BELIEFS ABOUT NHS STOP SMOKING SERVICES AND NICOTINE REPLACEMENT THERAPY IN PREGNANCY: EXPLORING THE POTENTIAL ROLE OF THE THEORY OF PLANNED BEHAVIOUR IN PROMOTING UPTAKE OF SMOKING CESSATION SERVICES

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ABSTRACT

A number of women continue to smoke in pregnancy despite the associated risks to their health and that of their unborn child. Little is known about their attitudes towards the smoking cessation support which is available to them and this thesis used a Theory of Planned Behaviour (TPB) approach to investigate this further.

Study One was a qualitative investigation designed to elicit pregnant women's views about NHS Stop Smoking Services and Nicotine Replacement Therapy (NRT). Interviews were conducted with 18 pregnant smokers, recent quitters and new mothers who smoked in pregnancy, and 18 health professionals working in smoking cessation services. A number of behavioural, normative and control beliefs were generated with respect to these behaviours. As there is evidence for inconsistent smoking cessation advice giving in pregnancy and a lack of confidence amongst health professionals in this area, a theory-based resource to facilitate the communication of smoking cessation information in pregnancy was developed in Study Two and tested in an exploratory randomised controlled trial. The 22 second year medical students who viewed the theory-based resource in preparation for a mock interview were not significantly better at eliciting the salient smoking cessation beliefs of the simulated patient (mean score 8.41) than the 18 second year medical students who received a standard information resource (mean score 7.67). However, the resource showed potential to facilitate the delivery of a more patient centred interview and is worthy of further testing. The themes generated in Study One were used to inform the development of a TPB questionnaire to predict NRT use in pregnancy (NRTP-LF) in Study Three. This questionnaire was completed by 100 pregnant smokers who were recruited from antenatal clinics and Stop Smoking Services. The NRTP-LF significantly predicted intention to use NRT in pregnancy, explaining 41.1% of the variance in the outcome variable, justifying the creation of a short form version of it (NRTP-SF). In Study Four, the NRTP-SF was tested on a further sample of 204 pregnant smokers recruited from antenatal clinics and Stop Smoking Services and was also shown to have predictive validity with respect to intention to use NRT in pregnancy. It also significantly predicted interest in participation in a trial testing the efficacy and safety of NRT use in pregnancy.

It is envisaged that the theory-based communication resource and the NRTP-SF could have practical utility in health care settings and the potential to increase smoking cessation service use and quit rates in pregnancy.

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OVERVIEW OF THESIS

There is much evidence to show that smoking in pregnancy is harmful to the mother, foetus and developing child. Despite this, many women continue to smoke whilst pregnant and the resulting costs to health-care organisations are large. Chapter One outlines many of the harmful effects of smoking in pregnancy, the estimated prevalence of smoking in pregnancy in the UK and the various characteristics which tend to typify the pregnant smoker.

Although the majority of pregnant smokers do not quit during pregnancy, effective and cost effective methods are available which can assist them to stop smoking. Chapter Two reviews the evidence relating to the non-medicinal and medicinal forms of smoking cessation support that are available in pregnancy and the current UK guidelines for this. It also reports on the attitudes pregnant women and health professionals have towards receiving and delivering this support respectively. Behavioural support, which tends to underpin the approaches adopted by NHS Stop Smoking Services, has been shown to have modest yet significant effects on cessation rates in pregnancy but these services are poorly attended by pregnant women. Very little research has investigated the possible reasons for this lack of engagement with services. The effectiveness and safety of nicotine replacement therapy (NRT) in pregnancy is still unclear, but it can now be offered to pregnant women after discussion with a health professional. Although studies have shown that pregnant women are interested in using NRT in pregnancy, their opinions about it have not been explored in any detail. As acceptability to the recipient is a key element for a successful smoking cessation strategy in pregnancy, this suggests that pregnant women's perceptions about Stop Smoking Services and NRT warrant further investigation.

The Theory of Planned Behaviour, which is a social cognition approach to heath behaviour, was considered to be an appropriate framework to guide this research. This theory posits that beliefs about outcomes of performing the behaviour (behavioural beliefs), beliefs about social pressure in relation to performing the behaviour (normative beliefs) and factors which are believed to facilitate and inhibit performance of the behaviour (control beliefs) determine an individual's intention to perform the behaviour. This, in turn, predicts actual performance of the behaviour. Chapter Three discusses the Theory of Planned Behaviour, including the evidence base with regards to its predictive validity, the operationalisation of the model and its use in intervention work.

Chapter Four describes a qualitative study (Study One) which was designed to elicit the salient beliefs of pregnant women with respect to NHS Stop Smoking Services and NRT. It was believed that acquiring this information could help to improve engagement with Stop Smoking Services and inform discussions about NRT which could assist a pregnant woman to make an informed choice about whether or not to use it. From 36 in-depth interviews, a variety of behavioural, normative and control beliefs were identified in relation to these two behaviours which were used to inform the subsequent thesis studies.

Research indicates that pregnant women generally value smoking cessation advice as part of routine care but that this is not always of a high quality or delivered consistently. Part of the reason for this appears to be because health professionals lack the knowledge and confidence to deliver such advice and require guidance to help them. Chapter Five reports on the development and exploratory testing of a resource designed to assist a health professional in the delivery of smoking cessation advice in pregnancy (Study Two). Using medical students and simulated patients in a randomised controlled trial (RCT), this intervention resource, which was based on the TPB and incorporated the beliefs about Stop Smoking Services identified in Study One, showed the potential to facilitate a more patient centred interview than a control 'information only' resource.

To further explore the determinants of NRT use in pregnancy, Chapter Six describes the development and testing of a TPB questionnaire designed to predict NRT use in pregnancy (Study Three). The NRT beliefs identified in Study One were converted into questionnaire items which formed part of this questionnaire. Using an initial sample of 100 pregnant smokers, this study showed that the TPB had predictive validity with respect to intention to use NRT in pregnancy and enabled the identification of the most influential beliefs for use in a short form version of this questionnaire. Chapter Seven describes the testing of the short form questionnaire on a further sample of 204 pregnant smokers (Study Four). This questionnaire was also found to predict intention to use NRT in pregnancy as well as interest in participation in a clinical trial testing the efficacy and safety of NRT in pregnancy. It is considered that this short form questionnaire could have practical utility in health-care settings.

Chapter Eight summarises the findings from the four thesis studies and discusses the implications for future research and practice.

CHAPTER ONE: HARMS AND PREVALENCE OF SMOKING IN PREGNANCY & CHARACTERISTICS OF PREGNANT SMOKERS

The following chapter outlines the potentially harmful effects of smoking in pregnancy, the prevalence of smoking in pregnancy and the general characteristics of the pregnant smoker and quitter.

1.1 HARMFUL EFFECTS OF SMOKING IN PREGNANCY

There is much evidence to indicate that smoking in pregnancy is harmful for the mother, the foetus and the developing child, with the resulting costs to health-care organisations being large (Adams & Melvin, 1998). It has been argued that stopping smoking is one of the most important actions a pregnant woman can undertake to improve her own health and that of her baby (McRobbie & Hajek, 2003). The main harms associated with smoking in pregnancy are outlined below.

1.1.1 EFFECTS ON THE PLACENTA

The fact that maternal smoking alters the blood flow to the placenta and impairs its development (Zdravkovic et al., 2005) may be a cause of adverse developmental effects (Rogers, 2008). A meta-analysis of 13 observational studies comprising nearly 1.4 million pregnancies indicated that cigarette smoking during pregnancy is associated with a two-fold increase in the risk for placental abruption, which is the premature separation of a normally implanted placenta before delivery (Ananth et al., 1999). Maternal smoking has also been associated with placenta previa, which is the implantation of the placenta over or near the internal os of the cervix, potentially resulting in partial detachment and severe bleeding towards the onset of labour (Rogers, 2008). Castles et al. (1999) reported an elevated risk of placenta previa for smokers, with a pooled statistically significant odds ratio of 1.58 (95% CI: 1.04 to 2.12).

1.1.2 STRUCTURAL MALFORMATIONS

There have been reports of a possible relationship between smoking and congenital abnormalities, such as cleft lip and cleft palate (Macleod Clark and Maclaine, 1992). However, many studies investigating this are limited by small sample sizes and biases in ascertainment of smoking exposure which might have resulted in inaccurate estimates of the effects of smoking (Shi et al., 2008).

1.1.3 SPONTANEOUS ABORTION

Some studies have shown there to be an association between smoking and spontaneous abortion (e.g. George et al., 2006). A review by Macleod Clark & Maclaine (1992) reported that, even when other potentially influential factors, e.g. maternal age, parity, SES, ethnicity and previous obstetric history are controlled for, an increased incidence of spontaneous abortion for women who smoke during pregnancy remains. Macleod Clark & Maclaine (1992) reviewed evidence that refuted the possibility that spontaneous abortions result from foetal abnormalities caused by smoking on the grounds that such abnormalities tend to occur much earlier in the pregnancy than spontaneous abortions.

1.1.4 STILLBIRTH

A large prospective study by Wisborg et al. (2001) demonstrated a two fold increased risk of stillbirth associated with maternal smoking, and an adjusted odds ratio for risk of infant mortality of 1.8 (95% CI: 1.3 to 2.6). For women who stopped smoking in the first trimester, the risks of stillbirth and infant mortality were similar to those of non-smoking mothers, thus supporting a causal relationship between maternal smoking and stillbirth or infant mortality (Rogers, 2008).

1.1.5 PRETERM BIRTH

When adjusting for other related factors, a dose response relationship between maternal smoking and the occurrence of preterm birth (delivery at 33-36 weeks gestation) has been consistently found, in addition to an increased risk of very preterm birth (delivery at less than 33 weeks gestation), both of which are major causes of neonatal morbidity and mortality (Rogers, 2008). A recent study found that, compared with non-smokers, there was a two-fold increase in risk of preterm labour among moderate smokers, rising to two and a half times greater risk among heavy smokers (Kyrklund-Blomberg et al., 2005). Castles et al. (1999) also found smoking to be strongly associated with an increased risk of preterm premature rupture of the membrane (PPROM).

1.1.6 BIRTH WEIGHT

The link between maternal smoking during pregnancy and lower birth weight was first recognised over 50 years ago (Simpson, 1957) and the fact that this finding has been replicated many times since provides unequivocal evidence that smoking causes decreased birth weight (Rogers, 2008). A meta-analysis of recent studies estimated that the pooled estimate for reduction in mean birth weight

attributable to smoking was 174g (95% CI: 132 to 220), and the population attributable risk of low birth weight due to maternal smoking in the UK is estimated to be 29-39% (Delpisheh et al., 2006). Furthermore, there is evidence that this is a dose-response relationship, with Habek et al. (2002) estimating a birth weight decrement of 250g for 5-20 daily cigarettes and 350g for more than 20 cigarettes per day. Although preterm delivery accounts for some of the low birth weight associated with smoking, intrauterine growth retardation is thought to be the main cause (Floyd et al., 1993) as cigarette smoke is postulated to deprive the foetus of nutrients and oxygen (Huizink & Mulder, 2006). Poor intrauterine growth has been reported as being associated with later growth and development of children, including an increased risk of emotional and behavioural problems, and lowered cognitive abilities and hyperactivity (DiFranza et al., 2004). Smoking during the last two trimesters greatly increases the risk of low birth weight, as well as spontaneous abortion, stillbirth and premature delivery already described (Brown, 1996). Women who manage to stop smoking before the third trimester have the same risk for low birth weight babies as healthy non-smokers (Klesges et al., 2001).

1.1.7 ECTOPIC PREGNANCY

Smoking is one of the major risk factors for ectopic pregnancy and numerous case-control studies have demonstrated an association between smoking and this outcome (Rogers, 2008). A meta-analysis by Castles et al. (1999) found an elevated risk of ectopic pregnancy amongst smokers with a pooled statistically significant odds ratio of 1.77 (95% CI: 1.31 to 2.22), and Bouyer et al. (2003) reported that smokers were 3.9 times more likely to have an ectopic pregnancy than women who had never smoked. There is also evidence for a dose-response relationship between the occurrence of ectopic pregnancy and amount of cigarettes smoked (Handler et al., 1989), and a sizeable risk at minimal smoking levels. For example, a study by Saraiya et al. (1998) reported a 60% risk propensity of ectopic pregnancy amongst those who smoked as few as five cigarettes a day.

1.1.8 SUDDEN INFANT DEATH SYNDROME

Rogers (2008) reported that evidence from over 60 studies consistently demonstrates a dose-response relationship between maternal smoking and risk of Sudden Infant Death Syndrome (SIDS), and suggested that nicotine effects on cardiorespiratory control may cause susceptibility to SIDS. Reviews by Maritz (2008) and Wang & Pinkerton (2008) have concluded that exposure to tobacco

smoke affects lung development which also lends support to the notion that smoking has a causal role in SIDS. However, as women who smoke in pregnancy usually continue to do so post-natally and are more likely to have partners who smoke (Macleod Clark & Maclaine, 1992), it is difficult to distinguish the effect of maternal smoking during pregnancy from that of infants' exposure to environmental tobacco smoke (DiFranza et al., 2004).

1.1.9 COGNITIVE AND BEHAVIOURAL EFFECTS

Many studies suggest a relationship between smoking in pregnancy and infants' cognitive, emotional and behavioural problems (Rogers, 2008), possibly caused by a neuroteratogenic impact of nicotine on the developing brain (Dwyer et al., 2008). Maternal smoking in pregnancy has been shown to have a negative impact on children's cognitive functioning, and their performance in intelligence and achievement tests. For example, infants born to women who smoked during pregnancy have been shown to have lower attainments in reading and mathematics up to age 16 and even in the highest qualification achieved by age 23 (Fogelman & Manor, 1988). However, cognitive deficits in children born to smokers have not been found as consistently as behavioural problems (DiFranza et al., 2004). More recent studies investigating cognitive functioning have controlled for a larger range of factors which may influence development. However, several of these have been criticised for not including many women of lower SES, so a large proportion of families studied may have had sufficient resources to compensate for the effects of their smoking during pregnancy (Olds, 1997). Olds (1997) reported that out of 11 studies reviewed, 10 demonstrated increased rates of child behaviour problems even after controlling for many potential confounding variables. An increased incidence of attention deficit hyperactivity disorder (ADHD) was found in offspring born to women who smoked during pregnancy (Ernst et al., 2001), a finding supported by a meta-analysis of studies which took place over a period of 30 years (Linnet et al., 2003). Whilst acknowledging the methodological limitations of the studies in their review, Wakschlag et al. (2002) concluded that existing evidence provides consistent support for an etiologic role for prenatal smoking and the onset of antisocial behaviour. Some studies have also suggested that heavy maternal smoking during pregnancy may predispose the offspring to early onset of smoking (Rogers, 2008).

1.1.10 TRANSPLACENTAL CARCINOGENESIS

Tobacco smoke is known to contain many carcinogens that can cross the placenta (Rogers, 2008). A review by Saco & Vainio (1999) concluded that tumours most often found associated with maternal smoking in pregnancy are childhood brain tumours and leukemia/lymphoma, with increased relative risks up to two or greater in certain studies.

1.1.11 CHILDHOOD OBESITY

A link between smoking in pregnancy and increased body mass index (BMI; a measure of weight for height) has been repeatedly reported, and it has been suggested that the first trimester might be the period for induction of obesity observed later in childhood (Rogers, 2008). However, it is methodologically difficult to prove that maternal smoking in pregnancy causes obesity given the presence of many potential confounders including environmental factors. The problems associated with inferring a causal link between smoking and harmful outcomes will be referred to again in Section 1.1.15.

1.1.12 ASTHMA

There is evidence to indicate that prenatal exposure to tobacco smoke is associated with increased risk of asthma in young children (Wang & Pinkerton, 2008), and recent research suggests that this may be due to the changes in biological receptors in the baby's immune system that are responsible for fighting infections and bacteria (Noakes et al, 2006).

1.1.13 DIABETES

A recent analysis of a British longitudinal birth cohort reported an increased risk of early onset type 2 diabetes from aged 16 in those of smoking mothers of 1.11, 4.13 & 4.55 for medium, variable, and heavy smokers respectively (Montgomery & Ekbom, 2002). Furthermore, the association between this condition and maternal smoking during pregnancy was independent of potential confounding factors such as own smoking at age 16.

1.1.14 REPRODUCTIVE ORGANS

There is evidence to suggest that maternal smoking can have a detrimental effect on the reproductive organs of her children. For example, in a cross-sectional study of nearly 2,000 young men from the general population in five European countries, an association was found between in utero exposure to maternal

smoking and reduced semen quality and testis size in adulthood after adjustment for confounding factors (Jensen et al., 2004).

1.1.15 METHODOLOGICAL ISSUES

As already touched upon, a degree of caution needs to be exercised when attributing a causal relationship between maternal smoking and the harms outlined above. In most studies, the measure of maternal smoking in pregnancy has been obtained retrospectively in cross-sectional studies and it is also difficult to separate the effects of smoking from other confounding environmental and genetic factors (Huizink & Mulder, 2006). A complex web of genetic and socioenvironmental factors influence human development (Eskenazi & Castorina, 1999) and very few studies have investigated the effect of smoking in terms of its interaction with other sources of biologic stress or social adversity (Olds, 1997). Although many cross-sectional studies have attempted to control for potentially influential factors, e.g. socio-economic status, there are likely to be differences between smokers and non-smokers that cannot be ascertained, and a failure to control for these is likely to bias the results toward finding an effect (Huizink & Mulder, 2006). On the other hand, there is also an indication that some studies may have adjusted for factors that are likely to have been associated with the effects of maternal smoking in pregnancy, e.g. birth weight, thus probably reducing the apparent effect of tobacco (Olds, 1997). Also, as postnatal ETS exposure is strongly associated with maternal smoking during pregnancy (Wakschlag et al., 2002), it is difficult to confidently establish whether observed adverse effects in many studies are due to damage caused in utero or by exposure to ETS after birth (DiFranza et al., 2004). Results of studies also rely on the accuracy with which the exposure variables and outcomes are measured. In terms of self-report of exposure, there is the possibility of recall bias or underreporting of smoking in pregnancy, and it may be difficult to obtain reliable assessments of infants' outcomes which are based on maternal report (Huizink & Mulder, 2006).

1.2 PREVALENCE OF SMOKING IN PREGNANCY

Women are more likely to attempt to quit smoking when pregnant than at other times in their life (Sit & Wisner, 2004) and the relative success of cessation in pregnancy compared with the general population highlights the added incentive that being pregnant presents (Tappin et al., 2005). The two main UK sources of information on smoking in pregnancy are the quinquennial Infant Feeding Survey

(IFS) which provides rates for each UK country and all the UK, and an annual series of English quota sampling surveys conducted by the former Health Education Authority (HEA) between 1992 and 1999. Findings from these two sources differ and are not considered to be directly comparable because of differences in the methods used (Owen et al., 1998). The IFS is a retrospective postal survey conducted recently after birth whereas the HEA surveys were carried out via in-home interviewing during pregnancy, thus being cross-sectional samples of current smoking behaviour at different stages of pregnancy (Owen & Penn, 1999). Also, differences in the wording of the questions used in each type of survey further limit their comparability (Owen & Penn 1999). One particular shortcoming of both the IFS and HEA surveys is the fact that smoking status in neither was validated by biochemical measure (Owen & McNeill, 2001). This is a pertinent issue given that, when validating a sample of self-reports using saliva cotinine, Owen & McNeill (2001) demonstrated an under-reporting of smoking status among pregnant women of around 3%, thus suggesting that the government estimates were too conservative. The following sections will predominantly report the findings of the 2005 IFS as this provides the most recent data on smoking behaviours in pregnancy and, where appropriate, reference will be made to the trends highlighted by the earlier HEA surveys.

1.2.1 SMOKING BEHAVIOURS

The IFS shows a downward trend in maternal smoking in pregnancy in the UK over the last two decades from 28% in 1990 to 17% in 2005. From the latest published figures in 2005, 48% of smokers in the UK were classified as giving up before or during pregnancy (IFS, 2005). In this survey, 53% of UK mothers reported that they had never smoked, and of those who smoked prior to pregnancy, 14% reported having given up more than a year before pregnancy, 4% in the year before pregnancy, 10% on confirmation of pregnancy, and 1% later in pregnancy. Of the 17% of women who continued to smoke throughout pregnancy, 5% reported trying to give up for a period during their gestation but starting again before their infants' births and 11% reported reducing their cigarette consumption. Although not contemporary data, the HEA surveys summarised by Owen & Penn (1999) reported little change in the rates of smoking amongst pregnant women from 1992 to 1999. According to these surveys, around 1 in 10 gave up immediately before they were pregnant, and more than 1 in 6 during pregnancy, producing a combined figure of 28% (Owen et al., 1998). From the nine HEA surveys, it was concluded that the small number of women who stop during pregnancy tend to do so in the first trimester. On

average, across all years surveyed, 32% of pregnant women were currently smoking in their first trimester, compared with 27% in their second trimester and 25% in their third trimester.

1.2.2 SMOKING AND SOCIO-ECONOMIC STATUS

There is a strong association between smoking in pregnancy and socio-economic status (SES), with UK women in routine and manual occupations being more than four times as likely as those in managerial and professional occupations to have smoked throughout pregnancy (29% and 7% respectively), and 48% of mothers in routine and manual occupations smoking before or during pregnancy compared with only 20% of mothers in managerial and professional occupations (IFS, 2005). Furthermore, those in routine and manual occupations were less likely than those in managerial and professional occupations to have given up at some point before or during pregnancy (39% and 63% respectively). A similar pattern has been reported in the HEA surveys, with smoking in pregnancy amongst skilled manual, unskilled manual occupations and those on state benefits being consistently about three times higher than those in professional, managerial, clerical and administrative groups (Owen & Penn, 1999).

1.2.3 SMOKING AND AGE

There is also an association between reported smoking status and the age of the mother (IFS, 2005), with UK mothers aged 20 or under being more than three times as likely to smoke before or during pregnancy than mothers aged 35 or over (68% and 21% respectively). Furthermore, mothers aged 20 or under were five times as likely as those aged 35 or over to have smoked throughout pregnancy (45% and 9% respectively). Only 34% of mothers aged 20 or under reported giving up before or during pregnancy compared with 54% of mothers aged 35 or over. The HEA surveys reported that, amongst pregnant women under the age of 24, smoking prevalence was particularly high with an average of 45% of 16-24 year olds reporting current smoking between 1992 and 1999 (Owen & Penn, 1999).

1.2.4 SMOKING AND OTHER HOUSEHOLD MEMBERS

A strong association between a mother's smoking status during pregnancy and whether or not she lived with other smokers has also been reported. For mothers who lived with at least one other smoker, 36% continued to smoke throughout their pregnancy compared with only 8% of mothers who did not live with a smoker (IFS, 2005).

1.2.5 SMOKING AND ADVICE RECEIVED

It was reported that mothers who received some type of advice or information about smoking were not more likely to alter their smoking behaviour compared with mothers who received no advice (IFS, 2005). Over half of the mothers (57%) who received advice on smoking continued to smoke throughout pregnancy compared with 22% of mothers who received no advice. Although 78% of mothers who received no advice gave up smoking compared with 43% who did receive advice, the survey acknowledged that this could have been because those who gave up smoking has already decided to do so before their pregnancy and thus did not require any advice. The type of information or advice given was associated with subsequent smoking behaviour (IFS, 2005). For instance, mothers advised to give up smoking completely were much more likely to have quit smoking before or during pregnancy than mothers advised to cut down (36% and 8% respectively). Whereas, mothers advised to give up completely were less likely to have reduced their cigarette consumption during pregnancy than mothers advised to cut down (41% and 69% respectively). Mothers who had received messages to both stop completely and to cut down were much more likely to have cut down during their pregnancy than to have given up completely before or during their pregnancy (58% and 14% respectively). The HEA surveys also showed that receiving advice had no impact on the quitting behaviours of pregnant women, although those who received advice from a health professional were more likely than those who received no advice to cut down their smoking rather than quit completely (Owen & Penn, 1999). Although these surveys report associations between smoking behaviour and advice received, linking two self-report measures in this way is methodologically weak and perhaps of questionable meaning.

1.3 CHARACTERISTICS OF PREGNANT SMOKERS AND QUITTERS

1.3.1 SMOKING AND QUITTING BEHAVIOURS IN PREGNANCY

The majority of women who smoke during pregnancy claim that they would like to give up (Haslam et al., 1997) and up to a quarter of pregnant smokers manage to quit before their first antenatal visit without professional help (Lumley et al., 2000). Compared with women who continue to smoke in pregnancy, these 'spontaneous quitters' are more likely to be less dependent smokers, come from higher socio-economic backgrounds, and have greater levels of social support (McRobbie & Hajek, 2003). Furthermore, they are more likely to be better educated, have higher incomes, be married or have a partner, be having their

first child with a planned pregnancy, have fewer smokers in their social network and be less likely to have a partner who smokes (Solomon & Quinn, 2004). In addition to those who spontaneously quit, a further 10% are likely to stop without support following the first antenatal visit (Lumley et al., 2000). Five out of six women give up in the first trimester and only one out of six in the second or third trimesters (Owen et al., 1998). However, women's smoking behaviour varies throughout pregnancy and many women make repeated quit attempts followed by relapsing back to smoking (Pickett et al., 2003). Of those women who continue to smoke during pregnancy, most report reduced consumption (Owen et al., 1998), but many underreport the number of cigarettes they smoke (Melvin & Gaffney, 2004). The unreliability of self-report of smoking status in pregnancy means that some smokers are not identified by midwives at antenatal clinic visits (Walsh et al., 1996).

1.3.2 REASONS FOR CONTINUED SMOKING

Owen & Penn (1999) reported that the main reasons women give for smoking during pregnancy are: habit (35%), addiction (31%), stress relief (19%), enjoyment (5%), relaxation (3%), weight control (2%) and boredom (2%). Studies by Wakefield & Jones (1991) and Gillies et al. (1989) have also cited mood control as an important benefit of smoking during pregnancy. Ebert & Fahy (2007) reported that pregnant women of lower SES viewed smoking as a break from daily hardships, and a means of relieving stress, controlling emotions, and dealing with the responsibilities of caring for others. Furthermore, smoking was said to help such women cope with living in disruptive environments and being isolated from social support due to a lack of transport. Ebert & Fahy (2007) also reported that pregnant women of lower SES may have less internal and/or external sources of 'feel good' experiences making them more reliant on cigarettes as a source of pleasure. Tod (2003) reported that some women use smoking as a means of controlling their weight during pregnancy, and that any existing lack of willpower to quit can be further compromised by a smoking partner. Other women have said that continuing to smoke is less harmful than the possible outcomes of quitting, e.g. protecting their children from the woman's anger (Graham, 1987). Furthermore, expecting a low birth weight baby and an assumed easier labour has been seen by some women as an advantage of smoking in pregnancy (Haslam & Draper, 2001). Despite the personal benefits of continued smoking, many pregnant women feel ashamed of their smoking habit (Lendahls et al., 2002) and some women report increased smoking in pregnancy, blaming the guilt associated with not being able to quit (McCurry et al., 2002).

Woodby et al. (1999) found that that low self-efficacy, i.e. the perceived inability to quit, emerged as a significant variable predictive of smoking in pregnancy.

1.3.3 REASONS FOR QUITTING

Owen & Penn (1999) reported that the main reasons given by pregnant women for changing their smoking behaviour were pregnancy (59%), health (34%), sickness (11%), stopped liking it (4%), publicity (4%), GP or doctor (4%), midwife (3%), partner (3%), financial reasons (3%) friends (1%), and anti-social habit (1%). Haslam, Draper & Goyder (1997) produced similar findings, with pregnancy (53%), own health (16%), nausea (12%), financial considerations (11%), and pressure from partner (4%) being cited as reasons for quitting. Likewise, in a study by Mullen et al. (1999), the most frequently reported reasons for cessation were the baby's health (59%) and sickness (8%). Although social pressure to conform can motivate a pregnant woman to quit, this does not appear to be the most powerful motivator (Woodby et al., 1999). Indeed, a further study by O'Campo et al. (1992) found that advice from physicians or family members was mentioned by only 8% of pregnant women as a decisive factor in quitting. Women intending to breastfeed have been found to be less likely to smoke in pregnancy (Haslam et al., 2003).

1.3.4 KNOWLEDGE ABOUT HARMS AND PERCEPTIONS OF RISK

The HEA surveys are comprehensive sources of information about the knowledge pregnant women have about the harms of smoking and their perceptions of the risks, and these findings are backed up by many other studies. Whilst in 1999, 81% of non smoking pregnant women felt that smoking during pregnancy was very dangerous to the unborn child only 35% of pregnant smokers shared this view (Owen & Penn, 1999). Furthermore, non-smokers were more than twice as likely as smokers to agree that smoking in pregnancy would increase the chances of having a small baby, and more likely to think that this outcome was a health concern. Current smokers (42%) were less likely than non-smokers (76%) to agree that smoking at the beginning of pregnancy causes most harm to the unborn baby, and less likely to agree that it is never too late to stop smoking in pregnancy. Eighty percent of current smokers also felt that there were things far worse for an unborn baby than smoking compared with only 51% of non-smokers. In a similar vein, women who managed to quit smoking at the beginning of their pregnancy and remain abstinent throughout reported stronger beliefs in the harm to fetal health from maternal smoking than those who continued to smoke (Solomon & Quinn, 2004), and those who failed to quit

demonstrated a lower perception of risk to the foetus (Grange et al., 2005). In the latter study of 979 pregnant women, out of those who had tried to reduce their smoking without success, only 6% stated that they had been motivated by medical information compared to 28% of the women who succeeded in quitting.

The HEA surveys have also highlighted a lack of knowledge of some health risks associated with smoking in pregnancy. For example, in 1999, 29% of pregnant smokers claimed not to know about the increased risk of cot death and 53% were unaware of the link to glue ear (Owen & Penn, 1999). In 1996, only half the current smokers agreed that their habit would transfer poisonous chemicals into their baby's bloodstream, and current smokers were less likely than recent ex smokers and never smokers to believe that smoking during pregnancy made the baby breathe slower and the baby's heart beat faster (Owen & Penn, 1999). Similarly, a study by Griffiths et al. (2005) found that whilst most of the 145 pregnant smokers knew about the maternal risks of smoking, e.g. lung cancer (92%) and myocardial infarction (76%), much fewer were aware of the fetal risks, e.g. miscarriage (50%), ante-partum haemorrhage (34%), decreased birth weight (44%), slower cognitive development (33%) and cot death (38%).

Although in a study by Viljoen & Odendaal (2005), most pregnant smokers (78%) knew about one or more of the following specific dangers: disturbed growth parameters (62%), respiratory risk (45%) and a threat to general health (23%), it cannot be assumed that this acknowledgment of risks necessarily means that women believe that their unborn child is likely to be harmed by their continued smoking (Haslam & Draper, 2001). Whilst nearly two-thirds of the pregnant smokers studied by Walsh et al. (1997) believed smoking was definitely harmful to the unborn child, their awareness and acceptance of the specific risks were reported as being inadequate. This is highlighted in other studies where few pregnant smokers knew of the link between smoking and low birth weight (Grange et al., 2005) and were less aware than non-smokers of the health problems associated with this (Stacy et al., 1994). A study by Mohsin et al. (2007) showed that the level of knowledge about the health risks of smoking during pregnancy was higher for non smoking pregnant women than smoking pregnant women, and Arnold et al. (2001) found that reading level was related to knowledge about health effects of smoking. Given that the educational level tends to be low in pregnant smokers, this latter finding might account for the lack of knowledge of the risks of smoking in this group.

Although pregnant women in a UK study by Tod (2003) were aware that smoking presented risks to the foetus, they were inclined to question the validity of the facts and minimise the risks to themselves or their babies. Similarly, pregnant smokers have talked about previous healthy pregnancies (Lendahls et al., 2002) or of other women who had smoked and still given birth to healthy babies (Hotham et al., 2002). Abrahamsson et al. (2005) too found that pregnant women denied the severity of the risks, and would rather rely on personal experience and hearsay. Believing that they are immune to the health risks has been suggested by Haslam et al. (1997) to be a means of coping with the cognitive dissonance generated by smoking in pregnancy. According to Haslam & Lawrence (2004), women who smoke during pregnancy are less likely to feel personally responsible for the health outcomes of their foetus and in a study by Haslam, Draper & Goyder (1997), two-thirds of pregnant smokers felt that the potential dangers of smoking during pregnancy were not personally relevant to them because they had cut down or they believed it was too late to quit. A failure to believe in the effects of smoking in pregnancy or denial of knowledge that smoking can be harmful in pregnancy can partly explain why some women continue to smoke during this period (Macleod Clark & Maclaine, 1992).

1.4 SUMMARY

The potential harms of smoking in pregnancy are plentiful including effects on the placenta, structural malformations, spontaneous abortion, stillbirth, preterm birth, low birth weight and ectopic pregnancy. Children born to a smoker also have an increased risk of Sudden Infant Death Syndrome, cognitive and behavioural problems, childhood obesity, asthma, diabetes and impairment of reproductive organs. Although there has been a downward trend in maternal smoking in pregnancy over the last two decades, many women continue to smoke whilst pregnant, particularly younger women of lower socio-economic status who live with smokers. Even though such women tend to feel guilty about their smoking they have reported that it helps to relieve stress and control their mood. Those who do manage to quit are most often motivated to do so to protect the health of their unborn child. Evidence suggests that women who continue to smoke during pregnancy have less knowledge about the potential harms and lower perceptions of the risks than non-smokers and those who quit in pregnancy.

CHAPTER TWO: SMOKING CESSATION SUPPORT IN PREGNANCY

Although the majority of pregnant smokers are unable to quit during pregnancy, effective and cost-effective methods are available which can assist a significant percentage to successfully stop (Windsor et al., 2000). The following sections review the evidence for the effectiveness of various types of smoking cessation interventions used in pregnancy, including NRT. The safety of NRT for pregnant women will then be discussed followed by the guidelines for smoking cessation support and NRT use in pregnancy.

2.1 EFFECTIVENESS, SAFETY AND GUIDELINES

2.1.1 EFFECTIVENESS OF INTERVENTIONS

Lumley et al. (2009) conducted a review of randomised and quasi-randomised interventions for promoting smoking cessation during pregnancy including advice and counselling based on cognitive behavioural therapy, motivational interviewing, educational techniques and stages of change, feedback of fetal health and measurement of by-products of maternal smoking, social support/encouragement using rewards/incentives and NRT. Pooled data from 65 trials revealed a significant reduction in continued smoking in late pregnancy in the intervention groups (relative risk (RR) 0.94, 95% CI 0.93 to 0.96). This equated to an absolute difference in the proportion continuing to smoke of 6%, i.e. 6 more smokers per 100 quitting in the intervention group than in the control group. The smoking cessation interventions reduced low birth weight (RR 0.83, 95% CI 0.73 to 0.95) and preterm birth (RR 0.86, 95% CI 0.74 to 0.98) and increased mean birth weight by 53.91g (95% CI 10.44g to 95.38g). The 45 trials classed as high intensity (strategy provision and continued support) were no more effective than those considered to be of low intensity (written and verbal advice), with RR of 0.94 (95% CI 0.92 to 0.96) and 0.95 (95% CI 0.93 to 0.96) respectively. However, the fact that there were only 3 trials in the latter category means that this interpretation merits caution. The success of the interventions in this meta-analysis led the authors to recommend that support for smoking cessation should to be a routine part of antenatal care.

2.1.1.1 Non-medicinal approaches

When the trials meta-analysed by Lumley et al. (2009) were grouped by intervention strategy, the cognitive behavioural group, which was the largest (31 trials), showed a similar pooled effect to that of the whole group (RR 0.95, 95% CI 0.93 to 0.97). Interventions where incentives were offered (four trials) resulted in a significantly greater smoking reduction than other strategies (RR 0.76, 95% CI 0.71 to 0.81) helping around 24% of pregnant women to quit. Overall, the eleven trials using 'stages of change' theory (RR 0.99, 95% CI 0.97 to 1.00) were not significantly different from CBT, and feedback (four trials) was not significantly effective (RR 0.92, 95% CI 0.84 to 1.02). In using such broad categories where interventions are likely to contain multiple components, it is difficult to isolate the specific aspects of the interventions responsible for their effects. A further problem in assessing intervention effectiveness is not being able to account for the fact that certain interventions might attract less addicted smokers who are likely to be more motivated to quit. To assess the effectiveness of a specific low-cost intervention approach, Naughton et al. (2008) meta-analysed 12 trials of self-help cessation interventions in pregnancy which on average were found to nearly double the odds of quitting compared with standard care (OR 1.83, 95% CI 1.23 to 2.73). Booklet-based self-help was found to be a more successful method for quitting than usual care, but face-to-face contact over 5 minutes did not significantly increase effectiveness. However, it was noted that the latter finding was based on limited information about contact and the study might not have had sufficient power to detect a difference in this. Greater intensity materials were not found to significantly increase quit rates over those of lesser intensity (OR 1.25, 95% CI 0.81 to 1.94), nor were tailored materials more advantageous than those which were non-tailored. However, a potential lack of power to detect differences was again noted for these two analyses.

It would appear that smoking cessation interventions which offer incentives are the most effective for quitting in pregnancy. However, because this assumption is based on only four trials (Lumley et al., 2009) more evidence is needed to be confident that this is the case. Drawing on a much larger number of trials, those interventions based on CBT were shown to have more modest yet still significant effects on cessation rates and, taken as a whole, the interventions were also shown to have positive effects on birth outcomes (Lumley et al., 2009).

2.1.1.2 Nicotine Replacement Therapy

Although Nicotine Replacement Therapy (NRT) is proven to approximately double a non-pregnant smoker's chance of quitting (Silagy et al., 2004), its effectiveness when used by pregnant women remains unclear. Randomised placebo controlled trials (RCTs) are the gold standard required to validate the efficacy of any new treatment (Fuchs et al., 2000), and six published randomised controlled trials assessing the effectiveness of NRT use in pregnancy have been identified (Wisborg et al., 2000: Kapur et al., 2001; Hegaard et al., 2003, Hotham et al. 2006; Pollak et al., 2007; Oncken et al., 2008).

2.1.1.2.1 Randomised controlled trials of Nicotine Replacement Therapy in pregnancy

In a prospective Danish trial by Wisborg et al. (2000), 124 pregnant smokers randomised to receive nicotine patches were no more likely to be successful in stopping smoking at 1 year than the 126 assigned to placebo. However, compliance with the trial protocol was low, the sample size was small and the trial was underpowered to determine NRT effectiveness (Herbert et al., 2005). Given that there is evidence that pregnant women metabolise nicotine and cotinine more quickly than non-pregnant individuals (Dempsey et al., 2002), Koren (2001) suggested that the women in this study might have needed higher doses of nicotine in the patch than was given. In a much smaller double-blind placebo controlled Canadian trial (Kapur et al., 2001), only 4 of the 17 who received active NRT completed the trial successfully and quit smoking, and none of the 13 women receiving the placebo completed the programme. There were no significant differences in quit rates between the two groups, although the small numbers in the trial make it difficult to be certain that NRT was not effective. The Danish study by Hegaard et al. (2003) was not placebo controlled, with women being randomised to either receive the intervention, i.e. intensive behavioural support with an option to use NRT or normal care, i.e. minimal smoking cessation advice. Even though 75 women chose to use NRT and the cessation rates were significantly higher in the intervention group, the multimodal nature of this trial makes it difficult to isolate the independent effects of NRT (Coleman et al., 2007). Furthermore, the lack of a NRT placebo group precludes any firm conclusions being drawn about the direct effect of NRT on cessation (Hegaard et al., 2004) and given there was much more behavioural support in the arm that also offered NRT, it is likely that the trial overestimates the effect of NRT.

Hotham et al. (2006) randomised 40 mid-trimester pregnant women in Australia to receive nicotine patches with counselling or counselling alone. Three women in the patch group had quit smoking at delivery compared to none in the control group. However, 11 of the 20 women in the patch group only used the patches intermittently and only 5 women used them throughout the entire 12 week period of the study. Pollak et al. (2007) conducted an RCT where US pregnant smokers were randomised to receive NRT plus cognitive behavioural therapy (CBT) or CBT alone. At 7 weeks and 38 weeks gestation, the women in the NRT + CBT group were approximately three times more likely to have quit than the CBT only group (24% vs 8%, p=0.02 and 18% vs 7%, p=0.04 respectively). However, this study was small (n=181) and the lack of NRT placebos in the control group means that the impact of NRT might have been overestimated (Coleman, 2008). Furthermore, the fact that the researchers were not blind to condition might have resulted in the higher follow-up rates in the NRT group and also influenced the findings (Coleman, 2008). The most recent trial of this nature by Oncken et al. (2008) randomised 194 pregnant smokers in the US to a 6 week treatment with 2mg nicotine gum or placebo, with both groups also receiving individual behavioural counselling. Biochemically validated cessation rates were not significantly different between the two groups at 32-34 weeks gestation (18% in the active group compared with 15% in the placebo group, p=0.56).

2.1.1.2.2 Systematic review of Nicotine Replacement Therapy

When five of the above trials (Oncken et al., 2008 was not included) were meta-analysed by Lumley et al. (2009), in line with CBT group in the same review, NRT was shown to have a small but significant effect on quitting in pregnancy (RR 0.95, 95% CI 0.92 to 0.98). The lack of a greater effect is likely to be in part due to the lower doses of nicotine in NRT relative to cigarettes, the fact that accelerated metabolism of nicotine and cotinine in pregnant smokers might be causing conventional dosages to be insufficient (Dempsey et al., 2002), and the lack of a behavioural component which accompanies smoking (Bull, 2003).

2.1.2 SAFETY OF NICOTINE REPLACEMENT THERAPY IN PREGNANCY

Little is known about the safety of NRT in pregnancy, and much of the data that does exist has been derived from observational studies, with few human studies which have been randomised.

2.1.2.1 Nicotine and cotinine levels

A number of studies have attempted to assess how the nicotine or cotinine levels in pregnant women using NRT compare with those of pregnant smokers and any differences in fetal effects. Compared to baseline measures, Oncken et al. (1996) found that nicotine and cotinine levels were significantly lower in women who received multiple doses of nicotine gum over a 5 day period than in control group women who continued to smoke 10 or more cigarettes per day. As there were also no significant differences in the changes in maternal or fetal hemodynamics between the two groups, the authors suggested that short term use of nicotine gum was safer than usual levels of cigarette smoking in pregnancy. In a clinical experimental study of pregnant women's use of 2mg nicotine gum, 15mg nicotine patch or both, the cotinine concentration fell in all 75 women compared to that when smoking (Hegaard et al., 2004). Also in terms of transdermal nicotine, Wright et al. (1997) found no measurable adverse maternal or fetal effects from patch use over a 6 hour period by women previously smoking between one and two packs of cigarettes per day. Furthermore, a study by Oncken et al. (1997) found that eight-hour use of 21mg transdermal nicotine yielded nicotine concentrations similar to those produced by hourly smoking in pregnancy. In support of the latter two studies, a later study by Ogburn et al. (1999) also found no evidence of fetal compromise or differing serum nicotine levels of 21 pregnant women from measurements taken when the women were smoking at baseline and after 4 days of nicotine patch use. However, it should be noted that the small sample sizes in the above studies do not enable firm conclusions to be drawn.

2.1.2.2 Birth outcomes

Although nicotine increases fetal heart rate, the most significant risk to the foetus could be due to the fact that animal studies have shown nicotine to be a neurobehavioural teratogen implicated in disrupted behavioural and cognitive development (Slotkin et al., 2008). Although this might explain the relationship between smoking in pregnancy and infants' cognitive, emotional and behavioural problems (Rogers, 2008), the dosages of nicotine administered in the original rodent studies were argued to have been much higher in relative terms than would be ingested by a human (Dempsey & Benowitz, 2001). Certain NRT studies

have been associated with severe adverse effects. The trial by Pollak et al. (2007) was terminated early when it became apparent that there was a higher rate of negative birth outcomes in the NRT arm. This was perhaps in part due to a higher rate of previous preterm birth as when this was controlled for in the final analysis, the difference in negative birth outcomes between the groups was not significant. Alternatively, the non-blinded nature of the trial might have led to an increase in adverse event reporting by the NRT group (Coleman, 2008). In a small, one sample study by Schroeder et al. (2002) where pregnant smokers were allocated to receive 8 weeks of nicotine patch therapy during their third trimester, three infants suffered severe neonatal morbidity. However, it was concluded that these problems were unrelated to nicotine patch therapy as it was considered that the congenital abnormalities in question would have developed before the treatment began. Finally, in a nonrandomised epidemiological study by Morales-Suarez-Varela et al. (2006), NRT increased the rate of congenital malformations. However, this finding was based on a small sub sample, was of borderline statistical significance (OR, 1.61; 95% CI 1.01 – 2.58), and might have resulted from inadequate control of potential confounders (Le Houezec & Benowitz, 2006). The fact that the active patch group in the trial by Wisborg et al. (2000) reported higher birth weights than the placebo group (mean birth weight difference 186g, 95% CI 35 to 336g) suggests that nicotine itself may not be involved in the intrauterine growth restriction caused by smoking (Coleman et al, 2004b). In line with this supposition, in the recent study by Oncken et al. (2008), the babies born to the women in the active NRT group gave birth to significantly heavier babies of significantly increased gestational age than those in the placebo group, which were described as the key predictors of neonatal wellbeing. Furthermore, in the one sample study by Schroeder et al. (2002) where pregnant smokers were allocated to receive 8 weeks of nicotine patch therapy during their third trimester, no significant preterm deliveries occurred (gestational ages of 36.3 - 41.1 weeks).

To date, there is no strong evidence to suggest that using NRT in pregnancy causes clinically significant fetal harm and no firm conclusion has yet been reached as to the relative safety of intermittent NRT in pregnancy over the steady state delivery from the nicotine patch (Benowitz et al., 2000).

2.1.3 GUIDELINES FOR SMOKING CESSATION SUPPORT IN PREGNANCY

2.1.3.1 NHS Stop Smoking Services

In 1998, the Government White Paper 'Smoking Kills' included a target to reduce the percentage of women who smoke during pregnancy in England to 18% by 2005 and 15% by 2010 (DOH, 1998), the prevalence figure of 23% from the 1995 Infant Feeding Survey being used as the baseline measure for this. In 2002, the Department of Health's Priorities and Planning Framework (PPF) included a further target to deliver a 1% point reduction per year in the proportion of women continuing to smoke throughout pregnancy, focussing especially on women from disadvantaged groups (DOH, 2002). After publishing the 'Smoking Kills' White Paper (DOH, 1998), the government introduced a comprehensive strategy to reduce smoking in England, targeting pregnant smokers as a priority group. Out of this initiative, new specialist smoking treatment services were set up, and improvements were made in the accessibility of medications for smoking cessation, e.g. Nicotine Replacement Therapy (McNeill et al. 2005). Intensive behavioural support for pregnant women delivered by appropriately trained smoking cessation counsellors has been shown to help women still smoking at antenatal booking to quit (Lumley et al., 2009). NHS Stop Smoking Services offering treatment which is consistent with the evidence base are now available throughout England and those services which offer multi-session treatment provided by full-time smoking cessation specialists tend to obtain the best results (Taylor & Hajek, 2001) although these findings are based on observational data.

