed several important features which differ from the mainstream, non-Indigenous population, reinforcing the need for smoking cessation interventions to be tailored for this target group. Several studies examining the predictors of antenatal smoking among

non-Indigenous groups have identified socio-economic status,³⁶ age,³⁷ parity and gravidity,²⁵ as important predictors of continued smoking during pregnancy. The demographic characteristics of this population and the high overall rate of smoking may differentiate Aboriginal and Torres Strait Islander women to such an extent, that a different set of markers is required to predict smoking status. The measures used to differentiate sub-groups of the non-Indigenous population and predict smoking, are so common among the Aboriginal and Torres Strait Islander community that their value as predictors is likely to be diminished. Further, with a good level of knowledge regarding the health risks associated with smoking during pregnancy, it is apparent that intervention efforts need to go beyond education if smoking behaviours are to change.

Consistent with literature relating to the low socio-economic status and level of disadvantage of this population, are the rates of women naming social security as their main source of income (77%), and average of 12 years of education, indicating that incomplete high schooling was common. While regional differences and cultural considerations may exist among individual subgroups, this study group is expected to be representative of the wider Aboriginal and Torres Strait Islander population. This is further supported by the 65% rate of consent by eligible women.

Predisposing factors

Knowledge of health risks associated with smoking during pregnancy

The results indicate a high level of knowledge among the study population, regarding the risks associated with smoking during pregnancy. Nine of the 12 knowledge items were answered correctly by the majority of participants. However, only 46% of participants believed that smoking during pregnancy could increase the risk of having a caesarean section, and 59% associated smoking with the risk of themselves getting diabetes. Sixty-seven percent connected smoking with the child having lower

intelligence. All other items were answered correctly by at least 74% of responders. This is consistent with suggestions that the Aboriginal and Torres Strait Islander population has a good general knowledge about the risks of smoking, but are less aware of specific health issues. No statistically significant differences were found in the responses given by smokers and non-smokers, with a consistent level of knowledge throughout the group. Interestingly, when compared with the non-Indigenous women recruited at a public hospital antenatal clinic in New South Wales, the women in the present study exhibited significantly greater knowledge on each of the matching items. The score of 9.2 out of a possible 12 compares with an average of 3.6 out of a possible 10 obstetric outcomes identified by non-Indigenous smokers in the study by Walsh et al., (1997)³¹ which is a highly significant difference ($p < 0.001$).

Attitudes regarding smoking during pregnancy

The attitudes regarding smoking and the health of the woman's baby were somewhat contradictory to the apparent level of knowledge. While very few women (4%) thought that having a small baby was a good thing, less positive results were obtained for other items. Ninety-seven percent of women agreed that stopping smoking would increase the chance of having a healthy baby, but 17% believed that light smoking would not cause harm to an unborn baby. A negative attitude to cessation emerged, relating to passive smoke exposure, with 23% of all participants, and 36% of smokers believing that 'if you are exposed to a lot of smoke from other people you might as well keep smoking yourself'. Consistent with the knowledge items, the level of recognition that stopping smoking would increase the chance of having a healthy baby was significantly higher in the present group than among women in the study by Walsh et al.³¹ The attitudes towards light smoking and passive smoking on the other hand, were more accepting among the present group.

The proportion of women found to have been accepting of, or neutral towards light smoking and passive smoke is disturbing, particularly in the context of the higher than expected knowledge levels. It appears that despite this knowledge of the risks, passive smoke exposure may be used as a justification for continued smoking during pregnancy. Significantly more smokers believed that light smoking would not cause harm to an unborn baby, and that personal smoking might as well continue if exposed to passive smoke. This trend is not unexpected, with continuing smokers likely to downplay the harms associated with smoking and attempt to exempt themselves from the socially desirable act of quitting. Women who agreed with the passive smoking item were more likely to be of Aboriginal origin as opposed to Torres Strait Islander, which is consistent with a higher proportion of smokers among the Aboriginal population, and a pattern of more cohabitating smokers, and more smoking partners among this subgroup.

These results illuminate the social factors influencing smoking behaviour, and particularly in the Aboriginal population, the normality of smoking in the community. The negativity expressed towards quitting if passive smoke exposure is present, suggests that the social environment plays a significant role in reinforcing smoking behaviour. This is further supported by the fact that while very few correlations were found between knowledge score and enabling or reinforcing factors, having a partner identified as a current smoker was significantly associated with a lower score. With a high population rate of smoking among Aboriginal men and women, and a greater number of adults per household,^{24 38} it may be that women feel somewhat powerless to quit smoking in such an environment, and to influence those around them. This provides a critical target for intervention in antenatal smoking; in order to help women to quit, it seems that consideration and involvement of the social context in which women live is essential.

While the data reported by Walsh et al., were collected in 1990-1992, there is little evidence to suggest that knowledge and attitudes of pregnant women regarding smoking has changed markedly since that time. Hotham et al., (2002) conducted focus groups with pregnant smokers to explore barriers to cessation and perceptions regarding smoking. In the small sample participating in that study, scepticism about the harms of smoking was widespread.³⁹ The Australian National Tobacco Campaign, launched in June 1997 has been evaluated based on recall and response of smokers and recent quitters to advertisements, generating indications that the campaign has been successful in increasing knowledge about the health risks of smoking in general, and influencing attitudes about smoking and quitting.⁴⁰ It is difficult to evaluate the impact of a National campaign, as is the translation of results from a small population sample into impacts upon specific groups such as pregnant smokers and those attending public healthcare clinics. Whether this general campaign successfully impacted upon pregnant smokers is unclear, but it may be hypothesised that there has been a population-wide increase in awareness regarding smoking and its associated risks over the last decade.

Enabling factors

The social environment in which Aboriginal and Torres Strait Islander women live contains several barriers to changing smoking behaviours. While the majority of these barriers are non-modifiable by smoking-related interventions, they are addressed here as enabling factors, demonstrating the difficulty in changing smoking behaviours in such a social context. The number of women relying on social security is indicative of the low socio-economic status of the group. The study population is significantly younger than the national average. The mean age of all women giving birth in Australia in 2003 was 29.5 years,²⁴ compared with the average of 26 in the present group. The percentage representation in each of the three age categories below 30 years of age

(<20, 20-24, and 25-29) was substantially higher in the study population than in Australian mothers overall.

Parity also differs between the Australian population as a whole, and the Aboriginal and Torres Strait Islander population, a difference which is reflected in the study group. In the present study, 28% of women were pregnant with their first child, 22% had one previous child, and 50% had two or more children. In what is a clear inverse trend, in 2003, 42% of women giving birth in Australia were having their first child, 34% had one other, and 24% had two or more other children. These differences between the study group and the overall population are consistent with those reported by the AIHW,²⁴ with the national Aboriginal and Torres Strait Islander population. This reinforces the view that the study group is representative of the wider Aboriginal and Torres Strait Islander population.

The uniformity of these enabling characteristics among the study group and of the Aboriginal and Torres Strait Islander population as a whole decreases the predictive value of these factors. Univariate analysis failed to identify an association between smoking and ethnicity, age, parity, gravidity, or income. The low socio-economic status, young age, and high rate of multiparity among this population act as barriers to changing smoking behaviour, and decrease the capacity for such factors to distinguish between smokers and non-smokers within this group. It appears that in this population, enabling factors are not likely to be a useful target for smoking-related intervention.

Reinforcing factors

Reinforcing factors were found in this research to be more important predictors of smoking behaviour than enabling or predisposing factors. The only significant predictors at the univariate level were having a partner identified as a smoker

($p < 0.001$), living with other smokers ($p = 0.010$) and high levels of daily 'hassles' ($p = 0.003$). Women who lived with one to three other smokers had three times the odds of smoking than women who lived with no smokers, and those living with four or more other smokers had eight times the odds. Partner smoking status, number of smokers in the house, and the ethnicity of the father all represent reinforcing factors for smoking behaviour in the Precede Proceed Model. These variables also explained a considerable proportion of the variance in the logistic regression model. When in the equation alone, they explained 17.3% of the variance in smoking. In multivariate analyses, having a smoking partner remained the most significant independent predictor of smoking status, followed by the ethnicity of the father, with women whose partner was Aboriginal at greater odds of smoking than those whose partner was non-Indigenous. These findings further highlight the importance of the social environment in reinforcing smoking behaviour, and as a useful target for intervention in antenatal smoking among Aboriginal and Torres Strait Islander women. The potentially greater impact of the social environment upon smoking behaviour in an Indigenous population compared to mainstream populations is supported by a US study, examining Caucasian women and the culturally distinct African-American women.⁴¹ While fewer African-American women smoked, those who did reported less social support, higher stress, and lower education than those who did not smoke.

Stress levels during pregnancy

A large proportion of the women reported having experienced a stressful event in the previous 12 months, potentially reinforcing their desire to smoke. While these experiences were not related to smoking behaviour, it is interesting to note the nature of events experienced. As illustrated in Table 5.6, many issues associated with the social environment in which women live, or their socio-economic circumstances were common. Thirty-five percent of women cited problems with their current partner, for

example, 37% referred to issues within their immediate family, and 21% cited financial concerns as a cause of stress. With the level of perceived stress significantly associated with smoking behaviour, these sources of stress within the social environment may be an important target for intervention.

These patterns are consistent with links reported in the literature, between stress and smoking during pregnancy. In a US study, African-American women who smoked during pregnancy reported higher levels of stress than non-smokers.⁴¹ Another US study, with women of low socio-economic status, reported negative relationships between smoking cessation, stage of readiness to quit, action towards quitting, motivation for quitting, self-efficacy and confidence, and the level of perceived stress reported.⁴² In Canada, a high level of perceived stress has been identified as a risk factor for spontaneous preterm birth among Aboriginal women.⁴³ Highlighting the complexity of the interaction between smoking and the social environment, these trends highlight the capacity for widespread efforts which take all social, reinforcing factors into consideration, to impact upon smoking behaviours.

Patterns of smoking behaviour

Characterisation of smokers in the study population showed consistencies with the evidence relating to smoking behaviour and quitting.^{35 44 45} A large proportion of smokers (71%) had made one or more quit attempt in the previous five years, and 69% (n=37) had decreased their level of smoking since they became aware of their pregnancy. Data from the six women who claimed to have increased their smoking level since discovering their pregnancy were examined to identify any indicators for this behaviour. Small numbers precluded the analysis of differences between the characteristics of these smokers with other smokers or with the group as a whole. Notable observations however, were a higher proportion of women with smoking

partners, and a high proportion being Aboriginal women. The stress levels and rate at which stressful events were experienced among this group were also high. Consistent with the literature, the ex-smokers reported having made an average of 2.7 quit attempts before succeeding,^{46 47} and the majority (79%) quit for their current or a previous pregnancy.^{48 49} Suggestions of a high proportion of the women who actually increased their smoking level having smoking partners, may be indicative of the importance of the social environment in reinforcing smoking behaviour.²⁵

Limitations of the study

The majority of knowledge and attitudes information was collected by a single project officer at Wuchopperen. Over the 17-month data collection period, there was the possibility that the increasing knowledge and experience of this individual influenced the interview style, and potentially, the responses given by women. While this approach may cause women to provide socially desirable responses, there is no reason to suspect that it resulted in any systematic bias in the data. Given the essential requirements of gaining informed consent, all participants were aware that the study related to antenatal smoking, and that the overall aim was to find out how to help women quit. This may have influenced the attitudes portrayed by women, and led them to give what may be viewed as more 'socially desirable' responses. Social acceptability of smoking, and negative attitudes towards smoking and smokers which are generated by public anti-smoking campaigns and 'demarketing', have the capacity to influence accuracy of self-reported smoking status, and increase concealment of smoking.⁵⁰⁻⁵² While the majority of women attending the clinic for antenatal care were assessed for eligibility, it is possible that the 43 women who were missed for assessment led to some degree of bias in the recruitment process. Women were missed due to logistical reasons such as the physical position of the project officer within the clinic, time constraints associated with the busy clinic environment, or inadequate communication

between staff members. The consent rate of 65% of eligible women is acceptable, but again, the 35% of women who declined consent may represent an important sub-group of the sample. The inclusion of ex- and never-smokers in this component of the study broadens the capacity to identify key characteristics, including demographics, knowledge levels and attitudes towards smoking, which may distinguish smokers from non-smokers. This works to reduce bias which may otherwise be associated with the selection of a group of smokers, and suggests that this group is likely to be adequately representative of the women attending the participating health services.

With the smoking status not identified for 15% of non-participants, it is hypothesised that the lower proportion of smokers identified in the participant group does not represent a true difference between groups. This point is somewhat concerning however, as the smoking status of all patients should be recorded in their medical records, and in particular, smoking status should be recorded at the first antenatal visit for all pregnant women. Feedback was provided to clinic staff where incomplete patient records were identified.

The high level of knowledge regarding the dangers of smoking should be interpreted with some caution. As mentioned previously, it is possible that the social desirability of smoking cessation, and presentation of the questions by a respected Torres Strait Islander health worker may have led to an over-estimation of the knowledge level of the women. The use of a prompted list of items regarding the risks associated with smoking may not be the most appropriate approach to generating these data. Future studies should perhaps consider the use of alternative techniques, such as asking women to nominate any risks known to them, avoiding the potential influence of the presented items.

This study examined just a small portion of the spectrum of factors which may influence smoking behaviour. As discussed in Chapter 2, a complex set of factors interact, leading to the overall vulnerability of Aboriginal and Torres Strait Islander women, and their high level of risk for adverse health outcomes. The study captured a selection of the predisposing, enabling, and reinforcing factors which may influence smoking behaviour. It is therefore recognised, that while the results of the present study may be valid and of critical importance, these are not the only factors which should be considered in the design of appropriate interventions. The factors which explain the remaining 57% of the variance in smoking may be important, and should be investigated for their potential impact upon the effectiveness of intervention efforts.

Conclusions

The results of this investigation suggest that rather than the traditional, mainstream predictors of antenatal smoking, interventions with Aboriginal and Torres Strait Islander women should focus on the social environment, and the influences of social networks and partners upon the behaviour of individuals. While parallels do exist between the characteristics of smokers within this study community with those among the wider non-Indigenous population, there are key differences which lead to the need for specifically tailored intervention programs. Interventions with Aboriginal and Torres Strait Islander women should consider the complex social and cultural environment in which they live.

The findings of the study also offer guidance to future researchers, with the identification of the most important predictors of antenatal smoking in this population providing not only targets for intervention, but markers for study and evaluation. It appears that the social environment in which women live is a critical influence upon smoking behaviour. The inclusion of social aspects in intervention efforts, aiming to

encourage smoking partners to quit, and to decrease daily stress levels experienced by women, may greatly improve the outcomes of smoking cessation efforts. Future questionnaires could potentially be simplified, using the key markers identified here, to predict smoking and assess smoking patterns, reducing the need for lengthy and complex questionnaires in research studies.

The knowledge and attitudes detected in this group suggest that smoking intervention efforts for antenatal Aboriginal and Torres Strait Islander women should focus less on education about the general dangers associated with smoking, and more on the social environment and dangers of passive smoking. The most appropriate approach to tackling the antenatal smoking issue should involve components targeted towards the individuals who influence, and can provide support to, women through attempts to quit smoking. By involving women's social network in intervention efforts, there is potential for such efforts to impact not only on antenatal smoking, but on smoking rates in the population overall, challenging the normality and acceptability of smoking among the Aboriginal and Torres Strait Islander community. If women are empowered to take charge of their own health and recognise the risks of their own, and other's smoking upon themselves and their unborn child, the social network may become more aware of these issues, and assist with cessation efforts.

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Appendix 5.1: University Certificate of Ethical Approval for study



The UNIVERSITY
of NEWCASTLE
AUSTRALIA

Form HE2:1/05

HUMAN RESEARCH ETHICS COMMITTEE

Certificate of Approval for a research project involving humans

Applicant	
Chief Investigator/Project Supervisor: (First named in application)	Professor Rob Sanson-Fisher
Co-Investigators/Research Students:	Dr Sandra Eades Dr Kathryn Panaretto Dr Mark Wenitong Conor Gilligan
Project Title: NHMRC Grant Application:	Assisting Aboriginal and Torres Strait Islander women to stop smoking during pregnancy - A randomised controlled trial Project ID: 320851 – A randomised controlled trial of a high intensity intervention to reduce smoking among pregnant Indigenous women

In approving this project, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the *National Statement on Ethical Conduct in Research Involving Humans*, 1999, and the requirements within this University relating to human research.

Details of Approval	
HREC Approval No: H-067-0705	Date of Approval: 20 July 2005
Approval valid for: 3 years, or until project ceases, whichever occurs first.	Progress reports due: Annually
<p>NOTE: Approval is granted subject to the requirements set out in the attached document <i>Approval to Conduct Human Research</i>, and any additional comments or conditions noted below:</p> <p>20 July 2005 Approved with comment. The Committee ratified the approval granted by the Acting Chair on 24 June 2005, which was subject to the questionnaire and participant documents being resubmitted to the HREC should there be any changes after piloting.</p>	

Signed for the Committee:

A. O'Connor

Ms Susan O'Connor
Human Research Ethics Officer

Appendix 5.2: TAIHS endorsement letter for study

TOWNSVILLE ABORIGINAL
AND ISLANDERS
HEALTH SERVICES
LIMITED



A.C.N. 010 113 603
A.B.N. 66 010 113 603

10th March 2005

Ms Susan O'Connor
Human Research Ethics Officer
Human Research Ethics
Research Office
The University of Newcastle
University Drive
Callaghan NSW 2308

Dear Ms O'Connor,

*Re: Helping Indigenous women to stop smoking during pregnancy – A randomised controlled trial of a high intensity intervention to reduce smoking among pregnant Indigenous women; and
Defining cotinine level as an outcome measure for antenatal Indigenous women*

This letter is written to provide the Human Research Ethics Committee with formal advice that the above research projects, led by Dr Sandra Eades and Professor Rob Sanson-Fisher, have the full support of the Board of Directors of the Townsville Aboriginal and Islanders Health Services Limited (TAIHS).

TAIHS is a community based organisation, which provides holistic primary health care to the Aboriginal and Torres Strait Islander community within the Townsville/Thuringowa region. It is managed by a Board of ten Directors elected annually by members of the community.

The above research projects were first negotiated with TAIHS in the latter part of 2003. Subsequently, in February 2004, an application for funding was submitted to the NH&MRC. The Board of Directors has considered the proposal in full and provided support for TAIHS to participate as a site for the proposed trial.

57-59 GORDEN STREET
CARBUTT
P O BOX 7534 G.B.C.
TOWNSVILLE
QUEENSLAND 4814

TELEPHONE: AREA CODE 07
ENQUIRIES 4759 4001
MEDICAL 4759 4000
EXECUTIVE 4759 4027
DENTAL 4759 4002
SOCIAL 4759 4022
EYE HEALTH 4759 4019
MUMS & BABIES 4759 4045
ACCOUNTS 4759 4006

FACSIMILE: AREA CODE 07
ADMINISTRATION 4759 4055
MEDICAL 4759 4066
EXECUTIVE 4759 4077

Page 1 of 2

We also advise that:

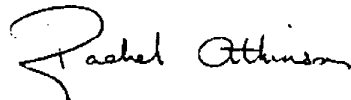
- As a way to ensure that the interests of our community and our service are factored into the study at each stage, the Senior Medical Officer at TAIHS is chief investigator on the NH&MRC grant for these projects.
- TAIHS has an established research committee which oversees community engagement with local health research projects. This committee will work with the Investigators throughout this project.
- In partnership with Community Health (Child Health) and The Townsville Hospital, a successful collaborative Maternal and Child health program has been operating from TAIHS for the past five years. To facilitate engagement with the broader community, the program has a reference group of 10–15 members from other maternal and child health service providers in Townsville as well as a consumer representative.

We very much look forward to being an active partner in these important research projects.

Kindly contact me, or our Senior Medical Officer, Dr Katie Panaretto, should you require any further information.

Yours sincerely,

TOWNSVILLE ABORIGINAL AND ISLANDERS HEALTH SERVICES LIMITED

A handwritten signature in black ink that reads "Rachel Atkinson". The signature is written in a cursive, flowing style.

Rachel Atkinson BSW Ass.CW
Chief Executive Officer

Appendix 5.3: Wuchopperen endorsement letter for study



10th March 2005

Ms Susan O'Connor
Human Research Ethics Officer
Human Research Ethics
Research Office
The University of Newcastle
University Drive
CALLAGHAN NSW 2308

Dear Ms Connor,

Re: *Helping Indigenous women to stop smoking during pregnancy – A randomised controlled trial of a high intensity intervention to reduce smoking among pregnant Indigenous women; and Defining cotinine level as an outcome measure for antenatal Indigenous women*

I am writing on behalf of the Wuchopperen Health Service to inform the Human Research Ethics Committee formally that the above research projects, led by Dr Sandra Eades and Professor Rob Sanson-Fisher, have been negotiated and planned with full involvement and support of the Wuchopperen Health Service. The project has developed with involvement of key staff members and Dr Mark Wenitong from this service is a chief investigator on the NHMRC grant for this project. The project has been considered and approved by the Board of Directors.

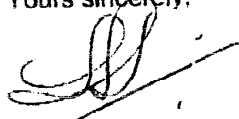
Wuchopperen Health Service is a key community based service, providing holistic primary health care services to Aboriginal and Torres Strait Islander people in the Cairns region. It is Aboriginal community controlled with a full Aboriginal and Torres Strait Islander Board of Directors and membership drawn broadly from the local community. The Board of Directors has a research subcommittee which oversees the service's involvement with any major research project. The proposed studies are considered a high priority by the Board and we look forward to the commencement of this work.



Wuchopperen Health Service Limited ABN 15 010 112 580
13 Moignard Street, Manunda, 4870 PO Box 878, Manunda, 4870
Phone 07 4080 1000 Facsimile (Results) 07 4032 4961 (Admin) 07 4032 4962 (Social Health) 07 4032 4963 Website www.wuchopperen.com
Donations of \$2.00 and over are tax deductible

Please feel free to contact the undersigned or our Senior Medical Officer, Dr Mark Wenitong, should you require further information.

Yours sincerely,



per.

Nancy Long
Executive Officer
Wuchopperen Health Service Limited

Appendix 5.4: Participant information statement and consent form



Information statement... ...for smoking cessation in pregnancy study for Aboriginal and Torres Strait Islander women

You are invited to take part in a study. The study aims to:

- ✓ Find out how many Aboriginal and Torres Strait Islander women smoke during pregnancy.
- ✓ Find out what things influence Aboriginal and Torres Strait Islander women who are pregnant and who smoke.
- ✓ Find out if the amount of cotinine (breakdown chemical from nicotine) in your urine matches the number of cigarettes you smoke.
- ✓ Help those women who smoke to try to quit smoking with help from their doctor and a specially trained Aboriginal health worker.

The study is being done by researchers from the University of Newcastle and the General Practitioners and the Board and Management of the Townsville Aboriginal and Islanders Health Services (TAIHS) Limited and the Wuchopperen Aboriginal and Islander Health Service in Cairns.

Why is this research being done?

We want to find out what influences Aboriginal and Torres Strait Islander women who are pregnant. We also want to help those women who smoke while they are pregnant to quit. These studies will help health care workers to understand the best ways to help Aboriginal and Torres Strait Islander women quit smoking while they are pregnant.

Who can take part in the research?

We are inviting all women aged over 16 years and over who attend TAIHS or the Wuchopperen Aboriginal and Torres Strait Islander Health Service for health care during pregnancy, to take part in Part 1 of the study.

Women who attend at or before 20 weeks gestation will also be invited to take part in Part 2 of the study. Also, people who live with these women and who come to the clinic with them are invited to take part.

What choice do you have?

Taking part in this research is totally your choice. You do not have to take part if you do not wish. Whether or not you decide to take part, your decision will not disadvantage you in any way and will not affect your medical care. If you do decide to take part you may withdraw from the study at any time without giving a reason.

What are we asking you to do?

Depending on your stage of pregnancy, and whether you smoke, you may choose to take part in one or all parts of the study. These parts are described on page 3.

If you agree to participate, the researchers would like to access your medical records to collect information about your ethnicity, source of income, education, pregnancy, and gynaecological history.

What are the risks and benefits of participating?

Some participants may be provided with nicotine gum to help them quit smoking. The side-effects of the gum will be explained by the general practitioner if it is supplied.

The most direct health benefit is being able to cut down or quit smoking as a result of this study. The findings will allow health care providers to understand the best ways to help pregnant Aboriginal and Torres Strait Islander women to quit smoking while they are pregnant.

How will privacy be protected?

All identifying information (such as your name) which is collected from you and your household members will be stored at the university, separately to the data collected. You will not be personally identified in any research reports. We will not give your information to anybody else. Reports about the project will not include information about specific patients.

How will information collected be used?

All data collected in the project will be coded and stored on computer files at the University of Newcastle. The results of this study may appear in a paper in a scientific journal. Information will not be revealed about any specific people in any way, in any reports arising from this project.

What do you need to do to take part?

Please read this Information Statement and be sure you understand its contents before you consent to take part. If there is anything you do not understand, or if you have any questions please ask the health worker providing you with the information. If you would like to take part, please complete the relevant section/s of the consent form.

Would you like more information?

You may keep this Information Statement. If you would like more information about the project, please don't hesitate to contact us. You can call Professor Rob Sanson-Fisher or Dr Sandra Eades using the contact details below to ask any questions about the project. A full list of the researchers is provided below.

Who are the researchers?

Principle Investigators:	Dr Mark Wenitong, Wu Chopperen, Cairns Dr Katie Panaretto, TAIHS, Townsville Prof Rob Sanson-Fisher, University of Newcastle Prof Sandra Eades, Sax Institute	07 4759 4017 07 4050 8834 02 4923 6189 02 93827648
PhD student:	This research will contribute to the PhD thesis of Conor Gilligan who is supervised by Professor Rob Sanson-Fisher.	
Local Study Teams:	TAIHS (Townsville) and Wuchopperen (Cairns) Medical Teams.	
Local Committee:	Ethics	TAIHS and Wuchopperen Board of Directors.

This project has been approved by the University of Newcastle
Human Research Ethics Committee: Approval number: H-067-0705



Complaints

Should you have any concerns about your rights as a participant in this research, or if you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to:

The Human Research Ethics Officer, Research Officer, The Chancellery,
The University of Newcastle, University Drive, Callaghan, NSW 2308.

☎ 02 49 216 333. Email: human-ethics@newcastle.edu.au.
Or: _____ for an independent local contact.

Thank you for considering taking part in this project

The Study



Part 1

What influences pregnant Aboriginal and Torres Strait Islander women?

What is the range of cotinine (breakdown chemical from nicotine) levels in the urine of Aboriginal and Torres Strait Islander women who are pregnant?

A.

If you agree to take part you will be asked to complete an interview during which a specially trained health worker will help you to answer some questions which ask you about your smoking history, your pregnancy, your family, and the people you live with.

B.

We would like to test for cotinine in the urine sample you provide at your clinic visit to see if the amount of cotinine in your urine matches the number of cigarettes you smoke.

You will be asked to complete a diary sheet detailing how much you have smoked, had to drink, and been exposed to passive smoke in the last 24 hours.

All of this information is very important because your exposure to passive smoke and your alcohol consumption may alter your level of cotinine.

Your support people will be asked to complete a diary sheet detailing their own smoking over the previous 24 hours, the number of smokers in the house, and you're smoking as well.

Part 2

Is an intervention provided by your doctor and a specially trained health worker in more helpful than normal pregnancy care in helping pregnant smokers quit?

If you are eligible and agree to take part in this section of the study, you will be randomly allocated to a group.

Half of the women in this part of the study will receive the normal care provided by the health service during pregnancy, and half will also receive extra intensive quit smoking support from their general practitioner and a specially trained Aboriginal Health Worker.

We have to do this to see if our extra support helps women to quit.

Both groups will be asked to:

- ✓ Complete another questionnaire late in their pregnancy, and 6 months after the baby is born,
- ✓ Provide urine samples at these times.

Also, extra intensive support will be provided to one group throughout their pregnancy, and especially during the first and second visits to this health service for antenatal care.

All aspects of the intensive support program are optional, so agreeing to take part does not mean that you have to agree to everything that is offered.

You can at any time let us know if you feel you are unable to cut down or quit smoking and wish to no longer be involved in the intervention part of this study.

Your decision will not affect your ongoing care at the clinic or your relationship with your healthcare provider.

Participant consent form

Rob Sanson-Fisher
Professor of Health Behaviour
Room 267, David Maddison Building
King Street, Newcastle, NSW, 2300
Ph: 02 4923 6169
Fax: 02 4923 6779

I agree to take part in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand that I can withdraw from the project at any time and do not have to give a reason for withdrawing.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Part 1

A. I consent to the researchers having access to my medical records to gather information about my ethnicity, source of income, education, pregnancy, and gynaecological history.

I consent to answer questions relating to my smoking history, my pregnancy, my family, and the people I live with.

Name: _____ Signature: _____ Date: ____/____/____

*Witness Name: _____ Signature: _____ Date: ____/____/____

B. I consent to the researchers having access to my medical records to gather information about my ethnicity, source of income, education, pregnancy, and gynaecological history

I consent to answer questions relating to my smoking history, my pregnancy, my family, and the people I live with.

I consent for the urine sample I provided for screening to be used for cotinine analysis.

Name: _____ Signature: _____ Date: ____/____/____

*Witness Name: _____ Signature: _____ Date: ____/____/____

Part 2

I consent to the researchers having access to my medical records to gather information about my ethnicity, source of income, education, pregnancy, and gynaecological history

I consent to receive routine pregnancy healthcare with or without additional support to quit smoking.

Name: _____ Signature: _____ Date: ____/____/____

*Witness Name: _____ Signature: _____ Date: ____/____/____

(*not a project investigator)		Participant Number:
Dr Mark Wenitong	Wuchopperen	☎ 07 4050 6834
Dr Kathryn Panaretto	TAIHS	☎ 07 4771 2241
Prof Rob Sanson-Fisher	University of Newcastle	☎ 02 49236169
Prof Sandra Eades	Sax Institute	☎ 02 93827648

Appendix 5.5: Knowledge and attitudes questionnaire

Participant #



The UNIVERSITY
of NEWCASTLE
AUSTRALIA

This page is
relevant as part
of the pilot
study
described in
Chapter 8

Health Issues during Pregnancy

Date / /

Confidential Information – This page will be removed to de-identify data

Name: _____

Address: _____

Postcode

Phone: _____

Date of Birth: / /

Alternative contacts

Name: _____

Relationship to you: _____

Phone: _____

Address: _____

Postcode:

Alternative health services: _____

Intervention (Please circle)

	Eligible	YES	NO
If yes:	Participant	YES	NO
If yes:	Additional care	YES	NO

Participant #

Section 1. To be completed by Health worker from patient records

Demographics

1. a. Are you of Aboriginal or Torres Strait Islander Origin?

- ☐ 1 No
☐ 2 Yes Aboriginal
☐ 3 Yes Torres Strait Islander
☐ 4 Yes both Aboriginal and Torres Strait Islander
☐ 5 Yes South Sea Islander

- b. Is the father of your expected baby of Aboriginal or Torres Strait Islander Origin?

- ☐ 1 No
☐ 2 Yes Aboriginal
☐ 3 Yes Torres Strait Islander
☐ 4 Yes both Aboriginal and Torres Strait Islander
☐ 5 Yes South Sea Islander

2. What is your main source of income?

Do you support yourself from:

- ☐ 1 Social Security
☐ 2 Full-time employment
☐ 3 Part-time/casual employment
☐ 4 Other (please describe) _____

Or are you supported by partner who is:

- ☐ 5 On social security
☐ 6 Employed full-time
☐ 7 Employed part-time/casual
☐ 8 Other (please describe) _____

Or are you supported:

- ☐ 9 From maintenance from another person

3. What was the highest year level you completed at school? (Please circle response)

5 6 7 8 9 10 11 12

4. Have you done any courses at TAFE or University?

- ☐ 1 Yes
☐ 2 No

Obstetric/Gynaecological History

5. How many weeks pregnant are you? weeks

6. How many times have you been pregnant? times

7. How many biological children do you have? children

Participant #

Section 2 To be completed by patients/ health workers to ask questions

Advice from health professionals

8. How many times have you seen a doctor, health worker, or nurse about this pregnancy?

0 1 2 3 4 5 6 7 8 9 10

9. Has your doctor, health worker, or nurse asked you about smoking in this pregnancy?

- | | | |
|--------------------------|---|-----------------------------|
| <input type="checkbox"/> | 1 | Yes |
| <input type="checkbox"/> | 2 | No |
| <input type="checkbox"/> | 3 | I haven't seen a doctor yet |

Lifestyle and Passive Smoke

10. How many smokers other than yourself usually live in your house? Smokers

11. Where do these people usually smoke?

- | | | |
|--------------------------|---|--------------------|
| <input type="checkbox"/> | 1 | Mostly outside |
| <input type="checkbox"/> | 2 | Mostly inside |
| <input type="checkbox"/> | 3 | Inside and outside |

12. Do these people smoke in the car with you (if you own or have access to a car)?

- | | | |
|--------------------------|---|-----|
| <input type="checkbox"/> | 1 | Yes |
| <input type="checkbox"/> | 2 | No |

13. In relation to your partner:

- | | | |
|--------------------------|---|---|
| <input type="checkbox"/> | 1 | My partner is a smoker |
| <input type="checkbox"/> | 2 | My partner doesn't smoke now, but used to smoke |
| <input type="checkbox"/> | 3 | My partner has never smoked |
| <input type="checkbox"/> | 4 | I don't have a partner at the moment |

Participant #

Knowledge and attitudes (Please circle response)

14. Do you think that smoking in pregnancy could increase the risk of:

	Yes definitely	Maybe	No	Don't Know
a. Damage to the placenta (the sac that provides air and food to your baby when its growing inside you)	1	2	3	4
b. Spontaneous abortion or miscarriage (losing the baby)	1	2	3	4
c. Having a caesarean section	1	2	3	4
d. Baby being born too soon (premature birth)	1	2	3	4
e. Low birth weight	1	2	3	4
f. Slower physical and mental growth of the baby	1	2	3	4
g. Breathing problems and sickness in infant	1	2	3	4
h. Lower intelligence when baby grows up	1	2	3	4
i. Problems with breastfeeding	1	2	3	4
j. Cot death (sudden infant death syndrome – SIDS)	1	2	3	4
k. Mother getting Diabetes	1	2	3	4
l. Mother having high blood pressure and increased heart rate	1	2	3	4

15. Please indicate how true the following statements are for you:

	Very true	Quite true	Not at all true	Don't know
a. It's good to have a smaller baby	1	2	3	4
b. It's highly unlikely that my baby will be unhealthy	1	2	3	4
c. Light smoking does not cause harm to unborn babies	1	2	3	4
d. Stopping smoking increases the chance of having a healthy baby	1	2	3	4
e. If you are exposed to a lot of smoke from other people you might as well keep smoking yourself	1	2	3	4

Participant #

Smoking Status and History

16. Which statement best describes you?

- | | | |
|--------------------------|---|--|
| <input type="checkbox"/> | 1 | I'm a smoker, I smoke daily (Go to 18) |
| <input type="checkbox"/> | 2 | I'm a smoker, I smoke occasionally (Go to 17) |
| <input type="checkbox"/> | 3 | I'm an ex-smoker; I never smoke now (Go to 24) |
| <input type="checkbox"/> | 4 | I'm a non-smoker, I have never smoked (Go to 27) |

17. Have you had a cigarette in the last 7 days?

- | | | |
|--------------------------|---|-----|
| <input type="checkbox"/> | 1 | Yes |
| <input type="checkbox"/> | 2 | No |

18. How many cigarettes do you usually smoke each day? Cigarettes

19. In the last five years, how many times have you tried to quit smoking? times

20. What is the longest amount of time you have been able to quit smoking for?

(please circle units) a Days b Weeks c Months d Years

21. Have you changed your level of smoking since you found out you were pregnant?
(Please circle most appropriate response)

- | | | | | |
|--------------------|-----------------------|----------------|-----------------------|--------------------|
| Increased
a lot | Increased
a little | Stayed
Same | Decreased
a little | Decreased
a lot |
| 1 | 2 | 3 | 4 | 5 |

22. How old were you when you first started smoking?

Social support

23. Is there someone close to you who will support you during your pregnancy, and whom you think might support you to quit smoking?

