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The development and evaluation of a smoking cessation programme for disadvantaged pregnant women in South Africa

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Overall abstract

Studies of smoking during pregnancy in South Africa have found exceptionally high smoking rates among disadvantaged women of mixed ethnic descent (46%) (Steyn et al., 1997; Petersen et al., 2009 a). As a consequence, these women are at high risk of smoking-related pregnancy complications and poor birth outcomes. It has long been recommended that a smoking cessation intervention be developed specifically for this high risk group.

There is strong evidence that best practice smoking cessation interventions for pregnant women can be effective in increasing quit rates, as well as in reducing the incidence of premature birth and low birth weight (Lumley et al., 2009). However, these interventions have only been studied in developed countries and it was unknown whether such programmes could be successfully applied to a South African setting.

From 2002, the Medical Research Council of SA undertook a programme of research for the purposes of developing and evaluating a smoking cessation intervention, specifically for disadvantaged pregnant women attending public-sector, antenatal clinics in Cape Town.

This thesis reports on several aspects of this research:

Chapter 3 describes the findings of one of the formative studies, conducted prior to the development of the intervention. The study involved 24 in-depth, qualitative interviews with midwives, who provide antenatal care primarily to women from this high risk community. The study aimed to investigate midwives' current opinions about and approaches to smoking cessation education/counselling, with a view to involving them in delivering the intervention in antenatal clinics. Three archetypes of midwives, characterised by different styles of communication and approaches to smoking cessation, emerged from the analysis of the interview data. These were described as *The Angry Scolders*; *The Benign Carers* and *The Enthusiastic Friends*. Those midwives who adopted a patient-centred approach – the Enthusiastic Friends – elicited the most positive response from pregnant women and found the task of education and counselling less frustrating than the other two archetypes. The findings highlighted the importance of the proposed intervention attending to not only the issue of what information is communicated to pregnant women about smoking during pregnancy, but *how* this is communicated. Training midwives in the patient-centred counselling methods of Motivational Interviewing (Rollnick et al., 2002) was recommended as a means of improving counselling outcomes among pregnant smokers.

Further studies, by other researchers, were also conducted as part of this formative research phase. These involved investigating pregnant women's smoking related knowledge, attitudes, beliefs and

behaviours, as well as the attitudes of midwives towards a potential smoking cessation intervention and the potential barriers to its delivery.

Chapter 4 describes the process of developing the smoking cessation intervention for pregnant women, using the Intervention Mapping protocol for planning health promotion programmes (Bartholomew et al., 2001). This model proceeds systematically through six key steps: 1) a needs assessment and analysis of the problem of smoking in pregnancy; 2) the definition of programme objectives; 3) the selection of theory-based intervention methods and practical strategies; 4) the design of the intervention; 5) and 6) the development of an implementation and evaluation plan.

Data from the scientific literature, behavioural change theory and the findings of the formative research studies that were conducted with both pregnant women and health care providers were reviewed and integrated into the design process. The result was an intervention based on best practice models, but tailored to the unique characteristics of the target group and local setting. The core of the intervention consisted of peer counsellors and midwives delivering the current, best-practice guideline for brief smoking cessation counselling (the 5As, Fiore, 2000). These guidelines were adapted to incorporate the key principles of Motivational Interviewing (Rollnick et al., 2002). A self-help Quit Guide and two other items of media were distributed to women in the context of brief counselling.

Chapter 5 describes the evaluation. A quasi-experimental design was used to assess the impact of the intervention on the smoking behaviour of pregnant women attending four antenatal clinics in Cape Town. Quit rates were measured by urinary cotinine, towards the end of pregnancy. The intervention was effective in improving quit rates among this group of high risk women. The difference in quit rates between the control and intervention cohorts in late pregnancy was 5.3% (95% CI: 3.2% to 7.4%, $p < 0.0001$) in an intention to treat analysis, which is in line with the average, absolute difference of 6% achieved by the 72 trials included in the latest Cochrane meta-analysis (Lumley et al., 2009). There was also a significant difference in reduction of smoking of 11.7% (95% CI: 5.0%-18.4%, $p = 0.0006$). The two cohorts were comparable at baseline. The process evaluation showed that the intervention was well accepted by clinic staff and was adequately implemented. Pregnant women rated the provision of social support from the peer counsellors as the most helpful aspect of the programme.

Conclusion

Best practice models, adapted to the particular characteristics of the target audience and setting can be successfully transferred to the South African setting. The commitment to following a rigorous formative research and development process contributed the success of the intervention and its high

degree of acceptability among pregnant women and health care providers. The moderate impact of these types of interventions in primary care settings can translate into significant clinical benefits if they are institutionalised and systematically applied to a large proportion of women at risk. The value of such interventions would be further enhanced if they were extended to also address psychosocial stress, drug and alcohol abuse, as these behaviours are often closely associated with smoking.

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Chapter 1

Literature Review

A) Smoking cessation interventions for pregnant women

Smoking during pregnancy is recognised as one of the most important, preventable, risk factors for a number of adverse pregnancy and foetal outcomes and has both immediate and long-term health implications for women and babies. This chapter reviews the literature on the risks of smoking during pregnancy; the maternal characteristics associated with smoking during pregnancy and the scope of the problem. It further reviews the evidence base for cessation interventions targeting pregnant women. Several decades of intervention research have led to advances in research methodology and clear recommendations for clinical practice. This review includes a description of the quality and completeness of the available evidence, the different types of intervention strategies that have been tested and the current best practice guidelines for smoking cessation counselling with pregnant women.

The evidence in this review is drawn from literature accessed through PubMed and Medline, using combinations of the following search terms: pregnant women/pregnancy/smoking/smoking cessation programmes/interventions. The interventions considered in this review are aimed directly at pregnant smokers in an antenatal care setting and have cessation as their primary aim.

1. Background

1.1 The risks of smoking during pregnancy

Maternal smoking during pregnancy is an important, independent cause of a number of adverse pregnancy outcomes. It is associated with increased risk of ectopic pregnancy, premature rupture of membranes, placental abruption, placenta previa and preterm delivery. Smoking during pregnancy also increases the risk for stillbirth, neonatal death and Sudden Infant Death Syndrome (SIDS) (US DHHS, 2001). Infants born to smokers weigh, on average, 250 grams less than babies born to non-smokers, primarily resulting from intrauterine growth restriction. This risk is highly dose dependent, with the greatest risk in the second and third trimesters (Jauniaux & Burton, 2007; Ward et al., 2007). Preterm birth and low birth weight are associated with increased risk for perinatal, neonatal and infant morbidity and mortality (US DHHS, 2001). There appears to be an inverse association between smoking during pregnancy and pre-eclampsia. However, if the condition develops, heavy smoking is associated with a higher risk of perinatal death, placental abruption and small-for-

gestational age (SGA) infants (Cnattingius et al., 1997). Smoking has also been consistently associated with a small increase in risk of oral-facial clefts (Little et al., 2004).

Women who smoke are less likely to start breast-feeding their babies than non-smokers, have more problems with milk production and are more likely to wean them earlier (Amir, 2001). Thus, many infants born to smokers are deprived of the important nutritional benefits and protective effects of breastfeeding. Passive smoking during pregnancy increases the risk of stillbirth (Subramoney et al., 2010), or of having a baby with lower birth weight, smaller head circumference and congenital anomalies (Salamasi et al., 2010). Infants exposed to environmental tobacco smoke (ETS) are at higher risk of respiratory tract infections, impaired lung function and otitis media (Di Franza et al., 2004) and their rates of hospitalisation for these conditions are three times higher than for non-exposed infants (Floyd et al., 1993). Both prenatal and postnatal exposure to smoking increases the risk of SIDS, defined as sudden, unexpected infant death between four weeks and one year. This has been consistently observed across various study designs and populations (Cnattingius, 2004).

Cigarette smoke contains nicotine, carbon monoxide, cyanide, lead, arsenic and thousands of other potentially toxic chemicals (Klesges et al., 2001). There are a number of proposed biological mechanisms for the adverse effects of tobacco smoke on the pregnancy and foetus. Nicotine causes vasoconstriction of uteroplacental blood vessels, which reduces blood flow to the placenta, thereby decreasing the delivery of oxygen and nutrients to the foetus. It may also reduce the amount of blood in the foetal cardiovascular system (Lambers & Clark, 1996). Nicotine readily crosses the placenta, exposing the foetus to relatively higher levels of nicotine than their mothers and has a direct action on the nervous system and developing foetal brain. This appears to increase the risk of a number of adverse neuro-behavioural effects in later life, including attention deficit/hyperactivity disorders and learning problems (Ernst et al., 2001; Batstra et al., 2003). Recent research suggests that the stimulatory effects of intrauterine nicotine exposure disrupt the auditory processes related to speech perception, negatively affecting reading and language development during childhood (Peck et al., 2010). It is also plausible that through the activation of the nicotine receptors in utero, the brain is predisposed to the addictive influence of nicotine in later life. This may be further enhanced by exposure to nicotine in breast milk or environmental tobacco smoke after birth (Hellstrom-Lindahl & Nordberg, 2002; Al Mamun et al., 2006). A study by Wang et al. (2002) suggested that maternal genotype may affect the risks associated with nicotine, with some mothers metabolising nicotine and clearing its toxic by-products more efficiently or quickly than others.

Carbon monoxide has an effect on the function and development of the placenta and leads to an increase in foetal carboxyhaemoglobinaemia, with a subsequent decrease in oxygenation to various developing organs and tissues (Bush et al., 2000). The free radical components of cigarette smoke

cause endothelial damage to uterine and placental blood vessels (Lain et al., 2003). Smoking has been found to significantly diminish the concentrations of serum folate in pregnant women, which is essential for normal cell function. This may be a mechanism for miscarriage, intrauterine death and abruption placenta (McDonald et al., 2002).

In addition, it has recently been hypothesised that the foetal metabolic and hormonal responses to intrauterine growth restriction, followed by rapid postnatal growth are likely to be key to the early pathogenesis of adulthood diseases, such as cardiovascular disease, type 2 diabetes and hypertension (Ong & Dunger, 2002; Gluckman et al., 2008). In utero exposures to tobacco may increase the risk of both diabetes and obesity through programming, resulting in lifelong metabolic dysregulation, possibly due to foetal malnutrition or toxicity (Montgomery & Ekblom, 2002). A study on atherosclerosis risk in the Netherlands found that young adults exposed to tobacco in utero had thicker walls of the carotid arteries, compared to unexposed children, leading to the conclusion that smoking during pregnancy can cause permanent vascular damage in children, thereby increasing their risk of stroke and heart attack in adulthood (Uiterwaal et al., 2007). Furthermore, there is a growing body of evidence that in utero exposure to tobacco smoke can produce persistent deficits in childhood lung function, possibly increasing the risk for chronic obstructive pulmonary disease and lung cancer in adulthood (Gilliland et al., 2000).

Quitting smoking before, or during, pregnancy is clearly one of the most important actions a woman can take to improve pregnancy outcome and the long term health of her child. The risk of premature rupture of membranes, preterm labour and low birth weight appear largely reversible, if smoking is stopped in the first trimester of pregnancy (McCowen et al., 2009). However, there are benefits to stopping at any gestational age. Improved pregnancy outcomes have been reported in women who stop smoking as late as 32 weeks gestation (Li et al., 1993; Klesges et al., 2001).

1.2. Prevalence of smoking during pregnancy

Substantial numbers of women in developed countries continue to smoke during pregnancy, despite increased knowledge of the adverse health effects. In the US, although smoking rates have been falling, approximately 22% of women of reproductive age still smoked in 2006 and 10-12% reported continuing through pregnancy (CDC, 2008). In the US, smoking accounts for 30% of all small-for-gestational age infants, 10% of preterm infants and 5% of infant deaths (Salihu et al., 2003).

Significant increases in quitting during pregnancy in some states suggest that efforts in targeting pregnant women have had some success (Tong et al., 2009). Smoking remains concentrated among younger, white women of low socio-economic status, as well as among American Indian and Alaskan Native women. The high prevalence of smoking in several other indigenous, minority groups of

women appears to correspond directly to their relative social and material disadvantage. This is the case, for example, among First Nation and Inuit women in Canada (Greaves et al., 2003) and among Aboriginal and Torres Strait Islander women in Australia, where over 50% of women report smoking during pregnancy, compared to 17% of women overall (Laws & Hilder, 2008). In New Zealand, 13% of non-Maori women smoke during pregnancy, compared to 39% of Maori women (NZ Ministry of Health, 2009).

In the UK in 2005, around 32% of women reported smoking in the year before they became pregnant and about 17% admitted that they continued smoking throughout their pregnancy (NHS, 2006). In the UK, smoking prevalence among the lower income groups has been consistently about three times higher than women in higher income groups. Surveys have also shown that a minority of women quit smoking (28%), compared to the number of women who reduce their smoking (43%) and that most women who quit, tend to do so in the first trimester of pregnancy (Department of Health UK, 2007).

Sweden is one country where there have been dramatic improvements in smoking rates among pregnant women. A sustained national campaign, carried out in maternity health clinics during the 1990s, succeeded in halving the number of women who smoked during pregnancy from 31% in 1983 to 12% in 2000 (Cancerfonden, 2003). Currently, 7.5% of women registering for antenatal care are self-reported smokers (National Board of Health and Welfare, 2008). However, these achievements have been partially offset by a pronounced increase in the use of snuff among young women (from 1% in 1989 to 4% in 2007) (Statistics Sweden, 2009).

Such data, which is collected via population-based surveys or from birth certificates and is based on self-report, is likely to be an underestimation of the prevalence of smoking among pregnant women, because of the greater social desirability of the non-smoking response during pregnancy (Lawrence et al., 2003).

From a population perspective, smoking remains the most modifiable risk factor for adverse pregnancy outcomes in developed or high-income countries. As the tobacco industry consolidates and shifts its marketing focus to low-to-middle income countries and previously protective cultural constraints continue to erode as a result of increasing globalisation, cigarette smoking during pregnancy is expected to become an increasingly important problem in the regions of Eastern Europe, Africa and Asia, jeopardising ongoing efforts to improving maternal and child health in poor countries (Shafey, 2009). Across the developing world, prevalence of smoking among women currently stands at around 9%, compared to 22% among women in developed countries, but this figure is expected to rise to around 20% in developing countries by 2025, if current trends continue

(Shafey, 2009). The historical advances in maternal and child health attributed to prenatal care, attended births and immunisations programmes will be adversely affected, if the preventable problem of tobacco use among women of reproductive age is not confronted (Bloch et al., 2010). According to the American Cancer Society, preventing this predicted increase in prevalence will have a greater impact on global health than any other single intervention (Shafey, 2009).

Information regarding the current prevalence of smoking in pregnancy among women in low-to-middle income countries is very incomplete. In parts of Eastern Europe, smoking prevalence among pregnant women is assumed to be high, given the generally high (and increasing) rates of smoking among women of reproductive age (Shafey, 2009). For example, in Poland and Hungary, prevalence among pregnant women is estimated to be about 30% (Polanska et al., 2004; Tombor, 2010). In South American countries, smoking in pregnancy varies from 28% in Chile, 18% in Uruguay, 6% in Brazil to under 1% in Ecuador and Guatemala (Bloch et al., 2008). In South Africa, a survey of pregnant women in four cities showed that 21% of pregnant women overall smoked, with marked differences between socio-economic and ethnic groups (Steyn et al., 1997).

In some developing countries the use of non-cigarette forms of tobacco is a socially acceptable cultural norm. Documented prevalence of snuff or chewing tobacco among pregnant women varies from 6% in the Democratic Republic of Congo (Bloch, 2008), between 5–33% in different states of India (Bloch, 2008) and 7.5% in South Africa (Steyn et al., 2006). Water-pipes are used by 5–6% of pregnant women in Lebanon (England, 2010). These behaviours appear to pose a similar and equally serious risk to the foetus and pregnancy, yet they are far less studied (Gupta & Sreevidya, 2004; Gupta & Subramoney, 2006). There is an urgent need for further research to develop accurate estimates of the burden of ill health related to these tobacco products. There is also a need to investigate the possible risks for pregnant women, who participate in tobacco agriculture in both developed and developing countries.

In many developed countries the implementation of smoking restrictions in public places and the workplace, coupled with the falling rates of smoking among men, has resulted in decreasing exposure of pregnant women to environmental tobacco smoke (ETS). Where such policies have not yet been introduced and where the smoking rates of men remain high, as is the case in many developing countries, large proportions of women continue to be highly exposed to ETS. For example, in a recent survey of nine developing countries, 50% of pregnant women in Pakistan and 30% in Argentina and Brazil reported being frequently exposed to indoor tobacco smoke (Bloch et al., 2008). In a survey in Lebanon, 70% of pregnant women reported exposure to ETS (Chaaya, et al., 2004). In the Philippines and in the Sichuan province of China, 60–75% of women reported that

their husbands or other male family members currently smoked in the home (Nichter et al., 2010; Yang et al., 2010).

The general paucity of epidemiological data on the prevalence of tobacco use and ETS exposure and the health effects among pregnant women in middle-to-low income countries is a significant gap in the information base and acts as a constraint to mounting an appropriate public health response in these countries. Such research has become all the more important, given the need to monitor and counter the tobacco industry's increased efforts to promote tobacco products to young women in developing countries, who represent a relatively untapped and potentially enormously profitable market.

1.3. Factors associated with smoking and quitting during pregnancy

Surveys have shown distinct differences between women who smoke during pregnancy and those who do not, consistently reflecting social disadvantage. Continued smoking and high daily tobacco consumption have shown strong associations with low socio-economic status, low levels of education, high parity, being single, living in a smoking household, attending public, rather than private, health services, as well as attending antenatal care later and less regularly (Bailey, 2006; Lumley et al., 2004; Mohsin & Bauman, 2005; Schneider et al., 2010; Tong et al., 2009). An association with alcohol consumption and prior pregnancy terminations has also been found (Hannigan & Armant, 2000; Raatikainen et al., 2007). Women who have smoked in previous pregnancies, with no apparent negative consequences, are less likely to quit during their current pregnancy, than women having their first baby (Schneider et al., 2010). Concern about weight gain also appears to be an important consideration for some pregnant women in continuing to smoke (Ashmead, 2003; CDCP 2002; Klesges et al., 1989).

The extent of nicotine dependence (as measured by the Fagerstrom test) and having a partner who smokes, appear to be particularly influential factors in women continuing to smoke and in quitters relapsing postpartum (Coleman, 2008) McBride et al., 1998; Schneider et al., 2010). Pregnant women of low socio-economic status are twice as likely to have a smoking partner, compared to women of higher socio-economic status (HEA UK, 1999). Pregnant smokers also tend to have more psychological and emotional problems than pregnant non-smokers. Depression, stress and a perceived lack of social support, particularly from the partner, are associated with persistent smoking (Crittenden et al., 2007; Dejin-Karlsson et al., 1996; McBride et al., 1998; Paarlberg et al., 1999; Scott et al., 2009; Weaver et al., 2008). Many women report that continued smoking helps them cope with stress induced by the pregnancy, particularly if it was unplanned or they are unsupported (Hakansson et al., 1999; Van Lieshout, 2001). In both a South African and US study, continued smoking was

associated with unplanned pregnancy (Petersen et al., 2009 a; Tong et al., 2009). Blalock et al. (2005) found that depressed women in their study were up to four times more likely to smoke than other women. In a recent study (Scott et al., 2009), smokers were significantly more likely to have higher depression and anxiety scores than spontaneous quitters, after controlling for socio-demographic and smoking variables. Pickett et al.(2009), found that psychosocial problems not only predicted smoking status during pregnancy, but increased across the pregnancy smoking continuum (non-smokers-spontaneous quitters-light smokers-heavy smokers), with the heaviest smokers having the most problematic psychosocial contexts. Problematic relationships and physical abuse during pregnancy are associated with higher use of tobacco, alcohol and drugs and detract from cessation rates (McFarlane et al., 1996; Wakschlag et al., 2003). These factors are more likely to be characteristic of the lives of economically disadvantaged women.

There is also a physical component: A recent US clinical trial with heavy smokers found that the most powerful predictor of long term abstinence was the extent to which people felt the negative, physiological effects of nicotine withdrawal and their confidence in how well Nicotine Replacement Therapy (NRT) might ameliorate the symptoms (Kenford et al, 2002). How a quitter deals with negative emotions associated with withdrawal also influences their ability to remain abstinent (McDonald, 2003).

In some cases, cultural taboo appears to play a more important role than social inequality in determining smoking status. For example, in the US, despite their relative socio-economic disadvantage, African American women, Pacific Islander and Hispanic women have a lower prevalence of smoking in pregnancy than white women (Weimann, 1994; CDC, 2008). Similarly, immigrants or refugees from Asia or the Middle East, who settle in Northern Europe, North America or Australia, retain a lower prevalence of smoking (Bush et al., 2003; Potter et al., 1996). In South Africa, women of mixed race have very high rates of smoking during pregnancy – 47% compared to 4% of African women, who constitute the majority and the least materially advantaged group (Steyn et al., 1997).

Whilst most pregnant smokers might continue smoking, a higher proportion of them quit during pregnancy than at any other time of their lives. The only other groups shown to have comparable cessation rates are patients with pulmonary or cardiac diseases and subjects in intensive risk factor intervention trials (Schwartz, 1987). About 25–33% of women who smoke before pregnancy, quit on their own before booking in for care (McBride et al., 2003; Windsor et al., 1998; Woodby, 1999). A category of these women decide to quit before becoming pregnant and sustain cessation through the pregnancy and post partum period. Another category of women, termed ‘spontaneous quitters’, quit on learning of their pregnancy.

Pre-pregnancy and spontaneous quitters, like non-smokers, tend to be of higher socio-economic and educational status, smoke fewer cigarettes per day, have a non-smoking partner, perceive more positive support for quitting, experience more nausea and have stronger beliefs about the risks of smoking during pregnancy, than those women who continue smoking (Quinn, et al., 1991; Panjari et al., 1999; DiClemente et al., 2000). They quit primarily for the health of the baby, rather than for themselves (DiClemente et al., 2000). While most of these women (85%) are able to maintain abstinence throughout their pregnancy, 50–80% relapse within 6–12 months to a year after delivery, implying that their intentions were to suspend smoking rather than give up permanently (Mullen et al., 1997; Stotts et al., 2000; Tong et al., 2009).

The category of women who have not been motivated to, or are able to, quit on their own prior to, or on learning of, their pregnancy can benefit from targeted smoking cessation interventions. Typically, such interventions can double the cessation rates achieved by women without help, or in response to, the basic level of advice and information provided as part of usual antenatal care (Klesges et al., 2001; Lumley et al., 2009).

There is also a group of women who have been found to actually increase their consumption of tobacco towards the end of pregnancy. Cope et al. (2003) found that while their intervention contributed to significant improvements in cessation and reduction, the greatest difference in measured cotinine between the intervention and control group at 36 weeks gestation was between those women who increased their nicotine intake towards the end of pregnancy: 11% in the intervention group and 46% in the control group. This demonstrates the importance of continuing to counsel pregnant smokers right through to the end of pregnancy, in an attempt to assist them to at least avoid increasing tobacco consumption, especially seeing as smoking in the last trimester is considered to be particularly harmful (CDC, 2002). It is speculated that possible reasons for increased smoking in the third trimester might be because of enhanced anxiety, boredom or immobility at this time, rather than any physiological changes (Cope et al., 2003). However, a more compelling reason may be because pregnancy increases the metabolic clearance of nicotine, with the consequence that women need to smoke more frequently than before they were pregnant to avoid the experience of physiological withdrawal (Dempsey et al., 2002). In this light, preventing increased tobacco consumption during pregnancy can arguably be regarded as a positive outcome for interventions.

2. The evidence for smoking cessation interventions with pregnant women

2.1. Behavioural impact and types of interventions

The US Preventive Services Task Force has stated that the effectiveness and net benefit of smoking cessation interventions for pregnant women is supported by a high level of evidence from well designed and well conducted studies in representative primary care populations (USPSTF, 2009). Numerous randomised control trials have demonstrated that clinic-based smoking cessation interventions can significantly improve cessation rates among pregnant women, as well as affect pregnancy related outcomes, achieving a close to 20% reduction in the incidence of low birth weight and premature births (Lumley et al., 2007) (LBW: RR 0.83, CI 0.73 to 0.95 and preterm labour RR 0.86, 95% CI 0.74 to 0.98, Lumley et al., 2009). It is this that makes a focus on such interventions an important public health issue.

The latest Cochrane Review (Lumley et al., 2009), which included a total of 72 smoking cessation intervention trials, comprising over 25 000 women, showed a significant reduction in continued smoking in pregnancy in the intervention groups (pooled risk ratio (RR) 0.94, 95% confidence interval (CI) 0.93 to 0.96). This equates to an absolute difference of 6% in the proportion continuing to smoke. This level of success may appear modest, but if such programmes were widely and consistently implemented across the antenatal health services, they could translate into a substantial public health benefit and cost saving (USPSTF, 2009).

Almost all the studies identified for Lumley's review were conducted in high-income countries: the majority in the USA, followed by the UK, the Netherlands, Australia, New Zealand and Canada. Only two trials had been conducted in middle-income countries: one in four Latin American countries (Belizan et al., 1995) and another in Poland (Polanska et al., 2004). Whilst biochemical validation of quit rates has become the norm in developed country studies, neither of these particular trials biochemically verified self-reported smoking status, rendering them at high risk of detection bias (over-reporting actual quit rates).

In the vast majority of trials, women in the control arm have received information about the risks of smoking in pregnancy and simple advice to quit. This has been defined as 'usual care'. Most of the interventions have been based on Cognitive Behavioural Therapy (CBT), a form of psychotherapy that emphasises the role of 'thinking' in how we feel and what we do (Beck et al., 1979). This category of interventions generally involves individualised counselling and the provision of information and self help materials, which assist the smoker make practical plans to quit, review past experiences, identify potential problems and enlist support from family and friends. It typically also includes the

teaching of coping and problem solving skills. Most programmes that have been tested have been eclectic, involving many different components. This kind of support is provided to those smokers who are willing to make a quit attempt and would like help in doing so.

These types of interventions have resulted in consistently enhanced quit rates. Other, additional strategies have included advice and counselling based on ‘Stage of Change’ theory (Prochaska & Velicer, 1997), written or personal follow up via the telephone, post or computer based programmes, feedback on foetal health status, by ultrasound or on tobacco consumption confirmed by cotinine or CO testing, the use of material incentives and the provision of pharmacological agents (Lumley et al., 2009; Walsh et al., 2001, Oncken et al., 2010). As can be seen in the table below, in a sub-group analysis, only one group of trials in the Lumley review (2009) showed a significantly larger effect: these were CBT trials, which incorporated an additional incentive or reward component. However, this group comprised only four trials. Cognitive Behavioural Therapy (CBT) interventions, which were tailored to women at different stages of readiness to change, did not manage to improve on the results achieved by trials in the general CBT category. This was also found in another review (Riemsma, 2003). NRT did not appear to have any significant advantage over other types of interventions in the sub-group analysis, but again, there are too few studies to draw any clear conclusions.

Other sub-group analyses, according to intervention intensity and risk of bias, showed no evidence of significant difference in treatment effect (Lumley et al., 2009).

Table 1: Effects of interventions on smoking rates during pregnancy

Type of Intervention	Number of studies	Relative Risk (95% CI)
Cognitive Behavioural Therapy (CBT) Strategies	30	0.95 (0.93, 0.97)
Stages of Change	11	0.99 (0.97, 1.00)
Feedback	4	0.92 (0.84, 1.02)
Rewards (financial or material)	4	0.76 (0.71, 0.81)
Pharmacotherapy	5	0.95 (0.92, 0.98)

*Data based on studies presented in the meta-analysis by Lumley et al., 2009 from Oncken et al., 2010

Studies have documented the behavioural impact of such interventions in optimal clinical or research conditions (efficacy evaluations) and with large representative samples of pregnant smokers under normal, clinical practice-programme conditions, (effectiveness evaluations), thus supporting internal

and external validity (Windsor, 2003). They have also been conducted in public health care settings, where clients are predominantly of lower income, as well as among private patients in relatively more privileged circumstances. The trials involving private clients have been found to have a stronger effect than those involving public clients, producing quit rates on average ranging from 22–25% (Ashmead, 2003; Ershoff et al., 1989).

2.2. Role of antenatal care providers

A variety of antenatal care providers have been found to be effective in delivering smoking cessation programmes for pregnant women. These include doctors, nurses, midwives and health education specialists. The most efficacious type of counsellor may vary from setting to setting and by socio-cultural environment. Midwives and nurses are seen as a particularly appropriate group to deliver interventions, as they usually spend more time with patients and see health education as an important aspect of their work. In addition, nurses and midwives have been found to have more positive attitudes than medical staff, who tend to give a lower priority to smoking cessation (Walsh et al., 1995; Clasper & White, 1995). Addressing the training needs of staff and including them in the planning of interventions has shown to be key to their acceptance and sustainability within primary antenatal care (Pullon et al., 2003). A lack of appropriate communication skills, confidence, good quality resources and time to do counselling, coupled with pessimism about the potential effectiveness of brief counselling have been reported as significant barriers to adopting smoking cessation interventions as a part of routine antenatal care (Grimley et al., 2001; Vaughn et al., 2002; Flenady et al., 2008; Baxter et al., 2010). Training has been shown to have a measureable effect on health care providers' performance in implementing cessation interventions, impacting on outcomes such as the numbers of patients receiving counselling and self help materials, setting a quit date, follow up, as well as quitting (Fiore et al., 2008). It is important that training is linked to organisational change to facilitate and sustain the intervention (Silagy et al., 1994; Flenady et al., 2008). Training can also be enhanced by providing prompts and resources which can be distributed to patients by the provider, such as self-help quit manuals.

The few studies, which have evaluated home visits by nurses in encouraging cessation and preventing post-partum relapse, suggest that they are acceptable to pregnant women, feasible and effective (French et al., 2007; Karatay et al., 2010; Olds et al., 2002). Home visits may be particularly important for women with low psychological resources (Olds et al., 2002). However, such interventions are more costly than brief, clinic-based interventions and are therefore less frequently implemented and studied.

There have been very few studies on the use of lay or peer counsellors in smoking cessation programmes for pregnant women, even though they have been used to positive effect in other aspects of prenatal care, such as the promotion of breastfeeding (Britton et al., 2007; Chung et al., 2008) and in reducing ante- and postnatal depression (Rahman et al., 2008). One intervention that used peer educators, failed to improve quit rates, even though it was a replication of an intervention that had proved efficacious elsewhere (Gielen et al., 1997). The authors argued that one plausible reason for the failure of their trial could have been because they used peer educators, rather than professional counsellors, as was the case in the other interventions. However, 'natural social support' from a peer was thought to be a key factor in producing a higher than usual quit rate among low income, high risk pregnant women in a study by Donatelle (2004) and another study (Malchodi et al., 2003), found that peer counselling significantly reduced daily smoking and increased infant birth weight, despite its failure to affect cessation rates. The key advantages of using peer counsellors who share many of the social characteristics of their clients are: that they are likely to have a greater ability to empathise with their life circumstances; possess an intimate understanding of community social networks and incorporate cultural beliefs and values into health information (Scott et al., 2007). They can disseminate information in a way that is easily understood and internalised and, furthermore, because women can identify more closely with them, they have greater potential for positive role modelling and are less likely to encounter resistance to health promotion messages (Lapierre et al., 1995; Rahman, 2007). However, further research is required to assess the effectiveness of lay counsellors in smoking cessation programmes, their acceptability to women and the kind of training they may require.

Group support programmes for pregnant women have been very poorly attended in virtually all trials where they were planned and are therefore not recommended (Lumley et al., 2009). It seems that a minority of women take up offers of referral to specialist support, but there is evidence that these services can be effective (Raw et al., 2005; McGown et al., 2008). For example, in the UK, despite the availability of specialist smoking cessation services for pregnant women, only about 10% of the 30% of smokers make use of them (UK Dept of Health, 2007). And in a French study, only 40% of pregnant smokers who registered with a specialised cessation service after referral ever returned for further assistance (Baha & Le Faou, 2009). However, telephone counselling, via a Quitline, has proven to be an important route for smokers to access support for cessation and clinicians are advised to recommend them where they are available (USPSTF, 2009).

2.3. Intervention strategies

While brief advice and the provision of risk information alone (low intensity CBT interventions) have the potential to increase cessation, the addition of intervention components, which teach skills

that assist smokers develop a quitting plan, monitor their smoking behaviour, help them overcome their conditioned cues to smoking and cope with withdrawal symptoms, significantly increases quit rates (US Preventive Services Task Force, 2009). Numerous self-help quit materials with this aim, including guides, booklets and videos, have been tested and shown to work with pregnant women from various demographic groups. It is clear that these materials need to be tailored specifically to pregnancy, as in cases where general smoking cessation materials have been used, they have failed (Dolan-Mullen et al., 1994; Walsh et al., 2001). It has also been demonstrated that there is a greater acceptance and use of intervention methods if materials are further tailored to the concerns and barriers to behavioural change of the specific target group (Windsor et al., 1998). For example, Lowe et al. (1998), found that a self-help manual, which had proven to be effective in a number of settings in the US, was poorly accepted by pregnant women in Brisbane in Australia.

Importantly, such materials appear to be effective when used as an adjunct to personal advice given by a health care provider and are seldom effective on their own (Fitzmaurice, 2001). Moore et al. (2002), for example, suggest that their self-help intervention, consisting of a series of five booklets mailed to pregnant women at various intervals, failed because of a lack of verbal reinforcement. In a study by Pullon et al. (2003), women commented that they responded to an educational resource only when a midwife introduced it to them during the course of an antenatal visit.

In the general population, it is clear that the more intensive the counselling sessions (either in duration or number), the greater the chance of quitting (Fiore et al., 2008). With pregnant women, however, there are mixed findings on this question. More resource intensive CBT interventions, which have used brief counselling at first prenatal visit, followed by additional support, either by telephone, post or further personal contact, have been found to yield larger benefits in some studies (Floyd et al., 1993; Dolan-Mullen et al., 1994; Manfredi et al., 2000; Dornelas et al., 2006), but not in others (Secker Walker et al., 1998; Melvin et al., 2000; Stotts et al., 2009). Ershoff et al. (1999) found that neither a computerised telephone cessation programme, nor the provision of motivational counselling by nurse educators, improved cessation rates over a tailored self help, book delivered within the context of brief advice from prenatal care providers. And Stotts et al. (2009) found that adding ultrasound feedback on foetal growth and a 50-minute counselling session failed to significantly enhance quit rates over best practice, brief cessation counselling.

However, adding material incentives appears to enhance success, both in terms of impacting on quit rates, and for retaining women in a study. This appears to be a particularly useful strategy with low-income women. For example, Donatelle and colleagues (2004) achieved quit rates of 32% for their intervention group (versus 9% in the control group) at eight months gestation when they provided \$50 vouchers to biologically confirmed quitters on a monthly basis. Another trial (Heil et al., 2008),

which offered vouchers exchangeable for retail items contingent upon smoking abstinence during pregnancy, also succeeded in achieving cessation rates considerably higher than those usually achieved. In this study, the intervention significantly increased point-prevalence, biochemically verified abstinence at the end of pregnancy (41% versus 10%), as well as the 12-week post-partum assessment (24% versus 3%). Serial ultrasound examinations indicated significantly greater growth in terms of estimated foetal weight, femur length and abdominal circumference in the experimental group, compared to the controls. Such incentive based strategies may also have the added benefit of improving retention of study participants: Nabil El-Khorazaty et al. (2007) reported dramatically improved retention of minority pregnant women in their trial, through the use of financial incentives. The use of such contingency management strategies is, however, controversial. Some argue that offering material incentives to quitters may cause subjects to lose internal motivation to modify their behaviour over the long term, whilst others argue that such monetary rewards are empowering for women (Donatelle, 2004; Greaves et al., 2003). The feasibility of incorporating incentives in routine antenatal care, as opposed to research settings, is also questionable. However, the possible contribution of such reward based interventions merits further investigation in the area of smoking cessation. Although their specific impact has not been studied, competitions where quitters can win prizes have proved successful in increasing participation and awareness in worksite and community programmes (Donatelle et al., 2004) and a meta-analysis by Lussier et al. (2006), supports the efficacy of voucher based reinforcement therapy for the treatment of substance use disorders. In addition, financial incentives have been effective in promoting immunisation among mothers in New Zealand for example (Wilson et al., 2003).

Feedback of biomedical information, such as cotinine test results, to pregnant women, can facilitate engagement with the health care provider about smoking, boost motivation to change, provide a point of comparison and create a sense of caring (DiClemente, 2001; McClure, 2002). Naturally, feedback is of greater value when there is no delay in returning the results. For this reason, Cope et al. (2003) have developed a rapid, inexpensive, point-of-care assay for urinary cotinine. In their trial of this method, the test was completed in the presence of the woman and provided visual and numerical feedback on smoking behaviour within only six minutes. The feedback formed the basis of the counselling that followed and women were invited to return for subsequent measurement during their next clinic visit. It was emphasised that the test was not a 'lie detector', but rather a tool to assess baseline smoking and any progress made in response to the cessation advice, support and encouragement provided during clinic visits. The control group received the same test, but were not given the results or any counselling, other than that usually provided by clinic staff. The results of the study showed, collectively, a highly significant fall in cotinine test results in the intervention group from the booking visit (median ratio 42.5) to 36 weeks gestation (median 27.6. $P < 0.0001$). In

comparison, there was no significant difference between the two measurement points in the control group (median 37.6. $P < 0.003$). The intervention contributed to a significant improvement in smoking cessation (22% v 7%) as well as reduction (42% v 33%), and was reportedly well accepted by women. Analysis of birth parameters showed that the test result at 36 weeks was related to birth weight, body length and, to a lesser extent, head circumference and that quitters had significantly heavier and larger babies, than those who continued to smoke. Adjustment for smoking test results showed a significant difference in birth weight between the two groups, implying that the provision of feedback on cotinine levels, coupled with brief, cognitive behavioural type counselling from a trained provider, can improve pregnancy outcome.

Feedback based on ultrasound may be less straightforward. Stotts et al. (2009) found that an intervention providing ultrasound feedback on general foetal health and growth actually appeared to have relieved the pressure on heavy smokers to quit. This was because, on the whole, the ultrasound examinations did not pick up any serious problems with the baby, which women reported to be very reassuring.

Given that pregnant women, who live with people who smoke, find it more difficult to quit, and are more likely to relapse, there has been some interest in involving partners and family members in smoking cessation interventions (Lumely et al, 2009). Interventions which have attempted involving 'significant others', have focused on training smokers in obtaining social support, providing training or written materials to partners to assist them in engaging in supportive behaviours, or intervening with smoker-partner pairs in couple therapy or in larger groups to encourage supportive interactions (Park et al, 2004). However, such interventions have, unfortunately, yielded disappointing results. In a study by Thompson et al (2004), women reported that although their 'significant others' were supportive of them quitting smoking, they themselves were unwilling to participate in the cessation intervention at the antenatal clinic. Similarly, McCurry et al (2002) found partners reluctant to accept smoking cessation advice for themselves. A meta-analysis of the limited data available on trials designed to enhance partner support for cessation (Park et al, 2004), showed that they failed to either increase cessation or improve the level of partner support. This suggests that support from significant others may be important, but that their behaviours are not easily changed by interventions in the antenatal setting.

A recent addition to the inventory of strategies which could potentially enhance intervention effectiveness is physical activity. A pilot study by Ussher et al. (2008), which encouraged women to participate in 15 sessions of supervised physical activity up to eight months gestation proved popular, helped more women remain abstinent and control their weight, suggesting that this strategy may be worth further investigation.

2.4. Motivational Interviewing

Motivational Interviewing (MI) has been advocated by a number of authors, as a means of improving the manner in which primary health care providers discuss smoking with pregnant women (Floyd et al., 1993; Rollnick et al., 1997; Ershoff et al., 1999; Tappin et al., 2000; Velasquez et al., 2000; Van Schayck, 2008). MI is defined as a client-centred counselling method, which is essentially cooperative, respectful and supportive in spirit. It stands in contrast to the traditional approach, which assumes that the health care provider should use his/her professional authority to persuade the patient to change and prescribe what the change should entail. In MI, smoking cessation is understood to be a complex and cyclical process, involving interaction between physical dependence, social factors and motivation, rather than a straightforward decision to change based on information about the health risks. It is important that the health care provider provides an open and non-threatening context for discussion of stigmatised behaviours, such as smoking during pregnancy, acknowledges the patient's autonomy in making a decision to change their behaviour and expresses empathy, without judging (or agreeing) with arguments against change (Rollnick et al., 2002). The aim of MI is to stimulate intrinsic motivation by encouraging patients to explore their ambivalence about and readiness to change, to see the contradictions between their personal goals and present behaviour and to make their own decisions about why and how to proceed. In this way, the reasons for change are elicited from the patient herself, rather than imposed by the health care provider. Good rapport is achieved by avoiding arguments, supporting self efficacy and by using skills such as reflective listening and shifting and reframing focus, which allows the counsellor to come alongside the client and sustain a constructive conversation about change (Emmons, 2001).

Ebert et al. (2009) argue that this approach aligns with the philosophy of midwifery, which emphasises the importance of developing a trusting and supportive relationship with the pregnant woman and planning antenatal care in partnership with her. In their view, a midwife's attempt to care for the baby, without the mother's full involvement and consent, is both futile and disempowering. On this basis, they recommend that midwives ask the patient's permission before making enquiries about smoking, as this would immediately lay a basis for a more constructive dialogue about behavioural change.

Motivational interviewing has been used to positive effect by midwives in Sweden as one component of their nationwide smoking cessation programme for pregnant women (Cancerfonden, 2002). A US study, which used usual care providers to deliver a low intensity intervention based on MI principles, succeeded in significantly improving quitting during pregnancy and longer term smoking abstinence (Valanis et al., 2001). In another study (Manfredi et al., 2000), the addition of a 15-minute follow-up phone call, based on MI principles, to a clinic-based, CBT intervention, produced better quit rates

than the clinic-based intervention alone. In contrast, in a pilot study in Glasgow, four MI sessions, delivered by a trained midwife at the woman's home, failed to have any positive impact on smoking behaviour, prompting the researchers to argue for definitive, randomised control trials to prove whether proactive, opportunistic MI can effectively help pregnant women stop smoking or not (Tappin et al., 2000). While it was not found to be the case in these interventions, other researchers have reported that the main obstacle to using MI in the context of the primary care consultation, is the amount of time it requires, particularly where there are shortages of staff (Velasquez et al., 2000; Rollnick et al., 1997). As a counter to this, Parker et al. (2007), in their feasibility study, found that telephone-based, motivational cessation counselling was a practical, acceptable and cost effective method for assisting low-income pregnant smokers to quit.

Both the updated US Public Health Service Clinical Practice Guideline for treating tobacco use (Fiore, 2008), and the US Preventive Services Task Force Reaffirmation Recommendation Statement (USPSTF, 2009), recommend the use of MI to improve smoking cessation rates among the general population, as well as with pregnant women. However, this remains a category B recommendation, meaning that it is based on a body of evidence with variable results and as yet an insufficient number of studies to warrant a Category A recommendation (which is based on a high level of certainty of substantial benefit and is unlikely to be affected by the results of future studies). A recent Cochrane meta-analysis showed, that smoking cessation counselling based on MI, significantly improved quitting rates above brief advice or usual care. However, the authors also state that the results should be treated with caution, due to the small number of studies available for review (14), and variations in study quality and treatment fidelity (Lai et al., 2010).

2.5. Use of Nicotine Replacement Therapy with pregnant smokers

Given that nicotine withdrawal is the main reason that most quit attempts fail within the first week, the use of Nicotine Replacement Therapy (NRT) with pregnant women merits serious consideration (Aveyard & West, 2007). In the general population of smokers, Nicotine Replacement Therapy (NRT), used as an adjunct to counselling, has been shown to be of unquestionable benefit (Fiore, 2000). However, to date, there have been too few studies on the use of pharmacotherapy in pregnant women to clearly establish its safety and efficacy during pregnancy. Furthermore, guidelines for doses and what types of pharmacotherapy agents may be suitable for pregnant smokers are lacking in the medical and pharmacokinetic literature (Little, 1999).

There are some studies which have suggested that the benefits of NRT in helping pregnant women quit may outweigh the risks of continuing to smoke. A study by Wright et al. (1997), found that the daily dose of nicotine and peak blood levels of nicotine in women using NRT gum or a patch, were

lower than those of smokers who continued to smoke a pack a day. On this basis, plus the fact that quitting would eliminate foetal exposure to carbon monoxide and the other thousands of toxic substances in cigarettes, the authors concluded that NRT would be less harmful for smokers who smoke more than twenty cigarettes a day. Two other studies on the use of NRT during pregnancy found no adverse effects on the mother or the foetus compared to smokers (Benowitz, 1991; Ogburn et al., 1999), but these were too small to be conclusive.

Due to the uncertainties around safety, very few randomised control trials have evaluated the possible impact of NRT on quit rates during pregnancy, or compared the use of NRT to other strategies. Two trials (Kapur et al., 2001; Hegaard et al., 2003) showed no evidence that NRT used in pregnancy is effective for smoking cessation, but were too small to exclude benefit of the size seen in non-pregnant women (Aveyard & West, 2007). A third, which was the largest randomised trial, reported no difference between the quit rates of the intervention and placebo control groups (Wisborg et al., 2000). However, the results were compromised by a low rate of compliance in the intervention arm of this study (17%). Adverse effects, such as skin irritations and headaches, were given by women as reasons for choosing to discontinue with NRT treatment. The fourth trial, which compared women randomised to Cognitive Behavioural Therapy only and women who received NRT as an additional intervention, found a non-significant, 11% difference in biochemically validated quit rates at 38 weeks in favour of the NRT group (18% v 7%) (Pollack, 2007). However, given that no placebo was used in this trial, this may have been an overestimation of the impact of NRT. Furthermore, differential rates of follow up in the NRT arm may have influenced the result.

Further work is required to determine how the concentrations of nicotine substitution compare with active smoking in pregnant women and at what level of smoking the benefits of NRT might outweigh the risks. Of concern is that conventional doses of NRT may be insufficient for pregnant women, given that nicotine is metabolised more quickly in pregnancy (Coleman, 2004; Dempsey et al., 2002). Until there is further information, it will be difficult to advise women about the potential benefits and risks of using NRT while pregnant. In the UK, since 2003, prescribing guidance to doctors contained in the British National Formulary, has listed NRT use in pregnancy as a 'caution', rather than a contra-indication, as it had done previously (Coleman, 2008). This change, combined with the provision of specialist smoking cessation services for pregnant women has resulted in a steady increase of the use of NRT in the UK (Coleman, 2008). These developments may assist researchers overcome the challenge of recruiting women to NRT trials. On the other hand, the updated US Public Service guidelines recommend greater caution than previously (Fiore et al., 2008), further illustrating just how un-definitive opinion is on this question.

There is even less information about the use of bupropion in pregnancy – a Class B drug used to treat depression, but also prescribed as an effective, non-nicotinic aid for smoking cessation. Whilst animal studies have shown no evidence of teratogenesis, there have only been two studies on the safety of bupropion in human pregnancy. Chun-Fai-Chan et al.'s study (2005) showed that bupropion, used for depression in pregnancy, did not increase the rates of malformation or low birth weight, but did appear to increase the rate of spontaneous abortion. However, the sample was small and more research is needed to determine whether the higher rates of spontaneous abortion were associated with bupropion or the underlying depression. The other, a study based on the manufacturer's pregnancy registry, found no differences in rates of malformations or spontaneous abortion between exposed and non-exposed women (Cole et al., 2007). The one study that has investigated the impact of bupropion on quit rates during pregnancy failed to demonstrate any significant difference in cessation (Miller et al., 2003).

On the basis of the current, very limited evidence, it is recommended that the use of pharmacological therapies be considered only when a 'best practice' intervention has failed, if the woman is highly motivated to quit and smokes more than 10 cigarettes a day (Coleman, 2008). It is also advised that pregnant and breastfeeding women use acute forms of NRT delivery, such as gum or the inhaler, rather than the patch and ideally be referred for specialist support (Aveyard & West, 2007). Further, on the basis of a study by Morales-Suarez et al. (2006) it is recommended that NRT not be prescribed in the first trimester, as this appears to increase the risk of congenital abnormalities.

Ethically, health care providers should disclose that use of NRT and bupropion in pregnancy may cause an unknown risk of harm to the foetus and that there is limited data to support the theoretical benefits (Silagy et al., 2005). The ultimate choice should be made by the woman herself, after being given the time to weigh up the available information. To date, there has been little attempt to understand women's views on this issue. In the one study identified (Ashwin & Watts, 2009), women who had succeeded in quitting reported that using NRT was helpful, but expressed reservations about the lack of information about its safety during pregnancy. They also reported that the support and continual encouragement they received from the midwife was the more important factor in determining their success.

To date, there is no clear, scientific evidence that alternative therapies, such as hypnotherapy, acupuncture or laser therapy, are effective for smoking cessation (Crawford et al., 2008).