Although Stop Smoking Services do vary in their approach, they tend to involve a pre-quit appointment for preparation, a quit day session in which the quit strategy is reviewed, and up to four weekly appointments to four weeks after the quit date to discuss lapses, CO readings to verify abstinence and other issues of concern (Taylor & Hajek, 2001). Most health authorities have pregnancy-specific advisors who the pregnant women are referred to by their midwife at antenatal booking. Services generally offer group (clinic) and individual (community) treatment, and are often willing to support family members who wish to quit alongside the pregnant woman. A variety of leaflets and smoking cessation tools are also made available to clients (Taylor & Hajek, 2001).

Recent UK clinical guidelines state that health professionals who come into contact with pregnant smokers should provide them with information about NHS Stop Smoking Services and encourage them to engage with their local service

(NICE, 2008). However, despite the potential for increasing their chance of quitting, only a very small proportion of pregnant smokers attend NHS Stop Smoking Services even when they are made very accessible via home visits. Based on Department of Health statistics, Coleman (2008) estimated that only between 9 and 10% of pregnant smokers in England used these services in 2005.

2.1.3.2 Nicotine Replacement Therapy

The aim of Nicotine Replacement Therapy is to assist smoking cessation by providing a level of nicotine above that associated with withdrawal, although no form of NRT can replicate the rapid nicotine delivery from a cigarette (Peters & Morgan, 2002). Despite some risk of nicotine in pregnancy, there are theoretical reasons for believing that NRT is a safer option than continued smoking because it provides lower doses of nicotine than smoking (McElhatton et al., 2000) and does not expose the unborn child and mother to the many additional toxins in cigarette smoke (McNeill et al., 2001). Despite the lack of empirical data to establish the effectiveness or safety of NRT in pregnancy, in 2002 the UK National Institute for Clinical Excellence (NICE, 2002) advised that a pregnant women could use NRT following discussion about the risks and benefits with a health professional. A year later, the British National Formulary guidance to UK doctors for prescribing NRT in pregnancy was changed from 'contra-indication' to 'caution' (BNF, 2003). This shift and the provision of NRT via NHS Stop Smoking Services mean that its use by pregnant women has steadily increased in recent years. The most recent UK guidelines state that the risks and benefits of NRT should be particularly discussed with pregnant smokers who do not want help from NHS Stop Smoking Services, and if they explicitly wish to use it, the health professional must judge whether it is appropriate or not (NICE, 2008).

The available forms of NRT in pregnancy are nicotine chewing gum, the inhalator and sublingual tablets which enable the delivery of low doses of nicotine at intermittent intervals decided by the woman, thus allowing her to adjust her requirements to fit her cravings. Transdermal patches which deliver constant low levels of continuous nicotine are also an option and if this method is chosen, it is advised that the patch is removed overnight to mirror the break from nicotine that the foetus would receive while the pregnant smoker is sleeping (NICE, 2008). As intermittent NRT delivers a lower total daily dose than the patch, this tends to be the preferred option for pregnant smokers in the US (Dempsey & Benowitz, 2001). However, if nausea precludes their use, Wisborg et al. (2000) recommended that a patch could be used but only for 16 hours per day.

2.2 ATTITUDES OF PREGNANT WOMEN TOWARDS SMOKING CESSATION SUPPORT

Although effective smoking cessation support is available to pregnant women, in spite of the fact that acceptability to the recipient is a key element for a successful smoking cessation strategy (Walsh et al., 2000), there has been relatively little attempt to investigate pregnant women's perceptions and expectations of the types of interventions available to them (Lindsay, 2001). A review of smoking cessation programmes in pregnancy by Oliver et al. (2001) showed that service users have rarely been involved in the design and evaluation of these. It was recommended that future programmes should draw on the input of pregnant smokers, and account for the personal issues that are salient to them, e.g. the role of smoking to reduce stress, the perceived advantages of smaller babies, and prior experience of favourable birth outcomes in pregnant smokers. The research that has elicited pregnant women's views about smoking cessation support will now be reviewed.

The following sections focus on pregnant smokers' attitudes towards smoking cessation support when delivered 1) as part of routine care, 2) outside routine care and 3) in the form of NRT. The first section addresses what women expect from health professionals in terms of smoking cessation support in routine care, how they would like this support to be delivered and to what extent they perceive it to be useful. The second section reviews the studies which have investigated pregnant women's views about different types of support and Stop Smoking Services. The third section assesses pregnant women's attitudes towards using NRT.

2.2.1 ATTITUDES OF PREGNANT WOMEN TOWARDS SMOKING CESSATION ADVICE DELIVERED AS PART OF ROUTINE CARE

2.2.1 1 Pregnant women's expectations of health professionals

McCurry et al. (2002) conducted semi-structured interviews to assess the views of pregnant smokers on the efficacy and relevance of the smoking cessation advice provided to them by health professionals in Northern Ireland. Generally, women considered the provision of this by health professionals to be an inevitable part of antenatal care and some women felt that smoking cessation advice should be provided at every opportunity throughout pregnancy. Although this study was based on a small sample of 15 women, it was considered that data saturation had

occurred with this number. Likewise, in a Swedish study by Arborelius & Nyberg (1997), pregnant women reported wanting their midwife to continually ask about their smoking and keep records of their consumption. Similar findings emerged in a further Swedish study where Lendahls et al. (2002) interviewed 24 women two to three years after delivery to establish what influenced their smoking or quitting behaviours during and after pregnancy. Even though it was considered nagging the women expected continued discussions with health care staff about their smoking and wanted facts about the negative effects on the baby. Indeed, the pregnant women who had only been asked about their smoking habits by the midwife in the antenatal clinic expressed some disappointment and surprise at this superficial approach. How generalisable the Swedish findings are is open to question given that childbearing age in this country is higher than in others. However, most of the 11 pregnant women in a New Zealand study by McLeod et al. (2003) accepted that it was the midwife's role to continue to ask about smoking throughout their pregnancy and expected it. Furthermore, this view appeared to be held by those motivated to quit and those not. Hotham et al. (2002) conducted focus groups with 19 pregnant smokers in Australia partly to investigate their perceptions of cessation counselling by care providers. Women expressed displeasure at the lack of follow-up, perceiving that this was influenced by the care provider's smoking status. Similarly, in a UK qualitative study by Haslam & Draper (2001), 19 of the 40 pregnant women interviewed had expressed surprise at how little their smoking habit had been discussed in the antenatal clinic visits, with some wishing that the health professionals had been more directive. In a further UK qualitative investigation of 40 pregnant women exploring the value of smoking cessation advice in the antenatal clinic, it was found that those women who wished to quit wanted more support from their midwives (Jones, 2003). Furthermore, they wanted this advice without having to ask in order to help them make an informed choice about their smoking habits and reassurance.

2.2.1.2 How pregnant women would like advice to be delivered

Whilst midwives were the professional group who most consistently performed smoking cessation interventions, women interviewed by McCurry et al (2002) considered their GP to be the most suitable person to provide smoking cessation advice. This was because the GP was seen more often, was better known to the women and was considered by women to have more influence on them than the midwife or nurse. Women viewed the midwife as a 'link' person whose role was to help them access further professional advice rather than actually providing

personal support for quitting smoking. However, some women reported feeling more comfortable talking honestly about their smoking with their midwife than their GP or hospital consultant who were sometimes perceived as judgmental in their approach. In line with this, Arborelius & Nyberg (1997) reported that pregnant women desired a friendly, never negative approach to smoking cessation. One women reported feeling uncomfortable when singled out as a smoker during her antenatal classes, and urged for smoking cessation advice to be targeted towards the whole group in such situations (Bull et al., 2008).

2.2.1.3 Perceived usefulness of advice

All the women interviewed in the study by Lendahls et al. (2002) stated that the midwife played an important role in their motivation to stop/reduce smoking during pregnancy, although it was suggested that this might have been due to the midwives being very experienced in smoking cessation. Similarly, pregnant women studied by Jones (2003) reported that smoking cessation advice from midwives had helped than to alter their smoking behaviour, even if they had not managed to quit and McLeod et al. (2003) found that women particularly valued being able to tell the midwife about the progress they had made. In contrast, very few of the women interviewed by McCurry et al. (2002) considered that health professionals had changed their opinion of smoking, but felt that the smoking cessation advice received did reinforce the message of the dangers of smoking in pregnancy and caused them to reflect upon it. Perhaps these women were more intransigent that other samples because they reported themselves to be committed smokers who had been smokers from an early age. Lendahls et al. (2002) argued that health-care staff need not fear initiating a candid discussion with pregnant women about their smoking, a conclusion borne out in the Swedish study by Arborelius & Nyberg (1997) where some women felt that a more authoritarian approach from their midwife would have increased their chances of quitting. However, in the same study, some women reported smoking more following an authoritarian approach to their cessation from a midwife, and similar has been found in the UK where pregnant smokers reported continued smoking after becoming upset and defiant in response to judgemental advice (Tod, 2003). Likewise, another UK study by Lowry et al. (2004) found that pregnant smokers were sensitive to 'hard hitting' messages from health professionals and criticised those who preached to them and lacked empathy.

The studies investigating the attitudes pregnant women have towards smoking cessation advice as part of routine care indicate that for those who are motivated to quit, advice and support is generally sought after and valued. Even women who are not ready to quit appear to derive some benefit from this input. On the whole, women appear to be accepting of midwives as the health professionals to deliver this support and seem to want continued enquiry throughout the course of pregnancy. Although Tod (2003) concluded that healthcare staff should be trained to provide empathic smoking cessation support to patients which is a style clearly favoured by many, it appears that certain individuals might respond better to a more directive or authoritarian approach. McLeod et al. (2003) suggested that problems can arise when the midwife's approach is not consistent with the woman's readiness to change, and perhaps this is a more crucial factor than the style adopted. It should be noted that most of the studies which have investigated pregnant women's attitudes towards cessation advice in routine care are qualitative in nature and based on small convenience samples who might hold different views to those who declined to participate. This, and the potential for socially desirable responding, limits the generalisability of the findings.

2.2.2 ATTITUDES OF PREGNANT WOMEN TOWARDS SMOKING CESSATION ADVICE DELIVERED OUTSIDE ROUTINE CARE

Relatively few studies have investigated pregnant women's views about the more intensive smoking cessation support which is available to them. A telephone survey of 206 pregnant smokers in the UK showed that pregnant smokers have a high level of interest in different types of smoking cessation support (Ussher et al., 2004). 87% (179/206) of pregnant smokers interviewed reported wanting to stop smoking, of whom 69% (124/179) expressed an interest in receiving help with stopping. Interest was highest for behavioural support (82%, 102/124) and self-help materials (77%, 95/124), with a significant preference for individual rather than group appointments. Despite this high level of interest, and the fact that intensive behavioural support as offered by NHS smoking cessation services is effective in helping pregnant women to quit smoking, only a minority of pregnant smokers in England actually make use of the behavioural support available in the NHS (Coleman, 2008). Tod (2003) found that women were restricted from attending smoking cessation services due to a lack of transport, childcare and crèche facilities, and suggested that telephone counselling might increase service access. To further explore the possible reasons for this low rate of uptake, Ussher et al. (2006) devised an internet-based decisional-balance questionnaire to assess the barriers to, and benefits of, attending a stop smoking

course during pregnancy. A focus group of 10 pregnant smokers was conducted to elicit items for the questionnaire. From 443 respondents, the most frequently endorsed barriers were the pregnant woman being afraid of disappointing herself if she failed to quit (54%), not tending to seek help for this sort of thing (41%), not having access to such a course (41%), not having the time to attend a course (40%) and fear of being judged by the smoking cessation advisor (37%). The most frequently endorsed benefits were advice about cigarette cravings (74%), praise and encouragement with quitting (71%), advice about medications to aid the quit attempt (69%), having someone to check on their progress (65%) and sharing their concerns about quitting (63%). A greater interest in receiving help with quitting from a counsellor was significantly associated with being older, lower income, husband/partner advising cessation and less confidence in quitting. However, only 5-6% of respondents in this study reported that they had attended a Stop Smoking course during their current or previous pregnancies (Bull et al., 2008), perhaps in part because 60% of those surveyed did not believe that such support would increase their chances of quitting (Ussher et al., 2006). Although based on a small sample, in a recent qualitative UK study by Ashwin & Watts (2009), the majority of pregnant women who had actually experienced such support felt that the motivation provided by the midwife advisor's regular visits was a crucial component for a successful quit attempt.

Although the study by Ussher et al. (2004) suggested substantial interest in accessing behavioural support in pregnancy, this information was obtained through very short interviews with seemingly little explanation of what this would involve. Furthermore, it is likely that those who agreed to be interviewed would have been more receptive to the idea of smoking cessation support than those who declined, potentially producing an overestimate of the true level of interest, and threatening the external validity of the findings. Also, it was noted that interest is not necessarily likely to be a reliable indicator of uptake. The follow-up study by Ussher et al. (2006) suggested that real and perceived barriers to engagement are responsible for pregnant women's poor attendance at Stop Smoking Services. However, the generalisability of the findings to the UK setting are compromised by the sample being of a higher SES than would be expected for this population and including participants from the US. Furthermore, although a number of the questionnaire items were associated with level of interest in receiving help, it was acknowledged that the questionnaire required further assessment for validity and reliability.

2.2.3 ATTITUDES OF PREGNANT WOMEN TOWARDS NICOTINE REPLACEMENT THERAPY

As with Stop Smoking Services, very little is known about pregnant women's attitudes towards using NRT. Ussher & West (2003) conducted a telephone survey to assess the level of interest in using NRT among 150 pregnant smokers in the UK. Of those women reporting that they were thinking about stopping smoking, 44.7% (67/150) expressed an interest in using NRT, and interest was significantly higher among women who reported smoking at least 10 cigarettes per day. Overall, 22% (33/150) of those reporting wanting to stop smoking were both interested in NRT and were smoking at least 10 cigarettes per day to be eligible for it. However, as pointed out by Coleman et al. (2004), this survey was drawn from an antenatal clinic population with a smoking prevalence of much lower than the national average, calling into question the generalisability of the findings. Ussher & West (2003) acknowledged that a more accurate measure of acceptability would be the degree of uptake, and although it might have limited relevance to the UK setting, a US study by Rigotti et al. (2008), where actual use of a smoking cessation medication in pregnancy was 10%, suggests that interest in NRT is likely to be an overestimation of actual use. This assumption is made more credible by the fact that those in the latter study were motivated smokers engaging with a smoking cessation trial who were thus considered to be more likely to use medication in pregnancy than a representative sample of pregnant smokers.

In a similar study by Griffiths et al. (2005), 145 smokers identified in the third trimester of their pregnancies from a UK antenatal department agreed to complete a questionnaire investigating the acceptability of NRT use in pregnancy. Seventy-four percent (107/145) stated that they would have liked help to stop smoking, and after discussing the NICE guidelines supporting NRT use in pregnancy, 68% (99/145) said would have been happy to accept an NRT product. Interest in using NRT was higher for moderate (10-19 / day) smokers [75% (45/60)] than light (<10 / day) smokers [70% (39/56)] or heavy (>20 / day) smokers [52% (15/29)]. However, whether these figures represent significant differences was not reported. Applying the eligibility criteria specified by Ussher & West (2003) of having to be smoking at least 10 cigarettes per day, 56% (60/107) of the sample in the study by Griffiths et al. (2005) were both interested in NRT and eligible for it. This figure is considerably higher than the 22% reported by Ussher & West (2003) perhaps because of the unrepresentative sample in this latter study. Ussher et al. (2006) found that only 35% of the

pregnant smokers in their survey reported probably or definitely choosing to use NRT during their pregnancy. However, as eligibility for NRT amongst these women (NRT was reported earlier as only being available to those smoking at least 10 cigarettes a day) was not specified, it is likely that the percentage both interested in and eligible for NRT in this study was less than 35%. A reason for this figure being much lower than that found by Griffiths et al. (2005) could have been because a proportion of the respondents were from the US where NRT is not available free of charge. In a recent Australian survey by Bedford et al. (2008), 87% of pregnant smokers felt that NRT should be offered to pregnant smokers but only 33% said that they had considered using it themselves during their pregnancy. However, 63% reported that they would be very likely to use it if it was provided free of charge at the antenatal clinic, a figure similar to that reported by Griffiths et al. (2005).

Hotham et al. (2002) investigated the influences on women's decisions to use or not use NRT in pregnancy via focus groups with pregnant smokers and recent quitters to assess their attitudes to nicotine patch use. Potential use of patches was acceptable to most women, in part because they were considered not to contain the additional chemicals present in cigarettes. However, some patients who had medical problems or had experienced previous obstetric complications expressed doubts about NRT safety and believed that continued smoking was preferable. Some women were sceptical about the effectiveness of NRT because they knew of others who had used it without being able to quit smoking. Also, some respondents felt that patches were not able to tackle the ritualistic nature of their habit. Cost was considered a deterrent, and some women were concerned about the danger of smoking whilst on NRT and the lack of definitive evidence about its safety and in particular the potential harm to their baby from the continuous nicotine release via NRT patches. Whilst some women were under the impression that they were not supposed to use NRT in pregnancy, others were prepared to try it, as long as they could be convinced that it was safe. However, the fact that this study was conducted in Australia means that the views held might not be generalisable to UK women, especially as at the time of the study, NRT was not approved for use in pregnancy.

The later randomised-controlled pilot study of NRT patches by Hotham et al. (2006) was conducted partly to test their acceptability to pregnant women. Forty per cent of the control group who received counselling only believed that patches offered an easier way to stop smoking. However, 25% the treatment group

stopped use because of reported adverse reactions comprising body rash, arm numbness, nausea, and low mood. Although based on a small sample, it was concluded that non-articulated concerns about patch safety and a weak commitment to cessation may have been significant factors in the lack of patch use in this study. Case studies of three participants in the treatment arm of the above trial highlight very different attitudes to NRT use in pregnancy (Hotham et al. (2005). One woman was keen to stop using the patches even though she still had cigarette cravings, whilst another felt they were not working and she would remove the patch in the evening in order to smoke. However, the third woman successfully quit after using the patches for a sustained period, stating that they were very helpful psychologically and she could not have managed without them.

Concerned that pregnant women are now expected to make a decision about using NRT in the absence of an evidence-base concerning their opinions about it, Ashwin & Watts (2009) conducted a small qualitative study in the UK to explore pregnant smokers' views about using NRT. Of those who had used patches, some disliked the marks they left and were keen to find an unobtrusive area on the body to put them, whilst another comment was that they were discreet and good to use because once on they could be forgotten. One woman was concerned that she would become addicted to NRT and would thus merely be replacing one addiction with another. However, the major issue for the pregnant women in this study was a concern that NRT could harm the baby, with some anxiety expressed about the mode of action of the patch. Some of these women had felt more confident about using NRT following discussion with a health professional. An underlying theme identified by Ashwin & Watts (2009) was that whilst NRT acted as a stimulus for cessation in pregnancy it was the presence of professional support that was the major influence.

From the available survey data it would appear that a number of pregnant smokers are interested in potentially using NRT but that actual uptake is likely to be considerably lower. Some scepticism has been reported about the effectiveness of NRT in addition to unwanted side effects. Women have expressed particular concern about the safety of NRT use in pregnancy and the potential harm to their unborn child and appear to value discussion about NRT use with health professionals.

2.2.4 PROVISON OF SMOKING CESSATION SUPPORT AS PART OF ROUTINE CARE

Although smoking cessation advice as part of routine care is generally valued by pregnant women (see Section 2.2.1) and current UK guidelines recommend that it should be offered at every available opportunity by health professionals who come into contact with them (NICE, 2008), evidence suggests that it not always delivered consistently. The following sections will 1) provide estimates of how often any type of advice has been offered by health professionals 2) highlight the extent of this advice when attempts were made to address smoking cessation and 3) specifically report advice and provision relating to NRT.

2.2.4.1 Estimates of prevalence of advice

According to the HEA surveys, the proportion of pregnant smokers who reported receiving advice about their smoking from a health professional was never higher than 55% between 1992-1999 (Owen & Penn, 1999). Furthermore, the quota sampling method used for these surveys, whilst not as rigorous as random-probability sampling, was considered to be the most cost-effective means of obtaining a representative sample. Another UK survey of pregnant women by Haslam et al. (1997) reported that only 34% of current smokers had received advice from a GP, 19% from a midwife, 12% from an obstetrician, and 26% claimed to have received no advice, a finding that did not appear to be due to a lack of contact with health professionals. Ussher et al. (2006) revealed from their Internet survey of pregnant women that only 65% (278/429), 51% (217/425) and 31% (124/396) had been advised to stop smoking by a physician, nurse or midwife respectively. As the above studies were not based on random samples, the results might not have been representative of all pregnant women, and because many of the respondents in the Ussher et al. (2006) survey were from the US, their results might not accurately reflect the UK population. However, the pattern described above does appears to be similar across different countries. For instance, a recent New Zealand survey by Bedford et al. (2008) reported that whilst pregnant women were receptive to quit advice, more than half did not remember receiving any advice or assistance, and nearly 40% thought that smoking cessation assistance was lacking. Interestingly, in the 2005 Infant Feeding survey, 87% of pregnant smokers in the UK reported receiving some type of advice or information about their smoking, with the most common sources being a midwife (89%), doctor (34%), and health visitor (17%). This suggests that, more recently, greater attempts have been made by health professionals to address this issue.

2.2.4.2 Extent of advice given

Even when advice is given by health professionals this often involves only instruction to stop or reduce smoking without further explanation (Macleod Clark & Maclaine, 1992). For example, although 83% (120/145) of pregnant smokers in the UK survey by Griffiths et al. (2005) recalled receiving advice to stop smoking from a health professional, only 30% (43/145) were given specific help to do this. Likewise, a recent study in the US by Rigotti et al. (2008) found that whilst 80% of the 296 pregnant smokers surveyed reported that their obstetric provider had talked to them about a potential quit attempt, only 43% of providers had elaborated on the methods available for this. Similar was also found in a French survey where 76% of the pregnant women who smoked at the start of pregnancy said they been asked about their smoking habit, but only 16% reported that a clinician or midwife had further investigated their attempts to quit, and only 7% had been offered a specialised consultation (Grange et al., 2006). A UK questionnaire-based study involving nearly 500 midwives, GPs & obstetricians reported that 67% offered advice on how to stop (Clasper & White, 1995), but it is possible that this relatively high figure is a reflection of socially desirable responding on the part of the health professionals. Abatemarco et al. (2007) found that only 38% of 196 midwives in the US had referred pregnant smokers for smoking cessation treatment, and in the UK, many pregnant women lack knowledge about Stop Smoking Services (Bull et al., 2008).

2.2.4.3 Advice about Nicotine Replacement Therapy

Studies indicate that pregnant smokers rarely receive advice from their routine care providers about the potential use of NRT. For example, Abatemarco et al. (2007) reported that only 36% of midwives discussed medication options with pregnant smokers in their care. Similarly, in a study by Rigotti et al. (2008), only 27% of pregnant women reported receiving advice about NRT from their obstetric provider, although it was argued that this might have been due to the provider not considering it to be appropriate for the patient. As it was not clear whether the provider or patient had initiated discussions about NRT or whether its use was encouraged or discouraged by the provider, it could not be inferred that the discussion rates represented recommendation rates. However, studies by Herbert et al. (2005) and Price et al. (2006b) where only 27% UK GPs and 26% US obstetricians/gynaecologists respectively reported prescribing NRT to pregnant women suggest that this might be so. None of the 145 pregnant women surveyed by Griffiths et al. (2005) reported having been counselled about the use of NRT.

Although many pregnant women appear to desire smoking cessation input from their routine care providers and current government guidelines specify that this should take place as often as possible, there is much evidence to suggest that this has not been occurring on a consistent basis. In some cases it would seem that smoking cessation advice was completely lacking, while in others there was only cursory acknowledgment of the issue. As such, it is possible that many pregnant women do not receive appropriate smoking cessation information in routine care and lack knowledge about the available cessation support. However, given the retrospective nature of the studies investigating provision of support, it cannot be assumed that all participants were accurately recalling what took place.

2.3 ATTITUDES OF HEALTH PROFESSIONALS TOWARDS SMOKING CESSATION SUPPORT IN PREGNANCY

The apparent inconsistency in the delivery of smoking cessation advice by health professionals during routine care is likely to result in many women not being given the chance to take advantage of an ideal opportunity to tackle their smoking behaviour appropriately. The lack of such advice or the variable quality of that given is likely to be at least in part due the attitudes that health professionals have towards undertaking this task. The attitudes that health professionals have towards delivering advice and support to pregnant smokers at part of routine care are reviewed in the sections below. The key areas covered relate to health professionals' confidence to deliver smoking cessation advice, how their knowledge base with regard to this can affect their attitude, time factors associated with giving advice, the impact that giving advice might have on their relationship with the patient and the influence of patient resistance to receiving advice. This will be followed by more specific attitudes towards NRT.

2.3.1 CONFIDENCE TO DELVER SMOKING CESSATION ADVICE

Whilst UK health professionals generally believe that they should offer smoking cessation advice to pregnant women, many report lacking the confidence to do so. For instance, most of the health professionals in a large UK survey believed that giving smoking cessation advice in pregnancy was part of their role, but less than 30% enjoyed giving this advice or felt that they had good skills to do so (Clasper & White, 1995). Over half the respondents considered that they were inadequately trained for the role, and 91% reported interest in receiving further training for this purpose. Also, a failure of nearly half the midwives in a UK study by Jones (2003) to routinely offer smoking cessation advice was put down to a

lack training (54%), with this being perceived as a way to increase their knowledge and confidence to offer more effective advice. Similar issues appear to be prevalent in other countries. For example, in a New Zealand postal survey, 88% (240/274) of the GPs and 77% (141/184) of the midwives considered that providing smoking cessation advice and support in pregnancy was part of their role (Pullon et al., 2004). However, whilst 89% of the GPs felt confident to give smoking cessation advice to pregnant women, only 66% of midwives reported being so, and less than half the respondents had received any formal smoking cessation training. Likewise, in a survey of Dutch midwives, the majority were motivated to provide smoking cessation support, but less comfortable in guiding women through the process (Bakker et al., 2005). A US study by Price et al. (2006a) reported that only 62% of nurse-midwives felt able to help pregnant smokers set a quit date and 53% felt competent to refer pregnant patients to smoking cessation services. Concerns have also been also raised about a lack of competence to address the smoking issue in ways other than simply giving information (Abrahamsson et al., 2005).

Even when health professionals indicate a proficiency to deliver smoking cessation advice in pregnancy, this does not always happen in reality. For instance, even though 73% of 78 maternity staff in a London hospital believed that assisting a pregnant woman to stop smoking was one of the most important aspects of their job, 71% reported not having given any advice in the previous week and only 25% said that they had referred women to smoking cessation services (Condliffe et al., 2005). Similarly, in a UK survey of health visitors, midwives and practice nurses, 72% of 65 respondents felt that giving smoking cessation advice to pregnant women was part of their role and that they were the right people to dispense this (Bull & Whitehead, 2006). Furthermore, 88% of the sample claimed that they could influence women to quit encouraging the use of specialist services, although very few directly referred smokers to their local cessation services. These studies suggest that health professionals might be expressing their level of competence in a socially desirable way or that practical barriers get in the way of service delivery.

2.3.2 KNOWLEDGE ABOUT SMOKING CESSATION SUPPORT

Although derived from a small focus group study, health visitors and midwives in the UK have complained about the absence of clear guidance on how to help pregnant smokers to quit, a point highlighted by their lack of knowledge about what were effective interventions for this group (Bull, 2007). Even where

guidelines exist, there is evidence to suggest that they are not used optimally. For example, Clasper & White (1995) found the use of guidelines for advising pregnant smokers to be low with only 6% of respondents reporting having referred to them. Also, a small South African interview study showed that doctors lacked awareness of the available guidelines for assisting pregnant smokers and felt ill-equipped to tackle this issue (Everett et al., 2005). Furthermore, more than half the midwives in the study by Abatemarco et al. (2007) claimed to be unfamiliar with US Public Health Service Guidelines to assist in smoking cessation. Some health professionals seem to lack knowledge about more intensive smoking cessation support and in particular its potential effectiveness. For instance, 14% of the nurse-midwives in the study by Price et al. (2006a) did not know where to send pregnant smokers for treatment and only 56% believed that referring women to smoking cessation services would reduce smoking rates in pregnancy. Also, although most of the 189 midwives in a German study by Thyrian et al. (2006) believed that discussing smoking was a requirement of their job, 81% perceived that this was unlikely to be successful. A study by Chapin & Root (2004) highlighted that 85% of obstetricians-gynaecologists were actually relying on self-taught smoking cessation methods and 95% were not sure which supporting materials were most appropriate for pregnant women.

2.3.3 TIME FACTORS

Bull (2007) found that midwives felt a conflict between what they believed they should be doing for pregnant smokers and what was achievable in the context of an under-staffed maternity unit. This issue was also highlighted by Jones (2003) where the inability of midwives to routinely offer smoking cessation advice was put down to a lack of time and by Everett et al. (2005) where doctors reported lacking time to effectively engage pregnant smokers. However, in the latter study, the health professionals did not view smoking as a priority issue in antenatal care.

2.3.4 HEALTH PROFESSIONAL/PATIENT RELATIONSHIP

McCurry et al. (2002) reported that health professionals were reluctant to discuss the issue of smoking with their pregnant patients for fear of compromising their relationship with the client. Clasper & White (1995) reported concerns that delivering such advice could increase pregnant smokers' guilt and anxiety, making them less likely to attend the antenatal clinic, a worry also expressed by midwives in the UK studies by McLeod et al. (2003) and Bull (2007). Similarly, according to a Swedish interview study by Abrahamsson et al. (2005), midwives

sometimes avoided raising the issue of smoking with their pregnant patients because of previous experience of it negatively impacting on their relationship with the client. However, this avoidance conflicted with their desire to take care of the health of the client and her baby, and to ease their guilty conscience they would often compromise by fulfilling the perceived minimum requirement of only asking about the patient's smoking habits. This could be one reason why many health professionals only superficially address the smoking issue in pregnancy. Midwives in this study also felt a tension between a desire to be frank with the pregnant smoker, thus risking a defensive response, and wanting to build a more person-centred relationship with her. Although it was noted that cultural differences in other countries might limit the generalisability of these results, midwives in the UK study by McLeod et al. (2003) also talked about there being a fine line between explaining the dangers of smoking to a pregnant woman and maintaining a good relationship with her, and avoiding raising the issue because of uncertainty about how best to do so. Likely for this reason, health visitors and midwives in the UK study by Bull (2007) were not in favour of using 'scare' tactics, believing instead in a more sensitive and tactful approach to discussing the health risks with pregnant smokers.

2.3.5 RESISTANCE TO RECEIVING ADVICE

Midwives have found it difficult to raise the issue of smoking in consultations very much focused on pregnancy issues, and lacked a motivation to do this when patients displayed a reluctance to quit (Bull, 2007). Similarly midwives in the study by Abatemarco et al. (2007) cited perceived resistance to advice (81%) and perceived lack of patient interest (78%) as barriers to delivering smoking cessation advice. All 15 doctors in the study by Everett et al. (2005) felt disillusioned that any advice they tried to give tended to be met with resistance, although some suggested this might have been because their approach was too authoritarian and acknowledged the need for training to help them provide a more empathetic style of support.

2.3.6 ATTITUDES TOWARDS NICOTINE REPLACEMENT THERAPY

Although based on a very small sample, 92% of 25 US obstetric providers reported that they would recommend or prescribe NRT to pregnant women if convincing research verifying its safety was available, compared to 44% of the sample who were currently recommending or prescribing it (Oncken et al., 2000). The results from a larger US study six years later suggest that health professionals still had concerns about the use of NRT in pregnancy as 47% of 154

obstetricians and gynaecologists reported not recommending NRT to pregnant women (Price et al., 2006b). However, the low response rate to this study does not allow firm conclusions to be drawn about the potential lack of attitude change towards prescribing NRT in pregnancy. In this study the primary concern of the health professionals was the lack of testing of NRT amongst this client group (32%) rather than believing it to be ineffective (3%). Those who perceived NRT to be safe for pregnant women were 20 times more likely to prescribe it than those who perceived it not to be very safe. Furthermore, those who reported being highly confident to assist pregnant patients in their use of NRT were nearly 4 times more likely to prescribe it to them than those who reported low confidence. When deciding whether or not to recommend NRT to pregnant women these health professionals reported being most influenced by patient requests for NRT, patient openness to quitting and the amount the patient smoked. Clinicians also seemed to be influenced by their colleagues, with those who believed that most of their colleagues were prescribing NRT to their pregnant patients being nearly 7 times more likely to prescribe it themselves than those who believed that few of their colleagues were prescribing it.

Most of the GPs and midwives surveyed by Pullon et al. (2004) in New Zealand reported wanting more information about NRT use in pregnancy, and only 24% of the sample agreed that NRT was appropriate for pregnant smokers, although it is possible that this figure might be higher now as NRT becomes more widely accepted in pregnancy. Although 70% of 368 GPs in the UK thought that NRT was safer than smoking in pregnancy, 45% expressed uncertainty about its safety per se and were less confident about prescribing it than in delivering other types of smoking cessation interventions in pregnancy (Herbert et al., 2005). Health visitors and midwives in the UK study by Bull (2007) felt that NRT in pregnancy was a controversial issue and that they would be uncomfortable about suggesting its use without the approval of a senior medical professional. Similarly, whilst 74% of the US nurse-midwives studied by Price et al. (2006a) believed that NRT could be effective for pregnant smokers, only 26% felt confident to recommend or prescribe it. Although 82% of the UK health visitors, midwives and practice nurses surveyed by Bull & Whitehead (2006) believed that NRT should be available for pregnant women, only 31% claimed to be familiar with the relevant NICE guidelines for its use in pregnancy. Whilst acknowledging that causality could not be inferred from their US cross-sectional study, Bonollo et al. (2002) found that health professionals' knowledge about NRT use in pregnancy was associated with past training.

Despite the potential impact to influence pregnant smokers at a time when they might be most receptive to quitting, evidence suggests that health professionals do not routinely provide appropriate smoking cessation advice and support to this client group. Studies indicate that the majority of health professionals do see the giving of this advice to be an important part of their role, but that barriers get in the way of this occurring in practice.

Many health professionals reported lacking confidence and skills to give advice, especially midwives, which is of particular concern given that this is the professional group most likely to be involved in this work. Lack of clear guidance on how to perform this task was also mentioned as was insufficient use of existing guidelines and the difficulties associated with fitting cessation advice into already busy work schedules.

Health professionals were also reluctant to broach this subject for fear of jeopardising the relationships they were trying to build with their clients, and also reported being put off doing so when their efforts were met with resistance from women. Many health professionals felt in need of training to deliver effective smoking cessation advice to pregnant women. However, difficulties with arranging such training have been experienced, suggesting the need for better support for this, including locum cover (Hajek et al., 2001).

Although believing NRT to be an effective option for pregnant women, a sizeable proportion of health professionals reported reservations about prescribing it on safety grounds. It is possible that training to increase knowledge about current NRT guidelines in pregnancy might increase health professionals' confidence to discuss this as an option with their clients.

It should be noted that the studies in this section have relied on self-reports of health professionals relating to their professional practice who may have been tempted to respond in accordance with their clinical guidelines. This raises concerns that the barriers to smoking cessation advice in pregnancy might be even more widespread than the literature suggests.

2.4 THEORETICAL APPROACHES TO THE INVESTIGATION OF HEALTH BEHAVIOURS

The above sections highlight the paucity of research into pregnant women's perceptions of the types of smoking cessation support on offer. The fact that Walsh et al. (2000) noted that acceptability to the recipient is a key element for successful smoking cessation strategies in pregnancy suggests that this is an important issue which warrants further investigation. Such research is considered especially pertinent given that NHS Stop Smoking Services are poorly attended by pregnant women and NRT is now an option which can be considered by this group.

In order to be able to identify the beliefs which underlie pregnant women's use (or not) of smoking cessation support, it was considered appropriate to employ a theory of health behaviour. Using such a framework would help to establish those factors which predict the use of this support and any subsequent modification of these could have the potential to bring about desired behaviour change. A social cognition approach to health behaviour, which is concerned with how individuals make sense of social situations, was selected for use in this thesis. This was because cognitive factors (or thought processes) are considered to be important in determining whether or not an individual practises health behaviours (Conner & Norman, 2005).

A number of social cognition models (SCMs) have been developed, incorporating key cognitions and how they are hypothesised to combine to regulate behaviour. Those commonly used are the Health Belief Model (Becker et al., 1977), the Theory of Planned Behaviour (Ajzen, 1988, 1991), Social Cognitive Theory (Bandura, 1982) and The Transtheoretical Model of Change (Prochaska & DiClemente, 1983). All of these models have unique aspects although there is considerable overlap between the constructs included within them. All have been widely applied in health settings, and their relative success in predicting outcomes means that they have served to increase understanding of the determinants of a variety of health behaviours. Beliefs, attitudes and knowledge are the social cognitive variables that are central to many social cognition models and are posited to predict future health-related behaviours (Conner & Norman, 2005).

The Theory of Planned Behaviour (TPB; Ajzen, 1988, 1991) was the social cognition model chosen to underpin this thesis because it has emerged as one of the most influential conceptual frameworks in health research (Armitage & Conner, 2001). Sutton (2004) specifically recommended its use for researching health behaviours as it is a general theory, its constructs are well defined and the causal pathways within the model are evident and there are precise recommendations for operationalising the model. The TPB has also been found to be a superior predictor of behaviour compared to alternative social cognition models (Armitage & Connor, 2000). Furthermore, Sutton (2005) argued that the TPB can account for the balance of motives at any given time and is sensitive to context, as the salience of beliefs may alter according to the situation (Sutton 2005). He also stated that the theory supports the notion that belief formation and modification are predominantly driven by automatic processes (Ajzen & Fishbein, 2000). Rimer (2002) stated that, because its components have been so well codified, the TPB comes closer than other social cognition models to meeting Kerlinger's strict definition of theory (Kerlinger, 1986). The TPB will be discussed in detail in Chapter Three.

2.5 SUMMARY

Behavioural support has been shown to be effective for helping pregnant women to quit smoking but there is no convincing evidence for the effectiveness and safety of NRT in pregnancy. Pregnant women appear to value receiving smoking cessation advice as part of routine care although this is not always offered consistently, perhaps because health professionals lack the confidence and time to deliver it. NHS Stop Smoking Services are poorly attended in pregnancy with a number of barriers being evident. Despite some concerns about the safety of NRT in pregnancy a number of pregnant women have reported interest in using it. There has been very little research investigating the perceptions of pregnant women with regard to the smoking cessation support available to them. It is considered that investigating pregnant women's beliefs about the support on offer could help to increase understanding of the factors which determine their use of such services and ultimately improve uptake. A social cognition approach to health behaviour, in the form of the TPB, was put forward as an appropriate framework within which to investigate this further, the details of which now follow in Chapter Three.

CHAPTER THREE: THEORY OF PLANNED BEHAVIOUR

Firstly, this chapter will describe the TPB and discuss some of the issues surrounding the conceptualisation of the model's variables. Secondly, evidence for the effectiveness of the TPB as a predictor of intention and behaviour will be summarised with reference to three meta-analyses, followed briefly by ways in which the model has been extended. Thirdly, the studies where the TPB has been specifically applied to smoking in pregnancy, smoking cessation programmes and NRT use will be reviewed as these are most relevant to this thesis. Fourthly, some of the model's conceptual limitations will be highlighted, followed by issues associated with operationalising its constructs. Finally, how the TPB can be applied to interventions will be outlined and its effectiveness in this regard will be summarised with reference to a meta-analytic review. Particular attention will be given to intervention studies employing similar methodology to that used in this thesis.

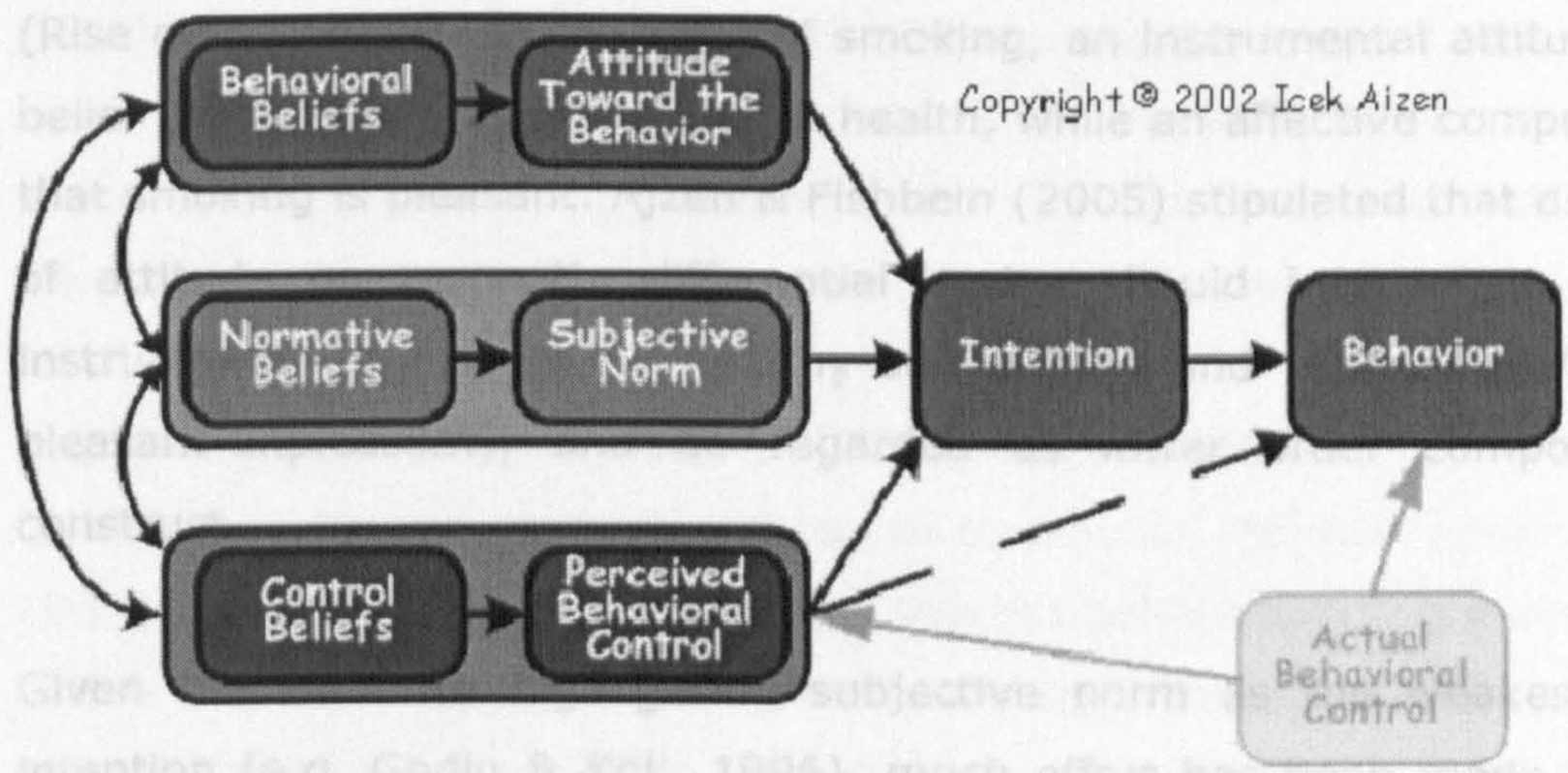
3.1 MODEL OVERVIEW

The TPB is an expectancy-value model which posits that human behaviour is driven by three different considerations: 1) beliefs about the likely outcomes of performing the behaviour in question weighted by evaluations of the favourability of these outcomes (behavioural beliefs), 2) beliefs about the expectations of others with respect to performance of the behaviour weighted by the level of motivation to comply with these expectations (normative beliefs), and 3) beliefs about factors that would facilitate or impede performance of the behaviour weighted by the perceived power of these factors (control beliefs). Although people can hold a number of beliefs about a behaviour, it is only the small number they can attend to at any given moment (salient beliefs) which are considered to determine the behaviour. The combination of salient behavioural beliefs (indirect attitude) produces an overall attitude towards the behaviour, the combination of salient normative beliefs (indirect subjective norm) produces an overall subjective norm with respect to the behaviour (i.e. the perceived social pressure to perform the behaviour) and the combination of control beliefs (indirect perceived behavioural control) produces an overall perception of control over the behaviour (perceived behavioural control). Attitude, subjective norm and perceived behavioural control (PBC), referred to as direct measures, are assumed to emerge spontaneously and automatically as their underlying beliefs are created and together, these three components form an intention to carry out the

behaviour. Generally speaking, the more favourable the attitudes toward the behaviour, the more influential the subjective norm and the greater the PBC, the stronger a person's intention will be perform to the behaviour (Aizen, 2002).

Intention is considered to be the immediate antecedent of behaviour, and given a sufficient degree of actual control over the behaviour (i.e. the skills, resources and other prerequisites needed to perform the behaviour) people should act on their intentions when an opportunity presents itself (Ajzen, 2002b). The aim of PBC is to account for factors beyond the control of the individual that may influence intention and behaviour, based on the premise that behavioural performance is determined by both motivation (intention) and ability (behavioural control) (Montano & Kasprzyk, 2002). As there are many instances where people do not have complete control over specific behaviours and actual control is difficult to assess (Rise et al., 2008), PBC can be used as a proxy measure for this. If it is an accurate judgement of actual control it can contribute to the prediction of behaviour. A second rationale offered by Aizen for the direct link between PBC and behaviour is that a person with a high level of PBC over a behaviour is more likely to succeed in carrying it out (Sutton, 2004). Thus PBC is considered to influence behaviour both indirectly via intentions and directly. For behaviours with high volitional control, it is hypothesised that PBC will not exert any influence on the intention-behaviour relationship, and hence intention should be the only predictor. However, assuming that PBC accurately represents actual control, it should be independently predictive for nonvolitonal behaviours (Armitage & Conner, 2001). The effect of intention on behaviour is expected to be stronger to the extent that an individual has a high perception of control rather than low (Rise et al., 2008). The TPB implies that background factors, for example sociodemographic variables, influence intentions and behaviour indirectly by their effects on behavioural, normative or control beliefs, and through these beliefs, on attitudes, subjective norms, or perceptions of control (Ajzen & Fishbein, 2005). A diagram highlighting the causal links in the TPB is shown in Figure 3.1.