Relationship to you _____

Relationship to you _____

Questions 23 to 25 are for ex-smokers only

24. When did you stop smoking cigarettes regularly? Year Month

25. How many times did you try before you finally gave up? times

26. What caused you to quit smoking?

- | | | |
|--------------------------|---|---|
| <input type="checkbox"/> | 1 | Pregnancy |
| <input type="checkbox"/> | 2 | Health Scare |
| <input type="checkbox"/> | 3 | Money Problems |
| <input type="checkbox"/> | 4 | Influence of doctor, nurse or health worker |
| <input type="checkbox"/> | 5 | Influence of partner or friends |
| <input type="checkbox"/> | 6 | Children in the house with asthma |
| <input type="checkbox"/> | 7 | Television |
| <input type="checkbox"/> | 8 | Other |

Participant #

Stress

27. On average, how would you rate the level of your daily hassles?

Very low	Low	Moderate	High	Very high
1	2	3	4	5

28. Have you had any of the following major life events that distressed you in the last 12 months or so?

YES
NO

Please tick box for yes:

Personal health problem	<input type="checkbox"/>	Pregnancy complication	<input type="checkbox"/>
Personal problem such as depression or anxiety	<input type="checkbox"/>	Moving house	<input type="checkbox"/>
Problem with current partner	<input type="checkbox"/>	Problem with previous partner	<input type="checkbox"/>
Problems within close family	<input type="checkbox"/>	Problems with your own children	<input type="checkbox"/>
Death in close family	<input type="checkbox"/>	Serious illness in close family	<input type="checkbox"/>
Financial insecurity	<input type="checkbox"/>	Loss of job	<input type="checkbox"/>
Partner being away	<input type="checkbox"/>	Partner in jail	<input type="checkbox"/>

Thankyou for helping us

Appendix 5.6: Univariate analysis of variables for their association with smoking behaviour

Variable	n	%S	Odds ratio	95% CI	p value±
Predisposing factors					
Knowledge score					0.676
0-5	14	43	*		
6-9	50	36	1.33	0.31-3.04	
10-12	80	44	0.96	0.40-4.45	
Overall attitude					0.093 [†]
Positive	67	31	1.03	0.36-2.97	
Negative	59	49	2.19	0.76-6.31	
Neutral/Don't know	18	50	*		
Enabling factors					
Age					0.822
</=19	25	46	*		
20-29	88	41	0.82	0.33-2.03	
>/=30	32	38	0.71	0.24-2.08	
Ethnicity					0.292
Aboriginal	49	41	*		
Torres Strait Islander	76	36	0.56	0.20-1.61	
Both	20	55	0.45	0.17-1.22	
Education level					0.084 [†]
Less than year 10	12	67	*		
Year 10 to year 12	55	44	0.39	0.10-1.44	
Tertiary education	26	33	0.25	0.07-0.91	
Income					0.311
Social security	111	43	0.66	0.29-1.48	
Work – own or partner	33	33	*		
Parity					0.412
Primiparous	42	33	*		
1	35	37	1.18	0.46-3.02	
>/=2	168	46	1.68	0.75-3.73	
Gravidity					0.400
Primigravidas	40	33	*		
2	32	38	1.25	0.47-3.30	
>/= 3	73	45	1.71	0.77-3.84	
Level of daily stress					0.001** [†]
Low	34	23	*		
Moderate	64	39	2.12	0.92-5.17	
High	36	67	6.80	2.53-18.28	

Appendix 5.6 continued

Variable	n	%S	Odds ratio	95% CI	p value±
Reinforcing factors					
Partner Smoking status	123	37			
Smoker	66	53	4.72	2.09-10.68	<0.001**†
Number of other smokers in the household					
0	44	21	*		0.006**†
1-3	83	48	3.43	1.47-8.04	
>4	15	60	5.67	1.60-20.13	
Ethnicity of father					
Non-Indigenous	20	35	0.88	0.25-3.12	0.063†
Aboriginal	32	59	2.38	0.77-7.34	
Torres Strait Islander	68	31	0.73	0.26-2.01	
Both	21	38	*		

%S=refers to the percentage of women within each response category who are smokers

± p-value is of LR test

Unadjusted odds ratio and p-value for Chi-square tests of each variable with smoking status

* Reference group

** Statistically significant at $p<0.05$ level

† Included in multivariate analysis, as $p<0.25$

Appendix 5.7: Percentage of women who believe that smoking in pregnancy could increase the risk of each adverse outcome

	Yes	Maybe	No	Don't know
Damage to the placenta (the sac that provides air and food the baby when it is growing inside you)	60, 56 (31)	20, 24	1, 0 (11)	18, 20 (59)
Spontaneous abortion or miscarriage (losing the baby)	60, 64 (40)	14, 9	11, 10 (15)	15, 17 (45)
Having a caesarean section	22, 22 (13)	24, 24	18, 15 (29)	35, 39 (59)
Baby being born too soon (premature birth)	77, 78 (55)	14, 12	2, 2 (16)	7, 9 (28)
Low birth weight	88, 90 (77)	4, 2	4, 5 (11)	5, 3 (13)
Slower physical and mental growth of the baby	68, 73 (41)	17, 15	4, 5 (23)	10, 7 (36)
Breathing problems and sickness in infant	90, 90 (57)	6, 8	1, 0 (12)	3, 2 (31)
Lower intelligence when baby grows up	47, 53 (12)	30, 25	8, 9 (41)	16, 14 (48)
Problems with breastfeeding	55, 46 (29)	21, 22	7, 10 (24)	17, 22 (47)
Cot death (sudden infant death syndrome – SIDS)	54, 53 (16)	13, 15	5, 3 (26)	29, 29 (58)
Mother getting diabetes	39, 48	19, 20	9, 5	33, 27
Mother having high blood pressure and increased heart rate	74, 76	14, 14	4, 2	9, 9

Number of women n=145

The first number is the percentage of all respondents (n=145), and the second is the percentage of those who identified themselves as daily or occasional smokers (n=59). The number in brackets indicates the answers given to the same questions in the study conducted by Walsh et al., (n=276).

Appendix 5.8: Percentage of women who agree with the attitude statements

	Very True (Agree)	Quite true	Not at all true (Disagree)	Don't know
It's good to have a smaller baby	0, 0 (8)	4, 2	86, 92 (75)	10, 7 (18)
It's highly unlikely that my baby will be unhealthy	18, 21	22, 24	42, 33	18, 22
Light smoking does not cause harm to unborn babies*	9, 7 (3)	7, 10	78, 70 (65)	6, 14 (31)
Stopping smoking increases the chance of having a healthy baby	86, 93 (82)	10, 3	1, 2 (4)	2, 2 (14)
If you are exposed to a lot of smoke from other people you might as well keep smoking yourself*	9, 10 (15)	15, 25	73, 58 (71)	4, 7 (13)

Number of women N=145

The first number is the percentage of all respondents (n=145), and the second is the percentage of those who identified themselves as daily or occasional smokers (n=59). The number in brackets indicates the answers given to the same questions in the study conducted by Walsh et al. (n=276).

* Significant differences between responses from smokers and non-smokers found in χ^2 tests.

CHAPTER 6

A critical examination of publications relating to the validation of cotinine as a gold-standard measure of cigarette consumption

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Chapter 6

A critical examination of publications relating to the validation of cotinine as a gold-standard measure of cigarette consumption

Introduction

Cotinine is the primary metabolite of nicotine and is a widely applied biomarker of cigarette smoking and exposure to environmental tobacco smoke.¹⁻³ The metabolic profile of nicotine has been widely studied, with cotinine emerging as the most appropriate biomarker due to its stability,^{4, 5} with a half-life of around 20 hours,⁶ and the ability for measurement in a number of biological fluids including blood, saliva, urine,^{6, 7} as well as hair.⁸ Advancing laboratory techniques and reduced costs in recent years have increased the applicability of cotinine analysis in population-based studies in which cost and practicality have previously precluded its use.

While accumulating evidence claims the utility of cotinine as a measure of cigarette smoking, results have been obtained under a wide range of conditions, with limited testing in 'real-life' settings. Differing analysis techniques, sampling conditions and data handling approaches, along with potentially confounding variables in biological and demographic conditions, all influence the results obtained from analyses, and the interpretation of these results.

Extensive research efforts have tested laboratory techniques to quantify cotinine levels in biological samples, but the utility of these techniques under varying environmental and physiological conditions is not clear. A wide range of cut-off points have been used in

different studies and with different analysis techniques, to distinguish smokers from non-smokers. The cotinine cut-off levels which have been used to distinguish between smokers and non-smokers in various studies range from 0ng/mL to 500ng/mL with sensitivity ranging from 77-100% and specificity ranging from 79-100%.⁵ Critically, some studies that have compared cotinine levels with self-reported smoking status have failed to provide information on the biochemical cut-point used.⁹⁻¹¹

Nicotine metabolism and cotinine level are reported to vary substantially both within and between subjects.¹¹⁻¹³ Variables such as age, gender, body composition, genetic variations, alcohol use and patterns of cigarette smoking itself (such as smoking menthol cigarettes, and depth of inhalation) have been reported to influence the rate of nicotine metabolism and thus the level of cotinine in body fluids.¹²⁻¹⁷ Cotinine levels can be detected at a level of sensitivity which enables assessment of exposure to environmental tobacco smoke (ETS).^{18, 19} An increase in the metabolic clearance of nicotine and cotinine by more than 50% has been found to occur during pregnancy, along with an alteration in the profile of nicotine metabolites in urine.²⁰ High intake of some foods such as teas and plants belonging to the Solanaceae family, including tomato and potato, has also been suggested to influence urinary cotinine levels. Davis et al., (1991) report a range of potential values for urinary cotinine concentrations of 0.6 to 6.2ng/mL based on estimated average and maximal consumptions of these foods and beverages.²¹

A number of studies have reported racial differences in serum cotinine levels of cigarette smokers, with higher levels recorded in Black American* smokers than in White or Mexican American smokers, not correlating with smoking rates.^{13, 15, 16, 22, 23} Benowitz et

* "Black", "White" and "Mexican American" are the terms used by the particular authors, and are repeated here by the candidate for correctness.

al., (1999) reported a significantly higher plasma cotinine level normalised for cigarette consumption for 'Blacks' relative to 'Whites' (17.0ng/mL versus 12.6ng/mL).¹⁶ Mustonen et al., (2005) reported similar results, with salivary cotinine/cigarette per day ratios of 18.8ng/mL for 'Blacks' and 28.2ng/mL for 'Whites'.¹³ A study with Chinese-Americans reported that this group had a 35% slower clearance of nicotine, and lower nicotine intake per cigarette than Latinos or Caucasians.²³

While the importance of biochemical validation in smoking cessation trials is widely recognized, another school of thought argues that biochemical validation, and particularly cotinine assessment has questionable usefulness given the potential for inter-subject variability and variations associated with the context of the study.²⁴⁻²⁶ Examples of the limitations of laboratory tests and quantitative measures are found throughout clinical medicine. No gold-standard test for a condition is foolproof, with potential for error or variation in the testing procedure itself, and in both within- and between-patient biological variation.^{27, 28} Examples of tests whose results should be interpreted with some consideration of these influences, include high sensitivity C-reactive protein in cholesterol analysis,²⁷ and glycated haemoglobin (HbA1c) concentration in identifying diabetes mellitus.²⁹ In other cases, such as the diagnosis and assessment of rheumatoid arthritis, no gold-standard tests exist. Limitations are found in each of the approaches to disease assessment, including joint counts, radiographs, and laboratory tests.³⁰

In recognition of the complexities in applying diagnostic or analytical tests to clinical and epidemiological situations, Sackett et al., (1991) have explored the key considerations required to assess the clinical usefulness of a diagnostic test.³¹ This Chapter describes the adaptation of Sackett's eight criteria to develop a set of methodological criteria which are critical in the context of using cotinine measurement to validate self-reported smoking

status in research studies. This required the effective transition from, and interpretation of, laboratory-based tests to draw population-based conclusions. The plethora of potential confounding factors influencing cotinine metabolism and measured levels should be considered in any study using cotinine as a biochemical validation tool. While cotinine is widely accepted as a 'gold standard' it seems that this biomarker and specifically, the cut-points used to distinguish smokers from non-smokers, require validation in the context of population, individual variation, and analysis techniques. This review sought to identify publications relating to such validation studies and to assess these publications against a set of appropriate methodological criteria.

Methods

Literature Searches

Literature searches were conducted to identify publications focusing on the adequacy of cotinine cut-points, or the validation or assessment of tests for cotinine in biological samples. *Medline*, *CINAHL*, *EMBASE.com* and *PsychINFO* were searched, as these databases encompass many major journals publishing findings in the health field including both population-based and biochemical studies.

The search terms were designed to limit the results to those publications which related to the accuracy or validation of a test of actual smoking levels. Thus, publications which included the words 'cotinine', as well as 'validation', including similar terms or derivatives were included. Further searches were performed for publications including the words 'cotinine' as well as 'analysis', 'analyse', or 'measure', and 'accuracy' or 'accurate' were included. Any publications which included these words in the title, article, abstract or

MeSH heading were obtained. Searches were performed to include all publications up to December 2007. The reference lists of included studies were also manually studied to identify any other potentially relevant articles.

Inclusion Criteria

Those publications that dealt with exposure to ETS measured in non-smoking adults or children were eliminated, as the context of these studies made comparison with other validation studies difficult. Also, those that assessed the use of newly developed questionnaires or psychometric analyses and used cotinine for comparison as a 'gold standard' were manually eliminated from further study. It was important for the current study to focus on publications that assessed cotinine analysis methods and used self-report as a 'gold-standard' for comparison, rather than those which used cotinine assessment to validate self-reported smoking status. Searches were limited to English language articles only. Studies that tested a particular laboratory technique or assay for cotinine analysis using laboratory-derived samples as opposed to clinical- or population-derived samples were also eliminated. While these studies are essential in the process of establishing tests to analyse cotinine levels, they do not validate the assays as measures of actual cigarette consumption. Also, studies examining the kinetics of nicotine metabolism in various populations were used as background to this study, but were not scrutinised against methodological criteria.

Development of methodological criteria and coding of papers

Sackett et al., (1991) present eight criteria for assessing the clinical usefulness of a diagnostic test.³¹ These have been adapted as criteria for assessing the credibility of studies which analyse cotinine as a measure of cigarette smoking. The guides that Sackett

and colleagues derived from a number of sources,³²⁻³⁴ as well as their relevance in the context of this study, are described here and summarised, along with the results of the critical review, in Table 6.1.

Table 6.1: Criteria used to assess the adequacy of tests for cotinine and summary of results

Criteria	Number of publications meeting the criteria (%)
<p>1. <i>Has there been an independent, 'blind' comparison with a gold standard?</i></p> <ul style="list-style-type: none"> - Alternative measure used - Blinded assessment 	<p>Total 14 (52)</p> <p>12; CO analysis</p> <p>1; other qualitative test</p> <p>1; questionnaire</p> <p>6 explicitly mentioned (22)</p>
<p>2. <i>Has the test been evaluated in a patient sample that included an appropriate spectrum of high and low levels of cigarette consumption, plus individuals with different but commonly confused cases?</i></p> <ul style="list-style-type: none"> - Smoking level - Alcohol consumption - ETS exposure - Level of ETS exposure - Pregnancy - Gestation - Ethnicity - BMI - Age - Gender - Time since smoking/ETS exposure 	<p>21 (78), 2 N/A</p> <p>1 (3.7)</p> <p>7 (26)</p> <p>4 (15)</p> <p>5 (18) explicitly studied pregnant women, 4 excluded (15)</p> <p>4 (15)</p> <p>10 (37)</p> <p>5 (18)</p> <p>22 (81)</p> <p>22 (81)</p> <p>8 (30), 1 N/A</p>
<p>3. <i>Was the context of the evaluation adequately described?</i></p> <p>Specimen used</p> <ul style="list-style-type: none"> - Blood - Urine - Saliva - Combination 	<p>6 (22)</p> <p>15 (56)</p> <p>9 (33)</p> <p>3 (11)</p>

Table 6.1 continued

Criteria	Number of publications meeting the criteria (%)
<p>3. <i>Was the context of the evaluation adequately described?</i></p> <p>Analysis technique</p> <ul style="list-style-type: none"> - Mass spectrometry/chromatographic methods - ELISA or other enzyme immunoassay - Colorimetry - Radioimmunoassay - Test strip/dipstick - Combination <p>Details regarding collection of test (overt/covert, stimulated/unstimulated)</p> <p>Setting</p> <ul style="list-style-type: none"> - Recruitment specifically for current study - Data or subjects derived from separate study - Intervention studies (smoking cessation trials) <p>Subjects</p> <ul style="list-style-type: none"> - Number - Details of recruitment methods given <p>Consent rates/withdrawal details provided</p>	<p>17 (63)</p> <p>5 (18)</p> <p>2 (7.4)</p> <p>4 (15)</p> <p>2 (7.4)</p> <p>6 (22)</p> <p>7 overt (26), 3 covert (11), 1 N/A (3.7), 16 not clear (59). 14 gave details on collection (52)</p> <p>15 (56)</p> <p>12 (44)</p> <p>9 (33)</p> <p>Number given in all studies. Mean 444, Median 173, Range 10-4532. Total 11995.</p> <p>14 gave some information on recruitment (52)</p> <p>6 provided some details on consent (22)</p>
<p>4. <i>Has the reproducibility of the test result (precision) and its interpretation (observer variation) been determined?</i></p> <ul style="list-style-type: none"> - Reproducibility assessed - Sensitivity - Specificity 	<p>12 (44)</p> <p>13 (48)</p> <p>14 (52)</p>
<p>5. <i>Has the term 'normal' been defined sensibly as it applies to this test?</i></p> <p>Details of the level of smoking used for classification</p> <p>Cut-points provided</p>	<p>11 categorised current smoking level (41), 7 gave definition of level for inclusion criteria but not current level (26).</p> <p>17 gave cut-points (63), N/A in 2.</p>
<p>6. <i>Have the tactics for carrying out the test been described in sufficient detail to permit their exact replication?</i></p>	<p>15 (56)</p>
<p>7. <i>Has the utility of the test been determined?</i></p>	<p>19 (70)</p>

1. Has there been an independent, 'blind' comparison with a gold standard?

Assessment of any diagnostic or screening method should include a comparison of results with those obtained from another recognised, reliable source. Proper validation should include groups of patients shown to be 'positive' or 'negative' by a gold standard analysis, and re-analysed using the test being assessed. In the present study, we consider the need for analyses to use alternative measures of smoking in addition to self-report, such as Carbon Monoxide (CO) analysis, to enable accurate comparison with the result of the cotinine assay. It is also important to consider whether alternative measures and cotinine analyses are performed under circumstances, or by individuals, who are blinded to the self-report data.

2. Has the test been evaluated in a patient sample that included an appropriate spectrum of high and low levels of cigarette consumption, plus individuals with different but commonly confused cases?

The number of cigarettes smoked per day and/or number of smoking days in a week are questions often asked of study participants in order to place them in an appropriate exposure range. It is also important to consider non-smokers, as well as smokers and non-smokers who may be exposed to ETS, which may be seen as a different but commonly confused case.

Considerations which appear to be important in the analysis of cotinine levels in body fluids include the level of cigarette consumption, ETS exposure, time between exposure/cigarette consumption and sample collection, alcohol intake, pregnancy, BMI, age, gender, and ethnicity.^{12-14, 20, 35} Each of these variables may contribute to the level of cotinine measured, and should therefore be taken into consideration when assessing

cotinine levels. The criteria used in the present assessment examines whether a study has taken these potential confounding factors into consideration.

3. Was the context of this evaluation adequately described?

This principle has been related to the need for publications to include details on the type of specimen used. The concentration of metabolites may vary significantly between body fluids such that additional steps may be required in the assay methodology. For example, some samples may require pre-concentration for ease of measure.³⁶ Benowitz et al., (1993)¹⁷ found that cotinine in urine is approximately six times more concentrated than in serum. Jarvis et al., (2003)¹ found that the average cotinine concentration in saliva is 25% higher than that in plasma across the full range of smoking levels. For comparison of results between studies, the specimen used, collection technique, and analysis technique must be taken into consideration. This includes, for example, whether saliva samples were stimulated or un-stimulated, and the method used to inform patients about why a saliva, urine, blood or hair sample is being collected. This factor, as well as whether self-report is gained before or after sample collection or advice of sample collection are important issues, as the accuracy of self-report may be affected by knowledge of the pending biochemical validation.⁵

Another component of study context relates to the setting (type of study and sample population), the subjects (number, characteristics, and methods of recruitment), and the consent and withdrawal rates. Just as in intervention studies, the results of validation studies may be influenced by selection and attrition bias associated with participants.^{24, 37} Given the importance of the ability to generalise results to a wider population, such information is an important component of reporting on validation studies.

4. Has the reproducibility of the test result (precision) and its interpretation (observer variation) been determined?

Many studies test all samples in duplicate in order to assess this measure and ensure that duplicate samples yield very similar results. It is important, particularly with technical analysis procedures that the results are precise, and can be repeated by different technicians or clinicians. This research has therefore examined whether studies report on the reproducibility of results, and the sensitivity and specificity of the tests used.

5. Has the term 'normal' been defined sensibly as it applies to this test?

This guide can be applied to two aspects of the cotinine publications. Firstly, when levels of smoking are grouped into ranges such as low, medium, and high, these need to be defined more specifically with a measure such as the number of cigarettes smoked per day and/or smoking days per week. Also, the cotinine cut-off level used to distinguish between smokers and non-smokers, must be provided in order to define what are classed as 'smokers' and 'non-smokers'.

6. Have the tactics for carrying out the test been described in sufficient detail to permit their exact replication?

Details such as the techniques used for sample collection, transport and storage of samples, solutions, chemicals or equipment used in analysis, and analysis methods should be provided in order to allow replication of the study by other groups.

7. Has the utility of the test been determined?

The efficiency and cost of the analysis methods used should be observed to assess the feasibility of their use in a range of circumstances.

Inter-rater reliability

Ten percent (10%) of papers were randomly selected and coded by a second independent researcher who was unaware of the results of the initial coding. Direct comparison of the coding allocated by each author, using a Kappa statistic revealed substantial agreement between the authors (Kappa 0.75, 88% agreement).

Results

One hundred and eighty three publications relating to the accuracy of cotinine analysis were found in initial searches. Eighty publications (43%) were excluded immediately due to not being relevant at all to this study. Eighty two of the remaining 103 publications (80%) were eliminated due to a focus on validation of self-report or a psychometric tool. These reasons included: eight (10%) focused on the examination of cotinine pharmacokinetics, thirty-five (43%) did not primarily focus on cotinine or were otherwise not relevant to the present study, fourteen (17%) were reviews or discussion papers with no data, twenty (24%) were based on the analysis of a method and used laboratory-derived samples, and three (4%) examined ETS rather than active smoking. Two (2%) potentially relevant studies were unable to be fully assessed as it was unavailable in full-text form.

To the remaining 21 publications, a further ten relevant papers were found and added, by way of trawling reference lists of included studies. Therefore, a total of thirty-one papers were classed as relevant to the present study and were scrutinised against the methodological criteria. The results of this coding are presented in more detail in Appendix 6.1. The list of 31 papers is presented in Appendix 6.2.

1. Has there been an independent, 'blind' comparison with a gold standard?

A total of 17 studies (54.8%) reported using an alternative measure of cigarette consumption as an additional comparison between cotinine level and self-report. Of these studies, 14 used carbon monoxide analysis, which is a useful semi-quantitative measure of recent tobacco smoke exposure.^{4, 38} Gariti et al., (2002) validated a new 'NicoMeter' dipstick method for measuring cotinine as well as more standard Gas Chromatography Mass Spectrometry (GCMS) techniques.³⁹ Holiday et al., (1995)⁴⁰ claimed that extensive questionnaire data was used to assess the degree of misrepresentation obtained from initial self-reported smoking status. Acosta et al., (2004)⁴¹ also used a urine test-strip to complement carbon monoxide analysis and self-report.

The degree to which assessors were blinded to the results obtained through other measures was rarely discussed. Blinding was explicitly mentioned in six studies (22.2%), but insufficient information was provided in the remaining studies for an adequate assessment to be made. A lack of blinding represents methodological weakness, as individuals collecting data may be biased by their knowledge of other results.

2. Has the test been evaluated in a patient sample that included an appropriate spectrum of high and low levels of cigarette consumption, plus individuals with different but commonly confused cases?

As shown in Table 6.1 potential confounding factors were not assessed consistently in the studies examined. Smoking level, age, and gender were the most commonly considered factors, with 25 studies (80.6%) recording smoking level, and 26 (83.9%) recording both age and gender. Nine studies (29%) assessed exposure to ETS, and only four of these considered the level of ETS exposure. Thirteen studies (41.9%) recorded the ethnicity of

subjects, and only six (19.4%) recorded body composition or BMI. Nine studies (29%) considered pregnancy as a confounding factor, including five studies that specifically involved pregnant women, and four that excluded pregnant women. Only one study (3.2%) recorded alcohol consumption of subjects, but did not consider volume or time in relation to sample collection. The time between smoking or ETS exposure and sample collection was recorded in only nine studies (29%).

3. Was the context of this evaluation adequately described?

The analysis technique varied substantially between studies and was, at a minimum, named in 29 (93.5%) of the articles. Seven studies used more than one laboratory technique. For example Gariti et al., (2002) used GCMS to confirm Enzyme-Linked Immunosorbent Assay (ELISA) results.⁴² All of the studies named the specimen used, with three employing two biological samples for comparison. Limited information was provided regarding sample collection however, with details provided in only 16 studies (51.6%). These studies indicated that 24-hour urine samples were collected or saliva excretion was stimulated using cotton wool. It appeared in the remaining studies, that spot urine samples were collected or blood samples were taken under non-fasting conditions, but detailed information was lacking.

Similarly, assessment of the subject's knowledge of the purpose of the sample or test was not possible in sixteen of the studies (51.6%). Of the remaining studies, 11 (35.5% overall) indicated that subjects were aware of the purpose of the sample, three (9.7% overall) indicated that participants were unaware, or the sample was collected after self-reported smoking status was recorded, and this criterion was not applicable in one study, in which the smoking behaviors and conditions were controlled as part of the study protocol.²⁰

The setting of the study varied substantially. Nineteen studies (61.3%) recruited participants specifically for the study in question, while twelve (38.7%) used data or participants derived from a separate study. Six studies (19.4%) were, or used data from, smoking cessation interventions while others used participants who were not under any pressure to quit. The number of subjects ranged from 10 to 4532, with a total of 12 500 subjects reported on in the 31 included studies. Eighteen studies (58.1%) provided some information on recruitment methods, and six (19.4%) gave details regarding consent rates. Only one study (3.2%) detailed withdrawal rates.

4. Has the reproducibility of the test result (precision) and its interpretation (observer variation) been determined?

A test of the reproducibility of the test results was explicitly mentioned in 14 (45.2%) of the included studies. Thirteen (41.9%) and fourteen (45.2%) of the studies discussed some measures of sensitivity and specificity of the analysis respectively. Of those studies that provided details in the form of a percentage, the sensitivity of tests ranged from 56.0%-100% (mean 91.51%, median 81.0%, 95%CI 82.6%-upper limit of confidence of 100%), and specificity ranged from 76.8%-100% (mean 92.6%, median 89.0%, 95%CI 88.5%-upper limit of confidence of 100%). Some studies reported on correlations between cotinine and certain variables using a regression coefficient. For consistency however, only sensitivity and specificity are reported here.

5. Has the term 'normal' been defined sensibly as it applies to this test?

While smoking level was assessed in 25 studies (80.6%), details of the level of smoking used to classify or group individuals were only provided in eleven studies (35.5%). A

further seven studies (22.6%) gave a definition of the smoking levels used in inclusion criteria, but failed to detail current smoking levels. Seventeen studies (54.8%) detailed the cotinine cut-point used to distinguish smokers from non-smokers. Where cut-points were provided and given in ng/mL, they ranged from 1.1 to 500ng/mL (mean 92.4ng/mL, median 50ng/mL, 95%CI 31.3–153.4ng/mL).

6. Have the tactics for carrying out the test been described in sufficient detail to permit their exact replication?

Only 19 studies (61.3%) were assessed as having described their methods in sufficient detail to enable replication.

7. Has the utility of the test been determined?

Some evaluation of the work involved, the cost of the analyses used, or the applicability of the tests in epidemiological studies was possible in 20 (64.5%) of the publications. Some tests are highly efficient, but cost or feasibility of sample collection in the field precludes routine use. On the other hand, other tests such as the urine test strip are practical for field situations and are relatively inexpensive, but not as reliable or efficacious as other tests. Boswell et al., (2000)¹¹ studied the levels of unconjugated nicotine and its metabolites in urine to determine the best combination to estimate nicotine intake. They concluded that the best estimate was obtained using nicotine and seven of its main metabolites in a 24-hour urine excretion sample, but that the added accuracy of this model over the analysis of fewer metabolites was not justified by the additional work and cost involved. Further, the use of 24-hour urine samples is rarely feasible in population-based studies.

Discussion

This study highlights the difficulties faced by investigators conducting population-based studies relating to cigarette smoking or nicotine intake from other sources. The findings presented here suggest that very few publications in the last decade have adequately validated the cotinine level cut-points or approaches to cotinine analysis and interpretation of results that are now routinely used to validate self-reported smoking status in research studies.

The need to validate cotinine cut-points presents an interesting situation, in that for studies that scrutinise the reliability of a test for cotinine, self-report becomes the 'gold standard' and is used as a comparison to enable calculation of the sensitivity and specificity of a particular approach. Treating self-report as an accurate measure of cigarette consumption can be highly problematic. Therefore it is critical that methods that do this also use an alternate measure of the accuracy of self-report, such as CO analysis or a collateral report.

Expired air CO levels are useful in assessing recent smoking behavior, but this measure is far less reliable and sensitive than cotinine analysis.^{1, 4, 43} In this case however, it is appropriate to use a less robust test for initial analysis to validate self-report before progressing to cotinine analysis. Such procedures are used in many clinical diagnostic settings, with an initial screen performed to assess the value of a more robust, usually more costly diagnostic test. For example in the diagnosis of breast cancer, an initial mammography is used to detect the presence of an abnormality before more extensive imaging or biopsy is performed. Of the twenty-seven studies examined, only half (n=14) used an alternate semi-quantitative measure. CO analysis was employed in ten of these studies. Secker-Walker (1997) reported that their cotinine measures (urinary

cotinine/creatinine ratio) were more highly correlated with CO than with self-report.⁴⁴ This raises a question over the validity of those studies which did not use an alternate measure.

The results show that very few studies assessed key variables such as ethnicity, ETS exposure, alcohol consumption, and pregnancy. The only variables assessed in more than 50% of the publications were age, gender, and level of smoking. None of the papers assessed all variables; raising the question “do any of these publications adequately validate cotinine analysis and cut-points for population-based studies?”

There was substantial variation in inclusion criteria and participant group between each study, highlighting the degree of variation in the setting for cotinine analysis. Participants included patients suffering from various chronic diseases,^{45, 46} pregnant women,⁴⁴ and asbestos workers.⁴⁰ The context of the studies varied substantially. While the majority of studies (n=19, 61.3%) recruited participants specifically for the validation research, the remaining 38.7% (n=12) used data derived from, or subjects recruited for a separate study. Further, 19.4% of studies (n=6) used data derived from smoking cessation trials, which influences the characteristics of subjects, and can subsequently influence the results in terms of the accuracy of self-report in a setting in which smokers may be under pressure to quit.

It has been argued that the usefulness of biochemical validation varies as a function of the type of population (randomly selected community members versus motivated volunteers), the type of study (descriptive versus intervention), and the demand characteristics (smoking status determined by a third party or as part of follow-up for an intervention).⁴⁷ These variations in context and the range of settings and participant groups used in included studies further highlights the need for validation, and for appropriate reporting of

these variables in validation studies. While most studies provided some description of the setting and sample population, only 58.1% described the recruitment methods used, and 19.4% provided information regarding consent and withdrawal rates.

Cut-points used to distinguish smokers from non-smokers ranged from 1.1ng/mL¹ to 500ng/mL⁴⁸ with the various assay techniques and samples used. It is interesting to note that in the two studies that used two different techniques to analyse the same samples, significantly different cut-points were used for each set of results. Hobbs et al., (2005) used a cut-point of 100ng/mL for results obtained through ELISA, and 500ng/mL for results of colorimetric assays.⁴⁵ Gariti et al., (2002) used 200ng/mL as the cut-point for ELISA results, and 50ng/mL for GCMS results.⁴² This result clearly illustrates the need for validation of cut-points and the inappropriate nature of using arbitrary markers to validate self-report. The cut-points appropriate for distinguishing smokers and non-smokers differ according to the estimates of cotinine concentration which can vary from one laboratory to another⁴⁹ and under differing conditions such as the antibodies and reagents used in analyses.⁴⁴

One study performed statistical analysis to estimate the cut-points which could distinguish non-smokers, passive, and active smokers. Sensitivity was sufficient to distinguish not only between these key groups, but between minimal and high levels of passive smoke exposure and active smoking.⁵⁰ While the study has great validity and provides highly useful information, these cut-points should not be applied to studies using different biological samples and analysis techniques, or different population groups.

While most studies reported good sensitivity and specificity of results, the sample collection and analysis techniques were inadequately described in many studies. Details

regarding sample collection were generally lacking, and only 19 studies (61.3%) provided sufficient detail of their methods to enable replication. This weakness reduces the value of many of these studies for other researchers. Validation of cotinine cut-points in various populations, with comprehensive consideration and documentation of the context (potential confounding factors and analysis methods) of each such validation, would provide invaluable information for other researchers who wish to employ cotinine as a gold-standard measure of nicotine intake.

This analysis may be flawed in that only four major health publication databases were searched, and searches were limited to the last decade. Therefore, all publications relating to the validation of cotinine analysis in population-based studies may not have been located. Extensive literature searching outside these search terms was conducted to establish a background for this study. No further eligible papers were identified in this process. The candidate is therefore confident that this review has captured the majority of relevant peer reviewed articles, and provides a useful insight into the literature in this field.

It is interesting to note that a large volume of work was identified, which related to developing and refining advanced laboratory techniques to identify cotinine and other nicotine metabolites in biological samples.⁵¹⁻⁵⁹ The utility of highly sensitive, but laborious assays in population-based studies is questionable. Useful information is however, provided by studies that examine the practicalities of analysis techniques and consider factors such as sample stability during shipment and storage, and sample collection approaches.^{1, 48, 60} A further body of work examines the kinetics of nicotine metabolism, and the differences in these processes in different ethnic groups or with behavioral patterns such as inhalation depth or the use of mentholated cigarettes.^{12-17, 23, 61}

With only 13 studies identified which could be classed as 'validation' studies, it appears that a gap exists in this field. Evidence exists for the efficacy of various laboratory techniques to analyse cotinine in biological samples, and for the applicability of cotinine as a biomarker of nicotine intake. Recently, a substantial volume of research has described the pharmacokinetics of nicotine metabolism and the spectrum of factors that influence cotinine levels and cause inter-subject variability.^{14, 16, 17, 23, 61, 62} The results of the present study suggest that these research findings have not been translated into the undertaking of validation studies necessary in population-based applications of cotinine measurement.

The fact that no studies appear to have adequately examined these factors before using cotinine to validate smoking status in population studies, suggests that the use of this biomarker as a gold standard may be flawed. If the use of cotinine analysis as a gold standard measure of cigarette consumption is to continue, it should be properly validated in each participant group and setting.

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Appendix 6.1: Characteristics of validation studies

(See following pages)

Author	1. Alternate measure		2. Confounding factors										3. Context					4. Reproducibility			5. Definition of normal		6. Replication possible?	7. Utility determined?		
	Measure	Blinded?	Smoking level	Alcohol	ETS	ETS level	Pregnancy	Gestation	Ethnicity	BMI	Age	Gender	Timing	Specimen	Technique	Overt/covert, stim/unstim	Setting	Subjects	Consent rate	Reprod.	Sensitivity	Specificity			Details of smoking levels	Cut-points
Abrams	CO	Yes	Y	N	N	-	N	-	N	N	Y	Y	Y	Saliva	RIA	Not clear Unstimulated	Smoking cessation programs	Worksite 63) or hospital employees (96) - recruitment method not detailed	Not clear	Y	95%	91%	Light <25, Heavy>=25 CPD	10ng/mL	No	Good accuracy and reliability - no discussion of lab tech
Acosta	CO	Not clear	Y	N	N	-	EX CL	-	N	N	Y	Y	Y	Urine	Test strip GCMS	Overt Not clear	Assessment of test strips as a measure of smoking status during a 96 hour period of attempted abstinence	44 smokers - recruitment methods not detailed	Not clear	NC	100%	83.8%	Controlled	100ng/mL	Yes	Yes - limitations of test strip
Altman	CO	Yes	N	N	N	-	N	-	N	N	Y	Y	N	Urine	ELISA GCMS	Not clear Not clear	Re-analysis of patient samples from a smoking cessation study of 240 one-or-more packs/day smokers	71 stored urine samples used from participants in smoking cessation study	Not clear	Y	Not clear	Not clear	> 1 pack/day	200ng/mL ELISA 50ng/mL GCMS	No	Yes - ELISA as less costly alternative to GCMS
Albrecht	CO	Not clear	Y	N	N	N	Y	Y	Y	N	Y	Y	N	Saliva	GCMS	Not clear Not clear	Smoking cessation intervention trial	109 pregnant adolescents in smoking cessation trial	Not clear	N	62.9%	86.5%	Min 1CPD	10ng/mL	No	Compared practicality and reliability of cotinine and CO

Author	1. Alternate measure		2. Confounding factors										3. Context					4. Reproducibility			5. Definition of normal		6. Replication possible?	7. Utility determined?		
	Measure	Blinded?	Smoking level	Alcohol	ETS	ETS level	Pregnancy	Gestation	Ethnicity	BMI	Age	Gender	Timing	Specimen	Technique	Overt/covert, stim/unstim	Setting	Subjects	Consent rate	Reprod.	Sensitivity	Specificity			Details of smoking levels	Cut-points
Behara	None	Not clear	N	N	Y	N	N	_	N	N	Y	Y	N	Urine	HPLC	Overt 24 hour	Specific recruitment for validation study from hospital community	130 healthy volunteers - recruited from attendents of patients in Department of Pulmonary Medicine, North India	Not clear	N	Not clear	Not clear	Min 1 CPD for min 1year	Not clear	Yes	Yes - useful marker of different types of tobacco use
De Leon	CO	Not clear	Y	N	Y	N	N	_	N	N	Y	Y	Y	Plasma	HPLC	Overt am/pm	Validation study - subjects recruited from community	76 White volunteers - hospital staff and their families	Not clear	Y	Not clear	Not clear	<= 20 CPD, > 20 CPD	Not clear	Yes	Yes - good biomarker for epidemiologic studies
Dempsey	None	Not clear	N/A	N	N	_	Y	Y	Y	Y	Y	Y	Y	Urine Plasma	GCMS	N/A Controlled	Specific recruitment for validation study from community	Eligible women (pregnant, smokers) recruited through newspaper advertisements and flyers. 10 completed study	Not clear	Y	Not clear	Not clear	N/A	N/A	Yes	No
Elter	None	Not clear	Y	N	N	_	N	_	N	N	Y	Y	N	Saliva	GCMS	Overt Not clear	Population sample in Geneva to develop more accurate self-report measures	Random sample of 2000 adults drawn from official registry of Geneva residents (98 included in cotinine analysis component)	25% return rate for baseline, 28% for saliva comonent	Y	Not clear	Not clear	Not given	Not clear	No	No N/A

Author	1. Alternate measure		2. Confounding factors										3. Context					4. Reproducibility			5. Definition of normal		6. Replication possible?	7. Utility determined?		
	Measure	Blinded?	Smoking level	Alcohol	ETS	Pregnancy	Gestation	Ethnicity	BMI	Age	Gender	Timing	Specimen	Technique	Overt/covert, stim/funstim	Setting	Subjects	Consent rate	Reprod.	Sensitivity	Specificity	Details of smoking levels			Cut-points	
Gariti (1)	2 tests	Yes	Y	N	N	_	N	_	Y	N	N	N	N	Urine	Dipstick GCMS	Overt Spot urine	Pulmonologist and thoracic surgeons offices	80 consecutive new outpatients	Not clear	NC	100%	91%	Current level not defined	100ng/mL dipstick 50ng/mL GCMS	Yes	Yes - valid, easy to use, inexpensive
Gariti (2)	CO	Not clear	Y	Y	N	_	EX CL	_	Y	N	Y	Y	N	Urine	ELISA GCMS	Covert Not clear	Trial of efficacy of psychosocial smoking cessation interventions	240 volunteer participants in university-based study	Not clear	Y	97.1%	76.8%	Not given	200ng/mL ELISA 50ng/mL GCMS	Yes	Yes - accurate and useful but expensive
Glasgow	CO	Not clear	N/A	N	N	_	N	_	N	N	N	N	N/A	Saliva	GCMS	Covert Unstimulated	Smoking cessation programs	798 in 4 RCTs (outpatient, inpatient, worksite, dental)	Average 73%	N	Not clear	Not clear	All self-reported quitters	25ng/mL	No	No
Greaves	None	Not clear	N	N	Y	Y	Y	N	N	N	N	Y	N	Urine	HPLC	Not clear Not clear	Smoking cessation intervention trial	173 pregnant smokers or 'recent quitters' enrolled in smoking cessation trial	Not clear	N	99.9%	89%	Current level not defined	28ug/mmol	Yes	Yes - fast, inexpensive, reliable
Heinrich	None	Not clear	Y	N	Y	Y	N	_	N	N	Y	Y	N	Urine	HPLC	Not clear am	Cohort of patients from German National Health Interview and Examination Survey of adults for Environmental Survey	Random selection of participants - representative sample, 4532 for final analysis	54.5% consent. Complete data available for 98% of original sample	N	Not clear	98%	</=2, 3-5, 6-10, 11-15, 16-20, 21-30, >30	Not clear	Yes	No