2.6. Harm reduction

The value of recommending harm reduction approaches is still under debate. A significant reduction in smoking, especially among heavier smokers, has been found to be a valid measure of the

behavioural impact of interventions in some evaluation studies and appears to offer some measure of protection for the foetus (Qing Li, 1993; Windsor et al., 1999; Windsor et al., 2000). Windsor et al. (1999) have recommended biochemical measurements as indicators of harm reduction in pregnant smokers, on the basis of their finding of a 92g increase in mean birth weight for babies of women who showed a reduction of 50% or more in the baseline saliva cotinine levels established at trial entry. However, this finding was not supported in another trial by Secker-Walker & Vacek (2002), which also analysed infant birth weight in relation to maternal cotinine. In an Australian trial (Panjari, 1999), whilst researchers did not find any significant effect on quit rates, they did find that babies born to women in the intervention group were on average 84g heavier than those in the control group, suggesting that reduced tobacco consumption during pregnancy can be beneficial. Raatikainen et al. (2006), in their analysis of a database of over 26,000 women in Finland, found additional risk of foetal growth restriction and low birth weight associated with smoking was avoided by reducing smoking, but the increased risks of preterm birth or perinatal death were not.

The 2009 Cochrane Review (Lumley et al.), summarised the available evidence for significant reduction of smoking among women in intervention groups as being limited, inconsistent and weak. In an earlier review, Lumley et al. (2004) had suggested that, although harm minimisation was less than an ideal outcome, it should be given due attention in smoking cessation programmes and that new measures of reliably measuring levels of daily tobacco consumption should be developed. Other authors have argued that for those women who continue to smoke right into the last trimester, it may, nevertheless, be worthwhile to encourage them to stop or reduce consumption just prior to delivery, to advise them to increase other health protection behaviours like vitamins and exercise and to address the issue of ETS exposure (DiClemente et al., 2000).

2.7. Postpartum relapse

Although women are more likely to quit smoking during pregnancy than at any other time, relapse rates are very high, particularly with women of low socio-economic status. Studies have shown an expected 60–80% relapse within 12 months after delivery (Dolan-Mullen, 2004; Fang et al., 2004; Flenady et al., 2008). It has been recommended that future smoking cessation trials incorporate a relapse prevention component and conduct follow up research during the first three to six months of the post partum period (Lumley et al., 2009; Windsor et al., 1998). Preventing relapse after delivery has the additional benefit of protecting the infant from environmental tobacco smoke, which has been linked to SIDS, respiratory infections, reduced lung function and otitis media (Charlton, 1994). It also has the potential to encourage and extend the duration of breastfeeding (Isselman-Disantis et al., 2010).

Pooled data from the few trials that have specifically included an intervention component for smoking relapse prevention among spontaneous quitters indicate that fewer women receiving the intervention relapsed during the course of pregnancy, but the effect did not reach statistical significance (RR 0.91, 95% CI 0.75 to 1.10) (Lumley et al., 2009). There are however, individual studies which support the notion that it is possible to reduce postpartum relapse among some women. For example, Mullen and colleagues (2000) showed significantly greater abstinence in their intervention group over the entire follow up period and at 12 months after delivery (55% v 45%). In this trial, videos and newsletters were mailed to women and their partners during the final weeks of the pregnancy and the first six weeks after birth.

The general paucity of research on how cessation interventions can be augmented to assist women avoid relapse, makes recommendations difficult. It is clear that greater attention needs to be focused on the critical transition period after delivery. The needs of pre-pregnancy and spontaneous quitters should also be taken into account when planning smoking cessation programmes. As a group, they are usually excluded from such programmes, because they define themselves as quitters or non-smokers at booking. Shifting their motivation for quitting, to include their own health and teaching them coping skills may be important. In addition, given that a woman's partner appears to play a critical role in both continued smoking in pregnancy and postpartum relapse, broadening the focus of interventions to include the woman's partner and family may be valuable in helping these women avoid relapse (McBride et al., 1998; DiClemente et al., 2000).

A small number of studies have investigated why pregnant women who quit during pregnancy, return to smoking after delivery. Their findings suggest that relapse is related to cravings, the increased pressures of motherhood, lack of sleep, concerns about weight gain, socialising with smokers, easy access to cigarettes and the ability to protect the baby from environmental tobacco smoke (DiClemente et al., 2000; Ripley-Moffitt et al., 2008.) It has been suggested that many women suspend smoking during pregnancy for the sake of the baby, rather than prepare themselves for permanent abstinence. They therefore do not undergo the typical internal, intentional cognitive affective processes of change required for permanent cessation, making them at high risk of relapse (Stotts et al., 2000). Higgins et al. (2009) found that self reported stress when booking in for prenatal care was a significant predictor of postpartum relapse, suggesting that interventions which include components that address co-existing mental health problems may improve cessation rates and reduce relapse.

Further research needs to be done to better understand the factors which contribute to relapse and to explore the benefit of extended use of NRT to prevent relapse during pregnancy, as well as postpartum (Hajek, 2009). It would also be of interest to determine whether women who have

experienced a cessation intervention while pregnant, are better prepared for quitting if, in the future, they decide to do so for their own health.

3. The quality of the evidence

Several reviews and meta-analyses have made important contributions to advancing the methodological rigour of smoking cessation evaluation research among pregnant women over time. These include Walsh and Redman (1993); Windsor, et al.(1998); Floyd et al. (1993); Dolan-Mullen et al. (1994); Melvin et al. (2000); Klesges et al. (2001); Walsh et al. (2001); Ashmead (2003); Windsor (2003); Greaves et al. (2003); Schneider et al. (2010), Oncken et al. (2010) and the Cochrane Reviews by Lumley et al. in 2004, 2007 and 2009. These papers provide a complete assessment of this area of evaluation research to date and show a positive trend in methodological standards over time.

3.1. Methodological issues

Poor measurement of smoking status was a major methodological weakness in much of the research conducted in the 1980s and 1990s. While population surveys of smoking status among adults may produce valid self reports, societal pressure for pregnant women not to smoke has been found to strongly influence self reports of smoking status during pregnancy in both experimental and control groups. In a review of 25 studies by Russell et al. (2004), deception rates among pregnant women, as determined by biochemical markers, ranged from 4–25% at baseline and 0–29% at follow up after initiation of smoking cessation interventions. For this reason, biochemical validation of smoking status is now an essential requirement for establishing the internal validity of evaluation trials. It is recommended that all self-reports should be confirmed biochemically at baseline, mid and end of pregnancy and that studies assess the levels of non-disclosure. Several biochemical measures have been used, including expired air carbon monoxide and tests for cotinine in urine, serum or saliva. Cotinine, a metabolic by-product of nicotine, has greater specificity and sensitivity than CO and is thus more widely used. The most practical way to measure cotinine during pregnancy is to test the urine samples that are routinely taken at every antenatal care visit. The new, point-of-care, cotinine urine test referred to earlier (Cope et al., 2003), has a major advantage over laboratory tests, in that it can make the results available to women immediately.

Intervention studies not using biochemical corroboration of self reports should be assumed to be at high risk of detection bias from misclassification. The latest Cochrane Review (Lumley et al., 2009), shows that this weakness in the research has progressively improved over time, with the vast majority of the more recent studies using biochemical validation of self report.

The sensitivity of screening, and disclosure of smoking status, can be improved by using questions which allow a greater range of responses. Mullen et al. (1991) showed that the use of a multiple choice question, including the option, 'I have cut down since becoming pregnant', improved disclosure at the first antenatal visit by 40%, above the simple question: 'Do you smoke?: Yes or No'.

A further potentially serious source for risk of bias in such evaluation studies is the generally high rate of withdrawal and loss-to-follow up (Greaves et al., 2003; Lumley et al., 2009). Reasons for women missing their second or third measurements include miscarriage, preterm labour, terminations, changes in residential address and moving to another antenatal care provider. Women who are single, less educated, unemployed and who use alcohol and drugs, are more likely to be lost to follow up (Nabil El-Khorazaty et al., 2007). Attrition is particularly common with poor populations reliant on public health services, Medicaid or food programmes, with about half these studies having missing outcome data for up to 20% of women (Lumley et al., 2009). Multiple early studies produced inflated quit rates, because they failed to include patients lost to follow up in their denominator to calculate end of pregnancy quit rates (in other words, they did not use an intention to treat approach in analysis). Of further concern is that women who have had a perinatal death or preterm birth are often excluded from outcome measures. This means that important outcomes linked to smoking are not ascertained (Lumley et al., 2009). To address this problem, it is suggested that smoking status be assessed at mid-pregnancy (at around 20–28 weeks), before most of these events occur, as well as at term. This may assist in reducing the numbers of women excluded from studies on the basis of adverse pregnancy outcomes.

Patients lost to follow up and patients for whom no biochemical tests are available should be fully described and classified as smokers, in an intention to treat analysis. According to Lumley et al. (2009) whilst levels of attrition remain relatively high, particularly for studies following up women in the postpartum period, it is now becoming standard practice to include those lost to follow up as smokers in the calculation of quit rates.

There are ways of improving retention even among traditionally 'difficult' populations: Nabil El-Khorazaty et al. (2007) dramatically improved retention of poor African American and Hispanic pregnant women in their intervention trial, through employing culturally competent research staff, providing extensive training in interviewing skills, frequent phone contact, regular updates of contact information using a computerised data management system and financial incentives.

A further criticism levelled by Lumley et al. (2009) is that many studies, even now, do not include a description of the number of women eligible for inclusion, or who were approached to participate, but not recruited. Such information is important for the assessment of selection bias and

generalisability (Lumley, 2009). They also point out that the method of randomisation is rarely described in sufficient detail to permit assessment of whether allocation was concealed at the time of trial entry. They concede that where usual antenatal care providers are used in the provision of the intervention, allocation to the intervention or control group usually cannot be concealed for practical reasons. However, where this issue not clearly addressed, the possibility of contamination or co-intervention cannot be ruled out.

Although, overall, the quality of trials has varied quite significantly, Lumley et al.'s (2009) sub-group analysis of trials with low, moderate and high risk of bias, found no significant difference in treatment effect. A summarised assessment of the different levels of risk of bias for each of the studies analysed in the Cochrane Review, the likely magnitude and direction of the bias and whether it was likely to have impacted on the findings, can be found on pages 11–12 of the review paper (Lumley et al., 2009).

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Table 2: Assessing methodological quality of smoking cessation trials (Greaves et al., 2003; Lumley et al., 2009)

Basis for rating methodology of randomised/controlled trials
Methods used for allocation: sequence, concealment and blinding of study participants and personnel
Baseline comparability on demographic variables, tobacco use and gestation
Participants lost to follow up considered smokers or adequate justification provided for why not (intention to treat analysis)
Incomplete outcome data: attrition bias through withdrawals, drop outs and the reasons provided; protocol deviation
Inclusion of spontaneous quitters in study
Biochemical validation of self reported smoking outcomes
Measurement of perinatal outcomes
Follow up into postpartum period
Statistical methods used for comparisons
Selective reporting bias: whether all pre-specified outcomes and expected outcomes for the review have been reported

3.2. Overall completeness and applicability of the evidence

Overall, there are limited data for some types of interventions. Most of the studies to date have focused on educational and basic CBT counselling interventions, with relatively few of them incorporating and comparing other strategies, such as NRT, incentives, additional social support, exercise or Motivational Interviewing. The role of family members and partners remains relatively un-researched and has been all but ignored in interventions.

At this point in the research, there is a need for further innovation, in order to enhance the demonstrated effectiveness of CBT interventions. Where programmes have included multiple components, there have seldom been efforts to evaluate the distinct contributions of various components and materials, as this has proved difficult to do.

Smoking cessation interventions for pregnant women have varied quite substantially in their intensity, their duration, the nature of their delivery and setting, thus making direct comparisons difficult. This may be one of the reasons for the relatively high level of heterogeneity found amongst the trials in the Lumley review (2009).

Relatively few trials have provided information on perinatal outcomes. The sub-set of 21 trials with perinatal outcomes in the 2009 Cochrane Review showed a reduction in low birth weight (RR 0.83, 95% CI 0.73 to 0.95), a reduction in preterm birth (RR 0.86, 95% CI 0.74 to 0.98) and an increase in mean birth weight of 39.26g (95% CI 15.77g to 62.74g) in the treatment group. There was adequate power to detect these differences for these outcomes ($n \geq 10\ 000$). There were no significant differences in very low birth weight, stillbirths, neonatal deaths, NICU admissions or perinatal mortality in the subset of trials which measured these outcomes, but they had very low power to detect differences in them ($n < 5\ 000$) (Lumley et al., 2009). More such studies are needed. However, the fact that these require large samples of women and are therefore very expensive and time consuming, poses an obstacle to their execution.

Lumley et al. (2009) also make the point that most reports do not make clear the extent of outcome data which was collected, making an assessment of selective reporting difficult.

The reviews of the 1990s (Floyd et al., 1993; Walsh & Redman, 1993; Windsor et al., 1998) pointed to the need to conduct more 'effectiveness evaluations', which rely on usual care providers to deliver programmes in the context of routine antenatal care. Earlier studies tended to use designated providers, whose specific job was to deliver the intervention, which said little about the applicability of such interventions to the 'real life' primary health care setting. There are now numerous studies, which have documented the impact of minimal smoking cessation interventions using existing providers in normal practice conditions. One of the most important of these is the Smoking for Cessation or Reduction in Pregnancy Trial (SCRIPT) by Windsor et al., 2000, which demonstrated the feasibility and effectiveness of an intervention disseminated to Medicaid recipients in 10 maternity clinics in Alabama, USA (this study achieved a cotinine validated quit rate of 17.3% in the experimental group, compared to 8.8% in the control group). Other studies have, however, reported significant barriers to implementation in the clinic setting: Five of the six cluster trials included in the latest Cochrane Review (Lumley et al., 2009), which used midwives to implement the intervention as part of routine care, experienced difficulties. These included problems recruiting midwives (Hajek, 2001; Lawrence, 2003); provider compliance problems and contamination of controls (Walsh, 2000); incomplete implementation and uneven exposure of women to the intervention (Kenrick, 1995; Moore, 2002; Dunkley, 1997; Hajek, 2001 and system barriers (Dolan-Mullen et al., 2000; Strand, 2003). Providers often report a lack of time, work pressure (Hajek, 2001), pessimism over the potential of interventions (Moore, 2002; McLellan, 2000), a deficiency of skills and training (De Vries, 2006) and a lack of high quality resources, as the main reasons for failing to adopt interventions (Cabana, 1999). To date, there have been only two dissemination trials. The one showed an uptake of the intervention, but not at sufficient levels to impact significantly on quit rates

(Campbell et al., 2006), and the other demonstrated significant success in uptake, using Roger's Diffusion of Innovations theory, but did not collect data on smoking outcomes (Lowe, 2002). In an Australian study, which used a prospective, before-and-after design to evaluate the introduction of a smoking cessation intervention guideline into practice at a large public maternity hospital, results showed a significant increase in the uptake of evidence-based procedures (Flenady et al., 2008). In addition, women reported higher levels of satisfaction with the prenatal care they received.

Whilst smoking cessation interventions for pregnant women have been researched extensively in high-income countries, there have been very few such studies in low-to-middle income countries (Oncken et al., 2010). Of further consideration for these countries is that many women use forms of tobacco other than cigarette smoking, such as snuff or chewing tobacco. These behaviours appear to pose a similar and equally serious risk to the foetus and pregnancy as cigarette smoking, but have been far less studied (Gupta & Sreevidya, 2004; Gupta & Subramoney, 2006). Only two interventions targeting chewing tobacco or snuff have been reported in the literature (Oncken et al., 2010). In order to prevent the predicted increases in tobacco use among women in developing countries and the resultant harm to maternal, foetal and child health, there is an urgent need to undertake research to test and measure the impact of interventions aimed at preventing the uptake of tobacco use among young women of reproductive age and increasing cessation among pregnant women in these countries.

3.3. Process evaluation data

A general lack of process evaluation data in reported randomised control trials was pointed out by Walsh and Redman as early as 1993 and reiterated by Windsor, Boyd and Orleans in 1998. However, this criticism remains a valid one (Lumley et al., 2004, 2009). Process evaluation has become even more important, as the research has moved beyond efficacy trials to effectiveness or pragmatic trials and as they have become more complex.

The importance of documenting the levels of provider compliance and patient exposure to the various intervention components, as well as the personal experiences and perceptions of acceptability of both staff and women who participate in such programmes has been emphasised. Research methods such as provider completed checklists, exit interviews with patients, focus groups and direct observation of the quality of interaction between patient and provider by using video or audiotape, are all appropriate in evaluating the process of interventions. Multiple methods are recommended, as each method has its own limitations: health care providers tend to overstate their level of preventive care, smokers over report receiving smoking advice and direct observation is intrusive, possibly inducing a degree of reactivity (the Hawthorn effect)(Walsh et al., 2000).

More detailed descriptions of the nature of interventions and usual care have been recommended (Lumley et al., 2009). In many cases, what constitutes usual care is not elucidated, but what is clear is that over time, 'usual care' has increased in intensity, as awareness of the risks of smoking during pregnancy have become more widely recognised. Furthermore, interventions are often described in general terms as cognitive behavioural interventions, without a full description of their specific elements, their level of intensity and the extent of their implementation. When interventions are said to be tailored to meet the needs of sub-groups of pregnant women, it is also often difficult to identify the precise nature of the tailoring and the theoretical basis on which it is done (Greaves et al., 2003).

Such process related information is essential in reaching conclusions about internal validity, in linking active intervention elements and observed outcomes, in explaining why some interventions fail and other succeed and in drawing comparisons between studies. In addition, it is helpful to future researchers or practitioners, who may wish to implement successful interventions in other settings.

This criticism applies not only to smoking cessation interventions, but to behaviour change interventions in general. Michie and Abraham (2008) argue that there is a collective failure to describe clearly the experimental procedures on which published findings are based, which has serious consequences for endeavours to understand what works and how, making the replication of effective interventions difficult. They suggest that intervention protocols or manuals should be published alongside intervention evaluations (on journal websites for example) so that it is clear to other researchers and practitioners what constituted the intervention and what techniques were used in practice. As an aid for authors to report on intervention content, they have compiled a nomenclature of standardised definitions for theory-linked behavioural techniques, which have been reliably identified across a range of behavioural change interventions (Abraham & Michie., 2008). Other authors have advocated the use of planning models such as Intervention Mapping (Bartholomew et al., 2006) and 'realist evaluation' methodologies (Douglas et al., 2010), as a means of ensuring a more systematic and transparent approach to planning the development of an intervention and evaluating its processes of implementation.

3.4. Pregnant women's views

Recently, the relative lack of research documenting women's views, concerns and experiences of smoking cessation interventions has been raised in the literature. Interventions have also been criticised for rarely involving or consulting women in the development of programmes and for not taking into account the possible negative effects smoking cessation interventions may have on pregnant women's psychological well being (Oliver et al., 2001; Ebert & Fahy, 2009). A further criticism is that most programmes have been 'foetal centric' and have failed to emphasise the benefits

of quitting for the women themselves (Greaves et al., 2003). Of particular concern is that women exposed to interventions who are unable to quit, especially those with high risk pregnancies, may experience increased guilt and anxiety, which could possibly have a detrimental effect on their relationships with their families, partners and antenatal care providers.

Thirteen trials in the Cochrane Review, 2009, included some assessment of women's views of the intervention, but it was difficult to make direct comparisons given the variety in interventions and measurements. Findings suggest that women consider personal contact with an antenatal care provider far more important than receiving self-help materials (Valbo, 1994), but that the content of advice and the manner in which the provider communicates is critical and often determines whether they participate in discussions on smoking or not (Baxter et al., 2010). For example, in Bullock et al.'s study of low income, rural women, smokers rated individualised social support from nurses positively, because they were non-judgemental and "there for them" in helping them resolve their personal problems (Bullock et al., 2009). These interpersonal skills also appeared to be the critical element in the exceptionally high rates of retention and intervention acceptability achieved in this trial. Ershoff (1999) found that women offered motivational interviewing expressed much greater satisfaction with the intervention than those offered only a booklet, although it made no statistical difference to the outcome. In another study, where women's views were specifically sought on an intervention involving cessation advice, coupled with feedback on cotinine test results, women expressed the view that the tests were a good idea and reported that it had helped them understand the impact of their smoking (Hotham, 2005).

A number of studies have reported that some women feel acutely guilty and ashamed about continuing to smoke and feel negatively judged by others (Ebert, 2007; Van Lieshout, 2001). However, the few studies that have measured the effect of smoking cessation interventions on psychological outcomes have not found any increase in symptoms of stress or depression among participants (Aveyard, 2004; Lawrence, 2003; Manfredi, 1999; Panjari, 1999; Rigotti, 2006; Solomon, 2006). In another study which examined this issue, almost three quarters of respondents in the experimental group agreed that the anti-smoking advice they had received had made them feel guilty, but most of them reported that nonetheless, they were pleased to receive the advice (Walsh et al., 2000). Moreover, Bullock's trial (1995) demonstrated significant decreases in stress and depression scores, as well as increases in self esteem scores, among women in the intervention arm.

4. Best practice smoking cessation interventions for pregnant women

Those interventions and components that appear repeatedly in successful interventions and have met standard plausibility criteria are recommended as 'best practices'. It is undeniable that a

comprehensive approach to smoking cessation, which would target pregnant women in a community, workplace and health care setting is ideal and would have a better chance of success than an intervention limited to the antenatal clinic. However, there is sufficient evidence to show that primary health care providers can play an effective role and that the antenatal care setting is an important context for smoking cessation (ACOG, 2000, 2005; Lumley, 2009).

An important consensus on best practice interventions for pregnant women was reached in 1998, at a workshop convened by the Health Resources and Services Administration and Centres for Disease Control. The workshop recommended that all prenatal health care providers adopt the evidence-based procedures for brief smoking cessation interventions as outlined in the Agency for Health Care Policy and Research's (AHCPR) clinical guideline (which has since been updated and published as a US Public Health Service Report, entitled 'Treating Tobacco Use and Dependence') (Fiore et al., 2000 & 2008). The compilation of these guidelines was based on a rigorous review by an independent panel of scientists and clinicians of the scientific literature since 1975 and over 35 meta-analyses. The findings and recommendations were externally reviewed by more than 90 other experts.

The extensive review, conducted for the workshop on pregnant women and smoking, confirmed that these guidelines are effective in an antenatal setting, when delivered by a trained provider and supported by educational and self-help materials specifically tailored to pregnant women. A single counselling session of five–15 minutes, using the guideline procedures, was found to achieve a modest, but clinically significant, effect on cessation rates across 16 evaluation studies, with an average risk ratio of 1.7 and a 95% confidence interval of 1.3 to 2.2, suggesting that the outcome of cessation was at least 30% higher in the treated versus the untreated groups (Melvin et al., 2000). It was concluded that these guidelines are appropriate to use with pregnant women during routine prenatal visits and feasible to implement in most clinic settings, even where they were severe time constraints, without inhibiting other important aspects of prenatal care or disrupting patient flow. It was recommended that antenatal care systems should make institutional changes to ensure the systematic identification of and intervention with pregnant smokers.

In 2000, the American College of Obstetricians and Gynecologists adapted the AHCPR guidelines specifically for pregnant women (further updating them in 2005). The ACOG guidelines (see **Table 3**, overleaf) are widely considered the current, best-practice methods for smoking cessation counselling with pregnant smokers and have been endorsed as such in the latest US Preventive Services Task Force recommendations (2009). The guidelines suggest that physicians, general practitioners, midwives, nurses, nutritionists, social workers and lay health educators, after appropriate training, perform all of the five steps outlined in the Guideline (*Ask, Advise, Assess, Assist*

and Arrange (the 5As). Alternatively, it is recommended that doctors provide *ask–advise–assess* and then refer the women to a midwife or nurse for steps *assist and arrange*. The five steps detailed in these Guidelines constitute the basic CBT smoking cessation intervention confirmed as effective in all the major meta-analyses since 2000, most notably the Cochrane Reviews (Lumley et al. in 2004, 2007 & 2009). This type of intervention achieves, on average, an effect size of about 6% (RR 0.95, 95% confidence interval CI 0.93 to 0.97)(Lumley, 2009).

As in the original guideline, the key intervention strategies for pregnant women are based on the following five steps: Ask, Advise, Assess, Assist and Arrange (Fiore et al., 2000, 2008). Each step is designed to take about one minute of the clinician’s time, except for Step 4, which is estimated to take three minutes or more. The recommended steps are outlined in detail below:

- Step 1) **Ask** about, and document, smoking status on the clinic record. If the woman stopped smoking before, or as she found out, she was pregnant, the clinician is advised to congratulate her on her decision to quit, review the benefits of quitting and offer ongoing support. If the woman is still smoking, clinicians are advised to proceed with the following steps.
- Step 2) **Advise** the patient to quit in a clear, strong, personalised manner. For pregnant women, this should include discussion of the multiple risks of smoking to the pregnancy, foetus and infant and the benefits of quitting for both the woman and the baby. Advice should be tailored to the woman’s existing level of knowledge.
- Step 3) **Assess** the willingness of the women to quit within the next 30 days. If the woman is ready to make a quit attempt, the provider can proceed to the next step. If not, it is suggested that the patient be given information to build motivation and confidence in making a quit attempt in the future and that the situation be reassessed during subsequent visits. The provider is also referred to the 5Rs, which provide further strategies for counselling those women who express a reluctance to make a quit attempt. The 5Rs help providers explore the following issues with the smoker: the personal Relevance of quitting; the potential Rewards of quitting; the perceived Roadblocks to quitting and encourage them to Repeatedly raise the issue during every visit to the clinic (Fiore et al., 2008).
- Step 4) **Assist** the patient in preparing to quit by offering practical counselling on quit strategies, prompting the smoker to seek social support from partners, family and friends and providing pregnancy specific self-help quit materials, such as booklets or videos. Such resources can save precious counselling time, can teach patients problem solving and coping skills related to cessation and can help them prepare a personal plan for quitting. It is recommended that women are encouraged to set a definite quit date, as this will make it more likely that they will make a serious quit attempt.

Table 3: Counselling procedures for pregnant smokers recommended by American College of Obstetricians and Gynecologists (ACOG) (2000)

Smoking Cessation Intervention for Pregnant Patients	
ASK – 1 minute	
<ul style="list-style-type: none"> Ask the patient to choose the statement that best describes her smoking status: 	
A. I have NEVER smoked or have smoked LESS THAN 100 cigarettes in my lifetime.	†
B. I stopped smoking BEFORE I found out I was pregnant, and I am not smoking now.	†
C. I stopped smoking AFTER I found out I was pregnant, and I am not smoking now.	†
D. I smoke some now, but I have cut down on the number of cigarettes I smoke SINCE I found out I was pregnant.	†
E. I smoke regularly now, about the same as BEFORE I found out I was pregnant.	†
If the patient stopped smoking before or after she found out she was pregnant (B or C), reinforce her decision to quit, congratulate her on success in quitting, and encourage her to stay smoke free throughout pregnancy and postpartum.	
If the patient is still smoking (D or E), document smoking status in her medical record, and proceed to Advise, Assess, Assist, and Arrange.	
ADVISE – 1 minute	
<ul style="list-style-type: none"> Provide clear, strong advice to quit, with personalized messages about the benefits of quitting and the impact of smoking on both the woman and foetus. 	†
ASSESS – 1 minute	
<ul style="list-style-type: none"> Assess the willingness of the patient to attempt to quit within 30 days. 	†
If the patient is ready to quit, proceed to Assist.	
If the patient is not ready, provide information to motivate the patient to quit and proceed to Arrange.	
ASSIST – 3 minutes +	
<ul style="list-style-type: none"> Encourage the patient to set a quit date. 	
<ul style="list-style-type: none"> Advise on the use of problem-solving skills for smoking cessation (e.g. help to identify ‘trigger’ situations and suggest how to manage withdrawal symptoms). 	†
<ul style="list-style-type: none"> Provide social support as part of the treatment (e.g. ‘We are here to help you quit’). 	†
<ul style="list-style-type: none"> Prompt patient to seek social support in her environment (e.g. encourage identification of ‘quit buddy’ and advise on the importance of a smoke-free home). 	†
<ul style="list-style-type: none"> Provide pregnancy-specific, self-help smoking cessation materials and refer women to quit lines where available. 	†
ARRANGE – 1 minute +	
<ul style="list-style-type: none"> Assess smoking status at all subsequent prenatal visits and, if patient continues to smoke, continue to encourage cessation. Communicate caring and concern. Affirm any progress. 	

Melvin C, Dolan Mullen P, Windsor RA, Whiteside HP, Goldenberg RL. Recommended cessation counselling for pregnant women who smoke: a review of the evidence. Tobacco Control 2000; 9: 1-5.

Step 5) **Arrange** for a follow up contact, during which smoking status is re-assessed and ongoing support is offered.

In the updated guideline (ACOG, 2005), it is emphasised that the 5As is likely to be most successful when a patient-centred/motivational interviewing approach is used. It is recommended that the clinician is empathetic, promotes patient autonomy and choice, avoids pressurising or judging the woman in any negative way and supports patient self-efficacy, for example, by identifying previous successes in efforts to change behaviour. Clinicians also need to be sensitive to concerns women may have about quitting.

Practitioners are urged to continue to encourage women to quit smoking throughout their pregnancy. Although quitting early in pregnancy yields the greatest benefits, quitting at any point can be beneficial. It is therefore recommended that smoking status be monitored throughout pregnancy, providing opportunities for health care providers to support success, reinforce steps taken towards quitting and continue to motivate those still in the pre- and contemplation phase of behavioural change. Relapse prevention counselling should be part of every follow up contact with women who have recently quit.

The type of behavioural counselling described in the guideline may not be sufficient for pregnant women who are heavy smokers. Only about 4% of patients who smoke more than 20 cigarettes a day typically quit with these methods, compared to 16% of light smokers and 12% of moderate smokers (Melvin et al., 2000). Clinicians are therefore advised to refer heavy smokers for more intensive or specialist counselling if brief counselling proves ineffective. If this fails, it is suggested that the use of NRT be judiciously evaluated with the patient.

Reported obstacles to the adoption of the Guidelines are a lack of: awareness, training opportunities, time for counselling, self efficacy and positive outcome expectancies (Chapin & Root, 2004). Certain tools can improve the adoption and adherence to the Guidelines. They include: a variety of promotional activities; the provision of free CME credited self instruction guides; checklists for the medical record, charts and reminders; patient educational resources; feedback on performance and the inclusion of the Guideline in the curriculum of trainee doctors and nurses (Chapin & Root, 2004). A study by Windsor and colleagues in 2000, showed encouraging results in integrating the '5A best practice' methods into diverse Medicaid care services. They attributed their success to carefully building consensus with health service staff at a policy, management and practice level, conducting patient flow analyses to determine how practices could be reorganised to incorporate the new methods without adding significant consultation time and to providing specific practice guidance and staff training. This study also demonstrated that the philosophy of providing 'best clinical practice'

methods is an important theme to use in persuading professional staff and primary care health educators to participate in quality improvement initiatives (Windsor, 2003). A recent evaluation of the introduction of the Guideline to the staff of a large public maternity hospital in Brisbane showed an increase in evidence-based practice for smoking cessation (Flenady et al., 2008). In this case, the Guidelines were accompanied by an implementation programme, which included educational sessions, reminders and feedback. In another Australian study, the 5As were successfully integrated into routine antenatal practice with high rates of provider compliance for the first three steps *Ask, Advise and Assess* (90%), but considerably less for *Assist and Arrange* (50%). It was not clear whether this was due to a lack of interest in quitting on the part of women or whether providers failed to offer practical assistance for quitting (Bowden et al., 2010).

A number of agencies have endorsed the 5As Guideline, including the US and UK government health services, which have recommended that all pregnant women receive interventions based on this model, to promote smoking cessation in pregnancy (Aveyard & West, 2007). In the US, the American College of Obstetricians and Gynecologists has published a toolkit for clinicians and office administrators on how to integrate the 5As into routine care; disseminated educational and training resources and has actively lobbied for the adoption of the guideline among other professional bodies, government agencies and training institutions. In Australia, the Smoke-Free Pregnancy Project, a model of intervention based on the 5As, has been funded and rolled out nationally to all antenatal services by the government.

5. Conclusion

The scientific basis for smoking cessation during pregnancy is definitive. If implemented widely, best practice interventions have the potential to achieve important reductions in adverse maternal, infant and pregnancy outcomes and to reduce associated, excess health care costs. Smoking cessation interventions confer immediate health gains for both mothers and babies and given the substantial savings associated with averting pregnancy complications and low birth weight deliveries, they have also proven to be highly cost effective, with an estimated \$6 saved for every dollar invested (Marks et al., 1990; Orleans et al., 2000). The accumulation of evidence in support of smoking cessation interventions for pregnant women is now sufficiently strong to warrant the highest category recommendation (Category A) by the US Preventive Services Task Force (2009). The recommendation is higher than the recommendation given to other common clinical activities, such as routine screening for anaemia in pregnancy or for gestational diabetes mellitus (US Preventive Task Force, 1996).

There are now clear guidelines for clinicians regarding the delivery of best practice, brief counselling interventions for pregnant women. Until further research suggests differently, cessation counselling on the basis of the 5As is the most effective means to achieve cessation among pregnant women. It remains for decision makers within the health services and professional bodies to promote such evidence-based procedures among all antenatal care providers, offer training and facilitate the integration of these methods into clinical practice, while researchers continue testing additional innovative strategies, which may enhance the effectiveness of basic best practice methods.

However, there is an important deficit in the current evidence base: the vast majority of studies on smoking and pregnant women have taken place in Western Europe, North America or Australasia and it remains unclear as to whether effective smoking cessation interventions conceived in these settings can be successfully transferred to pregnant women in less developed countries. To date, not one randomised intervention trial has been conducted in a low-income country and the two which have been undertaken in middle-income countries (Belizan et al., 1995; Polanska et al., 2004) were of too poor a methodological standard to be particularly instructive (Lumley et al., 2009). Current best practice methods for smoking cessation counselling, both for the general population and pregnant women, have therefore been derived only from developed country studies. There is pressing need to evaluate these best-practice methods in developing countries, where large numbers of women smoke. Such methods also need to be tested in interventions aimed at pregnant women using non-cigarette forms of tobacco.

Interventions based on models developed in high-income countries may require substantial adaptation to achieve acceptance and success in low-to-middle income countries (Bloch et al., 2010). Of consideration is that pregnant women in developing countries may differ in terms of certain key socio-demographic characteristics: for example, they generally have lower levels of literacy, education and income; they tend to be younger, enrol later for antenatal care and attend less regularly. They also have a lower threshold for poor perinatal outcomes, because of poorer nutrition and other health problems, which may possibly make the adverse effects of active and passive smoking even more significant (Salamasi, 2010). There is some research indicating that women in developing countries often have very low levels of knowledge of the risks of using tobacco during pregnancy and even believe that it has certain benefits (Nichter et al., 2010). This may be partly due to women's very limited exposure and access to information on the risks of smoking.

Health care settings in low-to-middle income countries are also likely to differ quite substantially in terms of structure, human and material resources. Competing priorities such as HIV pose a significant challenge to the delivery of interventions such as smoking cessation programmes, as does the shortage of staff and the health care provider's generally poor knowledge of the risks of tobacco

use and their lack of training in cessation counselling. For example, in a survey of obstetricians and gynaecologists in three cities in Argentina, about 50% reported insufficient knowledge to provide cessation advice and 75% believed that it was acceptable for pregnant women to smoke up to six cigarettes a day (Mejia et al., 2010). Strategies are urgently needed to enhance awareness and to engage diverse antenatal care providers in these countries, including physicians, nurses, midwives, traditional birth attendants and lay counsellors (Bloch et al., 2010). Compounding this problem is that, while smoking has declined among health care providers in most of the high income countries, this is not the case in many low-to-middle income countries, which may possibly make them less inclined to adopt smoking cessation interventions than their counterparts in developed countries (Nichter et al., 2010a). It is, therefore, particularly important to conduct effectiveness, rather than efficacy studies in developing countries in order to assess whether best practice interventions can be successfully implemented in situations where resources are relatively limited, services very over-extended and where women have multiple, competing health and psychosocial risks, as a result of material disadvantage and low levels of education.

The need for such research in low-to-middle income countries was clearly identified in the latest Cochrane Review (Lumley et al., 2009), as well as by multiple authors in a recent thematic issue on tobacco and pregnancy in the Swedish journal of *Acta Obstetrica et Gynecologica* (2010). In this issue, Oncken et al., Bloch et al., Giersson and Tolosa all recommend that a key research priority be the development and evaluation of culturally adapted, evidence-based, best practice interventions to prevent the uptake of smoking among young women, to increase cessation and reduce ETS exposure among vulnerable, pregnant women in low-to-middle income countries. They further recommend that studies evaluate whether psychosocial support, pharmacotherapy, incentives and simultaneously addressing other unhealthy behaviours can provide additional benefits to the 5A protocol. Use of non-formal health care providers for cessation counselling, such as lay workers, should be explored where there are acute shortages of professional staff and where women's access to health care is limited. The editorial (Giersson & Tolosa, 2010) called for urgent funding to support scientific enquiry into the question of tobacco use during pregnancy in low-to-middle income countries and urged clinicians, maternal and child health programme planners and policy makers to begin focussing on this issue.

This thesis describes a research study involving the development and evaluation of a smoking cessation intervention, based on the best practice guidelines for a sub-group of South African women at high risk of adverse pregnancy and birth outcomes related to tobacco use. The intervention and evaluation was the first of its kind in South Africa, and as far as we know, in a developing country setting. This study, by investigating if a smoking cessation intervention model

developed through research in high-income countries can be effectively transferred to a group of vulnerable pregnant women in a developing country context, makes an important contribution to filling a critical gap in the current knowledge base.

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Chapter 1

Literature Review

B) Theories and models for health behaviour change

Health education or promotion programmes which aim to help people or communities prevent disease, enhance their health or manage chronic disease, generally have a greater chance of success if they are guided by theories of behaviour change, as opposed to those planned on the basis of precedent, tradition, assumption or general principles (Bauer, 2004; Goldstein et al., 2004).

Theories on health behaviour first emerged in the discipline of psychology in an attempt to describe, explain and predict health related behaviours. However, as they propose various mechanisms whereby behaviour is affected, they have also provided conceptual frameworks on which to build and test health education and health promotion interventions. Theory-driven interventions attempt to impact on the constructs which have been identified through research, as being important for predicting change in a particular health behaviour. Evaluations of these interventions attempt to measure the extent to which these constructs have been realised through programme methods and strategies. No single theory dominates the research or practice of health education/promotion, perhaps because health behaviour and how to influence it, is far too complex to be explained by a single, unified theory. Effective interventions depend on selecting the most appropriate theories and methods for a particular situation.

This chapter presents an overview of the behaviour change theories and models that are commonly used in health education/promotion programmes (Glanz et al., 1990; Huttunen-Lenz et al., 2010; Rigotti et al., 2007) and, which I chose to use in the development of the smoking cessation programme.

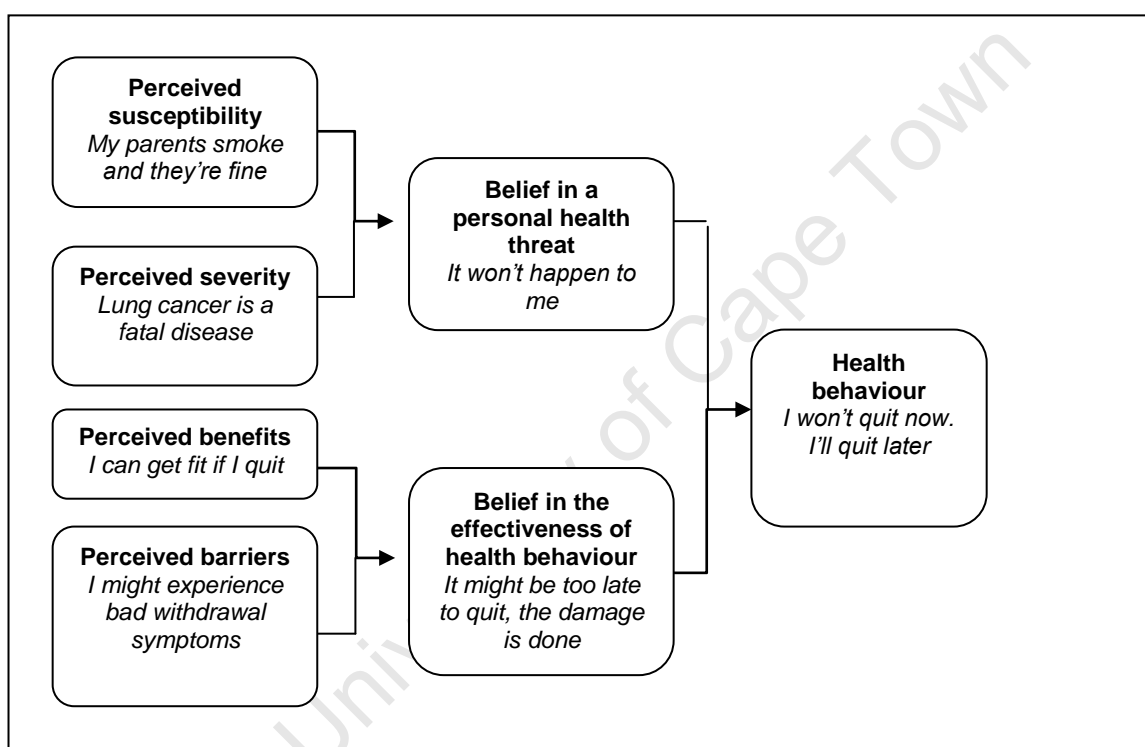
The theories are: the Health Belief Model (HBM) (Rosenstock, 1974); the Theory of Reasoned Action (TRA) (Fishbein & Ajzen, 1975); the Theory of Planned Behaviour (TPB) (Ajzen, 1985) and Bandura's Social Cognitive Theory (SCT) (Bandura, 1986). Reviews and meta-analyses on each of these theories show that all have empirical support for their utility across a variety of behaviours, including smoking (Harrison et al., 1992 (HBM); Hagger et al., 2002 (TRA/TPB); Strecher et al., 1986; Rosenstock et al., 1988; (HBM and SCT). The Transtheoretical Model (TTM) (Prochaska and DiClemente, 1983) is also discussed in this chapter as this model was originally developed with smokers and has been widely used in the building and testing of smoking cessation programmes (Goldberg et al., 2002; Huttunen-Lenz et al., 2010; Spencer et al., 2002).

Commonly used theories

1. Health Belief Model (HBM)

One of the first theories to be widely used in the study of health behaviour was the Health Belief Model (Rosenstock, 1974). The basic components of the model are based on psychological expectancy-value models, which hypothesise that behaviour depends mainly on the value an individual places on a particular goal and on an estimation of the likelihood that a given action will, in fact, achieve that goal (expectancy). The desire to avoid negative consequences is considered the prime motivation for people to take positive action (Bartholomew et al., 2001).

Figure 1: The Health Belief Model (Rosenstock, 1974)



The Health Belief Model (HBM) hypothesises that action to ward off, screen for or to control, ill health depends on the following:

Perceived threat: a) perceived susceptibility to the condition or illness b) perceived severity – the seriousness of the risk and the possible health or social consequences.

Outcome expectations: a) perceived benefit – the extent to which the recommended course of action would be beneficial in reducing susceptibility to, or the severity of, the condition b) perceived barriers – the potential negative consequences of taking a particular health action (this dimension has been found to be the most powerful single predictor of the model (Rosenstock, 1990)).

An unconscious cost-benefit analysis is thought to occur where the individual weighs up the anticipated costs of taking the action against its benefits (importantly, this may include costs and benefits other than those directly related to health). The outcome of this decision will then result in the likelihood of taking the recommended action or not.

In any given instance, demographic, socio-psychological and structural variables may affect an individual's perceptions, and therefore, may indirectly influence health behaviour. These characteristics represent history or stable characteristics that are essentially immutable to health interventions.

According to the HBM, this decision making process is triggered by a cue for action, which may be internal, for example, physical symptoms, or external, for example, advice from others, reminder cards from a physician or a mass media campaign (Rosenstock, 1990). In more recent modifications to the model, specific cues to action in the broader environment are acknowledged as being important for the initiation and maintenance of behavioural change (Rosenstock, 1990). For example, these cues could be the development of sports facilities, the availability of healthy food in the work canteen or a policy banning smoking in public places. Besides the cues to action, the HBM does not suggest specific methods for intervening. In this sense, it is limited to being a descriptive model, giving clear guidelines for what needs to be changed, but not how these factors may be changed.

Rosenstock later added a further construct to the HBM – the concept of self efficacy, first introduced by Bandura in his formulation of Social Learning Theory in 1977 (Rosenstock, 1990).

Self efficacy (Bandura, 1986) refers to the conviction that one can successfully execute the behaviour or tasks required to produce the desired outcomes in a particular circumstance. These competency beliefs are referred to as **efficacy expectations**. Even though an individual may have efficacy expectations, he/she might still not perform the required behaviour, because they do not believe that the outcomes of that behaviour are sufficiently beneficial to them. Stated another way, they may not believe that the reward or reinforcement of performing the behaviour is great enough. These beliefs are called **outcome expectations**, which are similar to the HBM concept of perceived benefits (Rosenstock, 1990). For example, in order for a woman to quit smoking for health reasons, she must believe both that she is capable of quitting (efficacy expectation) and that cessation will benefit her health (outcome expectation). Alternatively, for a health care provider to deliver effective health promotion counselling, they will need to believe that they have the ability to counsel patients and believe that their counselling will actually be of benefit to patients. In addition, they will need to

have strong 'adherence expectations' – in other words, they will need to believe that patients will follow through on their recommendations.

The concept of self efficacy is important in another theory called the Protection Motivation Theory (Prentice-Dunn & Rogers, 1986; Boer & Seydel 1996). This shares the HBM's emphasis on cognitive processes in mediating attitudinal and behavioural change. In this theory, it is emphasised that high threat or fear arousal may provide motivation to take action, but only when the person believes that the preventive action will be effective in averting the threat and only if they have high self efficacy. If these elements are absent, high threat may result in maladaptive behaviour and the person at risk may rather choose to deal with the fear by avoiding the health message altogether.

In summary, according to the amended HBM, for behavioural change to succeed, people must feel threatened by the perceived outcomes of their current behaviour and believe that change of a specific kind will be beneficial, resulting in a valued outcome at acceptable cost, but they must also feel themselves competent to implement that change (Rosenstock, 1990).

Whilst research has confirmed the validity of the HBM dimensions, including self efficacy, in predicting a variety of health actions (Janz & Becker, 1984; Harrison et al., 1992), it has been criticised for not having the kind of rigorous quantification achieved with the Theories of Reasoned Action and Planned Behaviour: the relationships between variables are not explicitly spelt out, no clear rules of combination have been formulated and it is assumed that the variables are not moderated by each other and have an additive effect. Other weaknesses are that it does not include social influence as an important determinant, does not consider that the cost-benefit analysis could include non-health related beliefs or offer guidelines for how the constructs in the model may be changed (except for the cue to action)(Bartholomew et al., 2001). A further limitation is that some of the concepts have been found to have predictive value with some health behaviours, but not with others. Thus the model may not apply equally in different situations (Armitage & Conner, 2000; Rosenstock, 1990; Stroebe & de Wit, 1996).

Nonetheless, it remains widely accepted that health education/promotion interventions should aim to increase perceptions of threat and attend to outcome and efficacy expectancies, in order to influence health behaviour. Formative research on the existing levels of related knowledge and beliefs of the individuals, groups and communities to be targeted, allows for interventions to be appropriately tailored to these constructs. For example, if it is found that the majority of the intended recipients of a programme accept their susceptibility to, and the severity of, a health threat, the intervention may need to rather direct its focus on increasing perceived benefits or reducing barriers.

2. Theories of Reasoned Action (TRA) and Planned Behaviour (TPB)

The Theory of Reasoned Action (Fishbein and Ajzen, (1975), like the Health Belief Model, is rooted in the tradition of value expectancy theories, which provide methods for defining and assessing the issues most important in a person's decisions about performing a specific behaviour (Rimer, 1990). Like the HBM, the TRA places a strong emphasis on the role of beliefs in predicting behaviour; however, the TRA model distinguishes between attitude, beliefs, behavioural intentions and behaviour and specifies how to measure the relationship between them.