Figure 3.1 Theory of Planned Behaviour (Ajzen, 1988, 1991)



A single behaviour is conceptualised as involving an 'action' which is directed at a 'target' and performed in a given 'context' and at a certain point in 'time' (Ajzen & Fishbein, 2005). The principle of compatibility (Ajzen, 1988) states that in order to maximise the predictive power of the model, all the variables in the theory should be measured at the same level of specificity or generality. This means that all measures should involve exactly the same target, action, context and time elements (TACT principle) whether defined at a very specific or at a more general level. Although the TPB holds that all behaviours are determined by the same limited set of variables, the relative importance of attitude, subjective norm and PBC may vary across different behaviours and the underlying behavioural, normative and control beliefs may also differ for different behaviours (Ajzen & Fishbein, 2005).

3.1.1 CONCEPTUALISATION OF DIRECT MEASURES

The simplest approach to the measurement of the TPB constructs (attitude, subjective norm and PBC) uses one combined measure for each which is referred to as a global or direct measure (Bennett & Bozionelos, 2000). There has been much ongoing debate about how the direct measures in the TPB should be structured, and the main issues are summarised below.

Although there has been some variation in the ways in which intention has been operationalised, the growing evidence for high internal consistency between measures of desire, intention and expectation means that these measures now tend to be used in combination (Conner & Sparks, 2005). A number of studies have identified a distinction between cognitive/instrumental (beliefs about the

consequences of performing the behaviour) aspects of attitude and affective/experiential (feelings associated with performing the behaviour) aspects (Rise et al., 2008). In the case of smoking, an instrumental attitude might be a belief that smoking is damaging to health, while an affective component could be that smoking is pleasant. Ajzen & Fishbein (2005) stipulated that direct measures of attitude on semantic differential scales should incorporate a mixture of instrumental items (e.g. healthy-unhealthy) and experiential items (e.g. pleasant-unpleasant), and be regarded as lower order components of this construct.

Given the evidence highlighting subjective norm as the weakest predictor of intention (e.g. Godin & Kok, 1996), much effort has been made to improve its predictive power. Whilst the evidence could simply be a reflection of a general lack of normative influence on behaviour (Conner & Sparks, 2005), Armitage & Conner (2001) saw this as being at least in part the result of inadequate operationalisation via the use of single item measures. More recently, Ajzen & Fishbein (2005) argued that to acquire a comprehensive measure of subjective norm, two sub-components needed measuring, i.e. injunctive norms (perceptions of what others think one should do), and descriptive norms (perceptions of what others are doing).

Although Ajzen (1991) posited that the PBC was analogous to Bandura's (1977) concept of perceived self-efficacy, some more recent evidence would suggest that PBC is multidimensional (Trafimow et al., 2002). An argument has been made for an independence between perceived control (the extent to which the behaviour is considered to be up to the individual) and self-efficacy (the perceived difficulty or ease of performing the behaviour). For instance, it is possible for a person to consider a behaviour to be under their control at the same time as perceiving it to be difficult to carry out (Armitage & Conner, 2001). Some researchers have conceptualised this distinction in terms of internal control (e.g. knowledge, skills, ability, motivation) and external control (e.g. cooperation of others, access to necessary resources, opportunities) (Conner & Sparks, 2005). Other researchers (e.g. Trafimow et al., 2002) have defined the distinction in terms of perceived control and perceived difficulty, concepts arguably related to external and internal resources respectively (Manstead & van Eekelen, 1998). However, Ajzen & Fishbein (2005) contested that there is no reason to assume that perceived difficulty refers to internal control or that perceived control refers to external control. Ajzen (2002a) proposed that self-efficacy and controllability are

subcomponents of the higher order structure of PBC and PBC is now often operationalised using items which measure both of these (Ajzen & Fishbein, 2005). Despite this, the structure of PBC as a unidimensional or multidimensional construct remains unclear and this lack of clarity, in addition to varying ways in which the components have been operationalised, is a probable reason for the low internal reliabilities often reported for this measure (Conner & Sparks, 2005).

3.1.2 CONCEPTUALISATION OF INDIRECT MEASURES

In the second more complex method of measuring attitude, subjective norm and PBC, measures are derived from the specific behavioural, normative and control beliefs held by the individual and their corresponding evaluations of these beliefs (Bennett & Bozionelos, 2000). For example, in the case of smoking behaviour, a behavioural belief might be that quitting smoking is good for the health, with the corresponding evaluation being that this would be a good outcome. A normative belief might be that the family would approve of quitting with the corresponding evaluation being that the smoker is motivated to comply with their wishes. A control belief might be that the smoker is not allowed to smoke in public places with the corresponding evaluation being that not being able to do this will make quitting more likely. Each belief and its associated evaluation are multiplied and the indirect measures of the TPB constructs are quantified by summing the behavioural, normative and control products. In line with the theory's assumption that the direct measures are underpinned by the indirect measures, some studies operationalise both sets of measures. If the expectancy-value model is valid, the belief-based measures should correlate highly with their respective direct measures (Ajzen, 1991).

3.1.3 META-ANALYSES

The following three meta-analyses were identified as being the only ones which assessed the utility of the TPB across various different behaviours. They reported the ability of attitude, subjective norm and PBC to predict intention, and PBC and intention to predict behaviour.

Across 12 studies of both health and general behaviours, Ajzen (1991) reported that the combination of intentions and PBC consistently predicted behaviour with multiple correlations ranging from .20 to .78, with an average of .51. In 2 studies PBC was the only significant predictor, with both these investigating weight loss. In 6 studies, each antecedent variable significantly contributed to the prediction of behaviour and in the remaining 4 studies, intention was the dominant

predictor. The weakest predictions appeared to be associated with those behaviours requiring more control and where there was a discrepancy between perceived and actual control. From another set of 16 studies, some of which had been included in the previous analyses, attitudes, subjective norm and PBC were reported by Ajzen (1991) to account for a considerable amount of variance in intention to perform the behaviour in question, with multiple correlations ranging from .43 to .94, with an average of .71. In all cases, PBC was an independently significant predictor of intention with attitude only failing to significantly contribute in one study. As the findings for subjective norm were more mixed it was surmised that, for the behaviours under consideration, factors more personal to the individual took precedence over perceived social pressure from others. Indeed, as the theory states, the relative contributions of the three constructs can vary, dependent on the type of behaviour or the population being investigated (Ajzen & Fishbein, 2005).

It was noted by Sutton (2004) that this meta-analysis was not restricted to prospective studies only, which raises the possibility that the association between a TPB construct and behaviour could have included a component due to the behaviour influencing that construct. For example, in a cross-sectional study, where the predictor and outcome variables are measured at the same point in time, it would be possible for the successful execution of a behaviour to influence a person to report a more positive attitude towards it or a greater sense of control over it. Furthermore, this review was only concerned with direct TPB measures and was limited to a small set of studies, some of which had never been published (Armitage and Conner, 2001). Also, it was not clear from the meta-analysis how each construct had been measured.

Godin & Kok's (1996) review, which focused only on health-behaviours in prospective studies, reported average correlations between intention and attitude, subjective norm and PBC to be .46, .34 and .46 respectively. This review indicated that the TPB performs very well for the explanation of intention (an average R squared of .41 was observed from 76 applications, ranging from .32 for eating behaviours to .47 for oral hygiene behaviours). PBC, attitude and subjective norm were found to be independently significant predictors in 85.5%, 81.6% and 47.4% of these applications respectively. As in the previous review, subjective norm appeared to have less influence on intention than attitude or PBC. It was suggested that this might have been due to inadequate operationalisation of the construct or because social influences exert their effects

via different routes. Average correlations between behaviour and intention and PBC were .46 and .39 respectively. From 35 applications, the prediction of behaviour yielded an average R squared of .34, suggesting that the TPB model accounted for around a third of the variance in behaviour. This ranged from .16 for clinical and screening behaviours to .42 for HIV/AIDS-related behaviours. Intention was generally the most important variable, although in half of the studies which measured the additional contribution of PBC, this was a significant predictor, with an average additional contribution of 11.5%.

This review showed that the TPB predicted certain behaviours better than others, perhaps because of differences between perceived and actual control (Godin & Kok, 1996). However, as Sutton (2004) comments, the small number of studies in this review and the lack of information about the samples used and the ways in which the constructs were measured makes it difficult to interpret these findings. Furthermore, Godin & Kok (1996) only reported values from studies which reported the relevant data, and the tendency for authors to mainly report significant findings might have biased their estimates (Armitage & Conner, 2001).

In their general review of 185 studies and weighting by sample size, Armitage & Conner (2001) reported average correlations between intention and attitude, subjective norm and PBC of .49, .34 and .43 respectively. The TPB accounted for 39% of the variance in intention, but subjective norm was generally a poor contributor to this, which the authors suggested was the result of it being poorly measured and the normative element being in need of revision. In this review, the TPB explained an average of 27% of the variance in behaviour, with PBC adding an average of 2% over intention to this prediction. Correlations between the belief-based and direct measures were .50 (attitude), .50 (subjective norm) and .52 (PBC) which represented medium to large effect sizes (Cohen, 1992). When behaviour measures were self-reports, the TPB accounted for 11% more of the variance in behaviour than when behaviour measures were objective or observed. Taylor et al. (2006) reported that this implies an objective figure of 21% of behavioural variance explained, commenting that this was lower than figure of 34% quoted by Godin & Kok (1996) which was not adjusted in this way. The fact that self-reports are likely to overestimate behaviour is an issue given that the goal of the TPB is to predict actual behaviour.

The above reviews show that across various different behaviours, the TPB was able to consistently explain between 39% to 50% of the variance in intention,

and 26% to 34% of the variance in behaviour, which are all large effect sizes (Cohen, 1988, 1992). PBC and attitude were generally the strongest predictors of intention relative to the weaker contribution made by subjective norm. Dependent upon the behaviour being investigated, the relative contributions of intention and PBC to the explanation of behaviour varied. Although the figures quoted define the TPB as a good predictor, a lot of variance nevertheless remains unexplained, with a noticeable dilution from intentions to behaviour. Some of the possible explanations for this are outlined below.

3.1.4 REASONS FOR LIMITED PREDICTIVE POWER

Sutton (1998) offered a number of explanations for why the amount of variance explained by the TPB is not as large as would ideally be liked, some of which are listed here (1) Intentions may change in the time period prior to behaviour measurement. Indeed, the theory is most predictive when the concepts are defined specifically and are measured in close proximity (Rimer, 2002). (2) Expressing an intention via a questionnaire may not equate to that which would be made in a real world setting (3) The principle of compatibility can be violated, in that the variables in the model are not measured at the same level of specificity or generality (4) the different scales used for intention and behaviour in terms of response formats and number of categories reduces the strength of the potential correlation (5) random measurement error (6) other factors in addition to intention might be causing the behaviour. However, the fact that the TPB has been found to be a superior predictor of behaviour compared to alternative social cognition models (Armitage & Connor, 2000) is impressive bearing in mind its parsimonious nature (Sutton, 2004). Furthermore, because it has fewer, more precisely defined components than other models may enhance the efficiency and consistency of its use (Taylor et al., 2006). Also, in contrast to alternative social cognition models, the TPB does attempt to incorporate social and environmental factors in the form of normative beliefs, and includes a role for past behaviour within the measure of PBC (Ogden, 2004).

3.1.5 ADDING OTHER VARIABLES TO THE MODEL

One of the important features of the TPB is that the model is 'sufficient', i.e. external variables will not contribute additional variance in intentions or behaviour over and above the model's components (Ajzen & Fishbein, 2005). However it has been argued that, as the large amount of unexplained variance in these outcomes is unlikely to be due to measurement error, there may be a role for other variables and numerous attempts have been made to increase the

predictive power of the TPB in this way (Rutter & Quine, 2002). Ajzen (1991) reported that such practice would be acceptable only if an additional variable could be shown to account for a significant proportion of the variance in intention or behaviour on top of the current constructs. Even then it should be added after careful deliberation and empirical exploration (Ajzen & Fishbein, 2005).

Sutton (2004) stated that an additional variable should only be considered for inclusion if the follow conditions are satisfied (1) there are strong theoretical motives for believing the additional variable will directly impact on the outcome (2) the new variable can be derived from salient beliefs related to the outcome (3) the new variable can be shown to be measuring a different entity to the existing components (4) the new variable is an independent predictor of outcome in studies where the existing constructs are operationalised as specified by the theory. Conner & Armitage (1998) too argued that, for any additional variable, the process by which it influences the outcome should be specified, along with its relationship to the existing constructs and the range of conditions over which it is anticipated to exert its influence. Additional constructs that have received particular attention include anticipated regret, moral norms, self-identity and past behaviour (Conner & Sparks, 2005). Aizen & Fishbein (2005) have argued that some additions are merely alternative representations of existing constructs and as such add very little extra variance.

3.2 PREDICTION OF SMOKING CESSATION IN PREGNANCY, ENGAGEMENT WITH SMOKING CESSATION PROGRAMMES AND NICOTINE REPLACEMENT THERAPY USE

The TPB has not been widely applied to smoking cessation. However, in his criticism of the Transtheoretical Model (Prochaska & DiClemente, 1983) which was specifically developed to research smoking behaviour, Sutton (2005) recommended the use of the TPB as an alternative model.

3.2.1 DATABASE SEARCH STRATEGY

In order to review the application of the TPB to the health behaviours relevant to this thesis, the following OVID databases were concurrently searched: PsycINFO (1987-2009), MEDLINE (1996-2009), EMBASE (1988-2009), British Nursing Index (1985-2009) and AMED (Allied & Complementary Medicine) (1985-2009). Different combinations of various search terms were used to ensure that all papers applying the TPB to the prediction of smoking cessation in pregnancy,

engagement with smoking cessation programmes and NRT use were elicited. Keywords used included theory of planned behaviour, smoking cessation, pregnancy, smoking cessation programmes, smoking cessation services and nicotine replacement therapy. Only full text, English language papers were searched and any intervention studies or studies where the TPB investigated smoking cessation outside of pregnancy were excluded as were health-related programmes other than smoking cessation. Seven studies were found to meet the inclusion criteria and the citing papers for each were screened to ensure that no other relevant papers had been missed. Those papers where the full text was not accessible were obtained from the corresponding authors. The seven studies are reviewed below and summarised in Table 3.1.

3.2.2 SMOKING CESSATION IN PREGNANCY

Godin et al. (1992) used the TPB to predict intentions to refrain from smoking in a group of pregnant women and a group of adults from the general population in Quebec, Canada. Attitude not to smoke was measured using eight sets of bipolar adjectives on semantic differential scales, e.g. unpleasant-pleasant, unhealthy-healthy. Subjective norm was assessed by the strength of the participant's belief that important others would think they should refrain from smoking and PBC by the difficulty/ease of refraining from smoking. For the 53 pregnant smokers, attitude, subjective norm and PBC together significantly predicted intention not to smoke 4 months after childbirth, explaining 54% of the variance. PBC and attitude were the significant predictors in the model ($\beta = 0.53$, $p < 0.001$, & $\beta = 0.31$, $p < 0.01$ respectively). Subjective norm was not a significant predictor and habit strength did not significantly contribute to the variance in intention when added to the model. PBC and intention together significantly predicted non-smoking behaviour explaining 46% of the variance, but only PBC was an independently significant predictor ($\beta = 0.80$, $p < 0.001$). Habit strength did not significantly contribute to the variance in behaviour when added to the model.

These results highlight the importance of PBC in predicting non-smoking intention and behaviour in pregnancy, particularly as this component played a more important role in explaining behaviour in this population than in those from the general population. This was said to highlight the difficulty of quitting and the need for a preconceived conviction of being able to do so. It also supports the assumption that PBC plays an important role for nonvolitional behaviours (Hu & Lanese 1998). The fact that habit strength did not influence smoking behaviour in pregnancy as it did in the general population was suggested to indicate that a

pregnant women's decision not to smoke is a determined one, less dependent on the negative impact of the smoking habit. Pregnant women were shown to have a stronger intention not to smoke and to perceive this to be easier to execute than those from the general population.

It was suggested that being pregnant might generate a strong belief in self-efficacy in not smoking cigarettes, and the study concluded that time would be well-spent trying to enhance self-efficacy in pregnant smokers. The fact that habit did not influence intention in either group of smokers was said to support the argument of Aizen (1988) that PBC is a mediator of this effect. The authors appear to state that because attitude was a significant predictor of intention not to smoke amongst pregnant women, this suggests that pregnant women perceive benefits not to smoke cigarettes during pregnancy (e.g. avoiding the harmful effects on the foetus). However, as only a direct measure of attitude was used (based on 8 bipolar adjectives), it could be argued that it is not appropriate to make inferences about specific beliefs underlying this construct. Also subjective norm and PBC were measured using one item only, which raises some concerns about the reliability of these measures. The fact that the behaviour measures were acquired over 6 months after the baseline measures is a strength of the study design even though these were ascertained by self-report, and thus could have been subject to bias.

De Vries & Backbier (1994) used a TPB framework to assess the determinants of quitting smoking amongst 144 pregnant women in the Netherlands. Attitude was assessed using 16 consequences of smoking and quitting for the health of the mother and baby. Social influences were ascertained using questions about social support from and perceived smoking of partner, children, relatives, friends, colleagues, GP and midwife. PBC (labelled self-efficacy in this study) was established by asking about the ease or difficulty of resisting smoking in different situations. Attitude, social influence and self-efficacy were each significantly correlated with intention to quit smoking during pregnancy ($r = 0.45, 0.37, 0.32$ respectively) and behaviour ($r = 0.32, 0.32, 0.52$ respectively). A stepwise multiple regression showed that attitude was a significant predictor of intention, explaining 20% of the variance ($p < 0.01$) with self efficacy and social influence adding a further 6% ($p < 0.01$) and 2% ($p < 0.01$) respectively. Intention explained 31% ($p < 0.01$) of the variance in smoking behaviour, with self-efficacy adding a further 14% ($p < 0.01$).

In line with the findings of Godin et al. (1992), attitude and PBC were the best predictors of intention to quit, and PBC made a unique contribution to the explanation of smoking behaviour, perhaps reflecting the impact of skills or actual control (De Vries & Backbier, 1994). The cross sectional nature of the study was acknowledged to be a limitation of the study as was the inability to be able to compare participants who participated in the study with those who did not. Also, whilst the TPB items used were indirect in nature, they were not operationalised in the expectancy-value multiple composite format specified by the TPB.

In a US study, Moore et al. (1996) used the TPB to investigate the determinants of cigarette use amongst 72 pregnant smokers. Using beliefs derived from a previous elicitation study, the TPB components were assessed in early pregnancy (Time 1 interview). Attitude was measured in terms of the likelihood of a set of positive and negative outcomes occurring multiplied by an evaluation of each outcome, and subjective norm was derived from the perceived strength of the belief that various significant others would or would not want the participant to continue to smoke during pregnancy multiplied by the motivation to comply with these wishes. Self efficacy was assessed by averaging participants' confidence to not smoke during pregnancy under a series of differing circumstances. Past behaviour (i.e. daily cigarette consumption) was assessed at Time 1 and an average number of cigarettes smoked daily from Time 1 through the first 6 months of pregnancy was requested in the 7th month of pregnancy (Time 2 interview). Each of the TPB components was significantly correlated with smoking behaviour later in pregnancy, with PBC being most strongly associated with the outcome ($r = -0.63$, $p < 0.01$), followed by subjective norm ($r = 0.30$, $p < 0.05$), and attitude ($r = 0.27$, $p < 0.05$). However, it was acknowledged that the cross-sectional nature of these relationships makes it difficult to establish whether higher self-efficacy contributed to less smoking or whether less smoking enhanced feelings of self-efficacy. Although a path analysis showed that more smoking in early pregnancy was related to lower smoking self-efficacy ($\beta = -.55$, $p < 0.001$), neither self-efficacy, attitude or subjective norm were related to later smoking once previous measures of cigarette use were entered into the model. It was therefore suggested that self-efficacy exerts its effects on later behaviour via its association with previous behaviour. Even though the outcomes were based on self report, collecting these data at a later time point than the independent variables was a strength of the study design, as was the multiplicative operationalisation of the attitude and subjective norm constructs. These findings contrast those of Godin et al. (1992), where habit strength did not influence

smoking behaviour in pregnancy. However, the fact that Godin et al. (1992) measured habit in terms of three categories (i.e. daily smoking, regular smoking but not daily, or occasional smoking) rather than daily consumption makes direct comparisons on this measure problematic.

Using indirect, belief-based measures of the three TPB constructs, Bennett & Clatworthy (1999) conducted a UK cross-sectional study to examine the power of the TPB to discriminate between 44 women who continued smoking and 21 women who quit smoking during the early stages of pregnancy. The seven attitude measures each derived from belief-strength multiplied by belief-evaluation focussed on the health of the child, weight and stress control, and enjoyment of smoking. The six subjective norm measures each derived from belief-strength multiplied by motivation to comply focussed on partner, family and friends, and the two PBC measures assessed perceptions about not being able to break the habit and ease of stopping smoking.

In terms of attitudinal beliefs, those who continued smoking considered smoking to be less harmful to their baby than those who quit but were more likely to believe that smoking would result in a low birth weight baby and an easier labour. Smokers were also less likely to believe that smoking would reduce the stress of family life. In terms of social norms, those who stopped smoking considered that their friends would more strongly believe that they would wish the participant to stop smoking and that smoking would harm the baby's health. No differences in the perceived beliefs of partners and family were found between smokers and quitters. In terms of control beliefs, smokers perceived themselves to have a stronger smoking habit and anticipated a greater difficulty to quit while pregnant. It is noted that, for the series of t tests employed to assess for differences between smokers and quitters, there is no evidence of correcting for multiple testing, thus the likelihood of a Type 1 error is increased, i.e. finding a difference when in truth there is none.

When the TPB variables which discriminated between continuing smokers and quitters were entered into a stepwise logistic regression, the variables relating to concern about impairing the health of the baby ($\beta = 0.53$, $p < 0.01$) and ease of stopping smoking ($\beta = 0.65$, $p < 0.05$) correctly classified 95% of the participants. A hierarchical logistic regression showed that the TPB variables did not add to the predictive power of a model already containing other factors that had discriminated between smokers and quitters (i.e. number of cigarettes

smoked, craving and partner smoking). In this case, craving was the only variable to enter the model ($\beta = -0.57$, $p < 0.01$), correctly classifying 78% of the participants. A potential interpretation of this finding was that nicotine addiction is the primary determinant of continued smoking and that the beliefs represent post hoc rationalisations to support the behaviour. The authors argued that this notion is supported by the fact that those who continued smoking reported reducing their cigarette consumption upon learning of their pregnancy, and set the level close to that required to alleviate withdrawal. These findings support the use of NRT as a potentially effective means of assisting with a quit attempt in pregnancy.

This study replicated some of the findings of Godin et al. (1992) in that PBC was strongly associated with smoking cessation in pregnancy, and that attitudinal factors also exert an influence. The findings are also similar to those of Moore et al. (1996) in so far that the TPB variables ceased to be primary determinants of outcome when measures of dependence were added to the statistical model. It was argued that enjoyment, stress and weight management were not related to smoking status in pregnancy because these smokers were more concerned about the health of the baby. It was also acknowledged that, because of the cross-sectional nature of the study, PBC might have been influenced by smoking outcome and assessing nicotine dependence retrospectively might have caused biased responses. It should be noted that the PBC items in this study appeared to take the form of a direct measure of this construct, i.e. 'smoking is a habit I cannot break' and 'I would find it easy to stop smoking during my pregnancy'. Thus, this was not consistent with the indirect measures of attitude and subjective norm which were derived from multiplicative composites.

3.2.3 SMOKING CESSATION PROGRAMMES

Babrow et al. (1990) used the TPB to gain an understanding of the beliefs underpinning college students' interest in participating in a smoking cessation programme. The authors argued that because engaging in such a programme is under the control of the individual by virtue of a conscious decision involving cognitive and affective assessment, the TPB was ideally suited to this phase of the cessation process. Beliefs about consequences of participation and control were generated in a formative study with student smokers, and the most frequently cited were used in the study. The devised questionnaire measured intention (2 items), attitude toward participation (2 items), beliefs about

consequences of participation (9 outcomes x evaluations), subjective norm (2 items), and PBC (5 control beliefs).

In support of the theory, the sum of the nine expectancy-value products significantly predicted attitude ($R = .41$; $F(1, 189) = 38.69$, $p < .0001$), and the three TPB components together explained 49% of the variance in intention, with attitude ($\beta = .53$), $p < .0001$), subjective norm ($\beta = .19$, $p < .001$), and PBC (sum of the control beliefs) ($\beta = .14$, $p < .05$) each making a significant contribution to the model. Splitting the intention variable into low and high intenders revealed that those with stronger intentions to participate tended to rate the positive consequences of doing so (i.e. quitting smoking, improving health, saving money, dropping a dirty habit, stopping offending others and getting involved in healthy activities) as being more likely and more favourable than those with weaker intentions. However, the negative consequences (i.e. gaining weight, feeling stressed or pressured and jittery or fidgety) were generally unrelated to intention. High intenders were also more likely than low intenders to believe that the facilitating control factors (i.e. flexibility of programme hours, opportunity to participate with friends, receiving reminders and convenience of programme location) would make programme participation easier. However, the one inhibiting control factor (i.e. concerns about a lack of time to participate) was not related to intention level.

As attitude was found to be the most powerful predictor of intention, and there were significant differences in both perceived likelihood and evaluation of positive consequences between low and high intenders, it was concluded that to promote uptake of such a programme, messages should target both perceptions of likelihood and evaluation of positive consequences of engagement. Although the study operationalised the attitude measures as specified by the theory, no attempt was made to explore the normative beliefs underpinning subjective norm. Also, rather than employing a direct measure of PBC in the prediction of intention, an indirect, belief-based measure was used including items such as programme flexibility, and these items lacked evaluative components.

A follow-up study by Black & Babrow (1991) using the same predictor variables as above showed that the TPB predicted interest in multiple group sessions and individual counselling, explaining 42% and 43% of the variance respectively. All three predictors significantly contributed to each model with attitude being the

Table 3.1 Theory of Planned Behaviour studies predicting smoking cessation in pregnancy, engagement with smoking cessation programmes and use of Nicotine Replacement Therapy

Study	Design	Participants	Predictor variables	Main outcomes
Godin et al. (1992)	Prospective	136 non-pregnant smokers 210 non-pregnant non-smokers 53 pregnant smokers 86 pregnant non-smokers	Direct attitude (8 items) Direct subjective norm (1 item) Direct PBC (1 item) Habit	PBC and attitude predicted intention to quit smoking in pregnancy. Only PBC predicted quitting behaviour
De Vries & Backbier (1994)	Cross-sectional	103 pregnant smokers 40 pregnant quitters in last year	Direct/indirect attitude (16 items) Indirect social influences (13 items) Direct/indirect self-efficacy (11 items)	Attitude, self-efficacy and social influence predicted intention to quit. Intention and PBC predicted quitting behaviour
Moore et al. (1996)	Prospective	72 pregnant smokers 169 pregnant non-smokers	Beliefs about consequences (46 items) Indirect norms * Indirect self-efficacy (24 items) Past behaviour	Only smoking level prior to pregnancy and at the start of pregnancy influenced cigarette use through first 6 months of pregnancy
Bennett & Clatworthy (1999)	Cross-sectional	44 pregnant smokers 21 quitters in early pregnancy	Indirect attitude (14 items) Indirect social norms (12 items) Control beliefs (2 items) Number of cigarettes smoked Degree of craving	Only craving predicted smoking status

Babrow et al. (1990)	Cross-sectional	191 student smokers	Direct attitude (2 items) Beliefs about consequences (18 items) Direct subjective norm (2 items) Control beliefs (5 items)	Attitude, control beliefs and subjective norm were significantly related to intention to participate in smoking cessation programme
Black & Babrow (1991)	Cross-sectional	191 student smokers	As above apart from additional 2 items for beliefs about consequences	Attitude, control beliefs and normative expectations predicted interest in multiple group sessions and individual counselling
Thomson et al. (2006)	Cross-sectional	207 female smokers	Direct attitude (6 items) Direct subjective norm (2 items) Direct PBC (2 items)	Attitude, subjective norm and PBC each predicted intention to use NRT

* Number of items not specified

strongest predictor (β = .44 & .45, $p < .0001$), followed by control beliefs (β = .22 & .23, $p < .001$) and subjective norm (β = .16 & .15, $p < .05$). Although the authors acknowledged that interest was not a component of the TPB, the previous study had found this measure to be strongly correlated with intention ($r = .69$, $p < .001$). It was concluded that to promote interest in either multiple group sessions or individual counselling, attitudes and control beliefs ought to be the primary targets for change with normative expectations being a secondary consideration. Using the same belief items as in the previous study, there tended to be stronger associations between positive rather than negative outcome likelihood/outcome evaluations and interest in multiple group sessions/individual counselling. Thus emphasising the positive aspects related to interest in participation in these activities was again recommended.

3.2.4 NICOTINE REPLACEMENT THERAPY

Only one study could be identified that has utilised the TPB to investigate NRT, although this was not specific to pregnancy. In this UK study by Thomson et al. (2006), 207 female smokers provided information about their views and attitudes regarding NRT use by completing a questionnaire containing items designed to capture the direct measures of the TPB. Attitude to NRT was assessed using semantic differential scales with 6 bipolar adjectives, e.g. ineffective-effective, punishing-rewarding. Subjective norm was assessed in terms of the degree to which participants perceived that important people would think they should/should not be using NRT and would approve/disapprove of this behaviour. PBC was measured on scales assessing the degree of control the participant felt they had over using NRT and how difficult or easy they would find this. A multiple regression analysis showed that attitude, subjective norm and PBC together significantly predicted intention to use NRT, explaining 41% of the variance. Each variable make a significant contribution to the model with attitude being the strongest predictor ($\beta = 0.42$, $p < 0.01$), followed by subjective norm ($\beta = 0.23$, $p < 0.01$) and PBC ($\beta = 0.22$, $p < 0.01$), the latter being measured using two items with a correlation of only 0.30. Although this study demonstrated that the TPB components were each influential in shaping women's intention to use NRT, it does not provide any information about the underlying beliefs.

Collectively, these studies would seem to provide positive support for utilising the TPB to investigate pregnant smokers' beliefs about using NHS Stop Smoking Services and NRT to assist with smoking cessation in pregnancy.

3.3 CONCEPTUAL LIMITATIONS

Along with all health behaviour theories, the TPB has its limitations (Rimer, 2002). Some of the more conceptual issues will be discussed in this section, and those which closely relate to the operationalisation of model will be covered in Section 3.4.

3.3.1 CAUSALITY

Schwarzer (1992) has criticised the TPB on the grounds that its lacks a temporal element and does not describe the order of the different beliefs or any direction of causality. Sutton (2004) too indicated that the causal assumptions within the model remain ambiguous in the absence of experimental studies, i.e. where participants are randomly assigned to an experimental and control condition, and the determinant of interest is manipulated independently of other potential causes. As it stands, the majority of TPB studies have employed cross-sectional or prospective designs where correlational analyses do not provide direct evidence for causal effects (Ajzen & Fishbein, 2005).

3.3.2 RATIONALITY

The TPB has been often criticised for assuming that all behaviour is rational and for inadequately accounting for non-cognitive or irrational influences on behaviour (Conner & Sparks, 2005). However, Ajzen & Fishbein (2005) have argued that emotional factors exert influence on intentions and behaviour via their effects on beliefs and evaluations. That said, Ajzen & Fishbein (2005) do acknowledge that when completing a TPB questionnaire, individuals might be unable to accurately anticipate those emotions which would become salient in a real-world setting. The fact that this could lead to poor representations of the TPB constructs which in turn become good predictors of behaviour is a concern for those attempting include emotional factors within the TPB (Conner & Sparks, 2005).

3.3.3 INTENTION-BEHAVIOUR GAP

Even when measures of intention and behaviour have sufficient variance, are relatively stable, and the measures are compatible, relatively low intention-behaviour correlations sometimes still occur (Ajzen & Fishbein, 2005). This has led researchers to explore this 'intention-behaviour gap' in an attempt to find variables to bridge it. Most research in this regard has focussed on the notion of implementation intentions (Gollwitzer, 1993), where acting out a goal intention is conceptualised as a two stage process. The first stage is a motivational one

equivalent to 'intention' as proposed by Ajzen (1991), which is followed by a planning stage where one specifies what one will do and where one will do it in order to achieve the intention. The environmental situation within which these plans (implementation intentions) are couched is considered to serve as a cue which commits the individual to the specific behaviour and thus facilitates their movement from intention to behaviour (Ajzen & Fishbein, 2005).

3.3.4 CRITIQUES OF THE MODEL

Ogden's (2003) claimed that models such as the TPB have three main conceptual flaws. Firstly, she stated that when such a model performs poorly, authors tend to put this down to incorrect operationalisation, sample characteristics or the type of behaviour being investigated, rather than rejecting the model. Concluding that no data can be collected to show that a TPB model is wrong, she argued that they are not falsifiable and cannot be tested. She suggested that the model should be rejected if one of the theory's antecedent variables fails to predict the outcome measure and if the theory's predictors do not explain most of the variance in intention or behaviour. Ajzen & Fishbein (2004) countered this by reiterating the fact that the relative importance of the TPB constructs is expected to vary across behaviours and populations and, although the three antecedents should be sufficient to predict intentions, only one or two may be necessary. Furthermore, they stated that the theory could be disconfirmed if all antecedent variables failed to predict intentions or behaviour. Ajzen & Fishbein (2004) also argued that there is no clear criteria in terms of how much variance a model has to explain for it to be judged acceptable, but highlighted that the TPB's performance is superior to other theories and that unexplained variance could be accounted for by random measurement error, a lack of variance in the behavioural criterion or inadequate operationalisation of the constructs.

Secondly, Ogden's (2003) claimed that operationalisations of the cognitive variables in the TPB, such as PBC and intention, are so similar that a strong correlation between them is virtually assured. Ajzen & Fishbein (2004) noted the inconsistency between this and her assertion that hypothesised relations among model components are often not confirmed. Furthermore, they stated that operationalisations of these components have been validated through structural component analyses and tests for convergent and discriminant validity. Thirdly, Ogden (2003) suggested that questionnaires used to test the TPB may create or change cognitions rather than assess existing ones. Ajzen & Fishbein (2004) replied that whilst this is a potential issue for all questionnaire studies, the

chances of this occurring can be minimised if the beliefs associated with the TPB are elicited in a free-response format as recommended.

Greve (2001) argued that because behaviours are logically tied to intentions, theories which include the latter are not explaining the former (Norman & Conner, 2005). However, Norman & Conner (2005) suggested that Greve's definitions for intention and behaviour were narrower than those specified in the TPB (i.e. dichotomous rather than a dimension of strength), and because of this there seems no reason to believe that intention must predict behaviour by definition. Norman & Conner (2005) also stated that even if it is accepted that a behaviour presupposes an intention, this does not necessarily mean that an intention has to imply a corresponding behaviour. Furthermore, they highlight evidence which shows the impact of other factors on the extent to which intentions influence behaviours, and issues of planning which suggest that the intention-behaviour relationship is more complex than Greve proposed.

3.4 OPERATIONALISATION OF THE MODEL

According to Armitage and Conner (2001), many studies using the TPB have inadequately operationalised the model. This is likely to be in part due to the confusion caused by the range of differing views on how to go about this process (Giles et al., 2007). The various ways in which TPB measures have been conceptualised likely has some bearing on this (see Sections 3.1.1 & 3.1.2), along with the following methodological issues.

3.4.1 ELICITATION STUDY

It has been argued that the best way of capturing salient beliefs is via free-elicitation with the first five to nine beliefs mentioned by an individual being considered salient (Conner & Armitage, 1998). On this basis, a crucial step when applying the TPB involves conducting in-depth, open-ended elicitation interviews to identify the salient outcome, normative and efficacy beliefs held by the population under study for the specific behaviour (Montano & Kasprzyk, 2002). However, a number of TPB studies have failed to undertake this process (Conner & Sparks, 2005). According to Montano & Kasprzyk (2002), at least 15-20 individuals from the population under investigation should be recruited for this purpose, ideally including some individuals who have performed or intend to perform the behaviour and some who have not performed the behaviour. These elicitation interviews are then content or thematically analysed, preferably by two

independent researchers, and the questionnaire content is derived by creating items to measure each theme (Francis et al., 2004). Although these interviews are ultimately useful, they can be demanding in practice (Rimer, 2002), especially as it is necessary to comprehensively identify and measure all the important beliefs in order to obtain good predictions (Montano & Kasprzyk, 2002).

Conner & Armitage (1998) reported the concerns of some researchers that using modally salient beliefs (i.e. those derived from a representative sample) rather than individually salient beliefs will result in a failure to capture the beliefs salient to the individual. However, they note that beliefs elicited in this way do appear to be predictive of behaviour and are much less labour intensive to handle than those elicited individually. Also, using individual beliefs can reduce the sample size when participants' inability to generate them results in missing data (O'Sullivan et al., 2008). It has been argued that the questions recommended by Aizen (2002b) for eliciting behavioural beliefs are biased towards producing cognitive (i.e. instrumental beliefs), and fail to elicit the affective beliefs which are more difficult to articulate (Conner & Armitage, 1998). Sutton et al. (2003) demonstrated that using questions with a more affective slant (e.g. like or enjoy, dislike or hate) did produce different responses to those elicited by the standard questions (e.g. advantages, disadvantages) but whether this impacted on the final set of modal beliefs was dependent on the selection criteria used.

3.4.2 SELECTION OF BELIEFS

Deciding on the number of beliefs that should be considered salient is problematic in that selecting too many might compromise the descriptive validity of the model, and selecting on the basis of an individual's processing capacity could result in an insufficient representation (Conner & Armitage, 1998). There are no set criteria for this and, as such, the decision rules used differ across studies. Although including a larger set of belief items is likely to improve the validity of the study, this should be weighed against the possibility of reduced participant motivation and response rates as a result of a longer questionnaire (Francis et al., 2004).

3.4.3 EXPECTANCY-VALUE FORMULATIONS

A number of criticisms have been levelled at the use of expectancy-value measures in the TPB which will be discussed in turn. French & Hankins (2003) argued that the common practice of correlating a multiplicative composite with other variables is unacceptable as the expectancy-value belief only has an

arbitrary zero point selected by the researcher, rather than the required true zero on a ratio scale. A further problem related to this formulation is that the TPB does not inform the researcher how to scale the multiplicative function of the belief-based measures. This is a considerable issue given that whether unipolar or bipolar scoring is used can have a substantial impact on the correlation of the belief composite with any other variable (Aizen, 2002b). As a solution to this problem, Aizen (2002b) suggested optimal scaling, i.e. testing all possible combinations of unipolar and bipolar scoring and using the scales that produce the strongest correlation between the belief composite and the direct measure. However, this procedure has been criticised because it involves the belief that groups of participants can have different true rational zero-points on similar questionnaires (French & Hankins, 2003) and the coding corresponding to the way beliefs are formed might differ from the one computed (O'Sullivan et al., 2008). Using beliefs without multiplicative composites makes it much easier to interpret the influence beliefs have on the direct measures (French & Hankins, 2003) and procedures omitting both composites and optimal scaling have been recommended (O'Sullivan et al., 2008). In spite of optimal scaling, often only moderate correlations are found between global and belief-based measures which led Aizen (1991) himself to suggest that the expectancy-value formulation may not adequately capture the way in which individual beliefs combine to produce the global response.

Respondents often see the TPB questionnaire as being repetitive in terms of the expectancy-value items in that they do not appreciate that each element is measuring something subtly different about that belief (Giles et al., 2007). Also, some of the answers to the value components can be obvious (e.g. my baby being harmed by smoking would be bad-good) and because this results in all respondents giving the same answer, these items add no more variance to the model. If items such as these are included, the questionnaire risks losing face validity which may impact on participant concentration levels and validity of responses. Ajzen (1991) reported that sometimes the 'motivation to comply' element of normative beliefs does not add predictive power, perhaps because it is unusual for people to want to act against the wishes of significant others.

3.4.4 SELF-REPORT MEASURES

The majority of studies using the TPB have tended to utilise self-report measures despite suggested concerns that these are vulnerable to bias (Conner & Sparks, 2005). Ogden (2003) argued that self-reports of behaviour can be contaminated

by self reported cognitions, an assertion that Ajzen & Fishbein (2004) have questioned. They stated that any bias in self-report is usually concerned with overestimating performance of socially desirable behaviours, and that although this will serve to inflate the correlations between cognitions and behaviour, it does not invalidate the model. The accuracy of self-report has been shown to vary across behaviours (Ajzen & Fishbein, 2004), and of the few TPB studies which have attempted to measure for social desirable responding, some have found evidence for it while others have seen few effects of this on relationships between TPB constructs (Armitage & Conner, 2001). In their meta-analysis, Armitage and Conner (2001) reported that the TPB was able to predict an average of 31% ($p < .001$) and 20% ($p < .001$) of the variance in self-reported and observed behaviour respectively. Although the prediction of objective behaviour was less accurate, the authors noted that the model's ability to predict so much variance in actual behaviour was encouraging. Conner & Sparks (2005) reported that researchers should be mindful of the potential biases associated with self-report and whenever possible acquire objective multiple measures of behaviour. However, Ajzen & Fishbein (2004) noted that for certain health behaviours, self-report is the only feasible option and that collection of objective measures can be both time consuming and costly.

3.5 INTERVENTIONS

To date, the TPB has been mainly used to predict behaviours and rarely utilised to inform the design of interventions (Hardeman et al, 2002). However, the TPB would seem to have potential in intervention work as Ajzen & Fishbein (2005) argued that successfully modifying the TPB predictors should bring about a change in intentions and behaviour. The TPB requires that, to change behaviour, one firstly needs to determine which variables should be targeted (Conner & Sparks, 2005), and then either change existing salient beliefs about the behaviour, make existing non-salient beliefs salient, or create new salient beliefs (Sutton, 2002). Walker et al. (2001) suggested that the beliefs most likely to be effective targets are those that underlie variables strongly associated with intention. As the theory specifies that behaviour change can only be brought about by acting on the indirect TPB measures (i.e. beliefs), Sutton (2002) argued that it is necessary to assess the percentage of variance explained by these (effective variance explained), as well as by the direct measures. Interventions may be unsuccessful if the targeted constructs were already strong and psychological ceiling effects occur (Watson et al., 2006). Sutton (2002) argued

that in order to influence intentions and behaviour in the desired direction, the net effect of any changes in underlying beliefs must have a positive impact on the direct measures of the TPB. Sutton (2002) suggested that to develop a TPB intervention one must, in essence, work through five stages: (1) define the behaviour and population under investigation (2) establish the modal salient beliefs via an elicitation study (3) convert these beliefs into questionnaire items to assess the relative contribution of the TPB constructs and thus identify the most appropriate constructs to target in an intervention (4) identify the beliefs which best discriminate between low and high intenders (5) develop an intervention to change these beliefs. To identify the targets for the intervention, Sutton (2002) argued that one can either assess the belief items, the evaluations of these beliefs or the multiplicative composites.

3.5.1 SYSTEMATIC REVIEW OF INTERVENTIONS

Hardeman et al. (2002) conducted a systematic review of 24 TPB behaviour change interventions, half of which used the theory to inform the intervention with the other half using it to assess the effects of the intervention. The most common methods used to develop the intervention were information and persuasion which the authors considered to be the most appropriate for a primarily cognitive theory. About half of the interventions reported a change in intention, but in only half of these was the change in the desired direction. Of the studies that reported on behaviour, about two-thirds resulted in a change in the desired direction. However, effect sizes were generally small for both intentions and behaviour. According to Conner & Sparks (2005), interpretation of the findings is clouded by the fact that many studies did not incorporate an elicitation phase to establish appropriate targets for their interventions, or did not first test for any impact on targeted cognitions. Hardeman et al. (2002) concluded that many of the studies were poorly designed and in order to be able judge the effectiveness of the TPB in developing interventions, the model needs to be applied more comprehensively and targeted components should be more explicitly specified and measured. Furthermore, they pointed out that the majority of methods used were not particularly appropriate because they were more behavioural than cognitive in nature. Despite the inconclusive findings, Hardeman et al. (2002) reported that the TPB has potential utility in this area because it is able to accommodate people whose intention is low or whose motivation has not been established and it can suggest which cognitions to change in order improve intention levels.

3.5.2 INTERVENTIONS USING PERSUASIVE TECHNIQUES

Although the TPB does not specify what kind of intervention will be most effective (Aizen, 2004), Aizen (1991) reported that a persuasive message aimed at beliefs about an object usually changes attitudes towards that object, and considered the same was likely to be true for subjective norms and PBC. As reported by Chatzisarantis & Hagger (2005), the TPB theorists stated that such a message should include arguments in favour of the behaviour and factual evidence to support these. Making the arguments credible in this way is said to lead to acceptance of the message which in turn leads to belief change. Also, it can be easier to provide information designed to form new beliefs rather than alter existing ones, and an elicitation study may generate beliefs that many women do not associate with the outcome. On this basis, a novel belief may well be a pertinent target for an effective intervention (Aizen, 2004).

3.5.2.1 Database search strategy

In order to review the application of the TPB to interventions using a similar methodology to that employed in this thesis, the same databases as listed in Section 3.2.1 were searched, using a variety of different keyword combinations. Given that the aim of the thesis intervention is to use persuasive messages based on the TPB to improve the communication of health information, search terms used included theory of planned behaviour, randomised controlled trial, health, intervention, persuasive messages and communication skills. Only full text, English language papers were searched and those which used the TPB to inform a health-related intervention and compared this to some form of 'standard information' control condition or related the TPB to communication skills were retained. Five studies (reported in 6 papers) were found to meet the inclusion criteria and the citing papers for each were screened to ensure that no other relevant papers had been missed. These studies are reviewed below and summarised in Table 3.2.