Author	1. Alternate measure		2. Confounding factors										3. Context					4. Reproducibility			5. Definition of normal		6. Replication possible?	7. Utility determined?		
	Measure	Blinded?	Smoking level	Alcohol	ETS	ETS level	Pregnancy	Gestation	Ethnicity	BMI	Age	Gender	Timing	Specimen	Technique	Overt/covert, stim/unstim	Setting	Subjects	Consent rate	Reprod.	Sensitivity	Specificity			Details of smoking levels	Cut-points
Hobbs	CO	Yes	Y	N	N	-	N	-	N	N	Y	Y	N	Urine	ELISA Colorimetry	Not clear am	Assessment of smoking status in patients with peripheral arterial disease	100 consecutive patients diagnosed with intermittent claudication in vascular surgical outpatient department	Not clear	N	100%	98%	Not given	100ng/mL	Yes	Yes - discussed pros and cons CO vs cotinine
Holiday	Q'aire	Not clear	Y	N	N	-	N	-	Y	N	Y	Y	N	Serum	RIA	Not clear Not clear	Beta Carotene, retinol, and lung cancer prevention project	614 - recruitment methods not detailed	Not clear	N	100%	96.1%	Not given	22.2ng/mL	Yes	Yes - useful for detection of smokeless tobacco use
Jarvis	None	Yes	Y	N	N	-	N	-	N	Y	Y	Y	N	Plasma Saliva	GCMS	Not clear Stimulated	Sample of respondents on 1998 Health Survey for England	567 respondents	Not clear	Y	Not clear	Not clear	1-4, 5-9, 10-14, 15-19, 20-24, 25+ CPD	Not clear	No	No
Jones-Burton	CO	Not clear	Y	N	N	N	N	N	N	Y	Y	Y	N	Urine	HPLC	Overt 24-hour urine	Specific recruitment to validate cotinine among CKD patients	61 Chronic kidney disease patients	Not clear	Y	Not clear	Not clear	CPD - not defined	Not clear	Yes	Yes - urinary cotinine remains strong predictor of smoking even with CKD

Author	1. Alternate measure		2. Confounding factors											3. Context					4. Reproducibility			5. Definition of normal		6. Replication possible?	7. Utility determined?	
	Measure	Blinded?	Smoking level	Alcohol	ETS	ETS level	Pregnancy	Gestation	Ethnicity	BMI	Age	Gender	Timing	Specimen	Technique	Over/covert, stim/unstim	Setting	Subjects	Consent rate	Reprod.	Sensitivity	Specificity	Details of smoking levels			Cut-points
Kemmeren	None	Not clear	Y	N	Y	Y	N/A	-	N	Y	Y	Y	N	Plasma	GCMS	Not clear Nonfasting	Participants derived from study on effects of Beta carotene on genotoxicity in smokers	268 healthy male volunteers, recruitment method not detailed	Consent not clear, 5.2% withdrew	Y	56%	89%	>15 CPD	1.1 ng/mL	No	Yes - good applicability in population
Malaiyandi	CO	Not clear	Y	N	N	N	N	-	Y	N	Y	Y	N	Plasma	HPLC	Not clear Not clear	Recruitment from health centre specifically for validation	152 Caucasian smokers	Not clear - volunteers	Y	Not clear	Not clear	CPD - not defined	Used level only	Yes	No
Mustonen	CO	Not clear	Y	N	N	-	EXCL	-	Y	Y	Y	Y	Y	Saliva	RIA	Not clear Not clear	RCT of individualising transdermal patch therapy - sample of participants used for this investigation	359 participants - recruited through newspaper advertisements - all smoked min 10CPD and motivated to quit	Not clear	Y	Not clear	Not clear	Min 10 CPD	Not clear	No	No
Neibala	CO	Not clear	Y	N	N	-	N	-	N	N	N	N	N	Urine	EIA, GCMS	Covert Not clear	Recruitment specifically for validation	281 volunteers	Not clear	Y	96.2%	98.4%	0-1, 1-10, 11-20, 21-40, >40 CPD	500ng/mL	Yes	Yes - applicable to population, accurate

Author	1. Alternate measure		2. Confounding factors										3. Context					4. Reproducibility			5. Definition of normal		6. Replication possible?	7. Utility determined?			
	Measure	Blinded?	Smoking level	Alcohol	ETS	ETS level	Pregnancy	Gestation	Ethnicity	BMI	Age	Gender	Timing	Specimen	Technique	Overt/covert, stim/unstim	Setting	Subjects	Consent rate	Reprod.	Sensitivity	Specificity			Details of smoking levels	Cut-points	
Prez-Sable	None	Not clear	Y	N	N	N	N	-	Y	Y	Y	Y	N	Serum	GCMS	Not clear	Not clear	Participants in Hispanic Health & Nutrition Examination Survey	745 participants randomly selected from population survey	Not clear	Y	Not clear	Not clear	0, 1-9, 10-19, >=20 [0-4mg/mL= NS, 15-100 =light, 101-200= moderate, >200= heavy]	14ng/mL	No	Limited
Pickett	None	Not clear	Y	N	N	-	Y	Y	Y	N	Y	Y	N	Urine	Not clear	Not clear	Not clear	Data from prospective study in neighbourhood health clinic - ante- and post-natal nicotine exposure	998 provided data at visit one, 305 for CO and cotinine correlations	73% of eligible women attending clinic	N	88.4%	99%	NS 0, light 1-5, med 6-10, heavy 11-15, v. heavy 16+ CPD	200ng/mL	No	Yes - authors question the practicality of cot testing in atenatal setting
Secker-Walker	CO	Not clear	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Urine	RIA	Not clear	Not clear	Part of RCT of smoking cessation and relapse-prevention counseling among pregnant women	521 smokers recruited at first antenatal visit	96%	NC	Not clear	Not clear	Not given	cot/creat </=550ng/mL	Yes	Yes - discussed pros and cons CO vs cotinine
Smith	None	Not clear	Y	N	N	-	N	-	N	N	Y	N	N	Urine	Colorimetry	Not clear	Not clear	Diabetic clinic - validating procedures in diabetic patients	251 - recruitment methods not detailed	Not clear	N	95%	100%	Not given	20ng/mL	Yes	Yes - rapid, simple qualitative assessment

Author	1. Alternate measure		2. Confounding factors											3. Context					4. Reproducibility			5. Definition of normal		6. Replication possible?	7. Utility determined?	
	Measure	Blinded?	Smoking level	Alcohol	ETS	ETS level	Pregnancy	Gestation	Ethnicity	BMI	Age	Gender	Timing	Specimen	Technique	Overt/covert, stim/unstim	Setting	Subjects	Consent rate	Reprod.	Sensitivity	Specificity	Details of smoking levels			Cut-points
Stepanov	Nicotine, cotinine, and 3-hydroxycotinine in plasma	Not clear	Y	N	N	N	N	N	N	N	Y	Y	N	Toenail	LCMS	Overt Not clear	Specific recruitment for validation of new method	105 healthy smokers	N/A volunteers	Y	Not clear	Not clear	Smoked >= 1 year - amount not defined	Not used	Yes	Reflects exposure over several months, cost not discussed
Stokey	CO	Yes	N	N	N	N	N	_	N	N	N	N	N	Saliva	GCMS	Not clear Stimulated	Participants in smoking cessation trial	216 smokers and 102 proclaimed quitters from trial + 20 known non-smokers	Not clear	Y	99.1%	100%	Not clear	10ng/mL	Yes	Compared practicality and reliability of cotinine and CO
Swan	None	Not clear	Y	N	N	_	N	_	N	N	Y	Y	Y	Saliva	GCMS	Overt Unstim (abs)	Recruitment specifically for validation	116	Not clear	NC	Not clear	Not clear	1-9, 10-14, 15-30	N/A	No	No
Zielinska-Danch	None	Not clear	Y	N	Y	Y	N	_	Y	N	Y	Y	N	Urine	HPLC	Not clear Fasting	Recruitment specifically for validation	187	Not clear	Y	Not clear	Not clear	CPD, time actively smoking, time spent with smokers in a day	50, 170, 550, 2100 ug-1 to distinguish various groups	Yes	No
Ziegler	None	Not clear	Y	N	Y	N	N	_	N	N	Y	Y	Y	Urine	ELISA	Not clear Mid-stream am	Examining appropriateness of routine ELISA in plastic surgery and operative disciplines	165 patients recruited from department of surgery	Not clear	Y	Not clear	Not clear	1-9, 10-19, >/= 20 CPD	Not clear	Yes	Yes - claim good sensitivity and specificity

HPLC; High performance liquid chromatography, ELISA; Enzyme-linked Immunosorbent Assay, GCMS; Gas Chromatography Mass Spectrometry, LCMS; Liquid Chromatography Mass Spectrometry, RIA; Radio-Immuno Assay.

Appendix 6.2: Thirty-one papers classed as relevant to the present study

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5. Behera, D., R. Uppal, and S. Majumdar, Urinary levels of nicotine & cotinine in tobacco users. *Indian Journal of Medical Research* 2003. **118**: p. 129-33.
6. Boswell, C., Curvall, M., Elswick, Jr, R.K., and Leyden, D., Modelling nicotine intake in smokers and snuff users using biological fluid nicotine metabolites. *Biomarkers* 2000. **5**(5): p. 341-354.
7. de Leon, J., Diaz FJ, Rogers T, Browne D, Dinsmore L, Ghosheh OH, Dwoskin LP, Crooks PA. Total cotinine in plasma: a stable biomarker for exposure to tobacco smoke. *Journal of Clinical Psychopharmacology* 2002. **22**(5): p. 496-501.
8. Dempsey, D., P. Jacob, 3rd, and N.L. Benowitz, Accelerated metabolism of nicotine and cotinine in pregnant smokers. *Journal of Pharmacology and Experimental Therapeutics* 2002. **301**(2): p. 594-8.
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11. Gariti, P, Alterman AI, Ehrman R, Mulvaney FD, O'Brien CP. (2). Detecting smoking following smoking cessation treatment. *Drug and Alcohol Dependence* 2002. **65**(2): p. 191-6.
12. Glasgow RE, Mullooly JP, Vogt TM, Stevens VJ, Lichtenstein E, Hollis JF, Lando HA, Severson HH, Pearson KA, Vogt MR . Biochemical validation of smoking status: pros,

cons, and data from four low-intensity intervention trials. *Addictive Behaviors* 1993. **18**(5): p. 511-27.

13. Greaves R, Trotter L, Brennecke S, Janus E. A simple high-pressure liquid chromatography cotinine assay: validation of smoking status in pregnant women. *Annals of Clinical Biochemistry* 2001. **38**(Pt 4): p. 333-8.
14. Heinrich, J., Holscher B, Seiwert M, Carty CL, Merkel G, Schulz C. Nicotine and cotinine in adults' urine: The German Environmental Survey 1998. *Journal of Exposure, Analysis, and Environmental Epidemiology* 2005. **15**(1): p. 74-80.
15. Hobbs, S.D., Wilmink AB, Adam DJ, Bradbury AW. Assessment of smoking status in patients with peripheral arterial disease. *Journal of Vascular Surgery* 2005. **41**(3): p. 451-6.
16. Holiday, D.B., McLarty JW, Yanagihara RH, Riley L, Shepherd SB. Two biochemical markers effectively used to separate smokeless tobacco users from smokers and nonusers. *Southern Medical Journal* 1995. **88**(11): p. 1107-13.
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22. Niedbala, R.S., Haley N, Kardos S, Kardos K. Automated homogeneous immunoassay analysis of cotinine in urine. *Journal of Analytical Toxicology* 2002. **26**(3): p. 166-70.
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CHAPTER 7

Establishing cotinine cut-points for smoking in antenatal Aboriginal and Torres Strait Islander women

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Chapter 7

Establishing cotinine cut-points for smoking in antenatal Aboriginal and Torres Strait Islander women

Introduction

It is of critical importance in the conduct of methodologically rigorous research to clearly define outcome measures. With an array of potential biases and influences upon individual's responses, where these measures are based on self-report they should be validated using biochemical markers.¹ As discussed previously (see Chapter 6), cotinine is regarded as the gold standard biochemical measure of cigarette consumption, and has been widely utilised in smoking cessation research. However, with substantial variation in cotinine levels according to ethnicity, gender, body composition and environmental tobacco smoke exposure, this measure should be validated in the specific context of each study in which it is used.

What individual and environmental factors influence cotinine levels?

It is important to ensure that any biochemical marker used to distinguish between smokers and non-smokers is appropriate for the group under study. With unique genetic profiles, influences of metabolic changes associated with pregnancy and high levels of exposure to passive smoke in some groups, the cut-points used with high sensitivity and specificity in other populations may have decreased utility in a group of pregnant Aboriginal and Torres Strait Islander women. Potential influences of ethnicity, stage of pregnancy, BMI, alcohol consumption, medication use, and exposure to passive smoke should be considered. As discussed in Chapters 1 and 2, Aboriginal and Torres Strait Islander Australians are at risk of high BMI and obesity, high levels of

passive smoke exposure and risky levels of alcohol consumption. Each of these factors has the potential to impact upon cotinine concentration. The nature of any relationship between cotinine and these factors, and their impact upon the capacity for cotinine to validate self-report and quantify smoking levels has not been characterised in this group. With different population norms, it is possible that individual and environmental factors, and their impact upon the concentration of cotinine in urine, may also differ. It is beyond the scope of this Thesis however, to examine these possible differences.

The validation of cotinine as a measure of smoking requires comparison with another biochemical measure.² As discussed in the previous Chapter (Chapter 6), this leads to a complex situation in which the validity of a less robust measure must be trusted over that of a gold-standard. In such a situation, the secondary measure should be assessed to ensure its highest possible accuracy. Expired air carbon monoxide analysis has been widely used as a secondary validation tool in smoking research.³⁻⁷ While this measure is less powerful than cotinine in quantifying the level of nicotine consumption,^{8,9} it is sufficiently accurate for the clinical detection of smokers.⁹

What is the most appropriate cotinine cut-point to distinguish smokers from non-smokers among antenatal Aboriginal and Torres Strait Islander women?

Just as the unique characteristics of the Aboriginal and Torres Strait Islander population have the potential to influence relationships between cotinine concentration and its various confounding factors, it is also possible that a different cut-point will be required to differentiate between smokers and non-smokers. It is necessary to establish a cut-point appropriate for this population.

What proportion of women accurately report smoking status?

A significant level of misreport occurs during questionnaire-based analysis of smoking behaviour.^{10 11} In particular during intervention studies there is a tendency for participants in the trial group to under-report smoking behaviours.^{12 13} Several American and British studies have reported that up to 25% of pregnant smokers falsely declare themselves to be non-smokers due to social pressure or knowledge of adverse effects.^{14 15} As such, it is critical to validate self-report with a quantitative biochemical marker.

As discussed in Chapter 6, the culture of Aboriginal and Torres Strait Islander Australians is distinct from the non-Indigenous population in many key areas, including the perception of normality about smoking among this group. High rates of cohabitation and smoking are associated with passive smoking levels and social practices which may impact upon a woman's attitude towards admitting to smoking during pregnancy. It might be hypothesised that the normality of smoking leads to a higher accuracy of self-report, with women less inclined to deny smoking due to social stigma. On the other hand however, with substantial levels of knowledge regarding the risks associated with antenatal smoking (Chapter 6), women may be inclined to deny their continued smoking.

In order to establish an estimation of the error associated with the assessment of smoking status and smoking cessation in a research or intervention context, it is important to examine the overall accuracy of self-report among this population.

Objectives

The research described in this Chapter consists of three components which aim to establish a sound methodological background for the measurement of smoking and smoking cessation rates with pregnant Aboriginal and Torres Strait Islander women.

The three main aims of this study are to:

1. Explore the influence of environmental and individual variables upon urine cotinine levels detected in pregnant Aboriginal and Torres Strait Islander women, assessing the robustness of cotinine as a measure of cigarette consumption among this group;
2. Establish accurate, reliable cut-off levels for cotinine analysis to detect smoking in this population group; and
3. Use these cut-points to assess the accuracy of self-reported smoking status among this group.

Ethical approval for this research was granted from the University of Newcastle Human Research Ethics Committee, and was endorsed by the Boards of Townsville Aboriginal and Islander Health Service and Wuchopperen Health Service. Refer to Appendix 5.2 and 5.3 from Chapter 5. Refer to Appendix 7.1 for University Certificate of Approval.

Methods

The criteria used in Chapter 6, based on Sackett's approach to assessing the validity of a diagnostic test,² formed the basis of the rationale and methods used to address aims 1 and 2 (Refer to Box 7.1).

Box 7.1: Adapted criteria for the validation of a diagnostic test

Sackett's approach emphasises the need for studies to address the following points in the validation of a diagnostic test:

1. An independent, 'blind' comparison with a gold standard;
2. Evaluation in a patient sample including an appropriate spectrum of high and low levels of cigarette consumption, plus individuals with different but commonly confused cases
3. The context of the evaluation
4. Interpretation and reproducibility of the test
5. Defining smoking and smoking levels
6. The test tactics
7. The utility of the test

Recruitment

Aboriginal and Torres Strait Islander women aged 16 years or over, who attended Townsville Aboriginal and Islander Health Service (TAIHS) or Wuchopperen for antenatal care were eligible for the study. At TAIHS, only women taking part in the pilot randomised controlled trial (i.e. smokers only) were invited to participate in this study. Exclusion criteria were the current treatment of chemical dependency other than tobacco or alcohol (i.e. cannabis or heroin) and any florid mental illness. Recruitment was performed by a trained project officer at each health service (see Chapter 9), who provided a detailed verbal and written explanation of the study during routine clinic visits. Women were asked for written informed consent to allow a portion of their routinely provided urine sample to be used for cotinine analysis (refer to participant

information statement and consent form in Appendix 5.4). Individuals recruited at Wuchopperen from February 2005 to April 2007 also participated in expired air carbon monoxide analysis. Data from this sub-group were assessed in the validation of cotinine measurement and establishment of appropriate cut-points. If women consented, they were also provided with assistance to complete a 24-hour retrospective diary detailing their smoking level, alcohol intake and exposure to environmental tobacco smoke, as well as their BMI and any current medications. The 24-hour diary is presented in Appendix 7.2. Both smokers and non-smokers, unexposed, or exposed to varying levels of environmental tobacco smoke were examined to ensure a full spectrum of nicotine exposure.

Urine samples collected from all participants (recruited at both Wuchopperen and TAIHS), along with the accompanying self-report data collected in 24-hour retrospective diaries was included in the analysis of environmental and individual influences upon cotinine level, as well as the examination of the accuracy of self-report for aim 3.

Urine cotinine analysis

Urine samples were collected into specimen cups and a portion of the sample was transferred to a dedicated 1.5mL tube before any dip-stick tests were performed. Samples were refrigerated immediately after collection and frozen at –20 degrees celcius at Queensland Medical Laboratory (QML) Pathology labs close to each health service. Samples were then kept frozen and shipped overnight by TNT Couriers to an Immunology laboratory at The University of Newcastle, NSW, for analysis. Evidence exists for the stability of cotinine in urine being frozen for up to ten years¹⁶ and during frozen long-distance transport conditions.¹⁷

A 'Cozart'® microplate ELISA test kit was used for analysis. The kit was used according to the manufacturers instructions. Briefly, samples were thawed at room temperature, and 10µL of sample or cotinine calibrator (0ng/mL, 50ng/mL, 500ng/mL, 1250ng/mL, 2500ng/mL, 5000ng/mL) was added to each well. All samples were analysed in duplicate, and depending upon the nature of any substantial discrepancies, the value outside of the standard range was eliminated, or analysis was repeated. 100µL of cotinine enzyme was added to each well, and plates were incubated at room temperature for 30 minutes. Plates were then washed four times with 350µL of wash buffer and 100µL of substrate solution was added to each well. After incubation for 30 minutes at room temperature, 100µL of stop solution was added to each well and absorbance was read at 450nm within 30 minutes. Plates were read using a 'Fluostar' plate reader. The standard curve derived from cotinine calibrators was used to obtain an equation for the calculation of the cotinine concentration in each sample. Final results were based on the average of the results of paired wells. In cases where the paired results were significantly different from each other, samples were re-analysed.

Expired carbon monoxide analysis

All women recruited from February 2006 to April 2007 at Wuchopperen were asked to take part in expired air carbon monoxide analysis to enable comparison with cotinine measures. Women were told after completion of questions relating to self-reported smoking status, that their smoking could be checked using the carbon monoxide meter. The BreathCo Vitalograph® monitor was used by asking patients to breathe into a tube attached to the machine for ten seconds. Tubes were disposable, with a clean tube used for each participant.

It was not feasible, due to time constraints and staff pressures, to conduct blinded carbon monoxide analysis. The project officer, who was aware of the participant's self-reported smoking status therefore conducted these measurements. Participants were unaware of the ensuing carbon monoxide test when they reported their smoking status.

Statistical analysis

Thorough data checking was performed to ensure that each 24-hour diary and cotinine reading were paired, to check for any discrepancies in the data, or errors during entry, and to check distributions for continuous variables. In order to simplify the variables for assessing influence on cotinine levels, the smoking status of women and level of exposure to passive smoke were combined to create a single variable indicative of the level of nicotine exposure. Women were regarded as having been exposed to passive smoke if they reported being in a house with other smokers in the previous 24-hours, or reported that any cigarettes had been smoked by others around them during that time. Women were then categorised as non-smokers or smokers (based on any cigarette consumption in the previous 24-hours), with or without exposure to passive smoking. Age was also categorised for analyses; grouped as less than 19, 19 to 24, 25 to 29, or 30 years of age and over.

Each cotinine measurement was associated with a set of 24-hour measures for gestation, alcohol consumption, time since last cigarette smoked, number of cigarettes smoked by the individual and by others and expired air CO. The relationships between cotinine and the range of individual and environmental variables (aim 1), were initially examined using non-parametric Spearman correlations for continuous explanatory variables (the number of cigarettes smoked in the previous 24-hours, gestation, BMI, time since last cigarette and CO reading), non-parametric t-tests (Mann Whitney) for

binary explanatory variables (alcohol consumption and medication use) and the Kruskal-Wallis test for other categorical variables (level of nicotine exposure, age, and ethnicity). To assess any variation in cotinine level resulting from the variation in characteristics between participants, the potential confounders which had a p-value of >0.25 in univariate analysis were entered into a general linear model for regression analysis. Variables were removed in a step-wise fashion based on the p-value associated with the t-statistic in the model. Regression diagnostics were performed to ensure that the data met the assumptions associated with linear regression. Assumptions include the linearity of the relationship between the potential predictors and the cotinine level, normal distribution of the errors, homogeneity of variance, independence of the variable errors, and specification of the model.

In order to establish a cotinine cut-off level which is relevant to antenatal Aboriginal and Torres Strait Islander women, the sensitivity and specificity of cotinine level in the measurement of smoking status, relative to expired air CO analysis, was assessed using a range of cut-points (aim 2). A review of the literature was undertaken to obtain the relevant value of CO which defined smoking status. This included the eight studies which used CO analysis, among those reviewed in Chapter 4. These studies used a variety of CO cut-points to identify/classify smokers, ranging from 6 to 10ppm, with an average cut-point of 6.9ppm. In order to ensure that an appropriate cut-point was used and to assess whether this was the optimal sensitivity and specificity, a range of values either side of this median were tested for sensitivity and specificity with the study population. Cut-points of CO of 2ppm, 4ppm, 6ppm, and 8ppm were compared with a range of potential cotinine cut-points from 25ng/mL to 250ng/mL (in increments of 25ng/mL), and the area under the Receiver Operator Characteristic (ROC) curve was also assessed for each combination of cut-points. The sensitivity and specificity of each cut-point, as well as the area under the ROC curve were used to determine the most

appropriate cut-point to distinguish between smokers and non-smokers. This cotinine range was selected as it allowed the differentiation of the majority of samples in the group. The area under the curve (AUC) is a useful marker of test precision, with values closer to 1, or 100% suggesting that the test being scrutinised is highly accurate.¹⁸ This was used as an indication of the precision of the test with each possible cut-point.

To explore aim 3, the cut-point established in the validation population was used to dichotomise urinary cotinine and thus define the gold standard for smoking status. Self-reported smoking status (yes or no) was compared to cotinine determined smoking status and sensitivity and specificity obtained with 95% confidence intervals.

Sample size

At TAIHS, women who were recruited to the ongoing randomised controlled trial were also eligible to participate in the cotinine validation study by providing a urine sample and completing the 24-hour diary. Expected numbers for TAIHS were therefore based on the assumption that approximately 200 Aboriginal or Torres Strait islander women would visit TAIHS for antenatal care over a 12-month period, and 283 over the 15-month recruitment period for this study. At Wuchopperen, it was expected that approximately 300 women who were any stage of a pregnancy would attend the clinic over a 12-month period. Therefore, with recruitment occurring over a 17-month period, 425 pregnant women were expected to attend the clinic. An eligibility rate of 70% and consent rate of 60% at TAIHS would lead to the recruitment of 118 women at this site. A higher eligibility rate was expected at Wuchopperen with fewer criteria. An eligibility rate of 90% and consent rate of 60% would lead to the recruitment of 229 women at this site, giving a total of 347 women for aims 1 and 3 of the study.

Aim 2 relies upon the collection of CO readings which were only possible at Wuchopperen for a 15-month period due to equipment availability. Therefore, a sample of 202 women was expected for establishment of a cotinine cut-point.

A sample of 300 would provide 80% power with a 5% significance level for detection of differences in cotinine of at least 0.4 of a standard deviation for dichotomous variables (assuming a ratio of at least 5:1 for the two categories) and correlations of 0.16 for continuous variables.

Assuming that approximately 50% of the population would be smokers, a sample of 300 would allow estimation of sensitivity and specificity of self report versus urinary cotinine with 95% confidence intervals within $\pm 7\%$ of the point estimate, assuming at least 80% sensitivity and specificity.

Results

Study Sample

A total of 298 women were assessed for eligibility at TAIHS. After exclusion of seven non-Indigenous women (2%), two with unviable or terminated pregnancies (0.7%), one with a florid mental illness (0.3%), 50 who were over 20 weeks gestation (17%), 124 (41%) self-reported non-smokers (including two who were also over 20-weeks gestation), and eight (3%) women who were not local or planned to leave the area during their pregnancy, 106 women (36%) were eligible for the randomised controlled trial and were also invited to participate in this component. Of the 106 eligible women, nineteen (18%) declined the invitation to the study, five (5%) were missed for recruitment, and 82 (77%) completed the baseline questionnaire, provided urine for

cotinine validation, and were randomised to the additional care (AC) or usual care (UC) group of the trial (see Chapter 9).

Aboriginal and Torres Strait Islander women attending Wuchopperen for antenatal care at any stage of pregnancy were invited to take part in this study. Of the 145 women taking part in the knowledge and attitudes study (see Chapter 6), 122 gave consent and provided urine samples at baseline for cotinine analysis. In 20 cases, women declined to allow their routinely provided urine sample to be analysed for cotinine, failed to provide samples, or their samples were discarded before an aliquot was taken for analysis.

What individual and environmental factors influence cotinine levels?

The characteristics of the participant group are outlined in Table 7.1. Of the 204 participants, 45 (22%) were teenagers, and 43 (21%) aged over 30 years, with an average age of 25. Eighty-nine (44%) of the women were Aboriginal, 82 (40%) were Torres Strait Islander, and 28 (13%) identified as both Aboriginal and Torres Strait Islander. Thirty-six women, representing 32% of those for whom BMI data was available, were classed as obese, with a BMI over 30. Twenty-six women (13%) had consumed some alcohol in the previous 24-hours.

Univariate analysis (Table 7.2) found significant correlations between cotinine level and ethnicity ($\chi^2=7.846$, $df=2$, $p=0.020$), the number of cigarettes smoked in the previous 24-hours (Spearman's $Rho[\rho]=0.734$, $p<0.001$), and the level of nicotine exposure ($\chi^2=163.19$, $p<0.001$). Current medication use and BMI were assessed among a subgroup of the sample only, with no data having been collected relating to medication use at

one site, and incomplete data for BMI. No significant correlations were found with either of these variables.

Table 7.1: Characteristics of the population assessed for environmental influences and individual variation

	N	%
Self-reported smoking status and passive smoke exposure		
Non-smokers with no passive smoking	46	22
Non-smokers with passive smoking	47	23
Smokers with no passive smoking	37	18
Smokers with passive smoking	74	36
Age		
<=19	45	23
20-24	64	32
25-29	47	47
>=30	43	22
	<i>*5 missing</i>	
Ethnicity		
Aboriginal	89	45
Torres Strait Islander	82	41
Both	28	14
	<i>*5 missing</i>	
BMI **		
<19 (underweight)	11	10
20-25 (acceptable)	36	32
26-30 (overweight)	31	27
>30 (obese)	36	32
	<i>*90 missing</i>	
Alcohol consumption in previous 24-hours	26	15

Number of women=204

**BMI n=21

Table 7.2: Univariate analysis of potential confounding factors for cotinine

		Test statistic	p-value
Cigarettes in last 24 hours	Spearman's rho	0.734	<0.001
Gestation		-0.052	0.475
BMI		-0.048	0.612
Alcohol	Mann-Whitney U	1823.5	0.634
Medications		1206.0	1.000
Level of nicotine exposure	Kruskal-Wallis Chi-square	104.13	<0.001
Age		1.062	0.786
Ethnicity		7.846	0.020

Linear regression was conducted including the variables that had p-values less than 0.25 in univariate analysis (level of nicotine exposure, ethnicity and the number of cigarettes in the last 24-hours). After excluding ethnicity due to non-significance, the final model accounted for 41.7% of the variance in cotinine concentration (41.1% adjusted), refer to Table 7.3. The only significant predictors of cotinine level were the level of nicotine exposure and number of cigarettes smoked in the previous 24 hours. Regression diagnostics indicated an approximately normal distribution of the residuals, with some right skew.

Table 7.3: Final linear regression model of factors associated with cotinine level

Variable	Beta coefficient	t statistic	p-value
Level of nicotine exposure*	0.425	6.916	<0.0001
Number of cigarettes in previous 24 hours	0.322	5.232	<0.0001

** Level of nicotine exposure is graded 1-4 according to personal smoking and exposure to passive smoke*

What is the most appropriate cotinine cut-point to distinguish smokers from non-smokers among antenatal Aboriginal and Torres Strait Islander women?

Of the 57 individuals who participated in CO analysis, 13 (23%) were teenagers, and 11 (19%) aged over 30 years, with an overall mean age of 25. Twenty (35%) of the women were Aboriginal, 29 (51%) were Torres Strait Islander, and 8 (14%) identified as both Aboriginal and Torres Strait Islander. Eleven women, representing 52% of those for whom BMI data was available, were classed as obese, with a BMI over 30. Ten women (18%) were taking medications at the time of the sample collection, and eight women (14%) had consumed some alcohol in the previous 24-hours. Thirteen women (23%) were categorised as non-smokers with no passive smoke exposure, 21 (37%) as non-smokers with passive smoke exposure, six (11%) and, 19 (30%) as smokers without, and with, passive smoke exposure respectively. The average number of cigarettes consumed in the previous 24-hours by self-reported smokers was 10.6. Smokers had an average CO level of 5.5, and non-smokers, 0.7. The characteristics of this sub-population are presented in Table 7.4.

Table 7.4: Characteristics of the validation sample

	N	%
Self-reported smoking status and passive smoke exposure		
Non-smokers with no passive smoking	13	23
Non-smokers with passive smoking	21	37
Smokers with no passive smoking	6	11
Smokers with passive smoking	17	30
Age		
<=19	13	23
20-24	17	30
25-29	16	28
>=30	11	19
Mean, med, std dev	25, 24, 5.6	
Ethnicity		
Aboriginal	20	35
Torres Strait Islander	29	51
Both	8	14
BMI (n=21)		
<19 (underweight)	1	5
20-25 (acceptable)	8	38
26-30 (overweight)	1	5
>30 (obese)	11	52
	*36 missing	
Any current medications	10	18
Alcohol consumption in previous 24 hours	8	14

Table refers to those women with results for CO, cotinine, and self-report (n=57)

Table 7.5 shows the sensitivity, specificity, and area under the ROC curve for the full range of cotinine cut-points compared with CO cut-points of 2, 4, 6, and 8ppm. A consistent pattern emerged, whereby the optimal area under the curve, sensitivity, and specificity were obtained with a maximal cotinine cut-point of 250ng/mL, and the next best results were achieved with a cut-point of 175ng/mL for all four cut-points of CO. For each of these cotinine cut-points, the optimal values were achieved with a CO cut-point of 2ppm. Assessment of smoking status using cotinine cut-points of 250ng/mL

and 175ng/mL relative to 2ppm CO generated an area under the ROC curve of 0.891 and 0.884 respectively, indicative of strong predictive power.

Table 7.5: Examination of cut-points for CO and cotinine

Cotinine ng/ml	CO cut-point 2ppm			CO cut-point 4ppm			CO cut-point 6ppm			CO cut-point 8ppm		
	Sens	Spec	AUC	Sens	Spec	AUC	Sens	Spec	AUC	Sens	Spec	AUC
25	100	18	59	100	15	58	100	14	57	100	14	57
50	100	39	69	100	37	67	100	35	66	100	33	65
75	100	61	80	100	54	76	100	51	75	100	49	73
100	100	68	84	100	61	79	100	57	77	100	55	76
125	100	71	86	100	63	81	100	59	79	100	57	77
150	100	75	87	100	67	82	100	63	80	100	61	79
175^o	100	77	88	100	70	83	100	65	81	100	63	79
200	96	77	86	100	70	84	100	65	82	100	63	80
225	96	77	86	100	70	84	100	65	82	100	63	80
250^o	96	82	89	100	72	86	100	67	84	100	65	82

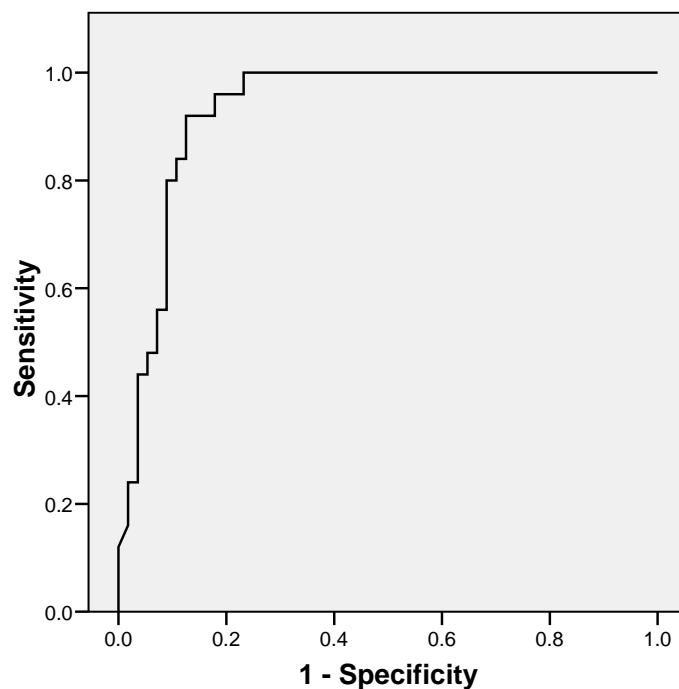
Sens=sensitivity, Spec=specificity, AUC=Area under the curve

^o These cut-points were used for subsequent analysis in this Chapter

An additional ROC curve (Figure 7.1) was also constructed by plotting the sensitivity and specificity resulting from a tabulation of actual cotinine levels with the smoking status determined by CO analysis. Examination of this curve and the points plotted (Appendix 7.3) confirmed that the most appropriate cut-point for cotinine would lie between 153.2 and 267.7ng/mL as these points formed the corner of the curve indicating optimal sensitivity and specificity. Within this sample population, the 250ng/mL cut-point had 96% sensitivity and 82% specificity when compared to the

detection of smoking by CO analysis, and 94% sensitivity and 75% specificity for the validation of self-reported smoking status.

Figure 7.1: Receiver Operator Characteristic (ROC) curve of carbon monoxide determined smoking status and cotinine levels



Diagonal segments are produced by ties.

*Determined using 2ppm cut-point.
Area Under the Curve = 0.931*

The 175ng/mL cut-point had 100% sensitivity and 77% specificity when compared to the detection of smoking by CO analysis, and 84% sensitivity and 100% specificity for the validation of self-reported smoking status. Thus, both cut-points will be examined in this chapter, and a cut-point of 175ng/mL will be used to validate self-reported smoking in Chapter 8.

What proportion of women accurately report smoking status?

Table 7.6 illustrates the sensitivity and specificity of the cotinine analysis. Based on a cut-point of 250ng/mL, it appears that 23 (25%) of the self-reported non-smokers may have falsely declared themselves as such. The cross-tabulation produces a sensitivity of 94% (104 of 127 cotinine validated smokers were identified by self-report), and specificity of 75% (70 of 77 self-reported non-smokers were deemed to be non-smokers in cotinine analysis).

Table 7.6: Sensitivity and specificity calculations for self-reported smoking status with cotinine validated smoking status at 250ng/mL cut-point

Self-reported smoking status	Cotinine validated smoking status		
	Smokers	Non-smokers	Total
Smokers	104 (94%)	7 (6.3%)	111 (54%)
Non-smokers	23 (25%)	70 (75%)	93 (45%)
Total	127 (100%)	77 (100%)	204 (100%)

As 250ng/mL was the maximum cut-point in the range tested, the 175ng/mL cut-point was also tested as a sensitivity analysis. As is illustrated in Table 7.7 the lower cut-point did not substantially impact upon the results, but did lead to a slight overall improvement in sensitivity and specificity, decreasing the former to 81% but increasing the latter to 94%.

Table 7.7: Sensitivity and specificity calculations for self-reported smoking status with cotinine validated smoking status at 175ng/mL cut-point

Self-reported smoking status	Cotinine validated smoking status		
	Smokers	Non-smokers	Total
Smokers	107 (81%)	4 (5.6%)	115 (54%)
Non-smokers	25 (19%)	68 (94%)	92 (45%)
Total	132 (100%)	72 (100%)	204 (100%)

The level of nicotine exposure, based on self-reported personal smoking and exposure to passive smoke was also assessed for accuracy using the 175ng/mL cut-point (Table 7.8).

Table 7.8: Sensitivity and specificity calculations for self-reported smoking status and passive smoking level with cotinine validated smoking status at 175ng/mL cut-point

Self-reported nicotine exposure	Cotinine validated smoking status		
	Smokers	Non-Smokers	Total
Smokers, no passive	36 (27%)	1 (1.4%)	39 (18%)
Smokers, with passive	71 (54%)	3 (4.2%)	76 (36%)
Non-smokers, no passive	15 (11%)	31 (43%)	44 (22%)
Non-smokers, with passive	10 (7.6%)	37 (51%)	48 (23%)
Total	132 (100%)	72 (100%)	207 (100%)

This may be a useful measure of risk to the foetus during pregnancy, with capacity for cotinine validation of this measure with high levels of sensitivity and specificity. The capacity for cotinine to differentiate between smokers and non-smokers is not greatly reduced when the sensitivities of passive smoking are considered. An examination of the mean and median cotinine level for each level of nicotine exposure demonstrated that the highest mean cotinine level occurred for smokers who were also exposed to passive smoke (3721.03ng/mL, median 3491.16ng/mL). A slightly lower level (3060.29ng/mL, median 2334.36ng/mL) described smokers who were not exposed to passive smoke. A substantial gap between the mean cotinine levels for smokers and non-smokers was found, with non-smokers exposed to passive smoke having a level of 264.42ng/mL (median 50.06ng/mL). Interestingly, the mean level for non-smokers who were not exposed to passive smoke was higher, at 697.15ng/mL, but the median level was lower at 35.43ng/mL. This may suggest that the capacity of this cotinine analysis technique is limited in detecting the subtleties associated with passive smoke, or may reflect an inaccuracy in the self-report of passive smoke exposure among non-smokers in particular.