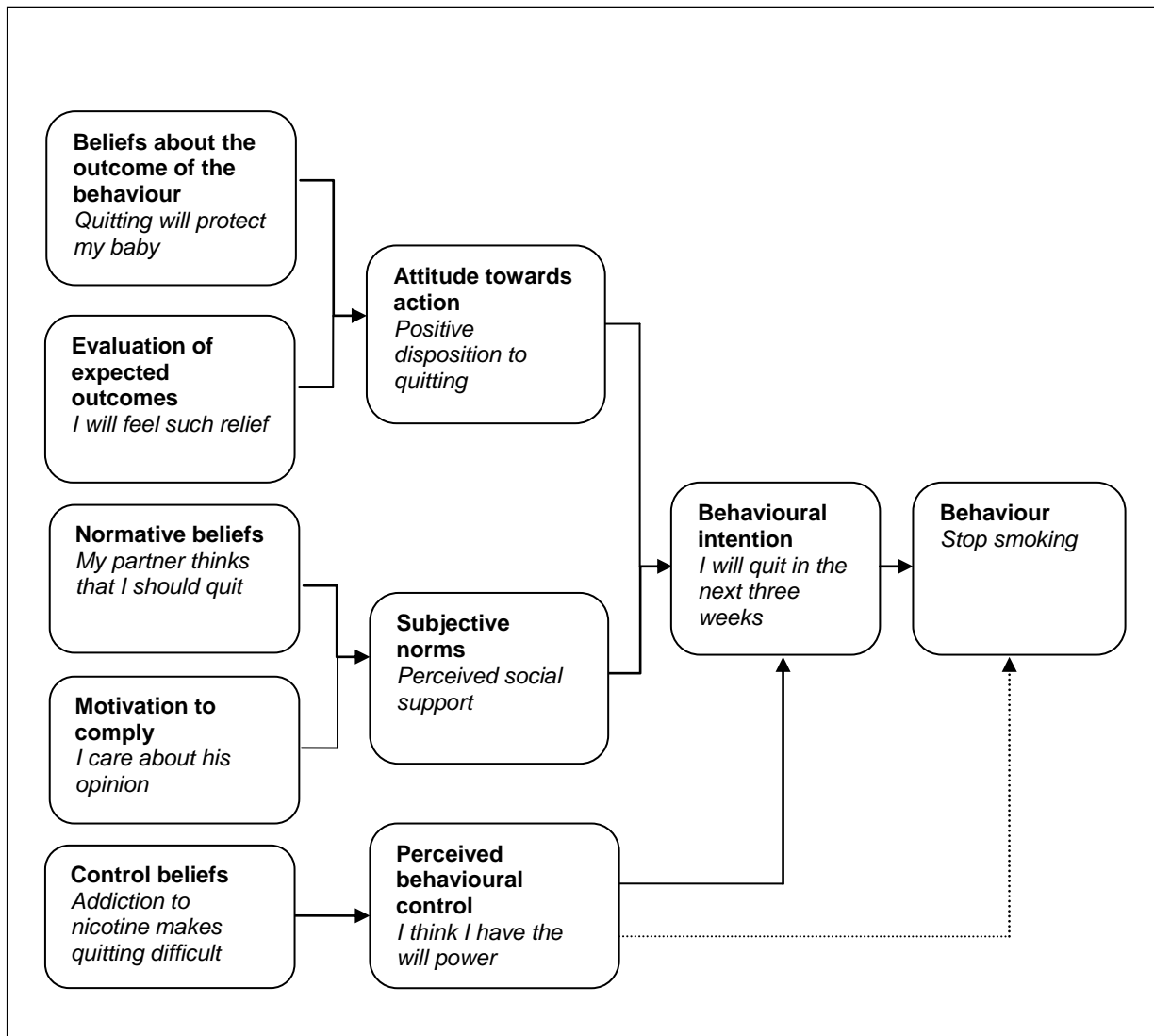
According to this model, an individual's intention to perform a given behaviour is a function of: 1) his or her **attitude** towards performing that behaviour (attitude being defined as the individual's positive or negative predisposition to performing the behaviour) and 2) his or her perceived social expectations relating to performing the behaviour, or what the authors term **subjective norms**.

Each construct has two antecedent components. An attitude towards a given behaviour is determined by both an individual's belief that a given outcome will occur if she or he performs the behaviour and by an evaluation of this potential outcome. A subjective norm is determined by a person's normative belief about what others think she/he should do, weighed by their motivation to comply with the opinion of those others. In other words, the individual's intention to perform a given behaviour is dependent partly on their belief of what others think they should do and partly on the fact that they care about what these other individuals or groups think. Behavioural intention, the most proximal determinant of behaviour, is viewed as a special type of belief and is indicated by the person's subjective perception and report of the probability that he/she will perform the behaviour (Parcel, 1983). Behavioural intention or the choice to perform a particular behaviour thus ends the phase of deliberation.

The **Theory of Planned Behaviour (TPB)** (Ajzen, 1985, 1988) is an extension of the Theory of Reasoned Action. This model is distinguished by the addition of a third conceptually independent determinant of intention – perceived behavioural control. This was added to address the problem of applying the theory to behaviours that are not under full volitional control (Ajzen, 1988). For example, a smoker may have a high intention to quit, but fail to do so because of non-motivational factors, such as addiction to nicotine. Or a person may intend to exercise more, but experience very limited opportunities. The construct of perceived behavioural control refers to the perceived ease or difficulty of performing the behaviour, which is determined by control beliefs concerning the presence or absence of factors, which act to facilitate or impede the performance of the behaviour, weighted by the perceived power of these factors. These factors can include skills, past experiences or external circumstances. In the TPB, perceived behavioural control has motivational implications

for intention: without perceived behavioural control, intentions could be minimal even if attitudes towards the behaviour and subjective norms were strong. However, perceived behavioural control can also influence behaviour directly, as was the case in a study of pregnant smokers by Godin et al. (1992).

Figure 2: Theory of Planned Behaviour (Ajzen, 1985, 1988)



There is some debate as to whether the concepts of perceived behavioural control and self efficacy (Bandura, 1977) are the same or not. Whilst Ajzen (1991), regards them as essentially interchangeable, others define self efficacy in terms of perceptions of control based on internal, individual factors and perceived behavioural control more in terms of the controllability of general, external factors (Schwarzer, 1994). Another, similarly related concept, is that of ‘locus of control’ (Rotter, 1954), which refers to the extent to which an individual believes that they themselves can control their health or are responsible for it, or ascribe responsibility to external factors such as fate, luck or chance.

In summary, the Theory of Planned Behaviour postulates that the more favourable the attitude and subjective norm and the greater the perceived behavioural control, the stronger the individual's intentions to perform the behaviour under consideration. When applied to smoking for example, TPB predicts that a smoker will give up when he/she has a positive attitude towards quitting, thinks others whom he/she values would approve if he/she quit smoking and believes that he/she has control over whether he/she quits or not. A direct measure of subjective norm would be for example, 'my partner thinks I should quit ...' and 'how much do you care about what your partner thinks?'

It is accepted that before being able to change, individuals need to be aware of the health risks in question and feel susceptible to them. For this reason, it is useful for practitioners to use both the HBM and TPB in the development of health education/promotion programmes. Moreover, the inclusion of 'perceived susceptibility' allows for the recognition of an emotional aspect (e.g. fear), whereas the TRA and TPB assume that the decision making process is almost entirely rational (Carter, 1990).

These models specify the inter-relationships among the constructs and provide an operational methodology for combining them to predict intention and behaviour, thus representing an improvement on the HBM. They also give clear guidelines for measuring determinants of behaviour – starting with open, qualitative methods to elicit the salient factors and then measuring prevalence and strength through quantitative methods (Bartholomew et al., 2001).

Both theories have been successfully applied to understanding and predicting a variety of health behaviours, as well as the behaviour of intermediaries who implement health programmes (Armitage & Conner, 2001; Paulussen et al., 1995). Many smoking studies have also used the TPB (Hanson, 1997; Hu & Lanese, 1998; Norman et al., 1999; O'Callaghan et al., 1999; Rimer, 1990). However, some studies with smokers have found a distinct discontinuity between intention and actual quitting, suggesting that when it comes to an addictive behaviour like smoking, individuals often have serious difficulty in sticking to their plans (Moan & Rise, 2005; Rise et al., 2008). Rise et al. (2008) found that the addition of: 'number of cigarettes' (an indication of nicotine addiction) and 'planning' (self-regulation) significantly improved the prediction of subsequent quitting behaviour. Self-regulation was by far the strongest predictor: smokers who made specific plans of when and how to quit were more than twice as likely to quit compared to smokers who made no such plans. Gebhart and Maes (2001) and Wienstein (1988) have also found the hypothesised relationship between intention and actual behaviour to be less than perfect. Wienstein found that the three main reasons for not acting on a formulated intention to adopt precautionary behaviour were situational obstacles, a lack of skills or a lack of perseverance when the precaution became difficult or unpleasant.

The TPB has also been tested in several studies on smoking in pregnancy. In two studies, smoking status was most strongly predicted by women's attitudes towards their smoking harming their foetus in the one (Bennet & Clatworthy, 1999) and by perceived behavioural control in the other (Godin et al., 1992). In an Israeli study by Ben-Natan et al. (2010), all the TPB variables were significantly related to women's intention to stop smoking during pregnancy. Of particular interest was the importance of women's perceptions of their physician's opinions of smoking while pregnant in predicting intention.

Although the TRA and TPB do not suggest specific methods for behavioural change interventions, they are helpful in assisting health educators understand some of the specific variables that need to be changed.

3. Social Cognitive Theory (SCT)

Social Learning Theory (SLT) (Bandura, 1977, 1997), or **Social Cognitive Theory (SCT)** as Bandura re-labelled it in 1986, is a particularly attractive theory for health education/promotion practitioners, as it not only explains the psycho-social dynamics underlying health behaviour, but also gives direction to the design of intervention strategies for promoting behaviour change. A large number of diverse intervention studies, including ones on smoking, have provided support for the effectiveness of SCT as a theoretical base for designing comprehensive behaviour change programmes (Perry et al., 1990).

Perry et al. (1990) provide a summary of the constructs from SCT most applicable to health promotion programmes:

Behavioural capability: In SCT, if individuals are to perform a specific behaviour, they must first of all know what the behaviour is (knowledge) and how to perform it (skills). This is referred to as 'behavioural capability'. This concept leads to a distinction between learning and performance, because a task might be learned, but not performed. However, performance presumes learning. A smoking cessation programme, for example, would apply this construct by aiming to assist smokers to learn about how to quit and to acquire the behavioural skills to enable them to do so.

Self efficacy: This concept is proposed to be the most important prerequisite for behaviour change and refers to an individual's internal judgement of his or her ability to perform a certain desired behaviour or task in a given circumstance (as described earlier under the Health Belief Model). Individuals can develop self efficacy in several ways: 1) through personally mastering the task; 2) through vicarious experience by observing the performance of role models; 3) as a result of

verbal persuasion or receiving suggestions from others that they possess capabilities; and 4) through learning how to cope with anticipated emotional responses, for example, how to deal with anxiety around performing the behaviour. There is substantial evidence that self-efficacy is related to smoking outcomes (Bandura, 1997; Godding & Glasgow, 1985).

Expectations: This concept refers to the expectations that people develop about a situation or outcome before they actually experience it. These may be learned from previous experiences, from observing others in similar situations, hearing about the experiences of others or from verbal persuasion (Perry et al., 1990). For example, a smoker who quits might expect to put on weight as he/she has observed others to do or might expect to feel immediate health benefits based on the accounts of others.

Expectancies: are the values a person places on a particular outcome. If people value an expected outcome, they are more likely to perform the behaviour necessary to yield that outcome. Both expectations and expectancies should be assessed early on in programme development, in order to identify motivators for the desired health behaviour.

Self control: Individuals can gain self control through the monitoring of their own behaviour. Self control operates through self-observation, unambiguous specification of the target behaviour, goal setting and self-reward. These concepts are often used in self-help quit programmes where smokers are encouraged to monitor their daily smoking, cut down by a certain number of cigarettes a day, set a quit date and reward themselves on that day.

Reinforcement: Positive reinforcement or reward is a response to a person's behaviour which increases the likelihood that the behaviour will be repeated. These can be internal (for example, feeling proud at overcoming an addiction to nicotine or that quitting during pregnancy accords with important personal values around motherhood) or external through the occurrence of an event or act (for example, material incentives awarded for quitting). Removing a positive reinforcement can also be an effective strategy for change. For example, prohibiting people from smoking in public places can motivate smokers to cut down or quit. People can also learn from observing the positive and negative reinforcements others receive for certain types of behaviour. For example, if children observe other children receiving positive reinforcement for smoking (for example, acceptance from the peer group), they are more likely to initiate smoking themselves.

Environments and situations: The term 'environment' in SCT refers to the factors which can affect behaviour which are external to the person – the social and physical world within which the person must function. The term 'situation' refers to the person's perception of the

environment, which may be accurate, distorted or imagined. The environment and situation can limit thinking and preclude behaviour without the person even being aware of it, can provide cues about the types of behaviours which are socially acceptable or not and provide positive or negative reinforcement for certain behaviours. These factors can either facilitate the performance of the health behaviour or pose a barrier to it.

An underlying assumption of SCT is that behaviour is a function of a dynamic and continuing interaction between the individual's environment, personal characteristics, including internal cognitive processes, and behaviour (Bandura, 1997; Perry et al., 1990). This interaction, called '**reciprocal determinism**', is such that a change in one has implications for a change in others. The person can shape the environment and the environment can shape the person. This assumption underscores the importance of avoiding the simplicity of 'single direction of change' thinking and of focusing on behaviour in isolation from the environment in which the targeted individuals, groups or communities live. Health promotion programmes developed with an understanding of 'reciprocal determinism' would aim to stimulate changes at multiple levels of the social and physical environment simultaneously. In this sense, SCT encompasses a broader perspective of the influences of the environment on individual behaviour than the previous three theories. This is further developed in the 'ecological theories' of health promotion (which are briefly discussed later on in this chapter). However, a difficulty with SCT is that because of its wider focus, it is difficult to operationalise and test as a whole model. For this reason, it has often been used inappropriately, simplified or used only in part (Perry et al., 1990; Stone, 1999).

4. Transtheoretical Model (TTM)

The **Transtheoretical Model** (Prochaska & DiClemente, 1983; Prochaska & Velicer, 1997) is helpful in explaining the stages that the majority of people experience as they try and change their behaviour over time. The model has its roots in psychotherapy and was developed by Prochaska (1979), after he analysed and reviewed 300 therapy outcome studies and found that some common processes were involved in change (McKenzie & Jurs, 1993). The model has mostly been used to describe the stages smokers go through before they manage to stop smoking, but has also been applied to several other health behaviours (Bartholomew et al., 2001; Burkholder & Evers, 2002).

The model has two major constructs: the stages of change and the processes of change. In the stages of change, people are said to move from a stage of no motivation to change, through to stages where they actually start engaging in the new behaviour (Prochaska & DiClemente, 1983; Prochaska & Velicer, 1997).

The stages of change:

- **Pre-contemplation:** This initial stage is defined as a time when the person is not seriously thinking about changing their problem behaviour during the next six months. Individuals in this stage are usually not aware of the risks of a specific behaviour or are avoiding thinking about the risks, and so have not considered taking any action.
- **Contemplation:** In this stage, the person begins to think seriously about making a change in the next six months and has formed an intention to change. They are usually aware of the benefits and potential barriers and are weighing these up, but are not ready to change.
- **Preparation:** Individuals in this stage, begin to actively plan to make a change in the next month. Making a change seems possible. Often, they have already made at least one attempt to change behaviour.
- **Action:** This is the six-month period which follows the initiation of a specific change or modification in behaviour. Positive reinforcement and encouragement are very important, as the risk of relapse is still high.
- **Maintenance:** Once the person has performed the new behaviour for more than six months, they are said to be in the stage of maintenance.
- **Termination** is the final stage where the person is no longer tempted by the problem behaviour and feels confident in the ability to resist relapse in all situations.

Ideally, we would enter the contemplation stage and move smoothly through the preparation and action stages to maintain the change in behaviour from then on. However, it is common for people in the action or maintenance stages to relapse and to revert back their old behaviour. Fortunately, when this occurs, most people do not give up, but rather go back to the stage of contemplation before preparing again to take action (McKenzie & Jurs, 1993). Behavioural change in this theory is thus understood to be a dynamic, cyclical process, with people learning from relapse episodes and sometimes making numerous attempts to change behaviour before finally accomplishing their goal and maintaining the desired behaviour over the long term. This distinguishes it from the HBM, TRA and TPB, which regard behaviour change as a uni-directional or linear process, that is they fail to take into account the possibility that variables can act in a reciprocal manner and that consequences of performing the behaviour can influence future decisional processes (Gebhardt & Maes, 2001).

There appear to be consistent processes of change that people use as they progress through the stages of change. The processes of change as outlined in the model are determinants of moving on from one stage to another, but they are also useful in that they offer health educators/promoters various techniques for stimulating change in individuals at different stages (Bartholomew et al., 2001). Verbal processes prepare a person for action, whereas behavioural processes become more important once action is initiated. It is evident that these processes of change incorporate many of the constructs from earlier models of behaviour change discussed earlier (hence the name: Transtheoretical Model).

The processes of change, as suggested by the authors of TTM and others (Bartholomew et al., 2001), are outlined below.

Processes of change (Prochaska & DiClemente, 1983; Prochaska & Velicer, 1997):

From pre-contemplation to contemplation:

- Consciousness raising: this involves becoming increasingly aware of the problem behaviour through acquiring new information.
- Dramatic relief: experiencing and expressing negative emotions (fear, anxiety, worry) about the potential risks.
- Self examination: personalising the risk and reflecting on the impact on others.
- Perception of benefits: perceiving the disadvantages of the risk behaviour and the advantages of the healthy behaviour.
- Positive Framing: focusing on success rather than on failure.

From contemplation to preparation:

- Self re-evaluation: integrating the idea of behavioural change as an important part of identity.
- Self efficacy and social support: mobilising social support and skills training on the emotional disadvantages of change.
- Decision making: focusing on making the decision to change.
- Tailoring on time horizon: deciding on a time line for change.
- Trying out new behaviours: changing something and gaining experience from it.
- Modelling: being exposed to models who overcame barriers.
- Persuasion of positive outcome expectations: gaining new positive outcome expectations and reinforcing existing ones.

From preparation to action:

- Self liberation: making a firm commitment to change.
- Skills improvement: restructuring the environment to contain cues to support the new behaviour.
- Coping with barriers: identifying barriers and planning solutions to overcome obstacles. Understanding that set backs are common and are learning opportunities.
- Goal setting: setting specific and incremental goals.
- Modelling: perceiving models who receive social reinforcement of healthy behaviour.

From action to maintenance:

- Helping relationships: seeking and using social support for healthy behavioural change, talking about the difficulties.
- Counter-conditioning: substituting healthier alternative behaviours and cognitions.
- Stimulus control: avoiding stimuli that elicit the problem behaviour.
- Contingency management: rewarding oneself or being rewarded by others for taking positive action.
- Social liberation: realising that social norms are changing in the direction of the healthy behaviour, seeking people who encourage healthy behaviour.
- Self rewards: reiterating positive consequences and feeling good about progress.
- Skills enhancement: anticipating and circumventing obstacles.

Maintenance:

- Coping skills: identifying high risk situations, practising solutions and coping with lapses.

This model has been important in making health educators/promoters aware that an individual's readiness to change may be an important factor in determining their response to health education or counselling. It makes common sense that some may be more ready to make an immediate change than others. Tailoring education or counselling interventions to meet the needs of individuals or

groups at different stages of change can be helpful in avoiding patient resistance or avoidance (Rollnick et al., 2002). Taking different stages of readiness into account can also be time saving. For example, raising awareness of the health risks and the potential benefits of quitting may be a more effective use of time with 'contemplators', than with 'preparers', who profit most from self efficacy enhancement and skills training (Dijkstra et al., 1998).

However, it must be noted that although the TTM has been widely applied in smoking cessation programmes, the available reviews draw conflicting conclusions about its validity (Riesma et al., 2003; Sutton, 2000; Spencer et al., 2002). A recent Cochrane Review (Cahill et al., 2010) concludes that smoking cessation trials which compared stage-based programmes with any control condition, showed better success rates for the intervention groups. However, the four available trials which directly compared the same intervention in a standard and stage-based version, showed that the stage-based one was neither more or less effective than the other, suggesting that the additional value of adapting the intervention to smokers' stage is uncertain. A trial with pregnant smokers (Aveyard et al., 2006) found a stage-matched intervention to be more effective than a standard one, but cautioned that this may have simply been because it was more intensive. There are however, studies that have shown evidence of stage effects which conform to the model, that initial stage of change predicts cessation at follow up and that individuals do use all ten 'processes of change' in quitting (Velicer et al., 1999; Riesma et al., 2003; Sutton, 2000; Spencer et al., 2002), signifying that there are nonetheless valuable lessons to draw from the theory for the design of smoking cessation programmes.

The TTM teaches us that changes in one's understanding of the behaviour; decision-making; being able to see oneself differently in the future; commitment to change; changing the patterns of behaviour and altering one's relationship with the environment are all involved in the process of change. Movement through each stage builds a foundation for the next. From the paradigm of the TTM, helping relationships (for example, between nurse and patient) support and facilitate change. The theory gives health care providers a greater understanding of the complexity of change, the opportunity to assess where their patients are in the cycle of change, teaches us that any shift in stage is valuable and offers techniques to assist patients master the necessary skills for each stage. In this way, the TTM has succeeded in bringing a more discerning, deliberative, empathetic and optimistic approach to counselling patients about smoking cessation (Goldberg et al., 2002).

5. Ecological Models of Health Promotion

A longstanding criticism of the models described so far is that they have placed too little emphasis on broader environmental factors as determinants of individual behaviour. Often, an individual, even if he or she may intend to change behaviour, may not be able to because of certain constraints in the

socio-economic-physical environment that are insurmountable by individual action alone. Larger structural forces, such as socio-economic class or inequalities, can shape a range of contextual factors which influence health related behaviour. Sometimes, behaviour is more dependent on access to social, educational and economic resources than on motivation (Liske, 1984; Sorenson et al., 2003).

Ecological models of health behaviour (McLeroy et al., 1988; Green & Kreuter, 1999, 2004; Sallis & Owen, 2002) emphasise the importance of the inter-relationship between individual characteristics and the environment. They propose that health and well being are affected by a dynamic interaction between biology, behaviour and the social and physical environment. These models suggest that there are multiple determinants of behaviour change at different levels: the intrapersonal; interpersonal; institutional or organisational; community and societal (individual knowledge, beliefs, attitudes etc would still be important at the first level). The various levels are viewed as embedded, reciprocal systems, where an impact on behaviour at one level can exert an influence on another level.

By implication, health promotion interventions need to be multi-pronged and aim, not only to stimulate behaviour change at the individual level, but also at the level of the broader environment, in order to support and sustain individual level behaviour change. The health promotion framework helps translate ecological models into intervention strategies (Green & Kreuter, 1999). Health promotion has been defined as, 'a combination of educational, political, regulatory and organisational environmental supports for actions and conditions of living conducive to the health of individuals, groups or communities' (Green & Kreuter, 1999, p. 14). Programmes may, for example, involve community mobilisation, organisational change, coalition building, media advocacy and lobbying government in order to facilitate changes in social norms, policy and legislation and the allocation of resources (Rimer, 1990). Potential decision makers, or those individuals or groups who are in influential positions and exercise control over others, are targeted to take action at the different levels. Higher level, system type, interventions are assumed to have effects downstream on population health and are believed to be more cost effective and sustainable over time (Bartholomew et al., 2001; Orleans, 2000). Bartholomew (2001) and Glanz (2002) provide an overview of the organisational, community and socio-political theories which inform the ecological perspective on health.

The renowned Minnesota study (Luepker et al., 1995) on cardiovascular risk reduction was among the first generation of studies to synthesise these broader theoretical perspectives into the design of community intervention programmes (Nigg et al., 2002). Tobacco control interventions, which have achieved reductions in smoking on a population wide basis through targeting multiple levels of influence, perhaps best illustrate the success of this approach. There is by now broad consensus

among researchers and practitioners that there should be an integration of behavioural and social science with public health approaches (Scheiderman et al, 2001). Green and Kreuter's (1999) and McGinnes's (2002) historical reviews describe improvements in population lifestyle behaviours that were achieved through a combination of behavioural and policy interventions.

The models and theories of intrapersonal behaviour such as the HBM, TRA and TPB are therefore, likely to be most useful when used within the framework of a broader model, that directs attention to analysing and addressing the multiple layers and dimensions of a health problem. The SCT can be applied to the multi-level strategy of health promotion because of the inclusion of environmental constructs and because its methods are relevant to multi-component interventions.

Integrating theories of behaviour change

Despite the large amount of research on theory testing, empirical comparisons of the various models for behaviour change are rare in the literature (Noar & Zimmerman, 2005). Comparisons of existing studies in meta-analyses, even on the same theory, are problematic, because of various methodological difficulties (Prochaska et al., 1992). Clearly identifying those theoretical constructs, which are most effective across different interventions, is also difficult, because there little standardisation in the published literature of the description of intervention elements, methods and strategies, as well as of the measurement of behaviour change (Abraham & Michie, 2008). As a consequence, there is still little consensus on: whether some behaviour change models are more accurate than others; more suitable in certain situations or with specific behaviours; whether certain constructs across theories are similar or exactly the same and which constructs are the most influential. Noar and Zimmerman (2005) and Abraham and Michie (2008) argue that this is a significant shortcoming in the evidence base and make a plea for further comparative studies to be conducted, in order to further advance our understanding of the health behaviour change process and move towards greater consensus and integration. Nigg et al. (2002), on behalf of the US National Institutes of Health Behaviour Change Consortium (BCC), argue similarly for further theory-comparison research, in order to develop effective theory to understand and intervene with multiple risk behaviours, which has become all the more important in the light of growing evidence that multiple risk behaviour interventions have the potential for a much greater impact on public health, than single-behaviour interventions.

There are several integrated theories available, but it is not clear to what extent they have been validated. Fishbein (2000, 2003) has combined variables from the HBM, TRA and SCT into a model called, **The Integrative Model of Behavioural Prediction** (see **Figure 3**, overleaf). This model proposes that any given behaviour is likely to occur if the person has a strong intention to perform

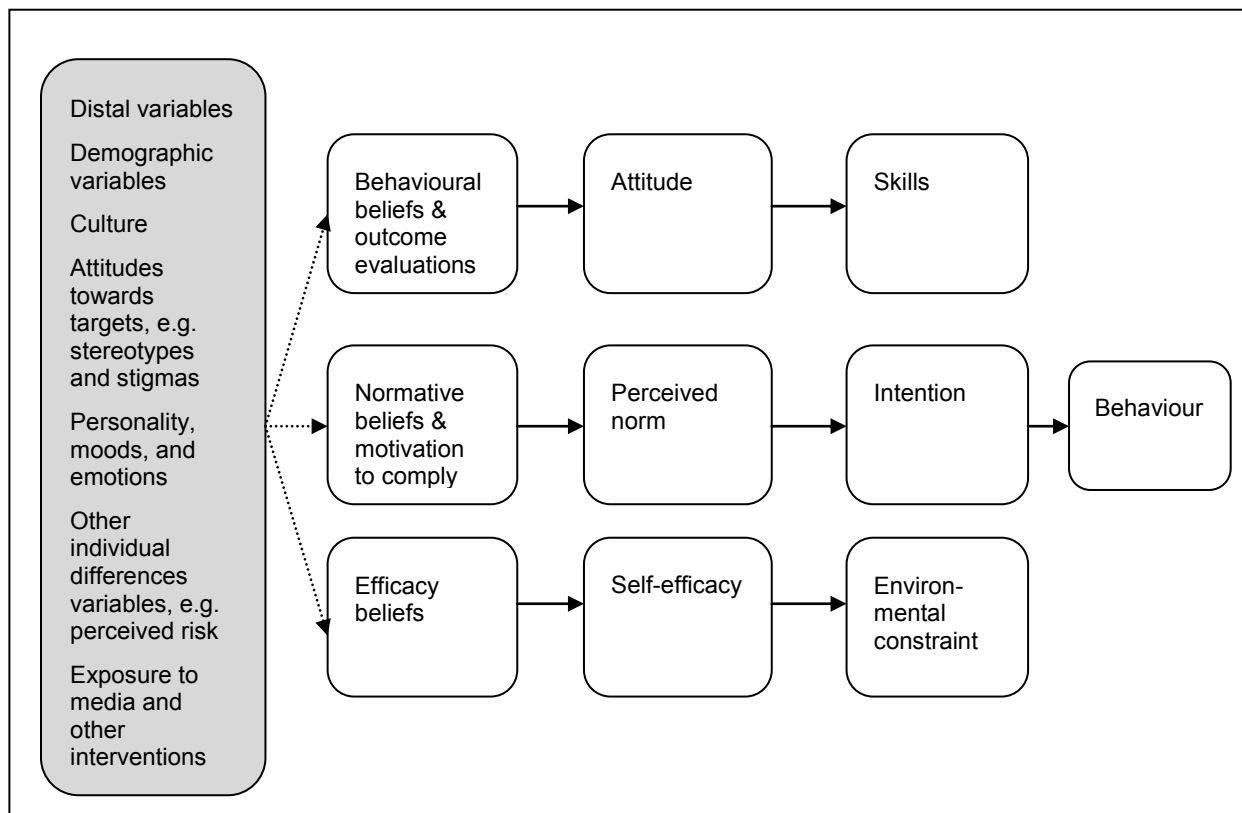
the behaviour, the necessary skills and abilities required and there are no environmental obstacles preventing behavioural performance. In a situation where people have formed an intention, but cannot act on it because of a lack of skills or the presence of environmental constraints, interventions should address skills building or help people overcome the environmental obstacles. On the other hand, if strong intentions have not yet been formed, interventions should focus on the three primary determinants of intention: attitude; perceived social norms and self-efficacy. The model recognises that these three determinants are all, themselves, functions of underlying beliefs about the outcomes of performing the behaviour, the normative prescriptions of certain referents and specific barriers or facilitators of behavioural performance (Fishbein, 2000, 2003). Finally, the figure also shows distal variables, which are reflected in people's underlying belief structure and are seen to play a primarily indirect role in influencing behaviour.

Gebhardt and Maes (2001) have also proposed an integrated model called **The Health Behaviour Goal Model**, which incorporates the concepts of outcome expectancies, social influence and perceived competence (albeit with added dimensions), but places personal goals at the core of the model. The basic tenet of the model is that progression towards the target health behaviour is dependent on the degree of compatibility between the behaviour, the person's values and personal goals (all that is important to the person and the things he/she wants to do with his/her life). People often initiate behaviour change once it is expected to serve a highly valued goal. Changes in personal goal structure can be stimulated by influencing knowledge, beliefs, attitudes, social norms and self efficacy and environmental factors.

Kasprzyk et al. (1998) tested an integrated model incorporating elements from the HBM, TRA, TPB and SCT, which was efficacious in understanding and predicting condom use among injecting drug users. The study found that perceived control and facilitators/constraints are distinct constructs and both, along with attitudes and social norms contributed to explaining intention. Testing such integrated models does not appear to have been conducted with smoking as a target behaviour.

Finally, Sorenson et al. (2003), propose a conceptual framework, which integrates concepts from individual behaviour change theory and social ecological approaches and emphasises the importance of recognising the influence of the contextual realities to health related behaviour, particularly when working with poor communities. The framework outlines the causal pathways whereby socio-economic class and other socio-demographic characteristics may be expressed through social context to influence patterns of health.

Figure 3: The Integrative Model of Behavioural Prediction (Fishbein, 2003)



Conclusion

The theories discussed in this chapter have become integral to much health education/ promotion and constructs from them can be beneficially applied to the modification of individual, social and environmental factors that influence health behaviour. Together, they have helped health educators and health promotion practitioners move away from the simplistic assumptions that simply raising awareness, or educating people about a health problem, can and should change their behaviour.

Theories such as the HBM, TRA, TPB, TTM and SCT, which emphasise a social cognitive perspective on behaviour, have been important, because not only have they shed light on the processes underlying individual behaviour, but they have also allowed us to identify mechanisms of change and guide us in developing better research and interventions. However, as various meta-analyses (Harrison et al., 1992 (HBM); Hagger et al., 2002 (TRA/TPB); Strecher et al., 1986; Rosenstock et al., 1988 (HBM and SCT) have borne out, constructs from these theories at best account for only a moderate proportion of variance in behaviour. By implication, a focus on them is important, but by no means sufficient.

Ecological models point to the critical importance of locating our understanding of individual behaviour and interventions to change it, within the relevant social, economic and physical

environment. For interventions to become more effective, the influence of environmental factors on motivation, intention and behaviour require full consideration in both health promotion research and practice.

Planners usually bring multiple theoretical and experiential perspectives to a health problem, as the application of a single theory or model in the development and evaluation of health promotion programmes in real-life settings is seldom adequate or appropriate. This is especially the case if a programme consists of multiple components. A greater integration of the multiple theories that are available would facilitate the use of theory in programme design, as this would make translating the theory into practice a less daunting task. Further comparative studies of theory-based interventions would also help as they would clarify which theories (or combinations thereof) yield the most effective results.

Using a planning model, such as Intervention Mapping (Bartholomew et al., 2001), can help practitioners make use of and integrate constructs from the different theories into the development processes of health education/promotion programmes.

My application of Intervention Mapping to the planning of the smoking cessation intervention for pregnant women is presented in **Chapter 4**.

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Chapter 2

Overview of project and outline of thesis

Rationale for MRC Smoking during Pregnancy Project

The most significant reductions in smoking prevalence are achieved by a combination of macro-level tobacco control measures, as outlined in the WHO Framework Convention on Tobacco Control (FCTC) (Shafey, 2009). In SA, comprehensive tobacco control laws were first introduced in 1999, and further amendments were passed in 2007 and 2008. These laws placed warnings on cigarette packets, banned tobacco advertising and sponsorship and restricted smoking in public places. This initiative, along with progressive increases in taxes on tobacco, has succeeded in reducing smoking rates among the general population (Steyn et al., 2002). However, this decline has been among men (42% in 1998 to 35% in 2003), whilst prevalence among women has remained essentially unchanged at 10 - 11% (Peer et al., 2009). Importantly, the sub-group of so called coloured women retained their status as the group with the highest smoking rates over the period of 1998 to 2008 (40% and 39% respectively) (Peer et al., 2009). It has been recommended that greater attention be directed to the question of what more could be done to reduce rates among women in particular (Peer et al., 2009; Steyn et al., 2002).

The Medical Research Council of SA (MRC) assumed a central role in lobbying for this legislation and, along with the National Department of Health, set up the Demographic and Health Survey, in order to monitor its impact (Dept of Health, MRC, 2007). Since that time, the MRC has turned its attention to research at a community level. The Health Promotion Unit of the MRC undertook a comprehensive survey of smoking among South African youth and subsequently developed and evaluated a programme aimed at preventing the uptake of smoking among school going children (Resnicow et al., 2008). In 2002, the Chronic Diseases of Lifestyle Unit of the MRC, under the directorship of Dr Steyn, initiated a research study aimed at developing and evaluating a smoking cessation intervention for disadvantaged, pregnant women.

Such an intervention had long been called for by the MRC, as an earlier research study, in 1996, had found exceptionally high smoking rates and poor knowledge of the risks among one particular sub-group of women attending public sector, antenatal clinics (Steyn et al., 1997). These were South African women of a distinct ethnic/cultural/language group, who self-identify as 'coloured' women (see more detailed explanation overleaf). The public sector antenatal services did not have any policies or programmes, which encouraged and supported pregnant women to quit smoking. Even

basic information on the risks of smoking during pregnancy was not available. The urgent need for an intervention targeting this particular population of pregnant women was underscored by a clinical study undertaken at Tygerberg Hospital in 2000, which found that smoking was associated with an 8% increase in preterm delivery and a 3-fold increase in abruptio placentae, among the predominantly coloured women, attending antenatal care services at the hospital. These conditions remain the most common causes of early neonatal and intrauterine death at Tygerberg, together accounting for 46% of perinatal deaths. Smoking in this study was also associated with a 256 grams mean reduction in birth weight (Odendaal et al., 2001).

On this basis, the MRC and the Department of Gynecology and Obstetrics at Tygerberg Hospital resolved to collaborate on a research project, which aimed to develop and test a smoking cessation programme for pregnant women. The overall project was called the Smoking during Pregnancy Project. The planned intervention was to be based on best practice models proven effective in other countries, but tailored to the needs and characteristics of high-risk women in South Africa. An evaluation of its effectiveness was planned to take place under typical clinical conditions in four, community based antenatal clinics which referred to Tygerberg Hospital.

The ultimate goal of the project was to provide the Department of Health with a tried and tested smoking cessation programme, which could then be more widely disseminated. If such an intervention could succeed in significantly decreasing smoking rates among pregnant women, it would confer immediate and long term health gains to both the baby and mother and reduce the costs associated with smoking-related complications during pregnancy, delivery and neonatal care. The provision of a smoking cessation programme for pregnant women would also improve the quality of antenatal care offered by the state and assist the Department of Health in attaining an important standard of care set by antenatal services elsewhere in the world.

Aims and objectives

The larger Smoking during Pregnancy Project was divided into three phases. Each phase had different aims and objectives and included several sub-studies. The sub-studies and my role in them are outlined later on in this chapter. This series of studies provided a systematic, evidence-based approach to developing an appropriate smoking cessation intervention for pregnant women. The aims and objectives for each phase of the research programme follow:

Phase 1: Formative research for programme development

Aim: To assess the potential for a smoking cessation intervention in public sector antenatal clinics and to describe the intended target audience and potential users of the intervention

Objectives:

1. To investigate the knowledge, attitudes, beliefs and practices of health care providers in relation to smoking in pregnancy
2. To investigate the knowledge, attitudes, beliefs and behaviours of pregnant women in relation to smoking in pregnancy
3. To identify the possible barriers and opportunities for the implementation of a smoking cessation intervention in the typical, antenatal clinic environment

Phase 2: Development of the smoking cessation intervention

Aim: To adapt a best practice smoking cessation intervention for pregnant women, using the Intervention Mapping planning model as a guiding framework

Objectives:

1. To develop an effective, brief, smoking cessation intervention based on best international practice guidelines (Fiore, 2000), certain key principles of Brief Motivational Interviewing (Rollnick, et al., 2002) and behavioural change theory (Glanz et al., 1997)
2. To tailor the intervention to the needs, values and characteristics of disadvantaged, coloured pregnant women, as the high risk group
3. To produce an intervention, which was acceptable to health care providers and feasible to implement in public sector antenatal clinics

Phase 3: Implementation and Evaluation of intervention

Aim: To implement and evaluate the impact of the adapted best practice smoking cessation intervention on the smoking behaviour of pregnant women

Objectives:

1. To do a natural history study to determine the typical smoking and quitting rates of pregnant women attending four selected antenatal clinics and the referral hospital, Tygerberg, over a one-year period
2. To evaluate the impact of the intervention on the smoking behaviour of pregnant women attending the same clinics in the following year
3. To assess the feasibility and acceptability of using midwives, and peer educators, to deliver the smoking cessation intervention to pregnant women
4. To evaluate the intervention process and identify factors which inhibit or promote the implementation of the intervention from the perspective of health care providers, peer educators and pregnant women

Study population and setting

Disadvantaged, pregnant women – the intended recipients of the intervention

Since the introduction of national tobacco control legislation, population surveys in South Africa have shown a fall in national prevalence from 34% in 1995 to 24% in 1998 (Steyn et al., 2002).

However, people of mixed, ethnic descent, known in South Africa, as coloured people, have maintained remarkably high smoking rates – 57% for men and 39% for women.. The term ‘coloured’

has its roots in South Africa's colonial and racially divided past, but is still a term with which this group of people self-identify, in terms of language and culture, and is not necessarily regarded as offensive or derogatory. For the purposes of this thesis, the term is used in the detailed description of the study population in this chapter, but from then on, the study population is simply referred to as 'disadvantaged, pregnant women'.

The forefathers of this group of people include the original inhabitants of Southern Africa, the Khoi and San people; imported slaves from Asia; various settler populations and indigenous black Africans. While people of African descent retained their own distinct languages, so called coloured people adopted the language spoken by the Dutch settlers of the time, which was transformed into a unique, creole language, called Afrikaans. This is the language still spoken by the majority of these people today. As a group, people of mixed ancestry were classified as non-white under the Apartheid government's Population Registration Act of 1950. Consequently, they, along with black African people, suffered racial discrimination in all spheres of life. Although the advent of democracy has provided previously disadvantaged South Africans with many more opportunities for social and economic advancement, the legacy of discrimination and exclusion is still very much evident today among both black African and coloured communities. The majority of coloured people remain lower middle class or working class, receive sub-standard education and are compelled to rely on the under-resourced public health services. Furthermore, they live in communities which suffer the social problems typical of many poor communities around the world: high levels of unemployment, alcohol and drug abuse, crime, gangsterism and violence against women. Low socio-economic status and poor levels of education among this group are strongly associated with smoking, as well as with the abuse of drugs and alcohol (Department of Health, 2007). This sub-group of South African people has long completed the epidemiological transition to a typical Western lifestyle in respect of diet, making them at high risk of chronic diseases such as heart disease and cancer (Dept of Health, 2007).

Studies of smoking during pregnancy have found very high rates of smoking among women of this particular population. An MRC study in 1997 (Steyn et al., 1997), found that 47% of coloured pregnant women smoked, compared to 4% of African women and 3% of Asian women. A 2002 MRC national survey of pregnant women attending public sector antenatal clinics, showed little change in this figure: 46% of coloured women reported that they continued to smoke during their pregnancy (Petersen et al., 2009a).

A perinatal care survey, published by the Department of Health in 2001 (Medical Research Council and National Department of Health, 2001), reported spontaneous pre-term labour, abruptio placentae and intrauterine growth retardation as among the six top obstetric causes of perinatal death in the Western Cape Province. Smoking was cited as one of the important avoidable factors. The

high rates of low birth weight (LBW) in the Northern and Western Cape provinces, estimated to be 18% and 22% respectively, (Medical Research Council and National Department of Health, 2002), have also been identified by the state health services as a priority concern. Birth weight statistics for the Cape Town metropole showed the following differences in the LBW rates between ethnic/cultural groups: 7.8% for Whites; 12.1% for Africans; 9.8% Asians and 17.2% for coloured women (Dhansay, 2003). A study of risk factors for LBW among coloured pregnant women attending a public sector clinic in Cape Town showed a relative risk of 1.5 for both LBW and preterm delivery among women who continued to smoke during pregnancy. In this study, 52% of pregnant women reported that they smoked (Dhansay, 2003). Given these statistics, a smoking cessation intervention targeting coloured women is likely to have a significantly beneficial effect on perinatal outcomes.

In South Africa, it is clear that coloured women of low socio-economic status are at highest risk of the adverse pregnancy and birth outcomes related to smoking in pregnancy. On this basis, the intended target audience for the planned intervention, and thus the primary study population for the research, was pregnant women who fitted this profile. The majority of these women live in the Western Cape Province of the country.

Midwives and nurses – potential agents for delivery of intervention

The MRC Smoking during Pregnancy Project saw midwives and nurses as the primary agents for the delivery of the potential intervention. It was therefore necessary to include them in the formative research phase, in order to assess their knowledge, attitudes and current practices in relation to smoking in pregnancy, as well as their openness to playing a key role in implementing the intervention as part of routine care.

Pregnant women of low socio-economic status, who cannot afford private medical care, attend state funded, community-based, public sector clinics. The research therefore focused on those midwives and nurses employed in public sector, antenatal clinics situated in predominantly, so called, coloured communities. These clinics are managed and staffed by midwives and nurses who assess pregnant women at their first booking visit, provide ongoing antenatal care and deliver the babies at facilities within the same premises. Only when there are complications, do they refer women to a doctor. Whilst women can see visiting doctors at the clinic, those with ongoing complications are referred to Tygerberg, a tertiary level hospital, for continued antenatal care. Doctors were therefore conceived of as playing a supportive role in this project, rather than being considered as the primary agents for the delivery of the intervention.

The majority of women register by 16 weeks' gestation and attend the clinic, on average, five times during their pregnancy, thus offering repeated opportunities for midwives/nurses to advise and counsel women to stop smoking. Despite the extent of the problem, midwives working in these state health services are not obliged by any state policy to provide smoking cessation education or counselling to pregnant smokers and do not have any educational resources or guidelines to assist them. As part of history taking, it is standard procedure for the nurse to ask women whether they smoke or not and record this information on the clinic card. Some nurses may advise smokers to quit and offer information about the risks of smoking during pregnancy, but this is by no means a consistent practice.

Public sector antenatal clinics – the setting for the intervention

The study was conducted in a total of four clinics servicing the needs of pregnant women from the target population. These clinics were situated in Elsies River, Bishop Lavis, Belhar and Kasselsvlei, which are working class, residential areas in the Cape Town metropole, in the Western Cape Province of South Africa. The clinics in Belhar and Kasselsvlei are satellite clinics of Bishop Lavis and Elsies River. The staff from Bishop Lavis and Elsies River clinics are required to travel to the neighbouring suburbs of Belhar and Kasselsvlei to run an antenatal clinic on certain days of the week. This is because there is not enough staff available to run a full time clinic in these areas.

The clinics, which provide antenatal care in these areas, are called Maternal Obstetrics Units (MOUs). These facilities are located in the residential areas, so as to be easily accessible to women. The midwives and nurses who staff the clinics are supported by staff in the Obstetrics and Gynaecology Department at Tygerberg Hospital., which is a local, tertiary level, academic hospital attached to the Medical School of the University of Stellenbosch. The midwives work strictly according to protocols in order to identify high risk pregnancies, which are then referred for more specialised care at Tygerberg. In addition, the MOUs have direct ambulance links which allow them to refer deliveries, which have developed complications, to Tygerberg.

These clinics suffer the typical shortcomings of public sector healthcare services in South Africa: they are understaffed and overburdened by increasing patient numbers; they have serious constraints in terms of facilities and equipment and very limited health education resources (Dept of Health, 2006).

Ethical considerations

The protocol for this study and the research instruments were approved by University of Stellenbosch's Ethical Research Committee. Permission was granted by the National and Provincial Departments of Health, as well as by the facility and clinic managers at each site.

The purpose of the study, its procedures and inclusion criteria were explained to the clinic staff and all participants in Afrikaans and English. Midwives and participants were also given an information sheet with the researcher's contact numbers. All research participants were required to give written consent, prior to recruitment. The information sheet and consent form were available in the languages of Afrikaans and English (see Appendix).

The women in the comparison group were exposed to usual practice in 2006, the year before the intervention began. Usual practice generally involves the midwife providing very brief, prescriptive advice to quit smoking during pregnancy. The women in the intervention group were exposed to best practice smoking cessation counselling by midwives and peer educators and received educational material. The intervention was implemented in 2007. All information was treated as confidential.

The pregnant women who were willing to participate in the study and who completed all three interviews were each given a package of toiletries for their baby as an incentive. They received this on completion of the third interview.

A full presentation of study findings was given to the midwives, research participants and interested community members during two events held in the community on World No Tobacco Day, 2008. Research participants were individually invited by letter. The audience was given an opportunity to discuss the study results and ask further questions. They were also offered a range of free health tests on the day, which included lung function and blood pressure checks.

Candidate's role in Smoking during Pregnancy Project

I have played the role of principal investigator in the overall MRC Smoking during Pregnancy Project, with responsibility for the conceptualisation of the overall study design; the project management, including the fundraising and financial management; the execution of the research agenda; the actual development of the intervention and the quantitative evaluation of its effectiveness.

Several sub-studies were undertaken by exchange students from the Department of Health Promotion and Education at the University of Maastricht in the Netherlands. They worked under my direction, with support from Professor Krisela Steyn, the director of the Chronic Diseases of Lifestyle unit at the MRC. Zaino Petersen has also worked on this project for her PhD thesis, which is registered with the University of Umeå in Sweden. The following table (Table 1) serves to place my PhD in the context of the larger project and identifies my role, as well as the role of the other students.

Table 1: Smoking during Pregnancy Project: Sub-studies and responsibilities

Phase 1: Formative research for programme development		
Research with midwives/nurses (the potential agents for the delivery of the intervention)	Research with pregnant women (the intended recipients of the intervention)	Research with obstetricians and healthcare administrators (important stakeholders)
<p>Quantitative methods</p> <p>Survey of 102 midwives, investigating knowledge, beliefs and practices related to smoking in pregnancy.</p> <p>Survey conducted by Eva de Feijter.</p> <p>Outcomes:</p> <p>Article: Everett-Murphy K, Steyn K, Mathews C, Petersen Z. & De Feijter E. Submitted to <i>Curationis</i> 2010.</p>	<p>Quantitative methods</p> <p>Survey of 709 pregnant women, investigating smoking behaviour in pregnancy, knowledge, beliefs and attitudes.</p> <p>Survey conducted by MRC intern: Zaino Petersen.</p> <p>Outcomes:</p> <p>Masters thesis by Zaino Petersen, UCT, 2005.</p> <p>Article: Petersen Z, Steyn K, Lombard C, Everett K. & Emmelin M. 2009a. <i>African Journal of Midwifery and Women's Health</i>, 3(4): 187-192.</p>	
<p>Qualitative methods</p> <p>In-depth interviews with 34 midwives.</p> <p>10 exploratory interviews conducted by Famke van Lieshout and Kathy Everett-Murphy.</p> <p>24 interviews conducted by Jeske Paijmans and Kathy Everett-Murphy.</p> <p>Outcomes:</p> <p>Masters theses by Famke van Lieshout (2001) and Jeske Paijmans, Maastricht University (2003).</p> <p>Findings further analysed, developed, written up by Everett-Murphy as Chapter 3 of this thesis.</p> <p>Article: Everett-Murphy K, Paijmans J, Steyn K, Mathews C, Emmelin M, Petersen Z. 2010. <i>Midwifery</i>. doi:016/j.midw.2010.04.003.</p>	<p>Qualitative methods</p> <p>In-depth interviews with 22 pregnant women.</p> <p>10 exploratory interviews conducted by Dutch exchange student, Famke van Lieshout and Kathy Everett-Murphy.</p> <p>12 Interviews conducted by Zaino Petersen.</p> <p>Outcomes:</p> <p>Masters thesis by Famke van Lieshout, Maastricht University (2001).</p> <p>MPH mini- thesis by Zaino Petersen, Umeå University, Sweden, 2004.</p> <p>Article: Petersen, Z, Nilsson, M, Everett, K. & Emmelin M (2009b). <i>Midwifery</i>, 25: 382-391.</p>	<p>Qualitative methods</p> <p>In-depth interviews with 14 obstetricians and health administrators.</p> <p>Interviews conducted by Kathy Everett-Murphy.</p> <p>Outcomes:</p> <p>Article: Everett-Murphy K, Odendaal HI, Steyn K (2005). <i>SAMJ</i>, 95 (5). (included in Appendix of this thesis).</p>
Phase 2: Development of smoking cessation intervention		
<p>The smoking cessation intervention was developed on the basis of the formative research conducted in Phase 1 and evidence-based guidelines for best practice smoking cessation interventions. The Intervention Mapping model for design of theory based, health promotion programmes was used to guide the development process.</p> <p>Outcomes:</p> <p>Intervention developed by Kathy Everett-Murphy. Written up as Chapter 4 of this thesis.</p>		

Phase 3: Implementation and Evaluation of intervention in clinics

The impact of the intervention on pregnant women was evaluated using a quasi-experimental design: A Natural History survey was conducted in four antenatal clinics in 2006, followed by an intervention survey in the same four clinics in 2007.