Brubaker & Fowler (1990) designed a TPB intervention to promote testicular self-examination (TSE) amongst students, where 114 participants were randomly assigned to either a theory-based message group, an informational message group or a no message group. The theory-based group listened to an audio-taped role play scenario based on the TPB where misconceptions about TSE as established in previous research were challenged. These centred around beliefs about how difficult TSE was to perform, the time it took to perform and its role in early detection of cancer. By contrast, the informational message group heard a

more general message including incidence and treatment of testicular cancer. When followed up, those who received the theory-based and informational messages reported more TSE, and greater intentions and more positive attitudes towards the behaviour, although no differences were found between the two sets of messages. Conner & Sparks (2005) concluded that this study had been successful in modifying beliefs, and that a failure to find a difference between the two message conditions could have been due to the intervention method chosen. As the TPB offers no specific guidelines for this, they argued that it is possible that different methods will work better in different situations, and this will to some extent be governed by how amenable to change the target attitudes and behaviours are.

Wyer et al. (2001) used a TPB intervention in an attempt to increase acceptance and attendance at a cardiac rehabilitation programme (CRP). The study involved randomisation of 87 patients referred to the CRP to either an intervention or control condition. Those in the control condition received a standard letter thanking them for agreeing to take part in the study, whilst those in the experimental condition also received a letter based on the TPB constructs. The intervention letter highlighted the positive outcomes that could ensue from attendance (attitude), the fact that such a programme was endorsed by health professionals (subjective norm) and that the advice and information offered would aid an informed decision (PBC). Three weeks later, those in the control group who had accepted the offer to join the CRP received a standard letter informing them about the programme, whilst those in experimental group who agreed to join also received a second TPB letter, similar in structure to the earlier one. Those in the experimental group were found to be significantly more likely to accept the invitation to attend the CRP and to actually attend it than the control group, a finding which was seen to be unrelated to extraneous factors, e.g. distance lived from programme. Although acknowledged as being a small-scale study, it was concluded that the TPB was useful in that it enhanced both motivation (acceptance) and implementation of action (attendance).

Armitage & Conner (2002) conducted an intervention designed to reduce fat intake which took the form of three four-page leaflets, two based on the TPB and one providing information only. In total, 517 individuals were randomised to receive either information only (i.e. types of fat, government recommendations, current UK fat consumption) or theory-based leaflets derived from this general information. Specifically, the attitude leaflet aimed to strengthen those positive

beliefs which had been found to be discriminatory in previous research, e.g. low fat diets helping with fitness, weight control, & general health, and refute those which were negative, e.g. low fat food being less tasty and requiring too much processing. The self-efficacy (PBC) control condition incorporated the general information along with simple advice on eating a low fat diet, e.g. providing recipes that were cheap and quick to prepare using easily acquired ingredients. There was some evidence that the theory-based interventions improved people's attitudes towards eating low fat diets, and had an effect on reducing total and saturated fat intake. However, the information only condition also reduced saturated fat intake.

So, consistent with the findings of Brubaker and Fowler (1990), the theory-based interventions were generally no more effective in altering behaviour than the information only conditions. Armitage & Connor (2002) argued that this might have been due to minimal quantity of information in the leaflets reducing differences between the conditions. They further stated that providing any sort of information about a behaviour is likely to increase its salience, but acknowledged that the absence of a subjective norm component might have been a reason for a lack of theory-based effect. They also suggested that the influence of intention and PBC might have been too small to produce a behavioural change, or that by targeting the most distal predictors (i.e. beliefs), any effect was too diluted when it reached the end of the causal chain (i.e. behaviour). Furthermore, the authors acknowledged that there was no way of being able to ascertain the attention participants paid to the written information provided, and that although more cost effective, written material has achieved less success in changing attitudes than video or audio messages. Finally, Armitage & Conner (2002) suggested that the modal salient beliefs upon which this study was based might not have adequately captured those held by the participants, and as such advocated targeting individuals' most important beliefs.

Chatzisarantis & Hagger (2005) devised two written persuasive communications to promote physical activity, one of which was based on previously defined modal salient behavioural beliefs about the behaviour, and the other on modally nonsalient behavioural beliefs about the behaviour. Support for the TPB was found in so far that those students who were allocated to the salient belief condition reported more positive attitudes and stronger intentions towards the behaviour than those in the nonsalient belief condition. However, neither

condition was found to enhance actual physical activity and a number of possible explanations were offered for this.

As also suggested by Armitage and Conner (2002), the authors argued that the diminishing effect through the causal chain of the model could have been responsible, or the modal belief sets used might have been inadequate. Alternatively, even though behavioural beliefs were specifically targeted because attitude had been the dominant predictor in previous research in this area, the fact that normative and control beliefs were not included could have contributed to the lack of effect. Also, the authors stated that the TPB is not a volitional theory and as such is not able to facilitate the acting out of behavioural intentions, or perhaps any effects of the intervention on behaviour had been washed out by the time behaviour was assessed 5 weeks later. In conclusion, it was acknowledged that the study was limited by only assessing direct measures of the TPB.

Collectively, these studies would seem to suggest that the TPB has some role to play in belief modification and enhancement of intention, although the evidence for subsequent behaviour change is weaker.

The one study (reported in two papers) found where the TPB has been utilised to improve communication skills in health settings was a small feasibility study in which 30 medicine counter assistants (MCAs) were randomised to either a theory-based communication skills training package comprising 2 x 4 hour sessions or a control group (Cleland et al., 2007; Watson et al., 2007). The components of the intervention were mapped on to the TPB constructs theorised to mediate behaviour change. For example, demonstration of the consequences of the behaviour was designed to influence attitude, reflection on change in attitudes and behaviour was designed to influence subjective norm, provision of a 'handy hints' sheet to assist practice was designed to enhance PBC, and discussion about the rationale for training was designed to influence intention. Participants' subsequent communication skills with regard to product requests and advice-seeking as informed by the Calgary-Cambridge model of communication skills (for more details, see Section 5.1) were assessed via covert visits by trained simulated patients. Also, participants' cognitions about finding out about patient symptoms and use of other medications were assessed at baseline and after each training session via their completion of a TPB questionnaire. Compared to baseline,

Table 3.2 Intervention studies using persuasive techniques based on the Theory of Planned Behaviour

Study	Design	Participants	Intervention	Main outcomes
Brubaker & Fowler (1990)	Randomised controlled trial	114 male students	1) theory-based message group 2) informational message group 3) no message group	Those who received messages reported more testicular self-examination, greater intentions and more positive attitudes. No differences between the theory-based and informational message groups
Wyer et al. (2001)	Randomised controlled trial	87 myocardial infarction patients	1) TPB-based letters group 2) nominal letters group	Acceptance and attendance rates at the cardiac rehabilitation programme were significantly higher for the group who received the TPB letters
Armitage & Conner (2002)	Randomised controlled trial	421 females, 96 males	1) attitude leaflet group 2) self-efficacy leaflet group 3) information only leaflet group	The theory-based interventions improved attitude to low fat diets and reduced total and saturated fat intake. Information only condition also reduced saturated fat intake
Chatzisarantis & Hagger (2005)	One-way factorial	41 male students 42 female students	1) persuasive message targeting salient behavioural beliefs 2) persuasive message targeting nonsalient behavioural beliefs	Those in the salient belief condition reported more positive attitudes and stronger intentions, but neither communication influenced physical activity participation
Cleland et al. (2007) / Watson et al. (2007)	Randomised controlled trial	30 medicine counter assistants	1) TPB-based communication skills package group 2) control group	Some improvement in communication in intervention group in terms of number of questions asked, but no improvement with use of open questions

the number of questions asked by the intervention group increased at the first and second follow-ups, but did not in the control group. However, no statistically significant differences were found between the groups in terms of the use of open questions, and questioning in accordance with professional and good practice guidelines. Scores on the TPB questionnaires showed that, irrespective of condition, MCAs continued to have negative attitudes and low confidence towards seeking information from patients, did not feel a social pressure to do so, and had low intentions to carry out the behaviour. Overall, these findings suggested that the TPB-based intervention only had limited impact in terms of the extent of questioning. However, the results should be treated with some caution given the small sample size, the lack of information about the control condition and the fact that blinded coding was not performed in all cases.

3.5.3 CURRENT USE OF THEORY IN HEALTH SETTINGS

Even though health psychology interventions have played an increasing role in the delivery of health care services over the last 30 years, and those derived from theory have had the greatest clinical impact (Nicassio et al., 2004), their use remains limited. Although 57% of respondents in a survey of Australian health promotion practitioners reported being familiar with the TPB, it was seldom used in the planning and action phases of heath promotion programmes (Jones & Donovan, 2004). Furthermore, the authors noted that the greater likelihood of receiving responses from practitioners who were more familiar with health promotion theories suggested that the figures were probably overestimates. They suggested that behaviour change models require further testing in health-care settings and urged for more theoretically derived trials in this area. Watson et al. (2007) stated that the use of theory in intervention work enables changes in cognitions and the relationships between them to be assessed, and Foy et al. (2001) argued that interpretation can be problematic when the lack of an established theoretical framework makes it difficult to isolate the influential factors in an intervention. In a review of 235 implementation studies cited by The Improved Clinical Effectiveness through Behavioural Research Group, only 14 were explicitly theory-based, even though, by providing specific causal mechanisms, such approaches allow for more focussed measurement and evaluation of interventions (ICEBeRG, 2006). This group recommended the use of rigorously evaluated, parsimonious, general theories with validated and clearly measurable constructs, citing the TPB as an example. They stated that using such theories can make interventions more replicable and generalisable. Eccles et al. (2005) too acknowledged that empirical testing of any theory is currently very

limited amongst health professionals, and that exploratory studies are needed to establish the theoretical basis of interventions. They also particularly recommended the TPB for this purpose because it is an effective predictor of behaviour across different settings, its constructs are potentially modifiable, and it includes a nonvolitional component.

3.6 RATIONALE FOR THESIS STUDIES

Despite the substantial risks associated with smoking in pregnancy, many women do not quit during this period even though the majority would like to be able to. Although pregnant women have reported considerable interest in accessing the type of behavioural support available through NHS Stop Smoking Services, these services are poorly attended by pregnant women, in spite of being effective for reducing cessation rates. Very little research has systematically investigated pregnant women's views about these services as a means of establishing possible reasons for this. NRT is now an option which can be considered by a pregnant woman following consultation with a health professional. However, although certain studies have shown that a proportion of pregnant women are interested in using NRT, their opinions about it have not been explored in much detail. Being able to identify the beliefs, attitudes and knowledge pregnant women have with respect to NHS Stop Smoking Services and NRT should help to increase understanding of the determinants of these behaviours. This information has the potential to inform strategies to increase engagement with NHS Stop Smoking Services and facilitate discussions about NRT which would help a pregnant woman to reach an informed choice about whether or not to use it. The TPB provides an appropriate framework within which to identify those beliefs which both facilitate and hinder engagement with NHS Stop Smoking Services and NRT. Therefore, Study One will be a qualitative TPB-based elicitation study using in-depth interviews designed to identify the salient beliefs of pregnant women which determine their engagement with NHS Stop Smoking Services and NRT. The Stop Smoking Services and NRT data generated in this study will then be used to inform the subsequent thesis studies outlined below.

Research suggests that pregnant women value smoking cessation advice from health professionals as part of routine care but this varies in quality and is not provided on a consistent basis. Part of the reason for this lack of provision appears to be because health professionals lack the necessary knowledge and confidence to deliver such advice, and require guidance and training to do so.

Therefore, Study Two will be an exploratory RCT involving the development and testing of a training resource aimed to ultimately facilitate health professionals' communication of smoking cessation advice to pregnant women. Given the call for more theory-based intervention studies in health care settings, the resource will be designed as a TPB intervention. An important facet of a health professional's communication is to conduct a patient centred consultation where the beliefs of the client are elicited and addressed. Therefore, the resource will incorporate the Stop Smoking Services beliefs generated in Study One and the primary outcome measure will be whether the resource helps the trainee health professional to elicit the salient beliefs of the interviewee with respect to smoking cessation support.

To further test the appropriateness of the TPB in terms of investigating smoking cessation support in pregnancy, Study Three will be a quantitative study where the beliefs about NRT generated in Study One will be converted into a set of questionnaire items. These will inform the development of a TPB questionnaire which will be tested to ascertain whether it predicts NRT use in pregnancy. Assuming this questionnaire has predictive validity, the items which have the strongest influence on intention to use NRT in pregnancy will be identified and used in a short form version of it.

Study Four will be a further quantitative investigation to test the predictive validity of the short form version of the questionnaire, and to identify those beliefs from this questionnaire which have the strongest influence on intention to use NRT in pregnancy. It is considered that this questionnaire has the potential to have more practical utility than the fully specified version.

It is envisaged that this selection of studies could ultimately prove useful to health professionals who wish to address the smoking habits of this client group. It was not considered feasible to conduct a quantitative investigation of Stop Smoking service use in pregnancy given that a large proportion of respondents to the TPB questionnaires in this thesis would be drawn from pregnant women already engaged with these services. To the author's knowledge, no studies to date have used the TPB as a framework for specifically investigating pregnant women's beliefs about engagement with NHS Stop Smoking Services and NRT use, or in an intervention designed to facilitate the communication of smoking cessation information in pregnancy.

3.7 AIMS OF THESIS

1. To elicit the salient beliefs held by pregnant women with respect to engagement with NHS Stop Smoking Services and NRT (Study One)

2. To develop and evaluate a TPB training resource designed to ultimately facilitate health professionals' communication of smoking cessation information to pregnant smokers (Study Two)

3. To develop and test a TPB questionnaire designed to predict NRT use in pregnancy and to identify the most influential beliefs for use in a short form version of this questionnaire (Study Three)

4. To assess the ability of the short form TPB questionnaire to predict intention to use in pregnancy, interest in participation in a clinical trial testing NRT, and to identify the most influential beliefs (Study Four)

CHAPTER FOUR: A QUALITATIVE STUDY TO ELICIT PREGNANT SMOKERS' BELIEFS ABOUT NHS STOP SMOKING SERVICES AND NICOTINE REPLACEMENT THERAPY

4.1 STUDY ONE INTRODUCTION

As outlined in Chapter Two, NHS Stop Smoking Services provide effective support for quitting smoking (see Section 2.1.3.1) but are poorly attended by pregnant women (Coleman, 2008). Although eliciting the beliefs of pregnant women in relation to these services might help to explain the low uptake, only two studies by Ussher et al. (2004) and Ussher et al. (2006) have attempted to investigate pregnant women's views about attending a Stop Smoking course (see Section 2.2.2). Given that NRT has recently been sanctioned for use in pregnancy (see Section 2.1.3.2), it is becoming more widely prescribed to pregnant women in the UK. However, very little is known about the beliefs pregnant women have about using NRT in pregnancy beyond their level of interest in using it (see Section 2.2.3). As discussed in Chapter Three, the Theory of Planned Behaviour (TPB; Ajzen, 1988, 1991) has been shown to significantly predict a wide range of health behaviours (see Section 3.1.3) and has demonstrated specific utility in explaining smoking and quitting behaviours in pregnancy (see Section 3.2.2), interest in smoking cessation programmes (Babrow et al., 1990) and intention to use NRT (Thomson et al., 2006). Therefore, in an attempt to address these gaps in the research, this study employed a TPB framework to illuminate the perceptions of pregnant women concerning NHS Stop Smoking Services and NRT. Gaining further understanding about their beliefs about Stop Smoking Services could help to highlight the perceived benefits of and barriers to engagement with such services and inform strategies to improve uptake. As health professionals working in routine care have reported lacking the knowledge and skills needed to deliver smoking cessation advice to their pregnant patients (e.g. Clasper & White, 1995; see Section 2.3), the Stop Smoking Services data from this study informed the development of a resource that might be used to increase their confidence in undertaking this role (see Chapter Five). The TPB stresses the importance of eliciting salient beliefs from the population under study to inform quantitative investigation of the behaviour to be investigated (see Section 3.4.1). Therefore, the beliefs pregnant women have about NRT which were generated in this study were used to inform the development of a questionnaire to predict NRT use in

pregnancy (see Chapters Six & Seven). Such a questionnaire could help health professionals tailor their advice about NRT use in pregnancy more appropriately.

4.2 STUDY ONE AIMS

1) To elicit the salient beliefs pregnant smokers have about NHS Stop Smoking Services by interviewing pregnant smokers, recent quitters, new mothers, and health professionals who work with pregnant smokers. These findings will help inform the development of a resource to facilitate the communication of smoking cessation information (see Chapter Five).
2) To elicit the salient beliefs pregnant smokers have about Nicotine Replacement Therapy (NRT) by interviewing the same people as above. These findings will inform the development of a TPB questionnaire to predict NRT use in pregnancy (see Chapters Six and Seven).
3) To contrast the health professional and patient views and to consider the implications of differing perceptions for engagement with Stop Smoking Services and NRT use.

4.3 STUDY ONE METHOD

4.3.1 STUDY DESIGN

A cross-sectional qualitative study, using semi-structured interviews informed by a TPB framework.

4.3.2 SAMPLING STRATEGY

In order that the beliefs explored were salient to interviewees, participants were eligible for inclusion in the study if they were women with experience of smoking in pregnancy or health professionals with experience of providing smoking cessation services to pregnant women. The former were recruited purposively, using a maximum variation sampling strategy, which involved purposefully picking a wide range of women across the social spectrum to get variation on the dimensions of interest (Patton, 2002). This enabled both the identification of unique or diverse variations in relation to different conditions and important common patterns cutting across variations. Three groups of women with experience of smoking in pregnancy were targeted, namely, pregnant women identified from the antenatal clinic who were currently smoking, pregnant women identified from the antenatal clinic who had given up smoking during their current pregnancy (recent quitters) and women identified from the community who had

smoked during their recent pregnancy. The community sample was recruited through two inner city Sure Start programmes sited in areas of high deprivation in order to widen the range of views obtained. Health professionals from a range of different NHS Stop Smoking service settings across the UK who had specific experience of providing cessation support to pregnant women were also targeted and asked what they perceived the beliefs of their clients to be with respect to Stop Smoking Services and NRT.

4.3.3 INSTRUMENTS

Three interview schedules were devised for use with the pregnant women (clinic sample), new mothers (community sample) and health professionals respectively. The clinic schedule commenced with questions about smoking history which differed depending on whether the interviewee was a current smoker or a recent quitter. The community schedule commenced with questions about smoking which determined whether or not the interviewee smoked throughout the whole or just part of her pregnancy. The health professionals' schedule commenced with questions about the type of service offered to pregnant smokers by the interviewee. All schedules incorporated a series of open-ended questions designed to tap into the TPB constructs as recommended by Francis et al. (2004), Ajzen (2002b) and Conner & Sparks (2005). Specifically, these questions aimed to elicit the modal salient behavioural beliefs, normative beliefs and control beliefs of each group with respect to Stop Smoking Services and NRT. As such, this satisfied the recommendation of Ajzen (1991) to conduct an elicitation study with representatives of the target population in question using open-ended questions to identify salient consequences, referents and circumstances with respect to the target behaviour.

Firstly, the pregnant women and new mothers were asked what they believed to be the advantages and disadvantages of engaging with Stop Smoking Services in pregnancy (behavioural beliefs), any individuals or groups they believed would approve or disapprove of them engaging with Stop Smoking Services in pregnancy (normative beliefs), and what factors or circumstances they believed would facilitate or inhibit engagement with Stop Smoking Services in pregnancy (control beliefs). Secondly, the women were asked the same set of questions but this time with respect to them using NRT in pregnancy (see Appendices 1 & 2 for interview schedules). Using similar questions, health professionals were asked about their perceptions of pregnant smokers' beliefs about NHS Stop Smoking Services and NRT (see Appendix 3 for interview schedule). Participants were

encouraged to provide multiple answers to each question, in line with Conn (1998) who reported that the suggested methodology for TPB research is to elicit beliefs until the person cannot elaborate on the question further. The questions were designed to observe the 'principle of compatibility' which, as stated in Section 3.1, requires that all the TPB constructs are defined in terms of exactly the same target, action, context and time elements (Ajzen, 2002b). In this case, the targets were NHS Stop Smoking Services or NRT, the actions were either engagement with NHS Stop Smoking Services or NRT use, the context was pregnancy and the time was at any point during that pregnancy. The questions were asked in the same sequence for each participant as TPB elicitation studies have not generally shown order effects (Darker et al., 2007). A series of prompts, some based on previous research (e.g. Etter & Perneger, 2001) were devised for use with the interview schedules to encourage more reticent participants (see Appendix 4). Pregnant women and new mothers were also asked for some demographic information including age, ethnicity, marital status, qualifications, employment, number of weeks pregnant or age of new baby, parity, smoking behaviour and previous use of NHS Stop Smoking Services and NRT. It was not considered necessary to collect detailed demographic information from the health professionals given that they were not giving their own views, but relaying those of their clients.

Semi-structured interviews were chosen because they facilitate rapport and empathy, promote a conversational approach, allow flexibility and thus provide rich data (Smith, 2008). They were chosen over focus groups because it was felt that pregnant smokers would be more forthcoming in this setting and to ensure that individual views obtained were not influenced by others. The majority of the interviews were conducted over the telephone primarily due to their cost effectiveness and time efficiency (Harris et al., 2008). These were particularly important considerations given that the health professionals were drawn from across the UK. This effective method of data collection has also been said to reduce the risk of response bias, and because of its relative anonymity, enables participants to be more forthcoming with their responses (Musselwhite et al., 2007). It is also strengthens confidentiality and is well suited to eliciting information from professionals who have considerable demands on their time (Harris et al., 2008).

4.3.4 PROCEDURE

4.3.4.1 Clinic sample recruitment

Access to Nottingham City Hospital antenatal clinic was granted by the responsible consultants. A covering letter (see Appendix 5) and a Participant Information Sheet (PIS) (see Appendix 6) were sent out to pregnant women by clinic administrative staff at the time of first booking them for antenatal care. The PIS outlined the purpose of the study and informed the recipients that, at their first antenatal clinic visit, they may be invited to participate in the study. Recruitment took place between July 2006 and January 2007 with the researcher (JT) accessing up to 3 clinics per week during this period. Pregnant women attending their first appointment were asked by clinic staff to complete a brief questionnaire to ascertain their smoking status, and if a current smoker or recent quitter, whether they would be willing to consider participating in the study (see Appendix 7). If they were willing, their name was passed to the researcher who approached them and gave them time to reread the PIS. Those who agreed to participate then signed a consent form (see Appendix 8) and completed a contact details form (see Appendix 9). The researcher contacted participants at a later date for a telephone interview.

4.3.4.2 Community sample recruitment

Permission to access Sure Start programmes in Hyson Green and New Basford, Nottingham was granted by the Health & Social Care Coordinator of these areas. Two weekly programmes, 'Watch me Grow' and 'Messy Play', at New Basford Community Centre and Hyson Green Library respectively were advised to be the most appropriate for accessing pregnant women and new mothers. Invitation letters (see Appendix 10) and a PIS (see Appendix 11) were given out and posters advertising the study (see Appendix 12) were displayed in these settings prior to recruitment which occurred between November 2006 and February 2007. The Sure Start staff running the programmes established which new mothers had smoked through all or part of their recent pregnancy and introduced the researcher to them. Potential participants were given time to read the PIS and those willing to be interviewed were asked to sign a consent form (see Appendix 13). Participants were given the option to be interviewed at the time of recruitment in a side room at the Sure Start centre or at a later date by telephone.

4.3.4.3 Health professional sample recruitment

The Directors of the 2006 UK National Smoking Cessation Conference granted permission for the researcher to briefly present his work and afterwards request input from any Smoking Cessation in Pregnancy specialists in the audience. All health professionals at the session were provided with a brief presentation and information sheet about the study (see Appendix 14) along with a contact details form (see Appendix 15). After presenting his work, the researcher asked those interested in being interviewed to complete the contact details form and hand it in at the end of the session. Those willing to be involved in the study were sent a confirmatory letter (see Appendix 16) and a PIS (see Appendix 17) and asked to return a signed consent form (see Appendix 13). Upon receipt of the consent form, participants were contacted to arrange a telephone interview.

4.3.4.4 Data collection

Telephone interviews with the clinic sample and the health professionals were conducted between August 2006 and February 2007. Interviews with the community sample were conducted between November 2006 and February 2007, one by telephone and the rest face-to-face at the Sure Start venues. Interviews varied in length, but generally lasted approximately 30 minutes. All participants were interviewed by the same researcher (JT), and each interview was audio-taped and transcribed verbatim, either by the researcher or a secretary.

4.3.4.5 Ethical considerations

This study received ethics approval from relevant ethics committees. NHS research ethics approval (COREC) was obtained by the researcher (JT) from Nottingham Research Ethics Committee 2 on 9 June 2006 (see Appendix 18) and from the Nottingham City Hospital NHS Trust Research and Development Department on 21 June 2006 (see Appendix 19) to recruit pregnant women from the antenatal clinics at City Hospital, Nottingham. Approval was obtained from the University of Nottingham Medical School Ethics Committee on 19 June 2006 to recruit pregnant women and new mothers from the community and health professionals from the 2006 UK National Smoking Cessation Conference (see Appendix 20).

4.3.5 DATA ANALYSIS

The material relating to NHS Stop Smoking Services and NRT were analysed separately, with coding being based, in part, on the recommendations of Francis et al. (2004). The type of thematic analysis used was in line with that proposed

by Joffe and Yardley (2004) where an existing theory is used to dictate the questions asked and facilitate the understanding of the answers. This method is also favoured by Bauer (2000) who argues against a purely inductive approach, stating that codes should be derived from existing theory. Each transcript was first coded deductively into high level categories predefined by the TPB, i.e. behavioural beliefs, normative beliefs and control beliefs. On the basis of the raw data, the codes under each of these three categories were then inductively organised into themes to form sub-categories of the TPB constructs. Given that the NRT themes were to form items for a subsequent questionnaire, they were not collapsed into a smaller number of broader themes as the Stop Smoking Services data were. Each interview was read and reread to identify sections of text (coding units) that were potentially of interest. Each code was scrutinised to ensure that it adequately reflected the TPB construct of interest and that only one construct was contained in each piece of text. Each coding unit was coded exclusively into just one category rather than into multiple categories. As specified by Joffe and Yardley (2004), this allows very clearly defined coding categories to be developed which enhances the development of the theoretical basis for the coding decisions. Themes were identified at a semantic level, i.e. from explicit or surface meanings of the data (Braun and Clarke, 2006) and a latent level, i.e. from underlying, implicit references to semantic content (Joffe and Yardley, 2004). Each theme was quantified in terms of total instances and the number of interviews in which it occurred. If a specific belief was mentioned more than once within an individual interview, it was coded only once. Separate frequencies were calculated for the pregnant women/new mother interviews and the health professional interviews to allow comparisons to be made between these groups. Whilst thematic analysis tends not to be quantified, Braun and Clarke (2006) and Boyatzis (1998) state that it can be. In this study, the frequency counts merely acted as a guide to the important issues arising from the data. It was not assumed that the number of instances of a theme necessarily equated to its relative importance. Given that the health professional interviews tended to be longer than those of the women themselves, caution was taken when comparing the frequencies of these two groups.

4.3.6 INTER-RATER RELIABILITY

After the themes had been identified, each theme was labelled using the five elements outlined by Boyatzis (1998) as being a requirement for a 'good' code, namely, a label, a definition of what the theme concerns, a description of how to know when the theme occurs, a description of any qualifications or exclusions to

the identification of the theme, and examples, both positive and negative, to eliminate possible confusion when looking for a theme. On the basis of this information, two codebooks were prepared to enable inter-rater reliability assessment of the derived themes for the NHS Stop Smoking Services data (see Appendix 21) and the NRT data (see Appendix 22) respectively. An independent researcher (CB) used the codebooks to assign themes to a sample of quotes taken from the transcripts. For the NHS Stop Smoking Services data, the sample included a maximum of 5% of examples of each theme and a minimum of 3 examples, resulting in sample of 41 quotes (see Appendix 21). For the NRT data, the sample included a maximum of 5% of examples of each theme and a minimum of 3 examples, except for the least frequent themes, 'becoming addicted' and 'forgetting', which were represented by 2 and 1 examples respectively. This resulted in a sample of 65 quotes (see Appendix 22). The number of matches of themes, i.e. themes identified by both raters as a proportion of the number of examples of themes was calculated to give an overall percentage agreement score for the NHS Stop Smoking Services data and the NRT data.

4.4 STUDY ONE RESULTS AND DISCUSSION

4.4.1 RESPONDENT CHARACTERISTICS

4.4.1.1 Clinic sample

Twenty-five participants initially consented to interview but one later withdrew. Of the remainder, 14 were interviewed and 10 could not be contacted within the study period. Participants were between 9 and 28 weeks pregnant at the time of interview and were all White British, ranging in age between 17 to 36 years. Ten were current smokers and four had given up during their pregnancy. The average reported number of cigarettes smoked whilst pregnant was 8 per day. Most reported having reduced their daily consumption of cigarettes since becoming pregnant. Eight of the women were cohabiting with a partner, 1 was married, and 5 were single. Five of the 14 women were in employment, and of the 9 who had educational qualifications, 7 were educated to NVQ/GSCE level, 1 to Diploma/HND level and 1 to Degree level. For 6 out of the 14 women, this was to be their first child. At the time of interview, only 3 of these 14 women reported having used NHS Stop Smoking Services before, but 7 reported having used NRT in the past. Due to the time taken to recruit and interview this sample of pregnant women, it was not feasible to continue this process beyond the six month period.

4.4.1.2 Community sample

Data were collected from 4 out of the 5 new mothers who consented to be interviewed. One woman could not be contacted. Participants had given birth to their child between 6 and 20 months prior to the interview and were all White British, ranging in age between 21 and 32 years. Three women had smoked throughout their pregnancy, two of whom reported reduced smoking whilst pregnant. One had quit smoking upon finding out that she was pregnant. The average reported number of cigarettes smoked whilst pregnant was 9 per day. Three of the women were cohabiting with a partner and 1 was married. Two of the 4 women were in employment, and 2 were educated to NVQ/GSCE level, 1 to BTRC/A level and 1 to Degree level. For 3 of the 4 women, this had been their first child. At the time of interview, only 1 of these 4 women reported having used NHS Stop Smoking Services before, but 2 reported having used NRT in the past. Due to the time taken to recruit and interview this sample of pregnant women, it was not feasible to continue this process beyond the three month period.

4.4.1.3 Health professional sample

A convenience sample of 24 NHS health professionals was recruited via the 2006 UK National Smoking Cessation conference. Three were Smoking Cessation Service Managers who subsequently arranged for a colleague working directly with clients to be contacted instead. Data were eventually collected from 18 smoking cessation advisors (17 female, 1 male) in UK NHS Stop Smoking Services with experience of delivering smoking cessation support to pregnant women. A substantial number had a nursing or midwifery background. After these 18 interviews it became clear that saturation had been achieved as no new issues were emerging from the data, and thus no more interviews were required. At this point a letter explaining this and thanking them for their interest in the study was sent to those who had consented but had yet to be interviewed (n=3) and to those who had agreed to be interviewed but had not provided written consent (n=3).

In total, 36 interviews were subjected to thematic analysis.

4.4.2 NHS STOP SMOKING SERVICES THEMES

The 11 major themes identified from the Stop Smoking Services information were: (1) Practical support (2) Emotional support (3) Service effectiveness (4) Improving health (5) Acquiring information (6) Social pressure (7) Access to services (8) Motivation (9) Stigma (10) Knowledge about services (11) Fear of

failure. Using the NHS Stop Smoking Services themes codebook, 37 of the 41 quotes provided were assigned to the correct theme by the second coder. This gave an overall agreement of 90.24% between the researcher (JT) and the second coder (CB). The number of instances of these 11 themes and the number of interviews in which they occurred are listed in Table 4.1.

4.4.2.1 Behavioural beliefs

The following themes relate to pregnant women's beliefs about the outcomes of attending Stop Smoking Services (i.e. behavioural beliefs).

4.4.2.1.1 Practical support – beliefs about the practical support provided by Stop Smoking Services

Across 30 of the 36 interviews, there were 65 instances of positive practical support and only 3 instances where the issue of practical support was viewed negatively, so this was largely a positive attitudinal belief. Having the facility to contact their Stop Smoking advisor between scheduled appointments was reported to be appreciated by pregnant women who required immediate support to help them manage times of craving.

> *They're good ... they give you their telephone number and that if you're struggling in the week and stuff (Pregnant woman 13; smoker)*

An important issue for many pregnant women was the fact that they could get ready access to free Nicotine Replacement Therapy through the Stop Smoking Services.

> *I suppose that's a good part of it [Stop Smoking Services], because you get help with the nicotine patches (Pregnant woman 12; recent quitter)*

Pregnant smokers particularly valued those advisors licensed to prescribe NRT themselves and who they could obtain it from straight away without the inconvenience of having to collect a prescription.

> *I think it's an easier way than going to the doctors ... because you get your things [NRT] there and then (Pregnant woman 13; smoker)*

However, some health professionals believed that obtaining free NRT from Stop Smoking Services was the pregnant woman's prime motivation for attending Stop Smoking Services, and that they were often not motivated to see the advisor.

> *All they want is the patch off you, half of them don't really want to see you, they just want the free patch (Health professional 18)*

Some women reported being motivated by other practical strategies employed by the Stop Smoking advisor to aid the quit attempt. For instance, many women gained satisfaction from being able to see their monitored carbon monoxide level dropping at sequential appointments and this tangible sense of progress kept them motivated.

> *They will often say 'I know you're coming therefore I'd better not smoke because of my carbon monoxide reading' (Health professional 13)*

However, the practical strategies designed to support the pregnant woman in her quit attempt were not always reported as being helpful. For instance, some health professionals stated that certain women are scared by the information they receive about the potential risks to their baby and would prefer more focus on the positive aspects of quitting rather than the negative aspects of smoking. Furthermore, some pregnant women felt that their service did not offer enough practical support, particularly with regard to the offer of alternatives if the strategies that were in place were not proving useful. It was reported by health professionals that texting clients is a particularly good compromise method of communication, in that the pregnant woman can be reminded about appointments and given encouragement without feeling that she has to reply to the advisor. As with the advice described in Section 2.2.1, it would appear that the nature of the intensive support desired by pregnant women can vary and it is important that the advisor attempts to tailor this appropriately to each individual.

4.4.2.1.2 Emotional support – beliefs about the emotional support provided by Stop Smoking Services

Across 29 of the 36 interviews there were 53 positive instances of pregnant women's beliefs about emotional support and only 9 instances relating to a lack of emotional support, so this was predominantly a positive attitudinal belief. However, positive emotional support was mainly raised by the health professionals with only 16 of the 53 instances relating to this being generated by

either the pregnant women or new mothers. This suggests that the health professionals might place more emphasis on this aspect of their role than their clients do. Many pregnant smokers reported worrying about the potential effects of their habit on their baby, e.g. low birth weight. Concerns that they might be harming the child coupled with an inability to stop smoking were said to bring about feelings of extreme guilt, and it was felt by pregnant women that input from a Stop Smoking service could help to ease these uncomfortable feelings.

> *Probably it [engaging with Stop Smoking Services] would make you not so ashamed and let you know that there is other people that do it and you're not on your own (Pregnant woman 7; smoker)*

The face to face contact with a skilled professional who can provide empathy was mentioned by health professionals to be an important factor in motivating engagement with services.

> *They like the fact that, in their words, somebody understands what they're going through (Health professional 12)*

Whilst some women find the service useful for helping them face up to their addiction, others reported being put off attending because they believed it would force them into admitting it.

> *You sort of deny it sometimes as well ... you sort of feel like you're not smoking as much, that I'm not really a smoker now, and it [attending a Stop Smoking service] would probably be making it real wouldn't it? (Pregnant women 7; smoker)*

Women reported being relieved when they realised that the service was friendly and non-judgemental, perhaps because their smoking was not handled as sensitively during routine care.

> *I was a bit nervous at first when I went, to tell that I'd started smoking again but obviously she understood ... she didn't turn around and say 'you've done terrible' or anything like that (Pregnant woman 4; smoker)*

Health professionals reported that women are also heartened when they find out that Stop Smoking Services will not pressurise them to quit.

> *We say to them 'what I'm not going to do is tell you to give up smoking' ... you see by their body movement that they actually start to relax (Health professional 6)*

As described in Section 1.2.2, a substantial proportion of the women who smoke during pregnancy are of lower socio-economic status (Owen & Penn, 1999). Many of this client group were reported by health professionals to lead difficult lives with significant social problems. Due to their social circumstances, these women were reported to often have feelings of low self worth. The time given to them and interest shown in them by the advisor was said to improve their self-esteem and confidence and make them more determined to quit. Health professionals reported that particularly if women were isolated with little support from family and friends, they particularly valued the regular contact and praise from the advisor to keep them motivated in their quit attempt, a benefit also cited by Ussher et al. (2006).

> *Other comments we've had are people just saying that the encouragement as well and the 'well done, keep it going' [are positive outcomes of attending a Stop Smoking service] (Health professional 10)*

Being able to build up trust and a rapport with an advisor was considered by the health professionals to be important for a successful therapeutic relationship. Some of the Stop Smoking advisors who had midwifery backgrounds reported that pregnant women often ask for advice about more general pregnancy issues that they didn't manage to ask at their antenatal clinic appointments and are reassured by this. Given their often difficult circumstances, pregnant smokers were also reported to sometimes like to discuss more general 'life problems' with their advisor, although some of the health professionals interviewed were wary about being drawn into issues outside their remit.

It should be noted that beliefs about the practical and emotional support provided by Stop Smoking Services tended to be mentioned by those women who had previously engaged with such services but who in some cases had initially been anxious about what to expect. This highlights the importance of finding ways to convey these positive aspects to women considering engagement so that they will acquire information that will encourage attendance and have any negative preconceptions about services dispelled.

4.4.2.1.3 Service effectiveness – beliefs about whether or not Stop Smoking Services would aid a quit attempt

Service effectiveness was mentioned in 28 of the 36 interviews, with 47 instances relating to the belief that Stop Smoking Services would be helpful for quitting smoking and only 5 relating to the belief that they would not. This therefore represents a largely positive attitudinal belief. Those who felt that such services would be effective often reported being influenced by people they knew who had successfully quit smoking with the assistance of these services.

> *I do know a lot of people who have actually used [Stop Smoking Services] who have actually stopped. My friends and things. So it obviously does work (Pregnant woman 1; recent quitter)*

Whilst the majority view is in line with objective evidence for service effectiveness (see Section 2.1.3.1), the difficulties in recruiting pregnant smokers to these services suggests that merely believing that the service will help is not sufficient to bring about engagement. Many women felt that these services would be a useful resource if they were unable to quit on their own. Health professionals reported that pregnant smokers were more motivated to quit when these services offered concurrent help to their smoking partners, family or friends. Even in cases where partners are reluctant to quit, health professionals stated that pregnant women appreciate the input of the Stop Smoking advisor in encouraging their partners to consider quitting alongside them.

> *It makes a big difference if their partners are doing it with them (Health professional 8)*

As quitting smoking has been reported to be more difficult for pregnant women who live with others who smoke (Tod, 2003) and people in their social network tend to also be smokers (Solomon & Quinn, 2004), promoting this aspect of a service could potentially make it a more attractive proposition for the pregnant smoker. Beliefs about the effectiveness of such services can also be influenced by the amount of personal responsibility the pregnant woman considers that she needs to take for her quit attempt. Health professionals reported that pregnant women are sometimes unrealistic in their expectations of the service, believing that the advisor will stop them smoking with minimal input from themselves. However, some women believed that for a quit attempt to be successful they would be required to make a considerable effort.

> *As much as they [Stop Smoking Services] can help you, you know it's going to be on your shoulders, that you're the one who's going to quit smoking (Pregnant woman 14; smoker)*

Not all pregnant women believed that attending a stop smoking service would be effective in helping them stop smoking. Although the majority of participants identified positive outcomes associated with attendance, some possible negative consequences of attendance were raised. For instance, it was considered that being around a group of people who were trying to stop smoking might lead to the temptation of succumbing to cigarette in a weak moment. Also, it was highlighted that some pregnant women found that discussing their smoking in a session threatened relapse.

> *Some say it brings the memories back and that if they were feeling OK, sometimes they feel that they're craving terribly after I've gone (Health professional 1)*

4.4.2.1.4 Improving health – beliefs that engaging in Stop Smoking Services would improve the health of mother and baby

Across 14 of the 36 interviews, there were 26 reported instances of beliefs relating to improved health being a motivation for attending Stop Smoking Services, thus representing a positive attitudinal belief. Only 4 of these instances were mentioned across 4 health professional interviews, suggesting that the women themselves might place a greater emphasis on this outcome.

> *Well it's going to improve my health, it's going to improve the baby, it's not going to make the small birth weight or any complications in the labour and stuff (Pregnant woman 8; smoker)*

This is in keeping with findings of Bennett & Clatworthy (1999) where concerns about harming the baby were found to significantly discriminate between pregnant smokers and quitters (see Section 3.2.2) and Hotham et al. (2006) where concern for the foetus was a major incentive not to smoke. Women also mentioned wanting to quit smoking via Stop Smoking Services to create a smoke-free environment for their existing children and to make the house fresh for when the baby arrived. Furthermore, women reported that a desire to breastfeed was a motivation for quitting smoking via Stop Smoking Services. These latter factors

and reported concerns for their own health are encouraging signs for maintaining abstinence post partum. Indeed, women in the study by Lendahls et al. (2002) said that transferring the health focus from their baby to themselves increased their motivation to remain smoke-free after the birth.

4.4.2.1.5 Acquiring information – beliefs that a Stop Smoking advisor would provide useful information about the harms of smoking, the benefits of quitting, and Nicotine Replacement Therapy

There were 19 instances of beliefs about acquiring information across 16 of the 36 interviews, and this positive attitudinal belief related to the risks of smoking, the benefits of quitting, and the use of NRT in pregnancy. However, the fact that this was only mentioned twice across 2 interviews by the women themselves suggests that the health professionals might be overestimating the importance of this to pregnant women. In keeping with the studies outlined in Section 1.3.4, it is apparent that a number of pregnant women are unaware of the extent of the risks of smoking which means that highlighting this could be an important role for Stop Smoking Services. Health professionals reported that, although pregnant women have a general notion that smoking is harmful, when given more precise details they are often shocked by this and dismayed that this information had not be made available to them before. This suggests that more detailed risk information needs to be made available, perhaps as part of the antenatal clinic information distributed to pregnant women. Health professionals stated that pregnant women attending Stop Smoking Services often want more information about the effects of smoking on their baby, e.g. low birth weight, and some pregnant women themselves reported that these services would be an important source of information in this regard.

> *Probably the advantages [of using a Stop Smoking service in pregnancy] would be making you aware of what it can do to the baby and things (Pregnant woman 7; smoker)*

A number of pregnant women were reported to be interested in finding out information about using Nicotine Replacement Therapy in pregnancy from a Stop Smoking advisor, also frequently cited as a benefit of these services in the study by Ussher et al. (2006) reported in Section 2.2.2. This particularly centred around seeking reassurance about the safety and efficacy of NRT use in terms of its effect on their unborn child, which is understandable given that NRT has only recently been sanctioned for use in pregnancy (see Section 2.1.3.2) and there is

still some controversy about whether or not it should be prescribed (e.g. Bull, 2007).

> *Some women do want to know about [NRT] studies and things that have been done (Health professional 10)*

4.4.2.2 Normative beliefs

The following theme relates to pregnant women's beliefs about the opinions other people have about them attending Stop Smoking Services (i.e. normative beliefs).

4.4.2.2.1 Social pressure – beliefs about the perceived social pressure to engage or not engage with Stop Smoking Services

Three main groups were identified which pregnant smokers believed could exert social pressure on them to either attend or not attend Stop Smoking Services in pregnancy. These were their family (including partners), health experts and friends. Most interviewees reported that social pressure would generally be in the direction of wanting them to seek help through Stop Smoking Services which stands to reason given the widespread negative societal attitudes associated with smoking in pregnancy (Bull et al., 2007). Forty-four instances of family (in 26 interviews), 63 of health experts (in 26 interviews) and 7 of friends (in 6 interviews) were reported as approving of engagement with such a service in pregnancy. It was reported that the family of pregnant women generally advocate engagement with Stop Smoking Services because they want them to quit the habit.

> *Family members tend to encourage them to use the service because they want them to stop smoking (Health professional 12)*

However, perceived family pressure to use Stop Smoking Services was often received negatively and was thus not conducive to quitting. For instance, some pregnant women were said to resent persistent nagging to quit from non-smoking family members, while others stated that they would quit when the time was right for them. Some health professionals indicated that pregnant smokers could become defiant in the face of this type of pressure and as a result make a deliberate decision not to engage with Stop Smoking Services. This could be a factor behind the low attendance rates which is unfortunate given that women who had engaged with these services were considered by health professionals to

value the different perspective of the advisor whose approach was to offer positive support beyond merely insisting that they quit. The fact that pregnant women come into contact with a number of different health professionals, for example, midwives, health visitors, GPs & hospital consultants, might account for the high number of reported instances of perceived social pressure from this group.

> *Because they get asked [about their smoking] so regularly [by health professionals], I think they feel 'well they keep asking me, maybe I ought to do something about it' (Health professional 13)*

However, only 16 out of the 63 instances (in 9 of the 26 interviews) relating to health expert pressure were reported by the pregnant women themselves, which could indicate that the health professionals are overestimating the influence of their colleagues to engage pregnant women in smoking cessation. This is feasible given the evidence for inconsistent advice giving (e.g. Owen & Penn, 1999), low levels of referral to Stop Smoking Services (e.g. Abatemarco et al., 2007) and the fact that pregnant smokers have reported feeling more pressure to quit smoking from their partners than from health professionals (Ussher et al., 2006). It was the view of many health professionals that women often feel pressured to attend Stop Smoking Services by health professionals when they lack the true motivation to do so. It was considered that certain health professionals, for example, hospital consultants or midwives, try to persuade pregnant women to attend these services when they are not actually that keen to do so, and this could be another reason why engagement with services is low.

> *Patients didn't always want to come for the right reasons if you like ... they were more pressurised from the midwives (Health professional 9)*

The multiplicative nature of the belief composites as specified by the TPB (see Section 3.1.2) illustrate that perceived social pressure to perform a behaviour will not be a good predictor of that behaviour if the individual is not motivated to comply with the wishes of the referent. Therefore perceived social pressure in the direction of seeking help might not necessarily be acted upon by the pregnant woman. This is highlighted in the study by Hotham et al. (2002) where some pregnant smokers viewed social pressure as an incentive to quit whilst for others it increased their stress levels. As the quality of the health professional-patient relationship can dictate how receptive pregnant women will be to messages

(Lowry et al., 2004), it is important that a health professional develops a good rapport with clients and delivers smoking cessation advice in a tone conducive to patient engagement.