Discussion

Limitations of this study

It should be noted that the relatively small sample size of the study may have limited the capacity to detect correlations between cotinine concentration and factors such as alcohol consumption, gestation and BMI. In this limited sample, only 14% of women reported having consumed alcohol in the previous 24-hours, and BMI information was only available for 116 of the 204 women (57%). It may be that relationships do indeed exist, but the power of this study was insufficient to enable their detection. With a

smaller sample size than predicted, the power of the study to detect such differences was reduced.

Notwithstanding the small sample size, the correlation of cotinine concentration with each of the smoking and nicotine exposure related variables, was highly significant. This increases confidence that these variables are highly related to the cotinine level, and that the influence of other confounders is likely to be minimal. The full spectrum of factors which potentially impact upon cotinine concentration was not studied. The variables included were those expected to have the greatest influence, to a degree which may be detected by the assay used. Dietary factors for example, are reportedly associated with a cotinine concentration of 0.6 to 6.2ng/mL¹⁹ which is not likely to result in consistent alteration in the levels detected by the ELISA used here. Further, the restriction of variable measurement minimised additional burden of this study on participants, who were also taking part in the pilot randomised controlled trial and the knowledge and attitudes component presented in Chapter 6.

What individual and environmental factors influence cotinine levels?

Exposure to passive smoke, when included in the categorisation of the level of nicotine exposure, was significantly correlated with cotinine concentration. Along with the number of cigarettes smoked in the previous 24-hours, this was the only significant predictor of cotinine level, indicating that in this population group, it is appropriate to establish a cotinine cut-point based primarily on measures of cigarette consumption or nicotine exposure, without the need to adjust for other factors in the validation of self-report. No individual-level factors had significant influence upon the cotinine concentration. This may be an artifact resulting from limited detection capacity of the analysis technique, or of the low statistical power of the study, with a small sample

size. It is possible however, that the result is indicative of differing interactions of these factors with cotinine levels in an Aboriginal and Torres Strait Islander population. Ethnicity did not appear to influence cotinine levels within the sample, but with a substantially lower average cut-point of 132.5ng/mL used in the intervention studies in Chapter 4 which assessed cotinine in urine, it is possible that this population group has an inherently higher cotinine level. The ethnicity variable examined here looked only at the differential cotinine levels for Aboriginal women compared to Torres Strait Islanders. These two groups may share physiological or genetic profiles which differ from the Caucasian Australian population. Patterns of disease such as diabetes and cardiovascular disease are suggestive of shared genetic or metabolic profiles between these groups,^{20 21} which differ from those among other Australian's. Further, a higher cotinine level overall may be influenced to a lesser degree by factors such as alcohol consumption and gestation than a lower level. The association between ethnicity and level of nicotine exposure was only slightly significant ($\chi^2=15.74$, $df=6$, $p=0.015$). It appears that in this population, cotinine remains a robust measure, without the need to adjust analyses for potential confounding factors.

Caution should be taken in the interpretation of the regression analysis, due to the slight skew in the distribution of residuals, and failure to meet the assumption of normality for cotinine. Cotinine had a rectangular distribution which was not transformable into a normal pattern. The results of the regression analysis are however, consistent with the non-parametric univariate analysis which does not rely on the assumption of normality. The regression analysis can therefore be interpreted with a degree of confidence.

Substantial effort has been made in the present study to validate cotinine as a gold-standard measure for smoking status. As discussed previously however, the validation

of a gold-standard requires comparison with a less robust measure, in this case CO analysis. With great care taken to measure cotinine independently and blinded to the results of CO analysis and self-report, and the strong correlations between CO and cotinine measures, it is expected that the reliability of these results is strong. The complex situation does however imply an inherent need for care to be taken in the interpretation of results and particularly, in the generalisation of the results to other studies.

What is the most appropriate cotinine cut-point to distinguish pregnant Aboriginal and Torres Strait Islander smokers from non-smokers?

The results demonstrate the capacity for cotinine analysis to both detect and quantify cigarette smoking and exposure to nicotine. When scrutinised against CO level and self-reported smoking status the sensitivity and specificity of this measure were high. An optimal sensitivity of 94% and specificity of 75% were obtained using a cut-point of 250ng/mL. Avoiding the use of a maximal cotinine cut-point, a sensitivity of 100% and specificity of 88% were obtained using a cut-point of 175ng/mL. These results compared with a sensitivity and specificity of 77% and 98% respectively, for CO at a cut-point of 2ppm. Both the 250ng/mL and 175ng/mL cut-points lie within a reasonable range of those used in studies reported in the previous chapter. This increases confidence that the marker established here is an appropriate one.

What proportion of women accurately report smoking status?

The 175ng/mL cut-point accurately identified 97% of self-reported smokers among the 207 participants. Based on this level, it appears that four women (3.5%) were misclassified as smokers, and 25 (19%) who reported themselves as nonsmokers were classified as smokers. A 19% level of misreport is not unexpected, given previous

suggestions of similar levels detected in pregnant women in other populations.^{14 15}

Given that this population has a relatively high level of knowledge regarding the risks of smoking (Chapter 6), it is possible that women are likely to deny continued smoking to health workers, due to a consciousness that they should quit. Rates of successful quitting are low in this population as a whole, indicating the normality of smoking in the community, and the difficulty of quitting in this social context. This level of misreport is substantial, and should be taken into consideration in routine screening of antenatal women in primary healthcare.

Is cotinine a reliable measure to quantify antenatal smoking?

While CO is sufficient for the detection of smoking in a clinical setting, cotinine analysis has the additional capacity to quantify the level of smoking, and to detect exposure to passive smoke. Correlations between cotinine concentration and the level of nicotine exposure and self-reported number of cigarettes smoked in the previous 24-hours were strong. Lack of correlation between cotinine concentration and the time since the last cigarette supports the concept that cotinine is less dependant upon time than is CO.⁹ This is also supported by the present data, with a strong correlation with time for CO (Spearman's $\rho = -0.456$, $p = 0.012$). This factor enhances the capacity for cotinine to accurately detect and quantify smoking in a clinical or research setting, where substantial time may elapse between smoking and measurement.

CO analysis is generally less costly than cotinine analysis, with a simple machine allowing for on-site readings. Depending on the purpose, and the level of accuracy required, biochemical validation can add exorbitant cost to research projects and clinical processes. The ELISA used in the present study for cotinine analysis was a very rapid analysis method, with the capacity to analyse duplicate samples from up to

400 participants per day. The method was relatively cost-effective, with calculations including the cost of purchasing the kit itself, and laboratory disposables, as well as the shipment of samples totaling approximately \$20 per sample analysed in duplicate.

Cotinine is clearly valuable for the detection of smokers and validation of self-reported smoking status. Cotinine analysis can identify 100% of smokers, while reliance upon self report may capture only 80% of smokers. This is an important consideration for clinical practice and intervention studies. If one in every five pregnant smokers misses out on intensive intervention and important support and advice regarding quitting, progress into this critical public health issue will be limited. Perhaps the cost of cotinine analysis is a worthwhile investment to ensure the identification and appropriate treatment of all pregnant smokers.

Conclusions

This study highlights the value of cotinine as a tool for detecting and quantifying smoking behaviour and exposure to passive smoke in a research or clinical setting. The analysis generated a cut-point of 175ng/mL which has high sensitivity (100%) and specificity (88%) for the validation of self-reported smoking status among antenatal Aboriginal and Torres Strait Islander women. This cut-point is expected to be robust for the measurement of smoking and successful cessation in an intervention context. When applied to a sample of women attending TAIHS and Wuchopperen, this cut-point revealed a rate of 27% misreport of smoking status by non-smokers. Future studies, and screening protocols for primary healthcare should take such a rate of misreport into consideration, and take measures to ensure that a greater proportion of smokers is detected.

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Appendix 7.1: University Certificate of Ethical Approval for study



The UNIVERSITY
of NEWCASTLE
AUSTRALIA

Form HE2:1/05


HUMAN RESEARCH ETHICS COMMITTEE

Certificate of Approval for a research project involving humans

Applicant	
Chief Investigator/Project Supervisor: (First named in application)	Professor Rob Sanson-Fisher
Co-Investigators/Research Students:	Dr Sandra Eades Dr Kathryn Panaretto Dr Mark Wenitong Mr Conor Gilligan
Project Title:	Defining cotinine level as an outcome measure for smoking among antenatal Aboriginal and Torres Strait Islander women

In approving this project, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the *National Statement on Ethical Conduct in Research Involving Humans*, 1999, and the requirements within this University relating to human research.

Details of Approval	
HREC Approval No: H-068-0705	Date of Approval: 20 July 2005
Approval valid for: 3 years, or until project ceases, whichever occurs first.	Progress reports due: Annually
<p>NOTE: Approval is granted subject to the requirements set out in the attached document <i>Approval to Conduct Human Research</i>, and any additional comments or conditions noted below:</p> <p>20 July 2005 Approved with comment. The Committee ratified the approval granted by the Acting Chair on 24 June 2005, which was subject to the questionnaire and participant documents being resubmitted to the HREC should there be any changes after piloting.</p>	

Signed for the Committee: 

Ms Susan O'Connor
Human Research Ethics Officer

Appendix 7.2: Cotinine diary

(See the following page)

Insert participant # sticker here

Date _____
Time _____
BMI _____

Medications: _____

The following questions relate to your cigarette smoking, passive smoking and alcohol consumption in the last 24 hours.

1. How long is it since your last cigarette? _____

2. Number of cigarettes in each period

Midnight--1--2--3--4am	4--5--6--7--8am	8--9--10--11--12pm	12--1--2--3--4pm	4--5--6--7--8pm	8--9--10--11--Midnight

In the last 24 hours:

3. Did you consume tobacco from any other source? ☐ 1 Yes
☐ 2 No

4. How many smokers were in the house?

5. Were you in the house?

☐ 1 Yes
☐ 2 No

6. How many cigarettes were smoked by other people in the house or around you?

7. Did you consume any alcohol?

☐ 1 Yes
☐ 2 No

8. Urine Cotinine concentration

9. CO Reading

Appendix 7.3: ROC curve coordinates

Test Result Variable(s): Cotinine level (ng/mL)

Positive if Greater Than or Equal To(a)	Sensitivity	1 - Specificity
-1.0000	1.000	1.000
6.0355	1.000	.982
12.5170	1.000	.964
14.6625	1.000	.946
16.8360	1.000	.929
17.4915	1.000	.911
19.0775	1.000	.893
20.6530	1.000	.875
21.5035	1.000	.857
22.2000	1.000	.839
24.9480	1.000	.821
28.3315	1.000	.804
29.0245	1.000	.786
29.2695	1.000	.768
32.3850	1.000	.750
35.4290	1.000	.732
35.6645	1.000	.714
36.4560	1.000	.696
37.7925	1.000	.679
40.5750	1.000	.661
42.7720	1.000	.643
45.9395	1.000	.625
50.1920	1.000	.607
51.4005	1.000	.589
52.7830	1.000	.571
54.6290	1.000	.554
55.7500	1.000	.536
57.4335	1.000	.518
58.5875	1.000	.500
59.7625	1.000	.482
61.8680	1.000	.464
65.0645	1.000	.446
70.5785	1.000	.429
74.4695	1.000	.411
77.3780	1.000	.393
80.3900	1.000	.375
88.1460	1.000	.357
95.3865	1.000	.339
99.8285	1.000	.321

Positive if Greater Than or Equal To(a)	Sensitivity	1 - Specificity
107.4515	1.000	.304
121.4115	1.000	.286
136.0335	1.000	.268
153.1635	1.000	.250
180.3505	1.000	.232
213.5850	.960	.232
233.0900	.960	.214
233.7515	.960	.196
246.3875	.960	.179
259.2795	.920	.179
281.2435	.920	.161
335.6955	.920	.143
403.9440	.920	.125
546.7815	.880	.125
1058.6565	.840	.125
1476.2660	.840	.107
1545.0980	.800	.107
1693.8145	.800	.089
1794.7400	.760	.089
1902.6850	.720	.089
2006.1780	.680	.089
2028.4635	.640	.089
2076.4445	.600	.089
2145.9900	.560	.089
2202.5550	.560	.071
2378.9045	.520	.071
2548.1575	.480	.071
2833.5020	.480	.054
3213.9050	.440	.054
3344.2430	.440	.036
3396.1395	.400	.036
3567.7900	.360	.036
3752.0405	.320	.036
3925.2980	.280	.036
4094.4810	.240	.036
4150.4665	.240	.018
4211.1700	.200	.018
5045.1915	.160	.018
6212.3150	.120	.000
6624.5065	.080	.000
6665.9220	.000	.000

The test result variable(s):Cotinine level (ng/mL) has at least one tie between the positive actual state group and the negative actual state group. The smallest cut-off value is the minimum observed test value minus 1, the largest cut-off value is the maximum observed test value plus 1. All other cut-off values are the averages of two consecutive ordered observed test values.

CHAPTER 8

A pilot randomised controlled trial to test the effectiveness of an intervention to help Aboriginal and Torres Strait Islander women quit smoking during pregnancy: Study design and preliminary results

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Chapter 8

A pilot randomised controlled trial to test the effectiveness of an intervention to help Aboriginal and Torres Strait Islander women quit smoking during pregnancy: Study design and preliminary results

Introduction

This Chapter describes a pilot study, of what will be the first randomised controlled trial of an antenatal smoking intervention, or any smoking cessation program in Aboriginal and Torres Strait Islander Community Controlled Health Services (ACCHS), within Australia. Preliminary investigations presented in previous Chapters, as well as extensive exploration of the literature led to the emergence of a multifaceted intervention approach expected to have the greatest possibility of assisting Aboriginal and Torres Strait Islander women in Far North Queensland to quit smoking during pregnancy. The study design has drawn on evidence from smoking cessation literature overall, as well as recommendations put forward by Lumley et al., in their 2004 Cochrane Review on antenatal smoking,¹ DiClemente et al.,² Fisher et al.,³ and Melvin et al.,⁴ in their recent reviews, and the experiences of others in conducting programs in Australian and International Indigenous communities (including the demise of an RCT in an urban Aboriginal Medical Service [AMS]).⁵

Key elements of intervention

(1) Identification of all smokers

With the high prevalence of antenatal smoking among the Aboriginal and Torres Strait Islander community and the capacity for interventions to improve this rate, it is critical to identify all smokers among antenatal clients. In a study of general practitioners (GPs) in a regional and an urban area in Australia, they identified just 66% of the patients who reported themselves as smokers.⁶ Among 100 smokers, an intervention which achieves a 10% improvement in cessation rates would help ten women to quit smoking. If only 50% of these women are identified as smokers by their healthcare providers, the same intervention will only help five women to quit smoking. Identification of smokers is the first step towards bringing about change.

Implications for intervention

All women attending clinics or health services should be asked about their smoking status and have it recorded in their medical records and routinely updated. In the research situation, screening of all women attending participating clinics for antenatal care or requesting pregnancy tests should be part of eligibility testing and be recorded for later assessment of eligibility and recruitment rates.

(2) The role of medical practitioners

The US Preventive Services Task Force (USPSTF) has made recommendations regarding counselling to prevent tobacco use and tobacco-caused diseases. The Task Force has reviewed the available evidence and suggests that "*Clinicians should screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counselling to those who smoke.*"(p1)⁷

A recent study of the role of various individuals in giving advice to women during pregnancy indicated that women rated their general practitioners as most persuasive in giving antenatal advice.⁸ Doctors are highly respected members of the community, and are in a unique position to intervene with women at an influential stage of their lives. During clinical consultations, practitioners can approach and offer advice on topics which may otherwise be regarded as overly personal. It has been suggested that a holistic approach to patient care, with practitioners addressing the overall well-being of patients is likely to be beneficial to physical and psychosocial aspects of health.⁹ While evidence is limited, potential exists for successful psychosocial interventions involving cognitive behavioural therapy and behavioural counselling, delivered by general practitioners.¹⁰

Implication for intervention

General practitioners should be responsible for the delivery of the primary intervention messages. Practitioners should give clear advice to all smokers, that quitting is the best thing that they can do for their health, and that of their baby. The final decision to quit must be that of the individual, but practitioners can ensure that women keep thinking about smoking by reminding them of the issue at each visit. A reminder each time a resistant patient visits the clinic can be framed in a casual conversation and may be enough to encourage women to try to quit.

2.1 Integration into routine care

The way in which advice is delivered to patients is strongly related to their resistance to, or success in, achieving behaviour change. Motivational interviewing techniques in addictive behaviour counselling grew from the recognition that brief advice delivered appropriately can generate equivalent improvements to more extensive and time consuming therapies. The motivational interviewing approach is based on the

assessment of and feedback on an individual's situation, an emphasis on the personal responsibility for change, provision of direct advice regarding behaviour change, the suggestion of strategies to accomplish the change and the use of an empathetic approach and efforts to strengthen the individual's self-efficacy to achieve change.¹¹ Motivational interviewing uses a supportive approach to help individuals resolve their ambivalence about behaviour change, and has great potential for success in the state of high motivation associated with pregnancy.¹² While this technique alone may not be sufficient to bring about change, the delivery of clear anti-smoking messages briefly and effectively, has the potential to increase the efficacy of interventions in routine care.

Implications for intervention

Healthcare providers are less likely to adopt new interventions and deliver them consistently in routine care if they involve significant additional time or workload. Using the principles of motivational interviewing, interventions can involve the delivery of brief counselling messages within the limitations of already-busy clinic schedules, without adding further pressures.

Brief interventions which can be easily repeated and delivered routinely during antenatal consultations are expected to have the greatest likelihood of uptake by providers, and success in increasing cessation. The practicalities of routine care must be considered in planning intervention protocols. While a certain level of flexibility is required to account for the dynamic nature of clinical practice and unpredictability of clinic operations, a simple, brief intervention could be delivered consistently by practitioners at various points within clinic processes. An intervention designed specifically to facilitate the incorporation of study procedures into a normal consultation context should be more consistently adopted.

2.2 Provider acceptance of and adherence to the intervention

Adoption of an intervention by healthcare providers during and after a study is critical if the intervention is to be successful. Encouraging antenatal care providers to adopt smoking cessation interventions has been recognised as a priority in a number of countries including Australia and the US.^{13 14} There is evidence to suggest that interventions are not routinely used by healthcare providers.¹⁴⁻¹⁶ Provider compliance was studied in an Australian antenatal smoking cessation trial, finding that only 26-38% of women in the intervention group were informed about risks relating to smoking during pregnancy.¹⁷ The Australian Guidelines for Smoking Cessation recognise enhancing the confidence and skills of healthcare providers (specifically GPs) as a major priority.¹⁸

A number of barriers contribute to the low rate of intervention delivery by healthcare providers. Barriers include a lack of policy support and training, lack of time, and individual uncertainty or lack of confidence.¹⁹ Adequate, interactive training with small groups of providers²⁰ and chart reminders²¹ have been shown to influence provider behaviour and improve patient outcomes. In the systematic review in Chapter 4, a trend was observed in which those studies that did not mention the inclusion of staff training were less likely to report good levels of adherence.

Implication for intervention

The design of an intervention to involve minimal time and disruption to routine care is expected to alleviate some of the resistance of providers to its uptake. Adequate training with repeat or booster sessions at intervals throughout a study, and systematic support such as encouragement from the organisation overall, and administrative

support, are likely to assist in overcoming some of the barriers to provider adherence to, as well as acceptance of an intervention.

(3) Multidisciplinary care

Several key differences exist in the systems and nature of healthcare delivery between mainstream general practice settings and Aboriginal Community Controlled Health Service (ACCHS) sites. Several studies have demonstrated different profiles of patients and management of problems between the two systems.^{22 23} The screening by Aboriginal and Torres Strait Islander health workers of the vast majority of patients seen at ACCHS sites is a fundamental difference, and represents an important opportunity for improvement in cultural awareness, communication, and appropriate intervention delivery.

Health workers have demonstrated effectiveness in delivering health interventions to their communities²⁴ and are recognised for their ability to bridge cross-cultural barriers²⁵ and aid communication between patients and health professionals. In a qualitative study of the dynamics between health workers and occupational therapists in rural and remote communities in North Queensland, it was demonstrated that good professional relationships and communication between these individuals were likely to result in better health outcomes for patients. Communication and a clear understanding of differing professional roles were perceived as critical in the development of effective relationships and promotion of positive outcomes.²⁶ These principles are expected to be applicable, not only to relationships between health workers and occupational therapists, but also to relationships with general practitioners, midwives, nurses and other health professionals.

The health worker is in a unique position to break through complex cultural barriers which may otherwise restrict effective communication with healthcare providers. An example of the difficulties in communication across cultures is presented by Cass et al., (2002) who describe the perception by Yolngu People in the Northern Territory, that it is impolite to contradict or give negative responses to questions. This led to significant miscommunications with patients which often were not perceived by healthcare providers.²⁷ The recognition of the broad skills of health workers within the ACCHS sites and their capacity to be trained in various facets of healthcare render these individuals valuable assets to healthcare delivery and research within Indigenous health.

Active community participation by Aboriginal and Torres Strait Islander communities is recognised as fundamental to effective research in these settings. In the context of Aboriginal Community Controlled Health Services, the role of the health worker is critical. This has been recognised recently by the NHMRC and national Aboriginal Health Strategy, which promote the involvement of health workers in all aspects of a health initiative.^{28 29} The involvement of health workers in research provides an opportunity to break the long-held negative perception of research among the Aboriginal and Torres Strait Islander population.³⁰

Implication for intervention

Key messages from the literature suggest that research with Aboriginal and Torres Strait Islander peoples should actively involve health workers in processes of planning, implementation and evaluation. In multidisciplinary healthcare settings, the role of each team member should be clearly defined and active communication and interaction between each team member should be promoted.

(4) Cultural sensitivity

Just as the acceptance of the intervention by providers is critical for its delivery, the appropriateness of the approach for the women at whom it is targeted, is critical for its uptake and efficacy. It is crucial in designing any intervention, particularly one for an Indigenous group, that the strategies are appropriate and relevant to the community, and accommodate cultural differences regarding expectations of healthcare. The WHO and USPSTF policies and Australian smoking cessation guidelines include a recommendation that the needs of special groups should be addressed, and more specifically, that pregnancy-specific materials and advice should be provided where appropriate.^{7 18}

The success of an intervention depends highly upon the degree to which women can relate to issues raised and materials provided. This was discussed in Chapter 4, in relation to the problematic attempts to use the the Windsor self-help manual with differing population groups in Baltimore, and in Australia.³¹⁻³³ The cultural factors associated with tobacco use, and attitudes to healthcare among Australia's Aboriginal and Torres Strait Islander population have also been discussed previously. Recent studies have recognised the associations between cultural and social circumstances and smoking among pregnant women, and recommended that smoking cessation interventions should take full account of these factors.³⁴

Implications for intervention

In community controlled health services, the Board, staff, and representative participants should be consulted in the planning and design of an intervention or any public health program. Wherever written materials are provided to intervention participants, the language, images, and designs used should be carefully chosen to ensure acceptability and understanding. Regional differences in language and artistic

style among Aboriginal and Torres Strait Islander groups and tribes require the careful development of all materials appropriate for each context. Cultural practices should also be consulted in the development of intervention protocols to ensure that sensitive issues are approached in an appropriate manner.

(5) Education alone is not a sufficient intervention

5.1 An outcome driven intervention

While some smoking cessation interventions and government materials are based on the trans-theoretical or stages of change model, there is little evidence to support the use of this approach in antenatal smoking cessation efforts.^{35 36} A number of studies have used a motivational interviewing technique based on this model, and have found no difference in smoking cessation rates between intervention and usual care groups.³⁷⁻³⁹ Stotts et al., (2004) reported that participants did not demonstrate any progression through the stages of change as a result of the intervention.³⁹ In a recent review of stage-based interventions by Reimsma et al., (2003) it was concluded that stage-based interventions were no more effective than non stage-based interventions in changing smoking behaviour.³⁶ Spencer et al., (2002) report that stage-based interventions are well-documented in US populations, but that further research is required to gather evidence on their use in other populations, and in particular special populations such as Indigenous groups.³⁵

Australia's Aboriginal and Torres Strait Islander women appear to have an adequate level of knowledge regarding the harmful effects of smoking during pregnancy, and yet they continue to smoke at rates far exceeding those of the mainstream population.^{40 41} Considering this point, as well as the questionable effectiveness of the transtheoretical approach, it appears that increasing knowledge and changing attitudes is important, but not sufficient to change behaviour. Pregnancy is recognised as a impressionable

time in the lives of women, during which they are likely to be more receptive to health advice such as that regarding smoking cessation.⁴²

Implication for intervention

It is hypothesised that clear messages, delivered using approaches such as motivational interviewing and firm advice to quit, may be an effective approach to tackle the smoking issue in this motivated population. Taking advantage of the potential for pregnancy to increase a woman's motivation for behaviour change, it is appropriate to focus on immediate smoking cessation rather than a progression along the often lengthy stages of change towards cessation. An intervention may be delivered in a step-wise fashion, providing the main components to all women, and adding more intensive interventions if required. Such an approach would potentially enhance the cost-effectiveness of an intervention, and minimise pressure on the providers involved and day-to-day running of a clinic.

5.2 Increasing the probability of participant adherence to the protocol

Low rates of patient adherence to treatment regimens or intervention protocols can be very costly in the clinical setting, as well as in research.⁴³ Previous interventions have used various techniques, such as providing incentives for attendance,⁴⁴ asking women to sign a contract or enter into a formal agreement to quit,^{45 46} in attempts to improve patient adherence to various therapies and regimens.

Implication for Intervention

A formal agreement to quit is expected to enhance the success of the intervention, and to allow an opportunity for measurement of initial intervention uptake. The use of

contracts or agreements has potential financial benefit compared to other more complex interventions, and also has potential for standardisation and replication.

(6) Enhancing social support for quit efforts

A key predictor for smoking during pregnancy is having a partner who smokes.⁴⁷

Households with Aboriginal and Torres Strait Islander Australians are larger on average than other households, and 51% of Aboriginal and Torres Strait Islander Australians are smokers.⁴⁸ Pregnant Aboriginal and Torres Strait Islander women are therefore more likely to be part of a social group which includes smokers, and it is important to consider the role of this social group in influencing a woman's smoking behaviour and likelihood of quitting. Social support and involvement of partner, family members, and close friends is recognised as potentially beneficial in smoking cessation programs.^{49 50}

The WHO states, in its policy recommendations for smoking cessation and treatment of tobacco dependence, that "*Promoting change in social norms is essential to successful smoking cessation, since the social environment provides the context for smoking cessation, and encourages smokers in their attempts to quit.*"(p1)⁵¹ While the systematic review in Chapter 4 did not show a statistically significant association between the use of social support and the success of an intervention, the actual involvement of partners or 'buddies', and rate of attendance at group support sessions was not thoroughly assessed. It may be the case that social support components may enhance the effectiveness of interventions when properly implemented and coupled with other aspects of design.

Implication for intervention

Interventions should make an attempt to understand, and involve the social circumstances in which women live. It is hypothesised that intervention messages which are relevant in, and can be transferred to a woman's social environment are more likely to be effective and bring about behavioural changes which are sustainable beyond the clinic consultation during which they are delivered.

(7) Breaking a physiological addiction

Nicotine addiction and withdrawal has been paralleled with that of heroin,^{52 53} it is a strong physiological reaction which is difficult to overcome.⁵⁴ Most people who quit smoking make several attempts to do so, with an average of seven attempts made by those who successfully quit.⁵⁵

7.1 A partnership to achieve cessation

The difficulty associated with quitting smoking can make it a long process, and one which cannot be tackled alone. While interventions should ideally be delivered in the form of brief, clear messages and firm advice to quit, the repetition of these brief messages over an extended period, and the provision of ongoing support are expected to enhance motivation to quit and encourage repeated attempts.

Implication for intervention

It is expected that by establishing a partnership with their patient as early as possible in a pregnancy and maintaining contact and encouragement throughout the period of the pregnancy, providers will have a greater chance of assisting women to successfully quit smoking. A process of successive approximation; encouraging women to increase the number of smoke free days they aim for at each successive attempt is expected to

minimise harm. Lengthening periods of non-smoking is likely to eventually lead to non-smoking status. It is important to encourage total abstinence rather than cutting down the number of cigarettes, as women who cut down are likely to inhale the same amount of nicotine from fewer cigarettes. It is hypothesised that by encouraging women to return within one week of an initial contact with their healthcare provider, it may be possible to encourage repeated attempts and prevent long periods of relapse. It is important to provide support during these early, very difficult phases of quitting.

7.2 Nicotine Replacement Therapy

Nicotine Replacement Therapy (NRT) has the potential to reduce the physiological and psychomotor withdrawal symptoms associated with smoking cessation.⁵⁶ As reported in a recent Cochrane review, cessation attempts using NRT are more effective than those in which NRT is not offered, or placebo is used.⁵⁷ Pollack et al., (2007) studied the use of cognitive behavioural counselling for smoking cessation with and without NRT in a sample of pregnant smokers in the US. The group reported that women using NRT were close to three times more likely than women exposed to behavioural therapy only, to have biochemically validated smoking cessation seven weeks after intervention delivery and at 38-weeks gestation. This improvement was not sustained at three months post-partum.⁵⁸

Despite increases in the metabolic clearance of nicotine during pregnancy,⁵⁹ both nicotine patches and gum, are able to substantially raise plasma nicotine concentrations in pregnant users.⁶⁰ Several human and animal studies have shown that fetal and maternal concentrations of nicotine are similar 30-60 minutes after nicotine intake.⁶⁰ Until recently, it was thought that utero-placental insufficiency or compromised blood flow and supply of oxygen and nutrients to the placenta, was caused by nicotine, and was responsible for the growth retardation associated with

cigarette smoking during pregnancy. Several more recent studies have found that the maternal cardiovascular effects associated with smoking a cigarette are not as pronounced or long-lasting when nicotine is delivered via patch or gum.^{59 61} This suggests that some or all of the 3000 other toxins in cigarette smoke may play a significant role in the utero-placental insufficiency and the fetal toxicity of smoking.⁶⁰ Pollack and colleagues (2007) were forced to suspend their trial when an interim analysis found a higher rate of negative birth outcomes among women using NRT, but this difference was not significant when the previous history of preterm birth was adjusted for in a later analysis.⁵⁸ Research is continuing to clarify the efficacy and safety of NRT during pregnancy.⁶²

Implication for intervention

Despite the lack of evidence for the safety of NRT in pregnancy, the view expressed in several reviews on the issue is that NRT reduces the intake of both nicotine and the other toxins which are contained in cigarettes, and thus is likely to be a better alternative to continued smoking.^{60 63 64} Recommendations put forward by reviewers are that behavioural counselling should accompany the use of NRT, and the social situation and psychological state of women should be assessed before a decision is made to provide smoking cessation advice with or without NRT.⁶³ Also, the general view is that intermittent forms of NRT would be more appropriate than sustained-release patches, as they have greater potential for an overall reduction in nicotine exposure.^{60 63} NRT use should be monitored, and the dose frequently revised to limit the duration of pharmacotherapy and achieve long-term abstinence.^{60 63 64}

An ongoing study

The present study is a pilot of a larger RCT being conducted by a team of researchers from the Sax Institute, the University of Newcastle, Wuchopperen Health Service, and Townsville Aboriginal and Islander Health Service in Far North Queensland. The PhD candidate was largely responsible for the development of the study, establishment of participant and provider materials and consultations with staff at health service sites. The PhD candidate took responsibility for the pilot phase of the project, which is reported here.

Objectives of the study

The RCT aimed to assess the effectiveness of a high intensity intervention to reduce smoking among pregnant Aboriginal and Torres Strait Islander women. The key outcomes measured in the main study were biochemically validated smoking cessation in late pregnancy and at 6-months post-partum. The pilot phase which is presented here, also aimed to assess the effectiveness of the intervention, as well as examining the implementation and uptake, with consideration of process measures and the views of participating healthcare providers.

Specifically, the pilot study aimed to determine:

1. The rate of identification of smokers and delivery of smoking related advice;
2. The rate of provision of advice to quit smoking by healthcare providers;
3. The rate at which women agree to make a quit smoking attempt;
4. The rate at which women actually attempt to quit smoking during their pregnancy;
5. The rate of activation of social support and its association with smoking cessation;
6. The effectiveness of NRT in assisting women to quit;

7. The extent to which the intervention was delivered according to protocol; and
8. Any possible contamination which occurred between groups.

This study also examined the practicalities and difficulties associated with conducting intervention research in Aboriginal and Torres Strait Islander health services, and sought to offer suggestions and recommendations for future efforts in this area.

Ethical approval for this research was granted from the University of Newcastle Human Research Ethics Committee, and was endorsed by the Boards of Townsville Aboriginal and Islander Health Service and Wuchopperen Health Service. Refer to Appendix 5.1 for University Certificate of Approval, Appendix 5.2 for TAIHS endorsement letter and Appendix 5.3 for Wuchopperen endorsement letter, all from Chapter 5.

Methods

Recruitment and randomisation

The setting, participant group, and recruitment process are described in Chapter 5. Briefly, Aboriginal and Torres Strait Islander women who were aged 16 years or over and attended either of the health services (TAIHS or Wuchopperen) for antenatal care at or before 20-weeks gestation were eligible if they identified themselves as current smokers or recent quitters (having quit during their current pregnancy), were local residents, and planning to remain in the area and attend the health service for the duration of their pregnancy. Exclusion criteria were the current treatment of chemical dependency other than tobacco or alcohol and any florid mental illness.

Recruitment was performed by trained project officers, who provided a detailed verbal, and written explanation of the study, obtained written consent from those who were willing to participate (refer to Appendix 5.4), and assisted women to complete the pre-test (baseline) questionnaire (refer to Appendix 5.5).

Recent quitters were included in order to assess the capacity for an intervention to decrease the rate at which spontaneous quitters return to smoking during a pregnancy. A previous self-report based prevalence survey of smoking in pregnancy among Aboriginal women found that 13% of women quit smoking during pregnancy with no intervention, however only 5.5% of these women were able to sustain the change until the end of their pregnancy.⁶⁵

Women were assigned to additional care (AC) or usual care (UC) conditions according to the week in which they were recruited. A computer-generated calendar randomly allocated clinic weeks to the AC or UC conditions, and was used as the basis for randomisation. Women in the UC care group received routine antenatal care throughout their pregnancy, and were followed up at 34 to 36-weeks gestation and 6-months post-partum (not reported here). A questionnaire was completed at these follow-up points (refer to Appendix 8.1). In addition to usual antenatal care, women in the AC group were provided with a high intensity intervention early in their pregnancy, as well as ongoing smoking cessation support. Women who made an agreement to try to quit were encouraged to return in three to seven days for follow-up and complete a questionnaire. An additional questionnaire was also completed by women in the AC group who were provided with NRT (refer to Appendix 8.2). Women who claimed to have quit smoking at late pregnancy and/or post-partum follow-up were asked to allow their routinely provided urine sample to be used for cotinine analysis for biochemical validation.

Biochemical validation of self-reported smoking cessation

For biochemical validation, health workers transferred a small amount of women's routinely provided urine sample into a separate tube before any dipstick tests were performed. This aliquot was immediately refrigerated before being transferred to a –20 degree freezer at a local pathology laboratory. Samples were periodically shipped interstate by overnight freight, kept frozen. Analysis was performed using a Cozart Microplate ELIZA kit and Fluostar absorbance reader and calculator, as described in Chapter 6.

Usual care

Usual care provided by general practitioners and health workers at both sites involved a brief discussion regarding the dangers of antenatal smoking with women identified as smokers, and the provision of Queensland Health Quit smoking materials. Screening and advice is based on Queensland Health's standard shared care documentation including an assessment of the Fagerstrom Nicotine dependence score⁶⁶ and the patient's stage of change. Any women who asked for assistance to quit smoking were referred to the social health department at each site.

During the trial, all participants were also exposed to posters and displays in clinic waiting rooms or consulting rooms, relating to antenatal smoking or alcohol consumption as part of the usual care environment at each clinic. At Wuchopperen, all women who participated in the trial were given a small gift of a baby singlet and washer after the birth of their baby. At TAIHS, all participants received an adult t-shirt or backpack at 34-36-week follow-up and a baby t-shirt at 6-months post-partum. Women were not informed about these gifts prior to giving their consent.

The Intervention

After identification and recruitment of eligible smokers by the project officer, women saw their general practitioner for a routine antenatal consultation. Study participants were identified by a coloured page taken to the GP by the project officer or patient, or inserted into the patient's chart. At Wuchopperen, an alert was also placed on the electronic patient chart in Medical Director (the patient database package used at this site) and a colour-coded sticker placed on the share-care card carried by the patient. The coloured pages indicated the UC or AC status of participants and acted as a prompt and checklist for the intervention team in delivering relevant components of the intervention and meeting requirements for follow-up throughout the intervention. The intervention protocol is described based on the key elements discussed in the introduction.

The role of medical practitioners

General practitioners played a key role in the delivery of the intervention, giving firm advice to quit smoking. During the initial consultation after recruitment, practitioners were instructed to address the issue of smoking, and explain that quitting smoking was the most important thing that the woman could do to improve her own health, and that of her baby. The practitioner aimed to establish a trusting, supportive partnership with each participant, emphasising the availability of ongoing support throughout the pregnancy, and an understanding of the difficulties of quitting.

Integration into routine care

Visits to each health service by members of the research team enabled the design of a program that was acceptable for both communities, consistent between sites, methodologically rigorous, but sufficiently flexible to be integrated into the routine

systems of operation within each service. Informal discussions were held with staff members at each site, both in the development phase, and throughout the study, assessing the acceptability and feasibility of the approach. These discussions led to ongoing improvements in the logistics of the intervention, including aspects such as the recording of data, and the handover and communication between staff members. This element of flexibility was judged to be a key aspect in the evolution of the intervention, and the ability for the health services to maintain momentum in the study.

Provider acceptance of and adherence to the intervention

Both health services welcomed the opportunity to trial an intervention aimed at reducing an issue which is recognised by the Aboriginal and Torres Strait Islander community as a health priority. Principles of teamwork, capacity building within the health services, and the involvement of social support to tackle antenatal smoking, complemented the services holistic, community-wide approach to healthcare.

All healthcare providers who were involved in the implementation of the intervention (practitioners, health workers, midwives and project officers) attended a one-day training session delivered at each health service, by Professor Rob Sanson-Fisher and Professor Sandra Eades who are experts in behavioural health and experienced in both research and education. The first half of the training covered background on the dangers of smoking during pregnancy, the benefits of smoking cessation and the evidence-base for cessation and counselling strategies. The second half of the training was based on the protocol for the intervention. A substantial proportion of this session was dedicated to role-play practice in the counselling to be provided, and feedback from the staff involved. Importantly, staff feedback was reviewed after training sessions at each site, and some important suggestions were integrated into the final version of the intervention protocol. A training manual was developed as a reference to guide all

members of the intervention team through the steps of the intervention process from recruitment to final follow-up at 6 months post-partum (Appendix 8.3).