Individual interviews were also conducted with the peer counsellors and nurses.

Outcomes:

Study designed and executed by Kathy Everett-Murphy, written up as **Chapter 5** of this thesis.

Article: Everett-Murphy K, Steyn K, Mathews C, Petersen Z, Odendaal H, Gwebushe N & Lombard C. 2010. The effectiveness of adapted, best practice guidelines for smoking cessation counselling with disadvantaged pregnant smokers attending public sector antenatal clinics in Cape Town, South Africa. *Acta Obstetrica et Gynecologica Scandinavica*, Vol 89 (4): 478-489.

Qualitative evaluation of pregnant women's responses to the intervention, conducted by Zaino Petersen.

Outcomes:

Written up as two chapters in her PhD thesis, registered with Umeå University of Sweden.

Article: Petersen, Z., Steyn, K., Everett-Murphy, K. & Emmelin, M. 2010. Pregnant women's responses to a tailored smoking cessation intervention: Turning hopelessness into competence. *Global Health Action*.3: 5370-DOI: 10.3402/gha.v3i0.5379.

Outline of chapters in thesis

This thesis comprises six chapters. Three of them present the findings of three of the sub-studies within the larger research project. These chapters include: an introduction; a description of the methods, data analysis and results; a discussion of the study's findings, and references. The content of each of these three chapters has been, or will be, published as an individual article in relevant, peer reviewed journals. I will be the first author on each paper.

Chapter 1: consists of a comprehensive literature review. (A) includes an overview of the scientific evidence of the risks of smoking during pregnancy, for both the foetus and the mother; the epidemiology of smoking during pregnancy and the factors associated with smoking during pregnancy. It also includes a description of the evaluation research on smoking cessation interventions for pregnant women to date and what constitutes internationally accepted best practice in this field. (B) consists of an overview of health behaviour change theory.

Chapter 2: (this chapter) presents the rationale, the overall aim and the objectives of the project as a whole. It also includes a description of the study population and the setting in which the research was conducted.

Chapter 3: presents the findings of a qualitative study on midwives and is titled: *Scolders, Carers or Friends: Midwives' contrasting style of communication when discussing smoking cessation with pregnant women*. This qualitative study was undertaken jointly with a Dutch exchange student from Maastricht University, called Jeske Paijmans. This student was placed under my supervision for the purposes of training. I

gave extensive input into the development of the protocol; trained her in qualitative interviewing techniques; undertook the fieldwork with her and jointly analysed the data. Jeske wrote up the descriptive findings as a mini-thesis for her Masters Degree in Health Sciences at Maastricht. I subsequently further developed and refined one aspect of the study's findings, which was the issue of communication between the nurses and pregnant women. This was *not* the focus of her thesis. The development of the midwife archetypes, their dimensions and the argument as to how different styles of communication have a direct effect on women's responses described in this chapter, represents my original work.

An article based on this chapter has been published in the journal of Midwifery on line (Everett-Murphy et al., 2010). The authorship for the article was: Katherine Everett-Murphy; Jeske Paijmans; Krisela Steyn; Catherine Mathews; Maria Emmelin; Zaino Peterson. Jeske had no interest in contributing to the write up of the article, however, she is acknowledged as second author, because of her role in the data collection and analysis.

Chapter 4: consists of a description of the application of the Intervention Mapping planning model to the development of a smoking cessation intervention for pregnant women. The methodology for developing the intervention is covered in this chapter. I was solely responsible for the design of all the elements of the smoking cessation intervention. I applied the Intervention Mapping planning model in developing the intervention. I wrote the education materials, supervised their production, planned the implementation of the intervention in the clinics, developed training tools and undertook the training of the nurses and peer counsellors to deliver the intervention. The educational materials can be found in the **Appendix** of this thesis.

This chapter is still to be written up as an article. The authorship for the article will be: Katherine Everett-Murphy; Professor Krisela Steyn and Dr Catherine Mathews.

Chapter 5: presents the findings of the evaluation study and is titled: 'The effectiveness of adapted, best practice guidelines for smoking cessation counselling with disadvantaged pregnant smokers attending public sector antenatal clinics in Cape Town'. I was the principal investigator in this study. I therefore took responsibility for all aspects of the quantitative evaluation: I developed the protocol; developed and tested the research instruments; recruited, trained and supervised the fieldworkers and peer counsellors; planned and managed the data collection, coding and analysis. I also conducted in-depth interviews with the peer counsellors and nurses in order to gauge their responses to the intervention. I took responsibility to organise an event in the Bishop Lavis and Elsie's River communities to feedback the research results to the community and other stakeholders and initiated

meetings with the Department of Health, in order to present the findings and lobby for further dissemination of the intervention.

I received mentorship from Professor Steyn in terms of the overall project, in her capacity as the Director of unit in which I worked. I also received assistance from the BioStatistics unit at the MRC in determining the sample size for the study; in determining the appropriate cotinine cut off point for measuring the outcome measure of quitting; in capturing the data and with the data analysis. Under the supervision of my two PhD supervisors, Dr Cathy Mathews and Professor Krisela Steyn, I have been the sole author in writing up the quantitative findings of the evaluation study. An article, entitled, “The effectiveness of adapted, best practice guidelines for smoking cessation counselling with disadvantaged pregnant smokers attending public sector antenatal clinics in Cape Town, South Africa”, based on this chapter has been published in *Acta Obstetricia et Gynecologica Scandanavica* (2010). The authorship is as follows: Katherine Everett-Murphy; Dr Krisela Steyn; Dr Catherine Mathews; Zaino Petersen; Dr Carl Lombard; Professor Hein Odendaal; Nomonde Gwebushe.

Part of the evaluation also involved in-depth interviews and focus groups with pregnant women in order to assess their personal experiences of the intervention. This aspect of the study is being written up as part of a PhD by my colleague, Zaino Petersen, who is registered with Umeå University in Sweden.

Chapter 6: provides an overall discussion and gives recommendations.

The Appendix: includes an article relevant to the project, published in 2005; copies of the education materials; the training manual, as well as the questionnaires and the interview schedules used in the evaluation.

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Chapter 3

Qualitative study with midwives

Scolders, Carers or Friends: Midwives' contrasting styles of communication when discussing smoking cessation with pregnant women

This chapter presents the findings of one of the studies undertaken as part of Phase 1 of the MRC Smoking during Pregnancy project, i.e. Formative research for programme development. It involved in-depth, qualitative interviews with midwives providing antenatal care in public sector clinics. This chapter focuses on the way midwives communicate with pregnant women about smoking.

Introduction

The numerous adverse outcomes caused by smoking in pregnancy have been described in **Chapter 1 (A)**. They include abruption placentae and preterm delivery, as well as increased risks for stillbirth, low birth weight, neonatal death and Sudden Infant Death Syndrome (US DHHS, 2001). Cessation confers immediate health benefits to both the mother and baby, making it an important health promotion goal for antenatal care providers (US DHHS, 1990).

The results of various reviews (Rice, 2008; Fiore et al., 2000; West et al., 2000) indicate the potential benefits of smoking cessation counselling/advice given by health providers. It has been suggested that nurses have a particularly important role, as they are by far the largest healthcare workforce, have a well defined health promotion role and are involved in almost all levels of the health service. Evidence-based smoking cessation guidelines, developed from best practice, have long existed to assist health care providers fulfil this role (ACOG, 2000; Fiore et al., 2000; West et al., 2000). However, research has shown that most nurses and doctors perform poorly when it comes to smoking cessation counselling. Even when they regard smoking in pregnancy as a serious concern, many providers do not actively or consistently promote cessation and seldom go beyond offering the most basic of information (Cooke et al., 2001; McLeod et al., 2003; Oliver et al., 2001; Pullon et al., 2003; Walsh et al., 2000; Walsh et al., 2001; Whyte et al., 2006; Windsor, 2003). Reasons for this include: uncertainties about the effectiveness of cessation counselling; too little time; a paucity of good quality educational resources and inadequate training (Clasper & White, 1995; Cooke et al., 2001; Pullon et al., 2004; Whyte et al., 2006). In addition, many providers anticipate patient resistance and disagreement, which they find challenging and stressful and fear may endanger their relationships with patients (Devonport, 1996; McLeod et al., 2003; Rollnick et al., 2002). This anxiety has also been found to be one of the main barriers to providers discussing other lifestyle related health risks, such as diet, alcohol and drug use (McCormick et al., 2006).

Such difficulties in communication have prompted some authors in the field to recommend a patient-centred, motivational approach to lifestyle counselling as an alternative to the authoritarian or paternalistic style of communication typical of most medical consultations (Butler et al., 1996; Rollnick et al., 2002) (a patient-centred approach can be defined, most simply, as one in which the patient is drawn in as an active partner in the consultation and where his/her perspective is taken into account). Butler et al. (1996) and Rollnick et al. (2002) argue that resistance is a predictable response in a situation where a patient is simply told that they *must* change, without any consideration given to their perspective. A possible mechanism underlying such resistance is the phenomenon of psychological reactance, where a threat to a patient's personal freedom is likely to be met with a corresponding assertion of autonomy (Brehm & Brehm, 1981) – resulting in what Miller and Rollnick (1991) call the confrontation-denial trap (the 'Yes, but ...' response).

The patient-centred counselling method, Motivational Interviewing (MI) (Miller & Rollnick, 1991) has proven to be particularly helpful in overcoming the problem of patient's resistance to behavioural change (Rollnick et al., 2002). MI, in its original form, was a counselling method used with noteworthy success in the treatment of substance abuse disorders (Burke et al., 2003). This form of MI is time consuming, specialised and requires repeated contact with patients for best results. It is, therefore, not particularly well suited to the primary care setting, where time is generally very limited. As interest in MI's application to other behaviours grew, its authors made efforts to adapt it so that it could be successfully used for behavioural change consultations in primary health care settings. They developed an abbreviated form of MI, which they called Brief Motivational Interviewing (BMI) (Rollnick et al., 1992). BMI embodies the spirit of the original MI, but employs only a selection of the counselling strategies to provide direction to the consultation, whilst encouraging the patient to be as actively involved as possible.

MI acknowledges that people have an intrinsic need to be self-determining, assuming that most people choose to engage in behaviour change, not when someone else demands it, but when it becomes important for them. The role of the health care provider in MI is to assist patients identify and resolve their feelings of ambivalence about behavioural change, through making their own assessments about the problem and appraising the benefits and losses associated with change in the context of their personal lives (decisional balance) (Miller & Rollnick, 1991). Through the use of counselling skills such as open questions and empathetic listening statements, the practitioner aims to elicit arguments for change from the patients themselves, rather than imposing them. The use of 'decisional balance' exercises and eliciting client 'change talk', appear to be the most important mechanism whereby MI exerts its therapeutic effect. Both techniques have been consistently associated with better counselling outcomes (Apodaca & Longabaugh, 2009).

A review and meta-analysis (Ruback et al., 2005) of 72 randomised trials, showed that Motivational Interviewing consistently outperformed traditional, advice-giving approaches in a range of interventions offered by health care providers, including ones focusing on alcohol abuse, drug

addiction, smoking, weight loss, physical activity, asthma treatment and diabetes management. Eight out of twelve studies that applied MI to smoking cessation showed a significant improvement in impact over the more traditional approach.

Several authors have recommended further research in order to establish whether patient-centred approaches, such as MI, can achieve improved cessation rates among pregnant women (Arborelius and Nyberg, 1997; Herzig et al., 2006; Hunt and Pearson, 2001; McLeod et al., 2004; Valanis et al., 2001; Velasquez et al., 2000). The main aim of this study was to assess the potential role of midwives in delivering an adapted MI type intervention to pregnant smokers in South Africa. This encompassed an investigation of how antenatal care providers currently communicate with women about smoking in pregnancy and the extent to which current practices diverge or align with MI.

Methods

The objectives of the study were: 1) to describe current communication approaches to smoking cessation education and counselling among midwives, 2) to explore the barriers to, and opportunities for, involving midwives in a patient-centred, motivational type cessation intervention for pregnant women.

Study design

The study used a qualitative research design using individual, semi-structured, in depth interviews with midwives. The interview schedule (see **Appendix**) was developed with reference to the theories described in **Chapter 1 (B)**. These models were helpful in identifying the behavioural constructs which would determine the likelihood of midwives forming an intention to participate in the potential intervention and what factors needed to be addressed in order to overcome midwives' perceived barriers to adopting the intervention.

Study population and setting

The intervention aimed to target a sub-group of women who have, by far, the highest smoking rates (46%) among South African women (Steyn et al., 1997). The profile of these women was described in the previous chapter (**Chapter 2**). This study therefore focused on those midwives who, in the main, provided antenatal care to this particular community. The study was conducted in public sector clinics in five major cities in South Africa. Midwives in these clinics offer antenatal care, deliver babies and provide limited post-natal care. They are well placed to deliver a smoking cessation intervention as they interview women during their first booking visit, ask about smoking status and maintain contact until the early postnatal period. At the time of the study, there were no smoking cessation programmes at the clinics and although health education is part of their remit, midwives were under no policy obligation to assist pregnant smokers to quit.

Sampling

A list of antenatal clinics was obtained from the health authorities in each of the five cities. The clinics were then purposefully sampled, so as to include only those clinics serving the target community. Most of the relevant clinics were in Cape Town. All nurses on duty were approached with permission from the clinic manager; however some were not able to afford the time required, especially if they were working in the labour ward at the time. Nurses who were willing and able to commit to the times available were interviewed by appointment.

Data collection

The interviews took place in a private venue on the clinic premises and lasted between 45–60 minutes. The discussion was initially prompted by the open question: ‘What are your experiences of discussing the issue of smoking with pregnant women?’ The subsequent use of ‘Clarification’ and ‘Reflective Summary’ prompts helped to further develop the discussion. This interview technique enabled the respondents to freely explore their experiences in their own terms and to raise issues of most concern or importance to them. If certain research questions were not addressed by the respondent the researcher would introduce them towards the end of the discussion.

Ethics

Informed consent was obtained prior to the interview and participants were assured of confidentiality. Interviews were audio-taped with permission from the respondents and transcribed verbatim.

Analysis

The data was analysed using the methods of Content Analysis (Bryman & Burgess, 1994; Graneheim & Lundman, 2004). As a first step, the two researchers (myself and J. Pajmans) simultaneously, but independently, examined the interview transcripts to identify the issues and concepts inherent in the data. ‘Units of meaning’ in each sentence or paragraph were given descriptive codes or labels. Some way into the process, the researchers came together to discuss the areas of agreement and discrepancy and to further refine the coding scheme. As the next step, the codes were grouped into more abstract categories with various dimensions and overall themes or core categories were identified. This is both a deductive and inductive process in that the data is scrutinised for a priori issues relating to the research questions, but also for new explanations and issues raised by the respondents. An analytical framework was then developed and applied across all the interviews as a means of re-organising the data at this greater level of abstraction. The framework was revised a number of times as its relevance and completeness was continually tested through the ongoing analytical process. The final step involved writing up memos on each theme which grouped views, experiences and quotes according to their appropriate thematic reference and helped the researchers

to further refine their explanations, draw associations and understand the weight and range of certain findings.

Findings

A total of 24 nurses participated in the study. 70% of nurses interviewed were registered midwives. The remaining nurses were either registered or staff nurses. They were all female, with an average age of 38 years and varying years of experience. None had received any training in smoking cessation counselling.

Final Sample:

Province	City	Clinics	No. of midwives interviewed
Western Cape	Cape Town	7	13
Northern Cape	Kimberley	4	4
Gauteng	Johannesburg	2	2
	Pretoria	1	3
Eastern Cape	Port Elizabeth	2	2
	Total	16	24

The central theme which emerged from the analysis related to the manner in which different midwives communicated with pregnant women about their smoking. This was encapsulated in the following quote from the data: *‘My attitude and how I approach the problem is very, very important. If I become aggressive, then the client will respond negatively. I want the patient to feel unthreatened and relaxed with me, then she will open up and talk to me.’*

Three main themes were developed, which characterised midwives’ different styles of communication and approaches to smoking cessation. These are presented as three different archetypes of midwives: *The Angry Scolders*, *The Benign Carers* and *The Enthusiastic Friends*. There were eight categories which defined each style of communication, including the features of the relationship that each style appeared to determine between the midwife and patient. These were: 1) midwives’ attitudes to pregnant smokers 2) their characterisation of pregnant smokers 3) their approach to smoking cessation education or counselling 4) their responses to non-compliance 5) their accounts of how pregnant women responded to them 6) their attribution of failure 7) their emotional reactions, and 8) their openness towards training.

The findings in relation to each of these categories are described in **Table 1, Typology of midwives’ styles of communication and their distinguishing features**, on the following page.

The quotes illustrate how the analysis is grounded in the data.

Table 1: Typology of midwives' styles of communication and their distinguishing features

Typology of midwives:	The Angry Scolder (Authoritarian Style)	The Benign Carer (Paternalistic Style)	The Enthusiastic Friend (Patient-centred style)
Midwives' attitudes to pregnant smokers:	<p>Disapproving, judgemental attitude: 'I tell them that it is very, very wrong to smoke during pregnancy. They can smoke as much as they like, but not when they are pregnant.'</p> <p>'I even said to one lady, I wish I could phone the police and report you for abusing your child. I feel very emotional about it.'</p>	<p>Paternalistic, sympathetic attitude: 'We serve the lower socio-economic part of the community and they have the most stress. These women need cigarettes to calm down. To just take smoking away is like taking away their support system. So, I tell them I know it is very difficult to give up.'</p>	<p>Empathetic, genial, non-judgemental attitude: 'You need to make yourself open to the patient and relate to them so that they feel they can ask anything. I try and make jokes to make them laugh. In that way I try and make friends with them.'</p>
Midwives' characterisation of pregnant women:	<p>Women regarded as irresponsible, uncaring, selfish: 'I don't know what the problem is with patients. They do not take responsibility. Most of them don't even plan their pregnancies.'</p> <p>'Sometimes you can show them that the baby is not growing as it should. But these women still don't want to give up. They just don't care!'</p>	<p>Women regarded as uneducated and as victims: 'Although we tell them what might happen to the baby, they don't believe us. They don't have the insight. If they had more education, they would understand you better.'</p> <p>'They tell us they have so much stress in their lives. Most of the time it's relationships and finances. Things like that cause them to smoke.'</p>	<p>Women regarded as equals: 'I am sure that people don't want to be spoken to as if they are children. I think it is very important that people feel their dignity.'</p> <p>'I try not to talk down to them, but to talk with them.'</p>
Midwives' approaches to smoking education/counselling:	<p>Dominant, prescriptive, forceful: 'It is not our baby, it is hers. It is for her to listen to me and for her to do something about it.'</p> <p>'The reason why I go hard on them is because I want them to know that they are doing something wrong. I want them to understand that what I am saying is the truth.'</p>	<p>Didactic, information intensive, insistent: 'I think repeating and emphasising is a good way for patients to understand. If I just keep on repeating the same thing, some of them will listen.'</p> <p>'I have a strong belief that knowledge and education are powerful tools. We are here to educate and make a difference.'</p>	<p>Supportive, affirming, interactive: 'When I give a talk, I don't stand in front of the women like I am the boss and I am going to tell them what to do. You don't need to be so professional and firm. I try to be a friend, sit amongst them, crack jokes and make them feel relaxed.'</p> <p>'I think it is important to try and give them confidence that they are in control of their lives, show them that I trust that they can make the change if they want to.'</p>
Midwives' responses to non-compliance:	<p>Angry, confrontational, cynical: 'When a patient comes to me and smells of smoke, I fight with her. I say, 'didn't I explain to you the first time that you must not smoke? Is this baby not important to you?''</p>	<p>Compassionate, non-confrontational, timid: 'I will rather tell her to try and cut down. It is unfair to tell somebody just to stop because it is very difficult to quit.'</p>	<p>Empathetic, encouraging: You should not tell the patient you must stop smoking or get angry with her, like some of the midwives do. You rather try and get her to talk to you and open up. Smoking might be harmful, but she still has a right to make her own choice.'</p>

<p>Midwives' accounts of how pregnant women react to their advice:</p>	<p>Women described as defensive, resistant:</p> <p>'They just listen to you and tune out. It is like talking to a brick wall.'</p> <p>'They laugh sheepishly and say they are smoking less because they don't want you to ask any more questions about their smoking.'</p>	<p>Women described as passive, fatalistic:</p> <p>'Patients just listen to what the sister is saying and say, 'yes...yes'. They don't form part of the conversation. They just agree with you.'</p> <p>'They think that however it is going to turn out, it would have turned out anyway. So, they listen to us, but they don't believe what we say will make a difference'.</p>	<p>Women described as trusting, engaged:</p> <p>'If they see you as an authority figure, they won't approach you. But they know that I am here to help and I can see that my patients feel comfortable asking me questions.'</p> <p>'If they feel relaxed with you, then they will talk to you about their smoking.'</p>
<p>Midwives' attribution of failure to succeed in changing women's behaviour:</p>	<p>Failure blamed on women's negative attitudes:</p> <p>'You get the impression that they don't care. It is very difficult to work with patients if they have attitudes like that.'</p> <p>'If their attitudes don't change, then the midwives here are just going to switch off. If they don't care, why should we care?'</p>	<p>Failure blamed on women's low levels of education and social problems:</p> <p>'I want to help them quit, but on the other hand they have all these stresses which I can't really involve myself in. I don't know how I feel...I become torn apart.'</p> <p>'They don't realise how smoke goes into the bloodstream and can affect the baby. Most of them only went up to Grade 7 so they just don't understand what I am trying to say.'</p>	<p>Failure blamed on midwives' authoritarian communication style:</p> <p>'We have a problem here with nurses treating patients like children and not explaining things to them, but just saying 'you better stop smoking.' That does not help, it only makes them resist.'</p> <p>'My attitude and how I approach the problem is also very, very important. I don't want to become aggressive because then the client will feel threatened and respond negatively.'</p>
<p>Emotional state of midwives in counselling moment:</p>	<p>Midwives felt exasperated, despondent, demoralised:</p> <p>'I get fed up. It is so de-motivating when you see something wrong and you talk and talk and they still don't quit.'</p>	<p>Midwives felt helpless, resigned, sad, confused:</p> <p>'We try as much as we can to get women off smoking, but I don't know if we ever will be able to.'</p>	<p>Midwives felt satisfied, optimistic:</p> <p>'It makes a difference to me to see even one person decide to change, then I am relieved and hopeful.'</p>
<p>Midwives' attitudes to training:</p>	<p>Resistant to training:</p> <p>'I have no problems with counselling. I have got lots of experience. It is the women who don't like counselling. They don't respond as they should do.'</p> <p>'I do my part of the education and if they don't want to listen, it's their fault. I don't think the nurses here need training.'</p>	<p>Open, enthusiastic about training:</p> <p>'Sometimes you know they (smokers) need more help, but you just don't know what kind of help you should give. We really need some in-service training. That would help a lot.'</p> <p>'I have never smoked myself, so I would like to know how to approach women who are smoking. It is not easy to say the right thing. I don't want to irritate them. So, I think training in counselling skills would be very good.'</p>	<p>Thought training was more relevant to others:</p> <p>'We have some midwives from the 'old school' who use that sort of dictatorship. They did not get the same training as we did. We are a younger group and are more primary health care orientated. Since we have come, the patients feel more free.'</p>

The three archetypes and their styles of communication

The *The Angry Scolders* used an authoritarian style of communication, where they assumed a dominant, expert role and prescribed what decisions the pregnant woman should take. Women were expected to respond in a rational way and comply with the midwives' professional advice. A distinguishing feature of this archetype was that there was little interaction with the woman.

The communication style of the *The Benign Carers* can be described as paternalistic, in that the midwife assumed a parenting, guiding role. This style was characterised by a strong emphasis on the role of education in changing behaviour. These midwives also prescribed what action the woman should take, but generally communicated this in a more sympathetic manner than the *Angry Scolders*. Once educated, it was presumed that women would make a logical decision to stop smoking. There was marginally more interaction with the pregnant woman than with those midwives using the authoritarian style.

Finally, there were the *The Enthusiastic Friends*. These midwives saw their primary role as helping women make an informed choice. They were more focused on 'process' issues, than on getting smokers to quit, consciously seeking more interaction with pregnant women and concerned to establish a constructive relationship with their patients.

Each archetype represented a typical approach adopted by various midwives; however, it is not necessarily so that any one midwife would always adopt a particular style of communication in every situation.

Midwives' attitudes to pregnant smokers

Midwives of the *Angry Scolder* type expressed strong moral disapproval of women who continued to smoke during pregnancy, describing them as irresponsible, selfish and uncaring. These midwives found it particularly difficult to comprehend how women who were experiencing problems with their pregnancies, could continue to smoke with apparent disregard for the consequences. One midwife went as far as to say that she regarded smoking during pregnancy as a form of child abuse.

The *Benign Carers* saw health education as being particularly important with disadvantaged women, who generally have little access to information and low levels of formal education. They assumed that most pregnant women who continued to smoke were ignorant of, or underestimated, the risks. They were sympathetic to the reasons offered by women for why they could not quit smoking. Most smokers told them it was too difficult to quit, because smoking helped them cope with the daily stressors in their lives such as relationship problems, unemployment, child care, loneliness and

financial insecurity. Some midwives believed that women who were overwhelmed by these social problems lacked the capacity to change and had resigned themselves to being powerless to assist them to stop smoking. Midwives in this category were therefore less hostile to women who continued to smoke in pregnancy than the *Angry Scolders*.

The *Enthusiastic Friends* were concerned to treat their patients as equals. They were more inclined than the other midwives to regard women patients who smoked as people struggling with difficult decisions, under challenging circumstances. They were sensitive to the stressful life circumstances of pregnant women from disadvantaged communities. They also acknowledged that tobacco was an addictive product, which made quitting very difficult. They therefore did not express the same levels of frustration and anger towards women in the face of non-compliance as the authoritarian midwives.

Perceived role in smoking cessation counselling

The *Angry Scolders* saw their role to be one of simply telling women about the potential risk to their babies and repeatedly exhorting them to stop smoking. When women failed to comply with their advice, these midwives felt exasperated and angry. Non-compliance was interpreted as an act of defiance and an affront to their professional authority. This would often lead to confrontation.

Midwives in the *Benign Carer* type were hopeful that providing information and education could facilitate a change in behaviour. They understood that women's low levels of education posed a significant barrier to understanding the concept of risk and the biological mechanism of potential harm to the foetus. They felt a strong sense of responsibility to ensure that every smoker fully understood the dangers of smoking in pregnancy and to continue in their education efforts, even when women chose not to follow their advice. These midwives were concerned to avoid potential conflict with the pregnant women. For this reason, they preferred encouraging women to reduce the number of cigarettes they smoked, rather than quit altogether. If a woman did not comply with their advice, midwives assumed that their health education had failed in some way, but they were uncertain as to what more they could do.

The *Enthusiastic Friends* understood their role to be to provide pregnant smokers with the relevant information and to encourage them to give up smoking in a supportive way. They defined their responsibility as enabling the woman to make an informed choice and consciously avoided presenting themselves as authoritarian figures. They wished to come across as empathetic and approachable, so that women would feel sufficiently comfortable to interact with them. If they suspected that a woman was concealing her smoking, these midwives would rather coax the woman

into trusting them, than provoke a confrontation. The objective was to create a more informal atmosphere, conducive to communication on a more equal basis.

Midwives' accounts of how pregnant women respond to them

The *Angry Scolders* had the impression that their efforts to encourage women to quit had very little impact. They attributed their lack of success to women's resistance to consider quitting. Midwives reported that women resented them intruding on what they considered a private and personal choice. They recounted how women lied about their smoking, understated their consumption or pretended to agree to quit, in an attempt to avoid answering questions or engaging in a discussion about smoking. These responses left them feeling demoralised and pessimistic that the discussion was worth pursuing. Most of the *Angry Scolders* felt that once they had warned a woman about the potential risks and advised her to quit, they had discharged their duty. The responsibility then lay with the woman to act on their advice, which meant that they were unlikely to follow up. Midwives in the other categories however, despite feeling disheartened, persisted with their smoking cessation efforts out of a sense of duty to protect the innocent, unborn baby.

The *Benign Carers* believed that, generally, women dismissed their advice, because they did not assume personal risk. This was partly because they struggled to fully grasp the concept, but also because they gave greater credence to anecdotal evidence from their peers, that contradicted the scientific information provided by the midwives. One midwife expressed the view that women did not act on their advice because they lacked confidence that they could exert control over their lives. The *Benign Carers* complained about the general passivity of pregnant women in their interactions with them. They stated that they would prefer pregnant women to communicate more openly with them. If women asked questions and raised their concerns, the midwives felt that they would be better able to gauge the women's level of understanding and their responses to their education efforts. One midwife understood that some women were reluctant to discuss smoking because they felt ashamed. She was hesitant about raising the issue because she was concerned it would only make women feel more guilty and stressed.

The *Enthusiastic Friends* were the only midwives who were aware that the manner in which they communicated could be important in determining how women responded to their advice. They understood that pregnant women's reluctance to engage in dialogue about smoking was often a direct response to the authoritarian communication style of midwives. In their view, when lectured or scolded by a midwife, women became passive in an attempt to avoid direct confrontation or they became defensive and argumentative. This, they argued, was counterproductive and harmful to the relationship between patient and provider. They were concerned to set themselves apart from this approach.

Perceived need for training

Whilst some *Angry Scolders* were aware that pregnant women responded negatively to midwives 'scolding' them for smoking, this did not lead them to question their approach or try out alternatives. These midwives felt confident that they were fulfilling their responsibility to educate women about the risks and that the difficulties they experienced in their interactions with women were related to pregnant women's attitudes. They did not, therefore, perceive a need for training in counselling skills in preparation for participation in the proposed intervention.

The *Benign Carers* were less certain than the *Angry Scolders* about whether their approach was adequate. They conceded that they could benefit from training on how to counsel women about smoking cessation and were supportive of the idea of an intervention.

In contrast to both the other types, the *Enthusiastic Friends* reflected critically on the issue of patient-provider communication. They were more confident than the other midwives about engaging women about smoking, because they felt that their patient-centred approach was more conducive to developing a trusting and cooperative relationship with their patients. Midwives in this group were of a younger age than the midwives in the other categories and identified themselves as having had a distinctly different training. In their view, their nursing training had been more 'progressive' than that of older midwives. They saw the authoritarian communication style as being outdated and inappropriate for a modern setting. They thus showed an awareness of the central supposition of the patient-centred counselling approach, whilst being uninformed about Motivational Interviewing in particular. Whilst they were open to being trained in MI methods, they felt that the midwives who would benefit the most from such training were those midwives 'from the old school'. They were enthusiastic about participating in the intervention.

Discussion

In this study, the manner in which the *Angry Scolders* communicated with pregnant women posed a significant barrier to them playing a constructive role in addressing the issue of smoking. Their style of communication conformed to the authoritarian style, which is widely regarded as the traditional form of relationship between health practitioner and patient (Roter & Hall, 1997). They were typically met with resistance, avoidance or passivity from women. This left them feeling angry and frustrated and often resulted in confrontation, with some midwives becoming ever more forceful in an effort to compel women to change their behaviour. Others simply gave up in exasperation. The *Benign Carers* who used a paternalistic, didactic style were also left feeling unsatisfied with their counselling efforts. They continued with their educational activities out of a sense of duty, but also believed that they were making very little difference. Precisely the same negative experiences have

been reported by health care providers elsewhere (Aveyard & West, 2007; Dunkley, 1997; Herzig et al., 2006; Hunt & Pearson, 2001; Rollnick et al., 2002; Ward, 1999).

Patients are generally blamed for these difficulties in communication, often being described by providers as irresponsible or unresponsive when they don't follow advice to quit (Rollnick et al., 2002). On the other hand, it has been argued that patients' responses in such interactions and their compliance with recommendations are, at least in part, associated with the way in which the provider communicates with patients and the social climate he or she establishes in the consultation (Rollnick et al., 2002; Stewart, 2005). The traditional approach is characterised by high provider control, where the provider's role is dominant and the patient's role is passive and dependent. The provider determines the decisions to be made about the course of treatment, or the required behavioural change from a professional point of view, usually without taking the patient's perspective into account (Roter & Hall, 1997). Whereas at one time, patients accepted the provider's authority without question, increasingly, patients desire to be more actively involved in making decisions that affect their health (Guadagnoli & Ward, 1998). It has been found that patients respond most positively to lifestyle related advice from health care providers when they are respectful, show interest and caring and attempt to understand the complexity and burden of the decision from the patients' perspective (Swenson et al., 2004; Taylor et al., 2000; Rollnick et al., 2005). Satisfaction also increases when providers facilitate the expression of patients' ideas, concerns and expectations (Butler et al., 1996). Seminal qualitative studies suggest that when doctors listen, patients begin to trust the relationship; feel better and become more active in their care. They also feel more empowered to mobilise their own resources, which in turn leads to an improvement in physiologic and psychological health status (McWilliam & Brown, 1997). A more interactive relationship can be more rewarding for health care providers too. Reported benefits include: improved relationships, higher satisfaction, better use of time and fewer complaints by patients (Stewart, 2005).

In this context, it is not surprising that, in our study, only the *Enthusiastic Friends*, who used a patient-centred style of communication consonant with Motivational Interviewing, expressed any enthusiasm for the job. They were critical of the prevailing approach to health education and understood women's resistance to be a predictable outcome of the authoritarian style. In their view, patients responded positively when their autonomy was respected and when they were drawn into the conversation in an empathetic, non-judgemental way. They were confident that this approach contributed to developing more trusting and cooperative relationships with their patients, without devaluing their expert role and knowledge. Their approach conformed to what Szasz and Hollender (1976) described as the mutual participation model, where the health practitioner views the patient as an equal participant in an 'adult partnership'.

Several studies on pregnant women's attitudes towards smoking cessation counselling suggest that they are indeed more receptive to a patient-centred approach. In Arborelius and Nyberg's qualitative study (1997), pregnant women rated those midwives who were not authoritarian and who did not rebuke them for smoking as the most helpful. The decisive factors that helped them succeed in reducing their smoking were that the midwife was friendly, did not judge them and consistently followed their progress. They admitted feeling guilty and ashamed about smoking and expressed the desire for midwives to affirm them in their roles as mothers, despite the fact they smoked. Not being made to feel guilty was also important to women in Tappin's study (2000). In another study, women believed that attempting to understand their predicament and relieve them of the pressure of seeing themselves as 'selfish, uncaring or irresponsible mothers' was important in building their self efficacy to make a change (Emmon & Rollnick, 2001). Stott and Pill (1990) found that whilst women thought it was appropriate for health care providers to show concern and advise them about lifestyle issues, they were keen to assert that they ultimately had the right to reject or accept their advice. Their perception of the provider's interest in them as a person and a genuine concern for their welfare, as well as the baby's, was crucial in determining the acceptability of any advice the provider had to offer.

Whilst such research suggests that pregnant women may prefer a patient-centred approach for smoking cessation counselling, what is less clear is whether this approach results in improved quit rates. It also remains to be seen how successfully such an approach can be incorporated into routine antenatal care, where there is generally very little time for counselling.

The few studies that have investigated the use of a patient-centred approach, such as Motivational Interviewing, with pregnant smokers show mixed results, making it difficult, at this stage, to draw any conclusions. A study by Valanis et al. (2001), which used a low intensity MI intervention specifically designed to add no more than a few minutes to routine clinical contacts, was associated with significant improvements in self reported quit rates during pregnancy, but the finding was compromised by not biologically confirming smoking status. A more rigorous New Zealand trial by McLeod et al. (2004) showed that women attending primary maternity clinics, who received a brief, structured, MI intervention from midwives, were significantly more likely to have reduced, stopped smoking or maintained smoking changes than women receiving usual care. However, a UK study by Tappin et al. (2005), in which pregnant smokers received home-based MI sessions from trained midwives failed to show significant improvements in cessation over usual practice. This was despite midwives achieving a high performance rating for MI throughout the study. Furthermore, in a trial by Ershoff et al. (2000), providing MI counselling to pregnant smokers via the telephone did not improve cessation rates over the provision of a self-help booklet, delivered in the context of the

usual brief medical advice by a prenatal care provider. Both trials were rated as high quality in Lumley's review (2007).

Further research is also needed to evaluate whether those midwives who are steeped in the traditional, authoritarian approach, such as our *Angry Scolders*, can adapt to a patient-centred method like MI. Velasquez et al. (2000) recommend that it may be more cost effective to identify a select group of providers who are interested in learning and applying new counselling skills, rather than to train everyone. In our case, these would be the *Enthusiastic Friends* and *Benign Carers*. In their experience of training in-service providers for three different prenatal smoking interventions, they found that there was a cohort of providers who immediately recognised the value of MI and easily incorporated it into their routine practice soon after initial training, while others never fully embraced the MI style. This was despite all providers rating MI as being very helpful in improving their ability and confidence in counselling patients in the training course. However, such findings should perhaps not preclude exposing those providers who are habituated to the traditional counselling approach to an alternative, which they might find considerably more rewarding. They may merely need more ongoing support to enable them to modify their counselling style.

Conclusion

Whilst best practice interventions for smoking cessation are well documented in the literature, there has been little focus on, or description of, *how* health care providers communicate with pregnant women about smoking in these interventions. Attending to the quality of providers' interactions with pregnant women around smoking could be a means of enhancing the effectiveness of such programmes. Using a patient-centred approach, such as MI, holds great potential for improving counselling outcomes by establishing a more positive and constructive social climate in which to discuss smoking, as well as other stigmatised behaviours. MI has been confirmed through research as an effective counselling method in other behavioural domains and in smoking cessation in the general population (Lai et al., 2010; Ruback et al., 2005). However, it is, as yet, unclear as to how antenatal care providers and pregnant smokers respond to an MI approach and whether such interventions can further improve quit rates among pregnant women, over other types of interventions.

MI was incorporated into our smoking cessation intervention by training the midwives and peer counsellors in the MI approach and by adapting the best practice 5As guideline (ACOG,2000) to include key MI principles. This is described in the following chapter, which gives a full description of the intervention's development.

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Chapter 4

The development of the intervention

Application of the Intervention Mapping planning model

The focus of this chapter is a description of how the smoking cessation intervention for pregnant women was designed, using the Intervention Mapping planning model (Bartholomew et al., 2001 & 2006) as a guiding framework.

Introduction

The processes involved in the design of health promotion interventions or programmes are seldom described in any depth in the published literature. This represents a significant gap in the existing knowledge base (Bartholomew, 2001 & 2006; Kok et al., 2004). This situation may be a result of the fact that many health promotion programmes are not adequately planned before they are implemented: often, the determinants of the health problem are not analysed in sufficient depth; objectives are not sufficiently detailed or precise; methods are not theoretically linked and formative research with the intended participants and users of the programme is not carried out (Godin et al., 2007). Furthermore, whilst there is broad acknowledgement among health promotion practitioners that theory is a useful tool in the planning of interventions, its actual application has proved challenging and has been less than optimal (Kok et al., 2004; Michie & Abraham, 2004). For example, in their review of 123 HIV prevention programmes, Godin et al. (2007) identified the lack of theory in the definition of intervention methods and strategies as a major weakness in project development, with decisions in this regard usually being made on the basis of intuition, accepted wisdom or simply because they had a certain popularity at the time.

The health promotion literature provides helpful models for conducting a needs assessment and programme evaluation, and it provides ecological models for conceptualising the multiple levels of health promotion intervention (see **Literature Review (B), Chapter 1**), but it lacks models for practical programme development (Bartholomew et al., 2001, 2006). Intervention Mapping (IM) emerged in response to the need for a coherent framework, which could be used to guide health promotion practitioners in properly considering and integrating the relevant empirical evidence from the literature, behavioural change theory and formative research data collected from the intended target audience in the planning of

interventions. Intervention Mapping is based on the premise that the better a programme is planned and the more grounded it is in theory and evidence, the more likely it is to be effective in attaining its goals (Bartholomew et al., 2001 & 2006; Godin et al., 2007; Green & Kreuter, 2005).

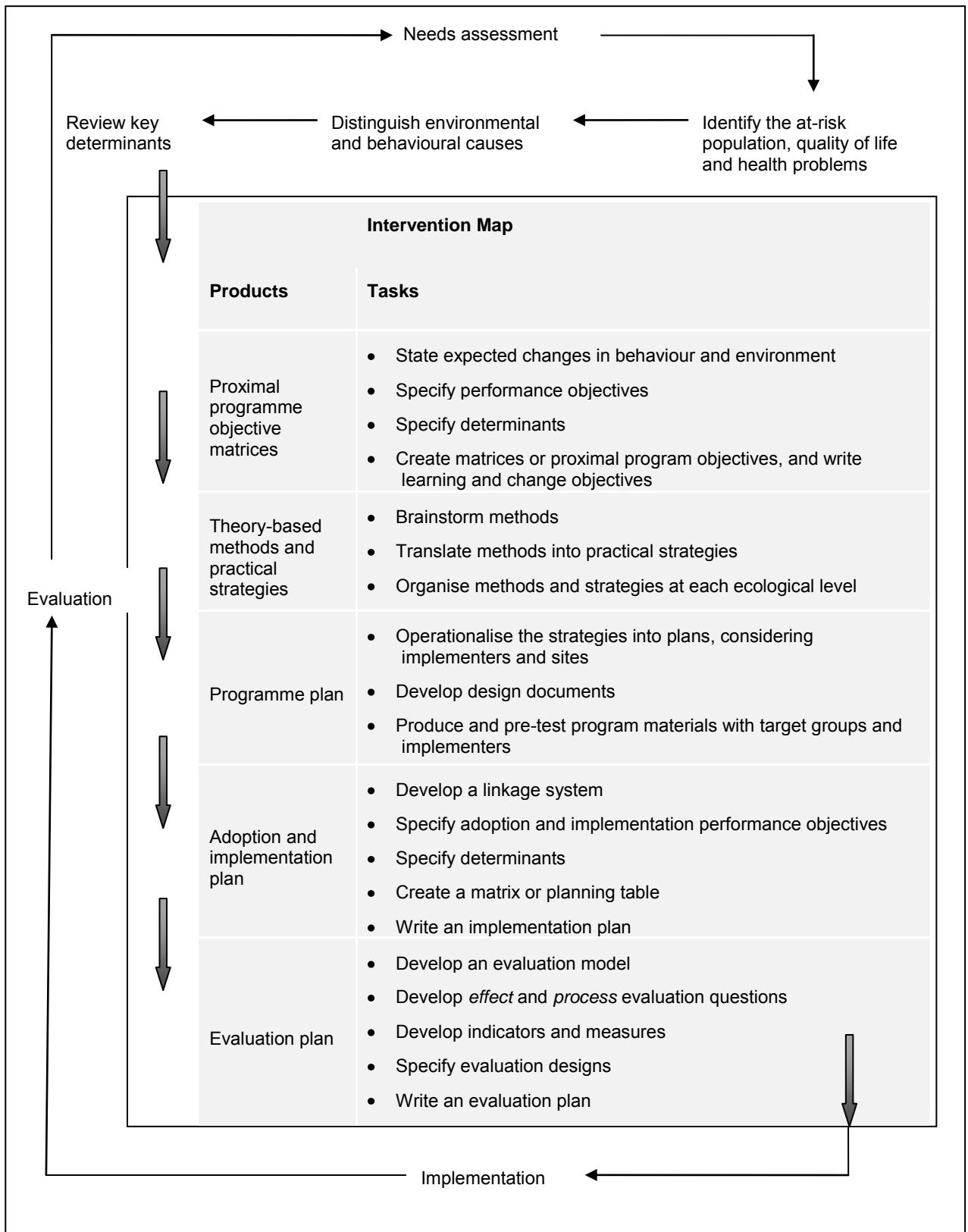
Intervention Mapping has been used to develop a variety of effective health promotion programmes, including ones for asthma management (Shegog et al., 2001); cervical cancer screening (Hou et al., 2004); nutrition (Draper et al., 2010; Perez-Rodrigo et al., 2005; Singh, 2006); HIV prevention (Caron, 2004; Tortolero et al., 2005; Wolfers et al., 2007) and the prevention of obesity (Zapka et al., 2007) and violence (Murray, 1998). It has been used to provide a systematic process to develop new interventions, as well as to adapt existing interventions to new populations in culturally appropriate ways (Tortolero et al., 2005).

There appears to be no evidence yet of how the efficacy or effectiveness of programmes designed using the Intervention Mapping protocol compare directly with that of programmes designed without using this methodology. Thus, the distinct advantages of using this theory-based methodology remain uncertain. To date, it appears that Intervention Mapping has not been used in the planning or adaptation of a smoking cessation programme.

Intervention Mapping proceeds systematically through six key steps: 1) a needs assessment and thorough analysis of the health problem 2) the definition of programme objectives 3) the selection of theory-based methods and practical strategies to realise behavioural change 4) the development of the programme itself 5) the generation of an implementation plan, and 6) the generation of an evaluation plan. Each step requires the completion of specific tasks as outlined in **Figure 1: The Steps of Intervention Mapping**, (Bartholomew et al., 2001). The final product, the Intervention Map, represents the blueprint for the development, implementation and evaluation of the programme.

Intervention Mapping has its historical roots in the PRECEDE-PROCEED model for health promotion planning (Green & Kreuter, 1999). This model is an ecological one, which emphasises the fundamental proposition that health behaviour has multiple determinants and that health promotion requires multi-sectoral and participatory efforts to effect behavioural, environmental, and social change. Green and Kreuter's model focuses on the need for targeted health interventions to have a sound epidemiological rationale and to specify desired outcomes of change at all ecological levels. Intervention Mapping is an elaboration on the programme development phase in this model.

Figure 1: The Steps of Intervention Mapping (Bartholomew et al., 2001)



Intervention Mapping

STEP 1: Needs assessment

Methods

Intervention Mapping begins with a needs assessment, which encompasses a review of the relevant scientific literature and theory, as well as the undertaking of formative research with the intended target community, in order to better understand the health problem from their perspective. In this step, one draws on the process outlined in the PRECEDE-PROCEED model by Green & Kreuter (1999). Data from the needs assessment is then used to identify specific intervention goals in terms of changes in individual health behaviour, quality of life, and social and environmental conditions.

The needs assessment should include a clear description of the health problem and the population at risk; an analysis of the behavioural and environmental risk factors and their determinants (those factors that have been found to be associated with the at-risk behaviours or environmental conditions). In the community assessment component, planners undertake research in order to better understand the community's unique characteristics, its culture and capacity to address its own social and health problems. The authors of Intervention Mapping argue that no matter how many experts are involved in programme development, the individuals for whom the intervention is intended can best convey the meaning of the health problem and its antecedents, and the people who will potentially deliver the programme can best convey the realities of the programme setting.

The analysis of community capacity often focuses on the potential facilitating and impeding factors related to the delivery of a programme (Green & Kreuter, 1999). This type of research can assist planners in identifying key community resources or figures, on which to draw in the implementation and diffusion of programmes in the future and in building strong partnerships between health professionals and various members of the community.

Bartholomew et al. (2001) recommend local, collaborative development of interventions, which are sensitive to the particular needs and experiences of a population in a specific context, rather than the simple transfer of interventions that may have proven effective in a very different setting.

For this project, I reviewed the literature for international, best practice smoking cessation interventions for pregnant women (see **Literature review (A), Chapter 1**); consulted behavioural change theories (see **Literature Review (B), Chapter 1**) and undertook

formative research with our intended target population – pregnant smokers of mixed ethnic descent and poor socio-economic status, attending public sector antenatal clinics. A survey of 797 pregnant women (Petersen et al., 2009a), supplemented by 22 individual interviews (Petersen et al., 2009b; Van Lieshout 2001) established their knowledge, beliefs, attitudes, self-efficacy, perceived social norms, behaviours and intentions with regard to smoking in pregnancy, as well as their perceived barriers to quitting and preferences for a potential intervention.