There was evidence to show that not all pressure was felt to be in the direction of urging the pregnant woman to seek help. There were 28 instances relating to pregnant women's beliefs that family (in 10 interviews) and friends (in 10 interviews) would discourage their engagement with a Stop Smoking service. Smokers in the family were reported by health professionals to sometimes actively discourage women from seeking help because they liked the controlling effect of keeping that person smoking. It was even mentioned that a woman may fear her partner's reaction if he was to find out that she was trying to quit.

> *She said to me 'he becomes very aggressive; I mustn't let him know that I'm stopping smoking' (Health professional 18)*

Friends or family who had used Stop Smoking Services before and found them ineffective were reported to sometimes put the pregnant woman off trying it herself. Also, family members who had managed to quit on their own were sometimes said to not see the necessity for the use of the services and transmit this to the pregnant woman. Women who lived with smokers indicated a stronger social pressure to continue smoking.

> *My boyfriend smokes as well so that makes it [quitting] harder (Pregnant woman 2; smoker)*

Younger pregnant smokers in particular reported feeling pressure from their peer group to continue smoking which made it difficult for them to stand out from a group of smokers and consider seeking help. A lack of support from friends was also indicated by a young pregnant woman attempting to quit whose smoking friend would not come visit her unless she was allowed to smoke in the house. Therefore, a further reason for low uptake of Stop Smoking Services in pregnancy could be that the social pressure to continue smoking is overriding other factors that might influence the woman to consider seeking help. This is likely to be a particular problem for pregnant women of lower SES where smoking is very much embedded within their culture (Bull et al., 2007). A lack of influence of social pressure to quit smoking in pregnancy is highlighted by O'Campo et al. (1992) in Section 1.3.3 and in a study where subjective norm scores indicated that

pregnant smokers felt less strongly pressured to quit than non-pregnant smokers (Siero et al., 2004). However, the extent to which this was due to not wanting to comply the wishes of those perceived as anti-smoking, or wanting to comply with the wishes of those perceived as pro-smoking is not clear.

4.4.2.3 Control beliefs

The following themes relate to pregnant women's beliefs about specific factors that would facilitate or inhibit their attendance at Stop Smoking Services (i.e. control beliefs).

4.4.2.3.1 Access to services – beliefs about ease of access to Stop Smoking Services and how this influences potential engagement with them

There were 130 references to the importance of access incorporated across all 36 interviews, suggesting that this external PBC factor is highly influential. Issues of access were considered to both facilitate and inhibit engagement. A health professional reported that the main reason given by pregnant women for not attending Stop Smoking Services is a lack of time as highlighted by the following quote.

> *Why I wouldn't [attend a Stop Smoking service] would be time with work and the children (Pregnant woman 7; smoker)*

Many pregnant women referred to the distance a Stop Smoking service was from their home as being important for attendance, with a lack of their own transport often cited as a reason.

> *It's far out most of these [Stop Smoking Services] ... well out of my reach. And the green buses with a pushchair, you can't get on (New mother 3; smoked throughout pregnancy)*

These findings are consistent with those of Tod (2003) and Ussher et al. (2006) where lack of time, childcare and transport were also highlighted as barriers to engagement. It was reported by health professionals that women were more likely to attend a service if it was integrated with another service they were already accessing, e.g. antenatal clinic or a Sure Start programme. Women who were aware of home visits valued the convenience of this service, especially if they had existing childcare issues.

> *That would be easier if they came to me, because I've got 3 kids and I'm pregnant with my 4th (Pregnant woman 8; smoker)*

Pregnant women were more likely to attend services which offered flexibility with regard to appointment times. For instance, those women who already had children were reported to need their appointment to be organised around the 'school run'. Also, working women or those who had a working partner who was quitting with them, said that they valued services which were available in the evening. Although flexibility with regard to appointments was generally viewed positively, a health professional noted that routine was important and to avoid the pregnant woman forgetting the appointment, it was better to offer her the same time slot each week. Women also valued being able to contact their smoking cessation advisor easily between regular scheduled appointments if required, and clients were reported to prefer this instead of contacting a stranger on the helpline.

> *They can quite easily get hold of you, they've always got a mobile number, and they use that I think because they come to trust you (Health professional 15)*

4.4.2.3.2 Motivation – beliefs about factors that would demotivate or motivate engagement with Stop Smoking Services

Across 30 interviews, there were 48 instances (in 26 interviews) and 14 instances (in 11 interviews) relating to factors demotivating and motivating engagement respectively. Therefore, this was largely viewed as inhibiting engagement. Some women reported a lack of motivation to engage with Stop Smoking Services because they had no desire to stop smoking.

> *I've never looked into it [Stop Smoking Services] because I've never been interested in stopping [smoking] (Pregnant woman 9; smoker)*

Some women reported enjoying smoking too much to consider giving up. Health professionals too reported that the majority of women who did not want to use Stop Smoking Services tended to be those who were happy, contented smokers who wanted to be left alone to carry on and were not comfortable having their habit challenged. As reported in other studies (e.g. Lendahls et al., 2002), some women rationalised not giving up smoking in pregnancy by referring to previously successful pregnancies during which they or somebody they knew had smoked.

> *I've got two other kids and it's never done them any harm (Pregnant woman 11; smoker)*

Other women reported a desire to be able to quit but that other issues in their lives made this task difficult.

> *I would've [liked to have been able to quit during the pregnancy] yes, the harm and everything but it is just too difficult ... a lot of stresses (New mother 3; smoked throughout pregnancy)*

Some pregnant women reported that the pressures of coping with other children and other lifestyle issues were too great to risk the further pressure of a quit attempt which backs up the findings which indicate that a motive for smoking in pregnancy is to control mood (e.g. Wakefield & Jones, 1991; see Section 1.3.2). This suggests that making other strategies available to relieve stress could prove beneficial, e.g. relaxation techniques, perhaps delivered in antenatal classes or via community Sure Start programmes. Health professionals remarked that pregnant smokers often live in difficult circumstances which mean that quitting smoking is not a priority for them. Low personal self-efficacy, which can be considered as an internal PBC factor, was cited as a particular issue for quitting amongst pregnant women in the TPB studies reviewed in Section 3.2.2. Also, Siero et al. (2004) found that scores on this measure were much lower for pregnant smokers compared to those of non-pregnant smokers and commented on the need to strengthen self-efficacy in this group if smoking behaviour is to be changed. Many women doubted that attending Stop Smoking Services would be successful if they were not properly motivated to quit.

> *If you're going for the sake of it and don't really want to stop smoking, if you haven't got the motivation, then it's not going to work (Pregnant woman 4; smoker)*

However, as previously mentioned, it appears that some women without sufficient motivation to quit can be inappropriately referred to these services. Health professionals suggested that in a clinical environment, the health expert, such as a midwife, may be seen as an authority figure who the pregnant smoker feels she should say 'yes' to, even if this goes against her private feelings.

> *Sometimes we'll get referrals because they're smokers, not because they want to stop (Health professional 13)*

This suggests that potential referrers to Stop Smoking Services might need to more accurately assess a pregnant woman's motivation to quit and develop strategies to increase motivation. It was reported that some pregnant women lacked the motivation to engage with Stop Smoking Services specifically because they were not comfortable with the idea of such a service. Other women reported choosing not to engage with the service because they felt they did not need it, either wanting to be able to or feeling that they could quit on their own.

> *And she [smoking cessation advisor] told me I could go to the clinic but I never went because I decided I could do it on my own (Pregnant woman 6; recent quitter)*

Conversely, it was reported by a health professional that motivation to engage with these services can stem from a feeling of desperation, in that everything else the pregnant woman has tried has been unsuccessful and that she now views using the services the last option available to her. It was noted by one pregnant woman that giving up smoking was a very personal thing and that although strategies employed by Stop Smoking Services might be helpful for some, it was not necessarily the way forward for others. She believed that smokers had to find their own way of quitting, and for some, cutting down slowly might be preferable to instant quitting.

4.4.2.3.3 Stigma – beliefs about the stigma associated with smoking in pregnancy and its influence on engagement with Stop Smoking Services

Pregnant women's beliefs about the stigma associated with smoking in pregnancy tended to be an inhibitory factor in decisions about engagement with Stop Smoking Services, as highlighted by 55 instances across 22 interviews. This might be expected given the negative societal attitudes towards smoking in pregnancy (Bull et al., 2007) and the normative beliefs elicited by this sample. Some pregnant women reported that sharing experiences of smoking with others in a group setting would make them feel awkward. Likewise, a health professional stated that pregnant women dislike going to clinics in the community because of the embarrassment of other people knowing that they are smoking. However, one pregnant woman stated that she wouldn't feel uncomfortable if the group was

solely pregnant women, but would fear judgement in a group session comprising non-pregnant people.

> *[I wouldn't feel uncomfortable going to a group] if you were with other pregnant people in the same situation. But if it was just normal people and then you're there pregnant, they'd think, you know (New mother 1; smoked throughout pregnancy)*

Although some women were reported by health professionals to feel intimidated by the idea of a one-to-one session with the advisor, the majority of women seemed to prefer this option to a group session.

> *I think on a one-to-one level I'd be happier if I could actually talk and discuss my own feelings privately (Pregnant woman 5; smoker)*

Health professionals too stated that home visits tend to be preferred by pregnant women, not only for convenience, but to avoid others finding out about their smoking. Whilst a lot of women prefer a home visit, it was mentioned that some women do not want the advisor coming to them because they are ashamed of where they live. The home visit was also reported as an issue for pregnant women so ashamed of their smoking that they had managed to keep it hidden from those around them.

> *I hide it as well, I don't let anyone see me at work or anything like that, I don't smoke where people can see me, and my parents don't know or anything like that. Even my son who's six doesn't think I smoke (Pregnant woman 7; smoker)*

Health professionals acknowledged that the overt act of engaging with a Stop Smoking service was extremely difficult for those keeping their smoking a secret from family members.

> *Sometimes their partners don't know so they don't want us to come into the house (Health professional 15)*

In cases such as these, advisors reported that they might agree to meet the women on neutral ground, such as at one of the smoker's friend's houses or a local café. A health professional reported that feelings of being judged was not

felt as acutely by her clients because the clinics were run in non-medical locations such as church halls and community centres. Some women reported being worried about being lectured to or judged by a smoking cessation advisor.

> *I guess at first I was a little bit [awkward] because there is the whole stigma that goes with it, so I was a little bit like, yeah they probably do think I'm sort of horrible (Pregnant woman 14; smoker)*

However, clients were often reported to be put at ease once they realised that the advisor was there to help in a friendly and understanding way. Some health professionals reported that the attitudes of potential referrers, such as hospital consultants, towards smoking could enhance pregnant women's feelings of stigma because of their dictatorial and lecturing approach. This mirrors the findings of Lowry et al. (2004) where a preaching style from health professionals was a viewed as a barrier to engaging in smoking cessation. Based on this it would seem that the recommendation made by Bull et al. (2007) for non-judgemental, empathetic delivery of smoking cessation messages in antenatal clinics is justified. As also highlighted by studies in Section 2.2.1, there appears to be a need to stress the importance of this approach to health professionals working with pregnant smokers and perhaps offering training in this style of delivery.

4.4.2.3.4 Knowledge about services – initial knowledge about Stop Smoking Services and the influence of this on engagement with them

Across 12 interviews, there were 23 instances relating to women's knowledge about services, which is can be viewed as another external PBC factor. Generally, this referred to lack of knowledge that would inhibit service use. Some women reported being totally unaware the existence of such services. Others said that there was a lack of advertising of the services and that information about them was only evident if you were already motivated to look for it.

> *Unless you want to give up and you seek the information out yourself ... then you don't really hear about it, you don't see it (Pregnant woman 6; recent quitter)*

This would seem to back up the evidence which suggests that these services are not being effectively promoted in routine antenatal care (e.g. Bull et al., 2008, see Section 2.2.4.2) which is concerning given that pregnant women have been reported to see the midwife as a link person whose role is to help them access

further professional help (McCurry et al., 2002). One woman suggested the need for more advertising about these services, stating that more information about the venue alongside descriptions of the service from previously satisfied clients would likely grab the attention of pregnant women and encourage uptake. It was evident that, even of those who knew something about Stop Smoking Services, some remained unaware of its exact nature. A health professional stated that not really knowing fully what the service can offer and being unsure of what it going to be expected of them when they come can put some women off making an appointment. Other women reported being unaware of options services offer that are designed to encourage attendance, e.g. home visits and individual appointments.

> *So if there was someone that could come to the house like you mentioned. I didn't know that that happens, that's helpful (New mother 2; quit during pregnancy)*

Also, although it appears that some women are motivated to attend Stop Smoking Services so that they can obtain free NRT, not all are aware that this is available through these services.

> *No [I'm not aware that the Stop Smoking Services offer NRT], that's what I mean, I don't know anything about it (Pregnant woman 10; recent quitter)*

A survey carried out by one of the services contributing to this study highlighted that the sort of information pregnant women want from Stop Smoking Services is knowing where to get the support, the type of support that is available and information about and availability of NRT. Some health professionals indicated that the type of information provided by potential referrers such as midwives had the capacity to influence whether or not the pregnant woman attends these services. However, despite the efforts certain smoking cessation advisors said they had made by providing midwives with some good phrases they could use for selling the service, the latter were reported to be very resistant to do this.

> *I think the biggest block is other midwives actually. The hospital based midwives that either haven't got the time to sit and explain to the women or who have preconceived ideas that the women aren't going to reciprocate and don't bother asking (Health professional 14)*

However, in other areas, midwives were reported to work well with the Stop Smoking Services and provide positive information to encourage attendance. Pregnant women have also reported dissatisfaction in the lack of information provided by the National Smoking in Pregnancy helpline, and that they would feel more confident about using services if they were able to glean some knowledge about the approachability of the advisor before their appointment.

On the whole it would appear that opportunities to provide pregnant women with knowledge about NHS Stop Smoking Services are being missed and that specific aspects of the service such as individual appointments, home visits and free NRT that might encourage attendance remain unknown. These findings further highlight the need to more effectively link smoking cessation support with routine antenatal care and for health professionals to take more responsibility in assisting pregnant smokers (Ussher et al., 2006). Establishing good relationships between potential referrers and Stop Smoking Services seems to be an important stage in this process. The provision of promotional material in the form of video presentations or leaflets in locations frequented by pregnant women, for example, antenatal clinics and Sure Start centres, could also be beneficial for increasing knowledge.

4.4.2.3.5 Fear of failure – concerns that they would be letting themselves and their advisor down if they failed to quit and the influence this has on engagement with Stop Smoking Services

Beliefs about not being able to quit were sometimes cited as reasons not to engage with Stop Smoking Services in pregnancy, highlighted by 17 instances relating to fear of failure across 10 interviews. Some women believed that a lack of confidence to quit could result in avoidance of service use or that a failure to quit would be letting themselves and the advisor down. These were also raised as barriers to service use by Ussher et al. (2006) and in the TPB context can be viewed as internal PBC factors related to self-efficacy (see Section 3.3.1).

> *I'd probably just think 'oh god if I don't do it' and maybe feeling under pressure to do it, once you've decided to go ahead and try and if you didn't then ... I probably would feel like I was letting myself and the advisor down if I didn't do it (Pregnant woman 7; smoker)*

Health professionals reported that women often feel very uncomfortable about telling their advisor about any relapses and are greatly relieved when they learn that the advisor will continue to support them. However, it was also reported that some women feel so awkward about their failure to quit that they are not able to bring themselves to tell the advisor and will avoid future appointments.

> *And then I'll not see them again then, because they're embarrassed about going back to smoking (Health professional 16)*

Conversely, one health professional stated that a fear of disappointing their advisor could actually provide some pregnant women with the drive to continue their quit attempt. On the whole, these findings indicate that when promoting the service, it should be made clear that the difficulties associated with quitting will be sensitively and constructively handled by the advisor.

Table 4.1 Summary of number of instances of NHS Stop Smoking service themes and number of interviews in which they occurred

Theme	PW Inst.	HP Inst. *	Total Inst.	PW Inter.	HP Inter. *	Total Inter.
Behavioural Beliefs						
Practical support	24	44	**68**	13	17	**30**
Emotional support	20	42	**62**	11	18	**29**
Service effectiveness	23	29	**52**	14	14	**28**
Improving health	22	4	**26**	10	4	**14**
Acquiring information	2	17	**19**	2	14	**16**
Normative beliefs						
Family	26	33	**59**	15	14	**29**
Health experts	16	47	**63**	9	17	**26**
Friends	8	12	**20**	7	9	**16**
Control beliefs						
Access to services	52	78	**130**	18	18	**36**
Motivation	34	28	**62**	16	14	**30**
Stigma	18	37	**55**	8	14	**22**
Knowledge about services	7	16	**23**	4	8	**12**
Fear of failure	4	13	**17**	3	7	**10**

PW = Pregnant women, HP = Health professionals, Inst. = Number of instances, Inter. = Number of interviews, * Beliefs of pregnant women as perceived by health professionals

4.4.3 NICOTINE REPLACEMENT THERAPY THEMES

Twenty-two specific themes were identified from the NRT information: 10 behavioural beliefs, 3 normative beliefs and 9 control beliefs. Using the NRT themes codebook, 60 of the 65 quotes provided were assigned to the correct theme by the second coder. This gave an overall percentage agreement score of 92.31% between the researcher (JT) and the second coder (CB). The number of instances of these 22 themes and the number of interviews in which they occurred are listed in Table 4.2.

4.4.3.1 Behavioural beliefs

The following themes relate to the pregnant women's beliefs about outcomes of using NRT in pregnancy, i.e. their behavioural beliefs: (1) Effective for quitting (2) Side effects (3) Reduction of cravings (4) Exacerbated sickness (5) Financial cost (6) Stress reduction (7) Improved health (8) Not the same as quitting (9) Satisfaction (10) Becoming addicted.

4.4.3.1.1 Effective for quitting – beliefs about whether or not NRT would be effective in helping with smoking cessation

In 33 of the 36 interviews there were 57 instances relating to NRT being helpful for a quit attempt and 20 instances relating to it not being helpful. Therefore, despite the lack of conclusive evidence (Lumley et al., 2009), the majority belief of pregnant women was that NRT would aid a quit attempt.

> *[NRT] makes you stop ... I suppose it just gives you the nicotine doesn't it that you need (Pregnant woman 1; recent quitter)*

It was reported that pregnant women believed NRT was effective because they had heard this from others who had used it or they had been previously quit themselves with NRT and wanted to use the same product again. Health professionals reported that some women felt that quitting smoking would have been too hard without NRT.

> *Well they say they couldn't have managed to quit without it (Health professional 1)*

It was reported by health professionals that some women viewed NRT as a substitute for their smoking, and being able to choose whether or not to use it enabled them to retain the sense of control they had acquired from smoking.

Furthermore, having to actively engage in the process of using NRT, such as going to the GP to collect it and putting the patch on every day, was considered by a health professional to be an important issue in relation to this sense of control. Also, the fact that women on NRT are told that concomitant smoking is potentially dangerous and will make them feel ill was reported by health professionals as being an incentive to remain abstinent. The women who had less confidence in the effectiveness of NRT were reported to be those who either knew of others who had not found it helpful or who had themselves used it before without success.

> *I mean the last time I was pregnant they prescribed them [NRT patches] and it didn't work at all (Pregnant woman 3; smoker)*

It is possible that the lower administered doses of nicotine than those derived from smoking and the accelerated metabolism of nicotine in pregnancy (Dempsey et al., 2002) contribute to the lack of effectiveness of NRT and that higher doses than usual might need to be considered for this group (Koren, 2001). Some pregnant women believed the inhalator to be a beneficial mode of delivery of NRT because it mirrored the hand to mouth action of smoking. However, it was reported by health professionals that others actually found it of no help because it kept in place the very action that they were trying to break. Some women were reported to view NRT negatively because of a belief that it would, on its own, stop them smoking and were subsequently disappointed when their expectations were not fully met.

> *And sometimes, it's unrealistic expectations, 'the patch is just going to make it all fine and I never want to smoke again' (Health professional 13)*

4.4.3.1.2 Side effects – beliefs about unwanted side effects accompanying NRT use

There were 75 instances in 27 of the 36 interviews relating to the negative attitudinal belief about unwanted side effects from NRT. Health professionals reported numerous side effects that pregnant women attribute to NRT use, such as light-headedness, dizziness, constipation, flu-like symptoms, and tingly hands. A similar range of effects were cited by pregnant women in the studies by Hegaard et al. (2004) and Hotham et al. (2006). Some of the beliefs about side effects were reported by pregnant women to stem from their own personal experience of using NRT.

> *I suffered quite a lot of headaches as well with them (NRT patches] ... I've had migraines a lot (Pregnant woman 13; smoker)*

Others beliefs were based on the unpleasant experiences of people they knew who had used it.

> *[I wouldn't want to use NRT] from stories that I've heard off other people ... nightmares and hot sweats and things like that (Pregnant woman 1; recent quitter)*

Pregnant women have also attributed arm ache, skin rashes, hallucinations and paranoia to patch use, and complained about the taste, appearance and texture of the oral products. However, some health professionals believed that pregnant women sometimes exaggerated the side effects of NRT because they weren't ready to quit and wanted an excuse to return to smoking.

> *Sometimes they say they had an awful reaction but often on further questioning it wasn't awful, it was maybe a bit of a local reaction and actually the time [for quitting] wasn't right and it was an unsuccessful quit attempt and they blamed the patch (Health professional 13)*

Some pregnant women reported a conflict between believing NRT to be beneficial but unpleasant at the same time.

> *I've heard that the chewing gum is supposed to be good but I haven't tried that yet. But it's supposed to be minging but it's supposed to help you stop smoking once you realise how horrible it is, but I don't know (Pregnant woman 3; smoker)*

Pregnant women might benefit from being given a realistic appraisal of the likelihood and duration of side effects from NRT and being reassured that if a particular product is not tolerated well, alternatives are available to which they may be better suited. This is particularly pertinent in relation to the oral products which can exacerbate pregnancy sickness.

4.4.3.1.3 Reduction of cravings – beliefs that NRT would reduce cigarette cravings

There were 28 instances specifically related to the positive attitudinal belief that NRT would reduce cigarette cravings which were mentioned in 23 of the 36 interviews.

> *I would imagine that it [NRT] would make life that little bit easier, the withdrawal from it [smoking] (Pregnant woman 5; smoker)*

A health professional pointed out that if women forget to use NRT they soon notice their cravings worsening.

4.4.3.1.4 Exacerbated sickness – beliefs that using NRT in pregnancy would exacerbate pregnancy sickness

Certain NRT products were reported to exacerbate pregnancy sickness and feelings of nausea experienced by a number of women in the course of their pregnancy, and thus put them off using it or even put them off their quit attempt. There were 24 instances (in 18 out of the 36 interviews) which specifically related to beliefs about sickness. However, this negative attitudinal belief was only mentioned 6 times in 4 of the women's interviews which suggests that this issue might not be as salient to them as the health professionals report. Perhaps this was because the pregnant women and their social network had limited experience of this as a potential outcome.

> *I think morning sickness if they come within the first few weeks, you know if they're using an oral product, they tend to feel sick and they don't want to use it (Health professional 9)*

4.4.3.1.5 Financial cost – beliefs about the financial impact of using NRT

Of the 25 belief items relating to cost, the majority view was that NRT is cheaper than smoking, with 21 instances where NRT was believed to be cheaper than continued smoking and 4 where it was not. This largely positive attitudinal belief was mentioned in 17 of the 36 interviews. However, although some women were aware that NRT is available free through Stop Smoking Services in pregnancy others were not.

> *They [Stop Smoking Services] give you the support and they give you the stuff [NRT] free (Pregnant woman 8; smoker)*

> *I've always thought you'd have to pay for NRT things and they are quite expensive (Pregnant woman 12; recent quitter)*

The lack of knowledge that NRT can be acquired free of charge in pregnancy could be a reflection of the inconsistencies in advice giving in routine care reported in Section 2.2.4.1 (e.g. Haslam et al., 1997). One pregnant woman said that she would rather continue smoking if she had to pay for NRT, whilst a health professional stated that some pregnant women who were not aware that it was free had told her that the cost of NRT had deterred them from using it. Knowing that NRT is available without charge in pregnancy was reported to be a motivating factor for a quit attempt.

> *The fact that it's free makes them want to use it (Health professional 4)*

Being able to save money which they could spend on their expected baby provided a further incentive. The fact that some pregnant women are unaware that NRT is available free in pregnancy and this has been shown to be an important factor in encouraging its use highlights the importance of making this information more widely known.

4.4.3.1.6 Stress reduction – beliefs that using NRT would reduce stress and improve mood

A number of beliefs were reported about NRT helping to reduce stress and improve mood when trying to quit smoking, appearing in 14 of the 36 interviews. Given there were 20 instances relating to the fact that NRT would help to reduce stress and only two relating to the fact that it would not, the majority view was that NRT would make a quit attempt more comfortable.

> *They're still getting the sense of having a fag. They're not getting a craving and they won't get as stressed (Pregnant woman 10; recent quitter)*

Health professionals reported that many pregnant women view NRT as a safety net which they can fall back on, and are reassured by the fact that they do not have to quit 'cold turkey'. However, there are reasons to believe that using NRT will not inevitably reduce stress. For instance, there were reported concerns about the safety of NRT amongst pregnant women as found by Hotham et al.

(2002), and it was also said that pregnant women who have turned to NRT as a last resort, can be fearful that there will be nothing else to turn to if it is unsuccessful.

> *Or fear of failure as well, 'if I use that [NRT] and it doesn't work what happens then?' It's like, you know, 'I've used up all my options' (Health professional 13)*

4.4.3.1.7 Improved health – beliefs that using NRT in pregnancy would improve the health of mother and baby

Another outcome of using NRT in pregnancy was believed to be improved health for the mother and baby. There was a much higher incidence of this positive attitudinal belief amongst the pregnant women themselves (20 instances in 11 interviews) than the health professionals (5 instances in 2 interviews). This suggests that health professionals might be underestimating the importance of pregnant women protecting their own health and that of their baby as a motivation for using NRT. A number of women believed that NRT provided nicotine without all the toxins that are present in cigarettes and thus saw using it as a healthier option than continued smoking.

> *It [NRT] has got to be better than smoking hasn't it? ... you're not going to get the rubbish you get with cigarettes (New mother 4; smoked throughout pregnancy)*

Whilst some pregnant women focused on the belief that using NRT instead of smoking would benefit their own health, such as not getting breathless all the time, others also focused on the health benefits for their unborn child.

> *You're not inhaling the smoke so therefore it's not hurting your baby is it ... it's better for you. It's probably better for the whole pregnancy isn't it? (New mother 1; smoked throughout pregnancy)*

In the study by Hotham et al. (2002), women too rationalised that NRT would be less harmful than smoking due to the absence of additional harmful chemicals in cigarettes. Furthermore, pregnant women's reported concern for the well being of the foetus as a major incentive not to smoke while using NRT (Hotham et al., 2006) further highlights the salience of this issue.

4.4.3.1.8 Not the same as quitting – beliefs that using NRT would not represent properly quitting smoking

Some women reported the belief that to use NRT would not represent actually quitting smoking, as they would still be relying on nicotine. Fourteen instances related to this negative attitudinal belief, 13 of which were reported by the pregnant women themselves (in 9 of the 10 interviews where this issue was mentioned). This suggests that the health professionals might be underestimating the importance of this as a factor in the decision making about NRT use in pregnancy.

> *I think you're still doing the same thing as smoking. Obviously maybe not as nearly as harmful but you're still putting nicotine into your body (Pregnant woman 6; recent quitter)*

Some women reported that to stop smoking would require not having nicotine in the body and that to use NRT would merely be replacing smoking with something else. This belief appeared to be far more salient for the pregnant women themselves than the health professionals perceive it to be.

4.4.3.1.9 Satisfaction – beliefs about whether or not NRT would replace the satisfaction derived from smoking

In 10 out of the 36 interviews there were 9 references relating to the fact that NRT would not adequately replicate the satisfaction derived from smoking and 4 pointing to the fact that it would. For some, the belief was that NRT would not provide the same experience of smoking.

> *I can't see it's like having a cigarette. I can't imagine it's the same (Pregnant woman 2; quit during pregnancy)*

This was backed up by reports from health professionals who highlighted problems with NRT compliance and a return to smoking as a result of NRT not giving the pregnant women what they needed. Not being able to get a sense of taste from a patch made one women unsure about whether it was exerting any beneficial effect. Another woman reported that the strength of the inhalator made her choke and likened the sensation to having ten cigarettes at once. Conversely, for other women this mode of NRT delivery seems to provide some satisfaction.

> *Women swear by the inhalator ... they like the hit it gives them (Health professional 1)*

There were suggestions that the satisfaction derived from smoking goes beyond the nicotine hit. For instance, it was reported that although one woman found that NRT took away her cravings, she missed the sensation of blowing smoke out. Another woman reported that for her the inhalator did not replace the hand to mouth action of smoking or stop her wanting to hold a cigarette. All these factors highlight that the behavioural component of smoking plays a crucial role in the addictive process (e.g. Bull, 2003) and that this can make NRT seem like a poor substitute to the smoker attempting to quit.

4.4.3.1.10 Becoming addicted – beliefs that NRT would be addictive

There were three reported instances (in 3 out of 36 interviews) of beliefs that NRT would be addictive, a negative attitudinal belief also raised by Ashwin & Watts (2009). This is very similar to the theme 'Not the same as quitting' in that both reflect a fear pregnant smokers have about not freeing themselves of their reliance on nicotine. One woman felt that using NRT would mean that there would be something else she would have to quit after quitting smoking. Another woman was concerned that receiving nicotine from NRT would ultimately make quitting smoking a more difficult process.

> *Because you're getting a sense of having a fag, you might not be able to stop on the thing that you're using [NRT]. And then if you stop [using NRT] you're just going to want a fag aren't you?' (Pregnant woman 10; recent quitter)*

4.4.3.2 Normative beliefs

The following themes relate to the pregnant women's beliefs about the most commonly occurring sources of social pressure to use or not use NRT during pregnancy, i.e. their normative beliefs: (1) Family (2) Health experts (3) Friends.

4.4.3.2.1 Family - beliefs about the social pressure felt from family members to use or not use NRT in pregnancy

Family members, e.g. partners and parents, were shown to exert a significant social pressure on pregnant women to use or not use NRT, being mentioned in 22 of 36 interviews. There were 22 and 4 instances of beliefs about family pressure to use NRT reported by the pregnant women and health professionals

respectively. This suggests that health professionals might not appreciate the importance of family pressure or support in relation to decisions about NRT use as much as the smokers themselves.

> *Yes, my family would approve [of me using NRT], definitely (Pregnant woman 12; recent quitter)*

There were 5 instances of family pressure not to use NRT. Some family members were reported to discourage the use of NRT because of their own negative experiences of using it, either in terms of it not helping them quit or them finding the side effects unpleasant. Others were reported to believe that NRT should not be used in pregnancy and transmitted these concerns to the pregnant smoker.

> *We do get the odd person that will come back and say 'my Nan said I shouldn't be on that' or 'my Mum said I'm pregnant and I shouldn't be taking that' (Health professional 2)*

NRT was also said to be discouraged by some family members because they did not see a reason why the pregnant woman would want to quit in pregnancy.

4.4.3.2.2 Health experts – beliefs about the social pressure felt from health experts to use or not use NRT in pregnancy

There were 30 instances relating to the belief that health experts would approve of or encourage NRT use, and 8 relating to belief that they would actively discourage it. This difference of opinion reflects the controversy that currently exists in the medical profession in terms of NRT prescribing in pregnancy (see Section 2.3.6). At least one health expert was mentioned as a source of social pressure with regards to NRT use in 18 of the 36 interviews. The majority of health professionals that the pregnant smoker comes into contact with during the course of her pregnancy, e.g. midwife, hospital consultant or health visitor, were viewed by the women as sources of social pressure to use NRT. They reported that these health professionals would approve of NRT use because they would see this as being a step in the right direction and be grateful for any attempt the pregnant woman was making to stop smoking.

> *Well I suppose anyone in the medical profession [would approve of me using NRT] because they'd say to do that rather than smoke (Pregnant woman 6; recent quitter)*

All seven of the health experts reported as not approving of NRT in pregnancy were GPs reluctant to prescribe NRT because they were unsure as to its safety, and all of these cases were reported by the health professionals and not by the pregnant women themselves. Some women were reported by Stop Smoking advisors to believe that their GP would not prescribe them NRT while others already using it were sometimes said to be influenced not to continue with it after negative advice from their GP.

> *I have had cases where women have had the patch and the GP has told them they shouldn't be wearing it, and they've taken it off (Health professional 12)*

4.4.3.2.3 Friends - beliefs about the social pressure felt from friends to use or not use NRT in pregnancy

Although not playing as prominent a role as family and health experts, friends were shown to exert influence on pregnant women's use of NRT. As for family, there were views for and against with 6 and 2 instances relating to beliefs about friends exerting pressure to use and not use NRT respectively, which were present in 8 out of 36 interviews. Similar reasons to those of family members were cited in that pregnant women tended to be influenced not to try NRT by friends who told them about their own unfavourable experiences of NRT or who believed that it should not be used in pregnancy.

4.4.3.3 Control beliefs

The following themes relate to the pregnant women's beliefs about factors or circumstances that would inhibit or facilitate NRT use in pregnancy, i.e. their control beliefs: (1) Safety (2) Unsure if allowed (3) Convenience of use (4) Ease of acquisition (5) Self consciousness/embarrassment (6) Knowledge about products (7) Smoking addiction (8) Wanting to quit without (9) Forgetting to use.

4.4.3.3.1 Safety – beliefs that NRT might not be safe to use in pregnancy

The belief that NRT might not be safe to use in pregnancy was reported 46 times across the 36 interviews, and at least once by 22 of the interviewees, showing it to be an important inhibiting factor.

> *At first they always ask, 'how safe is it?' (Heath professional 9)*

Given the uncertainty amongst health professionals about NRT use in pregnancy (see Section 2.3.6), concerns about its safety might be expected to exert a powerful influence on pregnant women's decisions about whether or not to try it. This issue has also been highlighted by Hotham et al. (2002). One pregnant woman reported being reluctant to use NRT because of the lack of definitive evidence to show that it is safe, whilst others lacked confidence to use it for fear of damaging their unborn child.

> *They say the nicotine is what stunts the baby's growth and things like that, so I think, well if I can stop smoking [without NRT], then what's the point in me putting a patch on (Pregnant woman 14; smoker)*

Some of these concerns stemmed from media reports the women were aware of which linked NRT to birth defects. Health professionals stated that the publishing of this study in newspapers caused quite a problem and some women doing well on NRT actually ceased treatment upon reading about this. Other women were concerned about what NRT was doing because they didn't know anything about it or were worried about the nature of the nicotine delivery from the patch being different to that of the cigarette.

> *But with the patch you would wear it all day and there's going to be a constant kind of supply of nicotine going to the body, and I just don't like the thought of that (Pregnant woman 14, smoker)*

Although Hotham et al. (2002) and Ashwin & Watts (2009) also found that pregnant women had reservations about how the patch exerts its effects some women appeared not share such concerns about NRT believing it to be safer than continuing to smoke.

> *It's better than lighting up a cigarette isn't it? (Pregnant woman 13, smoker)*

As also found by Ashwin & Watts (2009), receiving assurances from health professionals that NRT is likely to be safer than smoking was reported to increase pregnant women's confidence to use it.

> *The fact that the midwives are positive towards them using it has made a big difference (Health professional 12)*

The fact that safety was mainly mentioned in the health professional interviews suggests that pregnant women in this sample might not have been as concerned about this as indicated by the health professionals. This would certainly seem to tie in with the belief women had about using NRT to protect their health and that of their baby. Perhaps because NRT is now sanctioned for use in pregnancy and is becoming more widely prescribed to this group, there is a growing belief that NRT is a safe product. Maybe this issue remains more salient to health professionals because they have greater knowledge about the risk/benefit profile of NRT.

4.4.3.3.2 Unsure if allowed – beliefs that NRT might not be allowed in pregnancy

In a closely related issue to safety, women's uncertainty about whether they could use NRT while pregnant was a further inhibiting factor highlighted by 31 instances across 22 interviews. Some pregnant women reported not knowing that NRT could be used in pregnancy while others were unsure.

> *I don't know whether you're allowed to do it [use NRT] when you're pregnant (Pregnant woman 10; recent quitter)*

This uncertainty is probably indicative of the lack of consensus amongst health professionals (see Section 2.3.6) and the lack of discussion about its potential use in pregnancy (e.g. Griffiths et al., 2005). It is likely that being unsure whether NRT is allowed feeds into concerns about its safety and vice versa. Health professionals reported that GPs sometimes had a negative effect by telling pregnant women that they should not be using NRT, thus causing them to question their faith in it. Other women were said to believe that their GP would not prescribe it. It was reported that of the GPs willing to prescribe NRT some would warn the pregnant woman that it could cause them more damage. Furthermore, a health professional mentioned that certain midwives who perhaps lacked knowledge about NRT and were not very positive about it were a negative influence. This confirms the need for more consistent information giving about the current status of NRT use in pregnancy by routine care providers. It may well be that these health professionals require training in raising the issue of NRT use with pregnant women in a way that reflects current guidelines and sources of support. Pregnant women reported that they would feel more confident about using NRT if it had been authorised by a health professional. It is important that is made apparent to pregnant women that Stop Smoking advisors will be able to

offer comprehensive and unbiased information about NRT as they need to be aware of the pros and cons of using NRT in order to make an informed decision about whether or not to use it.

4.4.3.3.3 Convenience of use – beliefs about how convenient NRT would be to use

There were 26 instances relating to beliefs about the convenience of using NRT across 17 of the 36 interviews. Nineteen of these instances related to NRT being convenient and 7 related to it being inconvenient, making this a predominantly facilitating factor. Some women were reported to favour specific types of NRT product based on their perceived convenience.

> *[The inhalator] was discreet as well because it fits into your bag or you could put it in your purse ... it's not like the chewing gum where you've got to mess around with the box to get it out and then put it away, it was just a lot easier ... you can just get it out of your bag or out of your pocket, stick it in your mouth, suck on it and then put it away (Pregnant woman 4; smoker)*

Working women were also reported to like the convenience of the inhalator because they could either use it at their desk or on cigarette breaks to maintain the community they had with other smokers. Furthermore, the inhalator was reported to be a better option for women who were secret smokers, who by wearing a patch would be revealing their smoking to their family members. However, for other women the NRT patch was preferred because its mode of action meant that they were not required to continually take NRT orally throughout the day.

> *They prefer to put a patch on so they don't have to keep remembering to use something every hour, they just put it on and it's there for the rest of the day (Health professional 10)*

It was reported by a health professional that most women preferred the patch because it allowed them to get on with what they had to do. However, some women reported finding the patches inconvenient because of their failure to adhere to the skin, more of a problem during the summer according to one health professional.

> *[I'd find NRT easier to use] if the patches stuck a bit better (New mother 3; smoked throughout pregnancy)*

The oral products were reported to be inconvenient for working women who were not allowed to eat or chew gum in their workplace. However, a pregnant woman said she had found it handy to use when travelling on an aeroplane.

4.4.3.3.4 Ease of acquisition – beliefs about how easy it would be to acquire NRT

There were 23 instances (in 17 of the 36 interviews) relating to beliefs about how easy it would be to acquire NRT, 10 of which were beliefs about it being easy to acquire and 13 of it not being easy to acquire. It was reported that pregnant women sometimes believe that the process of acquiring NRT will be tedious.

> *A disadvantage is trying to get hold of it [NRT] ... they have to come in and see someone or someone has to go and see them, they don't want to see anybody really if they can help it (Health professional 18)*

Pregnant women reported that they would find it easier to use NRT if it could be supplied to them from multiple locations near to where they lived, directly from their midwife at the clinic, or out of normal working hours. Pregnant women aware of the service were said to value the ease of having NRT supplied to them directly by a Stop Smoking advisor.

> *Knowing that they're not going to run out and it's not going to be difficult [to access NRT], and that once they've got it it's going to be an ongoing supply for as long as necessary, rather than having to go and see the GP every time (Health professional 13)*

Health professionals reported that pregnant women did not want to have to do a lot of work in order to get their NRT and found it easier to be able to collect it from local Stop Smoking Services or have a Stop Smoking advisor deliver it to their home. This highlights the potential benefit of making it more widely known to pregnant women that NRT can be acquired without difficulty through these services. In terms of acquiring NRT via the GP, a pregnant woman reported not getting the chance to make an appointment, while some health professionals said that those required to use this route were often not motivated to make an appointment or collect their prescription.

> *When I contact them, quite a few women say 'Oh, I haven't got round to taking the form to the doctors yet' (Health professional 10)*

Other health professionals confirmed that physically having to go to the GP and collect the prescription was a barrier to NRT use, and particularly problematic for women whose GP refused to prescribe it or if the prescription was delayed. However, not all women believed that access to NRT via their GP would be difficult.

> *I think it's just easy to go to your doctor and get them [NRT] isn't it? (New mother 1; smoked throughout pregnancy)*

One health professional considered that the strict regime of having to make some effort to collect NRT from the GP was for some pregnant women a motivating factor for its use.

4.4.3.3.5 Self consciousness / embarrassment – beliefs about whether or not using NRT could cause feelings of self consciousness or embarrassment

There were 22 instances (in 12 of the 36 interviews) relating to self-consciousness or embarrassment about using NRT, 18 of which referred to feelings of self-consciousness or embarrassment, and 4 of which related to not feeling self-conscious or embarrassed. In terms of this largely inhibiting factor, many pregnant women were reported as being concerned that being seen using NRT would result in criticism from others.

> *What people say [can be a barrier to NRT use], perhaps they are wearing a patch and someone will say 'you shouldn't be doing that, that's dangerous for the baby' (Health professional 13)*

It was reported by health professionals that, although some pregnant women were satisfied with their NRT product and would use it at home, they would be too embarrassed to be seen using it in public. Some women were said to not find the inhalator discrete enough. For instance, one woman was reported to go all week without a cigarette but smoke when she went out at the weekend because she was too embarrassed to hold the inhalator. Patches were considered to be a preferred option for some women because they could be hidden under clothing.

Those who had been keeping their smoking a secret from their partner, family members or work colleagues were reported as not wanting to be seen using NRT and thus avoid it.

> *Because nobody knew that she smoked, she didn't want to wear patches because somebody would see it on her arm if it was a warm day ... she didn't want anyone to see her with this little plastic thing [inhalator] in her mouth (Health professional 16)*

Some women reported not necessarily fearing disapproval from others, but merely feeling self-conscious because of the nature of the product itself.

> *And I must admit I feel rather ridiculous on that plastic thing [inhalator] ... this is ridiculous to say really because I should feel stupid having a cigarette in my mouth (Pregnant woman 5; smoker)*

Another woman stated that she would prefer to use the oral products because she did not like the look of the patches. Not all pregnant women reported being sensitive to the potential criticism of others in terms of NRT use.

> *They see you walking street and you've got that thing in your mouth [inhalator], they'll think, 'hold on a minute, that's not good, she's not allowed to do that', you'd proper get some weird looks ... I don't care what people think (Pregnant woman 4; smoker)*

Some pregnant women were actually reported as viewing their use of NRT as a good talking point, and a health professional remarked that pregnant women were becoming less self conscious about using NRT as they saw it being more widely used.

4.4.3.3.6 Knowledge about products – the amount of knowledge a pregnant woman has about NRT

There were 15 reported instances (in 12 of the 36 interviews) relating to the amount of knowledge about NRT, 9 of which related to sufficient knowledge upon which to make an informed decision, and 6 of which related to insufficient knowledge. Some women reported not having much knowledge about NRT or knowledge about all the products that are available which is consistent with

studies that point to a lack of advice giving about NRT in pregnancy (e.g. Rigotti et al., 2008).

> *I don't know all of them [NRT products] ... I don't know a lot about it (Pregnant woman 11; smoker)*

Health professionals believed that receiving clear and unbiased information about NRT helped pregnant women reach a decision about NRT, and stated that part of the role of Stop Smoking Services was to facilitate this process. Some women reported that they would be more likely to consider using NRT if they had more knowledge about it.

> *If I knew more about it, more awareness [it would make NRT use easier] (Pregnant woman 7; smoker)*

It therefore appears that receiving more information about NRT and how the various modalities exert their effects would help a pregnant woman to make an informed choice about which option would suit her best.

4.4.3.3.7 Smoking addiction – beliefs about ability to quit smoking and its impact on NRT use

Pregnant women reported negative beliefs about NRT as a result of their struggle to quit smoking or their lack of motivation to try and quit. Issues around their smoking addiction were mentioned on 11 occasions in 9 of the 36 interviews, only 2 of which were health professional interviews.

> *You've got to have the will power I suppose, I just haven't got it at the moment ... I didn't think they [NRT] were working and it was just winding me up ... I wasn't in the right frame of mind at the time I don't think (Pregnant woman 13; smoker)*

The fact that this inhibiting factor was rarely raised by the health professionals suggests that they might be underestimating the importance of individuals' motivation to quit or be failing to fully appreciate the very real difficulties that women have in coping with their addiction to smoking during a quit attempt. Some pregnant women reported not finding NRT helpful in part because of being surrounded by smokers at work and at home. Some health professionals were of the opinion that being motivated to quit and receiving encouraging information

about NRT from a Stop Smoking advisor would help the pregnant woman because it would be reinforcing what she wanted to believe. Some women reported not being interested in NRT purely because of their lack of intention to quit.

> *The patches are alright, I wouldn't use them ... I just enjoy a fag too much (New mother 3; smoked throughout pregnancy)*

Some women said that even knowing that NRT was free in pregnancy would not motivate them to stop smoking while others said they would consider using NRT only when they felt ready to quit. These findings suggest that women need to be highly motivated to quit in order to fully benefit from NRT and health professionals should be mindful of this.

4.4.3.3.8 Wanting to quit without – beliefs about wanting or feeling able to quit smoking without using NRT

Some pregnant smokers stated that they did not want to use NRT because they wanted or felt able to quit smoking without using it. There were 6 instances relating to this issue across 6 interviews, 5 of which were pregnant women / new mother interviews.