Multidisciplinary healthcare team

An important aspect of the intervention strategy was the involvement of local Aboriginal and Torres Strait Islander health workers and project officer(s). These individuals possessed valuable skills in communicating with patients from their local community and represented a crucial part of the day-to-day running of Aboriginal and Torres Strait Islander Community Controlled Health Services. These individuals, along with the general practitioners and midwives involved in antenatal care at each site, made up the study team. The principle of teamwork was important in the day-to-day running of the intervention, with communication between team members viewed as an essential element in the ability to adhere to the intervention protocol.

Cultural sensitivity

Staff and community involvement and empowerment were promoted in unique ways at each site. Staff members assisted in ensuring that appropriate language was used in all study materials. All written materials were prepared to a reading age of grade 5. Artworks were developed by staff members at each site to act as logos for use on all study materials such as pamphlets and patient letters. Staff members directly involved with the research participated in brainstorming sessions to generate concepts for these artworks. A competition was run amongst staff at TAIHS to establish a unique name for the study at this site. Each of these features were seen as important in promoting overall staff awareness about, and interest in the project, as well ensuring that the intervention itself, and associated materials were culturally appropriate, and relevant to the community.

Written materials

Three 'Smoking, No way!' pamphlets were specifically developed for the study, and were distributed based on the progress of each participant. The message of the pamphlets was the same, but artwork and local contact details differed for each health service. Refer to Appendix 8.4 for the three pamphlets in sequential order for Wuchopperen, plus one example of the TAIHS pamphlet.

The first pamphlet, 'Protect you and your baby today' included general information about the dangers of smoking during and after pregnancy and gave contact details for the health services. All women were given this pamphlet at their initial intervention visit. The second pamphlet 'You have made the right choice to quit' was given to all women who agreed to make a quit attempt, and included positive points about quitting, strategies for quitting and coping with cravings, and an explanation of withdrawal symptoms. The third pamphlet 'Support your partner or friend who is quitting' was given to support people who attended appointments with women or was sent home to be given to support people, and included educational information about the dangers of smoking and exposure to passive smoke during pregnancy, and suggestions such as trying to quit as well, or avoiding smoking near the pregnant woman.

An outcome driven intervention - Flexibility and alternative strategies

In keeping with the concept of working towards complete smoking cessation as quickly as possible, an approach of repeated contacts and ongoing encouragement was used. The protocol allowed intervention strategies to be tailored to the situation of each individual participant, always working towards the goal of smoking cessation. If a woman did not agree to make a quit attempt at the initial visit, permission was asked to discuss the issue again at her next routine visit. Those who agreed were asked to return to the clinic for follow-up within three to seven days. This follow-up was designed

to capture women in the early, more difficult phases of quitting, providing support and encouraging repeated attempts or continued cessation efforts. Women saw the health worker or midwife before they left the clinic to arrange follow-up, reinforce quit messages, and finalise details for postage of the letter to household members. Progress was assessed at the follow-up visits and was recorded in a brief questionnaire. Subsequent advice was then tailored according the situation of each individual. Successful quitters were congratulated and offered advice and encouragement to maintain cessation. Those who were unsuccessful were encouraged to try again, gradually increasing the number of days they abstained from smoking until they were able to maintain abstinence. A slightly modified version of the intervention was required for 'recent quitters', as these women had already stopped smoking prior to their initial visit. This sub-group required support and encouragement, but it was not necessary to elicit an agreement to quit, arrange three to seven day follow-up or offer NRT.

Increasing the probability of participant adherence to the protocol - Eliciting an agreement to try to quit smoking

Practitioners explained that 'cold-turkey' is the most effective method of cessation, and that they would really like the woman to agree to stop smoking 'today'. If women agreed to make a quit attempt, they were given a small wallet-sized reminder card (Appendix 8.5) with contact phone numbers, places to write future appointment dates, and the four 'D's' advise on coping with cravings (Delay, Deep breathe, Drink water, Do something else). Both the patient and practitioner signed the card to symbolise their agreement and partnership. TAIHS participants were given a calendar to put on the fridge to mark their quit day and smoke free days (Appendix 8.6), as well as a beaded bracelet or stress ball, a coffee mug and water bottle. Practitioners were asked to use

their own judgement and where they felt it was appropriate, to invite women to handover any cigarettes in their possession to remove the temptation to smoke.

Social support for quit efforts

Women were asked to identify a support person who they felt would be able to help them through their quit attempt. Permission was sought to send a letter to the woman's household, indicating that the woman was attempting to quit smoking during her pregnancy for her health and the health of her baby (Appendix 8.7). The letter included techniques that household members could use to help in the quit attempt. A magnetic card with suggestions was also provided, to be placed on the fridge at home (Appendix 8.8). If support people attended subsequent visits, they were invited to make a quit attempt as well, and were offered advice on supporting their partner or friend in her attempt.

Breaking a physiological addiction - A partnership to achieve cessation

The schedule of follow-up was dependent upon progress through the intervention stages and success or otherwise in quitting. Routine clinic visits were scheduled monthly throughout pregnancy at both health services. In addition, health workers made phone calls or home visits wherever necessary to ensure that contact was made with all AC participants at least fortnightly, regardless of their success in quitting. Additional contacts were made with women who were actively trying to quit or required additional social support. At each contact, advice was tailored according the circumstances of each individual, and was based on a motivational interviewing approach, with positive feedback and ongoing support and encouragement.

Provision of Nicotine Replacement Therapy

Women who were unsuccessful in two or more consecutive quit attempts, and were still motivated to quit, were offered NRT. Nicotine gum was offered to women, along with advice regarding its actions, suggested method of use and warnings about possible side-effects. A double-sided sheet was distributed with the gum, which gave clear instructions on the proper use of the gum, as well as outlining possible side-effects (Appendix 8.9). Participants were advised to treat the gum as medication, and not to smoke while they were using it.

Gum was distributed based on guidelines that patients who smoke less than 25 cigarettes per day should chew 2mg gum for up to 12-weeks. Those who smoke 25 cigarettes per day or more should chew 4mg gum for up to 12-weeks. No patient should exceed 24 pieces of gum per day. One pack of gum was given per visit, with a maximum of three packs provided over one to two months for the use of the pregnant woman and her support person. The use of the gum was assessed at a visit scheduled for approximately one week after distribution, and progress recorded in a brief questionnaire.

NRT was also offered to the people supporting these women if they were current smokers and were willing to make a quit attempt. The same dosage protocol was followed here, and detailed instructions were given on the use of NRT.

Data collection instruments

The baseline questionnaire was described in Chapter 5 (Appendix 5.5). This was used to collect information on demographics such as age and ethnicity, as well as smoking patterns and current smoking behaviour. The three to seven day follow-up questionnaire was a simple interview-based questionnaire to assess any changes in

smoking status from baseline and explore the uptake of the intervention, including items relating to the receipt of written materials by household members. In an attempt to gauge the level of support of women's quit attempts by their household members, women were asked to rate their agreement with the statements 'most of my household members are willing to help me quit and/or minimise my exposure to passive smoke while I am pregnant', and 'most of my household members think it's a good idea for me to quit smoking while I am pregnant'. The five possible responses ranged from strongly agree to strongly disagree. In order to assess a woman's resolve to quit smoking, she was also asked to rate her agreement with the statement 'I really want to quit smoking and I think I will be successful'. The three to seven day follow-up questionnaire is presented in Appendix 8.10.

Seven to ten days after women were provided with NRT, they were asked to return for follow-up, and a questionnaire was used to gather information on the use of NRT by women and their support people. The questionnaire was designed to determine how much gum women and their support people had used, whether women had smoked since being provided with the gum, and any side-effects of its use. Women were asked to identify any side-effects experienced from a list which was derived from pharmaceutical information about the product. Women were also asked to rate their level of agreement with a series of ten statements regarding NRT use. The statements were facts about NRT use, or about the claimed effects of NRT, such as 'these products help people feel less irritable when they quit smoking', and 'these products help people quit smoking'. Women's attitudes were also explored with the statements 'I am wary of the products', 'I am worried about becoming dependent on these products', and 'I don't need these products to help me quit'.

The 34 to 36 week follow-up questionnaire repeated the questions regarding smoking status and history used in the pre-test questionnaire. This was designed to enable direct comparison with baseline data.

Primary outcome measures

Biochemically validated smoking cessation at 34-36 weeks gestation, and at 6-months post-partum are the main outcomes for the continuing randomised controlled trial. In the pilot sample presented here, the main outcome measure is biochemically validated smoking cessation at 34-36 weeks gestation. Smoking cessation was classed as self-reported status as 'not a current smoker', and no cigarettes in the last seven days, as well as a urine cotinine level less than 175ng/mL. In the continuing study, data are also collected on birth outcomes and breastfeeding. Time limitations of this pilot study prevented the inclusion of data regarding 6-month post-partum follow-up.

Secondary outcome measures and process measures

The progress sheet (printed on coloured paper for this study) was developed to monitor the involvement of each individual (both AC and UC groups) throughout the intervention process, and acted as a checklist to both prompt providers about their role, and assess their adherence to the intervention protocol (Wuchopperen AC form found in Appendix 8.11, UC form found in Appendix 8.12). Questionnaires were completed three to seven days after women made an agreement to make a quit smoking attempt, seven to ten days after NRT provision (AC only), and at 34 to 36-weeks gestation. Notes were also made by healthcare providers in the computerised chart system Medical Director, and by hand in folders containing the study-related paperwork for each participant. Each of these sources was used to gather information on the implementation and process measures of the intervention.

Rate of identification of smokers

Antenatal visit rates, assessment of smoking, and self-reported smoking rates were used to assess the identification of smokers among antenatal clients at the health services.

Delivery of smoking related advice

Evidence of 'episodes of advice or smoking-related discussion' between participants and practitioners that were recorded on participant progress sheets or in the patient medical records were counted. The number of episodes was compared with the number of clinic visits to assess the rate at which practitioners delivered advice or discussed smoking during consultations.

Provision of advice to quit smoking and the role of healthcare providers

The provision of advice to quit was measured based on a checked box in the participant progress sheet relating to a discussion regarding 'cold turkey' quitting. The participation of the multidisciplinary healthcare team was assessed by recording episodes of advice or discussion with a health worker or midwife during clinic visits, home visits or phone calls.

How many women agree to make a quit smoking attempt?

The proportion of smokers who entered into a formal, written agreement to quit was also assessed based on participant progress sheets or practitioners notes in the medical records. A secondary measure of the establishment of a partnership between the practitioner and patient was the number of antenatal visits before recruitment and intervention delivery, indicative of success in the establishment of contact as early as

possible during the pregnancy. This data was collected from Medical Director records and daily clinic visit lists.

How many women actually attempt to quit smoking during their pregnancy?

The number of attempts made to quit smoking during the pregnancy, collected in the 34 to 36-week follow-up questionnaire for both groups, was used as a measure of the success in communicating the concept that quitting smoking is an ongoing process, and required multiple attempts. The change in level of smoking in cigarettes per day or self-report as occasional-smokers as opposed to daily smokers was also assessed.

Was social support successfully activated, and was it associated with successful cessation?

Social support was measured based upon the identification of a social support person, the attendance of this individual at any antenatal clinic visits, the smoking status of this individual and whether they live in the same house as the participant. Also, the receipt of the quitting smoking letter by the support person, and the use of NRT by those who were smokers were used as measures of the availability and level of support. These data were collected in the three to seven day follow-up questionnaire for AC participants.

Was NRT effective in assisting resistant smokers to quit?

The provision and use of nicotine replacement therapy, side-effects experienced, and both short- and long-term success in increasing quitting were measured. All women provided with NRT gum were asked to return to the clinic for monitoring and follow-up seven to ten days after they received the gum, and completed the questionnaire relating to the use of the gum at this time. NRT gum was also offered to support people

who smoked and were willing to make a quit attempt. The follow-up questionnaire assessed the use of the gum by such individuals.

To what extent was the intervention delivered according to protocol?

Participant progress sheets were the primary source of data for the assessment of adherence to protocol. Notes in the participant databases established at each service, as well as notes in patient charts were also searched for evidence of intervention-related advice or contamination of the usual care group. The provision of the appropriate pamphlets, advice to quit cold turkey, number of contacts with participants, number of episodes of advice delivered by the practitioner, and evidence of advice delivered by the project officer were used as measures of adherence.

Protection against contamination

At 34 to 36-week follow-up all participants were asked to name any individuals known to them who were also participating in the study. Names were checked for any potential contamination between groups with any communication between AC and UC participants potentially giving UC participants access to intervention-specific written materials and messages.

Statistical analysis

Baseline characteristics of AC and UC groups (collected in the questionnaire described in Chapter 5) were categorised and compared using the Chi-square test. Dichotomous outcome measures including the proportion of self-reported and cotinine validated quitters in each group were compared using the Chi square test or Fisher's exact test where expected cell counts were less than five. Continuous outcomes such as number of cigarettes per day were compared between groups using the Mann-Whitney test due

to the skewed nature of the data. Logistic regression analyses were used to calculate odds ratios for successful quitting in the two groups. Initial analyses used an intention-to-treat approach. In order to address loss-to-follow-up, all women who were eligible for but failed to complete 34 to 36-week follow-up were included as continuing smokers. As a sensitivity analysis, separate analyses were performed including only those women who were not lost to follow-up.

Secondary outcomes were measured using frequencies and descriptive statistics of the data gathered in follow-up questionnaires and participant progress sheets. After checking for assumptions, chi-squared tests were performed to assess the relationship between smoking status at the end of pregnancy and the dichotomous process measures examined. This included making an agreement to quit smoking, the availability of social support, the receipt of written materials and the use of NRT. Process measures such as the number of visits to the clinic, number of episodes of advice from a GP and number of quit attempts during the pregnancy were assessed for their relationship to smoking outcomes using non-parametric Mann-Whitney analysis. Differences between groups and between quitters and continuing smokers were also assessed using mann-Whitney tests.

The sample size for the ongoing randomised controlled trial was based on an assumption that approximately 200 Aboriginal or Torres Strait Islander women would visit TAIHS before 20-weeks gestation each year, and approximately 100 would visit Wuchopperen. Therefore, over the proposed two and a half year recruitment period, 750 women would attend before 20-weeks gestation for initial antenatal care. If all of these women were approached to participate in the study, a smoking rate of 60%, and consent rate of 60% would lead to the recruitment of 270 smokers over the two and a half year period. Of the anticipated 270 smokers in the study, we would expect 135 per group. Assuming that 80% of women can be followed up, the sample size for outcomes

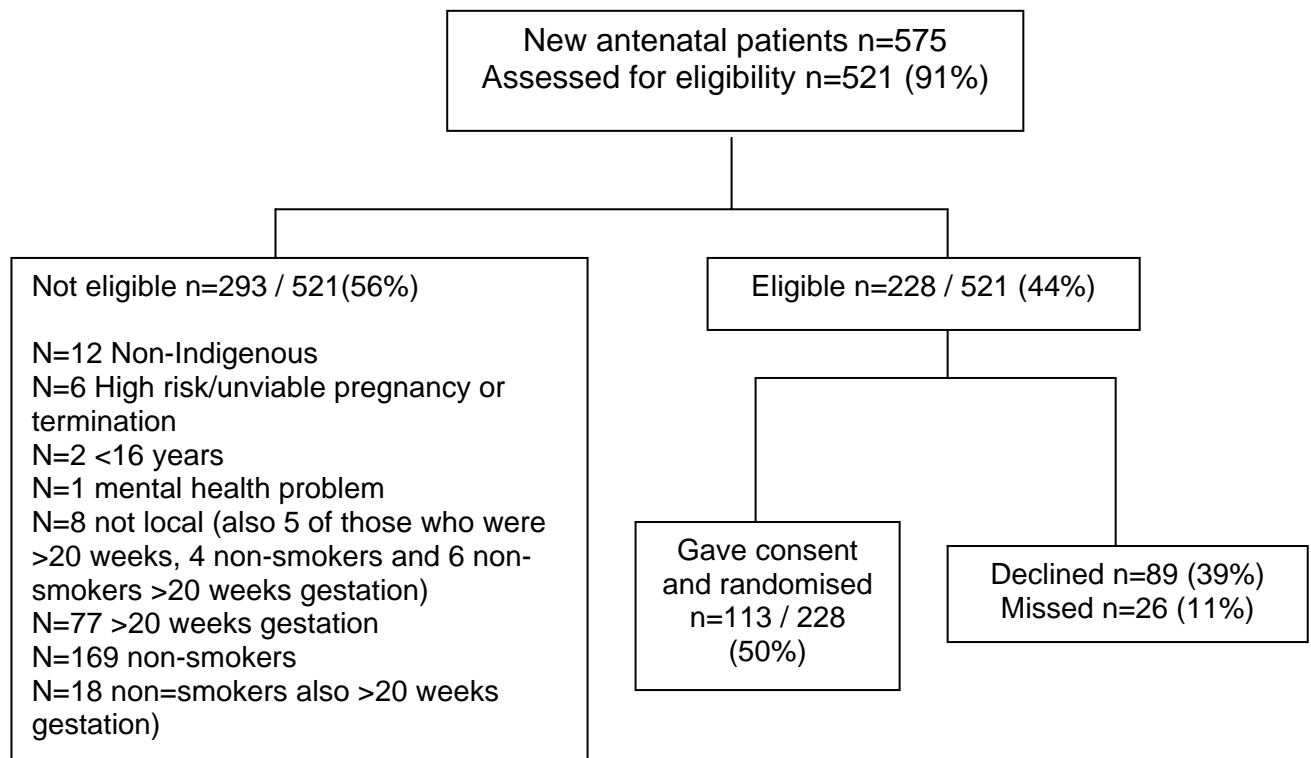
would be 108 per group. This would allow detection of a difference between intervention groups in smoking cessation and other dichotomous variables of 20% (assuming a quit rate of 15% in the control group) and a difference of continuous outcomes of 0.5 of a standard deviation, with 5% significance level and 80% power, and allowing for a design effect of 1.5 for clustering of participants within clinics. The effect of clustering will be minimised by randomising within clinics, rather than randomising clinics. While the continuing study is well powered, based on these predictions, the study presented here is a pilot only. The present study was not designed to have high power, but to use the early part of the ongoing study to assess the processes of research and the uptake of the intervention.

Results

Recruitment

Five hundred and seventy-five (n=575) new antenatal patients visited the participating health services during the recruitment period from November 2005 to April 2007. Of these women, 54 were missed, leaving 521 who were assessed for their eligibility for the study (91%), from which 228 were identified as being eligible (44%). The reasons for which women were ineligible are detailed in Figure 8.1.

Figure 8.1: Recruitment process for the pilot RCT to April 2007



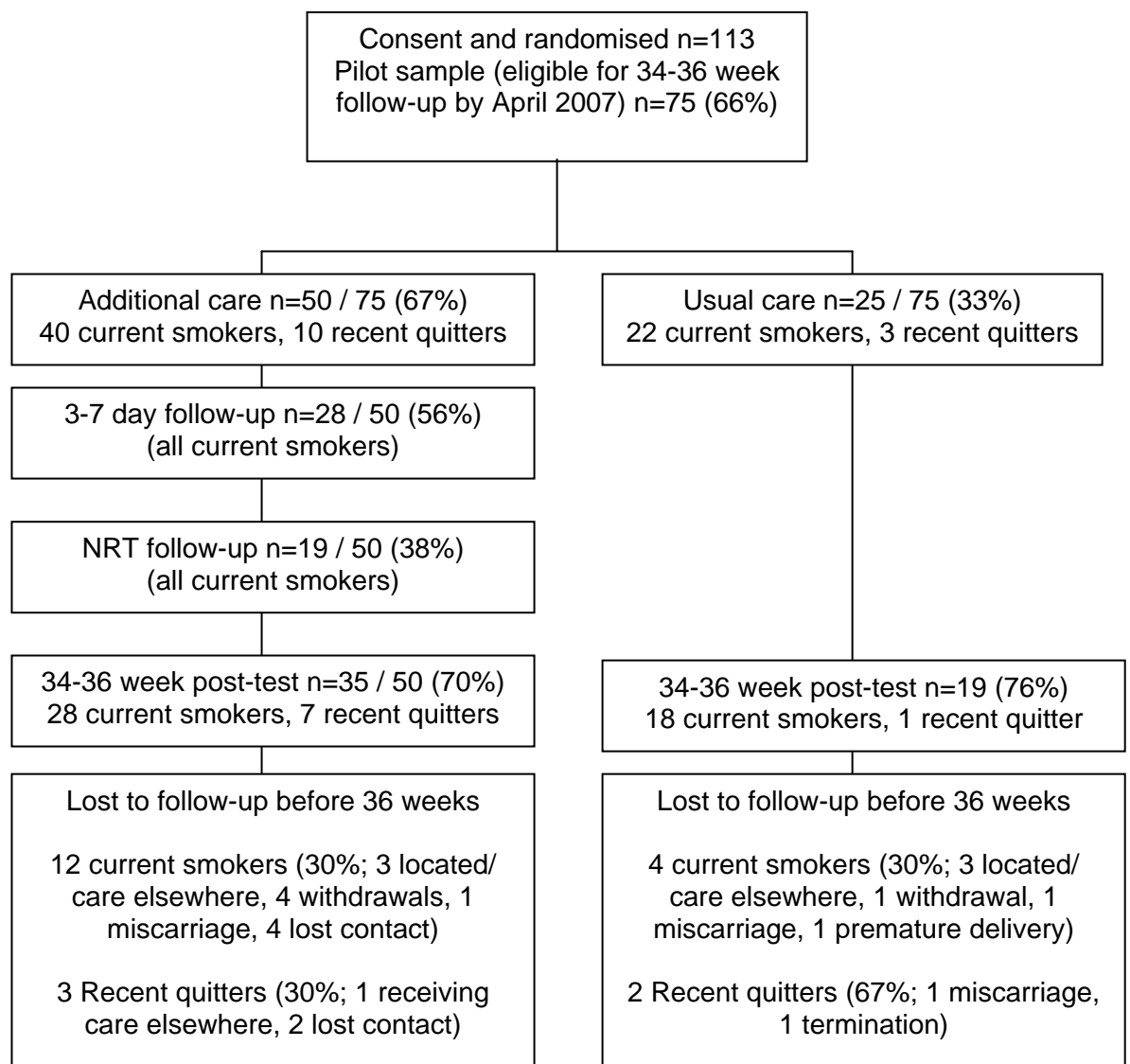
** 26 women were missed for invitation to the study by project officers.*

From the 521 women assessed as being eligible, 512 had their smoking status recorded: 302 were identified as smokers (59%), and 32 as recent quitters (6.3%). One hundred and thirteen (50%) of the 228 eligible women consented to take part in the study and were randomised to either the AC or UC group. Of the 76 women randomised to AC, 63 were current smokers (83%), and 13 were recent quitters (17%). Fifty-five women were randomised to UC; 50 current smokers (91%) and five recent quitters (9%).

It is important to note that follow-up data are reported for women who were eligible for 34-36-week follow-up at the end of data collection in April 2007, at the completion of

pilot-phase data collection. Here, 34 to 36-week smoking cessation outcomes will be presented for the 50 AC participants and 25 UC participants.[^] The process of recruitment, participant numbers for analysis and loss to follow-up are detailed in Figure 8.2.

Figure 8.2: Follow-up and analysis of pilot sample, those eligible for 34-36 week follow-up before April 2007



[^] Recruitment for the RCT will continue for a further 12-months, with an additional 12-months for follow-up of all participants. All participants will be analysed in the evaluation of the full, completed study with outcome measures at both 34-36 weeks gestation, and 6-months post-partum.

Follow-up data was available for 35 out of the 50 AC participants (70%), and 19 out of the 25 UC participants (76%). Respectively, the groups contained 28 and 18 women who were current smokers, and seven and one who were recent quitters at baseline. For intention to treat analysis, an additional 15 AC participants (12 current smokers and three recent quitters at baseline), and 6 UC participants (four current smokers and two recent quitters at baseline) who were lost to follow-up prior to completing the 34-36 week questionnaire, were included.

Recent quitters were recruited and involved in the intervention, aiming to prevent their relapse to smoking during pregnancy. As these individuals require a version of the intervention which is slightly modified from the main protocol, smoking rates at 34-36 weeks will be assessed for this group, but they are not included in analysis of process measures and other exploratory analyses.

Initial exploration of participant and non-participant groups

Table 8.1 presents results of a comparison of demographic characteristics between the 133 eligible women who consented to take part, and the 63 non-consenters for whom data was available. Fewer non-participants identified themselves as being from both Aboriginal and Torres Strait Islander origin but with ethnicity identified for fewer of these women, the importance of this apparent difference is questioned.

Table 8.1: Demographic characteristics of consenting and non-consenting eligible women at baseline.

	Intervention participants N=133		Non-participants N=63		Test statistic		
	n	%	n	%	χ^2	df	p-value
Age							
<=19	27	21	10	16	0.656	3	0.884
20-24	45	34	23	37			
25-29	30	23	12	19			
>=30	29	22	18	29			
Median							
Gestational age							
1 st trimester (wks 1-12)	65	52	21	55	0.533	1	0.465
2 nd trimester (wks 13-20)	62	48	17	45			
Median	12						
Smoking status*							
Smokers – current	113	44	44	69	1.277	1	0.258
Ex-smokers	19	9	9	14			
Ethnicity**							
Aboriginal	72	54	37	58	92.995	1	<0.0001
Torres Strait Is.	39	29	21	32			
Both	22	17	2	3			

Data was available for 63 of the 105 non-participants only.

Except for gestational age data which was available for 38 non-participants only.

** Smoking status was not identified for 11 (17%) non-participants.*

** Ethnicity was not identified for 4 (6%) non-participants.*

Initial comparison of TAIHS and Wuchopperen subgroups

The final intervention population was made up of 33 participants attending Wuchopperen, and 42 attending TAIHS for antenatal care (Table 8.2).

Table 8.2: Demographic characteristics of women recruited from Wuchopperen and TAIHS

	Wuchopperen participants N=33		TAIHS participants N=42		Test statistic		
	n	%	n	%	χ^2	df	p-value
Age							
<=19	8	24	7	18	1.607	3	0.658
20-24	8	24	15	38			
25-29	7	2	7	18			
>=30	10	30	11	28			
Median							
Gestational age							
1 st trimester (wks 1-12)	16	49	20	48	0.006	1	0.941
2 nd trimester (wks 13-20)	17	52	22	52			
Median							
Cigarettes per day							
<10	14	61	24	59	3.808	2	0.149
10-20	9	39	13	32			
>20	0		4	10			
Median							
Ethnicity							
Aboriginal	28	85	29	69	9.453	2	0.009*
Torres Strait Is.	5	15	9	21			
Both	0		4	10			
Father ethnicity							
Non-Indigenous	4	13	10	24	10.041	3	0.018*
Aboriginal	10	31	22	52			
Torres Strait Is.	15	47	6	14			
Both	3	9	10	10			
Income							
Social security	28	85	29	69	5.639	3	0.131
Own work	5	15	9	21			
Supported by partner/other	0		4	10			
Education							
Less than year 10	2	6	8	20	3.294	2	0.193
Year 10 – Year 12	15	46	18	44			
Tertiary education	16	49	15	37			

The comparison between these sub-groups indicates a slightly different ethnic profile was observed between the groups, with a greater proportion of Aboriginal women and fewer Torres Strait Islander women ($p=0.009$) recruited at TAIHS. Similarly, the women recruited at TAIHS were more likely to identify their partner as Aboriginal as opposed to Torres Strait Islander ($p=0.018$). Numbers were small, and power low to make these comparisons. With these minimal baseline differences, it was deemed appropriate to combine the samples.

Baseline characteristics of all participants

Table 8.3 outlines the characteristics of the AC and UC participants at baseline. The only statistically significant difference between groups was a higher level of cigarette consumption in the UC group, with more women smoking 20 or more cigarettes per day ($p=0.007$). Average cigarette consumption also differed between groups, with an average of 8.4 in the AC group compared to 12 in the UC group ($p=0.043$). Despite low power, the characteristics appear to be similar between groups.

Table 8.3: Baseline characteristics of AC and UC participants

	AC N=50		UC N=25		Test statistic		
	n	%	n	%	χ^2	df	p-value
Age							
<=19	10	21	5	20	2.853	3	0.415
20-24	16	33	7	28			
25-29	11	23	3	12			
>=30	11	23	10	40			
Median							
Gestational age							
1 st trimester (wks 1-12)	22	44	14	56	0.963	1	0.327
2 nd trimester (wks 13-20)	28	56	11	44			
Median							
Cigarettes per day							
<10	24	59	14	56	9.993	2	0.007*
10-20	17	42	5	20			
>20	0		4	16			
Median							
Ethnicity. Number (%)							
Aboriginal	25	50	15	60	0.789	2	0.674
Torres Strait Is.	16	32	7	28			
Both	9	18	4	16			
Father ethnicity. Number (%)							
Non-Indigenous	9	18	5	20	0.567	3	0.904
Aboriginal	20	41	12	48			
Torres Strait Is.	15	31	6	24			
Both	5	10	2	8			
Income							
Social security	38	76	19	76	2.344	3	0.504
Own work	10	20	16	16			
Supported by partner/other	2	4	2	8			
Education							
Less than year 10	8	16	2	8	0.997	2	0.607
Year 10 – Year 12	21	42	12	48			
Tertiary education	21	42	11	44			

Primary outcome measure

What was the effectiveness of the intervention at increasing the rate of smoking cessation at 34-36 weeks gestation?

At late-pregnancy follow-up, six (21%) AC participants, and two (11%) UC participants had successfully quit smoking according to self-report (Table 8.4).

Table 8.4: Primary smoking cessation outcomes

With all women included in analysis	AC (N=50) n %	UC (N=25) n %	Mann-Whitney U	p value
Ex-smokers at 34-36 weeks*	6 15	2 9.1	414.0	0.510
Ex-smokers at 34-36 weeks (of recent quitters at baseline)	5 50	1 33	12.5	0.626
Women who were followed-up only	AC (N=35) n %	UC (N=19) n %	Mann-Whitney U	p value
Ex-smokers at 34-36 weeks*	6 21	2 11	211.0	0.282
Average CPD [†] change*	0.9	0.5	35.0	0.924
Total antenatal visits*	5.4	5.7	213.5	0.851
Number of quit attempts*	2.6	3.6	123.5	0.315
Total number of contacts with healthcare providers*	7.0	6.0	164.0	0.209
Biochemically validated quit rates (with ITT) ^{††}	AC (N=50)	UC (N=25)		
Ex-smokers at 34-36 weeks*	2/3	1/1		
Ex-smokers at 34-36 weeks (of recent quitters at baseline)	4/5	1/1		

*Analysis includes current smokers at baseline only

[†]CPD; Cigarettes per day

^{††}For biochemically validated quit rates, results are presents as biochemically validated quitters/total number of self-reported quitters by whom urine samples were provided for cotinine analysis.

While the difference in quit rates generates an odds ratio of 2.8 in sensitivity analysis, due to the small numbers it does not reach statistical significance (95%CI of OR 0.389-12.246). When all women who were eligible for 34-36 week follow-up were included in the analysis, the odds ratio was reduced to 1.5 (95%CI 0.285-8.282). No statistically significant differences were reached between groups on reduction of the number of cigarettes per day, total number of quit attempts made, number of antenatal consultations, or total number of contacts with the health service during the pregnancy.

Of the women who had spontaneously quit smoking for their pregnancy, five (71%) and one (100%) remained abstinent in the AC and UC groups respectively. Of the six women who successfully quit smoking during their pregnancy, the average number of quit attempts made prior to success was 1.8 (median 2, SD 0.45), and the average gestation of quitting was 23 weeks (median 13, SD 9.56). Overall, participants made an average of 2.6 quit attempts (median 2, SD 1.87). Successful quitters were more often pregnant with their first or second child, than those women who were unable to quit. The mean number of pregnancies and parity for quitters were 1.8 and 0.6, and for continuing smokers were 3.7 and 2.6. Differences between quitters and smokers were not statistically significant in non-parametric analyses.

Urine samples were available for four of the eight self-reported quitters only. Two of the three AC participants for whom cotinine analysis was possible were biochemically validated quitters. The one usual care participant for whom analysis was possible was also biochemically validated as having quit. Of the women who were recent quitters at baseline and provided urine samples for cotinine analysis at 34-36 week follow up, four of five AC participants and one of one UC participant were biochemically validated non-smokers. The small numbers precluded any meaningful statistical analysis of these results. Due to the small numbers of women for whom validation was possible, the discussion of results is based on self-reported quit rates.

Secondary Outcomes

Rate of identification of smokers and delivery of smoking related advice

A total of 530 women (296 and 234 at TAIHS and Wuchopperen respectively) were assessed for eligibility during the first 17 months of the study. The average number of births per year to women who receive antenatal care at the two sites is 150 and 100 respectively. It is therefore expected that most women who attended either site, and were pregnant during the study period, were identified and assessed for eligibility. While the average birth figures would give a total of only 354 women over a 17-month period, the assessment of a greater number of women is expected to relate to those who leave the area or attend an alternate clinic for antenatal care after discovering their pregnancy. Eighteen women who attended the clinics were missed for assessment. The smoking status of 16 of these women is unknown, indicating that during routine visits, the smoking status has not been recorded in these patient's charts. Overall, 97% of women were assessed, and therefore it was assumed, based on accurate self-reports of smoking status, that 97% of smokers were identified.

Provision of advice to quit smoking and the role of healthcare providers

The average number of visits made to the clinic by AC women who were current smokers at recruitment and were followed through to 34-36 weeks was 5.4 (range 10, median 5, SD 2.14). The average number of episodes of smoking related advice or discussion with practitioners for these women was 2.3 (range 4, median 2, SD 1.2). This generates a ratio of visits to evidence of advice of 2.8, with smoking being raised during one in every 2.8 visits. With a total of 140 visits made by this group of women between recruitment and 34-36 weeks of pregnancy, and evidence that smoking was raised during 59 of these visits, only 41% of intervention opportunities were apparently taken up by practitioners. Interestingly, contact and smoking-related discussions with women were undertaken by the project officers on a total of 81 occasions, or during

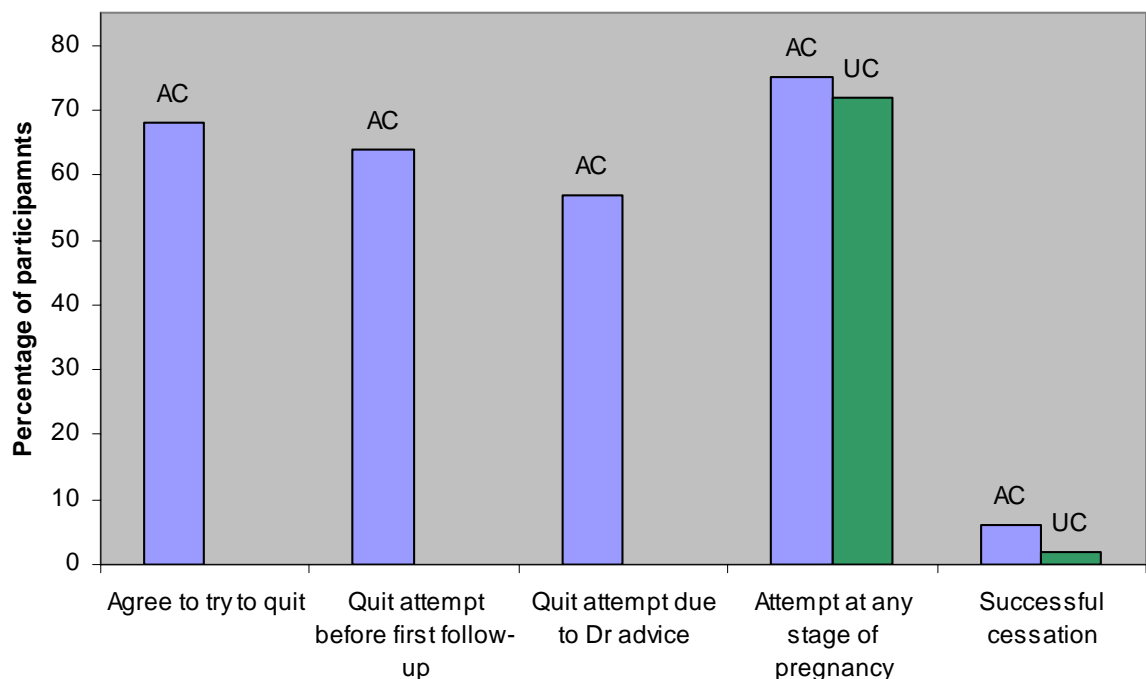
58% of the visits made. Midwives documented having discussed smoking on five occasions, or during 4% of visits.

No relationship was found between the number of episodes of advice and smoking status at 34-36 weeks. Non-parametric Mann-Whitney tests were used to explore the relationship of smoking at 34-36 weeks follow-up with the number of episodes of advice from the practitioner ($U=31.5$, $p=0.588$), number of contacts with a project officer ($U=34.0$, $p=0.757$), and the total number of antenatal visits between recruitment and end of pregnancy follow-up ($U=21.0$, $p=0.143$).

How many women agree to make a quit smoking attempt?

Evidence in any study documentation that women entered into an agreement with their practitioner to make a quit smoking attempt was regarded as a measure of the initial delivery and uptake of the intervention. Of the 28 AC women who were current smokers at baseline and were followed-up late in their pregnancy, 68% ($n=19$) made a formal agreement to try to quit. Figure 8.3 illustrates the uptake of the intervention and attempts by the women to quit smoking.

Figure 8.3: Uptake of the intervention and attempts to quit smoking



Initial uptake of the intervention demonstrated in the proportion of AC participants who agree to make a quit smoking attempt, those who quit before their first follow-up, and those who claim that their attempt was due to the advice received at the clinic. The number of women in each group who attempted to quit at any stage of their pregnancy, and the proportion who successfully quit are compared.

How many women actually attempt to quit smoking during their pregnancy?

Seventy-five percent (n=21) of women reported having made a quit attempt at some point during their pregnancy. No relationship between making an agreement and quitting smoking was found ($U=30.0$, $p=0.385$). Women reported abstaining from smoking for an average of 2.4 days (median 1, range 0-28, SD 4.7) after their first visit, but returned to the clinic after an average of 16 days (median 6, range 3-74, SD 18.7). Progress and uptake reported in the three to seven day follow-up questionnaire is presented in Table 8.5. Sixty-four percent of participants (n=18) made an attempt to quit between their initial visit and the three to seven day follow-up period, with 78% (n=14) of these women reporting that their quit attempt was the result of the advice

received by the doctor or other healthcare provider at their previous clinic visits. Fifty-seven percent of women (n=16) reported that their household members had received letters from the clinic, all of whom said that the quit smoking agreement was displayed on the fridge at home. Seventy-one percent (n=20) of the women completing the three to seven day follow-up questionnaire believed that their household members were willing to help them quit smoking, 82% (n=13) reported that their household members agreed that quitting smoking was a good idea. A total of 68% (n=19) of the women claimed that they wanted to quit and had belief in their ability to do so, while 21% (n=6) remained neutral and 11% (n=3) disagreed with this statement.