We also conducted research with the midwives who provide these women with antenatal care, through the public sector Maternal Obstetric Units (MOUs), which are based in their communities. This was necessary, as little was known about current smoking cessation activities in these clinics and the staff's capacity to deliver a programme. One hundred and two midwives were surveyed and 34 were interviewed. These studies investigated midwives' beliefs relating to smoking during pregnancy; their attitudes towards pregnant smokers; their approach to and feelings about, smoking cessation counselling and their perceived barriers to addressing the issue in the context of routine antenatal care (De Feijter, 2003; Everett-Murphy et al. 2010b (see **Chapter 3**); Paijmans, 2003; Van Lieshout, 2001) . A further qualitative study, involving 15 individual interviews, assessed similar issues with doctors and health service functionaries (Everett et al., 2005, see **Appendix**). In addition, these particular interviews served as a means of consulting key gatekeepers, in order to secure access to the clinics and build institutional support for the implementation of the intervention.

Results

Literature Review

The full literature review for this study is presented in **Chapter 1 (A)** of this thesis. The literature review, together with the rationale for the project in **Chapter 2**, serves to give the background to our decision to develop a smoking cessation intervention for pregnant women, and more specifically for disadvantaged, pregnant women of mixed ethnic descent in South Africa.

The literature review clearly identified the elements of best practice smoking cessation interventions for pregnant women. These interventions involve the provision of brief, structured, individual counselling by a trained provider, supplemented by various forms of media. These best practice methods have been derived from and evaluated in North America, Europe and Australasia. My conclusion was that there was a pressing need to adapt

and test best practice methods in middle-to-low income country settings, such as South Africa, and that formative research was necessary in order to inform our choices regarding the specific content and methods of the intervention, who could best deliver it and in what context.

Health Behaviour Change Theory

Intervention Mapping directs planners to consult behaviour change theory, in order to assist them in understanding the role of individual behaviour and its underlying determinants, as well as the role of the social and environmental factors in the causation of an identified health problem. These theories also help intervention planners identify viable psycho-social constructs as possible targets for change.

In **Chapter 1 (B)**, I reviewed the health behaviour theories, which have been the most widely used and tested in the context of health promotion. It was not our intention to confirm the validity of the various constructs of these theories of health behaviour change in predicting intention or behaviour, or to explicate their inter-relationships. Rather, theory was used as a conceptual basis or framework for the development of the research, the intervention and the evaluation.

Fishbein's 'Integrative Model of Behavioural Prediction' (2003) in particular served as a useful conceptual model for the intervention, as it combines constructs from: the Health Belief Model (HBM) (Rosenstock, 1974); the Theory of Reasoned Action (TRA) (Fishbein and Ajzen, 1975); the Theory of Planned Behaviour (TPB) (Ajzen, 1985) and Social Cognitive Theory (SCT) (Bandura, 1986). The hypothesised relationships between the variables in the model is depicted in **Figure 3** of **Chapter 1 (B)**. In summary, according to this model, behaviour is predicted to occur if:

- The person forms a strong positive **intention** or makes a commitment to perform the behaviour;
- There are no **environmental barriers**, which make it impossible to perform the behaviour;
- The person possesses the **skills** necessary to perform the behaviour;
- The person believes that the advantages of performing the behaviour outweigh the disadvantages (**outcomes expectancies or attitude**);
- The person perceives more normative pressure to perform the behaviour than not to perform it (**perceived social norms**);
- The person perceives that she or he has the capabilities to perform the behaviour (**self-efficacy**).

The first three factors are viewed as necessary and sufficient for behaviour to occur, while the remaining three are viewed as modifying variables influencing the strength and direction of intentions (Gielen & Sleet, 2003). These three determinants are all, themselves, functions of underlying beliefs about the outcomes of performing the behaviour, the normative prescriptions of specific referents and specific barriers or facilitators of behavioural performance (Fishbein, 2000, 2003). Appropriate knowledge is a pre-requisite for the formation of attitudes, subjective norms, self efficacy and skills that would predispose or enable someone to take the desired action. Socio-demographic variables are reflected in people's underlying belief structure and are seen to play a primarily indirect role in influencing behaviour.

These theoretical constructs guided and structured the formative research with pregnant women and with health care providers prior to intervention development. The survey instruments and qualitative interview schedules included questions which assessed model constructs (Petersen et al., 2009a & b; 2011; De Feijter, 2003; **Appendix** of this thesis). The qualitative interviews were, however, semi-structured and open-ended, so as to allow respondents to raise salient beliefs and opinions unanticipated by the researchers. Data analysis of both the quantitative and qualitative studies identified specific content for each of the theoretical constructs outlined above. The findings were then used in the detailed preparation of proximal programme objectives, which is the core task of Intervention Mapping. This process (Step 2) is described later on in this chapter.

Social Cognitive Theory (Bandura, 1986) and ecological theories of health promotion (McLeroy et al., 1988; Green & Kreuter, 1999; Sallis & Owen, 2002) were helpful in directing attention in the Needs Assessment to factors external to the individual that may influence smoking behaviour. Environmental factors influencing smoking, or that could potentially influence quitting, were identified at the various ecological levels: the interpersonal; organisational; community and societal (all levels other than the individual are called environmental levels)(Bartholomew, 2001). IM adopts the approach of looking for agents (those individuals or groups who are in influential positions and exercise control over others) at each system level that can be targeted to facilitate change. As with individual behaviour, agent decision making is influenced by personal and external psycho-social variables (Bartholomew, 2001). These environmental factors or conditions and the potential agents of change embedded in the different ecological levels are depicted in **Table 1: Analysis of the Health Problem** (overleaf), along with definitions for the determinants of behavioural

change. Cues to action; social norms; social support and reinforcement and organisational environment or culture are constructs theorised to influence such environmental factors. They might currently function to support the unhealthy behaviour, but through social change strategies, such as community mobilisation, lobbying and advocacy and social marketing they can be marshalled to support the healthy behaviour.

The Transtheoretical Model (TTM) (Prochaska & DiClemente, 1983) and Social Cognitive Theory (Bandura, 1986) were used to identify appropriate intervention methods and strategies in Step 3 of the IM process, which is also described later on in this chapter.

Formative research with the intended target group/s

The programme of research for the formative phase of the Smoking during Pregnancy Project is outlined in the scheme in **Chapter 2**. Formative research can be defined as research conducted prior to programme development, with the intention of improving feasibility, effectiveness and potential sustainability. This kind of research typically uses both quantitative and qualitative research methods to gather data on key constructs identified by theory as determining behaviour change, participants' and stakeholders' views on the problem and their reactions to a potential intervention (Zapke et al., 2007).

The key findings from the formative research conducted for the purposes of developing this smoking cessation intervention are summarised below:

Pregnant women

The first study undertaken as part of the formative research phase was a survey of 709 coloured, pregnant women in 2005 (Petersen et al., 2009a). It confirmed that despite the introduction of national tobacco control measures at a societal level in 1993 and 1997, the smoking rates among this sub-group of women remained alarmingly high: 46% of them continued to smoke, 15% were quitters and 39% had never smoked.

According to the Transtheoretical Model's stages of change (Prochaska and DiClemente, 1983), 28% of current smokers had no intention of quitting (and were thus categorised as being in the pre-contemplation stage of behavioural change). In accordance with other studies (Ussher et al., 2004), the large majority of pregnant women wanted to stop smoking: 36% were in the contemplation stage and 36% were in the preparation stage, implying that they were seriously thinking about quitting or were actively trying to quit, but needed further motivation and support, in order to do so. This was a positive indication that they would be receptive to a smoking cessation intervention and that health care providers should take

advantage of this opportunity to intervene. The 9% of women who had quit in the last six months would also need to be identified for an intervention in order to provide them with ongoing reinforcement to avoid relapse.

Analysis of the survey data showed that significantly more smokers than quitters and non-smokers had low levels of education, unplanned pregnancies, were problem drinkers, were unmarried and had no financial support from the partner. In addition, smokers were less informed of the harmful effects of smoking during pregnancy and were less convinced of the severity of the potential harm. From early qualitative interviews with women, it was clear that women struggled to understand the concept of risk, believed that quitting was difficult to achieve and were anxious about coping with the cravings and side effects (Van Lieshout, 2001). These negative outcome expectations are consistent with the findings of other studies (Rutter & Quine, 1990; Crittenden et al., 1994) and were important considerations for the tailoring of the intervention.

There was a high level of interest in a smoking cessation programme, with 94% of women surveyed reporting positive attitudes towards, and an intention to participate in, such a programme if it were available at the clinic. A clinic based programme was preferred to a community based one. Of the various types of smoking cessation support possible, women rated individual, face-to-face counselling by a health care provider the most highly, which accords with the findings of another study on women's preferences for intervention strategies (Ussher et al., 2004). Over 90% of women gave a clear endorsement for midwives to play a central role in an intervention, implying that they were important social referents. However, the qualitative data (Petersen Z et al., 2009b; Van Lieshout, 2001) indicated that women experienced significant difficulties in communicating with midwives about smoking, with many smokers reporting a reluctance to openly discuss smoking with them, as they expected to be 'scolded', 'lectured' or 'judged as bad mothers'. Women explained that if they felt negatively judged by the midwife, were made to feel guilty or were put under pressure to stop smoking, they would choose to conceal their smoking, or avoid discussing the issue, cut short the consultation or put up arguments against quitting. These findings indicated that, while midwives were expected to play a role with regard to cessation counselling, their current approach was inimical to women engaging with them about the issue or asking for help.

Table 1: Analysis of the health problem: The case of smoking during pregnancy

(PRECEDE model, Green & Kreuter, 1999)

Socio-demographic characteristics	↓	<ul style="list-style-type: none"> • Low socio-economic status • Low levels of education • Of mixed ethnic descent • Single marital status • Unplanned pregnancy
Determinants	↓	<p>Personal:</p> <ul style="list-style-type: none"> • Knowledge • Beliefs • Attitudes • Self efficacy and skills • Subjective norms • Intention <p>External:</p> <ul style="list-style-type: none"> • Cues to action • Social norms • Social support and reinforcement • Supportive organisational environment
Behavioural risk factors	↓	<ul style="list-style-type: none"> • Smoking during pregnancy (46% of target group continue smoking in pregnancy) • Exposure to environmental tobacco smoke (66% exposed to ETS in home) • Associated behavioural factors which confer added risk: 14% used drugs during pregnancy and 52% had used alcohol during pregnancy • Other factors: insufficient nourishment; hypertension; partner violence; stress and depression; lack of social support
Health problem	↓	<p>Adverse pregnancy and birth outcomes:</p> <p>Pregnant woman: increased risk of premature labour; placenta abruption; placenta previa; long term - cancer; heart disease</p> <p>Neonate: increased mortality and morbidity related to low birth weight and premature delivery; SIDS; mother less likely to breastfeed Infant/child: reduced lung function; asthma; learning difficulties</p> <p>Foetus: intrauterine growth restriction; low birth weight; retarded lung development</p> <p>ETS exposure after birth: respiratory problems; otitis media; asthma</p>
Implications for quality of life	↓	<p>Mother:</p> <ul style="list-style-type: none"> • referral and admission to tertiary hospital • increased medical intervention • traumatic emergency delivery procedures • extended care after delivery, causing disruption to work and family life • unanticipated financial costs • stress from feelings of guilt and anxiety • trauma if baby dies • tension and conflict with partner and health care providers <p>Child</p> <ul style="list-style-type: none"> • bonding process compromised • health problems • learning and behavioural problems • increased risk of nicotine addiction and chronic disease in later life

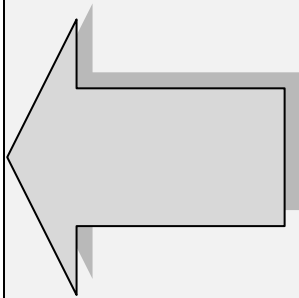
Environmental conditions which increase risk of smoking/decrease chance of quitting

Four ecological levels and influential agents at each level:

Interpersonal level:

- **Potential agents:** partner; family members; peers; colleagues; neighbours; friends
- **Factors related to smoking:** high social acceptability; high levels of smoking in immediate social network; overcrowding in home (exposure to ETS); lack of policies in workplace; lack of social support for quitting; low level of awareness of risk of smoking in pregnancy; poor socio-economic status and associated stressors; troubled or abusive relationship with partner
- **Implications for quality of life:** adverse pregnancy and birth outcomes may disrupt routine family life and place additional strain on relationships in the home; disrupt care of other children; mother's security of employment may be compromised; financial costs of medical intervention and not breastfeeding, impact on family as a whole.

Organisational level: (clinic environment)



- **Potential agents:** obstetricians; midwives; peer counsellors; clinic managers; district managers; Provincial Directorate of Maternal and Child Health; MRC researchers
- **Factors related to smoking:** absence of educational or self-help material; lack of effective and appropriate counselling by health care providers; cessation not afforded high priority in antenatal care; absence of policies and protocols; lack of training opportunities for clinic staff; smoke-free policies at health facilities not adequately enforced
- **Implications for quality of life:** Avoidable complications during pregnancy and delivery, place unnecessary pressure on clinic staff

Community level:

- **Potential agents:** lay health workers; church leaders; community leaders and development workers
- **Factors related to smoking:** high prevalence of smoking in community; high social acceptability; lack of enforcement of tobacco control policies; lack of community-wide campaigns; lack of awareness of risks and access to information; lack of educational, recreational and sporting facilities; lack of social capital; high levels of drug and alcohol abuse; high levels of crime and unemployment; other competing developmental issues and health priorities (HIV, TB, trauma)
- **Implications for quality of life:** community bears burden of preventable morbidity and mortality

Societal level:

- **Potential agents:** legislators and policy-makers, including Minister of Health; National Director General of Health; other health service functionaries; tobacco company executives; journalists and owners of the media; health activists and lobbyists
- **Factors related to smoking:** existing tobacco control laws and policies; availability and pricing of cigarettes; continued tobacco advertising, marketing and promotion; lack of mass media campaigns; political and economic power of tobacco companies; local groups of health activists and lobbyists remain small and under-resourced, but do have the advantage of links with international anti-tobacco lobby; SA government is a signatory to International Framework Convention on Tobacco Control (FCTC)

Implications for quality of life:

- Health services bear increased costs through increased hospital admissions; medical intervention; neonatal care; large proportion of health budget spent on preventable morbidity

Glossary

Behavioural risk factors: what the individuals are doing that causes/increases risk of the problem.

Environmental conditions: the conditions in the social or physical environment, which are related to the health problem directly, or to its behavioural causes and the influential individuals or groups, who have some control over the environment and the factors which contribute to the problem (Social Learning Theory and Ecological models of health promotion).

Personal determinants: these are internal factors, which can be targeted for change. Based on the 'Integrated Model for Behavioural Prediction', which integrates constructs from Health Belief Model, Theory of Reasoned Action/ Planned Behaviour and Social Cognitive Theory (Fishbein, 2003). See Chapter on 'Theories of Behaviour Change' for figure of model).

Knowledge: of the health risks is a pre-requisite for the formation of attitudes, subjective norms, self efficacy and skills.

Attitude: the individual's positive or negative appraisal of, and predisposition towards, performing the behaviour, as a function of underlying **Behavioural Beliefs:** perceived susceptibility (the belief that one is vulnerable to the condition or illness); perceived severity (the belief that the condition has potentially serious health or social consequences); outcome expectations or evaluations (the belief that the recommended course of action would actually be beneficial in reducing one's susceptibility to, or severity of, the condition, weighed against the belief that there are potential negative consequences to performing the recommended behaviour, which act as impediments to taking action).

Subjective norms: perceived social support for behaviour, as a function of **Normative Beliefs:** beliefs about what specific, important others think one should do, weighed by one's motivation to comply with these opinions, and the belief that others in the community are performing (or not performing) the behaviour.

Self efficacy: An estimation of one's capability or competency to carry out recommended action, as a function of **Efficacy Beliefs:** beliefs that one has the necessary knowledge, skills and ability to perform the behaviour, even in the face of various circumstances or barriers that make it difficult.

Skills: having the enabling, behavioural skills to accomplish the desired behaviour.

Attitude, subjective norms and self efficacy are primary determinants of intention or commitment to perform the behaviour. Intention, along with skills and environmental constraints, independently predict behaviour (even if one has formulated a strong intention, one might still not perform the behaviour, because of a lack of skills or the presence of environmental barriers).

External determinants: these are conditions in the environment, which either support, or pose obstacles to, adoption of behaviour.

Cues to action: cues in the social and physical environment, which can act to reinforce unhealthy behaviour or trigger the change process.

Social norms: the prevalent opinions or beliefs of others regarding the behaviour.

Social support and reinforcement: the emotional or practical support received from others for the change in behaviour; recognition and affirmation from others for taking the decision or acting to change behaviour.

Supportive organisational environment: an organisational environment and culture that supports the desired behavioural change. To create this, it is necessary to target agents or influential others in the environment for personal behaviour change; to provide access to resources and training opportunities; undertake social marketing or introduce and enforce appropriate policies and laws (Ecological theories of health promotion).

Socio-demographic variables: these play an indirect role and are reflected in the underlying belief structure; they are therefore less amenable to change through any health promotion intervention.

Midwives

Generally, midwives were positively predisposed to participating in a potential smoking cessation intervention. They were convinced that smoking during pregnancy was an important, preventive health problem and accepted that smoking cessation education/counselling was within their scope of work. The majority of midwives also

believed that their colleagues were of the same view, suggesting positive subjective norms. Both the qualitative (Everett-Murphy et al., 2010a; Pajmans, 2003; Van Lieshout, 2001) and quantitative studies (De Feijter, 2003) confirmed that midwives routinely asked pregnant women about their smoking status when they registered for antenatal care and documented this information on the clinic card. Smokers were usually advised to stop or reduce smoking. The survey established that midwives spend an average of 6.5 minutes, out of a total of 29 minutes discussing smoking during the first booking visit.

However, as was described in **Chapter 3**, it was clear that midwives did not systematically and effectively address the issue. A lack of access to best practice guidelines, insufficient scientific knowledge and a lack of training in communication or counselling skills, were all important organisational barriers. There were also no educational resources or aids available to assist them in their efforts. The belief that they could exert little influence on the smoking behaviour of disadvantaged women, who face multiple barriers to achieving health-enhancing behaviour, was an important component of midwives' negative outcome expectations related to cessation counselling. They attributed their lack of success to women's resistance to quitting, rather than to their practice or communication style. This resistance was understood to be associated with women's stressful life circumstances, their limited education and a selfish, irresponsible attitude to motherhood. Women's lack of compliance with midwives' advice affected their motivation to address the issue and left them feeling frustrated and despondent. The difficulty experienced by midwives in their communication with pregnant women about smoking was more fully explored in **Chapter 3**.

Other perceived impediments to providing smoking cessation interventions included a lack of institutional support and educational resources, as well as too little time available for health education due to acute staff shortages. Precisely the same reasons have been given by health care providers in other countries for not taking up the smoking issue (Cooke et al., 2001; Pullon et al., 2004; Whyte et al., 2006). However, despite these difficulties, midwives remained troubled about the issue and felt that it should be afforded greater priority (implying they felt a strong motivation to comply with social norms prescribed by their profession).

Doctors and health service functionaries

The formative qualitative research with doctors working in the public sector antenatal services (Everett et al., 2005)(see **Appendix**) showed that they were not routinely addressing the issue of smoking during pregnancy, despite acknowledging that smoking was implicated

in the most common adverse pregnancy outcomes. They too were unaware of clinical guidelines or best practice methods. However, most doctors had positive attitudes to cessation counselling: they were concerned to improve their communication with pregnant women about smoking and were open to adopting new approaches or tools that could assist them. The perceived organisational barriers to providing smoking cessation interventions were similar to those of the midwives, with lack of time due to other pressing priorities, like HIV infection during pregnancy, being the main concern. At the level of the clinics (the proposed intervention site), they played a clinical, supervisory role to the midwives and rotated through the clinic only on certain specified days. Their consultations with pregnant women were very pressured for time.

The interviews with selected health service managers (the hospital superintendent; clinic and facility managers, director of Maternal and Child Health in the national and provincial Departments of Health)(Everett et al., 2005) confirmed that the state health services did not have any policies, programmes, educational or training materials that addressed smoking during pregnancy. Routinely collected data from antenatal clinics under their authority had identified high rates of low birth weight, spontaneous preterm labour and intrauterine growth restriction. Internal reports had cited smoking as one of the important preventable factors (MRC, 2002). The proposed intervention was well received and seen to be in alignment with the national tobacco control policy.

Scope of the intervention

The formative research was valuable in informing our decisions about the scope and complexity of the intervention. These decisions were based on the potential facilitating and impeding factors related to the implementation of the intervention in the real situation, including what was feasible, given available funding and personnel resources; the significant work pressure on midwives in public sector clinics, and the genesis of the project as an initiative by clinicians at Tygerberg hospital and our ongoing partnership with them.

It was decided to limit the intervention to the antenatal clinic setting and to specify certain outcomes at the ecological levels of the individual, interpersonal, organisational and community. Identified targets for change were 1) the pregnant woman herself at the intrapersonal level 2) the woman's partner and family members at the interpersonal level 3) midwives, health service managers and supervising clinicians at the organisational level 4) local leaders at the community level. The recruitment and training of the peer counsellors

could be represented at both the organisational level, in their role as lay health care providers, and at the level of the community, as they themselves were members of the target community. They could, through their own social networks, influence social norms outside of their role at the clinic.

At a societal level, the programme was supported by national tobacco control legislation, which bans smoking in public places (including the health services), prohibits tobacco advertising and sponsorship and requires health warnings on cigarette packets, including one directed at pregnant women. Taxes on tobacco are also increased every year in South Africa, in line with the WHO International Framework Convention recommendations. The legislation banning smoking in public facilities still requires more vigorous enforcement and there is no ongoing mass media campaign to support the legislation, however, it was decided that these activities were beyond the scope of this intervention (with the exception of the clinic environment at the intervention site).

Four typical, public sector antenatal clinics, which referred to Tygerberg Hospital, were selected for the intervention. These clinics were situated in communities of our identified high risk target population.

In summary, the formative research indicated that our intervention should address women's needs for education, motivation and social support. In addition, it was critical that the organisational/social environment of the antenatal clinic become more conducive to women willingly engaging with health care providers about smoking. This primarily entailed a change in the attitudes and practices of midwives. It was feasible for doctors to only play a supportive role. The intervention also required the full support and commitment from clinic management and the Department of Health.

STEP 2: Defining programme objectives

Methods

A thorough needs assessment provides the planner with an understanding of the problem and its behavioural and environmental determinants, but it lacks the specificity needed to guide the design of the intervention itself. In IM, the basic tool to do this is the *matrix of proximal programme objectives*. These matrices provide clear statements of what needs to be changed by a programme, by specifying what individuals need to learn and what must be changed in the organisational or social environment to achieve the intended behavioural

outcomes. Once these matrices are complete, they provide the foundation for the conceptualisation of the intervention components and the evaluation of the programme.

Results

The first task was to define *programme outcomes*. The overall, **programme goal** was to reduce the high rates of poor pregnancy and birth outcomes associated with smoking among disadvantaged, pregnant women of mixed descent.

The planned behavioural outcomes for the programme follow: (outcomes 1 and 3 were the main focus of the intervention, whereas 2 and 4 were addressed in a very limited way).

- **Intrapersonal/individual behavioural outcomes:** for pregnant women to quit smoking; reduce smoking; avoid relapse.
- **Interpersonal behavioural outcomes:** for partners of pregnant women to support the pregnant woman in her effort to quit or reduce smoking and reduce her exposure and the baby's to environmental tobacco smoke (ETS).
- **Organisational outcomes:** for midwives and peer counsellors in the clinic to provide effective, best practice smoking cessation education and counselling to pregnant women; for clinic managers, supervising clinicians and health service management to support the midwives in this role and promote and sustain the smoking cessation intervention for pregnant women, as a standard of good antenatal care.
- **Community outcomes:** for members of the community in which the pregnant women lived, to support them in their efforts to quit or reduce smoking and to reduce exposure of the pregnant woman and baby to ETS.

The next task was to specify *performance objectives*. In Intervention Mapping, broadly formulated outcomes, such as 'to quit smoking', are not sufficiently detailed for planning an intervention. Planners need to specify exactly what 'sub-behaviours' they want the target group (or agents in the environment) to do as a result of the intervention.

It was decided that for the behavioural outcome: 'To quit smoking', the discrete actions required of a woman that would enable her to quit would be to:

1. Make a decision to quit;
2. Seek social support for quitting;
3. Prepare to quit;
4. Move from preparation to action stage of behavioural change;
5. Prevent/avoid relapse;
6. Protect the baby from environmental tobacco smoke while pregnant, as well as after delivery.

Using Nicotine Replacement Therapy was not included, as one of the performance objectives as its safety has not yet been sufficiently established during pregnancy. Current guidelines cautiously recommend that NRT be considered only when intensive counselling has failed (ACOG, 2000; Lumley et al., 2009).

For the behavioural outcome: ‘To adopt best practice procedures for brief smoking cessation counselling’, the specific actions we wanted health care providers (midwives, nurses or peer counsellors) to take were based on the ACOG 5As Guideline (2000, 2005):

1. To ask about and document smoking status on registration for antenatal care;
2. To initiate discussion about smoking in a non-judgemental and supportive manner;
3. To assess woman’s stage of change and tailor intervention accordingly;
4. To assist those women who want to quit;
5. To follow up to monitor progress and reinforce change throughout pregnancy;
6. And, additionally, to desist from smoking themselves or accepting anyone smoking on clinic premises.

The next task was to create the Intervention Mapping *matrices* for each *performance objective*. These are tables formed by entering the performance objectives on the left side of the table and the selected behavioural determinants (internal cognitive or affective aspects theorised to influence behaviour) or the environmental determinants (those factors external to the individual which impact on behaviour) along the top. *Learning* and *change objectives* are entered into the cells formed at the intersection of each performance objective and each determinant. These specify in detail what individuals need to learn (learning objectives) or what must be changed in the social environment and who must act to make the change (change objectives) in order to accomplish the performance objective. The matrices represent the pathways for the most immediate changes in behaviour or environmental conditions to occur.

The table, overleaf, contains an example of learning and change objectives for pregnant women. The full set of **Matrices of Proximal Behavioural Objectives** for pregnant women, partners and antenatal care providers, be they midwives or peer counsellors, is available at the end of this chapter.

Table 2: Example of Matrices of Proximal Behavioural Objectives

A: PREGNANT WOMEN: Behavioural objective or health promotion goal: to quit smoking

1) *Performance objective: Make a decision to quit*

Personal Determinants				
Knowledge	Beliefs	Attitudes	Self efficacy/ Perceived behavioural control	Subjective norms
Acquires full, detailed information on risks of smoking to foetus, pregnancy and herself	Assumes personal susceptibility to risk	Feels optimistic about making a decision to quit	Confident that she is capable of quitting, believes she can control this aspect of her life	Believes significant others approve of quitting during pregnancy
Understands physiological mechanism of harm to foetus	Believes potential harm could be serious	Feels responsibility for and concern about baby's health and own health	Believes quitting is possible (that it's not too difficult and many pregnant women have succeeded)	Is motivated to comply with the expectations of significant others
Understands the magnitude of the potential harm	Believes that quitting at any time in the pregnancy is beneficial and worthwhile	Places high value on baby's and own health	Confident can overcome addiction	Believes other pregnant women are also making the decision to quit
Understands risk concept (can dispel anecdotal accounts of no harm)	Stops denying that smoking can harm the unborn baby	Experiences negative emotions (concern or worry) about continued smoking		
Understands the full implications of having a low birth weight baby	Believes quitting is effective in preventing harm (outcome expectations)			
Understands the possible impact of an affected baby on her quality of life	Believes benefits of quitting will outweigh the personal costs or barriers (outcome expectations)			
Understands that smoking can adversely affect the delivery				
External Determinants				
Interpersonal Social Support	Social norms	Supportive organisational environment	Cues to action	
Significant others express support for quitting decision (partner, family members, peers, health care (HC) providers)	Significant others express approval of decision to quit Many other pregnant women have also decided to quit Significant others expect pregnant woman to quit	Smoking cessation programme available at clinic or in community	Educational media about smoking in pregnancy prompts decision HC provider raises issue of smoking when registering for antenatal care Counselling from HC provider at every antenatal visit Partner, peer or family member suggest that pregnant woman gives up smoking HC provider identifies a problem related to smoking in pregnancy and gives feedback to pregnant woman	

A separate matrix is constructed for each ecological level of the intervention. In our project, matrices were developed for pregnant smokers; partners and health care providers. Separate matrices can also be developed for different sub-groups within the target group, the rationale being that any population is made up of individuals who may have different needs or characteristics. For example, in this case, matrices could have been developed for women in the different stages of behavioural change or different archetypes of midwives as indicated by the findings of our formative research. The result of differentiation may be a separate programme for different groups or a single programme with components, methods and strategies, which can accommodate differences within a group. Although these considerations were important in influencing my selection of specific methods and strategies (see following step of Intervention Mapping process), I chose not to further differentiate the target groups of pregnant women and midwives during the step of matrix development. I decided that this would be repetitive and result in an overwhelming amount of detail.

STEP 3: Selecting theory based programme methods and practical strategies

Once the matrices have been compiled, the health promotion planner is then required to identify the methods that may be effective in accomplishing the specified proximal objectives and decide on practical strategies to put these methods into action.

A method is a theory-based technique, which is postulated to influence changes in the determinants of behaviour or in environmental conditions. For example, for the learning objective of increasing self efficacy, the method of modelling may be used. A strategy is a way of organising and operationalising such methods into a programme activity. Examples of strategies for modelling would be role plays, videos or testimonials in print media. Theoretical methods can often be applicable to a variety of strategies, which use different forms of media or channels to communicate health promotion messages. These planned activities make up the components of the intervention.

I drew up an inventory of possible methods and strategies to address the proximal performance objectives. I drew mainly from Social Cognitive Theory (Bandura, 1986), as well as the Transtheoretical Model (Prochaska & DiClemente, 1983) as these offered the most valuable information about theory-based methods. Certain methods and strategies were then decided on, depending on their appropriateness to our given context and target audience. The inventory was initially used as a menu to select from in the design and organisation of the programme. Later, once the programme had been developed, the inventory was used again in order to critically review its content and activities and to check that most of the recommended methods had been used. This is a different approach to that of the Intervention Mapping protocol, which requires creating a table

linking every proximal programme objective (learning and change objectives) to its appropriate method and strategies.

Results

Programme methods

Fundamental to our intervention were the following theory-based methods:

Social Support: defined as ‘aid and assistance, which is intended to be helpful, exchanged through social relationships and interpersonal transactions’ (Heaney & Israel, 1997, p. 181). Social support has been linked to improved health status in a number of studies. The mechanisms underlying the epidemiological findings have been hypothesised to include modelling and reinforcement of the desired behaviour, buffering the effects of stress on health and facilitating access to resources to cope with stress (Israel & Schurman, 1990). Social support was provided to pregnant women in our intervention through counselling by the midwives and peer counsellors. They were directed to provide the various forms of social support theorised to be important in enhancing health and self efficacy, i.e. informational (giving advice and information); emotional (the expression of caring and empathy); instrumental (tangible practical support with quitting) and appraisal (constructive feedback on follow up and affirmation of progress)(Israel & Schurman, 1990).

Persuasive Communication: as described by McGuire (1984). These are various basic methods that help ensure that a programme secures the attention of the audience and their comprehension, processing and integration of information. For example, in media development it is important to use simple, accessible language, appealing images, break down complex information into manageable chunks and frame messages in such a way that they are not too discrepant from the reader’s world view. Persuasive communication also aims to influence intra-individual processes relating to self-concept and perceptions of the value, desirability and feasibility of the desired behaviour. This idea is similar to Gebhardt and Maes’s (2001) notion that behaviour change can be initiated by introducing compatibility between the desired behaviour and an individual’s personal values and life goals. For example, by subtly linking quitting with the values the target audience associates with being a ‘good mother’ in a non-coercive way.

Tailoring: is when a programme is developed with reference to the known knowledge, beliefs, attitudes, self efficacy and prior experience of the specific target audience and messages are framed within the context of their lives, in order to enhance the perceived relevance and internalisation of the messages (Prochaska & DiClemente,1983; Witte, 1995).

Individualisation: involves the provision of opportunities for programme participants to have their personal questions answered and the sequence or pace of information transfer to be adapted to their

particular needs or personal progress with behavioural change (Prochaska & DiClemente, 1983; Mullen et al., 1992). For example, the content of counselling or education might need to be adapted to suit the specific, expressed needs of a person at a particular point along the change continuum (Prochaska & DiClemente, 1983).

Patient-centred communication: an approach which encourages the active engagement of a patient in the health care consultation and emphasises the importance of respecting the patient's perspective and autonomy in decision making (Rollnick et al., 2002). This was particularly important as one of the key findings which emerged from the formative research was that health care providers needed to change the way they communicated about smoking with pregnant women. As described in **Chapter 3**, the prevailing approach was one in which pregnant women were expected to be passive recipients of the midwives' professional advice and authoritarian prescriptions. When it came to smoking, this was, invariably, ineffective and counter-productive. It was hypothesised that if midwives could be trained to adopt a more patient-centred counselling method, they would be more likely to elicit a positive response from women, which would in turn, lessen their frustration and make their counselling efforts more rewarding.

Patient-centred communication is the foundation on which the counselling method of Motivational Interviewing (MI) (Rollnick, 2002) is based. This method was discussed in greater detail in the previous chapter (**Chapter 3**) and in the Literature review (**Chapter 1 (A)**). Motivational Interviewing clearly incorporates a number of methods suggested by the behaviour change theories reviewed in **Chapter 1 (B)**. For example, it emphasises the importance of assessing stage of behaviour change and tailoring the content of counselling accordingly, as in the Transtheoretical Model (Prochaska & DiClemente, 1983). Central to MI is also the notion of 'decisional balancing', which is an important construct in all the theories reviewed in **Chapter 1 (B)**. This is the idea that weighing up the pros and cons of changing behaviour or evaluating potential outcomes is an essential part of the behavioural change process. In addition, through the strategy of exploring ambivalence, MI aims to stimulate a process of self-reflection and re-evaluation, with a view to clarifying personal goals and values and creating emotional dissonance (when there is a perceived discrepancy between important values and the current behaviour). This is similar to the methods proposed for changing attitudes by Goal Theory (Gebhart & Maes, 2001) and the Transtheoretical Model (Prochaska & DiClemente, 1983). A further important concept in MI, and something which is critical to developing a genuine rapport with the person being counselled, is a recognition that individuals may vary in the value they place on their health, compared to other competing personal goals or other kinds of threats and life responsibilities which vie for their attention (Wienstein, 1988). An empathetic acknowledgement of this was of particular importance for our target group of disadvantaged pregnant women, if they were to develop more favourable attitudes to quitting.

Table 3, at the end of this chapter, presents the theory-based methods, their definitions and their accompanying strategies selected for the smoking cessation intervention. These included, for example, the methods of self-re-evaluation, values clarification and emotional arousal for changing beliefs and attitudes; and modelling, goal setting and skills training for changing self efficacy.

Programme strategies

In our formative research, individual counselling by a midwife was rated as the first choice of strategy by pregnant women, as it could be tailored to their individual circumstances and need for information. Women also rated group counselling positively. However, this strategy was impractical for our programme, due to an acute shortage of space and staff in the clinics. Furthermore, whilst individual counselling by a trained health care provider has been found to be effective in numerous studies, where groups have been used, they have been poorly attended and are therefore not recommended (Lumley et al., 2009).

Consistent with best practice, the core strategy in our programme was the provision of individual behavioural counselling by a trained health care provider, based on the 5As Best Practice Guideline for brief cessation counselling (ACOG, 2000, 2005). The rationale for each step and the behavioural change methods intrinsic to them are detailed in **Table 4: Adapted Procedures for brief smoking cessation counselling for pregnant women**, on the following page. While more intensive counselling might have had greater impact, the 5As Guideline was a feasible option for integration into the antenatal clinic environment, as it can be effectively delivered in as little as seven minutes. The 5As had the additional benefits of being simple to teach, easy for health care providers to remember and readily adaptable to delivery by a midwife or peer counsellor. Demonstrating or modelling this in training helped overcome the midwives' perception that the provision of behavioural change counselling was very time consuming and difficult.

The importance of *how* the 5As should be delivered did not receive attention in the protocol (ACOG, 2000). In order to assist health care providers to use a more patient-centred approach when delivering the guideline, I decided to integrate certain key principles of Motivational Interviewing (Rollnick, 2002) into each of its five steps and emphasise the importance of these in the training.

Table 4, on the next page, shows the original formulation of the 5As protocol and my additions/adaptations in grey scale, with explanations. To my knowledge, this kind of adaptation has not been done before.

Table 4: Adapted Procedures for brief smoking cessation counselling for pregnant women' (American College of Obstetricians & Gynecologists, 2005)

Note: My additions to the original 5As guideline are shown in the shaded text areas. Below each step, the rationale and the methods implicit in the procedure are described (I acknowledge an article by the *USPSTF (2002) as a source for some of these points. Further, I have included an explanation of how I applied specific methods of patient-centred communication, drawn from Motivational Interviewing, to the 5As protocol.

*Whitlock E., Orleans CT., Pender N., Allan J (2002). Evaluating primary care behavioural counselling interventions: An evidence-based approach. A Review. *American Journal of Preventive Medicine*. 22 (4): 267-284.

STEP 1: ASK: 1 minute (Midwife)

1. Ask about and document smoking status and cigarettes per day (cpd) on clinic card:

- A Never smoker
- B Quit before pregnancy
- C Quit since pregnant
- D Smoker: same cpd
- E Smoker: reduced cpd

Response A, B, C: Congratulate her on staying a non-smoker or having quit. Review benefits of not smoking.

Enquire if quitter is experiencing any problems with maintaining abstinence. Refer woman to peer counsellor for continued support. Mention risks of exposure to Environmental Tobacco Smoke. Offer Quit Newspaper to reinforce decision.

Response D, E: Document smoking status on card. Ask women what she knows about the risks of smoking during pregnancy in non-threatening manner. Respectfully affirm what she knows and request permission to provide further information on the risks of smoking during pregnancy. Provide the information in a neutral manner. Then go on to next step, *ADVISE*:

Rationale and methods: Step 1 in the guideline prompts the health care provider to ask about and document smoking status, making risk assessment proactive and routine. Using the multiple choice method improves disclosure compared to asking the simple question: Do you smoke or not? The choice of non-smokers and quitters is positively reinforced. The offer to quitters of continued support from the peer counsellor, information about ETS and the motivational Quit newspaper represent additions to the original protocol. Step 1 uses the methods of consciousness-raising to prompt risk appraisal and anticipated regret and information is tailored to the woman's existing level of knowledge.

Application of MI: Instead of assuming ignorance and foisting information and advice on a pregnant smoker, it is suggested that the midwife starts engaging the woman in a discussion about smoking by asking her what she already knows. By acknowledging that the women might already have some understanding of the risks and by building on what she already knows, the midwife immediately communicates regard for the woman as an equal. This is further reinforced when she asks for permission to provide further information and gives an explanation of the risks in a neutral manner – avoiding using a moralistic tone or fear tactics. This simple change in approach helps establish a non-threatening climate in which to discuss smoking and facilitates co-operation between the health care provider and pregnant woman from the outset of the consultation.

STEP 2: ADVISE: 1 minute+ (Midwife)

1. Give clear, strong and personalised advice to quit: For example, '*As your midwife, I need to say that quitting smoking is the most important thing you can do to protect your pregnancy, your baby's development and your own health.*' If there is already a tobacco related problem with the pregnancy, clearly link tobacco use to the problem

2. Ask how she feels about the information and advice provided, rather than tell her she *must* quit.

3. Offer support and assistance, but respect her decision: '*If you would like to seriously consider quitting, the clinic staff and I can help you.*'

Rationale and methods: Health care provider advice establishes behavioural issues as an important aspect of antenatal health care and is a uniquely influential catalyst for behaviour change. Such advice is the most powerful when personalised by specifically linking the behaviour change to the woman's concerns about the pregnancy, results from a scan or other form of examination or past experiences. Adding an expression of social support immediately after providing advice ('if you want to consider quitting ...') builds confidence and motivation.

Application of MI: Asking how the pregnant woman feels about the information and advice allows the woman to assess its personal relevance and helps elicit 'change talk' (statements of intention to change that come from the patient or client rather than the health care provider). It prompts active listening on the part of the midwife so

that she might understand the woman's perspective and helps her identify the most promising avenue for further discussion in the following steps. Well delivered advice supports the patient's self determination. Using minor qualifications such as, 'As your midwife, I feel I have a responsibility to advise you ...', for an advice message, rather than telling someone that they 'should' or 'must' quit smoking conveys respect for a patient's autonomy and can help avoid provoking resistance.

Offering support if the woman chooses to quit, re-defines the health care provider's role from that of someone who dictates change towards a health goal, to someone who can assist in achieving a health goal, if and when one feels ready to attempt the change. This type of open-ended exchange can successfully engage even the most minimally interested patient in a non-threatening way.

STEP 3: ASSESS: 2 minutes+ (Midwife and peer counsellor)

1. Ask whether pregnant woman is willing to make a quit attempt at this time.
2. Communicate caring and concern for the unborn baby, as well as for the woman's health and well being.
3. Offer opportunity for further discussion with and assistance from peer counsellor and make the referral.

If response is "No":

Ask about and acknowledge woman's concerns re quitting with empathy, whilst avoiding any arguments. Request that she considers quitting and offer help if she comes to a decision to quit in the future. Inform her of your continued availability at the clinic. Request permission to give woman Quit Newspaper to enhance motivation.

If response is "Yes": Go on to Step 4 and 5.

Rationale and methods: In Step 3, the provider assesses the woman's 'stage of change'. It is helpful to have established how the patient felt about the advice in the previous step, in order to assess whether they feel that change is personally important or not and how confident they feel about their ability to make a change. Here the patient and health care provider negotiate whether behavioural change is to be considered or undertaken. If there is agreement that change is warranted, the health care provider works collaboratively with the patient in the next step to identify various options for change and to define behaviour change goals.

If a patient expresses a reluctance to consider change, it is important not to pressurise him/her, but to suggest that they take time to think about it and to emphasise that help is available when they feel able to make a decision. Urging the woman to seriously consider quitting and expressing concern about her health and the baby's emphasises the gravity of the risk of continuing to smoke and reinforces the social norm which supports quitting. The Quit newspaper was designed to employ further strategies to stimulate self re-evaluation, enhance motivation and self efficacy for women in the pre-contemplation or contemplation stage of change.

Application of MI: The decision to change is clearly handed over to the pregnant woman. This gives the patient a greater sense of personal control and also means that any decisions that are made are more likely to be both realistic and congruent with their values. Asking about her concerns about quitting, helps her identify and reflect on the pros and cons of change and her feelings of ambivalence about change. It also enhances the health care provider's understanding of the barriers to behavioural change. Accepting that there may be valid reasons for why a woman is reluctant to quit or apprehensive about change, helps the health care provider avoid provoking a defensive response and getting involved in unconstructive arguments. In this moment, the midwife 'comes alongside the woman', rather than sets herself up in opposition to her. Nevertheless, she directs the woman to seriously consider change and reiterates the availability of support. Material is distributed only with the woman's consent. In this way each step of the process is negotiated in a respectful and cooperative manner.

STEP 4: ASSIST: 5 minutes+ (Peer counsellor)

1. Offer 7 day self-help Quit Guide and express confidence that use of Guide will help.
2. Communicate belief that woman *can* quit, that it is often easier than anticipated, many smokers have succeeded.
3. Prompt woman to set a quit date (preferably within 2 weeks) and to read through the Guide in preparation.
4. Prompt woman to think of someone who could support her during this time. Suggest woman should encourage partner or family members who smoke to quit or not smoke in her presence. Offer newspaper leaflet for partners and family members as aid to enlist support.

Rational and methods: If a patient is not ready to attempt change, the health care provider omits this step and goes straight on to Step 5. For those ready to change, the health care provider offers practical counselling in this step. This includes teaching patients problem-solving, self management and coping skills to help them substitute problem behaviours and tackle environmental and physiologic barriers to change. This step also includes prompting the patient to seek social support in their immediate social environment, referral to Quitlines and other community based resources if available and the provision of self-help materials. An added element in our intervention was reframing negative outcome expectations and strongly reinforcing positive ones. In our setting, it was necessary to for the peer counsellors to do most of the counselling required in this step as the midwives had too little time. The peer counsellors distributed the Quit Guide and Quit newspaper for women to

give to family members and/or partners and assisted women engage appropriately with these materials. They also promoted the Cancer Association's free Quit Line. No other community resources were available.

Application of MI: An important means of building motivation is to express the belief in a patient's capacity to change and in their ability to work out how best to go about making the change and overcoming obstacles. In this approach, the health care provider recognises that most people choose to change, not when they are pressurised to change, but when they themselves link the desired change to important personal values, have positive outcome expectations and feel sufficiently confident that they can achieve change.

STEP 5: ARRANGE: 2 minutes+ (Peer counsellor)

1. Document decisions made and materials given on clinic card, add reminder to discuss progress during next antenatal visit and inform woman of intention to follow up.
2. Schedule follow up contact.
3. Reiterate your availability and clinic staff's commitment to provide further information and support during quit process.
4. If any decision to change has been made, no matter how small, congratulate her and wish her good luck !

Rationale and methods: Behavioural risks are chronic problems which change over time, which makes some form of routine follow up assessment and support necessary. Furthermore, simply notifying a patient that follow up is going to occur seems to be a powerful motivating factor, communicating that behavioural change is important, that ongoing assistance is available and that the health care provider cares about the patient. In our intervention, the midwife scheduled the regular clinic follow up visit. The peer counsellors scheduled further visits where necessary (these were often scheduled to occur shortly after a quit date that had been agreed upon). They also phoned women who needed support between visits. Such follow up contact provided them with an opportunity to sustain motivation, assess progress and reinforce behavioural change maintenance and relapse prevention. During follow up visits, the midwives and peer counsellors were directed to simply repeat the 5As, taking into account the patient's change efforts, experiences and current perspective. Step 5 also involves referring patients for more intensive treatments or support if the provider deemed the brief 5 As intervention to be insufficient. In our case, the peer counsellors often referred women on to the local social worker or mental health nurse in consultation with the midwife.

Application of MI: Follow up and tailoring the intervention according to progress and state of readiness is integral to MI and the approach advocated in the 'Stages of Change' theory. Behavioural change is understood as a cyclical process, rather than a linear one. It often involves relapse and further change attempts, which require a review and adjustment of the initial behavioural change plan. Encouragement and positive affirmation of any progress towards change is important in sustaining motivation.

The formative research showed an urgent need, on the part of both midwives and pregnant women, for detailed information on the risks of smoking in pregnancy, the mechanism of harm and on practical behavioural strategies to prepare for, and sustain, quitting. Videos and TV programmes were the most preferred medium for health information, but none of the clinics had a video machine or a suitable place for viewing videos. A mass media campaign was outside the scope and budget of our project. Print media was acceptable to women and midwives, if visually appealing, written in simple, accessible language and of 'high quality'. The usual format of Department of Health pamphlets (small, Z-folded with small drawings and scant information) was not considered of adequate quality. Pamphlets such as these were rated the least positively of all intervention options. However, midwives thought that using print media had several advantages over audiovisual media in a potential intervention: women would be able to take information home to use as an ongoing resource, could use it to gain the support of family and friends and could pass it on to others. However, they emphasised that given the low levels of education in this population, it was going to be imperative that the media be mediated by a health care provider during the consultation. The

midwives also felt that they themselves needed more accurate and updated scientific information, in order to lend their advice to stop smoking greater credibility and authority.

Women suggested including graphic images of the harm caused by smoking during pregnancy in the materials, as they believed fear arousal to be an effective method in increasing perception of risk. The strategy of using true-to-life testimonials of women whose babies had been adversely affected by smoking during pregnancy, which is recommended in the theory as a strategy for modelling, was suggested by both women and midwives.

From the Stages of Change theory (Prochaska & DiClemente, 1983) I had learnt that women in different stages of change may require different forms of intervention. For, example, someone in the preparation phase would be ready to acquire practical quitting skills, whereas a woman in the contemplation phase would need more persuasion as to the benefits of quitting (positive outcome expectations) and confidence building in overcoming obstacles (self-efficacy). Interviews in the formative phase of the research suggested that midwives' failure to consider individual needs relating to their degree of readiness to change could have partly accounted for pregnant women's resistance to their advice (Van Lieshout, 2001). It appeared important that this theoretical construct was made integral to our intervention. The 5As Guideline includes a step which prompts the health care provider to assess the pregnant women's stage of change and adapt the content of the counselling accordingly.

An important aspect of the fourth step in the 5As (Assist) is to offer educational and motivational materials. These can provide the pregnant woman with more detailed information, which the healthcare provider does not have the time to impart and can teach the problem solving and coping skills required to make and maintain a change in behaviour. As mentioned in the literature review, such materials are considerably more effective when provided to the patient in the context of counselling, rather than when they are distributed on their own. In the consultation, the health care provider can verbally reinforce the main messages, can direct the patient to the information or materials most relevant to their individual 'stage of change' and can use the materials as an aid to actively engage the patient in discussion of the process of behavioural change.

I designed three different types of print media for pregnant women, which were tailored to different stages of behavioural change (the **Appendix** contains the three items of media).

1. a leaflet suitable for women in the stages of pre-contemplation (not thinking of quitting) or contemplation (thinking about quitting), which aimed to motivate women to make a decision to quit by enhancing their perceptions of personal risk, the potential severity of the risk, positive outcome expectations, self efficacy and perceived social support for quitting.