> *That's why I decided not to do it [use NRT] personally because you're going to give it [smoking] up, you're prolonging the process by having the nicotine still being put into your body ... you have to believe you can cope without (Pregnant woman 6; recent quitter)*

Another woman also felt that she would be using NRT as a crutch and preferred to try without. One woman stated that she would only use NRT if she had not been able to quit without it, while another reported wanting to try and quit without NRT because she had not found it helpful in the past. Some women felt that they did not need NRT to help them in their quit attempt and a health professional pointed out that some do not complete the 12 week course of NRT because they say they do not need it. Given that this inhibitory factor was mainly highlighted by the pregnant women themselves suggests that health professionals may not be fully accounting for pregnant women's wishes to quit without pharmacological assistance and their reasons for this. The greater knowledge that health professionals are likely to have about NRT might mean that they are generally less concerned than the pregnant women about the safety issues surrounding it.

4.4.3.3.9 Forgetting to use – beliefs about the ability to remember to use NRT

There were two instances in 2 separate interviews that highlighted that a lack of adherence to NRT could be related to a pregnant woman's failure to remember to use it.

> *It's memory [that makes it difficult for them to use NRT] (Health professional 3)*

A health professional remarked that women who forget to put a patch on recognise the increase in their cravings very quickly.

Table 4.2 Summary of number of instances of Nicotine Replacement Therapy themes and number of interviews in which they occurred

Theme	PW Inst.	HP Inst. *	Total Inst.	PW Inter.	HP Inter. *	Total Inter.
Behavioural Beliefs						
Effective for quitting	27	50	**77**	16	17	**33**
Side effects	28	47	**75**	11	16	**27**
Reduction of cravings	9	19	**28**	9	14	**23**
Exacerbated sickness	6	18	**24**	4	14	**18**
Financial cost	14	11	**25**	8	9	**17**
Stress reduction	3	19	**22**	3	11	**14**
Improved health	20	5	**25**	11	2	**13**
Not the same as quitting	13	1	**14**	9	1	**10**
Satisfaction	9	4	**13**	6	4	**10**
Becoming addicted	2	1	**3**	2	1	**3**
Normative beliefs						
Family	22	9	**31**	14	8	**22**
Health experts	16	22	**38**	7	11	**18**
Friends	4	4	**8**	4	4	**8**
Control beliefs						
Safety	13	33	**46**	6	16	**22**
Unsure if allowed	11	20	**31**	8	14	**22**
Convenience of use	8	18	**26**	5	12	**17**
Ease of acquisition	6	17	**23**	5	12	**17**
Self consciousness	5	17	**22**	4	8	**12**
Knowledge about products	9	6	**15**	6	6	**12**
Smoking addiction	9	2	**11**	7	2	**9**
Wanting to quit without	5	1	**6**	5	1	**6**
Forgetting to use	0	2	**2**	0	2	**2**

PW = Pregnant women, HP = Health professionals, Inst. = Number of instances,
Inter. = Number of interviews, * Beliefs of pregnant women as perceived by health professionals

4.4.4 STUDY STRENGTHS AND LIMITATIONS

4.4.4.1 Sample

The range of ages, SES and smoking habits of the clinic and community samples suggests that a spread of salient beliefs was accessed in this study. The inclusion of a community sample was designed to capture the beliefs of those who might not have attended antenatal clinic appointments and whose views could have been different to the clinic sample. Furthermore, the size of the sample and the fact that it contained some individuals who had used Stop Smoking Services and NRT and some who had not, satisfied the requirements of a TPB elicitation study (Montano & Kasprzyk, 2002). However, given that all the pregnant women and new mothers interviewed were White British means that the study did not determine the views of pregnant smokers from other cultures which may have been different. Being able to draw on insights from a number of health professionals working in diverse settings with a range of experience of different clients added a further perspective. It is possible that the patient sample might have underestimated issues such as stigma because they had to volunteer to participate in the study or been inclined to answer in a socially desirable way. Therefore, it was useful to be able to draw on the health professionals' insights as these were likely to be a more global representation of pregnant smokers' views even if they did give more emphasis to beliefs that were unusual or striking. For these reasons as well as the fact that the health professional interviews tended to be longer than those of the women themselves and this was a small qualitative study, any differences between these groups should be interpreted with extreme caution.

4.4.4.2 Interviews

While the study relied on telephone interviewing for ethical and pragmatic reasons and this might have resulted in different responses to those elicited face to face, this method has proved effective in previous studies (e.g. Musselwhite et al., 2007). Also, although the interviews with the women themselves tended to be less than 30 minutes long, the fact that there was a degree of structure to them and the goal was not to build a theory, they were of adequate length to achieve their purpose. Although the interview schedules provided some structure and ensured that all the important aspects of the interview were covered, the aim was to respond to participants' priorities. However, it is possible that having to prompt the more reticent participants biased the findings. Also, the fact that it was a male who interviewed the pregnant women could have resulted in different

responses than if a female had conducted the interviews. It is also possible that the questions used created a bias towards the elicitation of cognitive over affective beliefs (see Section 3.4.1). The study was reported with reference to consolidated criteria for reporting qualitative research in the form of a 32-item checklist for interviews (Tong et al., 2007).

4.4.4.3 Coding

Deciding which was the most appropriate category to assign a coding unit to was in some cases problematic given certain overlap between themes. For example, social pressure was closely related to stigma and motivation, and safety was similar to being unsure if NRT was allowed. In some cases it was difficult to decide whether coding units should be considered as behavioural or control beliefs. For example, it could be argued that beliefs about safety of NRT, wanting to quit smoking without using NRT, and feeling self-conscious or embarrassed about using NRT are attitudinal and not control beliefs. Conner & Sparks (2005) reported similar concerns, stating that that distinguishing between behavioural and normative beliefs is somewhat arbitrary. However the fact that allocation to themes is susceptible to coder bias, this was at least to some extent offset by the very high agreement with the second coder.

4.5 STUDY ONE SUMMARY AND CONCLUSION

The range of behavioural, normative and control beliefs elicited in this study indicates that the TPB provided a useful framework for the investigation of pregnant women's beliefs about NHS Stop Smoking Services and NRT. The use of this model highlighted much evidence for positive and negative attitudes, strong and weak subjective norms, and inhibiting and facilitating factors influencing PBC in relation to both these behaviours. As such, it has identified those beliefs which might be particularly salient in influencing pregnant women's decision-making about engagement with Stop Smoking Services and NRT use. It has also illustrated where these might differ from the perceptions that health professionals who work with pregnant women have about these beliefs.

Pregnant women's beliefs about the consequences of engaging with Stop Smoking Services were receiving practical and emotional support, effectiveness of services, improving health and acquiring information. They believed that social pressure to engage or not engage with these services would stem from three main sources, namely, family, health experts and friends. The factors or

circumstances that they believed would inhibit or facilitate their engagement with these services were access to services, motivation, stigma, knowledge about services and fear of failure. A number of these themes overlap with those reported by Ussher et al (2006) in Section 2.2.2 which adds validity to the findings. The data tentatively suggest that health professionals might be overestimating pregnant women's beliefs about emotional support, acquiring information and health expert pressure and underestimating their beliefs about improved health. This would suggest that a greater focus on health issues might be beneficial in health professionals' discussions about smoking cessation with pregnant women. The attitudinal beliefs were mainly related to positive outcomes and the control beliefs were generally inhibiting factors. Although social pressure was felt to engage with services, resistance to act on this was evident. Given that engagement with Stop Smoking Services in pregnancy is low, this study tentatively suggests that the negative beliefs that hinder engagement (i.e. PBC) are more influential than the positive beliefs which promote it (i.e. attitude). This would seem to contrast the findings of Babrow et al. (1991) and Black & Babrow (1991) where positive attitudes were the most powerful predictors of students' intention to engage with and interest in a Stop Smoking programme (see Section 3.2.3). However, this might be a reflection of the particular influence of low self-efficacy amongst pregnant smokers (e.g. Godin et al, 1992). A quantitative study would need to be undertaken to more accurately assess the relative influence of the associated factors, but as the definition of engagement with Stop Smoking Services could be a broad one, applying the TPB to this behaviour might be challenging. In order to encourage engagement, the positive outcomes of engaging in Stop Smoking Services in pregnancy ought to be accentuated and any negative beliefs addressed via the provision of more accurate and consistent information.

The beliefs pregnant women had about the outcomes of using NRT (behavioural beliefs) centred around effectiveness, side effects, reduction of cravings, exacerbated sickness, financial cost, stress reduction, improved health, not being the same as quitting, satisfaction, and becoming addicted. Social pressure to use or not use NRT in pregnancy (normative beliefs) was perceived by the pregnant women to come from family, health experts and friends. The factors or circumstances considered by the pregnant women to inhibit or facilitate NRT use in pregnancy (control beliefs) related to safety, being unsure if it was allowed, convenience of use, ease of acquisition, self consciousness/embarrassment, knowledge about the products, smoking addition, wanting to quit without NRT

and forgetting to use NRT. As for the Stop Smoking Services data, some of the issues raised in this study are consistent with previous studies (e.g. Ashwin & Watts, 2009). The data tentatively suggest that health professionals might be overestimating pregnant women's beliefs about exacerbated sickness and safety, and underestimating their beliefs about improved health, NRT not being the same as quitting, family pressure, smoking addiction, and wanting to quit without NRT. Pregnant women might be more receptive to NRT advice if health professionals were to focus more on the issues the women themselves consider more salient. There were a mixture of positive and negative attitudinal, normative and control beliefs associated with this behaviour. The quantitative studies reported in Chapters Six & Seven will more accurately assess the influence of these factors on intention to use NRT in pregnancy. Shedding more light on the decision-making processes of pregnant smokers presented with the option of using NRT could enable smoking cessation advisors and other health professionals to tailor their discussions about NRT so that they address issues that smokers themselves believe are the most important. As alluded to by Thomson et al. (2006), if NRT is to become more widely used by pregnant smokers it is important that information about it is delivered in a way that emphasises the positive outcomes of using it, promotes societal acceptance of it and enhances PBC to use it.

Using the TPB as a framework, this study's findings provided detailed insight into the beliefs that pregnant women have about Stop Smoking Services and NRT and illustrated where these might differ from the perceptions that health professionals who work in smoking cessation have about these beliefs. Given that pregnant women targeted by such services are those who have not spontaneously quit or been able to quit on their own, they represent the group of smokers who find it most difficult to quit or who do not want to quit. Therefore, this study represents an important piece of research that has the potential to improve uptake of smoking cessation support in this hard to reach group. The elicited beliefs also provide a platform for the development of the smoking cessation advice resource (see Chapter Five) and the questionnaires to predict NRT use in pregnancy (see Chapters Six & Seven).

CHAPTER FIVE: DEVELOPMENT AND TESTING OF A THEORY-BASED RESOURCE TO FACILITATE MEDICAL STUDENTS' COMMUNICATION OF SMOKING CESSATION INFORMATION TO SIMULATED PREGNANT PATIENTS

5.1 STUDY TWO INTRODUCTION

Although a health professional's communication skills are now viewed as an important aspect of clinical management, they are not always performed optimally. For instance, doctors often fail to elicit adequate information about the concerns and perceptions patients have, perhaps fearing that they will not have the resources to cope with the impact of a more partnership approach (Maguire & Pitceathly, 2002). However, evidence shows that these skills can be taught, and when applied effectively can benefit both patient and health professional in a medical encounter (Buckman et al., 2002). For example, Coulter (2002) reported that in a systematic review of 17 trials of training interventions to promote a patient centred approach to clinical consultations, the majority improved consultation processes and patient satisfaction. Also, in a review of doctor-patient communication, Ong et al. (1995) reported that patient centred care where the health professional encouraged the elicitation of the patient's feelings and thoughts was associated with feelings of being understood, resolution of concerns and overall patient satisfaction with the consultation. Furthermore, a patient is more likely to act on the recommendations of a health professional if the latter accounts for the former's own interests and concerns (Clark & Gong, 2000). Good communication facilitates more accurate diagnoses, better patient understanding, improved treatment adherence, and lessens patient vulnerability to anxiety and depression (Maguire & Pitceathly, 2002).

The Calgary-Cambridge Observation Guide (Silverman, Kurtz & Draper, 1998) is an application of an evidence-based model of communication skills which specifies the requisite skills needed by a health professional when conducting a consultation. This model encompasses a number of different aspects of verbal and nonverbal communication under the broad categories of initiating the session, gathering information, building the relationship, and closing the session. The learner acquires the skills through practice in simulated scenarios and real settings, receiving constructive feedback and engaging in personal reflection. Well trained simulated patients have been shown to be a valid measure of quality of

patient care in both medical education settings and actual practice (Luck and Peabody, 2002). Although initially designed to aid the teaching of communication skills, the Calgary-Cambridge Observation Guide has more latterly become a recognised academic assessment tool (Lakasing, 2007). As such, it has been used to assess the communication skills component of medical students' Objective Structured Clinical Examinations (OSCEs) which are reliable and valid competency-based assessments of clinical ability (Barman, 2005).

It has been reported that the preferred option by midwives is for them to identify pregnant smokers and give initial smoking cessation advice before referring onto NHS Stop Smoking Services (McRobbie & Hajek, 2003). However, many health professionals working in routine care lack the knowledge and confidence to undertake this role with pregnant patients and have requested training for this (e.g. Clasper & White, 1995). It is possible that the inconsistency in provision of this advice by routine care providers (see Section 2.2.4) is one of the reasons for the lack of uptake of smoking cessation support in pregnancy. This suggests that a resource to guide health professionals through the process of providing initial smoking cessation advice and information about Stop Smoking Services to pregnant women would be beneficial for improving their communication skills in this role and potentially increase uptake of services.

The resource to be developed was underpinned by the Theory of Planned Behaviour (TPB) for a number of reasons. Firstly, there is a need for more theory-based interventions in health settings (e.g. ICEBeRG, 2006; see Section 3.5.3) and interventions using persuasive messages based on the TPB have shown some improvement in health behaviours and heath professionals' communication skills (see Section 3.5.2). The qualitative study in Chapter Four revealed a range of beliefs related to smoking cessation and Stop Smoking service use in pregnancy and although these data was not subjected to quantitative analysis to establish the most appropriate targets for an intervention, such beliefs are potentially modifiable (Ajzen, 2004). Furthermore, as it is a belief-based theory, there is reason to suppose that organising smoking cessation advice within a TPB framework might be effective in eliciting patient beliefs, which is a key communication skill for a health professional to acquire as defined by the Calgary-Cambridge framework.

5.2 STUDY TWO AIMS

1) To develop a TPB computer-based resource to ultimately facilitate the communication of smoking cessation information to pregnant smokers
2) To evaluate the effectiveness and acceptability of this resource compared to standard information using medical students as interviewers and simulated patients as interviewees

5.2.1 RESEARCH QUESTIONS

Compared to students who use standard information to guide their interview, will those who use the theory-based resource guide:
1) Be more effective in eliciting salient beliefs of the simulated patient (primary outcome)?
2) Display better general communication skills during the interview (secondary outcome)?
3) Perceive their guide as preparing them better for the interview (secondary outcome)?
4) Perform better on a subsequent OSCE (secondary outcome)?

5.3 STUDY TWO METHOD

5.3.1 STUDY DESIGN

A pilot, double-blind randomised controlled trial (RCT).

RCTs are considered to be the most rigorous way of establishing whether an intervention causes an outcome, and randomly allocating to condition minimises the risk of systematic differences between the intervention groups in terms of known and unknown confounding factors that may influence the outcome. Thus, any differences can be more confidently attributed to the treatment under study (Pandit & Yentis, 2005). Furthermore, double-blinding ensures that any preconceived views of participants and researchers cannot systematically bias the assessment of outcomes (Sibbald & Roland, 1998).

5.3.2 PARTICIPANTS

Participants were 2nd year medical students at the University of Nottingham. Although the ideal would have been to recruit practising health professionals who might wish to use such a resource in the course of their work, e.g. midwives, this was not feasible from a cost and time standpoint. The group used was considered

to be an acceptable substitute given that they were trainee health professionals who might find such a resource beneficial in the future, for example, if practising as a GP. Furthermore, this was fundamentally an exploratory study to test whether the resource aided the communication of health information, which is a key skill for a medical student to acquire. There were no exclusion criteria within this cohort. A formal power calculation was not performed because the sample size was dictated by practical considerations, such as participant availability and time constraints on the researchers, and because this was a feasibility study.

5.3.3 MATERIALS

5.3.3.1 Standard information communication skills training resource (control condition)

The standard information resource consisted of 8 Powerpoint slides (see Appendix 23), the first of which was a title slide. The second slide listed the aims of the resource which were to help medical students give relevant information to pregnant smokers to encourage them to use NHS Stop Smoking Services. The information relevant to pregnancy on the NHS SmokeFree website (http://smokefree.nhs.uk/) was accessed in November 2007 and informed the content of this resource. Adapting the format used in the 'S is for smoking and pregnancy' advice leaflet on this website, the material was organised under the following headings: 'How smoking affects unborn babies', 'Risks of smoking in pregnancy', Benefits of quitting in pregnancy', 'What if partners, friends or family smoke?', 'Help with stopping smoking', 'Nicotine Replacement Therapy'. Bullet-pointed statements appeared under each of these headings, and all slides were created in as large an Arial font as possible using a white background, and illustrative photographs were included on all but the 'Aims' slide.

5.3.3.2 Theory-based communication skills training resource (intervention condition)

The theory-based training resource guide consisted of 10 Powerpoint slides (see Appendix 24), the title and 'Aims' slides being the same as those in the standard information resource. The third slide briefly outlined the TPB and the rationale for using it as a framework for organising the subsequent information. On the remaining slides, the same, identically worded information to that provided in the standard information resource was used, but was organised as appropriate under the constructs defined by the TPB, namely, outcomes and perceived control with respect to engagement with Stop Smoking Services. Outcomes were couched in

terms of the gains that could be expected from engagement with Stop Smoking Services, i.e. 'finding out about the risks of smoking in pregnancy', 'finding out about the benefits of quitting in pregnancy', 'receiving specialised support', 'becoming a non-smoker', 'helping partners, friends and family to quit with the pregnant woman', and 'Nicotine Replacement Therapy'. Perceived control was couched in terms of factors that would make it easy to use Stop Smoking Services, i.e. that local services were free of charge and could take place in groups or one-to-one.

Information informed by Study One not present in the standard NHS information was added to the theory-based resource. On the 'Gains' slides, additional statements highlighted the non-judgemental nature of services, the fact that friends and family who smoked could also engage with the service, and that such services could provide access to free NRT. On the 'Ease of use' slide, additional statements highlighted the availability of flexible appointment times and home visits. An additional slide was based on the TPB construct of social pressure, which was couched in terms of why health experts would advocate engagement with Stop Smoking Services, and how such services would offer specialist support that might be lacking from family and friends. The layout of this guide was made as similar as possible to the standard information guide, using the same font style and background slide colour with the same photographs inserted alongside the relevant information where possible. In line with the recommendations for TPB interventions (see Section 3.5), the information provided was designed to have the potential to influence attitude, subjective norm and PBC by challenging any negative beliefs and creating or enhancing positive ones.

5.3.4 MEASURES

5.3.4.1 Communication skills checklist

A 27-item checklist was devised to score each medical student's interview performance (see Appendix 25). Eighteen of the items related to general communication skills for an explanation task adapted from checklists informed by the Calgary-Cambridge framework used routinely in summative assessment at University of Nottingham Medical School (see Appendix 26). The remaining nine items, informed by Study One, were concerned with medical students' ability to elicit the salient beliefs of the patient with respect to seeking help with quitting. Each item was scored on a 3-item scale: Yes, No, Partially, which reflected whether the item had been fully achieved, not achieved, or partially achieved.

The 'Yes', 'No' & 'Partially' responses on the communication skills checklist were converted to scores of 2, 0 & 1 respectively. For each participant, a total belief score between 0 and 18 (summing items 11-19) was calculated to assess how well the interviewer had elicited the beliefs of the simulated patient, and a total communication skills score between 0 and 36 (summing items 1-10 & 20-27) was calculated to assess the quality of the interviewer's communication skills during the interview.

5.3.4.2 Communication skills quality

An outcome measure was devised to rate the quality of the communication skills in each interview in terms of three elements, namely, clarity, rapport and thoroughness (see Appendix 27) which were cognitive, affective and behavioural components respectively, adapted from the Medical Interview Satisfaction Scale (Wolf et al., 1978). Each element, which was preceded by a definition, was scored on a 5-point Likert scale from ranging from 'low' to 'high'. The clarity, rapport & thoroughness scores were then summed to give a total score (between 3 and 15) for the communication skills quality of each interview.

5.3.4.3 Perceptions of resources

A further outcome measure, which was added to the student version of the communication skills quality measure, was devised to assess the participants' opinion of the resource they had viewed prior to conducting their interview (see Appendix 28). This comprised 5 statements asking participants whether the resource had provided them with sufficient knowledge, helped them with structure, helped them elicit patient views, instilled them with confidence, and prepared them for the interview. Each statement utilised a 7-point Likert scale ranging from 'strongly agree' to 'strongly disagree', thus a score from 1 to 7 could be obtained for each. Below these statements was a free text box in which additional comments about the resource could be provided.

5.3.4.4 OSCE scores

Scores on the Communication Skills component of the OSCE in June 2008 were obtained from Faculty Office, University of Nottingham Medical School to assess for differences in scores between those who had participated in the intervention and control conditions. This part of the examination involved an explanation task informed by the Calgary- Cambridge criteria outlined in Section 5.1, where students could obtain a percentage score between 0 and 100.

5.3.5 INTERVIEW TASK

5.3.5.1 Simulated patients

Prior to the study, the two simulated patients (SP1 & SP2) were sent a hypothetical scenario that they would be required to enact in the interview situation (see Appendix 29), and a set of instructions on how to answer the types of questions that would likely be asked by the interviewer (see Appendix 30). The scenario outlined that the simulated patient was a pregnant smoker who wished to quit and had been asked by her midwife to receive some information about smoking cessation from a 2nd year medical student. Embedded within this scenario were 9 beliefs the woman had which were acting as barriers to her seeking help with quitting (see Table 1). At the bottom of the sheet there was a set question the simulated patient was instructed to ask if the interviewer was to ask if she had any questions. If asked, the simulated patient was told to say that she had little knowledge about smoking related harms in pregnancy, NHS Stop Smoking Services and NRT. She was also told to only give information about her beliefs about smoking cessation, Stop Smoking Services and NRT if specifically prompted to do so. Furthermore, within these three categories she was instructed to reveal each belief in the ordered sequence listed if probed further, i.e. one belief per separate probe (see Table 5.1). The researcher, who was present during each interview, was able to monitor whether the simulated patient was answering in accordance with the protocol she had received.

Table 5.1 Beliefs of simulated patient and ordered sequence in which they were to be revealed

Beliefs about smoking cessation:
1) She believes it will be difficult to quit because partner smokes
2) She believes that social pressure to quit from parents and GP is stopping her trying
Beliefs about Stop Smoking Services:
1) She does not believe Stop Smoking Services will help
2) She is concerned about having to talk in front of a group at Stop Smoking Services
3) She believes the Stop Smoking service advisor will make her feel more guilty about smoking
4) She believes she will not be able to attend regular clinics because of child
5) She is worried that if she can't quit she will be letting the advisor down
Beliefs about NRT:
1) She believes NRT is not safe to use in pregnancy
2) She believes she will not be able to afford NRT

5.3.5.2 Medical students

On arrival for the study, the medical student received a sheet explaining the explanation task they would be required to undertake. This contained a brief summary of the simulated patient scenario, but did not include any information about her beliefs. Below this was a list of headings from the resource the student was allocated to which he or she was advised to follow when interviewing the simulated patient. At the bottom of the sheet was a list of the main communication skills components informed by the Calgary-Cambridge framework for a medical interview that the student was also reminded to incorporate. Students received either a version of the explanation task sheet with headings from the standard information or theory-based resource as appropriate (see Appendices 31 & 32).

5.3.6 PROCEDURE

Second year medical students were given information about the study at the end of a lecture delivered by the communication skills module coordinator (VT) approximately one month before the study commenced. They were told that they were being asked to volunteer for a research project investigating the effect of preparation material on communication skills. Students were informed that participation in the study would offer exemption for a part of the communication skills module coursework requirements and would also be an opportunity for them to practice their explanation skills in preparation for the forthcoming OSCE. Students who emailed their consent to participate were allocated a time slot on one of four days in the study schedule between December 2007 and February 2008. Prior to study commencement, participant allocation to condition was pre-determined by the researcher (LJ[1] or JT) randomly assigning each time slot to the intervention or control condition using a coin toss. The two simulated patients were assigned to time slots on the basis of their availability. Upon arrival, the participant was shown to a private computer room in the Behavioural Sciences department where the PC had been set up by the researcher to show either the intervention or control resource guide, dependent on group allocation. The participant was given 2 minutes to read a set of standardised instructions for the study (see Appendix 33) which outlined that they would be required to view the Powerpoint resource as preparation for the subsequent explanation task, the details of which were on a sheet in front of them (see Section 5.3.5.2). Also in the computer room was a paper copy of the appropriate resource guide if

[1] Third year medical student coordinated days 1 & 2 of the study

participants preferred to use this instead of viewing the PC screen. Participants were given 10 minutes to view the resource and familiarise themselves with the explanation task appropriate to their group allocation, after which they were escorted to a recording studio to complete the interview task. Participants had a maximum of 10 minutes for this explanation task and were given a verbal reminder from the researcher when they had 1 minute remaining. The interviews were videotaped by the researcher to enable them to be independently rated at a later time. After the interview, the medical student and simulated patient were each requested to complete a questionnaire to assess their perceptions of the communication skills quality (see Section 5.3.4.2), and in the student's case, their views about the resource they had be allocated to (see Section 5.3.4.3). Video tapes of the interviews, identified by study numbers, were passed to the independent assessor for rating on completion of the study, along with a set of notes (see Appendix 34) as guidance for how to score the items on the communication skills checklist. The independent assessor also assessed the communication skills quality of each interview using the outcome measure described in Section 5.3.4.2. Although not blind to condition, the researcher (LJ) also used the communication skills checklist to rate the interviews that took place on the first two days in order to assess the reliability of the independent assessor's ratings.

5.3.6.1 Ethical considerations

As this study was classified as educational research, formal ethical approval was not required. However, the students were informed that they were participating in a research project and were reminded of their right to withdraw at any point if they wished to do so. They were also told that they would receive email feedback about the study and their communication skills as soon as all the interviews had taken place. No incentives were provided beyond informing the students that volunteering for this study would count towards their communication skills coursework requirements and be an opportunity for them to practice their communication skills in preparation for the OSCE.

5.3.7 DATA MANIPULATION AND ANALYSES

The data were made anonymous by use of study numbers and were analysed in SPSS for Windows (Version 15.0).

5.3.7.1 Testing for demographic, simulated patient allocation and interview duration differences between conditions

As a test of normality for a sample size of less than 50 (Shapiro-Wilk) showed that age was not normally distributed, a Mann-Whitney U test was conducted to assess for any age differences between the intervention and control group. Given that two cells had an expected frequency of less than 5, Fisher's Exact Probability Test was used to assess for any association between gender and intervention or control condition. As no cells had an expected frequency of less than 5, a chi-square test for independence (with Yates Continuity Correction) was used to assess for any association between simulated patient allocation and intervention or control condition. A Mann-Whitney U test was conducted to assess for any differences in interview duration between the intervention and control groups given that a Shapiro-Wilk test had shown that this variable was not normally distributed.

5.3.7.2 Reliability of independent assessor scoring using communication skills checklist

Interrater reliability analyses using intraclass correlation coefficients were performed on the 22 cases which were second rated to determine the level of agreement between the independent assessor and the researcher (LJ) for the belief item and communication skills item scoring on the communication skills checklist.

5.3.7.3 Belief elicitation

To assess whether the intervention group was more effective in eliciting salient beliefs of the simulated patient than the control group, a three-way between groups ANOVA was conducted with group, gender and simulated patient as categorical independent variables and total belief score as the continuous dependent variable. According to a Shapiro-Wilk test, the total belief scores were normally distributed and Levene's Test indicated equal variances of the dependent variable across the groups. The nine belief items were then dichotomised into either elicited or not by recoding the 'partially achieved' scores as 'not achieved'. Chi-square tests of independence (with Yates Continuity Correction) or Fisher's Exact Probability tests (where cells had an expected

frequency of less than 5) were conducted on these nine items to test for associations between belief elicitation and condition.

5.3.7.4 Communication skills

To assess whether those in the intervention group displayed better communication skills during the interview than those in the control group, a three-way between groups ANOVA was conducted with group, gender and simulated patient as categorical independent variables and total communication skills score as the continuous dependent variable. Although a Shapiro-Wilk test showed that communication skills scores were not normally distributed, this test is reported to be robust to deviations from normality (Glass et al., 1972) and Levene's test did indicate equal variances of the dependent variable across the groups. To test for differences in the simulated patients' perception of communication skills quality between the intervention and control condition, a Mann-Whitney U test was conducted because a Shapiro-Wilk test had shown that these communication skills quality ratings were not normally distributed. To test for differences in the independent assessor's perception of communication skills quality between the intervention and control condition, an independent samples t-test was conducted as a Shapiro-Wilk test had shown that these communication skills quality ratings were normally distributed. To test for differences in the medical students' perceptions of communication skills quality between the intervention and control condition, a Mann-Whitney U test was conducted because a Shapiro-Wilk test had shown that these communication skills quality ratings were not normally distributed. Interrater reliability analysis using an intraclass correlation coefficient was performed to determine the level of agreement between the independent assessor, simulated patient and medical student ratings for communication skills quality.

5.3.7.5 Perceptions of resources

To assess whether those in the intervention group perceived their resource more favourably than those in the control condition, Mann-Whitney U tests were performed on the items relating to 'knowledge', 'structure', 'patient views', 'confidence' and 'overall preparedness' given that Shapiro-Wilk tests had shown that none of the ratings on these five items were normally distributed. The qualitative data from the free text box were summarised.

5.3.7.6 Subsequent OSCE scores

To assess for differences in the subsequent Communication Skills OSCE scores between the intervention and control condition, a Mann-Whitney U test was conducted given that a Shapiro-Wilk test had shown that these scores were not normally distributed.

5.3.7.7 Correcting for multiple testing

None of the results from above tests were corrected for multiple testing as this study was deemed to be an exploratory investigation.

5.3.7.8 Post-hoc power calculation

Although a formal power calculation was not performed prior to the study, a post-hoc power calculation was conducted to assess the study's ability to detect differences in the primary outcome (total belief score) between conditions.

5.4 STUDY TWO RESULTS

Figure 5.1 shows the flow of participants through each stage of the RCT, and that once randomly allocated, all students followed the procedure. Table 5.2 shows that there were no significant differences in age, gender, simulated patient allocation and interview duration between the intervention and control groups.

5.4.1 RELIABILITY OF INDEPENDENT ASSESSOR SCORES ON COMMUNICATION SKILLS CHECKLIST

Using a two way random effects model with an absolute agreement definition, the single measures intraclass correlation coefficient for belief scores was 0.90 (95% CI 0.62, 0.97), $F(21, 21) = 30.78$, $p = .001$, and for communication skills scores was 0.63 (95% CI 0.18, 0.84), $F(21, 21) = 5.88$, $p = .001$. According to guidelines of Landis & Koch (1977), this represented 'almost perfect' and 'substantial' agreement between the two raters for belief and communication skills scores respectively. From these findings, it was assumed that the independent assessor was rating reliably across all four days of the study.

5.4.2 PRIMARY OUTCOME MEASURE (TOTAL BELIEF SCORE)

Table 5.3 shows that there was no significant difference between the total belief scores for the intervention and control group as independently rated using the communication skills checklist. The mean difference between the conditions was 0.74 (95% CI: −2.05, 3.54). The mean scores indicate that in both conditions the

beliefs were not very well elicited with only 46.72% and 42.61% of the total possible score (18) being achieved by the intervention and control groups respectively. A post-hoc power calculation was performed as follows. Based on a pooled mean value for total belief score of 8.08 (S.D. 4.30), alpha = 0.05 and 80% power, the detectable difference between the intervention and control group based a sample size of 20 per group would be between -3.90 and +3.90. Therefore, given that the mean for the control group was 7.67, the trial had 80% power to rule out a true mean of less than 3.77 or more than 11.57 in the intervention group. Although there was a statistically significant main effect for simulated patient, $F(1, 32) = 8.75$, $p = .01$, the interaction effect between group and simulated patient was not statistically significant, $F(1, 32) = .03$, $p = .86$. Thus, there were no significant differences in the effect of SP1 and SP2 on total belief scores for the intervention and control condition. There was no significant main effect for gender or significant interactions in the model.

5.4.3 SECONDARY OUTCOME MEASURES

Table 5.3 shows that medical students in the intervention condition were more likely, and those in the control condition were less likely, to elicit the belief 'social pressure to quit is stopping her trying'. This is a medium to large effect using Cohen's (1988) criteria. No associations between the remaining 8 beliefs and condition were found. Table 5.3 shows that there was no significant difference between the total communication skills scores for the intervention and control group as independently rated using the communication skills checklist. Communication skills were performed relatively well across conditions, with 80.17% and 78.86% of the total possible score (36) being achieved by the intervention and control conditions respectively. There were no significant main effects for gender or simulated patient or significant interactions in the model. Table 5.3 shows that there were no significant differences in the simulated patient, independent assessor or medical student perceptions of communication skills quality between the intervention and control groups. However, based on a maximum score of 15, the mean ratings indicate that communication skills quality was generally perceived to be of an acceptable standard from all three perspectives across both conditions. Using a two way random effects model with an absolute agreement definition, the average measures intraclass correlation coefficient for communication skills quality scores was 0.46 (95% CI 0.07, 0.70), $F(39, 78) = 2.15$, $p = .002$. According to guidelines of Landis & Koch (1977), this represented 'moderate' agreement between the simulated patient, independent assessor and medical student ratings.

Figure 5.1 Flow diagram of participant progress through phases of RCT

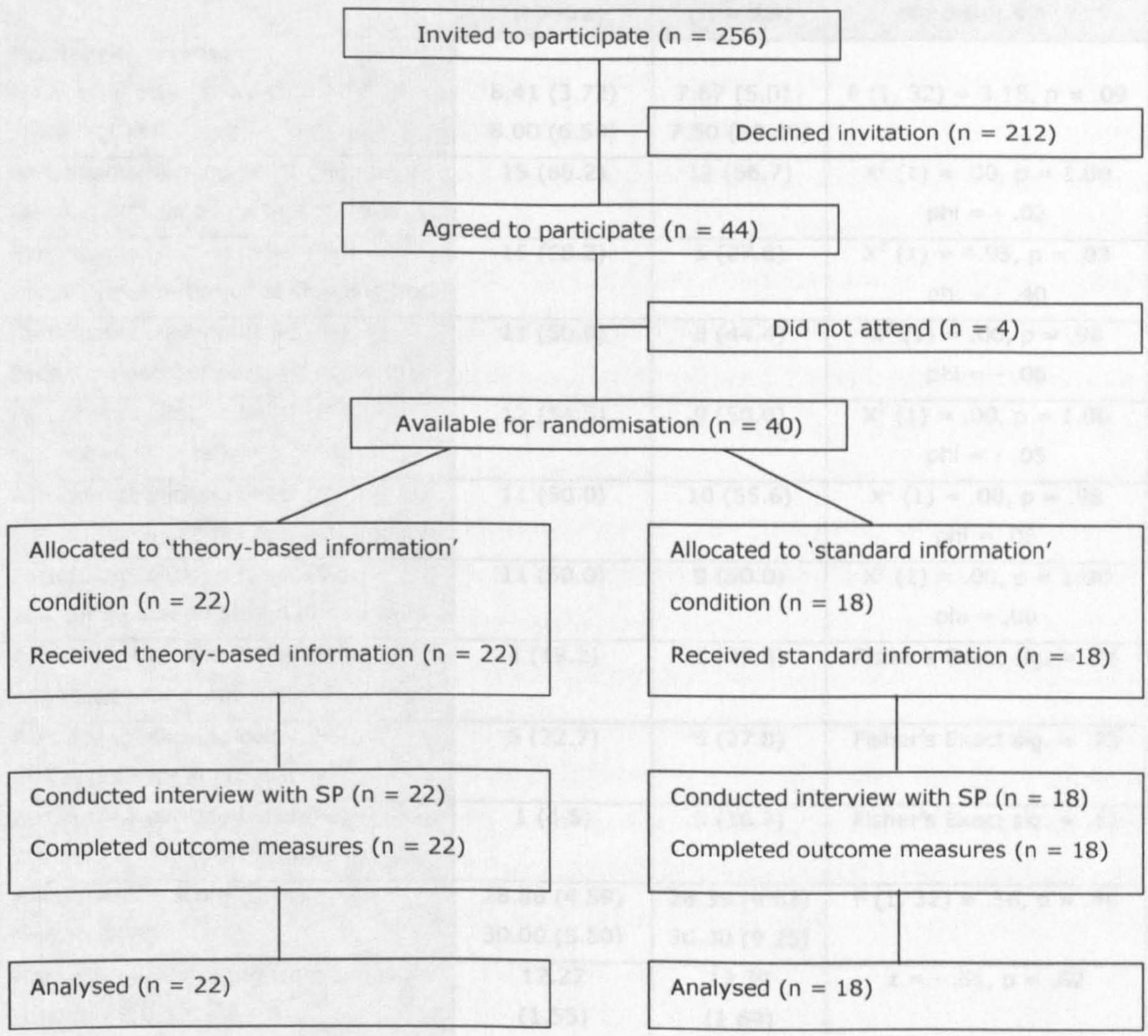


Table 5.2 Demographic characteristics of participants, simulated patient allocation and interview duration

	Intervention (n = 22)	Control (n = 18)	Difference between conditions *
Mean age of participant (S.D.)	21.00 (2.53)	22.06 (5.42)	z = - .66, p = .55
Gender of participant	5 male 17 female	3 male 15 female	Fisher's Exact sig. = .71
Interviewed SP1 **Interviewed SP2**	14 8	12 6	X^2 (1) = .00, p = 1.00, phi = - .03
Mean interview time (mins) (S.D.)	8.85 (1.67)	8.46 (1.87)	z = - 1.04, p = .31

* All 2-tailed / 2-sided tests

Table 5.3 Primary and secondary outcome measures

	Intervention (n = 22)	Control (n = 18)	Difference between conditions ***
Primary outcome:			
Mean total belief score (S.D.) *	8.41 (3.72)	7.67 (5.01)	F (1, 32) = 3.15, p = .09
Median (IQR)	8.00 (6.50)	7.50 (10.00)	
Participants eliciting belief (%): Quitting difficult as partner smokes	15 (68.2)	12 (66.7)	X^2 (1) = .00, p = 1.00 phi = - .02
Participants eliciting belief (%): Social pressure to quit is stopping her	15 (68.2)	5 (27.8)	X^2 (1) = 4.95, p = .03 phi = - .40
Participants eliciting belief (%): Stop Smoking Services will not help	11 (50.0)	8 (44.4)	X^2 (1) = .00, p = .98 phi = - .06
Participants eliciting belief (%): Will not want to talk in a group	12 (54.5)	9 (50.0)	X^2 (1) = .00, p = 1.00 phi = - .05
Participants eliciting belief (%): Advisor will make her feel more guilty	11 (50.0)	10 (55.6)	X^2 (1) = .00, p = .98 phi = .06
Participants eliciting belief (%): Will not be able to attend due to child	11 (50.0)	9 (50.0)	X^2 (1) = .00, p = 1.00 phi = .00
Participants eliciting belief (%): Will let advisor down	4 (18.2)	5 (27.8)	Fisher's Exact sig. = .71
Participants eliciting belief (%): NRT is not safe in pregnancy	5 (22.7)	5 (27.8)	Fisher's Exact sig. = .73
Participants eliciting belief (%) Will not be able to afford NRT	1 (4.5)	3 (16.7)	Fisher's Exact sig. = .31
Mean total CS score (S.D.) *	28.86 (4.59)	28.39 (4.62)	F (1, 32) = .56, p = .46
Median (IQR)	30.00 (5.50)	30.00 (9.25)	
Mean CS quality rating from simulated patients (S.D.) *	12.27 (1.55)	12.39 (1.69)	z = - .51, p = .62
Mean CS quality rating from independent assessor (S.D.) *	10.32 (2.73)	10.67 (3.03)	t (38) = - .38, p = .70
Mean CS quality rating from medical students (S.D.) *	10.27 (1.35)	10.61 (2.06)	z = - .33, p = .76
Mean student rating for resource providing knowledge needed (S.D.) **	6.41 (0.73)	6.67 (0.49)	z = - 1.04, p = .38
Mean student rating for resource helping with structure (S.D.) **	6.27 (1.03)	6.28 (0.96)	z = -.20, p = .86
Mean student rating for resource helping elicit patient views (S.D.) **	5.50 (0.91)	4.78 (1.35)	z = - 1.80, p = .09
Mean student rating for resource providing confidence (S.D.) **	5.95 (0.90)	6.17 (0.86)	z = - .81, p = .46
Mean student rating for resource preparing them well (S.D.) **	6.09 (0.75)	6.28 (0.67)	z = - .78, p = .48
Mean OSCE percentage score of medical student (S.D.)	69.77 (22.93)	75.50 (15.98)	z = - .76, p = .46

* Higher scores reflect better communication skills

** Higher scores reflect more favourable view of resource

*** All 2-tailed / 2-sided tests

Table 5.3 shows that there were no significant differences in the ratings given for the theory-based and standard information resource in terms of providing knowledge, aiding structure, helping to elicit patient views, instilling confidence and preparing the student for the interview. On the whole, the scores indicate that both resources were viewed favourably by the students who used them. Additional qualitative data about the resource guides provided by 14 students from the intervention group and 11 from the control group largely provide support for the above findings. Comments generally indicated that both resources were good preparation for the interview by increasing knowledge, understanding and confidence via a concise content that was easy to read. Although both resources were generally praised for their structure and layout, one student felt that the sequence of the theory-based resource was confusing, whilst a student in the control group felt that some of the statements were ambiguous and would have preferred a more interactive presentation. Whilst a few students felt that the resources lacked information, the main criticism across both conditions was a lack of time to digest the resource information prior to interview. Table 5.3 shows that there were no significant differences in subsequent OSCE scores between those in the intervention and control group. Neither were there any significant differences in OSCE scores between those 2nd year medical students who participated in the trial (Md = 73, n = 40) and those who chose not to (Md = 64, n = 216), z = -1.31, p = .19 (2-tailed).

5.5 STUDY TWO DISCUSSION

The RCT showed there to be a small (0.74 of a unit) increase in mean total belief score from the intervention group compared to the control group, which was not a significant difference. Therefore, those who received the theory-based resource were no better at eliciting the beliefs of the simulated patient than those who received the standard information resource. However, the p-value of 0.09 suggests a trend towards significance in the anticipated direction for this primary outcome. Based on the post-hoc power calculation (see Section 5.4.2), the trial had 80% power to rule out a true mean of less than 3.77 or more than 11.57 in the intervention group. As the detectable difference between the intervention and control group would be between -3.90 and +3.90, the trial was underpowered to detect small differences between intervention and control conditions if they existed. The total belief scores indicate that the beliefs were generally poorly elicited across both conditions so there was no ceiling effect, which can be a

reason for unsuccessful interventions (Watson et al., 2006). Those in the intervention group were more likely, and those in the control condition were less likely, to elicit the belief 'social pressure to quit is stopping her trying'. As this was the second item on the ordered sequence, this would suggest that the intervention group probed further about the patient's beliefs about stopping smoking. Also, the fact that normative beliefs are a core component of the TPB indicates that students in this condition were at least utilising the model to some degree. Given the extent of the social pressure felt by pregnant smokers to quit, eliciting these beliefs and attempting to modify them could be influential in changing smoking behaviour in this group. There were no significant differences between conditions on any of the other individual beliefs and it is possible that few differences were found because students were generally not very skilled or practised at eliciting patient beliefs.

There were no significant differences between the mean total communication skills scores for the intervention and control groups, indicating that those who received the theory-based resource displayed no better general communication skills than those who received the standard information resource. Compared to the belief elicitation, communication skills were performed relatively much better across both conditions, perhaps because of the training the students has already received on this. It is possible that the communication skills criteria acted against a belief effect as the students were entrenched in carrying out the explanation task in the way defined by their training. It is important to note that use of the theory-based resource did not detract from the quality of the general communication.

There were no significant differences in the simulated patient, independent assessor or medical student perceptions of communication skills quality between the intervention and control groups, but the mean scores showed that communication skills quality was perceived to be of an acceptable standard across both conditions. Although these were subjective ratings, the moderate agreement between the simulated patient, independent assessor and medical student scores indicates a degree of reliability. Neither were there any significant differences between the intervention and control groups in terms of their resource providing knowledge, aiding structure, helping to elicit patient views, instilling confidence and preparing the student for the interview. The favourable mean scores on these measures showed that both resources were viewed as equally acceptable to the users. There was a trend towards a significant difference ($p = 0.09$) between the

groups for the perception of the guide as a facilitator to the elicitation of patient views with a stronger agreement to this statement from those who viewed the theory-based guide than those who viewed the information only guide. This trend is similar to that found for the primary outcome and offers further tentative support for the potential utility of the theory-based guide in facilitating a patient centred interview. There were also no differences in subsequent OSCE scores between those in the intervention and control group, which suggests that neither resource provided a specific advantage in terms of preparation for an explanation task.

On the whole, these findings show that there were no significant differences on the outcome measures between the intervention and control groups. This is consistent with the findings of Brubaker & Fowler (1990) and Armitage & Conner (2002) where theory-based interventions were no more effective than standard information (see Section 3.5.2). The fact that both resources were rated favourably by the groups who viewed them suggests that simply having some good quality information on the topic was sufficient for user satisfaction. Both resources appeared to facilitate good general communication skills equally well and although they were less successful in helping students to elicit patient beliefs, there was some evidence to suggest that the theory-based resource showed more potential in this regard. Although Aizen (1991) and Hardeman et al. (2002) argued that information and persuasion are highly appropriate strategies for interventions based on the TPB, the TPB does not explain how to change behaviour or specify which methods to select for an intervention (Taylor et al., 2006). Therefore it is possible that the method chosen for this study was ineffective and another technique would have been more suitable in this context. Alternatively, students might have needed to be more familiar with the resource in order for it to be fully effective.

5.5.1 STUDY STRENGTHS AND LIMITATIONS

5.5.1.1 Study design

The RCT is considered to be the gold standard research design and double blinding further strengthened this rigorous approach (see Section 5.3.1). The students, simulated patients and independent assessor were not provided with feedback about the exact nature of the study until all the interviews were completed and rated. Use of standardised instructions further served to maintain consistency of procedure and reduce the likelihood of introducing researcher bias.