Table 8.5: Process measures recorded 3-7 days after intervention delivery

Process measure	Number of participants N=28	Percent (%)
Tried to quit since last visit	18	64
Attempt made as a result of advice from Dr	14	78 (of women who made attempt)
Letters received by household members	16	57
Agreement displayed in fridge at home	16	57
Household members willing to help		
Disagree	4	15
Neutral	4	14
Agree	20	71
Household members agree that quitting is a good idea		
Disagree	1	4
Neutral	4	14
Agree	13	82
Desire to quit and belief in ability to succeed		
Disagree	3	11
Neutral	6	21
Agree	19	68

Data refers to additional care (AC) participants who were current smokers at baseline (n=28)

Was social support successfully activated, and was it associated with successful cessation?

Twenty-four AC participants who were followed through (86%) identified an individual who would support them in attempts to quit smoking during their pregnancy. Only ten of these individuals (42%) attended any clinic visits with the pregnant woman to whom they were providing support. Documentation indicated that no support was provided to 16 women (67%). Of the 40 AC participants for whom three to seven day follow-up data was available, 25 (63%) indicated that their household members or support person had received the letter sent to them from the clinic.

Thirteen support people (46%) were identified as smokers, four (14%) as non-smokers, and for the remainder this information was not available. Of the 12 cases where information regarding the place of residence of support people was available, nine (75%) resided with the pregnant woman. Five support people were reported to have used NRT gum as part of their efforts to quit in support of the pregnant woman. Non-parametric analysis did not demonstrate any statistically significant relationship between the variables associated with social support (identification of support person, smoking status of support person, residence with woman, or evidence that support was provided) with smoking status at follow-up.

With studies in previous chapters emphasising the importance of the social environment in influencing the behaviour of individuals, it is possible that the low rate at which social support appears to have been engaged, has indeed influenced the quit rates achieved. While no relationship was found during statistical analyses of social support and quitting, the small numbers, and difficulty in gauging the actual degree to which social support was provided precludes meaningful interpretation of these results.

Was NRT effective in assisting resistant smokers to quit?

The data collected in the NRT follow-up questionnaire, from women who were provided with gum is summarised in Table 8.6.

Table 8.6: NRT use and success

Process measure	N=19	
	n	%
Provided with NRT AC current smokers at baseline	19	48 (of AC current smokers at baseline)
Used NRT previously	2	11
Smoked cigarettes since last visit	16	84
Days since last visit (AC current smokers)	Mean 23, median 7, range 3-120, std dev 35.1	
Amount of gum provided	Mean 57, median 45, range 1-200, std dev 52.2	
Amount of gum remaining	Mean 39, median 29, range 0-104, std dev 37.5	
Gum used by support person	5	28
Side effects experienced	9	47 (of all women using gum)
Nausea	4	
Indigestion	3	21
Vomiting	3	16
Mouth ulcers	2	16
Trouble sleeping	1	11
Sweats	1	5
Dizziness	2	5
		11
Would recommend gum to others	14	78

Nineteen (48%) of the women who were current smokers at baseline were provided with NRT after initial failed quit attempts, and completed the NRT follow-up questionnaire. Eleven percent of these women had used NRT products previously. Eighty-four percent of users had smoked since being provided with the gum, and despite the protocol for follow-up seven to ten days after providing NRT, the average number of days between the visit at which the gum was provided, and completion of follow-up was 23 (median 7). While there was a wide range in both the amount of gum provided, and that remaining at follow-up, the relatively small difference between the two figures raises questions over the actual usage of the gum. With 44% of users (n=9) experiencing some side-effects associated with the gum, it may be that these issues caused women to stop using the product after only a short period. Despite this apparent low rate of use, and the experience of side-effects, 78% of users (n=14) said that they would recommend the gum to their friends. Non-parametric analysis indicated that there was no statistically significant relationship between NRT and successful quitting at 34-36-weeks of pregnancy.

The most notable result regarding the attitudes towards NRT is perhaps the large number of women who were neutral regarding the potential of NRT to help with quitting and its side-effects (refer to Table 8.7). The responses suggested that overall, women recognised the capacity of NRT to help with quitting, but many were wary of the products (n=7, 50%) and only 14% (n=2) indicated that they 'needed' the products to help them quit. Thirty-six percent of women (n=5) agreed with the statement that they didn't need the products to help them quit, 29% (n=4) remained neutral, and 21% (n=3) responded that they didn't know.

Table 8.7: Percentage of women who were provided with NRT who agree with the statements

Statement regarding NRT (N=19) These products help people:	Agree		Neutral		Disagree		Don't know	
	n	%	n	%	n	%	n	%
Feel less irritable when they are quitting smoking	9	67	2	13	4	27		
Feel less depressed when they are quitting smoking	5	36	5	36	2	14	2	14
Cope with the cravings for cigarettes	10	71	3	21	1	7		
Quit smoking	8	57	5	36	1	7		
Feel less anxious when they are quitting	9	69	1	8	1	8	2	15
Resist the need to smoke in places or situations where it is not possible	10	71	4	29				
I am worried about the side effects of the products	6	46	2	14	5	39		
I am wary of the products	7	50	2	14	4	29	1	7
I am worried about becoming dependent on the products	3	21	3	21	8	57		
I don't need the products to help me quit	5	5	4	29	2	14	3	21

To what extent was the intervention delivered according to the protocol?

Extensive analysis of participant progress sheets and notes made by practitioners, project officers and health workers in the Medical Director system, patient charts and participant databases revealed a less than ideal level of adherence to intervention protocol. Study documentation indicated that only 20 women (71% of all AC participants) were given advice to quit 'cold-turkey'. This advice was not associated with smoking status at 34-36-weeks gestation for those who were followed through ($U=36.5$, $p=0.900$). Documentation of the provision of the appropriate participant pamphlets was available for 18 women (64%). Again, no relationship was found

between the provision of pamphlets and smoking status at follow-up $U=32.5$, $p=0.583$), but small numbers and low power limited the capacity to detect such a relationship.

Discrepancies between the number of clinic visits, and number of episodes of advice or discussion about smoking from practitioners, gives a clear indication that the principles of brief messages being repeated at each contact and an ongoing partnership between patients and practitioners were not fully achieved. The study protocol was for contact with AC participants every two weeks throughout their pregnancy. With an average of 1.4 phone contacts, and 0.2 clinic visits, participants would need to have made at least six visits to the clinic up to the 34-36-week follow-up. Fifty-eight percent of AC participants attended less than six clinic visits, and 19% attended six visits prior to late pregnancy follow-up. The median number of visits for AC participants was five, and average was 5.6.

Evaluation of paperwork also revealed a pattern of repeated delivery of advice and counselling by the project officers, often more frequent than intervention-related discussions with practitioners or health workers. The median number of times advice was given by a project officer, as evidenced by participant progress sheets and chart notes, was three per woman. The median number of times advice was given by a practitioner was two per woman.

Did the intervention successfully promote partnerships to encourage multiple quit attempts?

The partnership concept was based on practitioners establishing a relationship with women as early as possible in their pregnancy, and assisting them to quit smoking with multiple attempts if necessary. Women had an average of one antenatal visit prior to recruitment (median=0), with some attending up to three, suggesting that the

opportunity to generate a relationship as early as possible was often missed. The average number of quit attempts reportedly made throughout pregnancy was 2.6 in the AC group (median=2) and 3.6 in the UC group (median=3.5). While this difference did not reach significance, the figures suggest that the intervention and associated partnerships failed to increase the number of attempts made by women, or their motivation to quit. The small sample size and subsequent low power preclude more meaningful analysis of these results.

Was the intervention successful in employing the multidisciplinary healthcare team at each service?

An average of 1.4 phone calls were made with each participant (range 2, median 1, SD 1.29), along with 0.2 home visits (range 3, median 0, SD 0.71). Interestingly, an additional 2.1 phone calls were made with unsuccessful contact (range 14, median 1, SD 3.4), and 0.2 unsuccessful home visits (range 2, median 0, SD 0.51) to each AC participant. These figures are indicative of some level of multidisciplinary involvement. Evidence from participant's charts is also highly supportive of multidisciplinary involvement. The PhD candidate and research team observed active involvement in the study, from every level of the healthcare team.

Potential contamination

No participants, when questioned at the 34-36-week follow-up, were able to name any other individuals known to them who were also involved in the study. Discussions with members of healthcare team, as well as notes recorded by project officers and health workers however, uncovered incidents of contamination between study groups. One practitioner spoke of the change in routine practice which occurred with the implementation of the intervention: *"Before the study I always talked about smoking with every patient at their first visit, but I didn't always remember to check again at later*

visits. Once we started doing the intervention, I was always thinking about smoking, so it was really hard not to talk to usual care participants about it if I knew they were smokers". This practitioner suggested that the main difference between usual care and additional care became the written materials, rather than the level of advice or support given.

Notes in the Medical Director system at one site suggested that the project officer may have prompted the doctor to approach the smoking issue with a usual care participant who was known to be attempting to quit smoking. While such a patient may, under normal circumstances, receive advice and support from their doctor, reminders from a project officer who would not routinely be present and aware of the patient's smoking status potentially contaminates the process.

Records made by project officers and health workers indicated that NRT was distributed to three participants in the UC group, one of whom completed an NRT follow-up questionnaire, and a letter was sent to a 'support person' of one UC participant. Follow-up questionnaires were completed by five UC participants at three to seven days. In five cases, there was evidence of multiple contacts with the project officer and smoking related discussions with UC participants. Further, against instructions given by the researchers, the project officer at one site continued to pursue all participants for the collection of multiple urine samples for a separate study. While this in itself, did not involve intervention delivery, additional contact with the individual with whom patients are likely to associate 'the smoking study', may have led to contamination of the usual care group.

Discussion

During the study period, 15% and 9.1% of AC and UC participants who were self-reported smokers at recruitment, quit smoking. While the difference between groups in validated smoking cessation rates did not reach statistical significance, the rate of smoking cessation achieved in both groups, and overall cessation rate of 11% (15% using sensitivity analysis) is substantial. This study has great potential to examine the barriers to the implementation of interventions in primary healthcare settings, and in particular ACCHS sites. A number of limitations have been recognised in the internal validity of the study, but many lessons may be learned from the processes involved, and the experiences of researchers and health service staff in this endeavour.

Identifying smokers

While the smoking cessation outcomes do not reach statistical significance, positive results were recorded in a number of secondary outcomes. Importantly, the rate of detection of smokers at the health services appeared to be high. This is critical if any improvement in smoking rates is to be made in the future, and represents good potential for the delivery of interventions. The rate of smoking among all women whose smoking status was recorded was 59%. This is consistent with previous studies with Aboriginal and Torres Strait Islander women,⁶⁷ though the rate of 'spontaneous quitting' was slightly lower than expected from the literature.⁶⁸ A study of an urban Aboriginal population in Western Australia reported that 13% of women quit smoking spontaneously during their pregnancy, but only 5.5% were able to maintain abstinence for the duration of the pregnancy.⁶⁸ Other studies with non-Indigenous populations have reported that of women who quit smoking spontaneously upon discovering a pregnancy, up to 70% return to smoking at some stage of their pregnancy.^{69 70} Of spontaneous quitters in the present study, 75% remained abstinent at 34-36-weeks.

Although the sample size is small, and no difference was found between the AC and UC groups, these figures compare favourably with the literature.

Delivery of smoking-related advice

The data collected from participant progress sheets and charts indicated a higher rate of advice being given by project officers compared to practitioners. It is perhaps understandable that such a pattern should occur, with the project officers in a position of knowing the progress and intervention status of each participant, and being entirely focussed on monitoring their follow-up and maintaining contact. Practitioners on the other hand, have other patients to see, and other clinical tasks to attend to, operating within an often 'chaotic' clinic environment. While such an approach may be feasible in terms of time allocation by each individual, the capacity to generalise the results and implement the intervention more broadly in routine care is limited. At any time should the role of the project officer extend beyond those tasks specifically associated with research to the actual delivery of the intervention, the ability for the intervention to be implemented in routine care outside of the research setting, without the injection of additional funding is not fully assessed.

Ironically, even the figures relating to contact numbers and advice given should be interpreted with caution. Anecdotal evidence; observations of day-to-day clinic activities, and feedback from practitioners and project officers indicated that the participant progress sheets may have limited value as measures of adherence. While the practitioners generally stated that they made some attempt to deliver the intervention, they were not always diligent in their efforts to address the study protocol. Project officers at both sites indicated that often the "*Doctor's didn't fill in the sheets, so I [project officer] did it*". A certain level of guesswork was involved in the retrospective

completion of the sheets, with assumptions made regarding the interaction which had occurred between participants and practitioners.

Eliciting an agreement to quit

Perhaps the most promising result is the uptake of the intervention by antenatal women, and the rate at which they entered into agreements to quit smoking. While many women who made a quit attempt failed to remain abstinent, prompting attempts to quit is a critical starting point for any intervention. Critically, 74% of women who reported having made a quit attempt between their first visits and follow-up did so as a result of the advice delivered by their practitioner or other clinic staff member. This is an important result, suggesting that the initial delivery and uptake of the intervention were highly successful.

Was the delivery of an intervention requiring minimal input of time by practitioners more effective than those requiring extensive consultation times?

The present study achieved results which are comparable with those reported in the 2004 Cochrane review by Lumley et al.,¹ who reported a pooled relative risk in biochemically validated cessation of 0.94, and an absolute difference in quit rates of 6%. The relative risk of continued smoking in the present study is 0.96, and absolute difference in quit rates is also 6%. It is difficult to draw clear inferences due to the questionable level of adherence and implementation, but the results presented here do not differ substantially from those reported in the studies reviewed in Chapter 4. These studies also experienced adherence and contamination issues, which further hinder any capacity to compare the present study with those requiring more extensive time commitment by providers.

Adherence and intervention implementation

Many women appear to have returned to smoking after initial attempts to quit. It is expected that long term cessation may have been hindered by a low level of intervention implementation after initial delivery at early antenatal visits. Patient and provider factors both influenced the level of adherence to the intervention protocol throughout pregnancy. Further, the actual level of social support received may have limited the capacity for women to remain abstinent. The lack of significant associations between successful quitting and the level of social support received, the use of NRT, and episodes of advice from medical practitioners is expected to result from the small numbers of women in the analysis, and the low rate of NRT use and adherence to protocol.

Barriers to adherence and minimising contamination

The language of research

Many of the sources of contamination discussed in the Results section are fundamentally the outcome of a poor understanding of the concepts of research. Despite efforts at staff training, it appears that further up-skilling in the principles of research is required to ensure an adequate level of understanding among staff in primary healthcare settings. Self-admission by practitioners and other staff at the beginning of the study, that research is like a 'foreign language' to them provides the context for such suggestions.

With a lack of research experience among the Indigenous health field as a whole, it is no surprise that the individuals employed on this project required intensive, ongoing training in the methods, and the justification for certain aspects of the study. A lack of understanding and knowledge in the early stages led to some errors and oversights in data collection and procedures. The complications and intricacies of an RCT are

foreign to employees in this field. Research in this area has characteristically been descriptive, and 'interventions' have been implemented as programs with no control groups and very limited evaluation. Thus, the introduction of the concepts of a rigorous RCT required long-held opinions and understanding to be replaced with scientifically oriented ideas.

The researchers gained a sense that there may have been a general lack of understanding of the purpose of research, and the differences between the research phase and the implementation of an intervention once it has been shown to be effective. Undertaking a randomised controlled trial immediately introduces an array of limitations and complications to any public health or health promotion-based program. The requirements of randomised controlled trials mean that data collection and recording must be highly organised, accurate, and consistent between sites. The reluctance of organisations or health service staff to collaborate in achieving consistency and continuity in data collection and recording procedures generates complications surrounding collation and checking of data. The failure to recognise that a certain level of control is necessary to ensure effective and rigorous conduct of the study, or the misinterpretation of this approach as a desire for individual control, can limit the efficiency and accuracy of intervention implementation and documentation.

Educating administrative and healthcare staff in Aboriginal Medical Services about the need for methodologically rigorous research and randomised controlled trials was an ongoing challenge. It was necessary to repeatedly explain to health workers why additional support could not be given to all eligible patients, why study-related posters and advertising materials could not be developed for display in the waiting room and throughout the clinic, and that they need to record data methodically and consistently.

Provider attitudes and limitations of routine care

Despite enthusiasm expressed by practitioners to take part in the study, and to see it succeed, they commonly cited barriers to the actual implementation of the intervention. While the intervention was designed to take minimal time, the 'chaotic' clinic environment was often blamed for a failure to document intervention activities and to adhere to study protocol. Even remembering to deliver the intervention to participants, on top of other clinical tasks involved with routine antenatal care was found by some to be difficult. Ultimately, the intervention was not given high priority within the day-to-day delivery of primary healthcare. One practitioner stated, *"I really wanted it to work, but I can honestly say that I never delivered the intervention 100%"*. Practitioners can be quoted as saying that while they did 'talk about smoking' with patient's, discussions were not consistently structured around the intervention design. Also, comments regarding the difficulty of maintaining ongoing contact with additional care participants were common.

The attitude of practitioners was perhaps influenced to some degree by their work environment and level of organisational support. When staffing problems increased pressure on practitioners delivering antenatal care at one site, these individuals acknowledged that the intervention 'took a back foot', with essential clinical duties taking precedence. Lack of organisational support for team development and training relating specifically to the research may have also restricted the capacity to improve the running of the intervention. This is a widely accepted pattern. With attempts to promote evidence based practice having led to the establishment of an entire field of research focussed on changing healthcare provider behaviour, there is much literature on the attitudes of medical practitioners and barriers to change.

Logistics

Feedback from staff involved in intervention delivery consistently indicated that the intervention design and fundamental principles of clear advice to quit, an agreement with the practitioner and ongoing support were indeed acceptable, but the logistics of consistent delivery represented the greatest barriers to adherence. It appeared that some practitioners were somewhat overwhelmed with the routine requirements of antenatal care consultations, and found the additional checking of progress and recording of information associated with the intervention, daunting.

The difficulty of designing these logistical components of a study to fit with routine healthcare provision for several practitioners was highlighted by the different individual opinions on specific aspects of the intervention. In order for the study to be incorporated into routine care at each site, a level of flexibility was necessary, with teams at each site setting up logistical processes which worked best in the context of their clinic. Even practitioners working in the same clinic have unique personalities and behaviours which can limit the capacity for consistency in these areas. At one site for example, the project officer made notes on the daily appointment list regarding the intervention status and progress, or potential eligibility of patients. One practitioner found this extremely helpful to keep track of participants and act as a reminder throughout the day. Another practitioner however, found that this was an 'extra thing to look at' and did not find this approach helpful. This practitioner stated that she already had trouble with 'all the windows we have to look at', referring to the patient progress page, results, recalls, and other documents. It was admitted that even the notes added by the health worker or midwife immediately before the consultation were often not read until afterwards. For this individual, a phone call from the health worker or a pop-up window requiring the practitioner to address intervention components before proceeding, were suggested to be ideal. Such approaches would not be acceptable to

or feasible for all practitioners however, further illustrating the need for a great degree of flexibility, not only with the delivery of the intervention to individual participants, but with the communication and approach used for each intervention agent.

Different approaches to practice can create difficulties in achieving consistency in intervention systems. One practitioner felt that follow-up after three to seven days was not feasible, and that a more appropriate approach may be to deliver the intervention when patients return for the results of their initial dating scan, usually two weeks after their initial antenatal visit. This practitioner felt that patients were likely to respond to advice about smoking when it was linked with the visual image of their baby, with this potentially being an important teachable moment within the pregnancy. Also, it was suggested that more time would be available at this consultation, as opposed to the initial antenatal visit which was already full with essential tasks, and with participants having to see the project officer for recruitment, as well as the health worker and practitioner. Interestingly however, it was noted that another practitioner at the same clinic does not routinely refer patients for an initial dating scan, and attempted to recall them for review of blood test results one week after the initial visit. With busy appointment schedules however, this follow-up consultation was often held with the midwife rather than the practitioner, which proved problematic with attempts to maintain an ongoing partnership and repeated contact between the practitioner and participant throughout the intervention.

Other logistical considerations also have the capacity to impact significantly on recruitment rates and intervention delivery. The smaller team at one site was cited as an issue, with greater pressure on staff and fewer individuals available to perform recruitment or follow-up tasks. The simple situation of the project officer taking a lunch break when a new antenatal patient, or intervention participant arrived at the clinic without an appointment, was repeatedly cited as a problem, with health workers lacking

in confidence or training to perform study-related tasks. At one site, the project officer was located in an office separate from the women's health consultation rooms and waiting area. This was recognised as a barrier to recruitment and communication between team members. The data suggested a trend towards less intervention-related contacts between practitioners and participants at this site, where the project officer was less able to see and remind practitioners of a patient's status.

Communication and team dynamics

In efforts to improve the efficiency and consistency of intervention delivery, 'communication' became a mantra. Observations of intervention processes, and feedback from practitioners indicated that insufficient communication between project officers, health workers and practitioners limited the capacity for practitioners to track participants and deliver intervention advice when necessary. With practitioners admitting to their inability to remember to deliver the intervention, or remember the status and progress of intervention participants, they relied heavily on their clinical team to remind them of the intervention-related tasks which they should conduct under each individual circumstance. Communication between different sections of the clinic was also less than ideal, with several cases of patients recalled for antenatal care with the midwife, or for study-related follow-up, attending the general clinic, and being allowed to leave with no interaction between the general clinic staff and women's health. With more effective communication between team members and clinic staff as a whole, the level of adherence may have been significantly improved.

It appeared to be a personal, self-adopted perception of Indigenous health workers of themselves as 'the bottom of the food chain'. Despite organisational efforts to empower health workers and repeated attempts to encourage project officers to take control and lead the team of staff involved in the intervention, it seemed that some individuals were

limited by a lack of confidence or self-assurance in communicating with the practitioners and taking a lead role in managing and motivating the team. Previous studies examining the dynamics of professional partnerships between health workers and others have emphasised the importance of clear definitions of staff roles, and of regular communication to promote positive outcomes for patients.²⁶

Influences on and barriers for health workers

It may be said that the organisational system in place in these ACCHS sites was relatively hierarchical, with tight restrictions placed upon, and instructions given to, program and clinical staff. Such a system ensures that the clinical, operational components of the services are regulated and adequately staffed. It seems though, that these systems may also be necessary to overcome the limitations associated with staff skill levels and barriers to their confidence and reliability in independent, self-driven work.

Not only are health workers in a self-allocated position of low rank due to their confidence and possibly a cultural influence, but the reality is that they have limited training and education. It was widely acknowledged that materials and processes needed to be tailored and simplified as much as possible for Aboriginal and Torres Strait Islander clients, but a level of simplicity was also needed for the health workers to understand their role and be able to fulfil requirements. As has been previously discussed, the nature of primary health care and conducting any work in such a setting requires a level of flexibility to capture as many individuals as possible, and to fit research related processes as seamlessly as possible into routine care. This flexibility however, relies on a certain degree of initiative and confidence which isn't a guaranteed skill possessed by all health workers. Even precise, clearly delivered instructions were often misunderstood, yet alone instructions which could not be

presented in such a way, but which required extrapolation from a set of basic principles.

The skills and level of knowledge of health workers cannot be dismissed as inadequate and these roles given roles to others – Indigenous health relies on the involvement of these people and the potential for research in this field to build the capacity of Indigenous staff and health services, is one of its great strengths.^{71 72} This represents a great challenge; an attempt to conduct a research program at ACCHS sites takes individuals with no research experience or understanding, with a culture of negativity towards ‘university people coming and telling us what to do’, but a contradictory one of being given instructions and asked to follow protocol, and asking them to take control, to take initiative, and to work with their colleagues to conduct research and achieve a common goal.

Health worker attitudes towards encouraging women to quit smoking and broaching sensitive topics are also guided by cultural beliefs and expectations. It is an experience shared by others performing research in Indigenous communities, that health workers are reluctant to persist or pursue patients for follow-up, due to a firm belief in individual autonomy and privacy.⁷³ These issues are exacerbated by the closeness of the Aboriginal and Torres Strait Islander communities, with health service staff sharing many family and social connections with their patients, and feeling uncomfortable providing advice to their peers or elders.

One project officer openly discussed her initial experiences starting work in the role as an outsider, but finding strength and confidence as she connected with the participants. This individual gave up smoking herself as a result of her involvement in the study and gained great satisfaction from her role in helping women through the quitting process. While the study did not include a measure of health worker and project officer

knowledge and attitudes, observations indicated a great sense of empowerment and improvement in the confidence and skills of individuals through their involvement in the study. It may be said that these outcomes are equally important to the outcomes relating to smoking cessation of study participants. The sense of satisfaction felt by these individuals when dealing with the women who successfully quit was clear in discussions with them.

The high rate of smoking among health workers in Indigenous healthcare settings is well documented.⁷³⁻⁷⁵ While at face value this may be seen as a barrier to the capacity of these individuals to offer smoking cessation advice, the fact that a majority of smokers say that they would like to quit smoking, or have tried to quit, gives them a level of understanding of the difficulties of quitting, which may be useful in their counselling roles.^{73 74}

Participant Compliance

Discussions with various health service staff highlighted the vast differences in approach and manner between Indigenous and non-Indigenous patients. A classic example is a patient presenting to the clinic complaining only of a 'runny nose'. It was only the astute observational skills of the Registered Nurse involved that prompted further questioning of the patient about other symptoms such as headaches, which ultimately led to the discovery of a severe skull fracture. The patient had been in a violent argument with her partner three days prior to this consultation.

The 'shame' felt by patients presenting with cases such as this, may prevent them from openly discussing their problems with health professionals, despite their desire to be helped. A common difficulty experienced at both sites throughout the study was that of contacting participants for follow-up. Failure to attend clinic appointments and repeated

unsuccessful phone contacts and home visits limited the extent to which the bi-weekly contact protocol could be achieved. One project officer asked *“how do we do all the proper follow-ups when they just show up when they want to?”* Failure to attend may have been associated with the shame of unsuccessful quit attempts, or social issues such as work or childcare commitments or financial issues making transport to the clinics difficult.

It was clear to health workers and project officers that some participants *“just weren’t interested”*. After consenting to participation some women appeared to avoid discussions relating to their smoking, perhaps due to failed attempts to quit, or due to other health and social issues which took priority for them. It was possibly a cultural influence, or perhaps an indication of confidence levels that created an attitude with most staff that it was best to stop pursuing these participants regarding the intervention.

Capacity building among the multi-disciplinary healthcare team

The experience of participation in a research study such as this has the potential to enhance the skills and confidence of all members of the healthcare team. It is an important outcome of this study that each team member learnt about research and smoking-related issues, and developed skills in communication, planning and organisation. Such results have the potential for widespread impact in the Aboriginal and Torres Strait Islander health field.

What can be drawn from the results?

Despite the above limitations, the study provides a valuable indication of the nature of interventions likely to be effective in assisting Aboriginal and Torres Strait Islander

women to quit smoking during pregnancy. The results indicate that these women can quit smoking during pregnancy, at substantial rates. The role of assistance from health service staff and social supporters in bringing about quitting cannot be quantified due to potential contamination and difficulty in measuring the actual level of intervention implementation. It is hypothesised however, that even raising the issue of smoking on repeated occasions may have motivated some quit attempts both among AC and UC participants.

The extensive process measures and exploration of the implementation of the intervention highlight critical issues and complexities associated with attempts to conduct research in Indigenous health settings. These complexities are not unknown to researchers, with Sibthorpe et al., (2002) having published an influential paper on the demise of a randomised controlled trial for hazardous alcohol consumption in an Aboriginal Medical Service.⁵ Interestingly, the problems encountered by this group paralleled many of those experienced in the present study. This has led to a view that perhaps the randomised controlled trial and such rigorous research designs are not appropriate in the Indigenous health context.

Complex and distressing social issues experienced by women, co-existing health risks during pregnancy, and the reluctance of health workers to approach smoking in the context of so many other issues, all hinder the uptake and success of a specifically targeted intervention. As was discussed extensively in Chapter 2, Aboriginal and Torres Strait Islander women are vulnerable to adverse health outcomes during pregnancy, with a large number of risk factors concentrated in this population. Perhaps the focus on smoking, with its potential to influence other associated behaviours impact more broadly on the health of this population, is not the most effective approach. Interventions should look more widely at multiple lifestyle components and interacting

factors, and should use appropriate designs to tackle the broader spectrum of these issues.^{73 76 77}

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Appendix 8.1: Follow up questionnaire

Place participant # sticker here



The UNIVERSITY
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AUSTRALIA

Version #1 2/02/2008

Health Issues during Pregnancy - Post-Test (34-36 weeks)

Date ____/____/____

Smoking Status and History

1. Which statement best describes you?

- | | | |
|--------------------------|---|---|
| <input type="checkbox"/> | 1 | I'm a smoker, I smoke daily (Go to 3) |
| <input type="checkbox"/> | 2 | I'm a smoker, I smoke occasionally (Go to 2) |
| <input type="checkbox"/> | 3 | I'm an ex-smoker; I never smoke now (Go to 5) |

2. How many cigarettes do you usually smoke each day? Cigarettes

3. During this pregnancy, how many times have you tried to quit smoking? times

4. What is the longest amount of time you have been able to quit smoking for?

(please circle units) a Days b Weeks c Months d Years

Questions 5 to 6 are for ex-smokers only

5. When did you stop smoking cigarettes regularly? Weeks gestation

6. How many times did you try before you finally gave up? times

Place participant # sticker here

Knowledge and attitudes (Please circle response)

7. Do you think that smoking in pregnancy could increase the risk of:

	Yes definitely	Maybe	No	Don't Know
a. Damage to the placenta (the sac that provides air and food to your baby when its growing inside you)	1	2	3	4
b. Spontaneous abortion or miscarriage (losing the baby)	1	2	3	4
c. Having a caesarean section	1	2	3	4
d. Baby being born too soon (premature birth)	1	2	3	4
e. Low birth weight	1	2	3	4
f. Slower physical and mental growth of the baby	1	2	3	4
g. Breathing problems and sickness in infant	1	2	3	4
h. Lower Intelligence when baby grows up	1	2	3	4
i. Problems with breastfeeding	1	2	3	4
j. Cot death (sudden infant death syndrome – SIDS)	1	2	3	4
k. Mother getting Diabetes	1	2	3	4
l. Mother having high blood pressure and increased heart rate	1	2	3	4

8. Please indicate how true the following statements are for you:

	Very true	Quite true	Not at all true	Don't know
a. It's good to have a smaller baby	1	2	3	4
b. It's highly unlikely that my baby will be unhealthy	1	2	3	4
c. Light smoking does not cause harm to unborn babies	1	2	3	4
d. Stopping smoking increases the chance of having a healthy baby	1	2	3	4
e. If you are exposed to a lot of smoke from other people you might as well keep smoking yourself	1	2	3	4

Place participant # sticker here

Stress

9. On average, how would you rate the level of your daily hassles during your pregnancy?

Very low	Low	Moderate	High	Very high
1	2	3	4	5

10. Have you had any of the following major life events that distressed you during your pregnancy?

YES
NO

Please tick box for yes:

Personal health problem	<input type="checkbox"/>	Pregnancy complication	<input type="checkbox"/>
Personal problem such as depression or anxiety	<input type="checkbox"/>	Moving house	<input type="checkbox"/>
Problem with current partner	<input type="checkbox"/>	Problem with previous partner	<input type="checkbox"/>
Problems within close family	<input type="checkbox"/>	Problems with your own children	<input type="checkbox"/>
Death in close family	<input type="checkbox"/>	Serious illness in close family	<input type="checkbox"/>
Financial insecurity	<input type="checkbox"/>	Loss of job	<input type="checkbox"/>
Partner being away	<input type="checkbox"/>	Partner in jail	<input type="checkbox"/>

Appendix 8.2: NRT questionnaire

Place participant # sticker here



NRT Follow-up survey

1. Had you ever used nicotine replacement therapy products (patch, Inhaler, gum) before your last visit to the clinic?

- ☐ 1 Yes
☐ 2 No

2. Days since last appointment

- ☐ 1 7 days
☐ 2 8 days
☐ 3 9 days
☐ 4 10 days
☐ 5 Other _____

3. Have you had any cigarettes since your last appointment?

- ☐ 1 Yes
☐ 2 No

4. How many pieces of gum were you given?

- ☐ 1 25
☐ 2 50
☐ 3 100
☐ 4 Other _____

5. How many pieces of gum do you have left?

Pieces (estimate ok)

6. Did your support person use the gum?

- ☐ 1 Yes
☐ 2 No

Place participant # sticker here

If you used the gum:

7. Did you and/or your support person experience any side effects?

- ☐ 1 Yes – please tick appropriate boxes in the list below
☐ 2 No

Please tick appropriate box for 'yes'

Gastric problems:

Upset stomach (nausea)

Indigestion

Vomiting

Mouth sores or ulcers

Jaw pain

Headache

Hiccups

Trouble sleeping

Dizziness

Confusion

Rash

Cold sweats

Participant

Partner or
support

Other, please describe _____

8. Would you recommend the gum to your friends who might be trying to give up smoking?

- ☐ 1 Yes
☐ 2 No

Place participant # sticker here

Attitudes about NRT

9. The following statements relate to nicotine gum or other nicotine replacement therapy products. Please answer even if you haven't used the products.

Please circle the best answer.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know
These products help people feel less irritable when they quit smoking	1	2	3	4	5	6
These products help people feel less depressed when they quit smoking	1	2	3	4	5	6
These products help people cope with the cravings for cigarettes	1	2	3	4	5	6
These products help people to quit smoking	1	2	3	4	5	6
These products help people to feel less anxious when they quit smoking	1	2	3	4	5	6
These products help people to resist the need to smoke in places or situations where smoking is not possible	1	2	3	4	5	6
I am worried about the side effects of the products	1	2	3	4	5	6
I am wary of the products	1	2	3	4	5	6
I am worried about becoming dependant on these products	1	2	3	4	5	6
I don't need these products to help me quit smoking	1	2	3	4	5	6

**Helping Aboriginal and Torres Strait
Islander women quit smoking
during pregnancy**

An overview of research methods

Why are we concerned about smoking during pregnancy?

Smoking during pregnancy can lead to:

- Increases the risk of spontaneous abortion or miscarriage
- Doubles the risk of having a low birth weight baby – low birth weight babies are more likely to die during birth or in infancy, and to have health problems during childhood.
- Increases the risk of Sudden Infant Death Syndrome.

Approximately 60% of Aboriginal and Torres Strait Islander women smoke during pregnancy whilst about 20% of other Australian women smoke during pregnancy.

Women who quit smoking in the first 3-4 months of pregnancy have infants of the same average birth weight as women who have never smoked. Quitting smoking at any time during pregnancy improves birth weight and health outcomes.

Why should we do a study examining the effectiveness of an antenatal smoking cessation programme?

Advice from healthcare providers has been shown to increase smoking cessation rates to some degree. Unfortunately there is not much information about the success of different methods to reduce smoking amongst pregnant Aboriginal and Torres Strait Islander women. We need well designed studies so that we can ensure that we provide the best possible care and services. If the strategy is tested in this study is found to be effective it will allow all Australian Aboriginal and Torres Strait Islander medical services and their patients to benefit.

Who is involved in the study?

Aboriginal and Torres Strait Islander medical services in Townsville (TAIHS) and Cairns (Wuchopperen) are partners in the project. Experts in smoking control and research methods from the medical school at the University of Newcastle and the Sax Institute in Sydney are also involved to ensure that we use the most effective and vigorous intervention and research techniques.

Where is the project funding coming from?

Competitive funding has been obtained from the National Health and Medical Research Council (NHMRC) to test the intervention. Funding is provided by the NHMRC only to those projects, which meet strict requirements and are critically reviewed by experts in the field. Monies will initially be given for a three-year period, and extended if recruitment proceeds effectively.

What resources go to your community?

Money has been allocated to each health service to employ a local person as a project officer.

Does the research have ethics approval?

The project has ethics approval from the University of Newcastle ethics committee as well as the Board of Directors of both TAIHS and Wuchopperen. Careful consideration has been given to the needs of Aboriginal and Torres Strait Islander people.

Does your community benefit?

The health service will be provided with money to employ local people to help us with the study and to run community based activities. Your patients and their families will also benefit from the effects of quitting smoking.

Will involvement cause you to divert from clinical activities?

Your involvement in this project will involve some additional work as part of efforts to reduce smoking. The anti-smoking intervention will be performed during routine antenatal appointments.

Recruitment

It is very important that we are able to get as many pregnant Aboriginal and Torres Strait Islander people involved as is possible. This will help ensure that as many people coming to the clinic get high quality care and the research is completed in the necessary time. Continued funding from NHMRC is dependent upon high recruitment and maintenance of eligible women in the project.

Why will women who smoke be randomly allocated into usual care and additional care?

We are not yet sure whether anti-smoking treatment that we are developing will be significantly more effective than existing care. Until we have the answer to this question we cannot provide the intervention to all women.

Consistency in care is important

The anti-smoking intervention has been designed based on the best evidence from previous research. To make sure the research is high quality, it is important the same care is provided to each relevant patient. Please try to follow the script, which has been carefully written and discussed with staff at both TAIHs and Wuchopperen. It also would be very helpful if you could indicate your adherence to the protocol, and the progress of each patient by ticking the relevant boxes in the patient record sheet.

Two studies

There are two studies described in this handbook. The first examines the prevalence of smoking among pregnant Aboriginal and Torres Strait Islander women, their knowledge and attitudes about smoking, and the accuracy of their self-reported smoking status. The second study aims to test an intervention designed to help Aboriginal and Torres Strait Islander women to quit smoking during pregnancy.

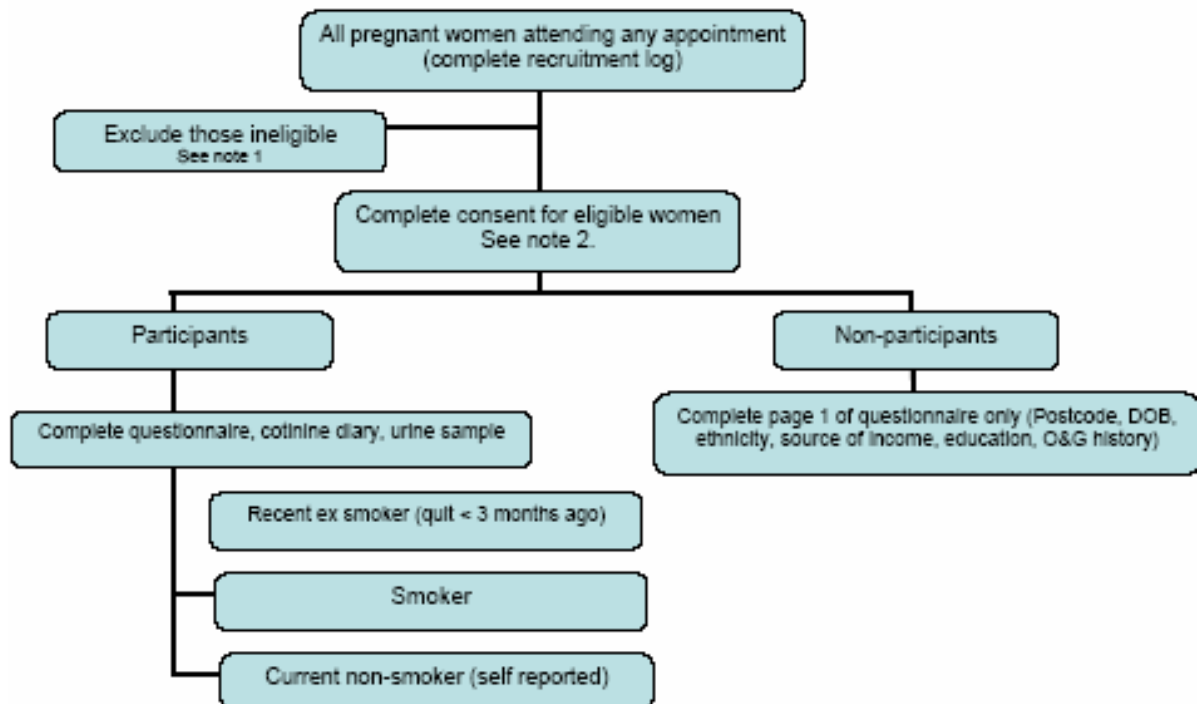
Review Process

We will be reviewing progress of recruitment, women's response to the questionnaire and intervention, provider adherence to the agreed protocol, and the overall acceptability of the intervention to both providers and consumers, at regular intervals to allow for any necessary changes to improve the study.