2. a Quit Guide suitable for women in the preparation stage of change (ready to quit). This guide contained a self directed, seven-day behavioural modification programme, which transferred quitting skills.
3. a leaflet designed as an aid for women in the action stage, to help them enlist appropriate social support from family members and their partner, as they tried to quit or avoid relapse.

Whilst delivering the 5As guideline, the midwives and peer counsellors were directed to select the material appropriate for distribution to each woman, depending on the degree of her readiness to change.

The formative research findings provided a vital source of reference for decisions on how to tailor these materials to suit the characteristics of our particular target audience. All the media was produced in English, as well as in the local, colloquial dialect of Afrikaans, in order to aid comprehension for women of low literacy and to facilitate identification with the materials. Care was taken to write in a simple accessible style, while maintaining a professional and respectful tone and to show sensitivity to the cultural values and difficult life circumstances of the target group. Pre-testing was undertaken to confirm the acceptability, appropriateness and appeal of the materials.

The two leaflets were modelled on a tabloid newspaper, *The Sun*, which has great popularity among the target community. The leaflets were A3 sized, folded like a newspaper, had large graphics in full colour and used recognisable, colloquial language. Both leaflets used a strategy called 'behavioural journalism' (McAlister, 1995) - media-delivered, behavioural modelling, which makes use of role-model stories that are based on authentic interviews with the target population. Modelling is most persuasive when the audience can identify closely with the role-model (Bandura, 1986) and when the model gives a realistic and credible picture of the target group's lifestyle (McAlister, 1995). Two women who had previously participated in the research were selected for interviews. Photographs to accompany the stories were taken of the women in their local context and the interview was conducted in familiar, colloquial language in order to increase readers' identification with the model and her story. The content was crafted to be appropriate to their level of understanding.

The first leaflet featured a young woman who had nearly lost her baby due to premature labour, which was believed to be as a result of her smoking. Her story aimed to increase a sense of vulnerability to the consequences, model positive outcome expectations for quitting, boost self-efficacy and convey changes in social norms. This leaflet included information on the harmful components of tobacco and how these reached the foetus; strong verbal messages on the risks of smoking and the immediate benefits of quitting to the mother and baby; a discussion on the concept of risk, as well as the dangers of using alcohol and drugs during pregnancy. In keeping with a finding from our formative research that women also wanted to be cared for as an individual, not just as the mother of an unborn child, the material also emphasised the risks of smoking and benefits of

quitting for the woman's own long term health and quality of life. The other leaflet featured a story of a young man who decided to quit with his girlfriend for the sake of their unborn baby. It aimed to model appropriate forms of social support (Israel & Schurman, 1990), which could be provided by family members and partners and to encourage a questioning of the prevailing norms around passive smoking.

I chose not to take up the suggestion by women to use shocking images of babies affected by smoking, because the research on fear arousal shows that it can often lead to people avoiding the health message if they do not feel confident that they can avert the threat (Ruiter et al., 1999). Appealing pictures of a baby, whose mother had quit smoking, were used instead.

The Quit Guide was a full colour, A4 sized, 46 page booklet on good quality paper. It contained numerous role model quotes and photographs of women from our target audience in their home and community environments. It included self-re-evaluation exercises assessing readiness to quit, current smoking behaviour and important personal values; activities which addressed negative cognitions and outcome evaluations (particularly the belief that quitting is too difficult) and built self efficacy; prompted the active seeking out of support from existing social networks (asking someone to be a quit smoking buddy or mentor); and contained exercises, which demonstrated the behavioural, problem solving and coping skills necessary to quit smoking, resist social pressure and prevent relapse. Given that 67% of women in our target population reported exposure to ETS in their homes (Petersen et al., 2009a), the Guide also contained information on the risks of passive smoking, suggestions on how to establish a smoke-free home and stickers for women to use as cues for this purpose.

Table 5 shows how theory-based methods and strategies were applied in the development of the Self-help Quit Guide. This example is placed at the end of this chapter, because of its length.

STEP 4: Developing a programme plan (the format of intervention)

Method

In Step 4, the educational strategies are combined into an organised programme. The various components are foreseen and decisions are made regarding their content, scope, sequence and delivery. The materials are designed and pre-tested and a coherent plan for the programme is developed. In this step, planners need to collaborate closely with the creative team who will design the materials (the writers, graphic artists, photographers or video producers). Of critical importance is that the health promotion planner provides the creative team with a clear and detailed brief and continually reviews the creative process, in order to safeguard the theoretical underpinnings of the programme.

In our case, I wrote all the print materials and supervised their design, thus providing continuity between the research and creative process. The matrices of programme objectives and the inventory of methods and strategies were referred to during the development process and then used as a checklist to evaluate whether the materials were meeting intended proximal programme objectives and that the selected methods had been adequately used.

Results

Role of peer counsellors and midwives

Our intervention was planned for implementation over a one year period in four, public sector antenatal clinics, which referred to Tygerberg Hospital and were typical of those servicing our target community. As midwives did not have sufficient time for in-depth counselling and because some of them had expressed reluctance to play a primary counselling role, peer counsellors were employed to assist in delivering the 5As best practice, counselling guideline. The peer counsellors were recruited from the target community and were ex-smokers themselves. However, the midwives still had a vital role in delivering the intervention. Their designated role in the intervention was to identify the smoker during routine history taking at the first booking visit, document smoking status on the clinic card, advise her about the risks of smoking and then assess whether she was interested in trying to quit. This was envisaged to take about five minutes. Once the midwife had delivered the first three steps of the Guideline (Ask, Advise and Assess), she was expected to inform all smokers of the availability of the peer counsellor and explain what assistance she could offer. Importantly, the assistance of the peer counsellor was offered by the midwife and it was made clear to the women that they were under no obligation to see her. The peer counsellor would then repeat steps two and three, tailor the intervention to the pregnant women's stage of change and proceed to Step 4 (Assist). It was recommended that the situation be re-assessed at every follow up visit to the clinic (Step 5: Arrange), by both the midwife and peer counsellor as following up to find out how things were going and to give positive affirmation for progress, no matter how small, appears to be highly valued by women trying to quit (McLeod et al., 2003).

The peer counsellors had the advantage of being able to spend more time with women, but they were also chosen to play the in-depth counselling role, because women were likely to feel more comfortable with them in disclosing and discussing their smoking status. The fact that they were from the same socio-economic/cultural community, had shared life experiences and had been smokers themselves, meant they were more likely to have empathy for the difficulties women faced in attempting to quit and a natural understanding of their perspective on life. They were also more likely to facilitate participant identification with the programme and thus had greater potential for positive role modelling and increasing self esteem (Lapierre et al., 1995; Earp et al., 1997). In addition, it was anticipated that they would be able to provide an important form of social support to

both pregnant women and the midwives and help bridge the difficulties in communication between the community and clinic staff.

Employing lay counsellors in our project was also in line with a Western Cape Department of Health policy position to further investigate the feasibility of using lay counsellors/educators in primary health care services, as a cost effective means of addressing the shortage of professional staff.

The intervention was planned to occur concurrently with routine antenatal visits to reduce the time burden for both the attending pregnant women and midwives. The intervention space was contiguous with normal clinic space and the peer counsellors cooperated closely with the midwives in order not to interrupt patient flow. If a woman missed her scheduled visit, the peer counsellor attempted to contact her by phone to urge her to attend the clinic. At times, the peer counsellor visited women at their homes. No postpartum sessions were envisaged, due to a lack of study resources for follow-up after delivery.

Training

Prior to the intervention, the midwives, along with the peer counselors, were trained to use the 5As ACOG Guideline for brief cessation counselling (ACOG, 2001, 2005). Given that the findings from the interviews with the midwives (Chapter 3) showed that the prevalent approach to smoking cessation counselling/education in the clinics was prescriptive and judgemental, the challenge in the training was to assist midwives approach the question of cessation with women in a more positive and constructive way. To this end, the Guidelines were adapted to incorporate certain key Motivational Interviewing principles (Rollnick, 2002) (see Table 4 in this chapter) and the training included an explanation of the patient-centred, MI approach.

The training consisted of two, two hour sessions during the afternoons when the clinics were less busy. The training included time for reflection and discussion (self re-evaluation) on their current approach to smoking cessation education/counselling and their personal experiences. MI was modelled as an alternative patient-centred method and midwives had opportunities for guided practice, reinforcement and feedback through role play ('enactive mastery experiences', Bandura 1997). The 'Stages of Change' theory (Prochaska & DiClemente, 1983) was discussed, so that the midwives and peer counsellors might understand the dynamic processes of behavioural change, be able to identify the stage of change a woman may be in and adapt the intervention accordingly. They were also encouraged to relate the 'stages of change' concept to their own experiences of behavior change. The training was consonant with the main principles of motivational interviewing, in that it encouraged active involvement in the learning process by the participants.

The midwives and peer counsellors were provided with a 'Health Care Providers Guide to Counselling Pregnant Women about Smoking', which was adapted from the guide developed by the ACOG (2002)(see **Appendix**). The Guide included updated scientific information on the risks of smoking during pregnancy; a discussion of the theory of Stages of Change (Prochaska & DiClemente, 1983) and a variety of scenarios which offered midwives suggestions of how to respond to commonly asked questions or rebuttals about cessation during pregnancy. Posters summarising the 5As were put up in the examination rooms to serve as 'cues to action'. Once the midwives and peer counsellors had tried out the new approach for several weeks, they returned to a group session to share their experiences and to discuss any difficulties they had encountered. This was an important opportunity for reinforcing self efficacy beliefs, re-framing negative experiences and providing social support. The research team held weekly meetings with the peer counsellors to monitor the implementation of the programme and to provide ongoing support. Midway through the project, a therapeutic counselling session was arranged for them with an experienced Lifeline counsellor, as working closely with women from very difficult social circumstances was proving stressful and emotionally draining. The workshop assisted them in processing their experiences and in acquiring coping skills.

Doctors and nurses at the referral hospital of Tygerberg were also trained so that they were fully aware of the intervention taking place in the clinics and could provide effective follow up, if a woman was referred to hospital for complications.

Media

The other components of the intervention were the three items of media described earlier. The media was only offered to pregnant women in the context of the brief counselling offered by the midwife or peer counsellor. This enabled the counsellor to mediate the information and allowed women to discuss the issues raised by the media. Only those women who expressed a readiness to make a quit attempt in the next couple of weeks were given the Quit Guide. If a woman was not yet ready to make a commitment to try and quit, she was offered the motivational leaflet, which focused on raising her awareness of the health risks and the potential benefits of quitting, rather than on teaching her skills on how to quit. The content of the counselling session and the media was therefore tailored to a woman's progress along the continuum of change. Counsellors provided reinforcement for successive changes towards cessation or reduction, as well as guided skills practice when appropriate.

The planning for the intervention was summarised into a 'Logic model', shown in **Figure 2**, over.

Figure 2: Intervention Mapping Logic Model for smoking cessation intervention

Programme Inputs		Programme outputs
Resources	Project activities	Programme strategies
<ul style="list-style-type: none"> • Funding • Time • Human resources: MRC researchers; Head of O&G Dept Tygerberg Hospital; media developers; clinic staff; peer counsellors. • Consultation with DOH (National and Provincial), clinic management and supervising doctors for permission and support • Best practice guidelines for smoking cessation interventions (5As) • Behaviour change theory; social ecological model; Intervention Mapping planning model; Motivational Interviewing 	<p>Phase 1</p> <ul style="list-style-type: none"> • Needs Assessment: formative research with target group and agents • Literature review • Review of health behaviour change theory • Intervention Mapping process • Development of educational/motivational and self-help materials • Development of training materials/aids • Development of research instruments <p>Phase 2 Delivery of programme:</p> <ul style="list-style-type: none"> • Training of nurses and peer counsellors • Provision of 5As Guideline and manual • Provision of Ed/Motivational and self-help materials for women • Project coordination • Weekly research meetings • Support group for peer counsellors <p>Phase 3</p> <ul style="list-style-type: none"> • Process evaluation • Outcome evaluation <p>Phase 4 Advocacy:</p> <ul style="list-style-type: none"> • Presentations to National and Provincial DOH and other stakeholders • Presentation to Midwifery Society • Feedback of study results to clinic staff, community and study participants at Community Health Days 	<ul style="list-style-type: none"> • One-to-one counselling by midwives and peer counsellors • Delivery of 5As using a Motivational interviewing approach • Quit Newspaper for women in Pre-contemplation or Contemplation stage of change • Self-help Quit Guide for women in Preparation or Action stage • Quit Newspaper for family and partner • Community Health Days to impact on community norms and provide social reinforcement

Glossary

5As = Best practice clinical guideline for smoking cessation counselling

PW = Pregnant women

MWs = Midwives

PCs = Peer counsellors

ETS = Environmental Tobacco Smoke

DOH = Department of Health

*For detailed learning and change objectives see Matrices for Pregnant Women and Midwives

Logic of Change			Outcomes		
*Learning & Change objectives	Determinants	Performance objectives	Behavioural & Environmental outcomes	Health	Improvement in quality of life
<p>PW, Partners, MWs and PCs</p> <ul style="list-style-type: none"> Acquire knowledge and understanding Develop beliefs conducive to behaviour Positive outcome expectations outweigh negative ones Develop positive predisposition to behaviour Develop strong self efficacy Perceive supportive social norms Acquire behavioural skills Develop intention Exposure to intervention/ training Primed for environmental cues Important referents develop positive attitudes Receive interpersonal support Receive role reinforcement and broader social support 	<p>Personal:</p> <ul style="list-style-type: none"> Knowledge Beliefs Attitudes Self efficacy Subjective norms <p>External:</p> <ul style="list-style-type: none"> Cues to action Social norms Social support and reinforcement Supportive organisational environment 	<p>PW:</p> <ul style="list-style-type: none"> Participate in cessation intervention Use media Make a decision to quit Seek social support Prepare to quit (reduce smoking) Move from preparation to action stage Avoid relapse Protect pregnancy and baby from ETS <p>Partner and family:</p> <ul style="list-style-type: none"> To quit smoking himself To refrain from smoking in front of pregnant woman To protect baby from ETS <p>MWs and PCs:</p> <ul style="list-style-type: none"> To participate in training Use cues and manual To ask about and document smoking status at first booking To initiate discussion on smoking To assess stage of change and tailor intervention To provide practical assistance to quit To follow up and reinforce progress To distribute media Smoking MWs to quit or desist from smoking at clinic To advocate for smoking cessation in own social networks 	<p>PW:</p> <ul style="list-style-type: none"> To quit smoking Reduce smoking Avoid relapse <p>Partner and family:</p> <ul style="list-style-type: none"> To support the pregnant woman To reduce exposure of the pregnant woman and baby to ETS <p>MWs and PCs:</p> <ul style="list-style-type: none"> Provide effective, best practice smoking cessation education and counselling To use a Motivational Interviewing counselling approach <p>For clinic managers, drs and health services:</p> <ul style="list-style-type: none"> To support, promote and sustain the smoking cessation intervention as a standard of good antenatal care <p>Community:</p> <p>Leaders to advocate for smoke free pregnancies and social support from partners, families and communities</p>	<ul style="list-style-type: none"> Prevention of adverse pregnancy and birth complications and outcomes Healthy pregnancy and normal delivery Improved foetal growth, healthy baby, normal development Breastfeeding more likely 	<ul style="list-style-type: none"> Avoidance of hospitalisation and medical intervention Less stressful pregnancy Positive affirmation for maternal role Avoidance of tensions in relationship with health care provider and partner Avoidance of economic costs Care of healthy baby less stressful, improved bonding

STEP 5: Generating an adoption and implementation plan

Methods

In Step 5 of Intervention Mapping, the planner begins by hypothesising determinants for the adoption and implementation of the programme by various groups or individuals. This is done on the basis of the theory relating to the diffusion of health promotion innovations (Rogers, 1983; Orlandi et al., 1990) and the findings of the needs assessment phase, which would have included research on the potential facilitating and impeding factors, related to the delivery of a programme and the identification of key resources or people to draw on for the implementation and dissemination of the programme in the future.

The planner then develops a set of detailed matrices as in Step 2, except in this instance, adoption and implementation performance objectives are developed for the personal and external determinants applicable to each group or individual, who could potentially take responsibility for implementing or championing the programme. For example, in our intervention, change objectives could have been developed for clinic managers, referring doctors and key decision makers in the health service, in addition to the midwives and peer counsellors.

Many researched health promotion innovations are not sustained because programme developers and evaluators fail to bridge the gap between themselves and those who ultimately will take responsibility for the diffusion and institutionalisation of the programme (Bartholomew, 2001). Intervention Mapping suggest that, from the very beginning, there needs to be a 'linkage system' (Orlandi et al., 1990) set up between those who research and develop a programme, key decision and policy makers, as well as the programme's potential users. Early co-operation between the different stakeholders can not only help ensure that interventions are replicable and sustainable within the organisational contexts in which they are to be used, but can also help ensure that they have the necessary political and community support and that plans for their diffusion are formulated well in advance (Wight & Abraham, 2000).

Results

A set of matrices for the midwives, which focused on the behaviours required for them to effectively implement the intervention, was compiled simultaneously with the matrices for the pregnant women in Step 2. The 'Health Worker's Guide to Counselling Pregnant Women about Smoking', developed in Step 4, was based on the change objectives outlined in these matrices. The Guide was envisaged as a resource for both the midwives and peer counsellors and formed the basis of their training. We did not develop matrices at this stage in the process for the other individuals and groups important for the successful adoption of the intervention. This was because we had already held various meetings

with key stakeholders and gatekeepers during the needs assessment phase, in order to secure permission to conduct the formative research. Furthermore, the interviews conducted with midwives, doctors and health service functionaries (clinic managers and health directors) in the formative research phase besides serving a research purpose, were a useful means of preparing the ground for the implementation of the intervention. The interviews were understood by the respondents to be part of an extensive consultation process, aimed at soliciting their views on whether the proposed intervention was warranted and what type of intervention was needed. This process also provided the researchers with the opportunity to build relationships, rapport and trust. By Step 5 in the planning process, much of the preparatory work motivating for the adoption and implementation of the intervention had been completed and all that remained was the training of the midwives, doctors and peer counsellors. This seemed to obviate the need to develop matrices with adoption and implementation objectives, methods and strategies for all potential implementers. Besides, developing the matrices for the pregnant women and midwives had been an exhaustive process, which I felt provided a sufficient template from which to plan the implementation and evaluation of the intervention.

Once the intervention had been evaluated, attempts were made to sustain and broaden the impact of the programme in the community and to lobby the state health department to disseminate the intervention more widely. The findings were presented to the research participants, their families and the community through two big events organised at local venues to mark the occasion of World No Tobacco Day on the 31st May, 2008. The midwives from the research sites and local Department of Health officials, not only participated in these events, but also assisted the research team organise and run them. This contributed to their sense of ongoing ownership of the project. Feeding back the results of the study was the fulfilment of an important ethical obligation on the part of the research team to research participants, but also had the objective of contributing to the changing of social norms in the community.

Presentations on the study's findings and recommendations were made to midwives' organisations and to various directorates in the provincial and national health departments. I have since been working closely with the directorates of Maternal and Child Health, Health Promotion and Mental Health in the Western Cape Provincial Health Department, in planning for the wider adoption and dissemination of our intervention. Executive management have recently approved the further piloting of the intervention model in a number of other clinics, with the view to provincial-wide dissemination in the future. Whilst the methods and strategies remain the same, the intervention has been modified to incorporate other risk behaviours in pregnancy, such as alcohol and drug use, stress and depression.

STEP 6: Formulating an evaluation plan

Methods

To evaluate the effect of an intervention, researchers analyse health indicators and quality of life outcomes, as well changes in intermediary variables such as knowledge, attitudes, self efficacy and behaviours. In Intervention Mapping, these variables are clearly defined early on in the planning process, which makes the specification of evaluation measures in Step 6 relatively easy. Outcome measures are developed with reference to the change objectives specified in the matrices of Step 2 and process measures are developed in relation to the change objectives of the matrices in Step 5 (for adoption and implementation).

Results

Chapter 5 presents the study design and methods used for the evaluation study, as well as the evaluation study's findings.

Again, I chose not to develop a set of matrices in planning for the evaluation as is recommended in the Intervention Mapping protocol, but rather used the matrices developed in Step 2 as a checklist and guide for formulating research questions and the measurement items in the questionnaires, as well as the qualitative interview schedules.

The table opposite sums up the steps I followed in the Intervention Mapping process.

Table 6: Summary of Intervention Mapping steps for development of smoking cessation intervention with pregnant women

Intervention Mapping Steps	Development of Smoking Cessation Intervention
1. Needs assessment	<p>Analysed the problem:</p> <ul style="list-style-type: none"> • Identified problem and at risk population • Identified individual and environmental factors influencing problem behaviour (Table 1: Analysis of the problem of smoking during pregnancy, Chapter 4)
2. Proximal programme objectives	<p>Developed matrices:</p> <ul style="list-style-type: none"> • Specified programme outcomes at individual and environmental level (Table 1: Analysis of Health Problem, Chapter 4) • Specified performance objectives (required actions to achieve outcomes) • Specified personal and external determinants for each performance objective to develop change objectives (Table 2: Matrices for Pregnant Women, Partners and Midwives/Peer counsellors, Chapter 4)
3. Theory-based methods and strategies	<ul style="list-style-type: none"> • Selected methods and strategies for change objectives (Table 3: Selection of theory-based methods and strategies for intervention, Chapter 4)
4. Producing programme plan, components and materials	<ul style="list-style-type: none"> • Developed programme plan/format (Figure 2: Logic Model for Intervention, Chapter 4) • Developed materials (Appendix)
5. Programme adoption and implementation	<ul style="list-style-type: none"> • Implemented programme in clinic setting (Figure 2: Logic model for smoking cessation intervention, Chapter 4)
6. Planning Evaluation	<ul style="list-style-type: none"> • Developed evaluation protocol • Process evaluation • Impact evaluation (Chapter 5)

Discussion

This chapter describes the processes involved in using Intervention Mapping in the development of a smoking cessation intervention for pregnant women. This included a literature review, extensive formative research and detailed preparation of Intervention Mapping matrices and other planning instruments. Designing health programmes in this way is challenging, very time consuming and expensive. However, using a protocol, such as Intervention Mapping, enhances the likelihood of a health promotion intervention being effective, acceptable to the programme participants and feasible to implement. If proper investment is not made in thorough planning and testing in the development phase, there is a high risk of wasting significant resources in disseminating programmes, which are ineffective, unusable, unsustainable or even counterproductive.

There were several advantages to using Intervention Mapping in this project. Firstly, it helped to ensure that the programme was founded on theory and evidence. In IM, the planner is compelled to give due consideration to the relevant theoretical and empirical information, before embarking on programme design and then to integrate it into every step of the development process in a systematic way. In this sense, Intervention Mapping helps bridge the gap between theory and practice.

The methodical, step-by-step methodology of the Intervention Mapping process ensured that I considered this information carefully and used it in a logical and transparent manner. It also enabled me to successfully incorporate methods and strategies established as best practice through broader scientific research, whilst tailoring the programme to suit the unique features of the local setting and intended target group.

Intervention Mapping is congruent with the health promotion approach, in that it is committed to bringing a multi-disciplinary, professional perspective, as well as a community perspective, to the planning of programmes. As a model, it accommodates multiple theoretical and experiential perspectives to a health issue. In addition, it directs planners to give credence to the views of the target community, potential users of the programme and other stakeholders. Drawing on these diverse experiences deepened my understanding of the dimensions of the health problem at hand, ensured that the programme addressed the determinants necessary to achieve change, was tailored to the community's unique needs, as well as to the capabilities and opportunities of the implementers and intermediaries.

Intervention Mapping's emphasis on an ecological approach to health promotion was helpful in inducing me to try and understand the role of agents at the different levels of the interpersonal, organisational, community and societal, who are in a position to exercise influence or control over the environment, which ultimately impacts on smoking behaviour. Even if the scope of the programme had to be circumscribed in the end, the exercise was valuable, in that the programme was designed with a heightened awareness of the potential barriers and facilitating factors for smoking cessation in the social and physical environment. Where it is possible to plan an intervention which addresses these multiple influences, the likelihood of achieving behavioural change is obviously significantly enhanced.

Using the Intervention Mapping model requires that the conceptual or theoretical basis for how a programme is intended to change behavioural or environmental determinants is made detailed and explicit. This rigour is very helpful in that it enables one to readily describe the critical assumptions underlying the intervention plan and to justify one's proposed research and intervention activities with greater confidence. It also makes the planning process open for scrutiny by funders, colleagues

and other stakeholders, and it enables a clear description of the intervention once it has been developed, making direct comparisons with other interventions and potential replication easier.

The detailed Intervention Map helps one lay a sound basis for planning the evaluation and helps ensure continuity between the stages of research, development and evaluation (for example, I found it easy to develop measurement items to match specific learning objectives in the matrices).

Of further benefit in using the IM process was its emphasis on communicating clear programme specifications to the writers and artists who will produce the material. This helps to ensure that the content of the selected strategies is closely related to specified programme objectives. All too often, there is little understanding on their part of the theoretical and empirical basis of health promotion programme development. This can result in much of the information gathered in the needs assessment being disregarded or undervalued by the creative team.

In summary, the use of a planning model as exacting as Intervention Mapping can protect against Type 2 error, that is, failing to find effectiveness, because the programme is poorly designed, adopted, implemented or evaluated (Bartholomew, 2001).

Although I found Intervention Mapping helpful and concede that it undeniably improved the rigour of the development process, I must admit to finding it difficult to follow to the letter. If I had undertaken to do matrices on different sub-groups within our target community, the various agents at multiple ecological levels and for the implementation and evaluation plan, I believe I would have become mired down by detail and would have struggled to maintain clear direction. It would have also caused unnecessary confusion among the research team and risked losing their participation in the process. With such a volume of detail, there is a danger of losing the proverbial wood for the trees and stifling more intuitive creative processes. Even the proponents of Intervention Mapping admit that such complexity can breed despair (Kok et al., 2004). However, they judge the dangers of oversimplification to be greater and entreat the planner to bear with the process.

Other researchers have reached similar conclusions. McEachan et al. (2008) submit that the creation of matrices for some 57 performance objectives for their worksite physical activity programme was particularly demanding and resulted in an overwhelming and confusing amount of information about what should be targeted. They had to then spend time sifting through the change objectives and strategies, to decide which ones could be pragmatically achieved. Kwak et al. (2007) caution that Intervention Mapping can become particularly unwieldy when used for planning programmes targeting complex and multidimensional behaviours such as weight loss. This caution could also apply to a situation where a complex organisation or institution is involved.

Singh et al. (2006) modified their original protocol by restricting the number and complexity of the matrices in the development of an obesity intervention, as did Martens et al. (2006) and Perez-Rodrigo et al. (2005), in the development of their school based healthy eating programmes. Wolfers et al. (2007), conclude that the application of Intervention Mapping in routine public health practice is not feasible, as there is rarely sufficient time or the theoretical knowledge available in health services for such a demanding planning process. Using IM in designing their HIV prevention project for a municipal health service in the Netherlands was only possible, because they had the assistance of university-based researchers.

Similarly, Jansen et al. (2004) relied heavily on their collaborators from Maastricht University for training, supervision and technical expertise in applying IM to the South African context, as they lacked the competencies required to apply the protocol on their own. They reported that it took considerably more time than expected to familiarise themselves with the tenets and methods of IM and that they struggled to keep up with the level of detail required by IM. The complexity and exigencies of the protocol also make it difficult to involve the range of stakeholders in the development process which IM intends. Jansen et al. (2004) and found it hard to maintain the interest of the community partners in the process over time. Although Corbie-Smith et al. (2010) showed that involving community partners in the IM process is feasible, equipping them with the necessary knowledge proved to be a challenging and time consuming task. This was made more difficult by their experience of a high turnover of community partners in the project. Successfully mediating the different perspectives which the university researchers, community members and stakeholders brought to the development process was also taxing.

Funding criteria which predetermine certain decisions about programme design can also compel developers to adapt and abbreviate the IM process, as Zule et al. (2010) report in their paper on the development of an intervention to reduce HIV risk among gay men.

McEachan et al. (2008) also make the point that it is difficult to attract funding for such a protracted and thorough development process. This may help explain why so few health promotion programmes are theory and evidence-based. Key considerations before embarking on the Intervention Mapping process are the budget available and the amount of time, project management and expertise required. Intervention Mapping may represent an ideal, but it may not always be feasible to use, without taking significant short cuts along the way.

Finally, the terminology of Intervention Mapping is difficult to grasp and retain. It takes some time to familiarise oneself with the basic tenets, concepts and language of the IM protocol, to the point that one can appropriately apply the model in practice. This problem prompted authors Tortolero et al. (2005) to include a table titled, 'A Guide for the Perplexed' in their article, in an effort to assist

readers in understanding the multitude of IM terms. Health promotion practitioners can be referred to Godin's practical planning tool, which is based on the conceptual framework of Intervention Mapping, but is somewhat easier to use (Godin et al., 2007). This tool can be used as a working checklist for developing new projects, or for the critical analysis of the extent of planning that was involved in programmes that have already been implemented.

Conclusion

Intervention Mapping was helpful in guiding the design of a theory-based smoking cessation intervention, which was tailored to a community of disadvantaged, high risk pregnant women. The evaluation of the intervention, which is described in the following chapter (**Chapter 5**), showed it to be effective in increasing cotinine validated quit rates, as well as smoking reduction rates among the target group. Focus groups and individual interviews with pregnant women and midwives showed a high degree of acceptability and appreciation of the intervention (Everett-Murphy, unpublished data; Petersen et al., 2010 & 2011). Our success may certainly, at least in part, be attributed to the commitment we made to a thorough and carefully considered development process. However, the Intervention Mapping model was not used with a high degree of conformity in Steps 5 and 6. Planning every phase of the process with the same amount of painstaking, documented detail seemed unnecessarily pedantic and would have limited the time available for the more practical work of preparing the ground for the implementation and evaluation of the intervention.

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MATRICES

A: PREGNANT WOMEN: Behavioural objective or health promotion goal: to quit smoking

1) Performance objective: Make a decision to quit

Personal Determinants				
Knowledge	Beliefs	Attitudes	Self efficacy/ Perceived behavioural control	Subjective norms
Acquires full, detailed information on risks of smoking to foetus, pregnancy and herself Understands physiological mechanism of harm to foetus	Assumes personal susceptibility to risk Believes potential harm could be serious	Feels optimistic about making a decision to quit Feels responsibility for and concern about baby's health and own health	Confident that she is capable of quitting, believes she can control this aspect of her life Believes quitting is possible (that it's not too difficult and many pregnant women have succeeded)	Believes significant others approve of quitting during pregnancy Is motivated to comply with the expectations of significant others
Understands the magnitude of the potential harm	Believes that quitting at any time in the pregnancy is beneficial and worthwhile	Places high value on baby's and own health	Confident can overcome addiction	Believes other pregnant women are also making the decision to quit
Understands risk concept (can dispel anecdotal accounts of no harm)	Stops denying that smoking can harm the unborn baby	Experiences negative emotions (concern or worry) about continued smoking		
Understands the full implications of having a low birth weight baby	Believes quitting is effective in preventing harm (outcome expectations)			
Understands the possible impact of an affected baby on her quality of life	Believes benefits of quitting will outweigh the personal costs or barriers (outcome expectations)			
Understands that smoking can adversely affect the delivery				
External Determinants				
Interpersonal Social Support	Social norms	Supportive organisational environment	Cues to action	
Significant others express support for quitting decision (partner, family members, peers, health care (HC) providers)	Significant others express approval of decision to quit Many other pregnant women have also decided to quit Significant others expect pregnant woman to quit	Smoking cessation programme available at clinic or in community	Educational media about smoking in pregnancy prompts decision HC provider raises issue of smoking when registering for antenatal care Counselling from HC provider at every antenatal visit Partner, peer or family member suggest that pregnant woman gives up smoking HC provider identifies a problem related to smoking in pregnancy and gives feedback to pregnant woman	

2) Performance objective: Seek social support for quitting

Personal Determinants				
Knowledge	Beliefs	Attitudes	Self efficacy	Skills
Knows that seeking social support is important for quitting	Believes that support will help her quit (outcome expectation)	Has a positive attitude towards the help when offered	Has confidence to ask for support from chosen person	Has communication skills to request and maintain social support
Knows what kind of support to ask for				
External Determinants				
Social support	Supportive organisational environment		Cue to action	
Partner (who smokes) agrees to quit with woman or agrees to stop smoking around her when she quits	HC provider offers support for quitting (practical and emotional support)		HC provider and educational material prompts woman to seek social support as important coping strategy for quitting	
Person who is asked for support is willing to give it and affirms woman's decision to quit				

3) Performance objective: Prepare to quit (reducing smoking)

Personal Determinants				
Knowledge	Beliefs	Self efficacy	Subjective norms	Skills
Knows of strategies that help one prepare to quit	Reviews health benefits of quitting and personal reasons for quitting	Is confident that she will be able to alter smoking behaviour	Believes others approve of her preparing to quit	Acquires skills to alter or modify smoking behaviour, cope with stress and urges to smoke
Develops understanding of smoking behaviour (recognises people, situations and feelings that make her want to smoke)	Believes that period of reducing smoking will assist in quitting altogether (outcome expectation)	Positively affirms herself as kind of person who can quit	Believes other pregnant women are preparing to quit	Has communication skills to seek social support
External Determinants				
Social Support	Social norms	Supportive organisational environment		Cues to action
Partner is aware of preparations to quit and offers encouragement	Widespread belief that all pregnant women should quit during pregnancy because of potential harm to baby and mother	Receives continuing encouragement, praise for efforts and acknowledgment of any progress by HC providers during each visit to clinic		Support materials prompt woman to start preparation and guide her through the preparation phase
If partner smokes, offers to reduce smoking at same time	Widespread belief that quitting is achievable	Smoking Cessation Programme available at clinic		

4) Performance objective: Moving from preparation to action phase of behavioural change

Personal Determinants				
Knowledge	Beliefs	Self efficacy	Subjective norms	Skills
Knows the typical physical reactions to withdrawal and how people cope with them	Reviews personal benefits of quitting and believes that they outweigh difficulties of quitting or benefits of smoking	Is confident that she is capable of quitting (that she can cope with withdrawal) and affirms her decision to quit	Believes significant others approve of and expect her to quit	Has skills to cope with withdrawal symptoms
Knows strategies for relaxation	Believes withdrawal symptoms are a positive sign of body beginning to repair itself	Is convinced that she is capable of coping with stress in alternative ways	Is motivated to comply with opinion of significant others	Has skills to cope with stress in alternative ways
Knows which trigger situations to avoid	Believes that she and her baby will experience immediate health benefits from quitting	Is confident that she can avoid trigger situations or cope with them	Believes other pregnant women are quitting	Has behavioural skills to resist social pressure to smoke
Knows importance of removing environmental cues to smoke	Believes quitting will actually safeguard herself and her baby from risks (outcome expectations) Believes that quitting at any stage in the pregnancy confers benefits Begins to define herself as a non-smoker	Is confident that she can remove environmental cues by negotiating with members of family		Has negotiating skills to enable removal of environmental cues
External Determinants				
Social Support	Social norms	Supportive organisational environment	Cues to action	
Receives encouragement, praise and acknowledgment for quitting from partner, family members, peer group, HC providers	Widespread support for non-smoking during pregnancy	Improved enforcement of Tobacco Control policies and legislation (national and provincial) which ban smoking in public places to create a more supportive environment for non-smokers	HC provider assesses progress and stage of change at every antenatal visit	
Receives admiration from others for having overcome tobacco addiction	Widespread belief that all pregnant women should quit during pregnancy because of potential harm to baby and mother	Communication and enforcement of ban on smoking in antenatal clinics (among mws, drs, pregnant women and the public)	HC provider counsels pregnant women on smoking cessation	
Receives concern and caring from HC providers, partner, family members, and friends about difficulties of quitting.	Widespread belief that quitting is achievable	Management of health services supportive of smoking cessation interventions for pregnant women in antenatal clinics Specific policy on smoking during pregnancy in antenatal services which requires involvement of staff in implementation of smoking cessation intervention	Provision of materials which provide practical suggestions on how to quit and cope with withdrawal from nicotine	

5) Performance objective: Avoid relapse

Personal Determinants				
Knowledge	Beliefs	Self efficacy	Subjective norms	Skills
Understands that relapse is a normal part of the cycle of change	Believes she has successfully given up and that a relapse episode does not necessarily mean failure	Is confident that she can maintain abstinence by coping with trigger situations, resisting peer pressure and coping with stress in alternative ways	Believes others want her to stay quit throughout her pregnancy and in the long term for her own health	Has skills to communicate decision to stay quit to significant others
Knows which situations put her at risk of relapse	Believes that the short and long term benefits of quitting outweigh the negative experience of quitting	Is confident she can resist the urge to smoke	Considers the opinion of others as important	Has behavioural skills to resist social pressure to smoke
	Believes that her health and that of her baby are improving day by day	Is confident she can maintain relationships where smoking was a shared activity	Believes other pregnant women have quit and are determined to stay quit	Has cognitive skills to cope with cravings to smoke and stress
	Defines herself as a non-smoker	Is confident that she can succeed again, if she relapses		
External Determinants				
Social Support	Social norms	Supportive organisational environment	Cues to action	
Woman receives continued support from partner, family, peers and HC providers	Widespread support for non-smoking during pregnancy	Improved enforcement of Tobacco Control policies and legislation (national and provincial) which ban smoking in public places to create a more supportive environment for non-smokers	HC provider at clinic is prompted to assesses stage of change at every antenatal visit	
If partner smokes, he does not smoke around woman	Widespread belief that all pregnant women should quit for duration of pregnancy and in the long term for her own health	Management of health services supportive of smoking cessation interventions for pregnant women in antenatal clinics	HC provider provides counselling for maintaining abstinence	
Receives admiration from others for overcoming tobacco addiction	Widespread belief that maintaining abstinence is achievable	Availability of smoking cessation at clinic which addresses maintenance of non-smoking	Educational materials discuss challenges of maintaining abstinence and strategies to avoid relapse	

6) Performance objective: Protect the baby from environmental tobacco smoke

Personal Determinants				
Knowledge	Beliefs	Self efficacy	Subjective norms	Skills
Understands effects of ETS on unborn baby, infant and child	Believes exposure of baby to ETS places baby and pregnancy at risk	Is confident that partner will agree to making home smoke free	Believes that people will be sympathetic to reasons for making home smoke free	Has communication skills to negotiate smoke free environment in home
Increased awareness of self as role model in protecting baby	Believes the risks of ETS are serious enough to warrant action	Is confident that others will respond positively to making home smoke free	Believes that others will comply with smoke free rules	
Knows places to avoid where baby will be exposed to ETS	Believes taking measures to protect baby will be effective Believes the advantages of protecting baby outweigh the difficulties in making the home smoke free	Is confident that she can assert herself with anyone who does not comply to smoke free rules in the home	Believes that other pregnant women are also making their homes smoke free	
External Determinants				
Social Support	Social norms	Supportive organisational environment	Cues to action	
Partner and family members are supportive of woman taking action to make home smoke free	Other parents have made homes smoke free	Clinic based smoking cessation programme with ETS component	Counselling by HC Provider on importance of smoke free home	
HC Providers at clinic are supportive and encouraging of woman making home smoke free	Widespread support for smoke free public places and compliance with legislation and policies	Smoke free policy in clinic and enforcement Smoke-free signs in the clinic	Educational materials which include information on risks of ETS and suggested strategies on how to make home smoke free Smoke free signs in the home	

B: PARTNER: Behavioural objective or health promotion goal: to support partner in quitting

1) Performance objective: if smoker, to quit smoking or not smoke in front of partner

Personal Determinants					
Knowledge	Beliefs	Attitudes	Skills	Self efficacy	Subjective norms
Has detailed knowledge of risks of smoking and passive smoking to health of pregnancy, mother and baby	Believes that his support is important to partner and that the most helpful way of supporting her would be to quit himself or at least stop smoking in front of her	Feels responsibility to support pregnant partner and protect her and baby from passive smoking (self and others in household)	If a smoker, successfully acquires relevant quitting skills to quit himself or modify his smoking behaviour	Feels confident that pregnant partner is capable of quitting (and if smoker, that he can quit or modify his smoking behaviour)	Believes pregnant partner, family, friends and HC Providers approve of quitting during pregnancy and his supportive role
Understands the magnitude of the potential harm	Believes that baby and mother are susceptible to risks of direct smoking and passive smoking and that potential harm could be severe	Has supportive and caring attitude to partner	Acquires problem solving and coping skills to prevent relapse	Feels confident that he and partner can control this aspect of their lives	Believes that significant others expect him to support partner in quitting, by quitting himself or modifying his smoking behaviour and is motivated to comply with these expectations
Understands physiological mechanism of harm to foetus	Believes quitting is effective in preventing harm	Places high value on baby's, woman's and own health		Feels confident that pregnant partner and himself can sustain behavioural change	
Understands concept of risk (can make sense of anecdotal accounts)	Believes quitting is not too difficult to achieve (for partner and himself, if smoker)	Experiences negative emotions (concern, worry) about pregnant partner's continued smoking		Feels confident that supporting partner in this way will improve their relationship	
Understands the full implications of having a low birth weight baby	Believes that partner quitting at any time in the pregnancy is beneficial and worthwhile				
Understands the possible impact of an affected baby on quality of his family's life	Believes his support for partner quitting will be good for the relationship				
Understands the importance of partner's role in supporting pregnant woman in quitting (quote research findings) and knows how to support her	Believes the benefits of quitting outweigh the difficulties or negative consequences				
Knows behavioural strategies for quitting					
Knows potential side effects of quitting and strategies which help one cope with them					
Knows potential trigger situations for relapse and how to deal with these (for partner and himself)					

2) Performance objective: to protect the baby from environmental tobacco smoke (ETS)

Personal Determinants				
Knowledge	Beliefs	Self efficacy	Subjective norms	Skills
Understands effects of ETS on unborn baby, infant and child	Believes exposure of baby to ETS places baby and pregnancy at risk	Is confident that partner and he will agree to making home smoke free	Believes that people will be sympathetic to reasons for making home smoke free	Has communication skills to negotiate smoke free environment in home
Increased awareness of self as role model in protecting baby and pregnant woman	Believes the risks of ETS are serious enough to warrant action	Is confident that others will respond positively to making home smoke free	Believes that others will comply with smoke free rules	
Knows places to avoid where baby will be exposed to ETS	Believes taking measures to protect baby will be effective	Is confident that he can assert himself with anyone who does not comply to smoke free rules in the home	Believes that other partners of pregnant women are also making their homes smoke free	
Knows importance of father's supportive role in protecting baby from ETS	Believes the advantages of protecting baby outweigh the difficulties in making the home smoke free Believes both parents have a responsibility to protect baby from ETS			
External Determinants				
Social Support	Social norms		Cues to action	
Partner and family members are supportive of pregnant woman and partner taking action to make home smoke free	Other parents have made homes smoke free		Pregnant woman initiates discussion with partner of importance of smoke free home	
HC Providers at clinic are supportive and encouraging of woman making home smoke free and involving partner	Widespread support for smoke free public places and compliance with legislation and policies		Pregnant woman brings home educational materials which include information on risks of ETS and suggested strategies on how to make home smoke free Smoke free signs in the home	

C: Health care providers (nurses, midwives, peer counsellors): Behavioural objective: to counsel pregnant women about smoking cessation
 1) Performance objective: for health care provider to ask about smoking and document smoking status on registration for antenatal care

Personal Determinants					
Knowledge	Beliefs	Attitudes	Self efficacy	Skills	Subjective norms
Understands the importance of asking about and documenting smoking status of every pregnant woman	Believes that smoking during pregnancy is an important, preventable cause of adverse pregnancy and birth outcomes	Has a supportive attitude towards the goals and objectives of the intervention and evaluation study	Feels confident to ask woman about status and document the information appropriately	Has communication skills to ask about smoking status	Believes that colleagues and Dept officials regard smoking as a priority issue in antenatal care
Has full, detailed knowledge of the adverse effects of smoking in pregnancy	Believes smoking in pregnancy is a priority issue in antenatal care	Feels positively predisposed to participate in the intervention and evaluation study and to undertake the required tasks			Believes colleagues and Dept officials expect HC providers to address smoking and participate in intervention
Knows where to document smoking status and what information is required	Believes that counselling about smoking is an important aspect of midwifery and that she has a responsibility to address the issue				Is motivated to comply with these expectations
	Believes that documenting smoking status will ensure effective monitoring of smoking status during course of antenatal care (outcome expectation)				Believes smoking cessation intervention in clinics complies with national tobacco control policies and represents policy in action

2) Performance objective: For health care provider to initiate discussion about smoking in a non-judgemental and supportive manner

Personal Determinants					
Knowledge	Beliefs	Attitudes	Skills	Self efficacy/ perceived behavioural control	Subjective norms
Has full detailed information on risks to foetus, pregnancy and longer term health of woman	Believes that quitting is important and effective in preventing harm	Has a positive attitude about discussing smoking cessation with pregnant women and about participating in an intervention	Acquires greater skills in communication and counselling	Feels confident about raising and discussing smoking cessation with pregnant smokers and using a more patient centred approach	Believes that colleagues and Dept officials regard smoking as a priority issue in antenatal care and routine counselling as a standard of good practice
Understands full implications of having a low birth weight baby	Is convinced that smoking cessation intervention can be effective with intended target group and feasible to implement in current working conditions	Is optimistic that his/her smoking cessation counselling will make a difference	Has those communication skills relevant to patient-centred, MI approach	Feels confident that she can use guidelines and educational aids effectively	Believes colleagues and Dept officials expect HC providers to discuss smoking with pregnant women and use a patient centred counselling method
Understands how smoking can adversely affect delivery	Believes that she/he needs to give smoking cessation counselling greater priority in antenatal care	Has a supportive, empathetic and non-judgemental attitude towards pregnant women who smoke	Has the necessary skills to use guidelines and educational aids/ resources for smoking cessation	Feels confident that she can facilitate behavioural change in patients (wrt smoking and other lifestyle issues)	Feels motivated to comply with these expectations
Understands the nature of addiction and has knowledge of relevant theories of behavioural change	Believes that most pregnant smokers are concerned about their baby's health and would like to quit, but are addicted/ dependent on tobacco and are anxious about coping with cessation	Feels that she has an important responsibility to encourage and support pregnant women to quit, but respects woman's right to make her own informed choice		Feels confident that pregnant woman will respond positively to her initiating discussion about smoking	Believes that a smoking cessation intervention delivered by HC providers in antenatal clinics is expected by policy makers to be one aspect of the implementation of the national tobacco control programme
Has knowledge of the determinants of smoking and quitting among this specific target group	Believes that quitting at any time in the pregnancy is beneficial and worthwhile	Has a respectful attitude to the pregnant woman who smokes, acknowledging validity of their reasons for smoking and fears of quitting		Feels confident that she can handle resistance, defensiveness and avoidance on the part of pregnant woman	
Has knowledge of the principles, values and methods of a patient centred approach to lifestyle counselling and how this differs from existing prevalent approach	Believes that a more patient-centred, non-judgemental and supportive approach is more effective and more rewarding than the prevalent prescriptive, moralistic and confrontational approach	Has a positive attitude to innovation, change and development in her professional field		Feels confident that intervention and study will be a success	

Personal Determinants					
Knowledge	Beliefs	Attitudes	Skills	Self efficacy/ perceived behavioural control	Subjective norms
Is aware of the research which shows the importance of the role of HC providers and partners in quitting	Believes that HC providers and the pregnant woman's partner play a significant role in assisting pregnant women to quit	Has a open attitude to attending training and regards it as an opportunity for professional and personal development			
Is aware of local research findings that show that pregnant women strongly endorse the role of HC providers in smoking cessation counselling	Believes that pregnant women want to discuss their smoking with HC providers, providing they adopt a supportive and non-judgemental approach	Believes that more patient- centred approach conforms to her values			
Has a clear understanding of what her role and responsibilities are wrt to pregnant women who smoke	Believes that discussing smoking with pregnant women will bring personal rewards and professional satisfaction and that these will outweigh the difficulties	Has a positive attitude to the role of research in improving health services and introducing new approaches			

3) Performance objective: For health care provider to assess woman's stage of change and tailor intervention accordingly

Personal Determinants					
Knowledge	Beliefs	Attitudes	Skills	Self efficacy	Subjective norms
Knows Stages of Change theory, its application to health behaviour change and smoking cessation in particular	Believes Stages of Change theory to be appropriate and helpful in counselling pregnant women to quit smoking	Accepts validity of Stages of Change theory	Applies knowledge of theory to counselling pregnant women about smoking cessation	Feels confident she can assess stage of change accurately and tailor her intervention accordingly	Believes colleagues regard Stages of Change theory as helpful and approve of its use in the smoking cessation intervention
Knows how to differentiate the stages of change, their characteristics and how to tailor her intervention appropriately	Believes use of theory can enhance chance of programme's success	Regards knowledge about Stages of Change as valuable for professional development	Has necessary skills to counsel women in different stages of change		Believes that colleagues and researchers expect her to apply Stages of Change theory to smoking cessation counselling
Knows how to meet different needs of women at different stages of change	Believes women at different stages have different needs and may require different interventions Believes knowledge about Stages of Change theory can be usefully applied in other behavioural change contexts	Feels positive about trying to assess stage and tailor intervention			Is motivated to adopt the innovation and comply with expectations of colleagues and researchers