The study was reported with reference to the CONSORT guidelines for randomised trials (Moher et al., 2001). Whilst the method of simple randomisation (via a coin toss) used to allocate participants to condition resulted in fairly equal numbers in each condition, it is recognised that this might not have been the case in a trial of this size (Kang, Ragan & Park, 2008). Had there been very unequal numbers in each condition, this would have reduced the precision of estimates of the difference in treatment effect and hence the efficiency of the study (Roberts & Torgerson, 1998). To guarantee that at no time would the imbalance be large, a block (restricted) randomisation strategy could have been employed instead (Altman & Bland, 1999). With the benefit of hindsight, it would have also been more appropriate to randomise each participant at the point of entry to the study, preferably with this process being concealed from the researchers by 'distance' randomisation (Torgerson & Roberts, 1999). Having designated time slots randomised to condition by the researchers prior to the study had the potential to introduce systematic bias into the allocation procedure.

5.5.1.2 Participants

There were no differences between the demographic characteristics of participants, the allocation of simulated patients and interview duration across the two conditions, and all the medical students who participated had received identical training on communication skills. The fact that participants in the study did not score differently on a subsequent OSCE compared to those who declined to participate would indicate that the sample was representative of the cohort in terms of communication skills ability. However, given that this was an exploratory pilot study, interpreting the findings was compromised by the small numbers in the trial which was underpowered to detect any small differences between conditions, i.e. the difference of 0.74 was too small to have been detectable as significant had it been so. In a more definitive RCT, an a priori power calculation would need to be performed by firstly specifying the minimum clinically important difference (MCID) in advance. Then this MCID could be used to calculate the sample size required in order to reject the null hypothesis. Nevertheless, this exploratory study could help to inform the required sample size for a more definitive study by making use of the standard deviation information which forms part of the sample size equation.

5.5.1.3 Resources

Attempts were made to match the theory-based and standard information guides as far as possible, using the same wording, fonts, and pictures where appropriate. However, the theory-based resource did contain more slides and text which might have made it more difficult to assimilate the information effectively, especially as the main complaint across both conditions was insufficient time to digest the information provided. It could also have been more challenging to deliver the information contained within this resource in the time allotted for the interview. However, the fact that the average length of interviews in the intervention and control conditions were similar suggests that this was not so, and would also indicate that 10 minutes duration was generally adequate. Consideration had been given to allowing students' to view the presentations ahead of time, but this was decided against because of a wish to control for the length of viewing time and for fear that letting students view their resource outside a controlled environment might cause contamination between conditions. Even with the strategy used, the possibility that students passed information about the task on to colleagues attending later cannot be ruled out. It is possible that only allowing students a relatively short amount of time to digest the information provided could have compromised their use of it, particularly in the case of the theory-based resource where novel concepts were likely being introduced. It was not feasible to give students longer for this task because of time constraints on the testing days, but setting up the presentations on a loop with manual control did give the students a degree of flexibility and allowed them to maximise the time they had in whichever way they saw fit. As with the study by Armitage & Conner (2002) reported in Section 3.5.2.1, there was no way of assessing the amount of effort students put into assimilating the information provided. However, given the voluntary nature of the task and the fact that it was promoted as further practice for their OSCE, it is likely that they were highly motivated. Although it was considered that organising the intervention resource in terms of the TPB would help the recipient to elicit salient beliefs, it is possible that this resource merely provided information in the same way as the control resource did.

5.5.1.4 Simulated patients

It is recognised that this study did not use real patients and that priming simulated patients to give standardised responses to specific types of questions in an artificial setting involving diverse interviews represented a challenge. Although every effort was made to instruct the simulated patients to respond appropriately

and consistently through the use of clear guidelines, it is acknowledged that contraventions to standardised instructions can occur when using simulated patients (Myford & Wolfe, 2003) and attempts should be made to control for this (Iramaneerat et al., 2008). Even though both simulated patients were blind to condition and were prepared identically for the task, significantly better total belief scores were achieved for one simulated patient compared to the other suggesting that the simulated patients were behaving differently in terms of volunteering beliefs. Perhaps this was because one simulated patient volunteered more information than was stipulated or the other was less sensitive to the cues of the interviewer. However, this effect was consistent across conditions. Although the simulated patients were told to volunteer a belief even if it had already been covered by the medical students as part of their explanation, it is possible that, when later prompted, they did not state this belief and the student was recorded as not eliciting it. Although the ideal outcome measure in terms of TPB research would have been intention to engage or engagement with Stop Smoking Services, it was not considered appropriate for simulated patients to estimate the hypothetical likelihood that they would engage on the basis of the interview. Furthermore, the primary aim of the study was to assess the patient centred communication skills of the students using the resources. The use of simulated patients is a valid means of testing communication skills as they reduce an important source of variability. However, to achieve this, it is very important that accuracy and consistency of their responses are acquired through good training. Great care should also be taken when selecting simulated patients and it is essential that debriefing and monitoring of simulated patients takes place (Wallace, Rao & Haslam, 2002). If this study was to be repeated, these issues would be addressed in greater detail.

5.5.1.5 Outcomes measures

It was felt that eliciting beliefs and concerns which had the potential to be modified in a high quality interview were both objective measures and realistic proxies for engagement. However, it is acknowledged that none of the measures used were validated. It also had to be assumed that the independent assessor was rating consistently across interviews, although the high level of agreement between their scores and those of the researcher (LJ) provided confidence that this was likely to be so.

5.6 STUDY TWO CONCLUSION

This exploratory pilot RCT represented an attempt to design an intervention specifically based on the TPB embedding salient beliefs established in a previous elicitation study which could be targeted. Although the RCT did not reveal any significant differences between the intervention and control groups, the theory-based resource showed some potential for facilitating belief elicitation without compromising general communication skills. Even though this study suggests that a theory-based smoking cessation resource has potential to encourage a patient centred interview, it cannot be assumed that the findings from this pilot would necessarily generalise to a real world setting. Future research would need to test the resource using a larger sample where the patients are real pregnant smokers and the outcome measure is intention to engage or engagement with Stop Smoking Services. In this situation, users of the resource would also have longer to assimilate the information contained within it and become familiar with its theoretical underpinnings. It would also be useful to measure the effects in the targeted the components to assess whether the method used had been effective in changing the underlying theoretical constructs (Eccles et al., 2005). If successful, such a resource could be a valuable asset to a health professional wanting to offer patient centred advice to a pregnant smoker and encourage uptake of Stop Smoking Services in this group.

CHAPTER SIX: DEVELOPMENT AND TESTING OF A THEORY OF PLANNED BEHAVIOUR QUESTIONNAIRE TO PREDICT INTENTION TO USE NICOTINE REPLACEMENT THERAPY IN PREGNANCY

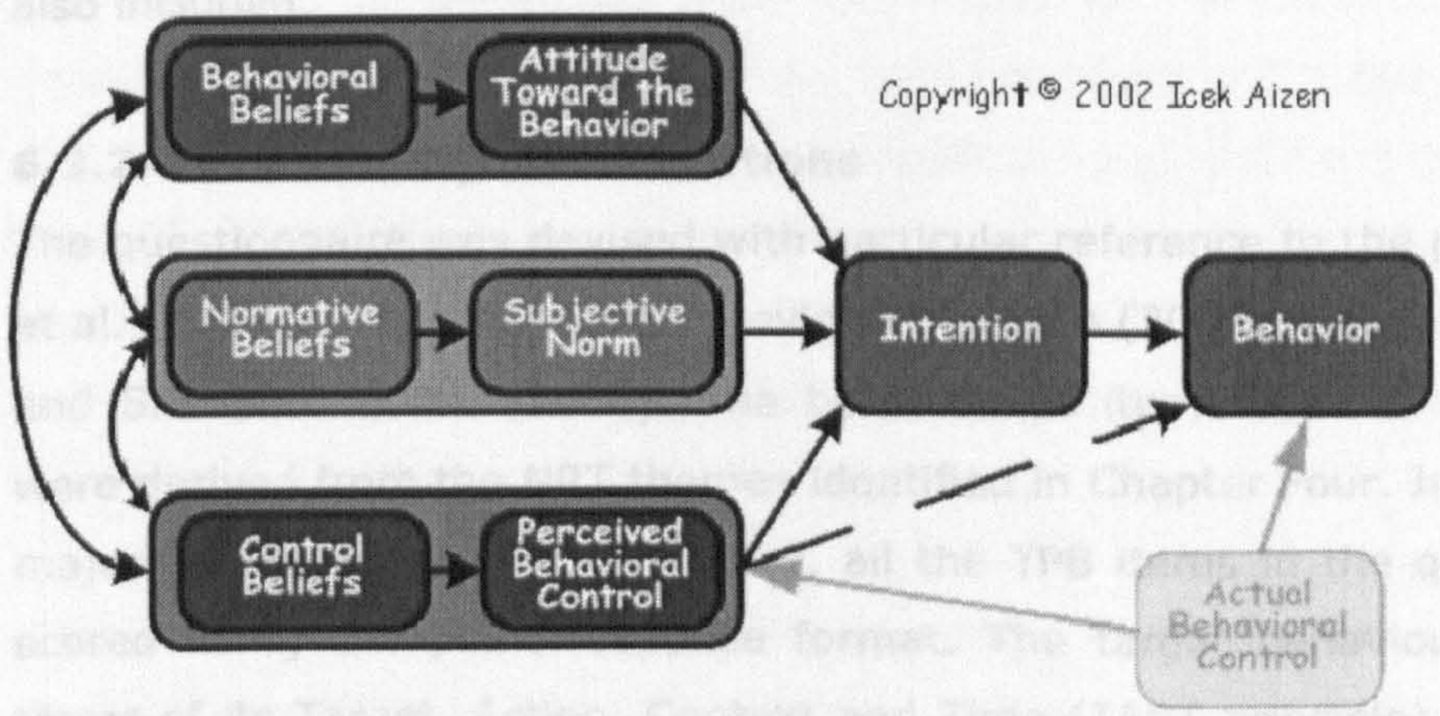
6.1 STUDY THREE INTRODUCTION

As highlighted in Section 2.2.3, very little research has been conducted into pregnant women's views about using NRT and consequently little is known about why some women are prepared to use it but others are not. Now that NRT is being prescribed to pregnant women in increasing numbers, it is important to find out more about the factors which predict pregnant smokers' decisions about using it. To the researcher's knowledge, no theory-based quantitative measure has been devised to predict intention to use NRT in pregnancy. Only one study by Etter & Perneger (2001) could be found where a measure was produced to assess attitudes to NRT, and this relates to the general public. In that study, qualitative data were used to inform item selection, and the resulting validated scale (ANRT-12) comprised two subscales: advantages of NRT (8 items) and drawbacks of NRT (4 items). Both attitude scales were associated with intention to use NRT and those who had experience of using NRT had more favourable attitudes towards it than those who had never used it. Attitude scores were also associated with duration of NRT use but not with age, number of cigarettes smoked per day, number of years as a smoker or intention to quit smoking. Although it was acknowledged that the causal nature of these associations could not be firmly established in a cross-sectional study, the authors suggested that the scale could be used as a screening tool in clinical practice to detect patients with negative attitudes towards NRT. It was reported that these patients could then receive specific counselling which may result in better compliance with NRT and increased chances of quitting.

The NRT themes derived from the qualitative study (see Chapter Four) will be used to inform the development of a Theory of Planned Behaviour (TPB) questionnaire to predict NRT use in pregnancy. This study employed both the direct attitude, subjective norm and perceived behavioural control (PBC) measures of the TPB as described in Section 3.1.1 and the indirect behavioural, normative and control belief measures which underpin these outlined in Section 3.1.2 (see Figure 6.1 for model description). These TPB constructs were

operationalised in accordance with the current guidance for such a questionnaire (see Francis et al., 2004). This questionnaire will provide information about the decision making processes of pregnant women presented with the option of using NRT, the findings of which should be relevant and useful for health professionals working in smoking cessation. It should provide further information on the perceived benefits and barriers to NRT use in pregnancy but, crucially, highlight the very specific beliefs and attitudes that influence whether or not women choose to use NRT.

Figure 6.1 Theory of Planned Behaviour (Ajzen, 1988, 1991)



As TPB questionnaires are often considered to be rather lengthy (Giles et al., 2007), if this long form Nicotine Replacement Therapy in Pregnancy questionnaire (NRTP-LF) proves to be a good predictor of intention to use NRT, the aim is to produce a short form version of it (NRTP-SF) which could ultimately have more practical utility. Given that the evaluative items can make such questionnaires appear rather repetitive and can comprise face validity (see Section 3.4.3), it is possible that these will be omitted from the NRTP-SF if they appear to add little extra variance. Another strategy to reduce the questionnaire in length might be to include only indirect measures, but this would need to be justified by assessing the validity of these in the NRTP-LF to check that they adequately cover the breadth of the direct measures and that they are also able to predict intention.

6.2 STUDY THREE AIMS

1) To develop a TPB questionnaire to predict intention to use NRT in pregnancy (NRTP-LF).

2) To test the predictive validity of this questionnaire using a sample of pregnant smokers.

3) To create a short form version of the questionnaire (NRTP-SF).

6.3 STUDY THREE METHOD

6.3.1 STUDY DESIGN

A cross-sectional survey

6.3.2 QUESTIONNAIRE ITEM CONSTRUCTION

To produce the NRTP-LF, it was necessary to devise direct measures to assess the constructs of attitude, subjective norm and PBC with respect to the behaviour, and the underlying belief-based (indirect) measures for each of these three constructs. Items to assess the demographic characteristics of respondents were also included.

6.3.2.1 Preliminary considerations

The questionnaire was devised with particular reference to the protocol of Francis et al. (2004), plus information provided by Aizen (2002), Conner & Sparks (2005) and Sheppard et al. (2006). The belief-based items used in the questionnaire were derived from the NRT themes identified in Chapter Four. In keeping with the majority view in the TPB literature, all the TPB items in the questionnaire were scored using a 7-point response format. The target behaviour was defined in terms of its Target, Action, Context and Time (TACT principle), a requirement of the TPB to maximise its predictive power (Sutton, 2004). In this instance, the target was NRT, the action was NRT use, the context was pregnancy and the time was any point during that pregnancy. Furthermore, the 'principle of compatibility' was observed in that all measures in the questionnaire referred to the same level of generality, which in this case was intention to use NRT during pregnancy. The construction of questionnaire items, drawing largely on the recommendations outlined in Sections 3.1.1 and 3.1.2, is described below (see Appendix 35 for questionnaire).

6.3.2.2 Direct measurement of attitude

To measure respondents' overall attitude, evaluative semantic differential scales with bipolar adjectives (i.e. pairs of opposites) were selected to incorporate three instrumental items (whether the behaviour achieves something), three experiential items (how it feels to perform the behaviour) and one overall evaluation. To minimise the risk of 'response set' (Bowling, 2005), items were worded with a random mix of positive and negative endpoints to the right. In line with published recommendations and the judgement of the researcher (JT), the seven chosen items were as follows: instrumental evaluations: helpful-unhelpful,

harmful-beneficial, useful-useless; experiential evaluations: calming-stressful, unpleasant-pleasant, foolish-sensible; overall evaluation: bad-good. Each of these items followed a single 'stem' which defined the behaviour under investigation, namely, 'In my opinion, using NRT while I am pregnant would be:'

6.3.2.3 Direct measurement of subjective norm

Direct measurement of subjective norm involved the use of questions to assess respondents' views about the opinions of people in general in terms of the target behaviour. As problems have been highlighted with single item measures (Armitage & Conner, 2001), three items were selected, namely 'Most people who are important to me would want me to use NRT while I am pregnant', 'It is expected of me that I use NRT while I am pregnant' and 'I feel under pressure to use NRT while I am pregnant'. Each response ranged from 'strongly disagree' to 'strongly agree', and endpoints were not mixed, as the researcher decided that keeping the endpoint wording uniform throughout would minimise the potential for respondent confusion and considered this to be a more important issue than concerns about 'response set' (Bowling, 2005).

6.3.2.4 Direct measurement of perceived behavioural control

The direct perceived control measure incorporated four items reflecting both perceived controllability and self-efficacy. The two controllability measures assessed whether performing the target behaviour was up to the respondent and how much control they felt they had over this behaviour, whilst the two self-efficacy items assessed the respondent's perceived capability of performing the behaviour by measuring perceived difficulty and confidence in relation to the target behaviour, Specifically, the questions were as follows: 'Whether I do or do not use NRT while I am pregnant is entirely up to me' and 'I am confident that I could use NRT while I am pregnant if I wanted to', both scored on scales ranging from 'strongly disagree' to 'strongly agree', 'How much control do you feel you have over using NRT while you are pregnant?', scored on a scale ranging from 'no control' to 'complete control', and 'For me to use NRT while I am pregnant would be...', scored on scale ranging from 'very difficult' to 'very easy'. Again, endpoints were not mixed for the reasons stated in Section 6.3.2.3.

6.3.2.5 Direct measurement of intention

The generalised intention method was chosen for the intention measure as this is most commonly used in the TPB literature where the majority of research is concerned with an individual's own health related behaviour (Francis et al.,

2004). This comprised three items, 'expect', 'want' and 'intend', reported by Francis et al. (2004) to exhibit considerable response consistency in relation to the target behaviour under investigation. Specifically, the items were, while pregnant, 'I expect to use NRT', 'I want to use NRT' and 'I intend to use NRT', each measured on a scale ranging from 'strongly disagree' to 'strongly agree'.

6.3.2.6 Indirect measurement of attitude

The 11 behavioural belief themes which emerged from the elicitation study (see Chapter Four) were considered to reflect the beliefs about outcomes of using NRT in pregnancy which might influence NRT behaviour in the target population. To assess the strength of these behavioural beliefs, the beliefs were converted into a set of statements and respondents were asked to rate the probability of each outcome occurring using scales ranging from 'very unlikely' to 'very likely'. To minimise the risk of 'response set' (Bowling, 2005), six of the themes were converted into positively worded statements and five into negatively worded statements which were randomised into the following order: 'NRT would reduce my cravings for a cigarette', NRT would cost me more than cigarettes do', NRT would make quitting smoking less stressful', NRT would help me to quit smoking', 'I would become addicted to NRT', 'NRT would be as satisfying as smoking cigarettes', 'NRT would give me unwanted side effects', 'NRT would be healthier for my baby than if I smoke', NRT would make my pregnancy sickness worse', 'NRT would be healthier for me than if I smoke', 'Using NRT would make me feel like I haven't really quit smoking'. Then, each of the belief statements was converted into a statement to enable respondents to express a positive or negative evaluation of each of these outcomes, e.g. 'Having fewer cravings for a cigarette', using a scale ranging from 'bad' to 'good'.

6.3.2.7 Indirect measurement of subjective norm

The three normative belief themes which emerged from the elicitation study (see Chapter Four) were considered to reflect the key sources of social pressure felt by pregnant smokers in relation to using NRT in pregnancy. To assess the strength of normative beliefs with respect to each referent group, these sources were converted into a set of statements randomised in the following order: 'My family would want me to use NRT while I am pregnant', 'My friends would want me to use NRT while I am pregnant', 'Health experts would want me to use NRT while I am pregnant, each of which was scored on a scale ranging from 'very unlikely' to 'very likely'. Aizen (2002) commented that the injunctive quality of such items (what important people think a person should do) can display low variability

because important others are generally perceived to approve of desirable behaviours and disapprove of undesirable behaviours. To help alleviate this problem, he recommended the inclusion of descriptive norms, that is, whether important others themselves perform the behaviour in question. However, for this study it was not considered appropriate to include items designed to capture descriptive norms given that the target behaviour was only relevant to a specific sub sample of the population. Each source of social pressure was converted into the form of a statement about the importance of the various sources social pressure to assess the strength of the respondent's motivation to comply with each of the 3 referent groups, e.g. 'I want to do what my family thinks I should do', scored on a scale ranging from 'not at all' to 'very much'.

6.3.2.8 Indirect measurement of perceived behavioural control

The nine control belief themes which emerged from the elicitation study (see Chapter Four) were considered to reflect the beliefs about both situational and internal factors which could inhibit or facilitate use of NRT by pregnant women. To assess the strength of these control beliefs, they were converted into a set of statements and respondents were asked to rate the likelihood of each occurring while they were pregnant using a scale ranging from 'very unlikely' to 'very likely'. To minimise the risk of 'response set' (Bowling, 2005), four of the themes were converted into positively worded statements and five into negatively worded statements which were randomised into the following order: 'I would be able to get a supply of NRT easily', 'I would forget to use NRT', 'I would think that NRT is safe to use in pregnancy', 'I would think that NRT is not allowed in pregnancy', 'I would know enough about the different types of NRT', 'I would find NRT convenient to use', I would struggle to go without cigarettes', 'I would want to quit smoking without using NRT', 'I would feel self-conscious or embarrassed about using NRT'. Then, to assess the power of each of these factors to influence behaviour, each control belief statement was converted into the form of an incomplete statement which enabled the respondent to rate the extent to which each factor would make it more unlikely or more likely that she would use NRT while pregnant, e.g. 'Being able to get a supply of NRT easily would make this...', scored on a scale ranging from 'more unlikely' to 'more likely'.

6.3.2.9 Ordering of questionnaire items

Although Aizen (2002) recommended that attitude, subjective norm and PBC items be randomly dispersed in the questionnaire, the researcher decided to group the 63 TPB items by construct in the following order to facilitate respondent

interpretation: Direct attitude (7 items); indirect attitude – behavioural beliefs (11 items), outcome evaluation (11 items); direct subjective norm (3 items); indirect subjective norm – normative beliefs (3 items), motivation to comply (3 items); direct PBC (4 items); indirect PBC – control beliefs (9 items), perceived power (9 items); intention (3 items). Armitage & Conner (1999) reported that there was no moderating effect of questionnaire format (random or structured) on TPB component relations.

6.3.2.10 Demographic measures

Following the TPB items, 19 questions were included to elicit demographic characteristics and information about the smoking behaviour of the respondent and her partner, if she had one. Firstly, the respondent was asked about her age, ethnic group, highest educational qualification, employment status, marital status, number of weeks pregnant, and if she had any other children. Secondly, if she had a partner, she was asked about his smoking status, highest educational qualification, and employment status. Thirdly, in terms of her smoking behaviour, the respondent was asked about her current daily cigarette consumption, daily cigarette consumption prior to pregnancy, number of years of smoking, intention to give up smoking during the pregnancy, and previous use of NRT.

6.3.3 PILOTING OF QUESTIONNAIRE

The questionnaire was pilot-tested on a sample of 16 pregnant smokers attending City Hospital antenatal clinic in March and April 2007. Respondents were asked to feedback on the ease or difficulty of questionnaire completion using a 5-point response scale and optional comments. Of the 16 respondents who completed the pilot questionnaire, 3 (19%) reported finding the questionnaire very easy to complete, 8 (50%) quite easy, 4 (25%) neither easy or difficult, and 1 (6%) quite difficult. The fact that the sample included a spread of ages and a bias towards lower educational qualifications and a lack of employment suggested that this sample was representative of this population as a whole. The only comments were made by the latter respondent who admitted to some confusion about how to answer certain questions perhaps due to her reported lack of awareness of NRT. However, the researcher's reading of the individual responses to the 16 questionnaires gave no indication that respondents had misunderstood the nature of the questions. Given that the majority of the sample had found the questionnaire easy to complete and no one had found it very difficult, and this was considered to be a representative sample, the questionnaire was deemed suitable for use without amendment.

6.3.4 PROCEDURE

6.3.4.1 Recruiting Leicester sample

Batches of questionnaires were sent by the researcher to the Stop Smoking Services in Leicester City PCT and Leicestershire County and Rutland PCT for distribution between August 2007 and July 2008. It had previously been agreed that Stop Smoking advisors working with pregnant smokers in these PCTs would send a questionnaire and a covering letter (see Appendix 36) about the study to new clients. Completed questionnaires would be collected from clients when seen and if no completed questionnaire was forthcoming, clients would be given another opportunity to fill it in at this time. It was important that the client completed the questionnaire before the advisor started to talk to her about NRT in order to capture her beliefs prior to any advisor influence.

6.3.4.2 Recruiting Nottingham sample

Questionnaires were distributed in antenatal clinics at City Hospital and Queen's Medical Centre (QMC), Nottingham between January and June 2008. At City Hospital, the researcher was present at the busiest weekly clinics to approach those pregnant women the receptionist had first identified as smokers. At clinics that the researcher did not attend, clinic staff were asked to distribute questionnaires on his behalf and return them in the Freepost envelopes provided. At QMC, staff agreed to distribute and return questionnaires without the researcher's input. Although the pregnant smokers were encouraged to complete the questionnaire in the clinic, they were given the option to take it home and return it themselves.

6.3.4.3 Behavioural follow-up

Questionnaires distributed to the Leicester sites also had a final section requesting permission to follow-up the respondent at the end of her pregnancy to ascertain whether or not she had used NRT during the pregnancy, with a space to enter her contact details if she consented to this. The women who agreed to be followed up had their due dates calculated from the number of weeks pregnant they were at the time they had completed the dated TPB questionnaire. A month after their due date, a follow-up questionnaire was posted to them to ascertain the extent to which they had used NRT during their pregnancy, for return in a Freepost envelope. In an attempt to obtain a reliable self-report measure of behaviour, more than one question was used comprising a rough numerical estimate and a rating scale as recommended by Aizen (2002). Specifically, NRT

use was assessed by asking the respondent to (1) select one answer from the following options: 'every day', 'almost every day', 'most days', 'on about half the days', 'a number of times, but less than half', 'a few times', 'never', and (2) select a number on a scale of 1 to 10 where 1 represented 'never' and 10 represented 'every day' (see Appendix 37). Non responses were followed up a month later with a duplicate letter, and multiple attempts were made to contact women via telephone, email and text if contact details allowed.

6.3.4.4 Ethical considerations

This study received ethical approval from the NHS National Research Ethics Service, Nottingham Research Ethics Committee 2 on 26 February and 21 May 2007 (see Appendices 38 & 39), Nottingham University Hospitals NHS Trust Research and Development Department on 1 & 7 August 2007 (see Appendices 40 & 41), and Leicestershire, Northamptonshire and Rutland Primary Care Research Alliance on 15 July 2007 (see Appendix 42). Participants' consent to participate in the study was considered to be their willingness to complete the questionnaire.

6.3.5 DATA MANIPULATION AND ANALYSES

Data from 16 pilot questionnaires and 84 post pilot ones comprising 48 from Leicester City PCT, 18 from Leicestershire County & Rutland PCT, 20 from City Hospital and 14 from QMC were entered into SPSS for Windows (Version 15.0). Prior to the main analyses, data were inspected for missing values and response validity, missing values imputed, the reliability of the direct measures assessed, specific indirect measure scales recoded, overall scores for the direct and indirect measures calculated and the validity of the indirect measures assessed. These steps are described in turn below.

6.3.5.1 Missing values analysis

From SPSS Missing Values Analysis on the 100 cases for the 63 TPB items, Little's MCAR test χ^2 (1669) = 1756.01, p = .068 showed that there was no significant deviation from a pattern of values missing completely at random (MCAR), thus MCAR was inferred. Therefore, data deletion or imputation methods were deemed appropriate. To retain the optimum number of cases whilst minimising the number of missing values to be imputed, cases which had more than 5% missing data across the 63 TPB items were removed. This left 76 cases for analysis comprising 36 from Leicester City PCT, 14 from Leicestershire County & Rutland PCT, 15 (including 12 pilot questionnaires) from City Hospital and 11 from QMC.

SPSS Missing Value Analysis was conducted on these 76 cases for the 63 TPB items, revealing 15 missing values: 1 (1.3%) value was missing on 13 variables and 2 (2.6%) values were missing on 1 variable, totalling 0.31% missing values. No values were missing on the 3 items comprising the intention variable. As no item was missing more than two values (2.6%) and this was below at least 5%, t-tests were not requested to see if missingness was related to any of the other variables (Tabachnick & Fidell, 2007). From SPSS Missing Values Analysis on the 76 cases for the 63 TPB items, Little's MCAR test χ^2 (741) = 759.67, p = .309 again showed that there was no significant deviation from a pattern of values missing completely at random (MCAR), thus MCAR was inferred. For each missing value, the median score for that item was imputed. The median was chosen in preference to the mean in order to retain the whole number format of the existing TPB scores.

6.3.5.2 Response validity

The 63 TPB items were checked for non-valid responses by ensuring that all values were whole numbers between 1 and 7 inclusive.

6.3.5.3 Reliability and composite scoring of direct measures

Firstly, the three direct attitude items which had negatively worded endpoints on the right (calming-stressful, helpful-unhelpful, useful-useless) were reverse coded so that higher numbers on the response scale always reflected a positive attitude to the target behaviour. Then using SPSS Reliability Analysis, an item analysis was conducted on the items for each direct measure to establish internal consistency, i.e. the extent to which the individual items were measuring the same construct. Francis et al. (2004) suggested that if all internal consistency coefficients were acceptable (0.6 as a rough guide), it would be appropriate to include all the items in the composite variables. A decision was made to retain only those items in each construct which produced a corrected item-total correlation of > 0.3, given that values of < 0.3 indicate that the item is measuring something different from the scale as a whole (Pallant, 2007). A composite variable for each direct measure (i.e. attitude, subjective norm, PBC & intention) was then computed by calculating the mean of the retained item scores to give an overall score.

6.3.5.4 Indirect measure scale recoding

Specific response scales relating to the indirect measures were converted from a unipolar (1 to 7) format to a bipolar (-3 to +3) format in line with the

recommendations of Francis et al. (2004). They argued that that response scales should be unipiolar or bipolar depending on whether the concept to be measured is unidirectional (probability), e.g. perceptions of the likelihood of quitting smoking in pregnancy or bidirectional (evaluation), e.g. whether quitting smoking in pregnancy is perceived to be good or bad. The 'motivation to comply' scale tends to be unipolar because people are considered unlikely to want to do the opposite of what they perceive to be the wishes of important others (Conner & Sparks, 2005). The three scales changed to bipolar as recommended by Francis et al. (2004) were the evaluation of the behavioural belief, the normative belief score, and the influence of the control belief. According to Francis et al. (2004) the important aspect of this measurement scheme (where one part of the multiplicative function is measured on a unipolar scale and the other on a bipolar scale) is that zero represents a neutral attitude, subjective norm, and PBC, and having scales with a zero midpoint aids interpretation. Having positive and negative scores representing attitudes, subjective norms and PBC in favour of and against the behaviour respectively makes it immediately clear whether the final score indicates an influence for or against carrying out the behaviour. Furthermore, by conducting tests with hypothetical data, it was confirmed that using this scheme meant that it was not necessary to reverse code any negatively worded belief-based items as these were counteracted by their corresponding evaluative item. Also, it avoids the use of optimal scaling which is a procedure that has been criticised (see Section 3.4.3).

6.3.5.5 Creating composite indirect measures

Using the recoded scales, the following calculations were performed. Each behavioural belief score on the very unlikely-very likely scale was multiplied by the corresponding outcome evaluation score on the bad-good scale to create a new variable representing the weighted score for each behavioural belief. Then all the weighted behavioural belief scores were summed to create a composite, indirect score for attitude. Similarly, each normative belief score on the very unlikely-very likely scale was multiplied by the corresponding motivation to comply score on the not at all-very much scale to create a new variable to represent the weighted score for each normative belief. Then the weighted normative belief scores were summed to create a composite, indirect score for subjective norm. Finally, each control belief score on the very unlikely-very likely scale was multiplied by the corresponding influence of the control belief score on the more unlikely-more likely scale to create a new variable to represent the

weighted score for each control belief. Then the weighted control beliefs scores were summed to create a composite, indirect score for PBC.

6.3.5.6 Validity of the indirect measures

A series of bivariate correlations between the direct and indirect measure of each construct were conducted to confirm the validity (or not) of the indirect measures. Preliminary analyses of the scatterplots were conducted to ensure that none of the three potential correlations violated the assumptions of linearity and homocedasticity as defined by Pallant (2007) (see Appendix 43). The test of normality for a sample size greater than 50 (Kolmogorov-Smirnov) was conducted for each direct and indirect measure to ascertain whether a Pearson or Spearman correlation was the appropriate test to use. Only if both variables to be correlated were normally distributed was a Pearson correlation used.

6.3.5.7 Analysis using direct measures of the predictor variables

Multiple regression ('enter' method) was used to assess the ability of the three direct measures (attitude, subjective norm and PBC) to predict levels of intention to use NRT. Preliminary analyses were conducted to ensure no violation of the assumptions of sample size, multicollinearity, normality, linearity, homoscedasticity, outliers in the solution and independence of errors as defined by Tabachnick & Fidell (2007) (see Appendix 43).

6.3.5.8 Analysis using indirect measures of the predictor variables

Three separate linear regressions were carried out to determine the effect of the three indirect measures on their corresponding direct measure. Firstly, preliminary analyses were conducted to ensure no violation of the assumptions of sample size, multicollinearity, normality, linearity, homoscedasticity, outliers in the solution and independence of errors (see Appendix 43). As already stated in Section 3.5, although the TPB states that it is the direct measures which predict intention, Sutton (2002) stressed the importance of estimating the percentage of variance in intention explained by the most distal variables in the model (effective variance explained). Therefore, a multiple regression ('enter' method) was used to assess the ability of the three indirect measures of attitude, subjective norm and PBC to predict levels of intention to use NRT. Preliminary analyses were conducted to ensure no violation of the assumptions of sample size, multicollinearity, normality, linearity, homoscedasticity, outliers in the solution and independence of errors (see Appendix 43). Also, the distributions of the belief

based items and the evaluative items were inspected separately to assess of variability in scores to further inform the development of the NRTP-SF.

6.3.5.9 Influence of specific beliefs on intention

Although the TPB assumes that each salient belief is equally important (Sutton, 2002), two sets of tests were performed to identify specific beliefs that had the greatest influence on intention. This was done as it was considered probable that if the criteria outlined in Section 6.1 were satisfied, it would be these items which would comprise the NRTP-SF.

Firstly, as recommended by Francis et al. (2004) and Sutton (2002), the intention variable was dichotomised into low intenders and high intenders, in this case using a mean split procedure. This entailed assigning all cases scoring below the mean on this variable to the low intender group and all cases scoring above the mean to the high intender group. Using a mean rather than a median split allowed the midpoint score to be categorised into one group or the other. As Kolmogorov-Smirnov tests showed that the belief items were not normally distributed, Mann-Whitney U tests were conducted to test for differences in belief scores between the two groups, and thus identify those beliefs which best discriminated between low and high intenders.

Secondly, as recommended by Walker et al. (2001), a series of bivariate correlations were conducted to assess the strength of the association between each belief item and the continuous intention variable. Preliminary analyses of the scatterplots were carried out to ensure that none of the potential correlations violated the assumptions of linearity and homocedasticity (see Appendix 43). Kolmogorov-Smirnov tests were conducted for each belief item and the intention variable, and as none of these were normally distributed, Spearman correlations were used to assess the strength of the association between each belief item and intention.

6.3.5.10 Behavioural follow-up

Behavioural follow-up was only applicable to the Leicester respondents who comprised 50 of the 76 retained cases. Of these, 16 people replied to the questionnaire, 3 had lost their baby, 6 wished not to be followed up or had not provided contact details for this, and the remaining 25 could not be contacted. Using SPSS Reliability Analysis, an item analysis was conducted on the numerical estimate and rating scale measures of NRT use in pregnancy to establish internal

consistency, i.e. the extent to which the two questions were measuring the same construct. Then multiple regression ('enter' method) was used to assess the ability of the direct measure of PBC and intention to 1) predict the numerical estimate measure of NRT use and 2) the rating scale measure of NRT use. Preliminary analyses were conducted to assess the assumptions of sample size, multicollinearity, normality, linearity, homoscedasticity, outliers in the solution and independence of errors as defined by Tabachnick & Fidell (2007) (see Appendix 43). Given that the sample size assumption was violated, the findings must be treated with caution.

6.3.5.11 Sensitivity analysis

In an attempt to justify that the median imputation method used had not introduced bias, the following analyses were rerun excluding the cases where values had been imputed for the TPB items: item analysis to assess the reliability of the direct measures, multiple regression to assess the ability of the three direct measures to predict intention and direct PBC and intention to predict behaviour, linear regressions to determine the effect the three indirect measures on their corresponding direct measures, and Mann-Whitney U tests and correlations to establish the most influential belief items.

6.4 STUDY THREE RESULTS

6.4.1 RESPONDENT CHARACTERISTICS

The demographics for those cases analysed are shown in Table 6.1.

Table 6.1 Respondent characteristics from NRTP-LF

Characteristic	Category	Count	%	N
Ethnic group	White	68	89.5	76
	Black-Caribbean	3	3.9	
	Indian	2	2.6	
	Pakistani	1	1.3	
	Other/Mixed	2	2.6	
Highest educational qualification [c]	None	20	27.4	73
	NVQ/GCSE	36	49.3	
	BTEC/A level	6	8.2	
	Diploma/HND	6	8.2	
	Degree	5	6.8	
Employed [a]	Yes	30	40.0	75
	No	45	60.0	
Marital status [d]	Married/Cohabiting	45	62.5	72
	Single	26	36.1	
	Separated/Divorced	1	1.4	
Already have children	Yes	43	56.6	76
	No	33	43.4	
Intention to quit smoking during pregnancy [b]	Yes, definitely	45	60.8	74
	Yes, probably	17	23.0	
	Don't know	8	10.8	
	Probably not	4	5.4	
Ever used NRT [a]	Yes	32	42.7	75
	No	43	57.3	
Characteristic	**Mean**	**S.D.**	**Range**	**N**
Age	25.28	5.99	15 - 43	76
No. of weeks pregnant [d]	17.88	9.21	5 - 39	72
No. of cigarettes smoked per day currently [a]	11.05	6.84	1 - 30	75
No. of cigarettes smoked per day before pregnancy [b]	17.85	5.87	3 - 40	74
No. of years smoked [b]	10.57	5.66	1 - 24	74
If used NRT before, no. of days on last occasion [c]	18.30	23.82	1 - 91	30

Missing values: a = 1, b = 2, c = 3, d = 4

6.4.2 RELIABILITY OF DIRECT MEASURES

For the attitude measure, all 7 items produced a corrected item-total correlation of > 0.3, Cronbach's Alpha = 0.81. For the subjective norm measure, all 3 items produced a corrected item-total correlation of > 0.3, Cronbach's Alpha = 0.66. For the PBC measure, all but 1 of the 4 items produced a corrected item-total correlation of > 0.3. The item 'whether I do or do not use NRT while I am pregnant is entirely up to me' with a corrected item-total correlation of 0.16 was deleted, with a resulting Cronbach's Alpha = 0.55 for the remaining 3 items. For scales with a small number of items (e.g. less than 10), it is sometimes difficult to get an acceptable Cronbach's Alpha value (Pallant, 2007) and internal reliability for this measure has often been found to be low (Conner & Sparks, 2005), as was found in the NRT study by Thomson et al. (2006). Therefore, this lower than ideal value was not considered to be problematic, especially as Bowling (2005) has reported values above 0.5 to be adequate. For the intention measure, all 3 items produced a corrected item-total correlation of > 0.3, Cronbach's Alpha = 0.97 (see Appendix 44 for complete Internal Consistency table).

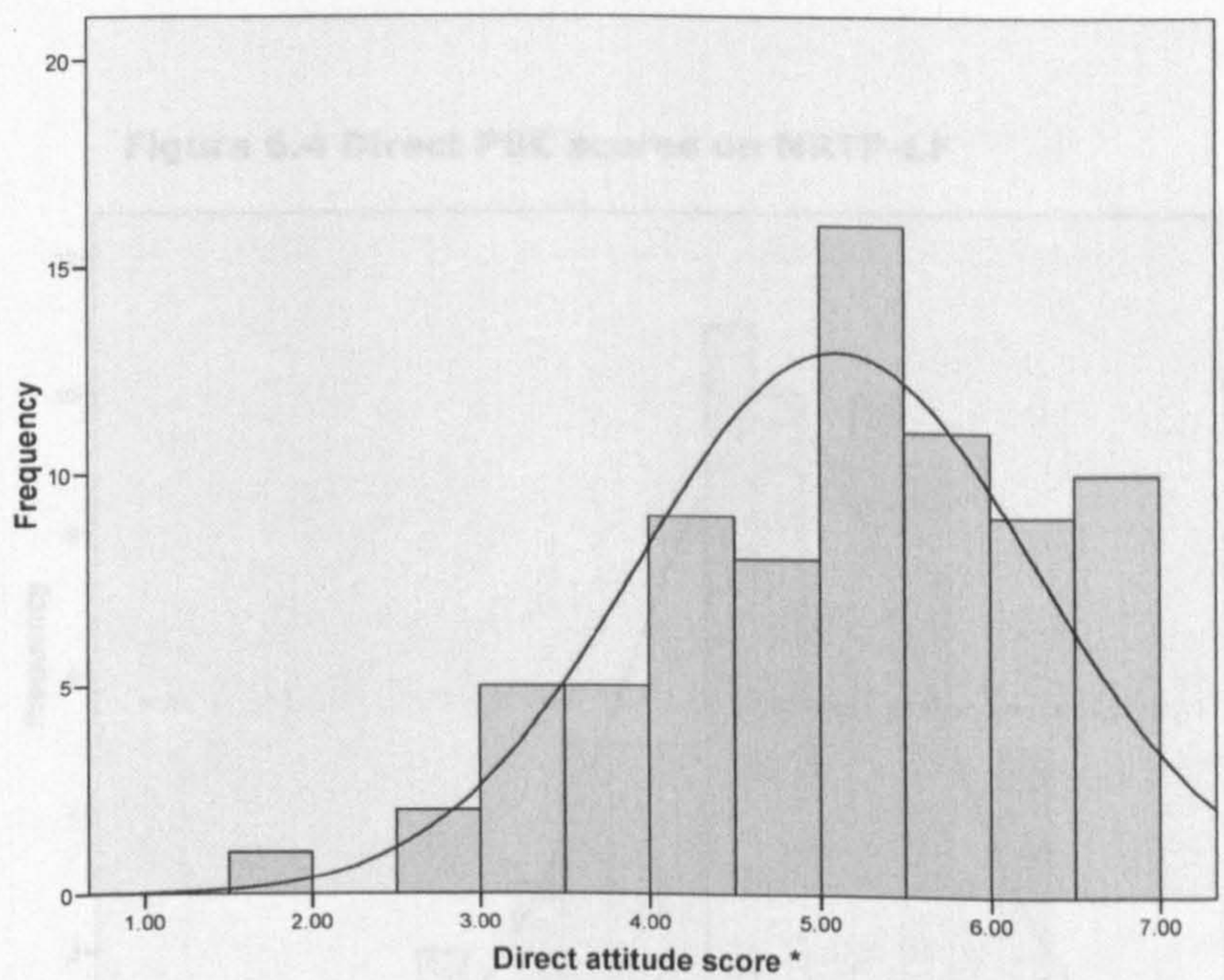
6.4.3 VALIDITY OF INDIRECT MEASURES

According to Cohen's (1988) guidelines, a Pearson correlation revealed a strong positive correlation between the direct and indirect measures of attitude, $r = 0.59$, $n = 76$, $p < 0.001$ (2-tailed), and Spearman correlations revealed strong positive correlations between the direct and indirect measures of subjective norm, rho = 0.58, $n = 76$, $p < 0.001$ (2-tailed) and between the direct and indirect measures of PBC, rho = 0.53, $n = 76$, $p < 0.001$ (2-tailed). None of the assumptions for a correlation were violated (see Appendix 43). As each direct measure was significantly positively correlated with its corresponding indirect measure, it was inferred that each indirect measure had been well constructed and adequately covered the breadth of the directly measured construct.

6.4.4 DESCRIPTIVE STATISTICS FOR DIRECT AND INDIRECT MEASURES

The distributions of scores for the direct measures are displayed in Figures 6.2 to 6.5. Figure 6.2 shows a bias towards a positive attitude to NRT while Figure 6.3 indicates that positive and negative social pressure to use NRT was felt in similar proportions. Figure 6.4 shows a bias towards perceived positive control over NRT use with Figure 6.5 indicating a greater proportion with higher than lower intentions to use NRT. The distributions of the indirect measures provided in Figures 6.6 to 6.8 provide a broadly similar picture. Whilst the indirect attitude scores indicate that few respondents had a negative overall attitude towards using NRT in pregnancy, the majority only had a weak to moderate positive attitude towards it (see Figure 6.6). The scores for indirect subjective norm reflect a weak to moderate positive social pressure to use NRT (see Figure 6.7), and those for indirect PBC reflect fairly weak levels of positive control over using NRT (see Figure 6.8).