Overview of study one: Prevalence of smoking during pregnancy

Aims:

1. To examine the prevalence of smoking during pregnancy among pregnant Aboriginal and Torres strait Islander women
2. To examine the accuracy of self reported smoking status among these women, using urine cotinine as a biochemical measure



Notes:

1. Women ineligible for this study are those who are under the age of 16, or who those have a florid mental illness and/or are undergoing treatment for chemical dependency other than tobacco or alcohol use.
2. Provide all women eligible for participation in the study with verbal and written information about the study, invite them to participate and seek written consent to participate.

Overview of study two: Randomised controlled trial of an intensive smoking intervention for pregnant women

Aims:

To test an intervention designed to help pregnant Aboriginal and Torres Strait Islander women to quit smoking – using behavioural counselling, support from their partner or close confidante, and nicotine replacement therapy if required. We need to test validated (using urine cotinine) smoking cessation rates at 34-36 weeks gestation and 6 months postpartum.

Women who complete study one will be invited to participate in study two – check initial eligibility criteria (see note 1)



Notes:

1. Women aged 18 years or more who are current smokers, have quit for their current pregnancy (recent quitters), are attending the clinic before 20 weeks gestation, and who have completed study one are eligible for study two.
2. Provide information about study two and complete written, informed consent for study two.
3. Women will be randomised to the intervention or usual care groups according to week of attendance.

Note that discussions during routine visits are designed to be integrated into the normal consultation, where appropriate.

Contact 1 – step 1

Recruitment – Project Officer

Approach any pregnant woman who comes to the main clinic or antenatal clinic for any reason.

- 1) If a woman is:
- pregnant,
 - aged 16 years or more,
 - is not currently suffering from a florid mental illness or being treated for high chemical dependency, and
 - is likely to attend your service for her whole pregnancy,

...you should invite her to take part in the study.

Look at the patient's charts for anything you should check with the doctor about her eligibility.

Please complete the patient log sheet for all antenatal women attending the antenatal clinic.

"We are trying to help pregnant women quit smoking. We are asking pregnant women questions about smoking and pregnancy. Would you like to help?"

YES: "I'll go through this information with you."

Work through the information statement with the patient. Start with part 1, and explain that she can choose to take part in that section only. Her eligibility for part 2 will depend on her answers to questions in part 1.

Answer any questions the patient might have.

Give the patient the information statement to take home.

- 2) If the woman agrees to complete the questionnaire: **Ask her to sign the first part of the consent form and complete the questionnaire.** If the patient is having difficulties or is not confident answering the questions, you could help by reading her the questions and then recording her response.
- 3) Once the woman has completed the questionnaire: **Ask her if she would be willing to complete the cotinine diary and provide a urine sample so that we could check her level of exposure to chemicals from her own, or other peoples cigarette smoke.**
- 4) If the woman agrees to provide a urine sample for cotinine and complete the cotinine diary: **Ask her to sign part 1 (B) of the consent form.** Transfer some of the urine into a small tube and label with participant number, and today's date.

Check if the woman is eligible to participate in study 2
(the intervention study).

**Is she a smoker or recent quitter and at 20
weeks gestation or less?**

- 5) Ask her if she is willing to be part of a study testing ways in which to help women quit smoking and tell her we want to involve women whether or not they are trying to quit smoking.
- 6) Mark the woman's response to the invitation to be a part of study 2 on the front page of the questionnaire.
- 7) If she agrees to be part of the study: Ask her to sign the last part of the consent form. Then go on to page 7.
- 8) If the woman does not want to be involved: Please make sure you have her postcode and date of birth on the front of the questionnaire. These women will continue to receive normal health care and not be approached for any further participation in the study.
- 9) If the patient indicates that she needs more time to consider the invitation to participate in study 2 then: Place the yellow sticker in the patients chart or an alert in MD, that will remind you to ask her again at her next visit if she is now willing to be involved in study 2 of the research program.

It is important that we have records of patient's involvement in the study, their smoking status, and the advice given to them. Please follow the above protocol carefully and fill in the patient record sheet. At the end of this consultation you should have a:

- Completed entry on the log sheet
- Signed consent form
- Completed questionnaire
- Completed cotinine diary and an accurately labelled urine sample

Ensure that patients are aware that if they decline the invitation to participate, their medical care will not be compromised or affected in any way.

Randomisation – Project Officer

- 10) If a woman agrees to participate in study 2 then: Check on the study calendar to see if it is an intervention or usual care week.
- 11) Complete the first part of the patient record sheet and place it in the chart – make sure the patient takes it to the Dr's consultation with her.
- 12) Place a sticker on the chart or an alert in MD, to indicate whether the woman is to receive the INTERVENTION or USUAL care.

Use GREEN data sheets for the INTERVENTION, or
ORANGE data sheets for the usual care group.

Contact 1 – step 1
Recruitment – Project Officer

Diagram 1. Approach to any pregnant woman attending the main clinic or antenatal clinic.

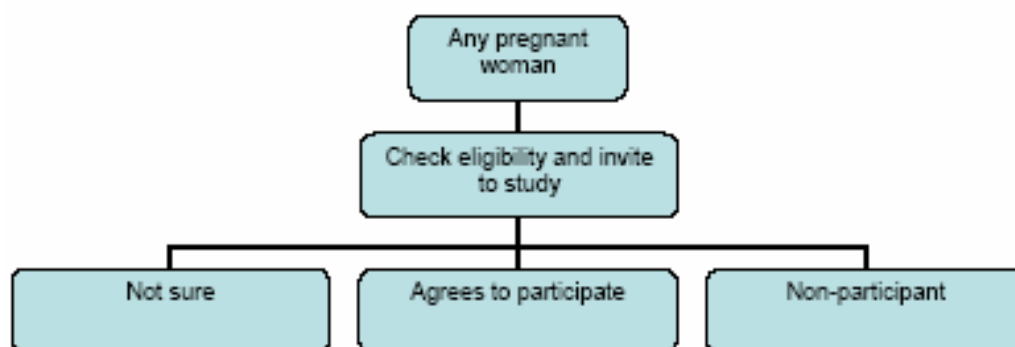


Diagram 2. Processes for study 1 participants

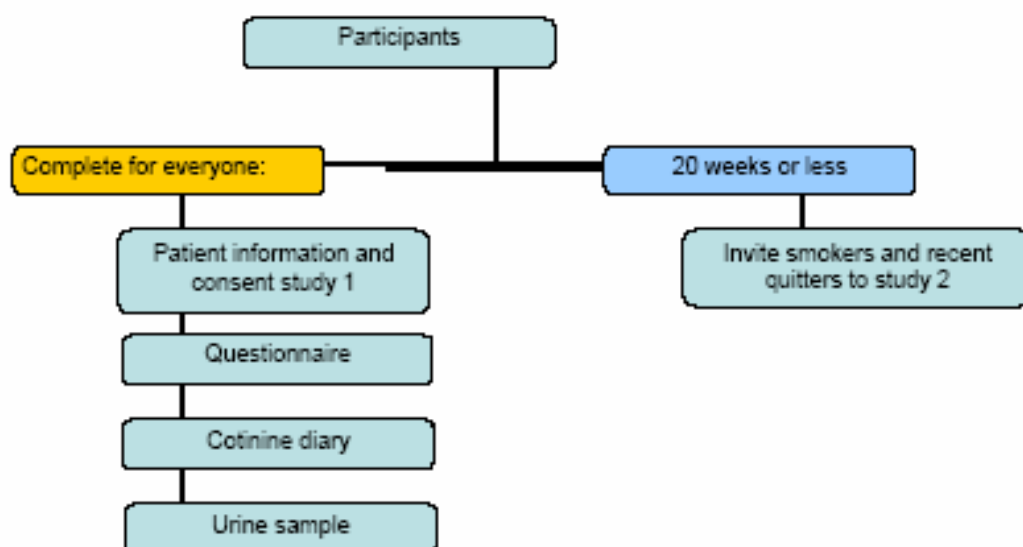
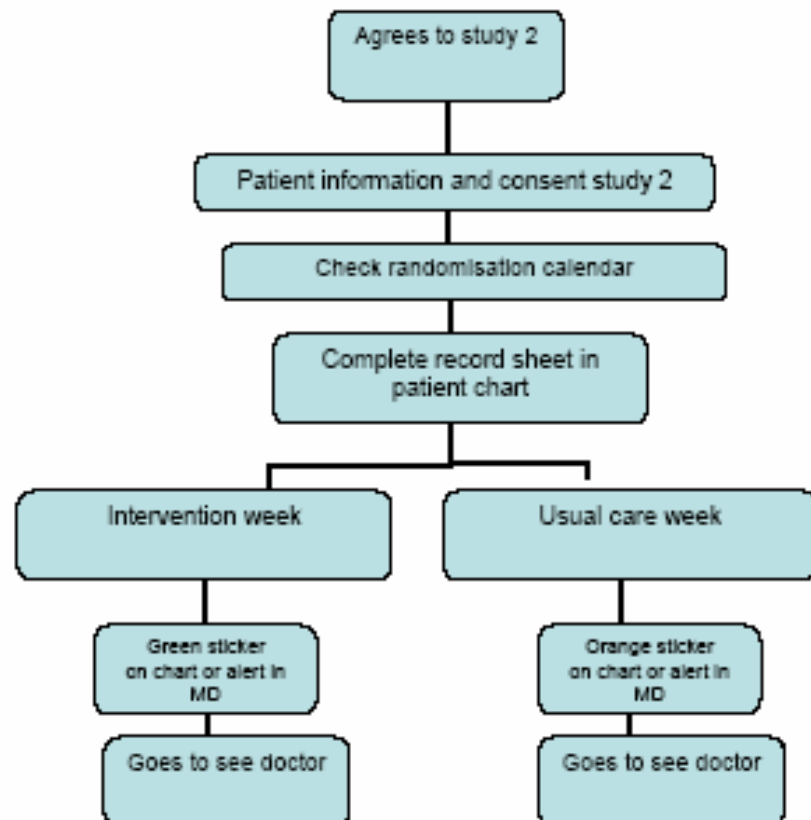


Diagram 3. Processes for study 2 participants



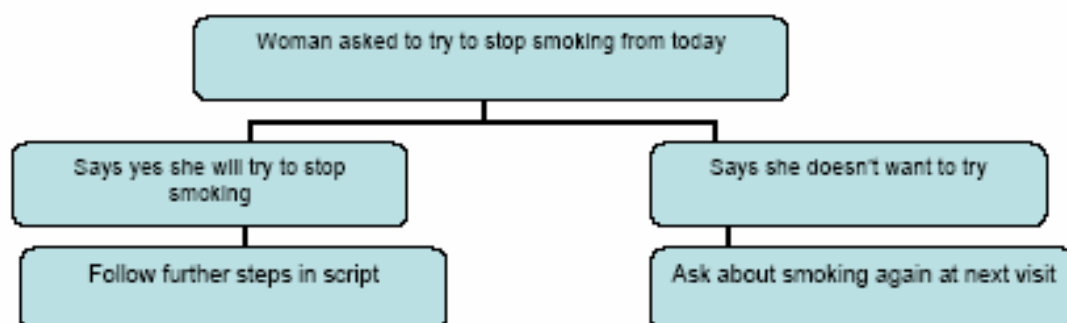
Contact 1 – step 2

Doctor/Patient Consultation – First Antenatal visit for Smoking Study

All women who have agreed to take part in study 2 and who have been randomised to the intervention group will have a green data collection sheet when they first come to see you. For all of these women please use the following points as a guide in a discussion about smoking in pregnancy and getting agreement to quit:

- 1) I see that you are a smoker. It is really important for you and your baby's health that you try to quit smoking. Stopping smoking is the most important thing that you can do to improve the health of you and your baby.
- 2) I know that quitting smoking is really hard but I would like to work with you to try to help you to quit smoking during this pregnancy.
- 3) I would really like you to agree to stop smoking today.
- 4) Would you be willing to try and stop smoking from today for as long as you possibly can?

Diagram 4. Initial decision tree for women approached to stop smoking today.



For women who don't agree to try to stop smoking from today, repeat points 1-4 in their next consultation.

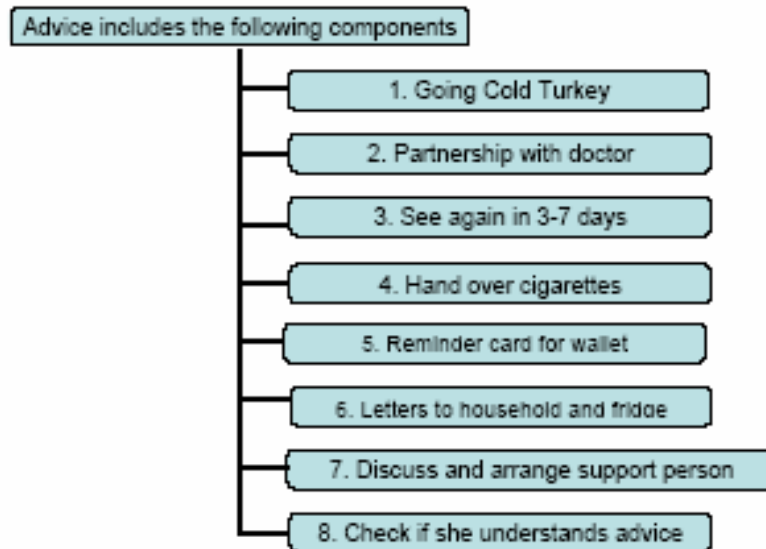
Say to these women: "I understand that it is difficult to stop smoking. However because it is so important I would like to talk with you again about it when you next

visit for antenatal care. **Would that be ok?"** Mark the patient record sheet indicating she said it is ok to ask again at the next visit.

For women who agree to try to stop smoking from today:

Affirm and congratulate her decision to try to quit smoking: **"I am really glad you have agreed to try to stop smoking as it is the best thing you can do for your health and your baby's health"**. Provide further components of smoking cessation advice.

Diagram 5. Components of advice to women who agree to stop smoking



The following are the key components of the advice you should give to all women in the intervention group:

- 1) "We know that the best way to get people to stop smoking is for them to go cold turkey. You should try to stop smoking today and not smoke for as long as you possibly can."
- 2) "I know that stopping smoking is really hard to do. I would like to do whatever I can to help you. Because you will have lots of cravings for a smoke I would like you to come back and see me in 3 to 5 days time to see how you are going. Lets book a time now for me to see you again....."
- 3) I want to see you again whether or not you have managed to stop smoking. "When you come back if you have stopped smoking that will be great and we could see what we can do to help you stay a non-smoker. If you have found it difficult we can discuss what we might do next to help you stop."
- 4) I know that it will be difficult for you to stop smoking if you still have your smokes with you. Would you consider leaving your smokes with me today as an important first step to stopping smoking?

- 5) Many women find it helpful to carry a written reminder card saying that we will work together to try and stop smoking. If you agree you and I will sign this card for your wallet which also has tips on how to cope when you have a craving for a cigarette and the date and time of your next appointment to see me.
- 6) I want other adults who live with you to understand how you are trying to quit smoking and how they can help you. Do you mind if I send a letter to people who live with you. The letter will tell them about ways they can help you and ask them to not smoke around you or consider quitting smoking themselves with you if they smoke. I would also like to give you a fridge magnet to advise people in your house how to help you.

Get the names and addresses of 2-3 people for individual letters signed by you as the woman's treating doctor asking them to support her efforts to stop smoking.

- 7) Next time you come it would be terrific if you could bring a support person so that I can explain the problems with smoking during pregnancy and we can talk about ways to help you quit.

The person should be someone:

- You see or can call regularly
- Who cares about you and your baby
- Could be a smoker or non-smoker

All patients who have a green sticker in their records are randomised to receive the intervention, and should receive the same care. Please follow the above protocol carefully. Indicate your adherence to it by completing the necessary form in the medical patient's record. At the end of this consultation you should have:

- Completed the patient record sheet
- Asked all women to consider stop smoking today
- Provided detailed advice to those women who did agree
- Checked and recorded if it is ok to talk about smoking at the next visit with women who did not want to stop smoking

Given the women attempting to stop smoking:

- ✓ An appointment time and date for next visit at 3-5 days.
- ✓ Arranged letters to household members and key support people
- ✓ Given a card of written agreement and next appointment for her to carry in her wallet

REMEMBER:

- ✓ To complete the patient record sheet
 - ✓ Make sure the patient sees the project officer on their way out to receive:
 - Finalised letters to household
 - Pamphlets and tips for quitting
-

Contact 1 – step 3

Health worker/Midwife or project officer – Advice after seeing the doctor for first Antenatal visit for Smoking Study

For all women who have a green data sheet: Ask women or look at the doctor's record sheet to see whether or not they have agreed to stop smoking.

For those who have agreed to stop smoking:

1) Tell her "I am really pleased that you have agreed to try to stop smoking. It is one of the best things that you can do to protect your health and your baby's health."

2) Here are some things you can do which might make it easier in the first few days and weeks as you try to stop smoking:

- Delay – wait for at least five minutes and the urge to light up a cigarette will pass;
- Deep breathe – breath slowly and deeply and try to relax;
- Drink water – sip slowly and take some time out;
- Do something else – try to take your mind off smoking by taking action...put on the radio, go for a walk, ring a friend.

There are some other tips in the 'how to quit' pamphlet.

3) You might like to read these pamphlets when you get home. They explain a bit more about the problems with smoking during pregnancy and what you can do to stop. Could you also give them to those in your household so that they know about the dangers?

4) Many people have several goes before they can become non-smokers. We will help you throughout your pregnancy so that if you find it hard to stop you should come back and discuss it with us so we can help you stop again. Hopefully the times of non-smoking will get longer until you are finally not smoking at all.

5) Has the doctor given you the fridge magnet with advice for your family? It is a way of telling other people that you are trying to stop smoking so that they can help you. Here is the full written advice, which you can put on your fridge door.

6) I will also send letters the doctor discussed with you to members of your household asking them to help you stop smoking by either stopping themselves or only smoking outside.

For those who have not agreed to stop smoking:

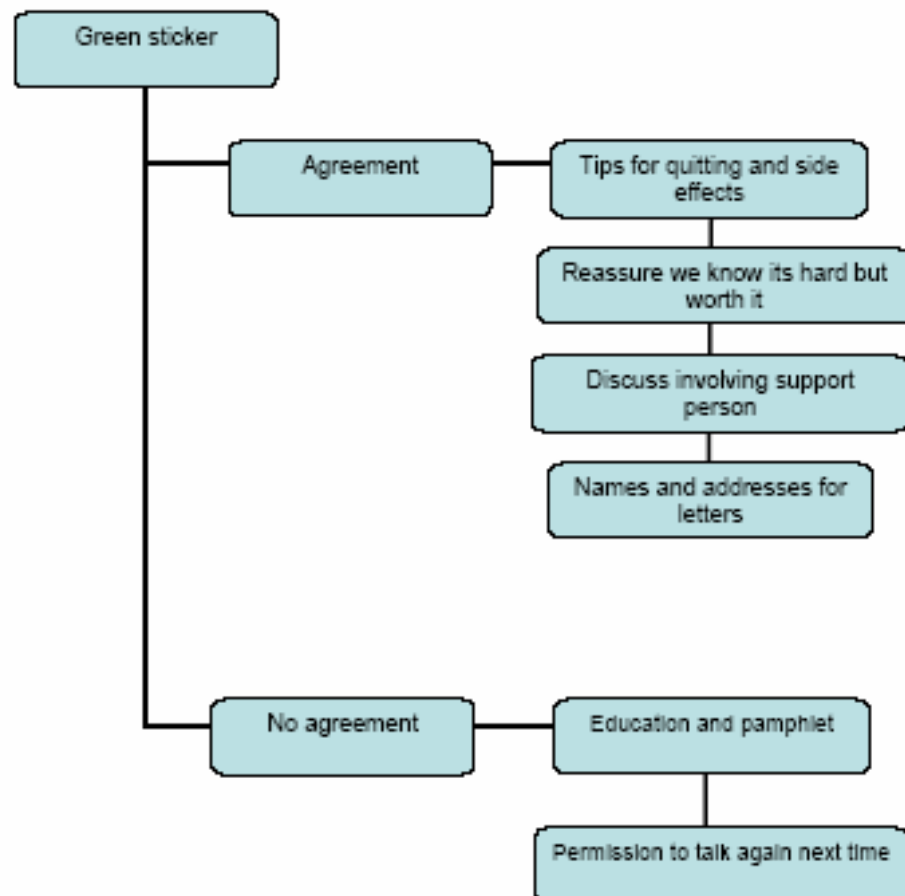
- 1) I can see that you have not agreed to stop smoking. It is a hard habit to break, but it is one of the best things that you can do to protect your health and your baby's health. Smoking during pregnancy is associated with miscarriage, SIDS, low birth weight babies who become prone to infections and other illness after their birth, as well as other health problems during infancy and childhood such as wheezing and serious chest infections. You might like to read this pamphlet when you get home. It explains a little bit more about the problems with smoking during pregnancy (Education pamphlet).
- 2) Perhaps we can talk to you about your smoking when you next visit and see what we can do to assist you at that time.

Please follow the above suggestions for all women with green stickers on their folder. When you have finished the session indicate on the patient record that you have followed the protocol. At the end of this consultation the patient should have:

- ✓ A reminder card for her wallet
- ✓ A fridge magnet and agreement for family
- ✓ Pamphlets to take home
- ✓ Completed addresses for letters to go to family members

REMEMBER TO COMPLETE PATIENT RECORD SHEET

**Diagram 6. Follow up from Health worker/Midwife/
project officer after consultation with doctor**



Contact 2 – step 1

Health worker–3-5 day follow up visit for women attempting to stop smoking

Diagram 6. Actions on review



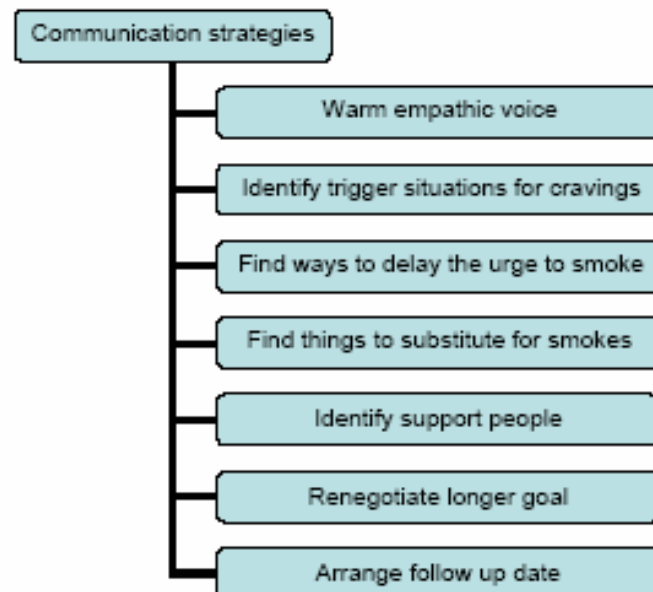
For women who report they have not had a smoke since their visit 3 days ago:

- 1) Congratulations on managing to not have a smoke – I understand it has been difficult for you.
- 2) Tell me about how you are going coping with the cravings for a smoke and what situations seem to trigger those cravings?
- 3) Repeat advice about delaying for 5 minutes when the craving comes on and ways in which to avoid the trigger situations for wanting a smoke.
- 4) See if she can try to go for longer without a cigarette and arrange to see her at 5-7 days this time. Make an appointment at a day and time she agrees is suitable and write it on her wallet card.
- 5) Summarise to check if you have communicated clearly and ask her to repeat what she understands about the information you have given her.

For women who have had a smoke in the past 3 days:

- 1) Encourage them by saying "I am glad you have been trying to stop smoking but understand how difficult it is to stop. The fact that you have had a smoke since I saw you 3 days ago shows how addictive the nicotine from cigarette smoke is.
- 2) Can you tell me about the cravings you have had for a smoke – in what situations do they occur and how long do they last for?
- 3) At this visit I would like you to try two things to cope with the cravings better:
 - ✓ Avoid triggers
 - ✓ Delay for 5 minutes or more the techniques outlines in this brochure (Delay 5 minutes, Drink water, Deep breathe, Do something else).
- 4) I would like to see you again in 3-5 days to see how you are going with the cravings. If you are still having difficulty stopping smoking we can talk about other ways to help you cope with the cravings. Make a date and time for next visit and write it on her wallet card.

Strategies to aid communication:



Contact 2 – step 2

Midwife/project officer–3-5 day follow up visit for women attempting to stop smoking

Ask the patient to fill in the short follow-up questionnaire.

Successful attempt:

- 1) Congratulations you have done very well.
- 2) Lots of people who try to quit go back to smoking a few times before they can stay a non-smoker. This might happen to you too. If it does happen, its ok, we understand how hard it is, but we'll keep trying. If you feel the urge to smoke or if you find that you have started smoking again, please ring us at any time. It is very important that you contact us as quickly as possible so we can help you.

Use the 'How to quit' pamphlet. Encourage women to deal with the side-effects.

Unsuccessful attempt:

- 1) Congratulations, you've done very well even to try. I know it's really hard. Lot of people who try to quit go back to smoking a few times before they can stay a non-smoker. The best thing that you can do is to try again straight away. Are you willing to have another go?
- 2) This time try to go longer without cigarettes.
For example if you went for 1 day last time without smoking ask that she try not to smoke for 2 days this time.
- 3) Book a time to see the patient again in 3-5 days as discussed by the doctor

Follow up of those who don't attend the arranged consultation:

Send out a reminder letter, ring the patient, ask someone to visit her at home and get her to come back to be seen at the clinic.

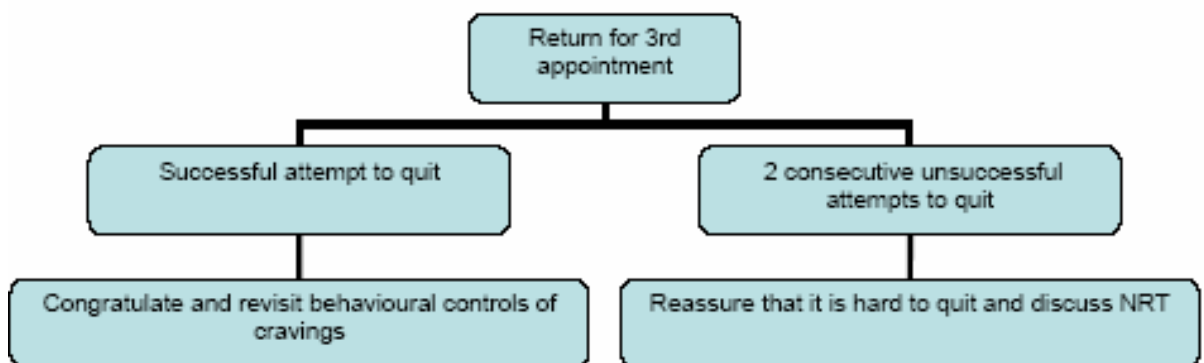
Contact 3 – step 1

Doctor – 3rd follow up visit for women attempting to stop smoking

Project officer and doctor – check their patient records for their smoking status and number of quit attempts.

Consideration of nicotine replacement therapy should be made only with women who have failed two consecutive attempts to quit smoking and who still are highly motivated to be able to quit.

3rd Follow up.

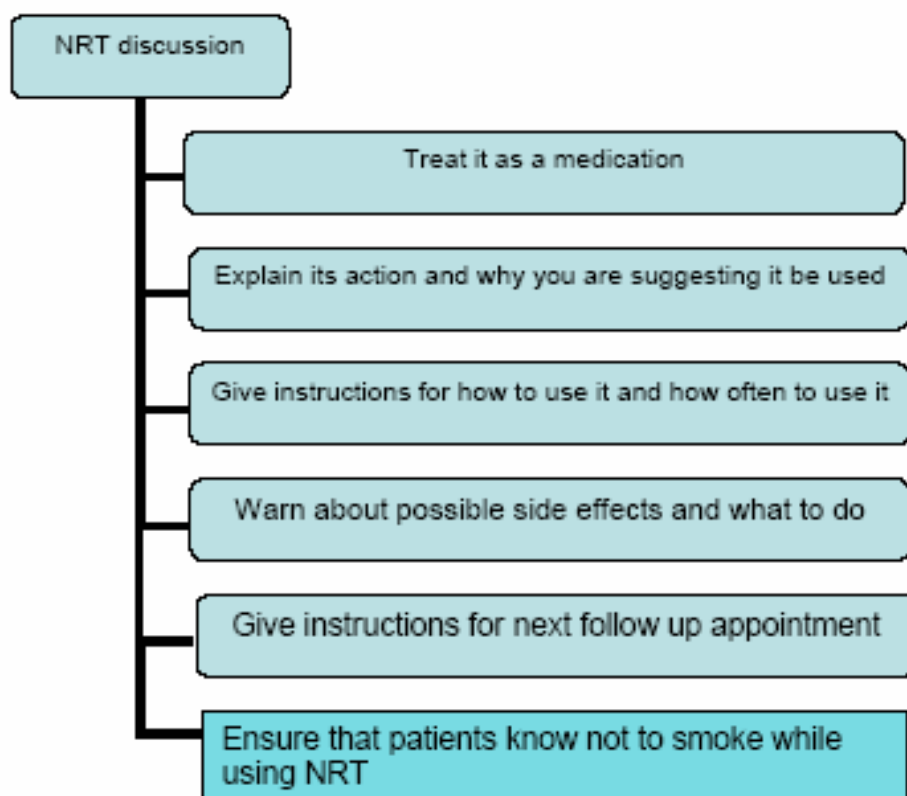


Successful attempt to quit smoking

- 1) Congratulations. You have done very well.
- 2) Lot of people who try to quit go back to smoking a few times before they can stay a non-smoker. This might happen to you too. If it does happen, its ok, we understand how hard it is, but we'll keep trying. If you feel the urge to smoke or if you find that you have started smoking again, please ring us any time. It is very important that you contact us as quickly as possible so we can help you.

Use the information in the 'you have made the right choice' pamphlet. Encourage women to deal with the side-effects.

Still smoking – unsuccessful attempt or no attempt – Discuss and offer Nicotine replacement therapy



- 1) Reassure the patient you understand how difficult it is to quit smoking.
- 2) That's ok, I know it is hard because of the cravings for a cigarette and the addictive nature of nicotine – "For that reason I think it may be worth trying the use of nicotine replacement therapy in the form of gum. It is a medication, not a gum or lolly and needs to be used like a medication to treat the cravings for a cigarette when you experience them".
This is likely to help you to quit but I should also tell you about some of the possible side effects because it is a medication.
- 3) Because this gum contains nicotine, it has a peppery like taste. It may cause a tingling sensation when you chew it. During the first few days of using the gum, you may experience mouth sores, jaw muscle aches, increased saliva production, indigestion or headache. These effects should disappear as use of the gum is continued. Chewing the gum too fast can cause light headedness, dizziness, hiccups, nausea, vomiting or insomnia (poor sleep). If these effects occur the chew the gum more slowly.

- 4) There are also some less common side effects. Please contact me if you develop symptoms of too much nicotine in your body: these include cold sweats, fainting, confusion, pounding heart. In the unlikely event that you have an allergic reaction to this medication then seek urgent and immediate medical attention. Symptoms of an allergic reaction include a rash, swelling, dizziness, trouble breathing. If you notice other effects not listed above contact us straight away.
- 5) We can offer you nicotine gum to try. It is really important that you follow the instructions, and don't just chew it like you would normal chewing gum. Remember it's a medication, not a lolly. We will start withmg gum and try to reduce the dose gradually. By the time you get to the last 12 weeks of your pregnancy you should try to cope without the gum. It is really important that you don't smoke while you are using the gum as you will be getting double the dose of nicotine.
- 6) Ask the patient to summarise and repeat the information you have just given them about NRT use to make sure there is no confusion.
- 7) Arrange the next appointment for 3 days time and write it on her wallet card.

Complete prescription details in writing for each woman:

If patient smokes <25 smokes per day, she should chew 2mg gum (maximum 24 pieces per day) for up to 12 weeks.

If patient smokes ≥ 25 smokes per day, she should chew 4mg gum (maximum 24 pieces per day) for up to 12 weeks.

Give only one pack of nicotine gum at each visit. A total of 3 packs can be provided over 1-2 months for each participant and her support person.

Support Person Present?

- 1) Also offer gum to the support person.
- 2) If support person doesn't wish to try the gum, it would be great if you could help the patient in using nicotine replacement therapy. Make sure she doesn't smoke while she's using the gum, and doesn't chew too much.

Record the advice you give on the patient record sheet. Make sure that you offer a lot of encouragement to those people who have quit, and tried to quit. Make sure you explain the dosage of nicotine gum very carefully.
--

Doctors – routine antenatal appointment **(7-10 day NRT follow-up)**

Check patient records for their smoking status and number of quit attempts. You need to assess the patient's progress in quitting with or without NRT. The NRT dose should be reassessed and altered if appropriate. Discuss any side-effects the patient is experiencing and offer advice on overcoming these side-effects.

Those who tried NRT

- 1) Most of the side-effects of NRT will only last a few days until your body gets used to getting nicotine a different way.
- 2) A lot of the side-effects of quitting are caused by the body getting rid of the chemicals from cigarettes and are a really good sign. These side-effects will pass.
- 3) Assist patient to complete NRT follow-up survey (or ask project officer to assist here).
- 4) Encourage the patient to persist with smoking cessation attempts or abstinence.

Unsuccessful attempt

- 1) That's ok, I know its hard. Its really important to keep trying.
- 2) What do you think made you start again? Reasons might be situational (eg: going to the pub or being in a stressful situation), or addiction-based (eg: couldn't cope with cravings).
- 3) Tailor advice to the individual: suggest ways to avoid situations that make women smoke, or methods for coping with cravings - remember the 4 D's.
- 4) How long did you manage last time without smoking?
This time we'll try to go longer without cigarettes.....
Suggest an increase of about 30%. If a woman abstained for 7 days, suggest she tries for at least 9 or 10 days.
- 5) You might find that at the end of this time, you can continue to avoid smoking, or you might have a cigarette or two, then try again. Remember to contact us if you find that you have started smoking again. It's really important to stop before you become a regular smoker again.

1. Record the advice you give on the patient record sheet. Make sure that you offer a lot of encouragement to those people who have quit, and tried to quit.
2. Make sure you explain the dosage of nicotine gum very carefully.
3. Make sure the NRT follow-up survey is completed

All subsequent antenatal visits for Additional care patients (Green Sticker)

Project Officer

- 1) Check and record smoking status
- 2) Keep encouraging women to stay non-smokers or keep trying to quit.
- 3) Talk to the patient and her support person about any problems they are having with quitting or staying off cigarettes and any concerns they might have,
- 4) Collect and label urine samples from additional care and control group patients at 24-weeks and at 6 months post-partum.
- 5) Encourage those who have relapsed to try again, and go longer without cigarettes at each attempt.

Doctor

- 1) Continue to offer support for repeated attempts or maintained abstinence.
- 2) Discuss any problems with the patient and her support person.
- 3) Assess any side-effects of NRT or of quitting.
- 4) Monitor the use of NRT and alter dose accordingly.
- 5) Discuss smoking-related issues at each antenatal visit.

For those who have relapsed to smoking

- 1) That's ok, I know it's hard. It's really important to keep trying.
- 2) What do you think made you start again? Reasons might be situational (eg: going to the pub or being in a stressful situation), or addiction-based (eg: couldn't cope with cravings).
- 3) Tailor advice to the individual: suggest ways to avoid situations that make women smoke, or methods for coping with cravings - remember the 4 D's.
- 4) How long did you last time without smoking?
This time we'll try to go longer without cigarettes.....
Suggest an increase of about 30%. If a woman abstained for 7 days, suggest she tries for at least 9 or 10 days.
- 5) You might find that at the end of this time, you can continue to refrain from smoking, or you might have a cigarette or two, then try again. Remember to contact us if you find that you have started smoking again. It's really important to stop before you become a regular smoker again.

If a woman indicates that she is having ongoing difficulties with stress management, invite her to attend the small group sessions, which meet once a week, to discuss alternative ways of coping with stress without cigarettes. If the problem persists, a referral to a psychologist may be required.

Midwife

- 1) Speak to the patient and her support person about their progress and answer questions/offer advice.
- 2) Reiterate material in education and 'how to quit' pamphlets where appropriate.
- 3) Encourage those who have relapsed to try again, and go longer without cigarettes at each attempt.

Smoking-related issues should be addressed at each visit

NRT survey 7-10 days after prescribing, Questionnaire and cotinine at 34-36 weeks and 6 months post-partum, consumer satisfaction at any exit point

Outline of discussions for
“Booster session” phone calls

(To be made by health worker/ project officer to ensure contact every 2 weeks)

“Booster session” phone call script

Hi [patient name], it's [Health worker name] from [service name] here.
I'm just calling to check how you're going with quitting smoking.

Choose appropriate script based on smoking status at last visit (check records).

Successful attempters:

Have you managed to stay off cigarettes?

YES:

That's great!!
How long is it now since you're last cigarette?
Keep going it will get easier every day.

NO:

That's ok. It's really great that you're trying.
How long did you go without cigarettes for?
Let's try going for longer this time [suggest 30% increase].

Do you have someone to support you through it?

YES:

Great, it's always easier with help.

NO:

Would you like me to put you in contact with someone who is going through the same thing so you can have a yarn and support each other?
[give details or ask permission to give details to another participant]

Unsuccessful attempters

Are you still smoking at the moment, or have you managed to stay off cigarettes?

STILL SMOKING:

That's ok, we'll give it another go.
How long did you go last time without smoking? Let's try again, this time we'll try for [30% increase].

NOT SMOKING:

That's great!!
How long is it now since you're last cigarette?
Keep going it will get easier every day.

Do you have someone to support you through it?

YES:

Great, it's always easier with help.

NO:

Would you like me to put you in contact with someone who is going through the same thing so you can have a yarn and support each other?