4) Performance objective: For health care provider to assist pregnant woman to quit

Personal Determinants					
Knowledge	Beliefs	Attitudes	Skills	Self efficacy	Subjective norms
Has knowledge of accepted behavioural modification strategies that assist people to quit smoking	Believes that quitting is not too difficult and that many pregnant women have succeeded in quitting when given appropriate support	Has a supportive and empathetic attitude to the smoker as she tries to quit	Has communication skills that enable her to impart information about quit strategies in a patient-centred (MI) way	Feels confident about assisting women to quit through using a more patient-centred approach	Believes that colleagues and Dept officials regard smoking as a priority issue in antenatal care and that providing practical assistance to women to quit is a standard of good practice
Knows how to advise women to cope with withdrawal symptoms	Believes that her assistance is important, of great value and will have an impact on behaviour	Feels optimistic that her involvement in intervention is going to make a difference	Has the necessary skills to use the guidelines and educational aids/ resources provided for the intervention	Feels confident that she can use guidelines and educational aids effectively	Believes colleagues and Dept officials expect HC providers to assist women to quit, using a patient centred counselling method
Knows the immediate health benefits of quitting that the pregnant woman can expect for herself and her baby	Believes pregnant women want to quit out of concern for the baby, but need encouragement and support to do so			Feels confident her assistance will be helpful and that pregnant women will respond positively to her efforts	Feels motivated to comply with these expectations
	Believes providing assistance to women to quit improves quality of antenatal care and is the responsibility of HC providers				Believes that HC provider delivered smoking cessation intervention for pregnant women is expected by policy makers to be one aspect of the implementation of the national tobacco control programme
	Believes quitting at any stage of pregnancy is beneficial				

5) Performance objective: For health care provider to monitor progress and reinforce change throughout the pregnancy

Personal Determinants					
Knowledge	Beliefs	Attitudes	Skills	Self efficacy	Subjective norms
Understands reasons why continual reinforcement of behavioural change is necessary	Believes continual reinforcement of choice to quit is necessary and important to prevent relapse	Has an empathetic and supportive attitude to smokers who are struggling to quit (but does not give up encouraging them to stop smoking)	Has communication skills necessary to affirm and reinforce behavioural change	Feels confident her continued intervention makes a difference	Believes that colleagues and Dept officials regard smoking as a priority issue in antenatal care and that monitoring smoking status throughout the pregnancy is a standard of good practice
Understands the difficulties of quitting and that quitting is a process of change (Stages of Change theory)	Believes that any progress towards quitting should be acknowledged and affirmed	Has a positive attitude to pregnant woman for any progress made towards quitting		Feels confident that women will respond positively to her routinely asking about smoking at every antenatal visit	Believes colleagues and Dept officials expect HC providers to monitor smoking and reinforce quitting at every opportunity, using a patient centred counselling method
Understands the risk of relapse is high among pregnant women	Believes that she should not give up encouraging any woman who says she wants to give up, but is struggling to do so Believes continued monitoring of smoking status conveys message to women that quitting in pregnancy is very important	Has an attitude of admiration (for succeeding at a difficult task) towards pregnant women who succeed in quitting			Feels motivated to comply with these expectations Believes that the delivery of a smoking cessation intervention for pregnant women by HC providers is expected by policy makers to be one aspect of the implementation of the national tobacco control programme

External Determinants for health care provider Performance Objectives 1-5

Social Support/reinforcement	Social norms	Supportive organisational environment (clinic)	Cues to action
Receives encouragement and support for involvement in intervention and evaluation from Health Dept officials, clinic managers, supervising clinicians, hospital superintendents and colleagues	Widespread support from pregnant women and health professionals for antenatal HC providers' involvement in smoking cessation	Support from all levels of antenatal service for intervention and evaluation and effective communication of this to all participating staff	Decision by National and Provincial Dept of Health, Hospital Superintendent and Clinic Management to lend support to the project and expectation that selected clinic staff become involved
Receives encouragement, support and assistance from researchers in fulfilling their role in smoking cessation intervention and evaluation	Widespread belief that it is particularly important for pregnant women to quit and that quitting is achievable	Training and agreed definition of role which acknowledges and is sensitive to HC providers' current working conditions and constraints	Training which includes local information on extent of preventable adverse outcomes related to smoking among target group; success of smoking cessation programmes among pregnant smokers and skills training
Receives encouragement and support from family and partner for involvement in smoking cessation intervention	Widespread belief that HC providers play a significant and effective role in smoking cessation	Refresher training for HC providers throughout the intervention	Intervention materials for HC providers which prompt them to ask about and document smoking status; initiate discussion with pregnant women about smoking cessation and assess change
Training which acknowledges HC providers' negative experiences and frustrations with pregnant women who smoke	Belief among colleagues that, despite current working conditions and constraints, smoking cessation interventions are still feasible to implement (belief that even a few minutes of time spent on discussing smoking can make a difference)	Continuing support from and presence of research team in clinic and reliable provision of all material required for HC providers to fulfil their envisaged role in intervention and study	Intervention materials which aid HC providers in discussing smoking cessation with pregnant women and in assisting them to quit
Acknowledgement by trainers and researchers of HC provider expertise, skills and knowledge		Broader policy within health services which recognises the extent and importance of smoking as a public health problem, identifies the role of HC providers in smoking cessation and prevention and gives special attention to smoking in pregnancy	Intervention materials which prompt HC providers to monitor smoking behaviour throughout pregnancy and reinforce behavioural change at every opportunity
		Health Dept understanding of, support for and cooperation with implementation of national tobacco control policy and legislation in areas of tobacco marketing, regulation of smoking in public places, taxation, regulation of sale to minors and public education	Evaluation materials which prompt HC providers to collect research data required

6) Performance objective: For health care providers who smoke to desist from smoking on clinic premises

Personal Determinants					
Knowledge	Beliefs	Attitudes	Skills	Self efficacy	Subjective norms
Is aware of how nurses/midwives' smoking on clinic premises undermines their role in smoking cessation and the credibility of the quitting message	Believes smoking on clinic premises is unacceptable, given role in smoking cessation intervention	Has compliant attitude to non- smoking policy in clinic	Has communication skills to persuade other nurses or midwives who smoke, to not smoke on clinic premises	Feels confident she can quit at the time of the smoking cessation intervention	Believes colleagues, Dept of Health officials and researchers expect staff not to smoke on clinic premises
Is aware of Dept policy on smoking in public places and understands rationale and aims	Believes as a HC provider she should quit smoking and provide a good example to pregnant women	Has positive attitude about involvement in smoking cessation intervention and evaluation		Feels confident she can disclose smoking status to researchers without fear of judgement	Is motivated to comply because she is sympathetic to policy rationale and aims
Is aware of the importance of being a good role model for pregnant women who want to quit	Believes involvement in smoking cessation intervention will be a good time to try and quit herself				
Is fully aware of the health risks of smoking for herself and others around her (ETS)	Believes it is important to protect family, colleagues and patients from risks of ETS				
External Determinants					
Social Support/reinforcement	Social norms	Supportive organisational environment	Cues to action		
Receives encouragement and support from colleagues, researchers and family to use involvement in smoking cessation intervention as opportunity to quit smoking	Widespread support from family, community, peers, colleagues for quitting smoking	Broader policy within health services which recognises the extent and importance of smoking as a public health problem, identifies the important role of HC providers in smoking cessation and prevention	Involvement in training for smoking cessation intervention and evaluation and in intervention itself		
Offer of opportunity to enrol at Tygerberg Smoking Cessation Clinic by research team	Widespread belief that it is particularly important for HC providers to quit as they have a responsibility to educate and counsel patients/clients to stop smoking	Clinic based policy which prohibits smoking on clinic premises by members of public and by staff	Referral to Tygerberg Smoking Cessation Clinic for assistance in quitting		
	Widespread belief that HC providers play a significant and effective role in smoking cessation and that this is undermined if they themselves smoke		Availability of educational materials on risks of smoking and materials to assist smokers to quit		
			Availability of Smokelyzer instruments to test levels of carbon monoxide		

Table 3: Theory-based methods and application to smoking cessation intervention for pregnant women

- The basic strategies selected for the programme were: 1) Individual counselling by peer counsellors and midwives 2) Leaflets for pregnant women in pre-contemplation and contemplation stage of behavioural change 3) Self-help Quit Guide for women in contemplation and preparation stage and 4) Leaflet to aid women seek appropriate social support from their partner or family. The table below provides further detail of how these strategies were planned to operationalise the methods listed in the left hand column.

These methods are suggested primarily by Social Cognitive theory (Bandura, 1986) and the Transtheoretical or Stages of Change model (Prochaska and DiClemente, 1983). They conform to the taxonomy of behaviour change techniques for interventions compiled by Abraham and Michie (2008).

Abbreviations: PW = Pregnant women; MW = Midwives; PCs = Peer counsellors

Theory based methods	Definition	Application
Methods to influence knowledge:		
Consciousness raising	Raising awareness of risk and implications; knowledge of how to avoid risk	Counselling and media to provide new information on adverse outcomes of smoking and costs of inaction (short and long term consequences); nicotine addiction; concept of risk; immediate and long term benefits of quitting for baby and mother
Persuasive communication	Information which is accessible, easily understood and internalised and is perceived as credible and trustworthy	Media to be of good quality, visually appealing, clearly organised; to use credible experts to convey biomedical information in clear, simple terms; breakdown of complex information
Individualisation and Tailoring	Adaptation of programme content and messages to characteristics of the target audience to enhance the perceived relevance and internalisation of information	Content and format of media to be suitable to level of education and literacy of PW; content developed with reference to prevailing knowledge, beliefs, attitudes, self efficacy and prior experiences; information suitable for different stages of change; use of PCs from same community; depiction of role models from target community in familiar, recognisable settings in the media
Provide instruction	Teach behavioural skills	Quit Guide and counseling to provide information on how to prepare for quitting, how to actually quit and maintain behavior change
Motivational Interviewing	Patient-centred approach to counselling	MWs and PCs to acknowledge and respect what woman already knows about smoking during pregnancy and use as basis for engaging PW in discussion
Methods to influence behavioral beliefs and attitudes:		
Personal risk appraisal Self-evaluation Counter unrealistic optimism Emotional dissonance	Weigh pros and cons of behaviour; identify future implications and potential impact on others Reflect on personal values and goals Realisation of discrepancy between important personal values and behaviour	Counselling to encourage self evaluation of pros and cons (including non-health related ones); validate PW's concerns and experiences about quitting; explore goals and values and assist in identifying discrepancies; consider future implications and impact on others; assess importance and ambivalence about change; integrate quitting as part of self-identity Media to link smoking to recognisable health problems in community to counter perceived lack of susceptibility; depict role models who experienced adverse effect of smoking in pregnancy; self- monitoring exercise (diary) in Quit Guide to prompt realistic appraisal of extent of smoking

Persuasive argument Respect autonomy in decision making	Provide and elicit arguments for change Respect need for self determination	Media to provide compelling and new arguments for quitting; MWs and PCs to encourage PW to personally engage with information on risks and express own reasons to quit; counsellors to avoid engaging in arguments about whether PW should quit or not; respect PW's autonomy to decide, validate stage of change (e.g. lack of readiness)
Biological feedback	Feedback on physiological indications of harm	MWs and doctor to undertake medical examinations to establish health and growth of fetus (palpitation, ultrasound, fetal monitoring, Doppler ultrasound) and to assist in interpretation of personal risk after assessment
Fear arousal and management of emotion Anticipated regret, dramatic relief through modelling	Provision of emotional stimuli accompanied with coping strategies to stimulate desire to change Emotional stimulation through identification with imagined scenario	Counselling to assist PW imagine scenario if pregnancy or baby were to be seriously affected by smoking; arouse concern and encourage its expression, while offering support and a quitting plan. Also emphasise quitting is successful in preventing/minimising harm and that the intervention will help her to quit. Personal testimonies in programme media and PCs to describe their negative experiences of harm and the dramatic relief they experienced when they quit
Reframing negative outcome expectations and promoting positive ones Barrier identification	Reinterpretation of anticipated negative outcomes of behaviour Identify barriers to performing behaviour and how to overcome them	Counselling and media to provide counter arguments to existing negative outcome expectations; emphasise positive outcomes and anticipated rewards of quitting; identify perceived barriers and offer strategies on how these can be overcome; convey confidence in PW's capabilities
Motivational interviewing	Patient-centred approach to counselling	In counselling, MWs and PCs to encourage interaction and facilitate self-evaluation; are willing to listen to woman's perspective; acknowledge the benefits of smoking and show sensitivity to PW's feelings, motivations and experiences; express empathy and non-judgement about smoking; express respect for PW's right to make an informed decision without pressure; avoid prescribing change and thereby creating resistance; validate stage of change Media to adopt non-judgemental or prescriptive tone and express PW's autonomy in making a decision
Methods for influencing efficacy beliefs, self-efficacy and skills:		
Verbal persuasion Social support/ reinforcement Locus of control	Verbal encouragement Tangible and emotional support from others; responses that increase or decrease likelihood of behaviour Belief that one can control one's health and life experiences	Counselling by MWs and PCs to affirm individual capabilities and express confidence that PW can perform behaviour; encourage feelings of confidence and belief in ability to determine their future; media to include testimonials of others who have succeeded; Quit Guide to include self affirmation exercises
Setting graded tasks in preparation for behavioural change/mastery learning Goal setting and behavioural contract	Structured learning/ seeing easier tasks first and then increasing difficulty until target behaviour is performed Setting goals for change and agreement to perform behaviour, witnessed by others	PCs to assist a woman who feels ready to make a quit attempt to focus on setting a quit date and begin to use the 7 day quit programme in the Guide. Quit Guide to include goal setting (specific and incremental) exercises and written commitment to a quit date, agreed with PC. For those not ready, encourage small steps towards goal (reducing smoking)

Skills training and practice	Teaching practical, behavioral skills to enable behavior change	Self- help Quit Guide to include the teaching of practical quitting skills, negotiating, problem solving, coping and relaxation skills, as well as exercises that teach how to identify and plan coping responses for high risk situations PC to mediate skills training exercises in Quit Guide (explain and encourage use of Guide and give instruction where necessary)
Modelling Social comparison	Good examples of others who have achieved change Observation of non-expert others who have succeeded in overcoming barriers to change	PC and models in media model achievement of quitting, appropriate coping responses, sub-skills and rewards of quitting
Self monitoring and practice	Self evaluation of progress, keeping records	Quit Guide to prompt self monitoring of progress, rehearsal and repetition of preparatory behaviours and skills to enhance efficacy and sense of personal control
Contingency rewards	Praise or material rewards from oneself or others, which are linked to achievement of behaviour or taking positive action	Quit Guide to suggest personal rewards for reducing smoking and quitting and seeking out of positive affirmation from others; reinforce value of inner rewards. Contained a special Award certificate for quitting, signed by the Medical Research Council and University of Stellenbosch
Re-attribution training, positive framing	Focusing on success and learnings rather than on failure	Counselling by MWs and PCs and Quit Guide to change attributions of failure. For example: relapse due to addiction, not personal weakness; to understand relapse to be a normal part of quitting process and an opportunity to learn more about one's smoking behaviour
Social inoculation	Resistance to social pressure to relapse	PCs and Quit Guide to help PW identify social situations which could lead to relapse, teach resistance skills for coping with social pressure and to prompt planning for these situations
Counter conditioning Substitution Averse stimulus	Creating new habits and behavioural routines Creating aversive physical responses to old behaviour	Counselling by MWs and PCs, and Quit Guide to suggest substitute behaviours for smoking and changes in routines and associated behaviours Quit Guide suggests making a "Yuck Jar" to function as aversive stimulus to smoking (collecting and smelling old cigarette butts) Quit Guide to include self-encouragement/affirmation exercises
Stimulus control	Teaching the person to identify cues in the environment that can trigger 'old' behaviour and which can support new behaviour	Counselling by PCs and Quit Guide to suggest removing or avoiding negative cues in environment (e.g. ashtrays, cigarettes) to aid quitting and to re-structure environment to support quitting and remind them to create new habit
Social support Reinforcement	Positive affirmation and tangible help from others/helping relationships Responses that increase or decrease likelihood of behaviour	PCs and MWs to offer encouragement, positive feedback, affirmation and reinforcement for progress (not matter how small) during every follow up visit to the clinic; express caring and concern Prompt PW to plan and ask for practical and emotional support from important others (family and partner) and to seek help from ex-smoker (stop smoking buddy or mentor)
Motivational interviewing	Patient-centred counselling	MWs and PCs to elicit 'self efficacy talk' from PW herself (self motivating statements); respect PW's pace of change

Methods for influencing normative beliefs and perceived social norms:

Social support/reinforcement	<p>Responses that increase or decrease likelihood of behaviour</p> <p>Perceived support for new behaviour from significant others</p> <p>Helping relationships</p>	<p>Media to model concern of family members and partners and provision of tangible social support (e.g. testimonial of partner who gives up smoking himself in Quit Newspaper) and provide evidence of approval by others for target behaviour; role model in Quit Newspaper to receive social reinforcement and contingency rewards for quitting</p> <p>Counselling, Quit Guide and leaflet for partners/family members to prompt woman to actively seek out social support for quitting in her immediate social environment (smoking buddy, support from partner, friends and family)</p> <p>MWs and PCs to provide encouragement, verbally praising progress or achievement; express caring and concern and convey empathetic attitude in counselling</p> <p>MWs to providing positive feedback on measurable health indicators (growth of baby; umbilical blood flow, health of pregnancy; health of placenta at delivery)</p> <p>Community leaders to praise women who quit and urge social support from community at Community Health Days</p>
Counter negative outcome expectations	<p>Evaluations of social consequences of performing new behaviour</p>	<p>Counselling by MWs and PCs and media to emphasise positive expectations in the social environment, affirm concerns of partner; discuss social norms, correct misconceptions about attitudes of peers; identify other quitters in community.</p>
Skills building	<p>Building skills to maintain new behaviour in social context</p>	<p>PC to assist in building skills to resist social pressure: negotiating and refusal skills, skills to enable coping with social rejection from peers. Quit Guide to guide woman in development of problem solving skills and to offer suggestions on how to resist social pressure</p>
Social inoculation	<p>Resistance to social pressure to not perform new behaviour or to relapse</p>	<p>PCs to present and elicit counter arguments from women themselves for resisting social pressure. Media to present counter arguments to social pressure through use of peer testimonials</p>

Methods for influencing intention:

Prompt specific goal setting	<p>Detailed planning of what person will do</p>	<p>Self-help Quit Guide to assist PW prepare to quit and develop specific behavioural skills over time to enable quitting; counselling and Quit Guide to prompt setting of quit date; identify different options for change and identify priorities</p>
Prompt intention formation	<p>Prompt person to resolve to act</p>	<p>MW and PC to encourage formulation of commitment to quit and discuss intention with family and friends</p>
Social reinforcement	<p>Approval for action from others</p>	<p>MW and PC to praise PW for decision to take action</p>

Table 5: Extract from Quit Guide illustrating use of theory-based methods and strategies for quitting

Extract from pg 4: Section: DECIDING TO QUIT	
<p>Smoking during pregnancy also increases the risk that you will lose your baby during pregnancy. Smoking causes miscarriage, premature birth and placenta abruption (where the placenta comes away from the wall of the womb). These are the three biggest causes of babies dying at Tygerberg Hospital in Cape Town.</p>	<p><i>Comment: Knowledge: risk of smoking to pregnancy. Perceived susceptibility: babies are dying from smoking at a local hospital known to the target group (referral hospital for target group). Arousing anticipatory regret.</i></p>
<p>An increased risk of something going wrong, means that there is an increased chance of this happening. Some women who smoke are lucky enough to not have any serious problems, but many others do. Also, if you did not have problems smoking during a previous pregnancy, it does not mean that you and your baby won't be affected this time.</p>	<p><i>Comment: Addressing lack of understanding of concept of risk</i></p>
<p>Smoking while you are pregnant can also have long-term effects on your baby. Children born to smokers are more likely to develop asthma by the age of seven and have learning and behavioural difficulties at school. Children whose parents smoke around them have more coughs, colds, chest infections, asthma attacks and earaches, than children living with parents who don't smoke.</p>	<p><i>Comment: Knowledge: risks of passive smoking; long term effects on children. Perceived risk: asthma very common and well known health problem in target group's community.</i></p>
<p>Quitting at any time in your pregnancy is good for your health and your baby's. It is never too late in your pregnancy to quit. In fact, smoking in the last three months is particularly harmful to your baby, because this is when he or she will grow the most.</p>	
<p>The moment you stop smoking, your baby will get more oxygen and nutrients and start growing better. Cutting down the amount you smoke reduces the risk of harm, but you and your baby are only safe if you give up smoking completely. It is of no use switching to light cigarettes or an 'okka' pipe. These are just as harmful as ordinary cigarettes.</p>	<p><i>Comment: Providing dramatic relief after arousing affective response: recommended action is effective; quitting results in immediate benefits for baby. Addressing the common belief that if you have not quit up until now, there is no point. Candid statement on cutting down – it does minimise harm, but does not offer full protection. Addressing misconception that light or herbal cigarettes are less harmful.</i></p>
<p>Smoking during pregnancy causes:</p> <ul style="list-style-type: none"> • Miscarriage, stillbirth, premature labour, placenta abruption • Poor growth of the baby in the womb • Low birth weight (baby born too small and weak) • Cot death or SIDS (baby dying in its sleep) • Breathing problems and asthma • Learning and behavioural problems 	<p><i>Comment: Repetition of factual information in a different format aids retention.</i></p>
<p><i>'I won't smoke again. I smoked a lot in my last pregnancy and it had a great effect on my daughter. She was very small and now she can't learn well at school. The doctors at Red Cross said it was the smoking. I felt so bad.'</i> Tanya, 32 years old.</p>	<p><i>Comment: Testimonial: arousing negative emotions about potential risks to enhance perceived susceptibility.</i></p>
<p>Pregnancy is a good time to try and quit, because you probably want to quit even more now than before. Try and use this time to stop! If you quit during pregnancy, you will be giving your baby a better start in life.</p>	<p><i>Comment: Acknowledging that most smokers want to quit. Persuasive argument for capitalising on additional motivation to protect one's baby. Emphasising and appealing to appropriate personal values (responsibility to try and do the best for one's children) and emotion (visual image of healthy baby). Creating emotional dissonance between personal values and current behaviour can stimulate self re-evaluation and ultimately, attitude change.</i></p>
<p><i>Image: Photograph of a healthy, happy baby.</i></p>	

Extract from pg 9: Section: ARE YOU READY TO QUIT?

'I was so scared because I did not know if I was going to be able to stop. But I did not want anything bad to happen to my baby. If that happened, I could not forgive myself. So I decided to quit. Once I had really made up my mind, it was not that difficult.' Alicia, 21 years old.

Comment: Beliefs reframing perceived behavioural control – widely held belief that quitting is very difficult.

Others may want you to quit, but the ultimate decision can only come from you. It takes real commitment to quit smoking, so think about whether you really want to do it.

Comment: Acknowledging that the choice to stop smoking lies with the woman herself. Respecting women's autonomy.

The following exercises will help you make a decision:

Comment: Stages of Change: assisting women assess their readiness to change behaviour, accepting that some women may not be ready to quit now

Make a list of the reasons why you smoke and what you like about smoking. Then think about what is not so good about smoking and the reasons why you want to stop. Your pregnancy is a good reason to quit, but think of other reasons too.

Comment: Cost benefit analysis: assisting women weigh up pros and cons of behavioural change. Encouraging woman to express their own arguments for change ('change talk'). Acknowledging the fact that smoking does offer smokers certain benefits and that quitting has some disadvantages. Suggesting that the pros and cons include factors other than those related directly to health.

What I like about smoking/ why I smoke

What is not so good about smoking/ Why I want to stop smoking

How important is quitting for you? Give yourself a rating from 1 to 4 by ticking the appropriate box.

- 1. Not at all important right now
- 2. Not important right now
- 3. Important
- 4. Very important right now

How confident are you that you can quit smoking? Give yourself a rating from 1 to 4 by ticking the appropriate box.

- 1. Not at all confident
- 2. Not confident
- 3. Confident
- 4. Very confident

Comment: Exercises from Motivational Interviewing. Dealing with ambivalence about behavioural change. Assisting woman assess the strength of her behavioural intention and self-efficacy

Think about what would make you feel more confident. Here are some possibilities:

- Ask for support from your family, the father of your baby and friends
- Find someone who will quit with you
- Talk to the nurse, counsellor or doctor, who will remind you about how important it is to quit
- Talk to someone who has quit smoking and feels great about it

Comment: Suggesting ways to enhance self efficacy

Using this Guide will make you feel more confident about quitting. It will show you how many other pregnant women have successfully given up smoking. If you really want to quit, you can do it too!

Many pregnant women have found quitting easier than they expected. A young woman, who was interviewed, said: 'For me it was not as difficult as I thought it was going to be. I just put smoking out of my mind and said to myself, I am not smoking anymore and that is that. I was not afraid. I had no real problems at all.' Carmen, 19 years old.

If you are ready to start preparing to quit, go on to read the next section of the Guide. If you do not feel ready yet, keep this Guide in a safe place. You can then use it again when you feel able to make a firm commitment to quit and set a definite date for your last cigarette.

Comment: Influencing self efficacy expectations/ perceived behavioural control by persuasive argument: this Guide can help women overcome barriers and obstacles to quitting and many other pregnant women have successfully quit using it. Positive framing – focussing on success. Modelling: using quote of pregnant women who overcame the barriers and succeeded in quitting

Comment: Page: 174 Acknowledging, in a non-judgemental and supportive way, that pregnant woman may not want to proceed in actually committing to quitting at this stage (Stages of Change). For those ready to quit, the importance of setting a quit date.

University of Cape Town

Chapter 5

Evaluation of intervention

The effectiveness of adapted, best practice guidelines for smoking cessation counselling with disadvantaged, pregnant smokers, attending public sector antenatal clinics in Cape Town, South Africa

This chapter presents the evaluation of the planned intervention, which was described in **Chapter 4**.

Introduction

As was discussed in the literature review in **Chapter 1 (A)**, a number of meta-analyses have concluded that smoking cessation interventions are effective in helping pregnant women quit smoking, and in reducing low birth weight and preterm birth (Dolan-Mullen et al., 1994; Windsor, 2003; Lumley et al., 2009). However, as has been already mentioned, these conclusions are based on studies conducted in the US, Europe and Australia and it remains unclear whether these achievements can be replicated in developing countries. Whilst tobacco use among women is falling in many Western countries, it is on the increase in the developing world, making tobacco use during pregnancy a growing concern (Shafey, 2009).

The 5As Smoking Cessation Clinical Practice Guideline (ACOG, 2000, 2005), is currently promoted as best practice for brief, cessation counselling by antenatal care providers. As was described in **Chapter 1 (A)**, the Guideline recommends that a 10–15 minute counselling session by a trained provider and the provision of pregnancy specific, self-help education materials become a standard component of routine antenatal care.

It was evident from our formative research, that midwives and doctors in South Africa do not actively and effectively promote smoking cessation among pregnant women and appear to be unaware of best practice guidelines (Everett et al., 2005; Everett-Murphy et al., 2010; De Feijter, 2003). Whilst pregnant smokers are routinely identified, they seldom receive support for cessation beyond very limited, prescriptive advice to quit. In addition, interviews with pregnant women indicated that they were reluctant to discuss smoking with antenatal care providers, as they anticipated little understanding of their concerns, negative judgement and no practical assistance with quitting (Petersen et al., 2009b).

The purpose of this study was to evaluate the impact of a smoking cessation intervention, which incorporated the ACOG best-practice guidelines, on pregnant smokers attending public sector antenatal clinics. To our knowledge, this was the first time that an intervention, based on models

found to be successful in developed countries, was tested in South Africa and, indeed, in a developing country setting.

Methods

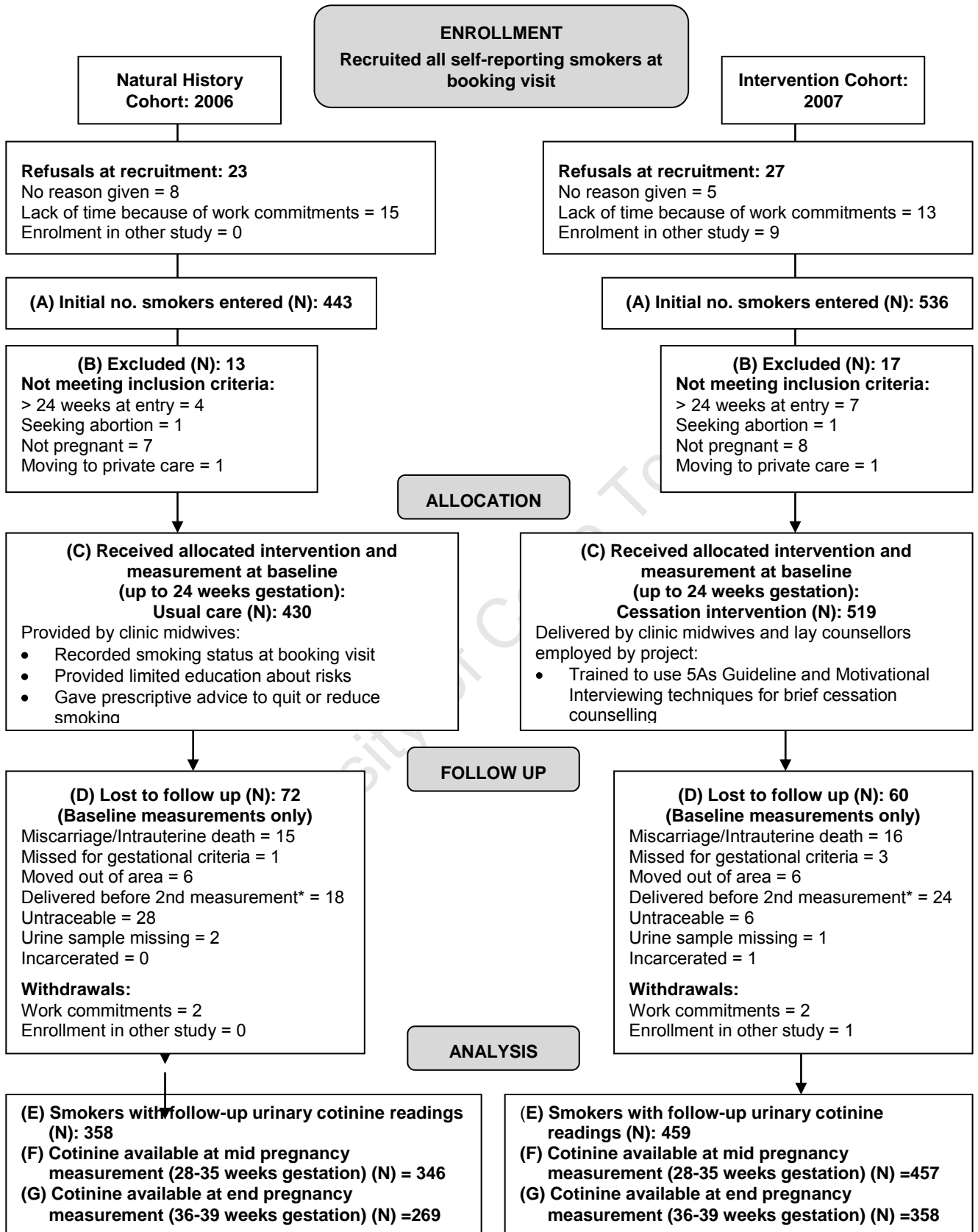
Study population and setting

The subjects of this study were a particular group of high risk, pregnant women, which were described in **Chapter 2** of this thesis. An alarmingly high percentage (46%) of these women continues to smoke during pregnancy (Steyn et al, 1997; Petersen, 2009a). The study was conducted in four, public sector antenatal clinics in Cape Town, which form part of the community based, primary health care facilities, typically used by low income communities. They are run by professionally qualified midwives, who provide ongoing antenatal care and manage deliveries at these facilities. A small proportion of pregnant women with high risk pregnancies or complications during delivery are referred to a nearby tertiary level hospital.

Study Design

The intervention was evaluated using a quasi-experimental design, with a natural history cohort and an intervention cohort (see **Figure 1: Scheme of study design**). The natural history cohort comprised all self-reporting smokers registering at the clinics between February and November 2006. They served as a control group to determine the usual quitting rate during pregnancy when receiving usual care. The intervention cohort registered at the same clinics, but a year later, between February and November 2007, when the intervention was implemented.

Figure 1: Scheme of study design and recruitment



* Either because of premature delivery or incorrectly calculated gestational age

Sample size determination

Sampling

The baseline quit rate was assumed to be 7.5% and the quit rate in the intervention group was expected to be 15.2%, based on the findings of a meta-analysis of smoking cessation interventions for pregnant women from varied populations in the US by Windsor (2003) and an NHS review (1998).

A two group chi-square test with a 0.05 two-sided significance level has 80% power to detect the difference between a control proportion of 0.080 and an intervention proportion of 0.150 (risk difference of .07), when the sample size for each group is 325. For both time periods, a drop-out rate of 20% was assumed. The sample size needed per time period was determined to be 407. The planned sample size was 450 pregnant women in each year, to ensure adequate numbers for analyses. The study was not powered to detect differences in the pregnancy and birth outcomes between the two groups.

All pregnant smokers were invited to participate in the study at their first antenatal clinic visit. They were identified by using the multiple choice questions below, recommended by Mullen et al. (1991).

Are you smoking cigarettes or rolled tobacco now?

No, I have never smoked cigarettes or rolled tobacco;

No, not now, but I was smoking more than six months ago;

No, not now, I stopped smoking before I became pregnant;

No, not now, I stopped smoking after I found out I was pregnant;

Yes, but I smoke less now that I am pregnant;

Yes, every day;

Yes, but not in the last 24 hours;

Yes, not every day, but at least one cigarette or rolled tobacco a week.

The following women were excluded from the study: those who were found not to be pregnant; those beyond 24 weeks gestational age at first booking (calculated on the basis of last menstrual period, palpitation by the midwife or ultrasound); women intending to see seek private antenatal care or an abortion; and women who refused to give consent.

Usual care versus the intervention

Pregnant smokers registering at the clinics in 2006 received usual care, which involved midwives asking about smoking status during history taking and then, typically, advising a smoker to quit or

reduce smoking in a prescriptive manner. The only complications usually mentioned by the midwives were growth retardation in utero and respiratory problems during and after delivery. Earlier formative research showed that the midwives' capacity to do counselling was severely limited by time constraints, staff shortages and increased patient load (Paijmans, 2003; De Feijter, 2003). Midwives also did not have sufficient knowledge to offer women any practical assistance in quitting. The only educational materials available were general pamphlets on pregnancy, with scant information on smoking (Paijmans, 2003; De Feijter, 2003).

Pregnant smokers registering at the same four clinics in 2007 were exposed to the intervention, which was incorporated into routine care. The different elements of the intervention were fully described in **Chapter 4**. See **Table 4** in **Chapter 4** for core of intervention.

Outcome measures

The primary outcome measure was quitting, defined as a urinary cotinine level below 100 ng/ml. Secondary outcome measures were: a significant reduction in smoking, defined as at least a 50% decrease in the level of urinary cotinine at study entry (Li et al., 1993); and self-reported quitting, reduction and quit attempts.

Data collection procedures

Women were interviewed by fieldworkers, who administered questionnaires during three routinely scheduled clinic visits: 1) at baseline, less than 24 weeks' gestation; 2) mid-pregnancy at 28–35 weeks; and 3) end of pregnancy at 36–39 weeks. Urine samples were collected at the same time points. Written consent was obtained from all participants after a full explanation of study procedures. If women did not attend the routine visits scheduled by the midwives, they were telephoned and arrangements were made to meet them, either at home or at the clinic, for follow up measurements. Patients who were referred to the tertiary hospital for complications were followed up at the hospital clinic or in the ward.

The baseline questionnaire collected data on various socio-demographic characteristics, as well as social support; relationship with the father of the baby; beliefs about smoking and quitting; exposure to environmental tobacco smoke; stage of behavioural change (DiClemente et al., 2000) and women's experiences of pre-intervention smoking cessation activities at the clinic. Self reported smoking was measured by number of cigarettes smoked per average day and level of addiction determined by the Fagerstrom Test for Nicotine Dependence (Fagerstrom & Schneider, 1989). Smoking behaviour was re-assessed at times 2 and 3. Alcohol consumption was measured, using the

definition of a standard drink by Wolmarens et al. (1993). Information on the delivery and birth weight was collected from the labour ward register at the clinic or referring hospital.

Women in the Intervention cohort completed questions which assessed their recall of exposure to the intervention and their level of satisfaction with various intervention components. In addition, midwives were obliged to note down their delivery of the 5As protocol in the clinic folder.

Cotinine, which is the primary metabolic by-product of nicotine, is currently regarded as the best means of bio-chemically validating self-reported smoking behaviour, as well as exposure to environmental tobacco smoke (Benowitz, 2002). In this study, current smoking status at all three measurements was determined by urinary cotinine assay. These were performed by using a Cotinine Direct ELISA kit, imported from Bio-Quant Inc. in the USA and following the instructions in the manufacturer's package insert. The urine samples were collected at the same time as the interviews, taken to the Medical Research Council's laboratory that day and refrigerated at below 20°C. The laboratory technician was blind to self reported smoking status and level of tobacco consumption. All women who supplied urine samples for cotinine testing received their results in writing.

There is an overlap between the cotinine readings of non-smokers exposed to high levels of environmental tobacco smoke and light smokers (Rebagliato, 2002). In order to validate the cotinine cut off point of 100ng/ml for active smoking in this particular study population, cotinine urine tests were conducted on two samples of passive smokers: a) 123 additional pregnant women recruited from the same clinics b) a convenience sample of 62 non-pregnant work colleagues. The cotinine distribution of these two groups of passive smokers was then compared to that of the study population, all of whom were self-reported active smokers. The definition of 100ng/ml or above, indicating active smoking, fitted the smoker distribution well and was maintained for the analysis of the cotinine related study outcomes (see **Figure 2**, over).

The Medical Ethics Committee at the University of Stellenbosch in Cape Town granted ethical approval for the study (see **Chapter 2** for further details on ethical considerations).

Results

Recruitment and follow up

A total of 979 self-reporting pregnant smokers were entered into the study at baseline (443 in the Control Group and 536 in the Intervention Group). **Figure 1**, shows the details of the recruitment process, the women excluded after initial recruitment, as well as those women who were lost to follow up by measurements 2 and 3. If women had at least one follow up measurement, they remained in the study.

Description of study participants

The women in the two groups came from the same residential areas, socio-economic and cultural backgrounds. There were no significant differences at baseline on demographic variables (see **Table 1**, overleaf), with the exception that more women in the intervention cohort had unplanned pregnancies and more of them lived in informal housing (under-serviced, temporary dwellings). Both these variables favoured the natural history cohort for better outcomes, rather than the intervention cohort (Lumley et al., 2007).

Twenty four percent of women in both groups were teenagers between 14- and 19-years old and less than half (NH: 44%; INT: 40%) were pregnant for the first time. A high proportion of women (NH: 63%; INT: 69%) had not planned their pregnancies. Whilst the majority of women had received some secondary school education, a minority had completed it by passing Grade Twelve 12 (NH: 22%; INT 17%) – the minimum requirement for any form of tertiary education – 7% of the natural history and 6% of the intervention sample had not gone further than primary school (Grade 7).

Despite over half of the women (NH: 54%; INT: 56%) not living with the father of the baby, the majority of women said that they were receiving emotional and financial support from them. A significant number also relied on family members, especially their parents for such support. More than two thirds of the women reported that they were exposed to ETS in their homes on a daily basis, indicating a very high prevalence of smoking in this community. The majority of women (NH: 81%; INT: 87%) said that the father of their baby was concerned about her smoking during pregnancy. Only a minority (NH: 20%; INT: 15%) dismissed their partner's concern out of hand, maintaining that he had no say in the matter.

Table 1: Profile of two groups at baseline (<24 weeks gestation)

VARIABLES	GROUP		P-value
	Natural History N=358	Intervention N=456	
Mean (Standard deviation)			
Pregnancy: duration in weeks	16.8 (5.5)	16.9 (5.8)	0.904
Gravidity (no. of pregnancies, including current one)	2.0 (1.2)	2.1 (1.3)	0.416
Parity (no. of live births)	0.8 (1.0)	0.9 (1.0)	0.451
Age in years	24.0 (6.0)	24.1 (6.0)	0.649
No. of other smokers in home	1.8 (1.7)	1.6 (1.4)	0.040
Housing density (no. of people per room)	1.5 (0.9)	1.5 (0.9)	0.721
EDUCATION (%)			
≤ Grade 8	19.7	17.2	0.349
> Grade 8	80.3	82.9	
PLANNED PREGNANCY (%)			
No	63.0	69.9	0.042
MARITAL STATUS (%)			
Married, living with the father of the baby	21.4	19.2	0.883
Married, not living with father of the baby	3.1	3.3	
Unmarried, living with father of the baby	24.2	24.5	
Unmarried, not living with the father of the baby	51.3	53.0	
TYPE OF HOUSE (%)			
Formal: Brick house/flat	84.2	75.0	0.003
Informal: Wendy house	11.2	15.6	
Bungalow in yard	3.2	38.3	
Shack in squatter camp	1.4	1.1	
EXPOSURE TO ETS* (%)			
Yes	66.8	68.7	0.543
SMOKING BEHAVIOUR			
Cotinine profile at baseline (%):			
≤100 ng/ml	1.5	0.7	0.139
101-300 ng/ml	5.4	3.1	
301-1000 ng/ml	31.0	34.8	
≥1001 ng/ml	61.9	61.2	
Self reported cigs per day: Mean (SD)	6.1 (5.4)	5.7 (4.5)	0.162
OTHER RISK BEHAVIOURS (%)			
Used alcohol	54.8	49.3	0.117
Used illicit drugs	13.0	14.9	0.459

*ETS = Environmental Tobacco Smoke

There were no significant differences at baseline between the two groups in cotinine profile or self reported smoking status (see **Table 1**). The mean tobacco consumption, according to self-report, was around six cigarettes per day in both groups, compared to nine per day before becoming pregnant. Level of addiction did not differ significantly either: about half of all women (NH: 45%; INT: 50%; $p = 0.110$) smoked their first cigarette within 5–30 minutes of waking and could therefore be categorised as heavily addicted to nicotine (Fagerstrom & Schneider, 1989). This suggests that the self reported mean of six cigarettes per day is an under-report. In both groups, reported and cotinine measured smoking at baseline was positively associated with age, with older women having progressively higher cotinine values.

When asked whether they were seriously considering quitting during the pregnancy, the vast majority answered in the affirmative (NH: 85%; INT: 95%). However, when asked whether they were planning to quit in the next 30 days, an indication of the seriousness of their intention to quit smoking during the pregnancy (Prochaska & DiClemente, 1983), the figure dropped to 59% in the natural history group and to 69% in the intervention group. Around half of women (NH: 57%; INT: 52%) had not yet attempted to quit smoking during their pregnancy (defined as not smoking for at least a full 24 hours), whereas 31% had tried to quit once or twice before the first interview.

In a question which asked women why they had not quit up until now, the most frequently cited reason was because smoking helped them cope with stress, followed by the fact that they lived or worked with smokers, which made it very difficult to give up.

Table 1 shows that there were no significant differences in terms of alcohol or drug use at baseline between the two groups. A worrying number of women (NH: 54%; INT: 49%) said that they had consumed alcohol since becoming pregnant. Binge drinking was the common pattern of consumption. The mean number for the most alcoholic drinks consumed in a single day since becoming pregnant was 6.1 (SD: 6.6) and 5.5 (SD: 4.3) for the natural history and intervention group respectively, with the most extreme value being 26 and 29 standard drinks a day.

Thirteen percent of smokers in the natural history group and 14% in the intervention group divulged that they had used illicit drugs during their pregnancy. The majority of drug users (NH: 78%; INT: 59%) had used crystal methamphetamine, a highly addictive nervous system stimulant known locally as 'tik'. Cannabis was the next most used drug (NH: 32% ; INT: 48%), followed by mandrax (NH: 4%; INT: 1%).

Primary outcome

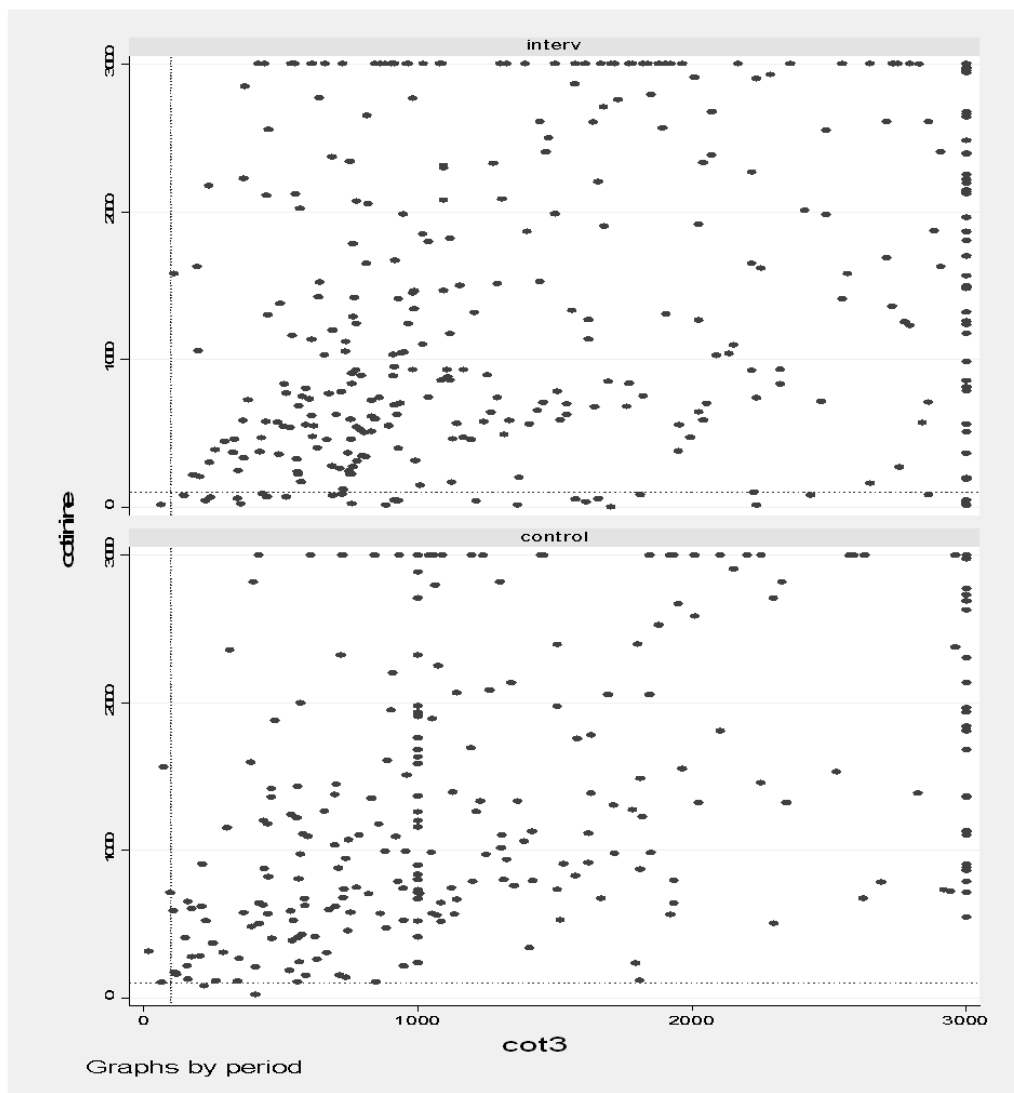
Table 2 summarises the cotinine validated, point prevalence quit rates for end of pregnancy (36–39 weeks' gestation). The difference in quitting between the two cohorts was 7.6% (95% CI: 4.6% to 10.7%, $p < 0.0001$). As there were hardly any quitters in the Natural History cohort ($n=2$), the rate observed in the Intervention cohort was close to the intervention effect. In an intention to treat analysis, where it was assumed that those lost to follow up had not quit, the difference in quitting rates was 5.3% (95% CI: 3.2% to 7.4%, $p < 0.0001$). An analysis of each of the intervention clinics separately showed a similar intervention effect in both clinics and both were significant.

Table 2: Primary and secondary study outcomes

OUTCOMES Frequency (%)	Natural History Cohort (N=269)	Intervention Cohort (N=358)	Risk difference between groups	95% Confidence Interval	P-value
PRIMARY OUTCOME: Quitting by urinary cotinine ($<100\text{ng/ml}$)					
A) Analysis excluding lost to follow up (NH: N=72) (INT: N=60)	2 (0.7%)	30 (8.4%)	7.6%	4.6%-10.7%	0.0001
B) Intention to treat analysis (those lost to follow up, classified smokers)	2 (0.5%)	30 (5.8%)	5.3%	3.2%-7.4%	0.0001
SECONDARY OUTCOMES:					
Quitting by self report	37 (13.4%)	66 (18.2%)	4.8%	0.8% - 10.4%	0.0619
Reduction by urinary cotinine (value reduced by at least 50%)	44 (16.3%)	101 (28.1%)	11.7%	5.0% - 18.3%	0.0006
Reduction by self report	144 (52.1%)	235 (64.9%)	12.7%	5.1% - 20.4%	0.0008
Quit attempts by self report Mean (SD)	0.27 (1.12)	1.55 (1.85)			0.0001

A logistic regression model for the Intervention cohort showed that there was no significant association with baseline cotinine ($p=0.091$). This can also be seen in **Figure 3**. It is clear from this scatterplot that there are more points at low values on the Y axis across the whole of the X axis in the intervention plot, compared to the natural history plot. This indicates that quitters in the Intervention cohort came from all categories of smokers, including those heavy smokers with high baseline cotinine readings.

Figure 3: Quitting and Baseline measurement



Secondary outcomes

Table 2 shows that by end of pregnancy, 101 (28%) of women in the intervention cohort had reduced their cotinine levels by at least half, compared to 44 (16%) in the natural history cohort – a difference of 11.7% (95% CI: 5.0–18.4%, $p=0.0006$).

The self reporting quitting rates also differed significantly at end of pregnancy. The data in **Table 2** shows a large discrepancy, with cotinine validated quitting and self reported reduction rates in both groups. Only 30 of the 66 (45%) women in the intervention group and 2 of the 37 (5%) women in the natural history group had cotinine readings commensurate with their self-reported quit status. Despite exposure to the intervention, the number of women misreporting quitting in the intervention cohort (36 women: 55% of the quitters) was similar to that in the natural history cohort: (35 women: 95% of quitters).

Women in the Intervention cohort reported significantly more quit attempts (defined as not having even a puff for at least 24 hours), than women in the Natural History cohort. This indicates a move to the stage of preparation for change, which is characterised by experimentation in adopting the new behaviour (DiClemente et al., 2000).

Although the study was not powered to detect a significant difference in any pregnancy outcomes, a comparison of the mean birth weight between the two cohorts (INT: 2949.5 grams; NH: 2905.7 grams) showed a positive difference of 44 grams in favour of the intervention group, although this was not statistically significant ($p = 0.249$; 95% CI: -30.74 to 118.26). Low birth weight is defined as below 2500 grams and the average difference in birth weight between infants born to smokers and those born to non-smokers is 250 grams. This difference increases with the amount smoked (US DHHS, 2001).

There was a notable drop in self-reported alcohol consumption from baseline to end of pregnancy; however this trend occurred in both cohorts and was not significantly different (NH: 54% to 19%)(INT: 49% to 14%). When modelling quitting on alcohol status at baseline, the quitting rate was lower in the sub-group reporting alcohol use, although the differential was not statistically significant. The estimated intervention effect was 9.1% (95% CI: 4.5% to 13.7%) in the non-drinkers, compared to 6.0% (95% CI: 2.1% to 9.9%) in the drinkers.

Process measures

As can be seen in **Table 3** (overleaf), dramatically fewer women in the natural history cohort, than the intervention cohort, reported they had been offered educational material on smoking or that a midwife had discussed smoking with them, since coming to the clinic. In both cohorts, recall of a midwife or nurse talking to them about smoking deteriorated over time, perhaps an indication that nurses typically only raise the issue of smoking during the first visit and seldom follow up.

Table 4 presents further data relating to the implementation of the intervention. The midwives referred women to the peer counsellors with great alacrity and 97% of women reported choosing to see the peer counsellor. Midwives were also reasonably efficient in delivering the first step of the 5As, as is shown in the marked improvement in their asking women about smoking between 2006 and 2007. The process evaluation records kept by the midwives in the clinic folders proved not to be useful. 17% of patients' folders did not have any information recorded in them and many others had inadequate information. According to these records, only 45% of pregnant women received the 5As protocol or part thereof from midwives, which is lower than the figure recalled by women in the questionnaire.

Table 3: Comparison of Intervention activities in the clinics

Process Questions	Mid pregnancy measurement (28-35 weeks gestation)	End pregnancy measurement (36-39 weeks gestation)	P value
Did the nurse/midwife ask/talk to you about smoking?			
Natural History Cohort	N=350	N=269	<.0001
Yes: Freq (%)	157 (45)	87(32)	
Intervention Cohort	N=444	N=375	
Yes: Freq (%)	376 (85)	281 (75)	
During your visits to the clinics, were you offered any educational material on smoking?			
Natural History Cohort	N=350	N=269	<.0001
Yes: Freq (%)	42 (12)	50 (18)	
Intervention Cohort	N=444	N=375	
Yes: Freq (%)	396 (89)	366 (98)	

As was intended, it was mainly the peer counsellors who delivered the remainder of the 5A Guideline. Almost every woman recalled being asked by the peer counsellor, rather than by the midwife, if they were willing to make a quit attempt; if they wanted the materials and whether it would be acceptable if they were asked about smoking again during follow up visits to the clinic.

Table 4, on the following page, illustrates that although women were positive about the attitudes of the midwives, they agreed more strongly that the peer counsellors were respectful when talking to them about smoking. Similarly, about twice as many women rated the peer counsellors and the education materials as ‘very helpful’, in comparison to the midwives.

Table 4: Implementation of intervention

Intervention Cohort		N = 375	
Process questions: End of pregnancy measurement (36-39 weeks gestation)			
1) Referral to peer counsellor : Freq (%)			
During your visits to the clinic, were you informed about the Stop Smoking counsellor?		375(100)	
If yes, did you go and see her?		362 (97)	
2) Brief counselling: Freq (%)			
Did anyone at the clinic ask if you were willing to try and quit? (Step no.3 in 5A protocol: ASSESS stage of change). If so, who was it?		375(100)	
Midwife/nurse:		11(3)	
Stop Smoking counsellor		367(98)	
Who informed you that smoking would be discussed again during your next visit? (Step no.5 in 5A protocol: ARRANGE for follow up)			
No-one:		8(2)	
Midwife/nurse:		4(1)	
Stop Smoking counsellor:		362(97)	
3) Provision of education materials: Freq (%)			
Were you offered any education material? (Step no.4 in 5A protocol: ASSIST in decision and strategies for quitting)			
No:		9(2)	
Yes, Quit Newspaper:		252(67)	
Yes, Newspaper for family/partner:		32(9)	
Yes, Self Help Quit Guide:		152(41)	
Other, e.g. pamphlet:		2(0.5)	
Who offered you the material?			
Midwife/nurse:		11(3)	
Stop Smoking counsellor:		357(96)	
4) Use of materials: Freq (%)			
Did not take any materials:		12(3)	
% who read Quit Newspaper:		252(67)	
% who read newspaper for family/partner:		24(6)	
% who read Self Help Quit Guide:		143(38)	
5) Did anyone else read the materials?			
No one:		49(13)	
Family:		209 (56)	
Father of baby:		198(53)	
Friend:		54(14)	
Work colleague:		10 (3)	
Other, e.g. boyfriend's mother:		4(1)	
Rating of intervention components: Freq (%)		Midwife	Peer Counsellor
1) Do you agree with the following statement?			
The midwife/peer counsellor was respectful when she spoke to me about smoking			
They did not discuss smoking with me:		90(24)	1(0)
Strongly disagree:		2(0)	2(0)
Disagree:		3(0)	3(0)
Agree:		225(60)	232(63)
Strongly agree:		55(15)	132(36)
2) What did you think of her counselling about smoking?			
Did not receive counselling:		92 (25)	8 (2)
Very helpful:		136 (37)	244 (66)
Helpful:		134 (36)	112(30)
Unhelpful:		8 (2)	5 (1)
3) What did you think of the education material?			
		Educational Materials	
Nothing, because I was not given any material:		10 (3)	
I did not read it:		8 (2)	
Very helpful:		232 (63)	
Helpful:		114 (31)	
Unhelpful:		6 (1)	

Discussion

This study demonstrated that the 5As Guideline for best practice smoking cessation interventions for pregnant women was effective in a developing country setting. It was encouraging that the intervention succeeded in assisting even heavy smokers in quitting, as the 5As model has tended to be less effective with this group (Melvin et al., 2000).

The level of cotinine validated smoking reduction in the intervention cohort showed that women truly did reduce their exposure to nicotine, rather than simply reducing the number of cigarettes they smoked per day, but then merely compensating by smoking those cigarettes more intensively. This was a further positive outcome of the intervention and supports the view that harm reduction, as well as quitting be given due attention in such interventions (Li et al., 1993; Raatikainen et al., 2006; Lumley et al., 2009).

The wide discrepancy between self reported and cotinine validated quit and reduction rates in our study support the necessity of using a biomarker to validate changes in smoking behaviour among pregnant women exposed to a smoking cessation intervention. Our study found even higher misreports (INT 55% and NH 95%) than other similar studies, such as Boyd et al. (1998), Patrick et al. (1994) and Avidano-Britton et al. (2003), who documented self-misclassification rates of around 25–35%.

It remains for further research to determine what additional elements of intervention could produce an increase in effect size. Providing incentives appears to be a promising strategy (Lumley et al., 2009) and the use of more intensive behavioural therapy, combined with judicious use of nicotine replacement therapy (NRT) with heavy smokers, may need to be considered, once it is clear that brief counselling has failed. However, the safety of NRT during pregnancy is yet to be clearly established (ACOG, 2000) and the cost may make it impractical in a resource-poor setting.

The results of the process evaluation indicate that the intervention was successfully delivered and met the main criteria proposed by Walsh and Redman (1993) for assessing whether a smoking cessation intervention is suitable for routine application within antenatal care services: the programme elements were well received by pregnant women and midwives, time commitments for training and delivery of the intervention were feasible, the intervention was easily incorporated into usual antenatal clinic procedures and the educational materials were readily available.

Public antenatal clinics in South Africa represent a particular challenge for the dissemination of interventions, because of acute staff shortages, high work load, competing health priorities and the complexity of meeting the needs of the growing numbers of pregnant patients with HIV, TB and

chronic disease. The extent to which the midwives in this study relied on the peer counsellors to implement the intervention is an indication of these constraints on their time. However, their support for the intervention and their appreciation of the peer counsellor's presence was unequivocal, as was demonstrated by their 100% referral of women to them. Women's openness to seeking the support offered by the peer counsellors (97% chose to see them), as well as their high ratings of their helpfulness, is an indication of their need for an opportunity to discuss their concerns about their pregnancy and positive predisposition to such social support.

When considering the use of the educational materials, it must be noted that the intervention protocol recommended that midwives and peer counsellors match the media to the Stage of Change (DiClemente et al., 2000). This meant that the Self Help Quit Guide was offered only to those women who felt ready to make a quit attempt in the immediate future. If a woman still needed further motivation to make such a decision, it was recommended that they were offered the Quit Newspaper. The fact that a greater percentage of women received the Quit Newspaper in comparison to the Guide is, in all likelihood, an indication of the fact that the majority of smokers remained in the contemplation stage of behavioural change. This is borne out by the finding that even late in their pregnancies, 86% of smokers in the intervention group stated that they were still seriously considering quitting. The qualitative research also revealed that the Quit newspaper, which was developed in the format of a popular local tabloid, held greater appeal for women, because it was perceived as more accessible to read and included a personal story (Petersen et al., 2010; Petersen, unpublished data). A minority of women took the Newspaper for partner and family members. It is encouraging that of those women who took the educational materials, just about all of them actually read them and shared them with family members and their partners.

Given the reported positive attitudes towards quitting of women's partners in this study and women's receptiveness to their concern, further consideration needs to be given to how best to utilise their support. Limited data from randomised trials suggest that interventions involving partners need to focus on enhancing the partner's supportive behaviour and minimising their negative and critical behaviour towards the smoker (Park et al., 2004).

The finding that 52% of pregnant women had drunk alcohol since becoming pregnant and 14% had used illicit drugs is of grave concern. It can be surmised that these figures represent an under-report, as using alcohol and drugs during pregnancy are more stigmatised behaviours than smoking in this community (Petersen, unpublished data). The concurrence of these risk behaviours and the failure to specifically address these in the intervention, may have limited its success in improving smoking cessation rates.

Limitations of the study

A limitation of the evaluation was arguably the fact that it was a quasi-experimental study, rather than a randomised control trial (RCT). A randomised control trial may have been the optimal research design, but this was not feasible for several reasons. Randomising patients at the level of the clinic was impractical, because of a severe constraint on space in the clinics for study procedures, as well as a lack of privacy. In addition, midwives believed randomising women within the clinic was ethically problematic. Randomising individual patients would also have risked contamination of the intervention by staff (because of a high turnover and shortage of staff, all nurses were trained and used for the intervention). Recruiting a natural history group as a control group, a year before the intervention began in the same clinics, ensured that the control group received usual care from the health care providers, before they were trained. A cluster randomised control trial was also not possible, as there were too few clinics servicing the intended study population to randomise into clusters. Significantly increasing the number of clinics would have introduced women of a different demographic profile into the study and would have been too expensive.

During the intervention year, the researchers remained alert to any other planned or unplanned interventions or events in the clinics, the community or broader society, which could have had an impact on the smoking behaviour of pregnant women. There were no media campaigns, no changes in public policy, taxation or health warnings that could have differentially affected pregnant smokers in 2007, which were not present in 2006. The quasi-experimental study design, proved robust: there were no baseline differences between the natural history and intervention groups over the one year period. I was, therefore, able to compare the two groups on the study outcomes.

The loss to follow up was greater than anticipated. Despite this, the intention to treat analysis showed an intervention effect. The main reason for loss to follow up, in both years, was delivery before second measurement. I could not ascertain whether these were true premature births (a known result of smoking during pregnancy) or due to incorrectly calculated gestational age at enrolment. As ultrasound is not available at the clinics, midwives rely on palpitation and the date of the last menstrual period to calculate gestational age, both of which are often inaccurate. A further important reason for loss to follow up was the difficulty in tracing many women, who did not attend the clinic for their regular scheduled visits. Efforts were made to contact these women, but many of them did not have phones or were not living at the address they had provided. Younger women especially, proved to be far more mobile than was expected. A number of women gave addresses of relatives or friends in the area, but were not residing there throughout their pregnancy. Home visits were done where possible, but fieldworkers were constrained by difficulties in finding women at home during the day. The high rates of attrition and the reasons for them in our study are common

in trials involving pregnant women of poor socio-economic status (Walsh & Redman, 1993; Lumley et al., 2007). However, innovative retention strategies need to be further explored with this population in future studies and incentives may need to be provided on an ongoing basis, rather than just at the completion of all measurements, as was the case in our study.

It is well known that the rates of relapse among pregnant women are very high (DiClemente et al., 2000). A limitation of this study is that we did not have the resources to follow up women post delivery and the relapse rates among the 32 quitters remains unknown. Efforts to continue supporting women during the post-partum period and follow up research on relapse rates are recommended for future interventions.

Further limitations of the evaluation included: the fact that whilst information on certain birth outcomes was collected, the study sample was not sufficiently large to determine any significant clinical differences between the two groups; and that the study design did not allow assessment of the relative contribution of the discrete components of the intervention to the overall impact. For example, subgroup analysis in the intervention group for the association between quitting status and the use of the self-help quit Guide was not possible, due to the small number of cotinine validated quitters in the natural history cohort. Moreover, the process evaluation would have been more comprehensive, if there had been direct observation of the peer counsellors and midwives in their interaction with women and a more in-depth assessment of their experiences of the intervention.

Lastly, the quantitative evaluation methods could only give limited insight into women's personal experiences of the intervention and the reasons why they rated it positively. Qualitative research methods are better suited to exploring these types of questions. A qualitative investigation of women's responses to the intervention was conducted by my colleague, Zaino Petersen. These findings have been reported elsewhere (Petersen et al., 2010; Petersen, 2011) and are briefly described in **Chapter 6** (Final discussion and recommendations).

Conclusion

In summary, smoking during pregnancy is an important, preventable risk factor for the most common causes of intrauterine and early neonatal death among disadvantaged, so called coloured women in South Africa (Odendaal et al., 2001). As illustrated by this study, a smoking cessation intervention which used trained peer, lay counsellors to deliver an adapted form of the ACOG Guideline and provide tailored educational and self- help materials was successfully implemented in public sector, antenatal clinics serving this particular, high risk population.

Future studies need to investigate the addition of further components which may enhance the modest quit rates achieved and the possibility of applying this intervention model to address multiple risk behaviours in pregnancy. These points are further discussed in the following chapter (**Chapter 6: Final discussion and recommendations**).

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Chapter 6

Final discussion and recommendations

Our intervention succeeded in significantly increasing quit rates in a population of disadvantaged, South African pregnant women over a control group receiving usual care. While such interventions have been well researched in high-income countries, this was the first study to demonstrate that best practice models can be successfully used in a developing country setting, if adapted and tailored to suit the characteristics of the local population. The effect size of 7.6% or 5.3% in an intention to treat analysis was modest, but coincides with the average, absolute difference in quit rates of 6.4 % achieved in high-income country trials (Lumley et al., 2009). The intervention was effective, despite the fact that our target population exemplified the profile of pregnant women who are typically less responsive to brief, cessation interventions in primary care (women who are poor, under-educated, heavy smokers and have social networks saturated with smokers) (Lumley et al., 2009) and that it was implemented in an overextended health care setting with few resources relative to high-income countries.

The study also makes an important contribution to the knowledge base by providing a detailed account of *how* the intervention was developed using the Intervention Planning protocol (**Chapter 4**). That this development process is so seldom fully described in the public health/health promotion literature, is an indication of how little attention is generally paid to methodological rigour in the design of health promotion programmes and the need for detailed descriptions of the development processes involved (Abraham & Michie, 2008; Godin et al., 2007; Kok et al., 2004). Often programmes are developed without proper consideration of the need for formative research for programme development and a sound theoretical framework to guide programme design, implementation and evaluation (Godin et al., 2007). To my knowledge, the use of the Intervention Mapping planning model has not yet been used in the development of a smoking cessation programme and has been explored in only two other research projects in South Africa – the one, an HIV/AIDS prevention programme (Jansen et al., unpublished manuscript) and the other, a programme aimed at preventing risk factors for chronic disease among school going children. To date, the development process of only the one programme has been published (Draper et al., 2010).

The experience of developing the intervention

The application of the Intervention Mapping planning model to the development of the intervention had both its advantages and disadvantages. Intervention Mapping's insistence on a thorough needs assessment prior to programme development and its guidelines on how to organise and integrate this

information, is perhaps its greatest strength. This helped to ensure that decisions about our programme were informed by the relevant body of scientific literature; by behavioural change theory, as well as by the needs and values of the intended target group/s and potential users of the programme. Using such a systematic approach, assisted me in clearly formulating performance objectives for pregnant women and midwives; selecting theory-based methods and practical strategies that were appropriate to the objectives; and creating continuity between the design, implementation and evaluation of the intervention. Other authors have assessed the benefits of using IM similarly (Corbie-Smith et al., 2010; Hou et al., 2004; McEachan et al., 2008; Van Stralen et al., 2008; Vermeulen et al., 2009).

However, the methodological rigour and depth of detail required in following the Intervention Mapping protocol to the letter can be problematic. It is a very time consuming and complex task, which may not always be practical, possible or fundable. Based on my experience, I would concur with Wolfers et al. (2007). They argue that the IM model is invaluable to use as a guide and checklist for taking the correct steps in developing an intervention, but in using it, one runs the risk of remaining too long in the process of researching determinants, developing matrices for specified performance objectives for different sub-groups and in pre-testing. As a consequence, one can run out of sufficient time and resources for the remaining steps of the planning process. Whilst I followed Steps 1–4 of the IM protocol with a degree of fidelity, I chose not to continue with the protocol in the same exhaustive way, in Steps 5 and 6 (developing an adoption, implementation and evaluation plan). For these steps, I continued using the IM protocol as a useful reference, rather than as a detailed manual for the application of a model. I doubted that the additional investment required, in terms of time and resources, to follow the protocol as closely at that stage, would have added meaningfully to the ultimate outcome. Instead, I relied on the matrices I had formulated in Step 2 to continue giving me clear direction for formulating an implementation and evaluation protocol.

As discussed in **Chapter 4**, using the IM protocol in this way is not uncommon. Several other authors have expressed similar reservations about following the IM protocol by the book and few have used the protocol faithfully right through to the end (Martens et al., 2006; Perez-Rodrigo et al., 2005; Singh et al., 2006; Zule et al., 2010). This makes it difficult to evaluate the IM process as prescribed, as a standard of best practice in the design of health promotion programmes. In addition, there have been no studies to date, which have directly compared an IM-based programme to an alternative programme not using this method. What is clear, however, is that if IM is to become more widely used by health promotion professionals working outside the domain of academia, it needs significant simplification, in order to become more user-friendly and efficient.

Strengths and limitations of the planned intervention

The design of the intervention conformed to the following key recommendations made in the most recent, major reviews on smoking cessation interventions for pregnant women (Fiore et al., 2008; Lumley et al., 2009; Melvin et al., 2000; Oncken et al., 2010; Schneider et al., 2010; USPSTF, 2009): the core of the intervention consisted of brief, structured counselling based on the 5As best practice guidelines; the principles of motivational interviewing were applied to each step in the guideline in order to ensure it was delivered using a patient-centred approach; relevant constructs from behavioural change theory (value expectancy theories, social learning theory and stages of change theory) were used to develop an intervention logic model, content and strategies (see Figure 2 and Table 3 in **Chapter 4**); the supplementary motivational and self-help materials were adapted to needs, cultural values, life circumstances and language of the intended target group; the influence of partners and family members was considered in the intervention; peer or lay counsellors were recruited to provide psychosocial support and to assist the midwives in implementing the intervention.

These elements are considered strengths of the intervention design. However, the intervention also had a number of limitations. The addition of financial incentives for quitters, which has appreciably enhanced the success of such interventions in several other trials (Lumley et al., 2009) was unfortunately, not feasible in our study, due to funding constraints. The use of pharmacotherapy was not viable, given the continued uncertainties around the safety of using NRT during pregnancy and the unavailability of such agents on the essential drug lists in the public sector health services. In addition, nicotine replacement therapies are expensive to buy privately. Cotinine results were not used optimally as a form of feedback, because the results were not immediately available to women at point of care. The time spent training midwives was very limited due to logistical constraints and there was little follow up and feedback to staff on their performance. Again, because of a lack of resources, the intervention did not extend into a sustained, community-wide campaign to address the factors in the broader social environment, which impinge on women's ability to quit, such as the lack of enforcement of policies prohibiting smoking in public places. Neither did the intervention continue into the post-partum period or provide practical assistance to midwives who might have wanted to quit. It is clear from the literature that the addition of these elements would have increased the likelihood of a larger and more lasting impact. Lastly, only current smokers, with cotinine levels indicative of active smoking, were recruited into the study. Smokers who had quit, just prior to, or on learning of their pregnancy, were welcome to participate in the intervention, but were not followed up, as part of the study. This cohort of women was at risk of relapse during pregnancy and could have benefited from closer inspection.

Strengths and limitations of the evaluation study

The design of the evaluation addressed a number of the methodological issues raised in the literature as important in improving the standard and value of evaluations of this kind: the evaluation assessed the impact of the intervention when delivered as part of routine care in four typical, very busy, public sector antenatal clinics (thus testing effectiveness, rather than efficacy); smoking status was measured at three points in the pregnancy (less than 24 weeks' gestation; mid-pregnancy at 28–35 weeks; and towards the end of pregnancy, 36–39 weeks); self-reported quitting and reduction in smoking was biochemically validated by urinary cotinine testing; a 20% rate of attrition was accounted for in calculating sample size and substantial loss to follow up was countered by using an intention to treat analysis; the evaluation included process measures to ascertain the extent of implementation, feasibility and acceptance of the intervention; qualitative research methods were used to gain in-depth insights into pregnant women's perspective on the issue of smoking in pregnancy and their personal experiences of the intervention (Petersen et al., 2010).

Further strengths of the evaluation were the fact that all smokers booking for antenatal care were recruited into the study; 100% of women in the intervention group were told about the peer counsellor by a midwife and 97% of women elected to see them. The validity of our findings was, therefore, not threatened by selection or volunteer bias.

The limitations of the evaluation study were fully discussed in **Chapter 5**.

Discussion and recommendations

'Prime teachable moments' is a term used to describe naturally occurring health events thought to motivate individuals to consider adopting risk-reducing behaviours (McBride et al, 2003). Antenatal visits represent such moments for smoking cessation, as pregnant women are naturally more motivated to quit during this time, in order to protect their unborn babies (Curry et al, 2001; Chang et al., 2008; O'Campo et al, 1992). As has already been argued in this thesis, there is strong evidence that smoking cessation counselling, offered by various health care providers as part of routine antenatal care and augmented with self-help materials specifically tailored to pregnancy, can increase quit rates among pregnant women and impact meaningfully on clinical outcomes (Lumley et al., 2009). The US Preventive Services Task Force has recently reaffirmed that there is a high level of certainty that the net benefit of such interventions in pregnant women is substantial and strongly recommend their widespread dissemination within the health system (USPSTF, 2009).

Our study demonstrated that the strategies recommended as best practice in developed countries can be successfully transferred to a South African setting, with certain adaptations. Further research is

needed to confirm whether such interventions are appropriate and effective with varied populations in South Africa and in other developing countries. Ongoing research is also needed to determine how the impact of best practice interventions can be improved. More comparative evaluations of intervention components, which are cumulatively added to the 5As protocol, would help in identifying what more can be done. The value of such interventions would be further enhanced if they were extended to also address psychosocial stress, drug and alcohol abuse, as these behaviours are often closely associated with smoking.

Providing psychosocial support

Behavioural change interventions can be particularly challenging with populations of low socio-economic status, because of the day-to-day challenges they face in meeting their basic needs. Often, health issues, such as smoking, are weighed up against more immediate and pressing problems and appear less important.

As described in the literature review (**Chapter 1: (A)**), persistent pregnant smokers of low socio-economic status, especially those who smoke heavily, are less likely to have supportive relationships with others, have low self esteem and locus of control and fewer social, financial and psychological resources on which to draw in an effort to change risky behaviour (Pickett et al., 2009). They are also more likely to have symptoms of depression and stress (Scott et al., 2009). Independent of their desire to quit, this sub-group of pregnant smokers is less likely to be able to benefit fully from brief cessation counselling, coupled with self-help materials, as these strategies, to a large extent, rely on women having the psychological and social resources to independently implement behavioural strategies (Pickett et al., 2009). Consideration needs to be given to more intensive methods of intervention to women of this profile, which would provide more in-depth and sustained psychosocial support to women as part of their antenatal care. In the context of increasing cultural expectations that women refrain from smoking in pregnancy, such support may be even more important, as smokers also have to deal with the added stress of social censure and possible conflict with their partners and family members, who want them to quit.

Nurses, midwives or lay health workers can play a positive role in mediating the impact of psychosocial stress with women who experience inadequate partner, family or peer support (Canuso, 2003; Navaie-Waliser, 2000). Antenatal care providers can also help women acquire emotional coping and problem solving skills (Canuso, 2003; Katz et al., 2008; Rahman, 2007). However, women with high levels of anxiety, or symptoms of clinical depression, should be referred to mental health professionals for help with managing their distress, before they attempt to quit smoking (Weaver et al., 2008; Scott et al., 2009). Some authors have made a strong argument that antenatal care is an

appropriate venue for the screening of pregnant women for mental health concerns (Lester et al., 2004; McBride et al., 2003). Women with symptoms of stress and depression are often the same women who continue using alcohol, drugs and tobacco during pregnancy, making them a group at particularly high risk for adverse pregnancy outcomes (Katz et al., 2008; Lester et al., 2004).

It may also be important to focus on stress reduction and cognitive-affective coping strategies in the postpartum period as the demands of caring for a new baby appear to be an important factor in pregnancy quitters relapsing soon after delivery (Bottorff et al., 2000). Coordination with resources outside of the health service, such as community-based or home visitation programmes run by non-government organisations or government social work services may help extend support for patients post-partum (Rahman, 2007).

Smoking cessation interventions which fail to provide broader and sustained psychosocial support to pregnant women who have difficult life circumstances, are likely to continue being successful with only a small minority of women, and, therefore, continue having only a modest impact. Our study suggests that trained peer counsellors may be particularly appropriate for providing such psychosocial support for pregnant women during their antenatal care.

Using peer counsellors

As is the case with many other low-to-middle income countries, South Africa is faced with a human resources crisis in the health care sector, mainly as a result of an ongoing exodus of skilled health professionals from the public health services, due to low salaries and poor working conditions. As a consequence, there is a growing interest in the potential role of lay health workers in extending services to hard-to-reach groups and in substituting for health professionals in a range of tasks (Lewin et al., 2010; Lehmann et al., 2009). As mentioned in the literature review, the key advantage of using lay, peer counsellors in behavioural change interventions, particularly with women of low socio-economic status, appears to be related to the creation of a non-hierarchical and empathetic relationship, which increases perceived social support and locus of control, and decreases stress (Canuso, 2003; Earp, 1997; Lapierre, 1995; Malchodi et al., 2003; Rahman, 2007). Training peer counsellors in Motivational Interviewing can accentuate this particular advantage, because of its strong emphasis on a collaborative, partnership approach, where the patient or client is actively engaged in decision making and problem solving.

Whilst the question of using peer counsellors in behavioural change interventions requires further investigation, the findings from our research suggest that this option can be effective and is well accepted by both health care providers and pregnant women. As mentioned in **Chapter 5**, the fact that 100% of women in the study recalled being informed about the peer counsellor by their

midwife, is testimony to the extent to which the midwives valued their presence in the clinic. Being able to refer women to the peer counsellors freed the midwives of the stress of trying to address behavioural or psychosocial issues, when they were extremely pressed for time, given their other clinical responsibilities. Midwives expressed gratitude that someone was attending to these kinds of issues as they believed them to be very important, but much neglected in the current circumstances (Everett-Murphy, unpublished data). The midwives' relief at this new division of roles was discerned, and welcomed, by pregnant women: *'It is as if the nurses and us are equally relieved that there is someone else to do that job. I'm not so afraid anymore of what questions she's (the nurse) going to ask me and she has also changed her attitude towards me because she can see that I make an effort to speak to S (the peer counsellor) about smoking.'* (Petersen, 2011).

The quantitative evaluation showed that 97% of women chose to see the peer counsellor when the midwife offered a referral, which can be interpreted as an indication of their desire and need for psychosocial support. The qualitative evaluation of the intervention, conducted simultaneously by my colleague, Zaino Petersen (Petersen et al., 2010; Petersen, 2011), added further insight into how the pregnant women responded to the peer counsellors.

Both the focus groups and individual interviews with pregnant women indicated that the provision of social support from a peer counsellor was the most appreciated and valued aspect of our intervention. It was clear that the peer counsellors were able to provide an appropriate and efficacious level of support to women, despite their lack of professional qualifications and the limited amount of training they received for the project (two sessions of two hours each). Women reported that the emotional support they received from the peer counsellor helped them cope with other stressors through their pregnancy and helped them feel more optimistic about being able to quit. In addition, the time the peer counsellors were prepared to spend with the women and the way they followed them up made them feel cared for and valued, which in turn, made them feel more motivated to try and help themselves (Petersen et al., 2010.)

Pregnant women reported feeling more comfortable discussing personal issues with the peer counsellor than with the midwives, because she was from the same background. This shared life experience and the fact that the peer counsellor understood, at a personal level, the interaction between lifestyle behaviours and the socio-cultural environment made it easier for both parties to establish a genuine rapport. As one respondent said, *'I don't think the nurses understand what we are going through, they are professionals, they don't smoke and they don't live in our area, so they don't know what it's like if everyone around you smokes. I wanted to cry when B (the peer counsellor) told me that she had smoked and how it affected her pregnancy, because I thought that the same could happen to me. So, she understands what we are all about*

and I think that is why we all connected with her. You can only really receive the help if you know that the person is genuinely feeling your problems.' (Petersen, 2011).

It was evident from the qualitative data that the peer counsellors gained a high level of trust and cooperation from women by adopting a Motivational Interviewing or patient-centred counselling approach. This is succinctly illustrated in the following quote: *'B (the peer counsellor) and I often talk about things that I wouldn't even talk to some of my friends about. I know that what I tell her stays between us. And whatever I tell her, I never get the feeling that she judges me for it, and she never tells me what to do. She listens and tells me to think about what is best. That is why I would talk to her about anything and why all the other women think that it is so important having her here.'* (Petersen et al., 2010).

However, it is clear from our experience that if peer counsellors are to be used for behavioural change counselling, they themselves need ongoing psychosocial support. The peer counsellors in our intervention often felt overwhelmed and distressed by the difficulties confronting some of the intervention participants. Weekly meetings with the research team and a workshop with a professional counsellor provided vital opportunities for them to debrief and solicit advice on how to deal with patients needing help. In addition, at times, they needed assistance in overcoming organisational barriers or challenges, such as securing a private venue for consultations with women. Rahman (2007) drew similar conclusions from his experience of implementing an intervention in rural Pakistan, which used lay health workers to assist pregnant women with signs of antenatal depression. In this study, lay health workers were successfully trained to use cognitive behavioural strategies after only 2 days, but relied heavily on monthly, support group sessions with mental health professionals. Sharing difficulties and successes with one another helped sustain motivation and supervision helped the lay counsellors negotiate difficult situations and understand their limitations in working with the most difficult cases.

The value of educational materials

Whilst the provision of psychosocial support may have been the most essential component of the intervention, the materials produced for the intervention also played a vital role. The peer counsellors reported that they relied heavily on the education materials in order to prepare themselves for the role and that the in-depth information they learnt from the materials lent their counselling greater authority and 'professionalism'. They also reported that having good quality, credible and attractive resources to distribute to pregnant women gave them the assurance that they had something of value to offer women and that this boosted their confidence (Everett-Murphy, unpublished data).

The qualitative evaluation (Petersen et al., 2010; 2011) showed that the materials were also greatly appreciated by the women. Whilst the Quit Guide was not often used as a sequential, seven day

quitting programme, women actively engaged with most of the exercises it contained, in order to help them prepare to quit or cut down. These included the self-monitoring exercises, such as the smoking diary; counter conditioning exercises such as tips on how to substitute smoking habits; the aversive stimulus exercises of smoke tasting and the Yuck jar; the suggested behavioural strategies to deal with high risk situations; and the contingency reward activities, such as the Quit Reward certificate. Women reported that they constantly referred to the information on the risks of smoking during pregnancy and the immediate health benefits of giving up, in order to sustain motivation to quit and avoid relapse. Furthermore, the materials and the 'No Smoking' stickers, enclosed in the Quit Guide, were used as cues in the home environment to remind the woman's partner and family of her efforts to quit. For example, one respondent reported: *My newspaper has one place, in the lounge for all to see, and the Quit Guide is next to my bed, for my husband to see. The one in the lounge is to remind guests that they can't just enter and light up ... and the one in my room, is for my husband to see that I don't want him anywhere near me or the baby with stinky breath.*' (Petersen, 2011). Respondents also reported that they encouraged their partners to read the materials and passed them on to other family members, friends and work colleagues.

The materials were particularly well accepted by all the women interviewed, because they were perceived as having been developed especially for them. The fact that they used images, stories and quotes of 'real' women from the community clearly increased identification with the information and messaging. For example, one woman said, *Everybody wanted to see the Quit Guide and everybody claimed to know someone in the book. It was a good idea to use people from our community because you think, "if they could quit, then you can do the same". The book and newspaper gives people like us hope.*' (Petersen et al., 2010).

It was clear from the data that it was the combination of the availability of the peer counsellors, the provision of tailored materials and the positive change in the midwives' attitudes that worked to inspire a desire to change in women. These elements worked synergistically and none would have been sufficient on their own (Petersen, 2011). Together, they added up to a perceived improvement in the standard of antenatal care offered by the clinic. As one participant recounted, *The programme was an eye-opener for me. I am so happy that I booked at this clinic, because you don't get this kind of service at the others.*' (Petersen, 2011). Another said, *When I spoke to B (the peer counsellor) it was like a whole new world opened up. I thought this is luxury treatment because then I knew that I could go to her, whenever I am having difficulty.*' (Petersen et al., 2010).

Addressing multiple risk behaviours during pregnancy

In general, socio-economically disadvantaged populations disproportionately bear the prevalence of manifold risky health behaviours and therefore, the burden of preventable morbidity and mortality

(USPSTF, 2009). Antenatal clinic visits represent repeated opportunities to assist pregnant women address multiple, risk behaviours, at a time when they are highly receptive to considering and initiating positive behavioural change (Chang et al., 2008; Hall & Van Teijlingen, 2006; Herzig et al., 2006; McBride et al., 2003). It was certainly our experience that, if given the opportunity to talk to a sympathetic health care provider (in our case, the peer counsellors), many women will disclose substance abuse during the course of their antenatal care, because they feel anxious about the potential consequences to their babies (Petersen et al., 2010).

Our finding at baseline, that 52% of pregnant smokers had drunk alcohol since becoming pregnant, indicates a high potential risk for Foetal Alcohol Syndrome and other extremely detrimental pregnancy outcomes among this population. A recent clinical study with the same population of women, found that the risk of pre-term labour, growth restriction and low birth weight increases exponentially with the combined use of smoking and alcohol (Odendaal, 2009). Of further, serious concern is the finding that around 14% of pregnant smokers disclosed to the researchers that they were using illicit substances. The fact that most drug using women were using crystal methamphetamine reflects the growing 'tik epidemic' in Cape Town. Since 2005, crystal methamphetamine has overtaken alcohol as the most common, primary substance of abuse among patients reporting for treatment at the 24 alcohol and drug treatment centres in the city (SACENDU, 2009). Whilst the effects of crystal methamphetamine exposure on the developing foetus are not yet fully understood, there are indications that it can cause a variety of birth defects, primarily associated with organ systems (Forrester & Merz, 2007), as well as foetal distress, growth restriction, premature labour and placental abruption (Wouldes et al., 2004).

Our evaluation, unfortunately, did not reliably confirm that the intervention had an impact on alcohol and drug use. Whilst self reported alcohol consumption dropped quite dramatically over time in the intervention group, the control group followed the same trend and there was no significant difference between the two cohorts. Change in self reported drug abuse was not determined. However, in the qualitative interviews, several women reported that the intervention had helped them to quit drugs and or alcohol. For example, one woman said: *I was on tik (crystal methamphetamine) on almost a daily basis. I didn't think that I could stop, and honestly, I didn't really want to. But then I came here (to the peer counsellor's room) and I realised what it could do and it scared me ... and I managed to quit and I think I will be able to stop smoking too.*' (Petersen, 2011).

It makes sense that behavioural counselling interventions with pregnant women be more responsive to addressing the multiple, and often associated, risk behaviours of pregnant women, rather than focussing on different risk behaviours as separate issues, as is usual practice (Herzig et al., 2006; Katz, 2008). In effect, the peer counsellors in our intervention were compelled to do exactly this. For

many pregnant women, the discussion about smoking was a useful entry point to discussing other more stigmatised risk behaviours, which were of greater concern to them than their nicotine addiction (Everett-Murphy, unpublished data). This finding lends support to the idea that addressing risk behaviours in concert can maximise the efficacy of such interventions, because change in one behaviour, can serve as a gateway for change in others (Hyman et al., 2007). Conversely, intervening with a single risk behaviour, may be unsuccessful because other risk behaviours continue to serve as barriers to the desired change (Stotts et al, 2004).

Furthermore, Heil et al. (2009) argue there needs to be greater recognition among antenatal care providers that the inability of some women, particularly heavy smokers, to stop smoking in pregnancy is because they are addicted to nicotine and that smokers should be treated as would women with other substance abuse disorders (SUDs). Overall, the literature overwhelmingly supports the efficacy of cognitive behavioural therapy interventions for substance abuse, but these tend to be more intensive and comprehensive than the brief, low intensity interventions for smokers. Whilst brief interventions appear to work well for lighter smokers, there may be much potential for improving outcomes with heavy smokers and women who use multiple substances, by borrowing methods and strategies from interventions used in the treatment of SUDs. These typically address multiple risk factors in an integrated fashion, are responsive to the client's needs for extended psychosocial support to change other aspects of his/her lifestyle and emphasise the need to promote an overall sense of mastery and self efficacy (Heil et al., 2009). Motivational Interviewing (Rollnick et al., 2002) is one such method from the addiction and counselling field which encompasses these elements and has already been used successfully in smoking cessation programmes for pregnant women (Chang et al., 2008; Katz et al., 2008; Stotts et al., 2004).

The few studies, which have assessed the potential effectiveness of simultaneously targeting multiple risk factors during pregnancy, suggest that such interventions are both feasible in a primary care setting and of significant benefit to pregnant women (Katz et al., 2008; Joseph et al., 2009; Ricketts et al., 2005). These studies have addressed smoking, alcohol and drug abuse; intimate partner violence and/or depression. A qualitative study by Hall and Van Teijlingen (2006), showed that a model using a 'one-stop shop' approach to antenatal care, where a primary care clinic offered a combination of health and social support on one site, was much preferred by pregnant drug users to usual care.

However, addressing alcohol and illicit drug use during pregnancy is a more complex and challenging task for antenatal care providers than smoking. Assessment is made more difficult for example, because women may be more concerned that disclosure may lead to prosecution or losing custody of their other children (Chang et al., 2008). Moreover, providers themselves may feel considerably more emotional and uncomfortable about discussing such issues with pregnant women (Chang et al., 2008;

Herzig et al., 2006; Kinsey et al., 2006). Additional training would be needed to educate providers about substance abuse and its treatment, as well as how best to communicate with women about such issues. It would also be necessary to ensure that antenatal care providers establish good referral systems and working relationships with local mental health and substance abuse professionals.

Whilst Joseph et al. (2009), Katz et al. (2008) and Ricketts et al. (2005) demonstrated that experienced counselling professionals could deliver such multiple risk programmes, the feasibility of using peer counsellors would require investigation. Certainly, in the South African context, the option of using peer counsellors in an integrated programme would need to be considered, as midwives would probably not have the time (or inclination) to undertake such counselling. Intensive training, the provision of various educational aids/resources, ongoing support and close cooperation with midwives and mental health professionals would all be necessary to equip peer counsellors to fulfil such an extensive counselling role.

The findings from our study give a positive indication that our intervention model would be a viable option for the delivery of a multiple risk behaviour intervention: both the midwives and pregnant women fully accepted the peer counsellors in a primary counselling role; women readily disclosed their personal problems to them (including drug and alcohol abuse and partner violence) and the peer counsellors' holistic, person-centred approach, was rated very positively by women, as the earlier quotes illustrated (Petersen et al., 2010; 2011). In addition, the peer counsellors implemented the adapted 5A intervention protocol without any significant difficulty and applied it to smoking, drug and alcohol use (Everett-Murphy, unpublished data). Lay workers have also been successfully used to implement a cognitive behaviour therapy intervention to poor, depressed women in rural Pakistan with little access to mental health care. In this trial, the integration of this intervention into the routine work of community health workers more than halved the rate of depression in prenatally depressed women, compared to those receiving usual antenatal care. In addition to symptomatic relief, women in the intervention group had less disability and better overall and social functioning. These effects were sustained after one year (Rahman et al., 2008).

Adapting the 5As model

The 5As protocol provides a workable framework, which can easily accommodate the counselling needs of pregnant women with multiple risk behaviours. And as our study demonstrated, the protocol is accessible to different categories of health care providers – in our case, both midwives and peer counsellors used the 5As effectively. The first three steps of *Ask*, *Advise* and *Assess* can be used to determine the relevant risk behaviours and which one/s the pregnant woman is most concerned about or feels most able to attend to immediately. Taking the cue from the women, the

antenatal care provider can then proceed with Steps 4 and 5 (*Assist* and *Arrange*), providing social support and assistance where she can and referring on to a more specialised health professional or social worker when she feels it necessary (this approach is congruent with the motivational interviewing strategy of agenda setting and assessing importance and confidence) (Rollnick et al., 2002). Future research efforts are needed to assess the impact of interventions, based on the 5As model, which target smoking, as well as other problem behaviours, like alcohol and drug abuse during pregnancy.

The proposition that primary care clinicians use the 5As construct to organise their general approach to assisting patients with behavioural risks, has already been made by the US Preventive Services Task Force (USPSTF) (Whitlock, 2002; USPSTF, 2009), the Canadian Task Force on Preventive Health Care (Elford et al., 2001) and the International Primary Care Respiratory Group (IPCRG) (Van Schayck, 2008). Whilst the strongest evidence for the effectiveness of 5As counselling interventions comes from tobacco cessation, there is accumulating evidence to show that similar, brief interventions, integrated into routine primary care, can effectively address risk behaviours such as problem drinking, poor diet, lack of physical activity, substance abuse and risky sexual behaviour (Elford et al., 2001; Whitlock et al., 2002; Walker et al., 2010). Whilst the information, educational tools and level of intensity, may need to vary from topic to topic, the 5As provides a unifying construct of evidence-based strategies for behavioural change counselling, which is simple and easy to remember and which health care providers can adapt to the time and resources they have available (USPSTF, 2009). Whilst more intensive counselling might have greater impact, the delivery of the 5As in five to ten minutes makes it a feasible option for integration into primary health care services (USPSTF, 2009).

Importantly, the effectiveness of the 5As protocol is likely to be affected by the manner in which it is delivered. Recommendations on how the 5As can best be delivered needs greater emphasis and clarity in the best practice guidelines. A non-judgemental approach is advocated as particularly important when dealing with personal risk behaviours, such as substance abuse (Hall & Van Teijlingen, 2006). Qualitative research has shown that antenatal staff's attitudes and relationships with clients can often be perceived as being even more important than the medical care they receive (Hall & Van Teijlingen, 2006). Applying key principles from Motivational Interviewing to each step of the 5As Guideline, as I did in for this study, assisted the nurses and peer counsellors to shift away from the traditional, prescriptive, advice giving approach to smoking cessation education/counselling, to a more patient-centred one. This was evident from the interviews with pregnant women during the intervention. For example, *'It used to be ok when the nurse does all the talking, but then I never really listened to what she was saying...now I want to talk to them (nurses and peer counsellors)*

because I feel like what I say is important. I was too shy and scared to talk before, but now it is surprising how much I talk during our meetings and I remember everything they tell me.' (Petersen et al., 2011).

The use of a simple, structured approach like the 5As, which can be adapted to address multiple risk behaviours, is all the more important given the numerous barriers to the systematic delivery of clinical preventive services, which exist in most health care settings, including those in South Africa. These barriers include the fact that clinicians often lack the knowledge, confidence and communication skills to efficiently provide behavioural change counselling (Everett et al. 2005; Elford et al., 2001; Katz et al., 2008; Whitlock et al., 2002). However, in service, skills training as brief as three hours has been shown to improve provider's delivery of preventive services and improve patient outcomes (Bakker et al., 2003; Marcus et al., 1997; Ockene et al., 1995). Concerns about time constraints in the clinic setting can be resolved by allocating appropriate roles to various members of the healthcare team and coordination with outside resources. Along with training, it is vital that clinicians are provided with appropriate system support, which can help them integrate these interventions into primary care. Such support would include processes which help identify those who need the intervention; prompts or reminders; checklists in patient records; sufficient good quality educational resources and clear referral systems.

Conclusion

As the US Preventive Services Task Force stated in their review of primary care behavioural counselling interventions, a full appreciation of the importance of brief, behavioural counselling interventions, like the 5As, requires a true population-based perspective (Whitlock et al., 2002). Brief interventions that are feasible in primary health care settings, often only have a modest impact on individual behaviour. Interventions targeting lifestyle risk behaviours have a similar effect to those of smoking cessation interventions for pregnant women of about 6-10% (Whitlock et al., 2002). However, the limited impact of these types of interventions in primary care translates into significant benefits to the health of the population (and to multiple individuals) when they are systematically applied to a large proportion of those in need. Only once they are widely adopted by health care providers, will the potential benefit of behaviour change interventions be fully realised. This requires that nurses, doctors and lay counsellors, be trained and equipped to deliver these types of interventions with conviction, proficiency and confidence, It also requires that behavioural risk assessment and counselling become a normal and expected part of routine, primary care in the public sector.

Addressing multiple psychosocial and behavioural risk factors is especially salient in the context of antenatal care. Depression, stress, partner violence, smoking, drug and alcohol abuse are often

closely associated and all have similar, synergistic, detrimental effects on the health of the pregnant women and the baby, with potentially profound long-term consequences for quality of life. Despite this knowledge, few interventions have addressed multiple risks during pregnancy in an integrated way and few studies have investigated the potential efficacy of these types of interventions (Katz et al., 2008). Best practice models for smoking cessation (the 5As) and the treatment of substance abuse exist (Motivational Interviewing). Research is urgently needed to assess the application of these models in multiple risk behaviour interventions, which could prevent common, adverse pregnancy and birth outcomes among pregnant women at risk. Without such interventions, it is unlikely that developing countries like South Africa will ever meet their development goals.

This study offers a workable model for a brief, structured, evidence-based, behavioural risk counselling intervention, which could become an integral part of antenatal services in South Africa (and indeed, public health, primary care services in general). I would further submit that using trained peer counsellors to provide the counselling and psychosocial support that disadvantaged, pregnant women clearly so badly need, would be a cost effective and viable option for a large scale programme.

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Appendices

Contents

1. **Published article:** Everett, K., Odendaal H. J. & Steyn K. 2005. Doctors' attitudes and practices regarding cessation during pregnancy. *South African Medical Journal*. 95 (5):350-354.
2. **Information sheets and consent forms for evaluation study (Chapter 5)**
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5. **Educational materials for intervention**
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