[give details or ask permission to give details to another participant]

Non attempters

Have you had a go at quitting since I last saw you?

YES:

That's great!! How did you go?

STILL NOT SMOKING:

How long is it now since you're last cigarette?

Keep going it will get easier every day.

SMOKING AGAIN:

That's ok. It's really great that you're trying.

How long did you go without cigarettes for?

Lets try going for longer this time [suggest 30% increase].

NO:

That's ok, maybe you'd like to try NRT?

[arrange appointment with Doctor to give NRT]

Do you have someone to support you through it?

YES:

Great, it's always easier with help.

NO:

Would you like me to put you in contact with someone who is going through the same thing so you can have a yarn and support each other?

[give details of another woman, or ask permission to give details to another participant]

All participants

Arrange next appointment.

Good luck!!

Glossary of terms

Randomised Controlled Trial (RCT): Participants are randomly allocated to receive additional intervention care or usual care (control group).

Block Randomisation: Allocation to groups is based on the week in which each participant is recruited. Participants will be assigned to the intervention group every second week, and to the usual care group in alternate weeks.

High intensity intervention: Involves repeated advice to quit smoking, and ongoing support throughout the pregnancy (booster sessions).

Booster sessions: Routine clinic visits, phone calls, or home visits every 2 weeks throughout the pregnancy. The project officer or health worker checks the smoking status and progress of the patient and encourages her to remain smoke-free or to try again to quit.

Self-reported smoking status: What the participants tell us about their smoking habits.

Validated Smoking Cessation: Self-reported smoking status checked against a biochemical measure (cotinine).

Cotinine: Nicotine from cigarette smoke is broken down in the body into cotinine. Cotinine can be measured in body fluids such as urine.

Eligibility criteria: To be eligible for this study

- Women must be pregnant,
- The woman must be of Aboriginal or Torres Strait Islander origin,
- Women must not be undergoing treatment for a chemical dependency (other than tobacco or alcohol), or show florid signs of mental illness.

Study 1: All of the above women.

Study 2: Any of the above women who are current smokers or recent quitters (stopped for current pregnancy) and attend the clinic before 20 weeks gestation.

Participants: Those who give informed consent to take part in the study.

Non-Participants: Those who decline the invitation to take part.

Current Smokers: Women who identify themselves as having had a cigarette in the past 7 days (check against questionnaire responses).

Recent ex-smokers: Women who identify themselves as ex-smokers, and as having quit for their current pregnancy (check against questionnaire responses).

Long-term ex-smokers: Women who identify themselves as ex-smokers, as having quit before their current pregnancy and as not smoking at the time of the consultation (check against questionnaire responses).

Successful attempt: Women who successfully tried to give up smoking in a defined time period.

Unsuccessful attempt: Women who are not are smoking (daily or occasionally) at the time of the consultation.

No attempt: Women who did not make a quit attempt after the intervention was delivered.

No previous agreement: Women who did not agree to make a quit attempt at their last visit.

Support Person: Any person who the woman identifies as being close to her and as willing to help her in trying to quit. If the participant does not have such a support, she could be partnered with another woman from the study for moral support.

Nicotine Replacement Therapy (NRT): Nicotine delivered in the form of gum to help people gradually break the addiction.

Background Literature

Smoking during pregnancy and its impact on health

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Appendix 8.4: Pamphlet 1, Pamphlet 2, Pamphlet 3 and Pamphlet 4

(See the following pages)



Wuchopperen 4080 1000
13 Moignard Street Manoora

Women's Health 4080 1039

Women's Clinic Tuesdays and
Thursdays 9am - 5pm



Smoking... No way!!

Protect you and your baby today



Smoking during pregnancy

Most people know that smoking is bad for them, and that smoking during pregnancy is bad for their baby.

We know that it's hard to give up smoking but there are lots of reasons why you should try to quit while you are pregnant.

Research tells us that smoking during pregnancy:

- Increases the risk of spontaneous abortion or miscarriage with every cigarette.
- Triples the risk of SIDS (Sudden Infant Death Syndrome).
- Doubles the risk of having a low birth weight baby.

Having a low birth weight baby can mean:

- Baby is more prone to infection and other health problems. Baby is more likely to become stressed during labor, leading to complications during the birth.
- Baby's birth will be no easier or quicker than with an average weight baby.



Did you know that smoking during your pregnancy:

- Reduces oxygen available for your baby.
- Increases mum's and baby's heart rate.
- Reduces breathing movements essential for baby to be ready to breathe in the outside world.
- Exposures baby to poisons.

After pregnancy:

- Mums who smoke pass on toxins to the baby through breast milk.
- Babies and children exposed to passive smoking are more prone to asthma, coughs, pneumonia and bronchitis.
- They also have slower growth rates and slower progress with reading, writing and other learning skills.

How can I stop smoking?

Ask your Doctor today. The best way is to quit straight away, and to stop altogether (go 'cold-turkey').

Remember we are here to help you!!



Caring for our future generation

Adapted from: 2005



Wuchopperen 4080 1000
13 Moignard Street Manoora

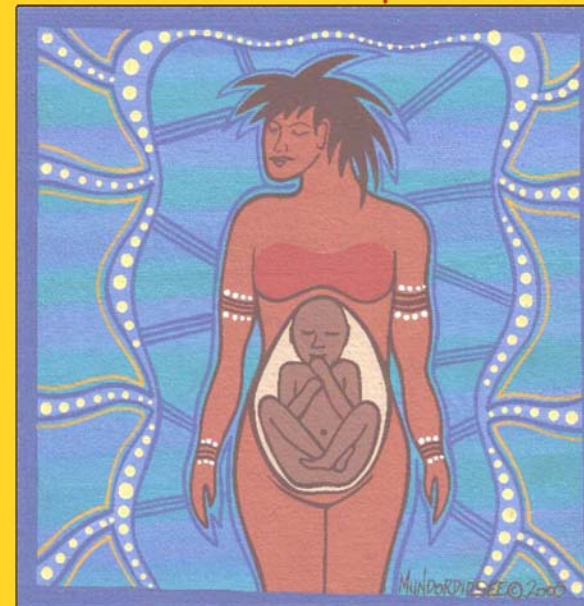
Women's Health 4080 1039

Women's Clinic Tuesdays and
Thursdays 9am - 5pm



Smoking... No way!!

You have made the right
choice to quit



Congratulations...

...for making the right choice in protecting you and your baby

Good things about giving up smoking

As the recovery symptoms pass you won't think about smoking as much, and you will feel like a new person.

You will feel healthier, breathe easier, and have more energy.

You will feel in control of your life - you won't have to worry about running out of smokes any more.

You will have more money - try to save the money you aren't spending on cigarettes and buy something for yourself or your family.

You will smell better.

Your baby will be healthier.

Here are some strategies to help you on the path to becoming a non-smoker:

Think about the times, situations, and places when you usually smoke, and try to do something else in these situations, or avoid them altogether. For example:

If you smoke when you feel stressed or anxious, try taking some time out to have a drink of water or juice, or call a friend.

If you smoke when you're with friends who smoke, ask them not to smoke around you, or go for a walk while they're smoking.

If you smoke because you are addicted or are in the habit of smoking while you do certain things, try replacing smoking with something else like chewing gum, drinking water, or eating a piece of fruit.

Quit Cold Turkey: this means stopping suddenly and completely. This works for most people and is the best way to go.

Coping with cravings...The 4 Ds

DELAY: wait for at least five minutes, and the urge to light up a cigarette will pass.

DEEP BREATHE: breathe slowly and deeply, and relax.

DRINK WATER: sip slowly, and take some time out.

DO SOMETHING ELSE: take your mind off smoking by taking action...put on the radio or some music, go for a walk, or ring a friend.

Remember: don't give in.

Having just one cigarette is the way most people go back to regular smoking.

But, if you do slip up and have a cigarette, don't feel that you are weak... learn from it and start again.

Withdrawal symptoms, such as...

cravings,

occasional headaches,

changed sleeping patterns,

irritability or anxiety,

or an increase in appetite...

are signs that your body is getting rid of nicotine and all the other chemicals in tobacco smoke. Think of these as recovery symptoms.

These symptoms will come and go, but you should be strong because they will be gone within two or three weeks.

How can I stop smoking?

We know it's hard to give the smokes away, but there are people who can help and support you.

Just ask your doctor, health worker or midwife for advice.



*We're here to support you
and care for our future generation*

Adapted from 2007



Wuchopperen 4080 1000
13 Moignard Street Manoora

Women's Health 4080 1039

Women's Clinic Tuesdays and
Thursdays 9am - 5pm



Smoking... No way!!

Support your partner or friend
who is quitting



Quitting smoking...

...is a difficult task, and requires support from close friends or partners. Your partner or friend needs your help to quit smoking so that she and her baby will be healthy.

You can help by encouraging your partner or friend and by trying some of the strategies suggested below.



Strategies:

- Try to quit as well - you will be able to support each other and to discuss the feelings you're having with someone who understands.
- If you don't want to quit, try to smoke outside. Make sure she can't breathe in any smoke from other people's cigarettes. When you go out together, don't take your cigarettes.
- When you go out for a coffee, drink, or meal, sit in a non-smoking area.

Remember that quitting smoking is best for the baby as well as the mother, and they need your help

Research tells us that smoking during pregnancy:

- Increases the risk of spontaneous abortion or miscarriage with every cigarette.
- Triples the risk of SIDS (Sudden Infant death Syndrome).
- Doubles the risk of having a low birth weight baby.

Having a low birth weight baby can mean:

- Baby is more prone to infection and other health problems. Baby is more likely to become stressed during labour, leading to complications during the birth.
- Baby's birth will be no easier or quicker than with an average weight baby.



How can I help my partner stop smoking?

We know it's hard to give the smokes away, but there are people who can help and support you. Just ask your doctor, health worker or midwife for advice.

We're here to support you and care for our future generation

Mitigating pregnancy risk 2005

Smoking during pregnancy

Most people know that smoking is bad for them, and that smoking during pregnancy is bad for their baby.



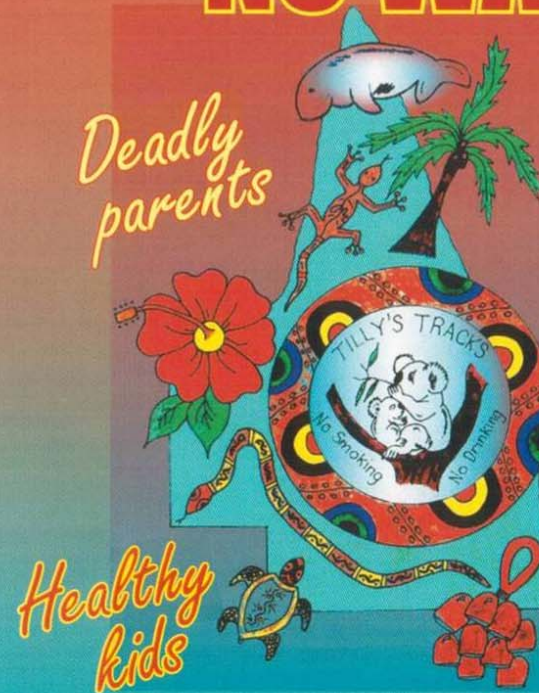
We know that it's hard to give up smoking but there are lots of reasons why you should try to quit while you are pregnant.

Did you know that smoking during your pregnancy...

- ◆ Reduces oxygen available for your baby.
- ◆ Slows the healing of, and increases infections in, Caesarean and episiotomy.
- ◆ Reduces breathing movements essential for baby to be ready to breathe in the outside world.
- ◆ Exposures baby to poisons.



SMOKING ... NO WAY!



Protect you and your baby today



Research tells us that smoking during pregnancy...

- ◇ Increases the risk of spontaneous abortion or miscarriage with every cigarette.
- ◇ Triples the risk of SIDS.
- ◇ Doubles the risk of having a low birth weight baby.

...and that having a low birth weight baby can mean:



- ◇ Baby is more prone to infection and other health problems.
- ◇ Baby is more likely to become stressed during labour, leading to complications during the birth.
- ◇ Baby's birth will be no easier or quicker than with an average weight baby.

After pregnancy

Mums who smoke pass on toxins to their baby through breast milk.

Babies and children exposed to passive smoking are more prone to asthma, coughs, pneumonia and bronchitis.

They also have slower growth rates and slower progress with reading, writing and other learning skills.

How Can I stop smoking?

Ask your doctor today.

The best way is to quit straight away and to stop altogether (go cold turkey).

remember - we're here to support you



- Well women's program
 - HPV project
 - Smoking cessation
- Foetal alcohol syndrome project
 - Maternal and child health/ Mums and Babies

Tilly's track project

Mums & Babies team



TAIHS

Mums and Babies
Ph: 4759 4045

Clinics

Monday to Friday: 8.30am-12.30pm

Townsville Aboriginal and Islanders Health Services Limited (TAIHS)
57-59 Gordon Street
Garbutt
Reception: 4759 4000



TAIHS... caring for our women's health

Appendix 8.5: Reminder card (front and back)

Remember we are here to help you!!

Phone numbers to remember:
Wuchoppereh 4080 1000
Women's Health Worker 4080 1039

Wuchoppereh

I am quitting smoking so that I can be a healthy parent and have healthy kids!!

To help cope with cravings:
Delay; wait 5 minutes. The urge to light up will pass
Deep Breathe; breathe slowly and deeply and relax
Drink water; sip slowly and take some time out
Do something else; to take my mind off smoking

It's hard but it's worth it!!

Doctor _____ and I are working together to help me quit smoking.

Signed:
Doctor _____

Patient _____

My next appointment at the clinic is

1. _____
at: _____

2. _____
at: _____

3. _____
at: _____

Appendix 8.6: Calendar for TAIHS participants

SMOKING... NO WAY!

**Smoke that comes out the end of a lit cigarette is 130 times more dangerous.
If you must smoke, only smoke outside**

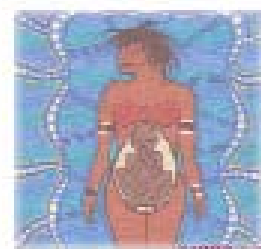


Deadly parents 2007 *Healthy kids*

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Delay; wait 5 minutes and the urge to light up will pass
Deep Breathe; breathe slowly and deeply and relax.
Drink water; sip slowly and take some time out.
Do something else; to take my mind off smoking.

Appendix 8.7: Support letter sent to woman's household



Insert Date

Dear _____ (support person),

Smoking is bad for Eleanor's health and for her baby's health.

The doctor and health care team at Wu Chopperen are supporting _____'s decision to stop smoking during this pregnancy.

You can help by:

- If she feels like smoking, encourage her to go for a walk, drink water or have a yarn - anything that will distract her.
- Try to avoid going to places where she would normally smoke, and where she will be around other people smoking.
- Try to understand that the side-effects of stopping smoking are sometimes very difficult and can involve headaches, coughs, and grumpiness
- If she starts smoking again, encourage her to come to the clinic where we will do everything we can to help her quit

People in the house can also help by:

- If there are any smokers in the house they can also try to stop smoking at the same time.
 - Ask any person who does smoke to always go outside the house to smoke, and never smoke in the car.
- Passive smoking (breathing in other people's smoke) is also very bad for a pregnant woman and her baby.

Research suggests that smoking in pregnancy:

- Increases the risk of spontaneous abortion or miscarriage with every cigarette.
- Doubles the risk of having a low birth weight baby - low birth weight babies are more likely to die during birth or in infancy, and to have health problems throughout childhood.
- Triples the risk of SIDS.

Thankyou,

_____, her baby and the team at Wu Chopperen appreciate your help.

Appendix 8.8: Magnetic card for the fridge

We are working with Wuchopperen to help us be healthy parents with healthy kids!!

_____ has agreed to:

- Quit smoking
- Keep in contact with Wuchopperen staff so they can help us

Smoking, and especially smoking around a pregnant woman is bad for her health and the health of her baby

Research suggests that smoking in pregnancy:

- Increases the risk of spontaneous abortion or miscarriage with every cigarette.
- Doubles the risk of having a low birth weight baby - low birth weight babies are more likely to die during birth or in infancy, and to have health problems throughout childhood.
- Triples the risk of SIDS.

We are trying to stop smoking:

- Inside the house
- In the car
- Around the kids
- Around _____ while she is pregnant.

To help cope with cravings:

Delay; wait at least 5 minutes and the urge to light up will go.

Deep Breathe; breathe slowly and deeply, relax.

Drink water; sip slowly and take some time out.

Do something else; take your mind off smoking by taking action...put the radio on, go for a walk, or ring a friend.

Wuchopperen 2005

Appendix 8.9: Information sheet for NRT gum

Proper Use of Nicorette Chewing Gum



- *When you feel the urge to smoke, chew one piece of gum very slowly until you taste it or feel a slight tingling in your mouth. Stop chewing, and place ("park") the chewing gum between your cheek and gum until the taste or tingling is almost gone. Then chew slowly until you taste it again. Continue chewing and stopping ("parking") in this way for about 30 minutes in order to get the full dose of nicotine.*
- *Do not chew too fast, do not chew more than one piece at a time, and do not chew more than one piece of gum within an hour. To do so may cause unpleasant side effects or an overdose. Also, slower chewing will reduce the possibility of belching.*
- *You should not drink acidic beverages, such as citrus fruit juices, coffee, soft drinks, or tea within 15 minutes before or while chewing a piece of gum. The acid will prevent the nicotine from being released from the gum.*
- *As your urge to smoke becomes less frequent, gradually reduce the number of pieces of gum you chew each day until you are chewing three to six pieces a day.*
- *Remember to carry nicotine gum with you at all times in case you feel the sudden urge to smoke. One cigarette may be enough to start you on the smoking habit again.*
- *Sucking on hard sugarless candy, or munching carrot or celery sticks between doses of gum may help to relieve cravings between doses of gum.*

Your symptoms

Ways to cope

Anger

- Get outside for a walk or try some other physical activity
- Call a trusted friend and talk about your feelings
- Try to stay positive

Anxiety

- Breathe deeply
- Try mind-relaxation techniques
- Exercise, even if it's just a brisk walk

Fatigue or feeling tired

- Try to get some moderate exercise
- Squeeze in a nap
- Plan your evenings so you can get plenty of sleep

Inability to concentrate

- Reduce your alcohol intake or avoid alcohol altogether
- Take time to exercise
- Breathe deeply, slowly
- Schedule your work and personal plans so you can focus on one thing at a time

Increased appetite or hunger

- Reach for healthy foods
- Take a walk after each meal
- Brush your teeth immediately after eating
- Chew gum
- Breathe deeply

Nicotine or cigarette cravings

- Discuss with your doctor what prescription medications may help
- Discuss with your pharmacist the stop-smoking aids that are available over the counter

Restlessness

- Take up a new hobby
- Get involved in a sport or other activity you've always wanted to try

Sleep disruption or insomnia

- Relax by clearing your mind
- Try slow, deliberate breathing
- Avoid alcohol and caffeine after 6 p.m.

Appendix 8.10: Three to seven day follow-up questionnaire

Place participant # sticker here



3-7 Day Follow-up Questionnaire for all patients in the intervention group

Date ____/____/____

1. A. Since your last antenatal visit, have you tried to quit smoking?
 - 1 ☐ YES
 - 2 ☐ NO

B. If yes, did you choose to quit smoking because of advice you received at your antenatal clinic visits?

 - 1 ☐ YES
 - 2 ☐ NO
2. How many days after your visit did you go without smoking?
3. Did your household members receive the letters sent to them about helping you quit smoking?
 - 1 ☐ YES
 - 2 ☐ NO
4. Have you put your quit smoking agreement on your fridge at home?
 - 1 ☐ YES
 - 2 ☐ NO
5. Most of my household members are willing to cooperate to help me quit and/or minimise my exposure to passive smoke while I am pregnant.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5
6. Most of my household members think it's a good idea for me to quit smoking while I am pregnant.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5
7. I really want to quit smoking, and I think I will be successful.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Appendix 8.11: Wuchopperen AC form



13 Molignard Street
Mancora Q. 4870

Telephone: 4080 1000
Facsimile: 4032 4961



Data Collection Information

NAME: _____

PARTICIPANT #: _____ CHART NO: _____ D.O.B: _____

FAGERSTROM NICOTINE DEPENDENCE SCORE: _____

SUPPORT PERSON: _____

RELATIONSHIP: _____

LETTER TO HOUSEHOLD:

NAMES: 1. _____
2. _____
3. _____

ADDRESS:

DATE: / / SENT BY:

[illegible]

Visit 1	Date: _____		Clinic / Home / Phone		<u>Discussions</u> Cold Turkey <input type="checkbox"/> Partnership <input type="checkbox"/> Support Person <input type="checkbox"/> Letters to Household & Notice for fridge <input type="checkbox"/> Hand over cigarettes <input type="checkbox"/> ARRANGE FOLLOW-UP
	Agreement	Yes <input type="checkbox"/> No <input type="checkbox"/> Talk Next time <input type="checkbox"/>	Reminder Card <input type="checkbox"/>		
	Pamphlet 1 <input type="checkbox"/>	Pamphlet 2 <input type="checkbox"/>	Pamphlet 3 <input type="checkbox"/>		
3-7 day follow-up	Date: _____		Clinic / Home / Phone		<u>Discussions</u> Cold Turkey <input type="checkbox"/> Partnership <input type="checkbox"/> Support Person <input type="checkbox"/> Letters to Household & Notice for fridge <input type="checkbox"/> Hand over cigarettes <input type="checkbox"/> ARRANGE FOLLOW-UP
	Successful attempt	Days without smoking _____	New <input type="checkbox"/>	Yes Date _____	
	Unsuccessful attempt	Agreement <input type="checkbox"/>	No <input type="checkbox"/>		
	No attempt				
	Pamphlet 1 <input type="checkbox"/>	Pamphlet 2 <input type="checkbox"/>	Pamphlet 3 <input type="checkbox"/>		
	Support Person Present? <input type="checkbox"/>	Support person smoker? <input type="checkbox"/>			
Other follow-up 1	Date: _____		Clinic / Home / Phone		<u>Discussions</u> Cold Turkey <input type="checkbox"/> Partnership <input type="checkbox"/> Support Person <input type="checkbox"/> Letters to Household & Notice for fridge <input type="checkbox"/> Hand over cigarettes <input type="checkbox"/> ARRANGE FOLLOW-UP
	Successful attempt	Days without smoking _____	New <input type="checkbox"/>	Yes Date _____	
	Unsuccessful attempt	Agreement <input type="checkbox"/>	No <input type="checkbox"/>		
	No attempt				
	Pamphlet 1 <input type="checkbox"/>	Pamphlet 2 <input type="checkbox"/>	Pamphlet 3 <input type="checkbox"/>		
	Support Person Present? <input type="checkbox"/>	Support person smoker? <input type="checkbox"/>			
Other follow-up 2	Date: _____		Clinic / Home / Phone		<u>Discussions</u> Cold Turkey <input type="checkbox"/> Partnership <input type="checkbox"/> Support Person <input type="checkbox"/> Letters to Household & Notice for fridge <input type="checkbox"/> Hand over cigarettes <input type="checkbox"/> ARRANGE FOLLOW-UP _____
	Successful attempt	Days without smoking _____	New <input type="checkbox"/>	Yes Date _____	
	Unsuccessful attempt	Agreement <input type="checkbox"/>	No <input type="checkbox"/>		
	No attempt				
	Pamphlet 1 <input type="checkbox"/>	Pamphlet 2 <input type="checkbox"/>	Pamphlet 3 <input type="checkbox"/>		
	Support Person Present? <input type="checkbox"/>	Support person smoker? <input type="checkbox"/>			
	NRT Prescribed? N/A <input type="checkbox"/>	Given <input type="checkbox"/>	Declined <input type="checkbox"/>	GIVE INFO SHEET AND ADVICE ON DOSE ETC	NRT Given to household? Yes/No Total amount given _____
Other follow-up 3	Date: _____		Clinic / Home / Phone		<u>Discussions</u> Cold Turkey <input type="checkbox"/> Partnership <input type="checkbox"/> Support Person <input type="checkbox"/> Letters to Household & Notice for fridge <input type="checkbox"/> Hand over cigarettes <input type="checkbox"/> ARRANGE FOLLOW-UP _____
	Successful attempt	Days without smoking _____	New <input type="checkbox"/>	Yes Date _____	
	Unsuccessful attempt	Agreement <input type="checkbox"/>	No <input type="checkbox"/>		
	No attempt				
	Pamphlet 1 <input type="checkbox"/>	Pamphlet 2 <input type="checkbox"/>	Pamphlet 3 <input type="checkbox"/>		
	Support Person Present? <input type="checkbox"/>	Support person smoker? <input type="checkbox"/>			
	NRT Prescribed? N/A <input type="checkbox"/>	Given <input type="checkbox"/>	Declined <input type="checkbox"/>	GIVE INFO SHEET AND ADVICE ON DOSE ETC	NRT Given to household? Yes/No Total amount given _____
34-36 week follow-up	Date: _____		Clinic / Home / Phone		Other participants known? _____ _____ _____
	Still Smoking <input type="checkbox"/>	How long without smoking? _____	Questionnaire completed <input type="checkbox"/>	Urine sample taken <input type="checkbox"/>	
	Successfully quit <input type="checkbox"/>				
6 months post-partum	Date: _____		Clinic / Home / Phone		
	Still Smoking <input type="checkbox"/>	How long without smoking? _____	Questionnaire completed <input type="checkbox"/>	Urine sample taken <input type="checkbox"/>	
	Successfully quit <input type="checkbox"/>				

Appendix 8.12: Wuchopperen UC form



13 Moignard Street
Mandara Q. 4870

Telephone: 4080 1000
Facsimile: 4032 4961

Data Collection Information

NAME: _____

PARTICIPANT #: _____

CHART NO: _____

D.O.B: _____

USUAL CARE PATIENT

INITIAL ANTENATAL VISIT

DATE: ____/____/____

Smoking status:

SMOKER

NON-SMOKER

FAGERSTROM NICOTINE DEPENDENCE SCORE: _____

Urine cotinine: _____

34 – 36 WEEKS ANTENATAL VISIT

DATE: ____/____/____

Smoking status:

SMOKER

NON-SMOKER

Names of other participants known to this individual: _____

Urine cotinine: _____

6 MONTHS POST PARTUM VISIT

DATE: ____/____/____

Smoking status:

SMOKER

NON-SMOKER

Urine cotinine: _____

CHAPTER 9

Future directions

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Chapter 9

Future directions

What do these studies add to the field?

This series of studies offers a useful background for future efforts in smoking cessation among Aboriginal and Torres Strait Islander women. While the pilot RCT failed to achieve a statistically significant improvement in quit rates in the additional care group who were allocated to receive an intensive intervention, a substantial proportion of women quit smoking overall, and the processes involved in research design, implementation and evaluation have provided invaluable knowledge and experience.

Antenatal smoking is one marker of the vulnerability of Aboriginal and Torres Strait Islander women

The rate of antenatal smoking was high among the Aboriginal and Torres Strait Islander women participating in these studies, particularly in the comparison between Aboriginal and Torres Strait Islander women and non-Indigenous women attending Cairns Base Hospital in Chapter 2. The alarming rate of smoking in this group is highlighted: 39% compared with 17% among non-Indigenous women, Aboriginal women alone smoked at a rate of 54%. The clustering of markers of low-socio-economic status and health risks among Aboriginal and Torres Strait Islander women illustrates the vulnerability of this population group to adverse health, and is indicative of significant impact on health systems and services. Co-existing risks and health problems place many Aboriginal and Torres Strait islander women and their infants in

positions of deprivation. Smoking is one modifiable factor which is at the centre of the myriad of social and behavioural risk factors which contribute to this deprivation.

What works in the effort to intervene in antenatal smoking?

The reviews presented in Chapter 3 and Chapter 4 highlight a severe gap in research efforts, and in knowledge regarding the intervention approaches which are most likely to be effective in increasing antenatal smoking cessation in general, yet alone among Aboriginal and Torres Strait Islander women. Over the past several decades, the antenatal smoking issue has been well documented, but descriptive research on the topic has not been matched by well-designed intervention studies. Those interventions which have been performed fail to offer a clear indication of the strategies which are most likely to reduce smoking rates. The reviews demonstrate the heterogeneity among intervention efforts, and the need for well-designed evaluations of interventions to assess the differential effectiveness of various approaches. Rigorous research designs are necessary to enable conclusions to be drawn with confidence regarding the impact of an intervention, and to minimise the potential impact of bias and confounding. It is unethical, and potentially not cost effective to base efforts to reduce smoking rates on intervention approaches which have not been rigorously scrutinised in a research context prior to their general implementation.

The social environment predicts continued smoking during pregnancy

The findings presented in Chapter 5 suggest that the markers which predict antenatal smoking in non-Indigenous women do not effectively differentiate between smokers and non-smokers among the Aboriginal and Torres Strait Islander population. High rates of antenatal smoking among this population group do not appear to be associated with a deficit in knowledge regarding the health effects of smoking, but rather with the

social environment in which women live, and the behaviours of significant others. The smoking status of partners was the most important predictor of continued smoking, and was significantly associated with a low knowledge score and a negative attitude towards quitting smoking. The social environment and exposure of women to other people smoking in the house represent key areas which should be addressed in smoking cessation intervention efforts.

Cotinine is a robust measure of smoking status and tool for the validation of self-report

While several environmental and individual factors have been shown to influence cotinine levels, any impact of alcohol consumption, age, gestation, BMI and medication use were not sufficient to systematically influence the cotinine levels detected. The relationship between cotinine and the level of cigarette consumption, exposure to passive smoke, and carbon monoxide level remained robust, despite substantial variation in individual factors. Cut-points of both 175ng/ml and 250ng/mL were found to be valid and effective in distinguishing between smokers and non-smokers in urine cotinine ELISA. These cut-points had sensitivity and specificity of 94% and 75%, and 81% and 94% respectively in the validation of self-reported smoking status. These cut-points will be a useful guide for future studies with Aboriginal and Torres Strait Islander women, having been tested and validated in a representative sample of women.

Detecting smoking and using opportunities for intervention

From the pilot RCT, it was difficult to draw conclusions regarding the aspects of intervention which were most likely to be effective. The data indicated that adherence to the intervention protocol by healthcare providers was low after its initial delivery, and therefore it was not possible to attribute any effects on smoking cessation to any

aspects of the intervention. The quit rates in both groups were substantial, with smoking having been raised as an issue with all participants at a minimum, during recruitment by project officers. Usual care also involved raising the smoking issue, and reports from practitioners involved indicated that the rate at which smoking was discussed during usual care increased during the study. Further, the initial uptake of the intervention was promising, with a large proportion of additional care participants making an agreement to attempt to quit smoking, reporting actually making an attempt, and reporting that attempts were the result of advice from their practitioner. These measures all suggest that this initial contact and discussion of the smoking issue may have had substantial impact on smoking among this group, and highlight the importance of minimal intervention with all pregnant women.

From these indications, it is suggested that efforts should be made to encourage all practitioners to at the very least, discuss smoking with pregnant women, and inform them that quitting would be beneficial to their health and that of their baby. While such a practice constitutes usual care in most health care settings, suggestions from the doctors involved in this study were that the consistency with which they did so was somewhat lacking prior to the study. Missed opportunities for intervention in primary healthcare settings represent avoidable costs and burden on the healthcare system. The first step in improving any health issue is to identify the vulnerable individuals. With an overall improvement in quit rates achieved in this study, it may be said that in the case of antenatal smoking cessation, merely identifying smokers, and approaching the smoking issue has the potential to go some way towards influencing smoking behaviour. Health policy and research should put emphasis on the critical need for practitioners to identify all smokers among their patients, and to discuss smoking at every opportunity.

Mobilising social support

Examination of the predictors of continued smoking during pregnancy in Chapter 6 highlighted the importance of the social environment and the influence of partners and individuals with whom women live, in influencing and reinforcing smoking or quitting behaviours. The high rate of smoking among partners of women who participated in the pilot RCT, as well as reports of social pressures and stress associated with families suggests that these women were perhaps hindered from quitting due to such influences. It seems that while the majority of women (86%, n=24) were able to name individuals whom they expected to support them in quit attempts throughout their pregnancy, and a large proportion of women felt that their household members agreed that quitting was a good idea (82%, n=13), very few women actually received an adequate level of social support. Evidence existed that support people had attended the clinic with 19 women. Very few partners or support people used the NRT provided or were reported to have attempted to quit with women (n=5 of 13 identified as smokers, 38%), or attended the clinic with women (42%, n=10). It seems that the pilot study was unable to effectively mobilise social support, and therefore the potential impact of this element remains unknown.

With the apparent importance of social factors in influencing the behaviours of women, future studies should take measures to ensure the mobilisation of social support, and active involvement of partners and confidants in the woman's pregnancy and efforts to quit smoking. Group sessions in a casual, neutral environment may encourage the participation of supportive individuals. It is expected that if practitioners can discuss smoking issues with support people and encourage these people and other household members to view the effort to quit smoking during pregnancy as a worthwhile, whole group activity, a family unit can be involved in promoting the health of the pregnant women and expected infant. Interventions therefore have the capacity to impact not

only on smoking, but on other aspects of the social environment which cause distress for women and make them vulnerable to health problems throughout the pregnancy.

The extra impact

Having had a substantial proportion of women quit smoking with what appears to have been minimal intervention or adherence to the intervention protocol, it seems logical to raise the issue of what is needed to make further inroads, and lead to greater cessation rates. It may be that components of this intervention design, such as social support, ongoing follow-up, and the provision of NRT do in fact hold the answer, but insufficient delivery in the present study and limited sample size have prevented the detection of their impact. A serious limitation of this pilot study may be research design used and inability to meet the strict requirements associated with an RCT. Such a suggestion derives from the difficulties associated with control and randomisation; particularly for the health service staff responsible for these components. With suggestions of the importance of including social networks in intervention attempts, the issue of control is further complicated. Particularly in the context of small, often very close-knit Aboriginal and Torres Strait Islander communities, effectively mobilising social support without contaminating the social network of usual care participants is extremely difficult. If future studies are to evaluate the effectiveness of various intervention components, it is possible that other research designs are more appropriate for the Aboriginal and Torres Strait Islander primary care context.

Implications for research design

The importance of evidence-based medicine is well recognised, and efforts to close the gap between evidence and practice are widespread and highly valuable. The drive towards level I evidence has placed great pressure on researchers to conduct RCTs or

(more recently) studies using other methodologically rigorous research designs such as controlled before and after studies, interrupted time series, or multiple baseline studies. The limitations of the RCT in population health have created a move towards other, more practical research designs for community-based studies. There is great recognition of the need for culturally-specific research to generate evidence for the most effective and appropriate healthcare practices and interventions for Aboriginal and Torres Strait Islander groups.

In her evaluation of the applicability of evidence derived from systematic reviews on tobacco cessation interventions to an Australian Aboriginal population, Ivers (2006) suggests that an approach based on evidence derived from mainstream trials may not be the primary consideration in planning interventions for this group¹. A cycle through measurement research, descriptive research, intervention research, systematic reviews and dissemination of evidence is recognised as the process required for generating sound evidence and facilitating its uptake into practice. Each step of this process should be conducted in a culturally appropriate manner, with particular consideration for the nature of Aboriginal and Torres Strait Islander communities.

Various Aboriginal and Torres Strait Islander groups and governing bodies have formally acknowledged the need for research and are requesting a balance between efforts which define and measure health problems, with those which explore clinical and public health interventions.² There remains however, an attitude of having been over-studied and a reluctance to consent to involvement in 'more research'. This attitude is often understood, and perhaps shared by health workers involved in research studies and recruiting members of their communities to participate.

The interconnectedness and social situation of Aboriginal and Torres Strait Islander communities can impact on the methodological vigour of research studies, increasing

the potential for contamination and other potentially confounding factors. Attempts to control for such variables may create such a chasm between the research and 'real' world, that the applicability of research results to a healthcare setting becomes questionable. The most appropriate design for this population may therefore be one in which the community is the unit of analysis.

While action research studies and uncontrolled research designs have long been viewed as flimsy and of limited value, it may be that in the Indigenous health setting, their value is underestimated. The value of the processes associated with research and in particular, intervention studies may not be fully recognised. The capacity building involved with staff training and education, as well as the input of resources and infrastructure into health services and communities that are often involved with research may be the very things which are needed, and which will drive healthcare improvement in this environment.

Numerous examples exist of the demise of,³ or failure to achieve significant results with, RCTs¹ in Aboriginal and Torres Strait Islander communities or health services. On the other hand, studies involving the implementation and concurrent evaluation of healthcare improvement programs or interventions have demonstrated positive outcomes – not only for health but for community development and the development of capacity within health services.⁴

Alternative evaluation designs

Given the complexity of population-based research, and the importance of scientific rigour in evaluating these studies and generating strong research evidence, there is a clear need for alternative, more appropriate research designs. The general principles of research design for any evaluation effort are the minimisation of bias and other threats

to internal validity (confounding and chance), and maximisation of generalisability.⁵ Studies should be designed in order to determine with a high level of confidence whether a change has occurred, whether that change is a result of the intervention, and whether the change is significant.⁶ These goals can be achieved using alternative research designs to the RCT, which are more practical in the population context, and may be more appropriate for Aboriginal and Torres Strait Islander communities.

Heller and Page (2002)⁷ have put forward a set of principles for generating strong research evidence in the population health field. These principles include statistical considerations (development and use of appropriate study designs to assess interventions without the RCT; use of routinely collected data for research; number needed to treat concepts; multilevel modelling to analyse clustered data appropriately at both individual and population levels), and implementation considerations (data collection across the health sector; simple methods of accessing data in order to calculate population measures of risk; methods to easily access the results of public health interventions; ways to present risk data to policy makers and the public in an easily understood manner; education of policy makers to use evidence; population services audit). These concepts provide a potential basis for the improvement of not only the health of communities, but also the systems responsible for delivering healthcare, and have the capacity to strengthen these systems using research designs other than the RCT.

A balance between unplanned, unevaluated programs and methodologically stringent research designs may be the key to advancing intervention research in, and thereby improving health of, Aboriginal and Torres Strait Islander communities. The results of the pilot RCT offer promise for interventions in this area, with a high level of initial uptake of the intervention and a large number of women attempting to quit as a result of the advice received from practitioners. Well-planned, properly evaluated programs

which implement and test improvement strategies in the communities to which they will be applied, by the individuals who will deliver them, have the potential to achieve substantial and important results, and to guide future intervention efforts. If the complexities of research were removed or at least reduced, there may be an increase in enthusiasm, participation, and feasibility of these efforts.

A way forward

The results from this series of studies suggest that successful interventions to reduce smoking amongst Aboriginal and Torres Strait Islander women will be those which involve the social networks of these women and consider the relationship of smoking to other social and behavioural risk factors. While individual intervention components could not be identified as successful here, suggestions from the background research are that smoking should not be tackled in isolation, and that women should not be dealt with in isolation. It may be that for Aboriginal and Torres Strait Islander women, an issue such as antenatal smoking is best tackled with an approach such as a community-based intervention, with perhaps only a limited amount of effort directed at individuals. Designs such as the multiple baseline design, or retrospective cohort studies, with the evaluation of intervention effects in a community as a whole, may be most appropriate to assess the strategies which are likely to impact on antenatal smoking.

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