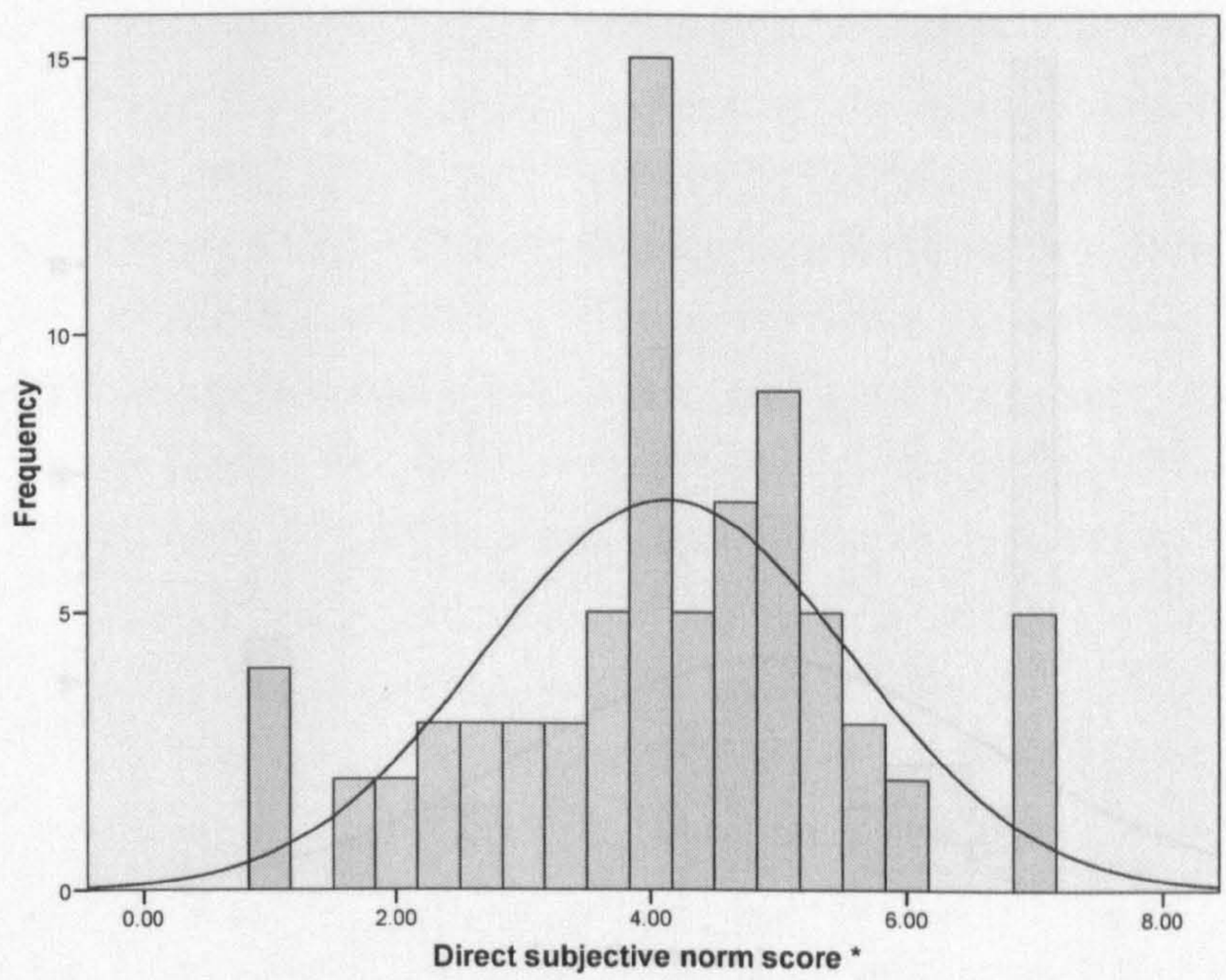
Figure 6.2 Direct attitude scores on NRTP-LF



* Possible range: 1 to 7, Mean = 5.10, S.D. = 1.17

Higher score represents more positive influence on outcome

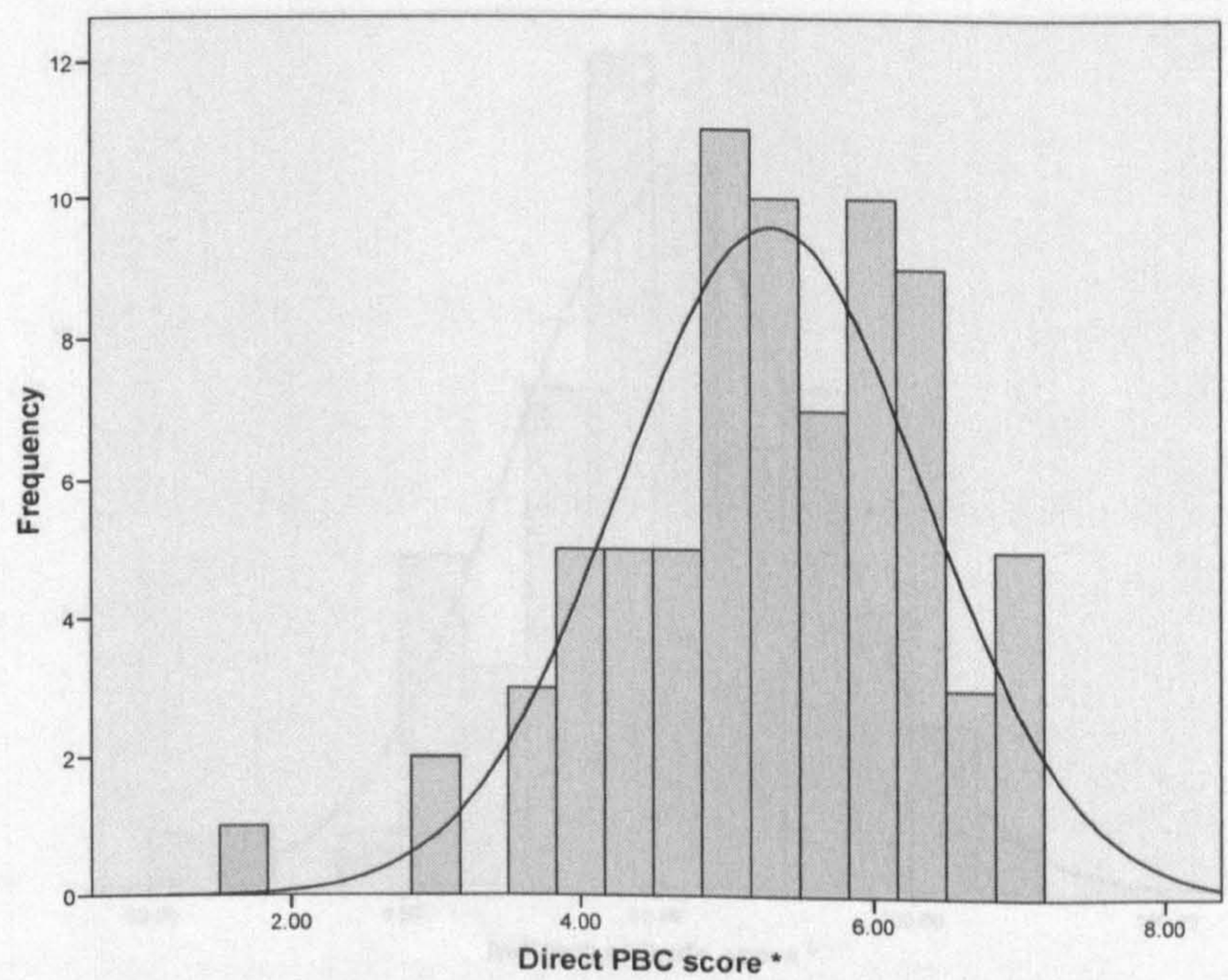
Figure 6.3 Direct subjective norm scores on NRTP-LF



* Possible range: 1 to 7, Mean = 4.13, S.D. = 1.44

Higher score represents more positive influence on outcome

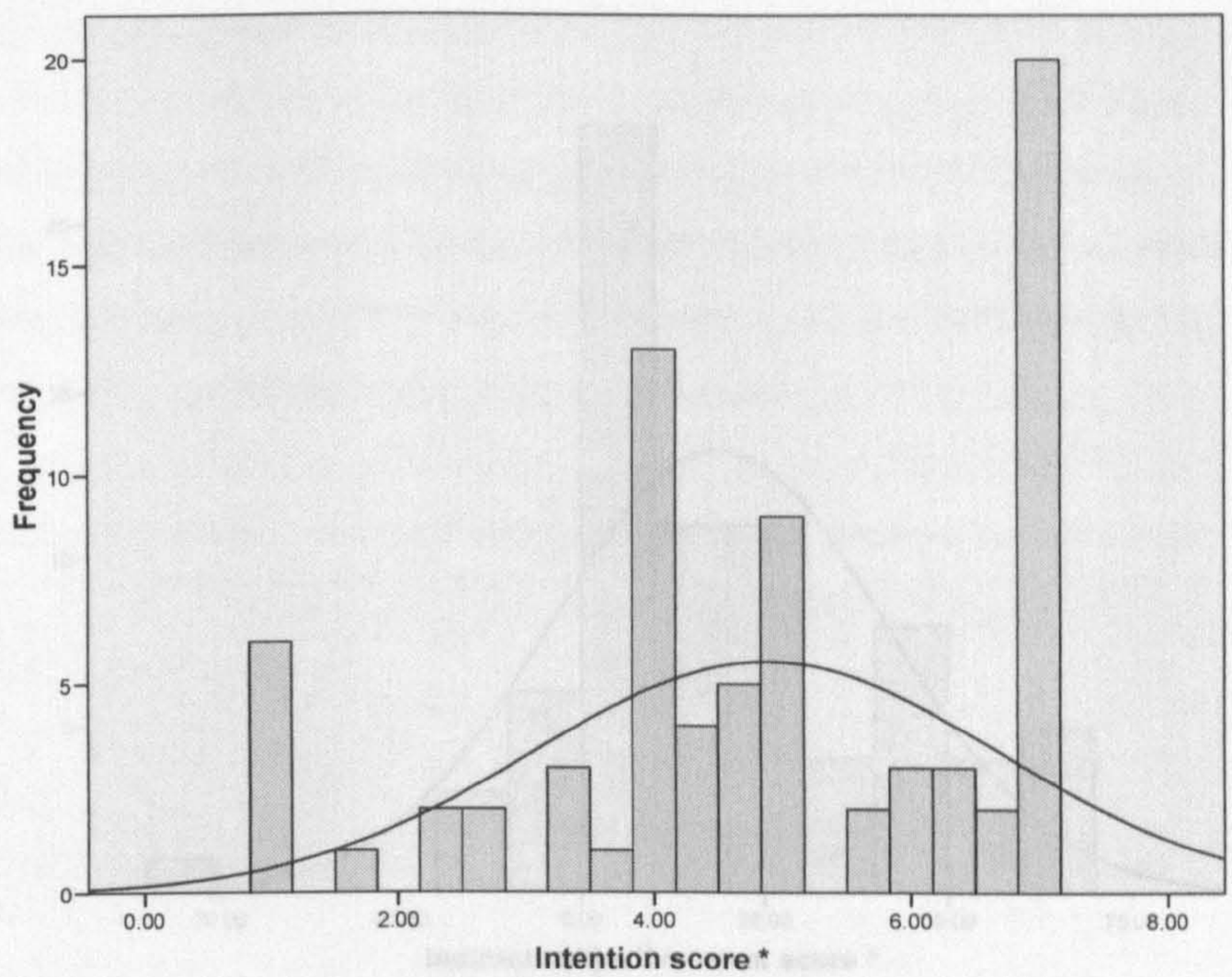
Figure 6.4 Direct PBC scores on NRTP-LF



* Possible range: 1 to 7, Mean = 5.31, S.D. = 1.05

Higher score represents more positive influence on outcome

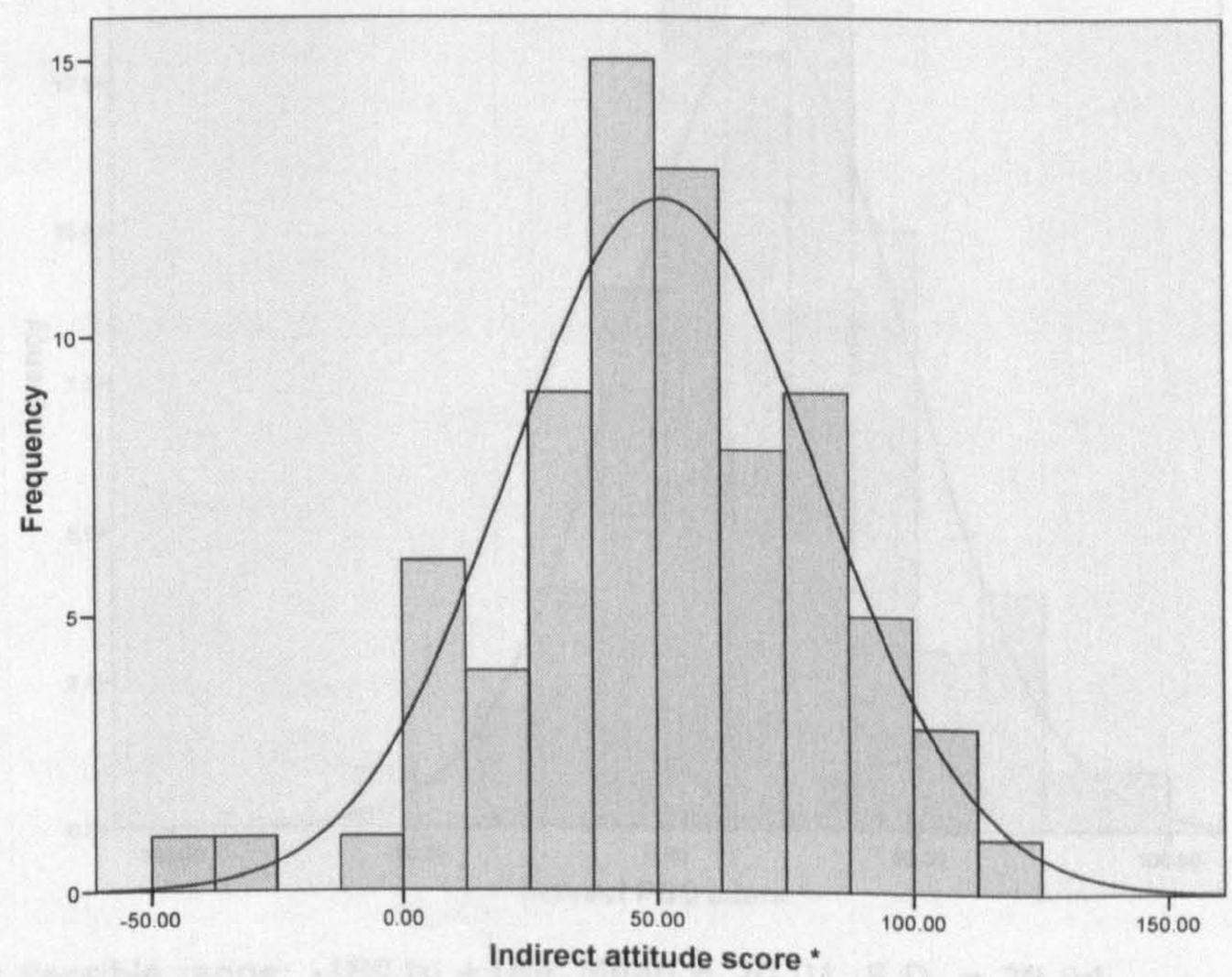
Figure 6.5 Intention to use NRT scores on NRTP=LF



* Possible range: 1 to 7, Mean = 4.88, S.D. = 1.83

Higher score represents stronger intention to perform outcome

Figure 6.6 Indirect attitude scores on NRTP-LF

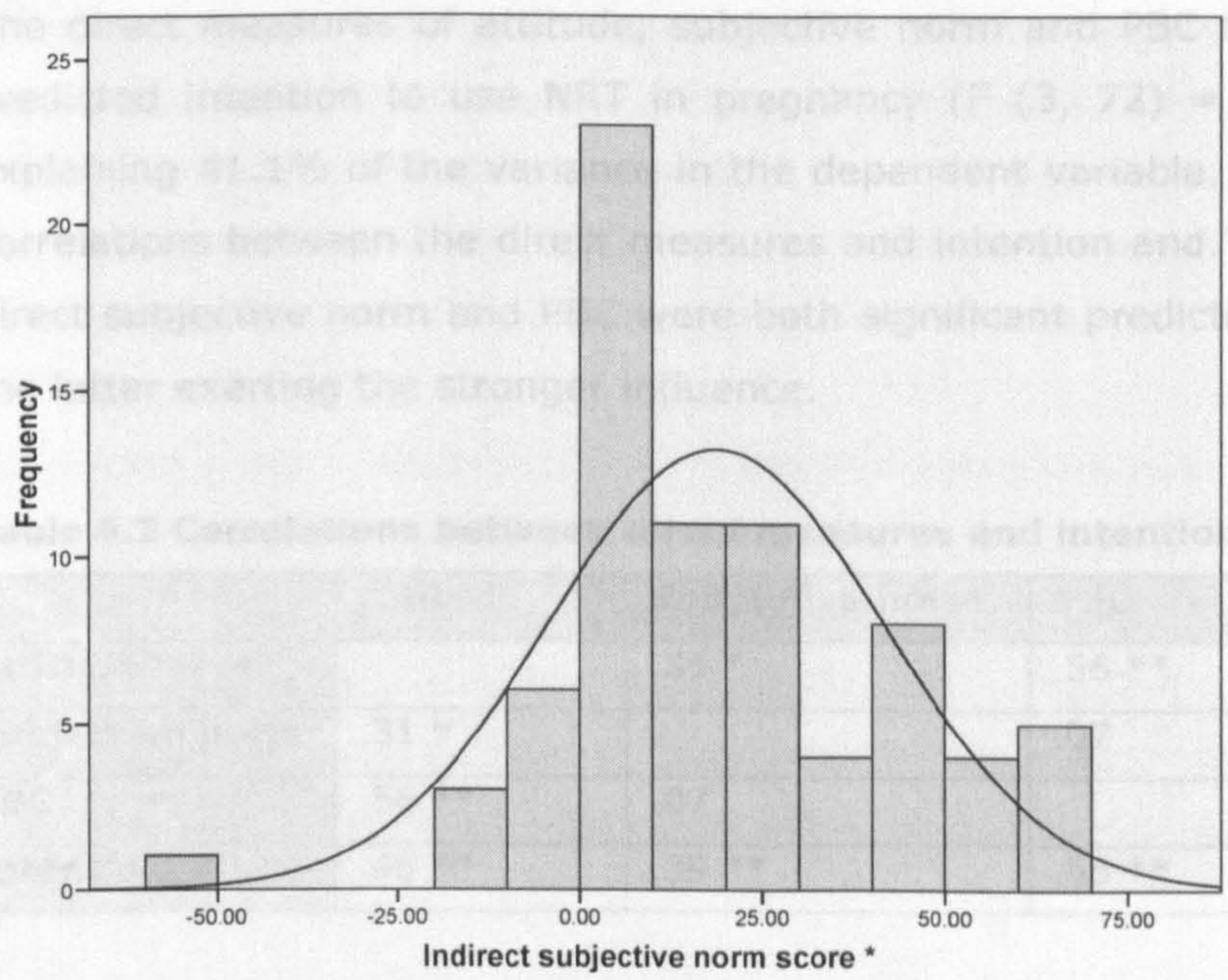


* Possible range: -231 to +231, Mean = 51.32, S.D. = 30.39

Positive score represents positive influence on outcome

Negative score represents negative influence on outcome

Figure 6.7 Indirect subjective norm scores on NRTP-LF

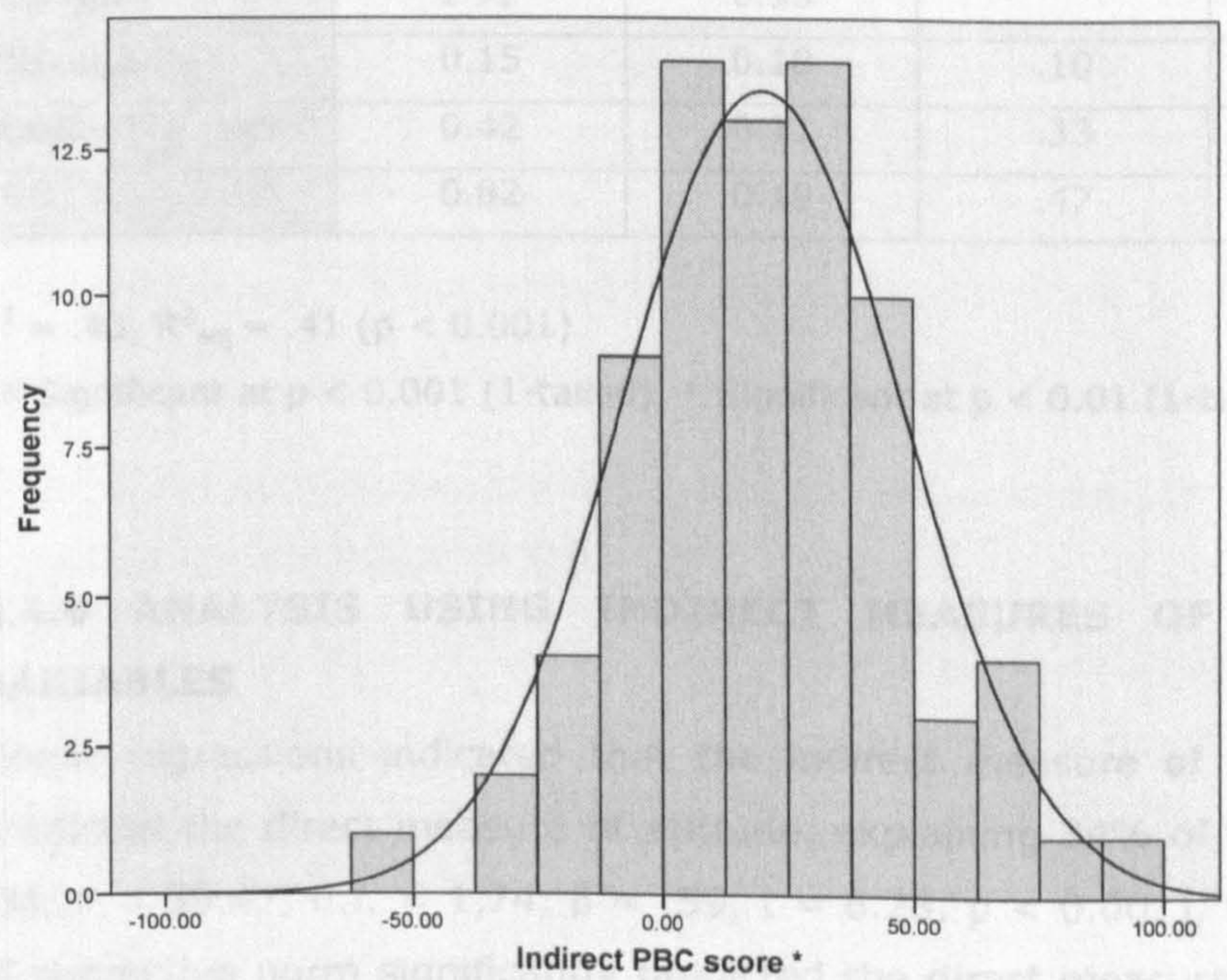


* Possible range: -63 to +63, Mean = 18.71, S.D. = 22.91

Positive score represents positive influence on outcome

Negative score represents negative influence on outcome

Figure 6.8 Indirect PBC scores on NRTP-LF



* Possible range: -189 to +189, Mean = 20.01, S.D. = 28.04

Positive score represents positive influence on outcome

Negative score represents negative influence on outcome

6.4.5 ANALYSIS USING DIRECT MEASURES OF THE PREDICTOR VARIABLES

The direct measures of attitude, subjective norm and PBC together significantly predicted intention to use NRT in pregnancy ($F(3, 72) = 18.41$, $p < 0.001$), explaining 41.1% of the variance in the dependent variable. Table 6.2 shows the correlations between the direct measures and intention and Table 6.3 shows that direct subjective norm and PBC were both significant predictors of intention, with the latter exerting the stronger influence.

Table 6.2 Correlations between direct measures and intention

	Attitude	Subjective norm	PBC
Attitude		.31 *	.56 **
Subjective norm	.31 *		.07
PBC	.56 **	.07	
Intention	.46 **	.39 **	.55 **

** Significant at $p < 0.001$ (2-tailed), * Significant at $p < 0.01$ (2-tailed)

Table 6.3 Beta coefficients and t values for direct predictor variables with intention as dependent variable

	B	SE B	β	t
Constant	- 1.99	0.95		- 2.10
Attitude	0.15	0.18	.10	0.85
Subjective norm	0.42	0.12	.33	3.50 *
PBC	0.82	0.19	.47	4.38 **

$R^2 = .43$, $R^2_{adj} = .41$ ($p < 0.001$)

** Significant at $p < 0.001$ (1-tailed), * Significant at $p < 0.01$ (1-tailed)

6.4.6 ANALYSIS USING INDIRECT MEASURES OF THE PREDICTOR VARIABLES

Linear regressions indicated that the indirect measure of attitude significantly predicted the direct measure of attitude, explaining 34% of the variance ($R^2_{adj} = .34$, $F = 39.47$, d.f. = 1,74, $\beta = .59$, $t = 6.28$, $p < 0.001$), the indirect measure of subjective norm significantly predicted the direct measure of subjective norm, explaining 32% of the variance ($R^2_{adj} = .32$, $F = 36.04$, d.f. = 1,74, $\beta = .57$, $t = 6.00$, $p < 0.001$), and the indirect measure of PBC significantly predicted the direct measure of PBC, explaining 25% of the variance ($R^2_{adj} = .25$, $F = 25.99$, d.f. = 1,74, $\beta = .51$, $t = 5.10$, $p < 0.001$).

All the assumptions for linear regression were met, apart from a single outlier being detected for PBC which had a standardised residual (-3.6) slightly outside the critical value of -3.3 as defined by Tabachnick & Fidell (2007). However, a maximum Cook's distance score of 0.12 was well below the value of 1 or greater which Tabachnick & Fidell (2007) consider to be the point at which a value might be having an undue influence on the results of a model.

The indirect measures of attitude, subjective norm and PBC together significantly predicted intention to use NRT in pregnancy ($F(3, 72) = 15.34$, $p < 0.001$), explaining 36.5% of the variance in the dependent variable. Table 6.4 shows the correlations between the indirect measures and intention, and Table 6.5 shows that indirect attitude, subjective norm and PBC were each significant predictors of intention, with indirect subjective norm and indirect attitude exerting the strongest and weakest influence respectively.

Table 6.4 Correlations between indirect measures and intention

	Indirect Attitude	Indirect Subjective norm	Indirect PBC
Indirect Attitude		.47 **	.51 **
Indirect Subjective norm	.47 **		.29 *
Indirect PBC	.51 **	.29 *	
Intention	.52 **	.47 **	.48 **

** Significant at $p < 0.001$ (2-tailed), * Significant at $p < 0.01$ (2-tailed)

Table 6.5 Beta coefficients and t values for indirect predictor variables with intention as dependent variable

	B	SE B	β	t
Constant	3.34	0.33		10.07
Indirect Attitude	0.02	0.01	.25	2.16 *
Indirect Subjective Norm	0.02	0.01	.28	2.63 *
Indirect PBC	0.02	0.01	.27	2.53 *

$R^2 = .39$, $R^2_{adj} = .37$ ($p < 0.001$), * Significant at $p < 0.05$ (1-tailed)

6.4.7 INFLUENCE OF SPECIFIC BELIEFS ON INTENTION

Dichotomising the intention variable by splitting at the mean score (4.88) resulted in 37 low intenders and 39 high intenders. Table 6.6 shows the series of 2-tailed Mann-Whitney U tests which identified those beliefs which significantly discriminated between low and high intenders. Inspection of mean ranks for low and high intenders showed that the direction of the difference in scores was as would be expected for the 13 positively worded beliefs and the 10 negatively worded beliefs, apart the belief 'I would become addicted to NRT'.

Table 6.6 Differences in scores between low and high intenders for each belief

	z	Sig.	Median Low	Median High
Behavioural Beliefs				
NRT would reduce my cravings for a cigarette (+)	- 2.70	.007 *	4.00	5.00
NRT would cost me more than cigarettes do (-)	- 2.89	.004 *	4.00	2.00
NRT would make quitting smoking less stressful (+)	- 1.83	.067	5.00	5.00
NRT would help me to quit smoking (+)	- 3.91	.001 **	5.00	6.00
I would become addicted to NRT (-)	- 0.55	.583	3.00	2.00
NRT would be as satisfying as smoking cigarettes (+)	- 1.66	.098	3.00	3.00
NRT would give me unwanted side effects (-)	- 1.97	.049 *	4.00	4.00
NRT would be healthier for my baby than if I smoke (+)	- 3.93	.001 **	5.00	7.00
NRT would make my pregnancy sickness worse (-)	- 2.08	.037 *	4.00	3.00
NRT would be healthier for me than if I smoke (+)	- 2.73	.006 *	6.00	7.00
NRT would make me feel like I haven't quit smoking (-)	- 1.51	.130	3.00	2.00
Normative Beliefs				
My family would want me to use NRT (+)	- 3.84	.001 **	4.00	7.00
My friends would want me to use NRT (+)	- 3.93	.001 **	4.00	7.00
Health experts would want me to use NRT (+)	- 2.57	.010 *	6.00	7.00
Control Beliefs				
I would be able to get a supply of NRT easily (+)	- 3.97	.001 **	4.00	6.00
I would forget to use NRT (-)	- 3.93	.001 **	4.00	1.00
I would think that NRT is safe to use in pregnancy (+)	- 2.48	.013 *	4.00	6.00
I would think that NRT is not allowed in pregnancy (-)	- 1.10	.270	4.00	2.00
I would know enough about different types of NRT (+)	- 2.27	.024 *	4.00	5.00
I would find NRT convenient to use (+)	- 3.11	.002 **	4.00	6.00
I would struggle to go without cigarettes (-)	- 0.74	.459	6.00	5.00
I would want to quit smoking without using NRT (-)	- 1.09	.276	4.00	3.00
I would feel self-conscious about using NRT (-)	- 1.80	.072	3.00	1.00

(+) Positively worded belief with respect to NRT use, (-) Negatively worded belief with respect to NRT use

* Significant at $p < 0.05$ (2-tailed), ** Significant at $p < 0.0022$ (2-tailed) - Sidak's correction for multiple testing

Table 6.7 shows the series of Spearman correlations which identify those beliefs which are significantly associated with intention to use NRT. Inspection of the correlations showed that all were in the direction that would be expected for the 13 positively worded beliefs and the 10 negatively worded beliefs, apart from the belief, 'I would become addicted to NRT'.

Table 6.7 Correlations between each belief item and intention

	rho	Sig.
Behavioural Beliefs		
NRT would reduce my cravings for a cigarette (+)	.43	.001 **
NRT would cost me more than cigarettes do (-)	- .33	.003 *
NRT would make quitting smoking less stressful (+)	.23	.042 *
NRT would help me to quit smoking (+)	.55	.001 **
I would become addicted to NRT (-)	.17	.142
NRT would be as satisfying as smoking cigarettes (+)	.26	.026 *
NRT would give me unwanted side effects (-)	- .17	.147
NRT would be healthier for my baby than if I smoke (+)	.44	.001 **
NRT would make my pregnancy sickness worse (-)	- .30	.009 *
NRT would be healthier for me than if I smoke (+)	.30	.008 *
NRT would make me feel like I haven't quit smoking (-)	- .17	.139
Normative Beliefs		
My family would want me to use NRT (+)	.49	.001 **
My friends would want me to use NRT (+)	.49	.001 **
Health experts would want me to use NRT (+)	.30	.008 *
Control Beliefs		
I would be able to get a supply of NRT easily (+)	.51	.001 **
I would forget to use NRT (-)	- .43	.001 **
I would think that NRT is safe to use in pregnancy (+)	.32	.005 *
I would think that NRT is not allowed in pregnancy (-)	- .18	.130
I would know enough about different types of NRT (+)	.38	.001 **
I would find NRT convenient to use (+)	.46	.001 **
I would struggle to go without cigarettes (-)	- .09	.427
I would want to quit smoking without using NRT (-)	- .21	.069
I would feel self-conscious about using NRT (-)	- .17	.139

(+) positively worded belief with respect to NRT use, (-) negatively worded belief with respect to NRT use

* Significant at $p < 0.05$ (2-tailed), ** Significant at $p < 0.0022$ (2-tailed) - Sidak's correction for multiple testing

When correcting for multiple testing, 7 of the 23 items both significantly discriminated between low and high intenders and were significantly associated with intention, namely, 'NRT would help me to quit smoking', 'NRT would be healthier for my baby than if I smoke', 'My family would want me to use NRT while I am pregnant', 'My friends would want me to use NRT while I am pregnant', 'I would be able to get a supply of NRT easily', 'I would forget to use NRT', 'I would find NRT convenient to use'.

At the 0.05 level of significance, a further 7 items both significantly discriminated between low and high intenders and were significantly associated with intention. These additional items were, 'NRT would reduce my cravings for a cigarette', NRT would cost me more than cigarettes do', 'NRT would make my pregnancy sickness worse', 'NRT would be healthier for me than if I smoke', 'Health experts would want me to use NRT while I am pregnant', 'I would think that NRT is safe to use in pregnancy', 'I would know enough about the different types of NRT'.

6.4.8 SELECTION OF ITEMS FOR NRTP-SF

The validity of the indirect measures was confirmed and each composite indirect measure predicted its respective direct measure and together the indirect measures predicted intention to use NRT. Furthermore, inspection of the evaluative items revealed a number of distributions with a poor spread of scores compared to the belief items which displayed good variability. It was therefore considered appropriate to select only belief items for the NRTP-SF based on the criteria specified in Section 6.1. In order to include a range of the most influential beliefs, it was decided to select all 14 beliefs which satisfied the selection criteria at the 0.05 level of significance, rather than only the 7 which met the criteria when accounting for multiple testing (see Tables 6.6 & 6.7).

6.4.9 BEHAVIOURAL FOLLOW-UP

The numerical estimate and rating scale measures of NRT use produced a corrected item-total correlation of 0.97, Cronbach's Alpha = 0.92, thus demonstrating very high internal consistency. The indirect measure of PBC and intention did not significantly predict the numerical estimate ($F(2, 13) = 1.77$, $p = .208$) or rating scale ($F(2, 13) = 1.03$, $p = .384$) of NRT use during pregnancy.

6.4.10 SENSITIVITY ANALYSIS

The sensitivity analysis, excluding the 12 cases where data had been imputed on the TPB items, was run on 64 cases. Item analysis of the direct measures showed

all Cronbach's Alpha values and corrected item-total correlations to be very similar to those in the original analysis, with the same PBC item, 'whether I do or do not use NRT while I am pregnant is entirely up to me' meeting the criteria for deletion (see Appendix 44). Using multiple regression, the three direct measures together predicted 43.1% of the variance in intention, much the same proportion as in the original analysis. The relative strength and significance of each predictor were virtually unchanged (β = .10, .32 & .49 for attitude, subjective norm and PBC respectively). Linear regressions showed that each indirect measure predicted its direct measure, with much the same proportion of variance explained as originally (35%, 31% and 26% for attitude, subjective norm & PBC respectively). The 13 belief items that both discriminated between low and high intenders and significantly correlated with intention were the same as those in the original analysis. The only additional significant item in the original analysis was the belief 'health experts would want me to use NRT while I am pregnant'. Excluding the cases where data had been imputed on the TPB items reduced the behaviour follow-up data by 2 cases. As previously, direct PBC and intention did not predict the extent of NRT use in pregnancy as measured by numerical estimate or rating scale. The similarity between the findings from the imputed and the unimputed datasets thus provides justification for the median imputation method used.

6.5 STUDY THREE DISCUSSION

In this study a TPB questionnaire (NRTP-LF) to explore factors associated with intention to use and use of NRT in pregnancy was devised and tested. The NRTP-LF significantly predicted intention to use NRT in pregnancy, with the three direct predictor variables (attitude, subjective norm and PBC) collectively explaining 41% of the variance in intention to use NRT, an identical figure to that found by Thomson et al. (2006) who investigated NRT use in female smokers (see Section 3.2.4). This figure is within the range of explained variance reported in the TPB meta-analyses (see Section 3.1.3). Subjective norm and PBC were independent significant predictors of intention in the model with the latter exerting a stronger influence. PBC being a significant predictor is in line with the majority of recent TPB studies (Armitage and Conner, 2002) and the fact that it was much more influential in this model (β = 0.47) than in the Thomson et al. (2006) study (β = 0.22) is consistent with other findings which highlight the particular influence this variable seems to have in cessation behaviours during pregnancy (e.g. Godin et al., 1992; see Section 3.2.2). Subjective norm tends to be the weakest predictor

in the model (see Section 3.1.1) so the fact that this exerts such influence in this study could be a reflection of the considerable social pressure felt by pregnant women to quit smoking (Bull et al., 2007) and the uncertainty about whether it is allowed in pregnancy. Although the direct measure of attitude was not a significant predictor in the model this does not disconfirm the theory, as the relative importance of the three factors can vary across different behaviours and populations (Ajzen & Fishbein, 2004). Each indirect measure was significantly positively correlated with and predicted its corresponding direct measure thus providing evidence for the validity of the indirect measures and justification for the way in which the themes were categorised in terms of the TPB components. Furthermore, when the indirect measures were regressed on to intention, all three composite measures were significant predictors in the model, and collectively explained 36.5% of the variance in intention. As one might expect effects to be more diluted when the distal variables are used as predictors (Armitage and Conner, 2002; see Section 3.5.2.1) this figure is not much less than that achieved by the direct measures and provides further support for using indirect measures to predict intention in the NRTP-SF. As specified as an issue with TPB evaluative items (see Section 3.4.3), a number of the distributions lacked variability in scores. Therefore, based on the criteria outlined in Section 6.1, 14 of the 23 belief items were deemed to be the most pertinent for use in NRTP-SF. Direct PBC and intention did not predict the extent of NRT use as self reported using a numerical estimate and a rating scale. However, the small number of cases available for this analysis means that firm conclusions cannot be drawn about the model's ability to predict this behaviour. In terms of the indirect, direct and intention measures, the findings provide evidence for the predictive validity of the NRTP-LF and lend further empirical support for the predictive power of the TPB. As such, it can be inferred that the NRTP-LF has provided an effective framework within which to understand intention to use NRT in pregnancy and justifies the development of a short form version of the questionnaire using the most influential belief items.

6.5.1 STUDY STRENGTHS AND LIMITATIONS

6.5.1.1 Reliability

Unlike much TPB research, this study was informed by the findings from an elicitation study (see Chapter Four) and attempted to operationalise the TPB in a rigorous manner using both direct and indirect measures in accordance with the recommended guidelines (see Francis et al., 2004). Apart from the direct PBC

measure, item analysis revealed the direct measures and the intention and behaviour outcome variables to have acceptable reliability. The often low internal reliability for PBC could be the result of uncertainty in how to operationalise this component (see Section 3.1.1). According the TPB, it is not appropriate to assess the reliability of the indirect measures using the internal consistency procedure given that people can hold both positive and negative views about a specific behaviour (Aizen, 2002b). Francis et al. (2004) recommended the use of test-retest reliability instead by administering the questionnaire twice to the same people with an interval of at least two weeks. However, this was not considered to be an appropriate test of reliability in this study given the researcher's view that beliefs about NRT have the capacity to change, especially if the respondent was to have contact with a Stop Smoking advisor during the interim period. The NRTP-LF was based on the most salient beliefs generated by an earlier sample (i.e. modal beliefs) for pragmatic reasons (see Section 3.4.1). However it is possible that this resulted in not adequately capturing the salient beliefs of the individuals completing the questionnaire (Conner & Armitage, 1998).

6.5.1.2 Data collection

Even though the pilot study indicated that the questionnaire was easy to complete, collecting a sufficient number to satisfy the requirements for regression analysis in the main study (see Appendix 43) was a slow process. This was perhaps in part due to the length and relative complexity of the questionnaire which have been reported as downsides to fully operationalising the TPB (see Section 3.4). Furthermore, as highlighted by Giles et al. (2007), missing data was largely found on the semantic differential items and this reduced the number of cases which could be analysed. These issues provided further support for creating a shorter version of the questionnaire using only indirect measures. The sensitivity analysis provided justification for the imputation method used on those questionnaires which had minimal missing data.

6.5.1.3 Sample

Nearly 77% of the study sample reported no or NVQ/GSCE level educational qualifications and as educational level serves as a proxy for socio-economic status, this distribution is skewed in the direction that would be expected for this population (see Section 1.2.2). There was good representation of women who were employed or not employed, living with partner or single, had or did not have other children, and had or had not used NRT before. The sample also displayed a wide range in terms of ages, stages of pregnancy, number of cigarettes smoked,

number of years smoked and number of days NRT had been used on the last occasion. Nearly 90% of the sample was White which means that the findings might not be representative of ethnic minority groups. Nearly 84% of the sample reported definitely or probably intending to quit smoking during their pregnancy. This might be an overestimation of the intentions of pregnant smokers in the general population given that the majority who completed the questionnaire were attending NHS Stop Smoking Services and were thus likely to be more motivated to quit. Furthermore, the remainder of the sample was recruited at antenatal clinics who may not have been representative of this population as a whole. It is also possible that those who were approached but declined to complete a questionnaire were more pro-smoking or anti-NRT than those who were recruited.

6.5.1.4 Analysis

As the sample size was not large enough to conduct multiple regression on the belief-based measures (see Appendix 43), a decision was made to select those beliefs which significantly discriminated between low and high intenders and were significantly associated with intention (see Section 6.3.5.9). Using two sets of criteria was considered to increase the likelihood that the most influential beliefs were being selected. Although both are recommended procedures (see Section 6.3.5.9), dichotomising continuous variables has been criticised by a number of researchers who argued that it reduces power (Royston et al., 2006) and can increase the probability of both Type I errors because the split sometimes produces groups which are different by chance (Maxwell & Delaney, 1993) and Type II errors (Streiner, 2002) because of the loss of power. It is also recognised that an alternative method could have been to select beliefs on the basis of which were most strongly associated with their respective direct predictor rather than intention (Conner & Sparks, 2005). It could be argued that this method is more in keeping with the causal pathways specified by the TPB and may have produced different results. It is noted that any method to select influential beliefs is a deviation from the TPB where salient beliefs are assumed to have equal weights (Aizen, 2002b). Whilst multiple regression is very often the statistical procedure of choice in TPB research and the particular analyses in this study were carried out with all the assumptions for this in mind, the study might have been improved by the use of Structural Equation Modelling instead. This is an extension of multiple regression which allows examination of how well individual variables are measured at the same time as the extent to which the variables are related to each other, thus aiding interpretation (Hankins, French & Horne, 2000).

6.5.1.5 Self-report

It is acknowledged that self-report can be a vulnerable collection method (Armitage and Connor, 2001), particularly with regard to response set and socially desirable responding. Although confidentially was assured, participants might have felt obliged to report more positively about NRT, especially if they completed the questionnaire in the company of their Stop Smoking advisor or in the antenatal clinic.

6.5.1.6 Behavioural follow-up

A further limitation of TPB research is that relatively few studies have attempted to measure behaviour longitudinally (Rutter, 2000). Efforts to address the issue in this study were thwarted by insufficient follow-up data making it difficult to reliably assess the ability of the NRTP-LF to predict actual NRT use in pregnancy. The largely cross-sectional nature of the study makes it difficult to draw causal inferences regarding the relationship between the TPB variables and further longitudinal research would enable more confident conclusions to be made in terms of the direction of causation.

6.6 STUDY THREE CONCLUSION

The NRTP-LF, which contained both direct and indirect measures, was shown to significantly predict intention to use NRT in pregnancy and thus provided justification for creating a short form version of the questionnaire (NRTP-SF). This intends to address some of the issues associated with TPB research, such as questionnaire length and complexity. Based on predefined criteria being satisfied, only the most influential belief items from the NRTP-LF were chosen to form this questionnaire which will be subjected to further tests of validity in Chapter Seven. If the NRTP-SF also proves to have predictive validity, it could potentially be of use as an assessment tool for clinicians advising pregnant women about NRT.

CHAPTER SEVEN: TESTING THE VALIDITY OF THE SHORT FORM NICOTINE BEHAVIOUR THERAPY IN PREGNANCY QUESTIONNAIRE (NRTP-SF)

7.1 STUDY FOUR INTRODUCTION

As described in Section 2.2.3, little is known about the factors which influence some pregnant smokers to use NRT and others to reject its use. A greater level of understanding about these factors and their impact on decisions about smoking cessation would be potentially useful for health professionals advising pregnant women about NRT.

Although the NRTP-LF in Chapter Six significantly predicted NRT use in pregnancy, its time consuming nature could discourage pregnant women from completing it. The aim was therefore to reduce this in length to produce a questionnaire with potentially more practical utility (NRTP-SF). Given that the indirect measures (behavioural, normative and control beliefs) in the NRTP-LF were shown to be valid in Study Three (see Chapter Six) and significantly predicted intention to use NRT, and the evaluative items added little extra variance, it was decided to select only the most influential belief items to comprise the NRTP-SF. Although the TPB states that it is the direct measures (attitude, subjective norm and PBC) which predict intention, Sutton (2002) stressed the importance of estimating the percentage of variance in intention explained by the indirect measures. This is because these are the beliefs which shape the direct measures and it is manipulation of these indirect measures which has the potential to bring about behaviour change (see Section 3.5). As such, if the NRTP-SF proves to be a valid measure, it could have utility as a screening tool to enable smoking cessation advisors to tailor their discussions about NRT so that they address the issues that the smokers themselves believe are the most important. It could also inform the development of an intervention to improve uptake of NRT in pregnancy by identifying the most salient beliefs to target, or be used as a pre and post measure to assess the effectiveness of any existing interventions which might be designed to do this. Although the lack of multiplicative composites does not allow testing for the expectancy-value interaction, this was not considered to be a hindrance given that the goal is to relate the beliefs to the outcome (O'Sullivan et al., 2008). Also, for the reasons stated in Section 3.4.3, the use of multiplicative composites is not recommended

and using belief items without an evaluative component makes interpretation of their influence easier. As actual use of NRT in pregnancy proved difficult information to acquire in Study Three, and because of study time constraints, it was decided to utilise interest in participating in a clinical trial investigating the efficacy and safety of NRT in pregnancy as the behavioural outcome measure since participants have to be willing to use NRT.

7.2 STUDY FOUR AIMS

1) To test the ability of the NRTP-SF to predict intention to use NRT in pregnancy.
2) To test the ability of the NRTP-SF to predict interest in participation in a clinical trial investigating the safety and efficacy of NRT use in pregnancy (a proxy behavioural outcome for actual NRT use).
3) To test the ability of the NRTP-SF to discriminate between low and high intenders.
4) To identify the specific beliefs from the NRTP-SF that most influence intention to use NRT.

7.3 STUDY FOUR METHOD

7.3.1 STUDY DESIGN

A cross-sectional survey

7.3.2 FORMAT OF NRTP-SF

7.3.2.1 Belief items

Based on the criteria outlined in Study Three, the 14 belief statements selected for inclusion in the NRTP-SF included six behavioural beliefs (beliefs about outcomes of using NRT), three normative beliefs (beliefs about social pressure to use NRT), and five control beliefs (beliefs about factors inhibiting or facilitating NRT use). To minimise the risk of 'response set' (Bowling, 2005), the beliefs for each construct were randomised into the following order: 1) NRT would help me to quit smoking, 2) My family would want me to use NRT while I am pregnant, 3) I would find NRT convenient to use, 4) NRT would make my pregnancy sickness worse, 5) I would know enough about the different types of NRT, 6) NRT would healthier for my baby than if I smoke, 7) My friends would want me to use NRT while I am pregnant, 8) I would forget to use NRT, 9) NRT would reduce my cravings for a cigarette, 10) I would be able to get a supply of NRT easily, 11)

Health experts would want me to use NRT while I am pregnant, 12) NRT would cost me more than cigarettes do, 13) I would think that NRT is safe to use in pregnancy 14) NRT would be healthier for me than if I smoke. Items 1, 4, 6, 9, 12 & 14 were behavioural beliefs, items 2, 7 & 11 were normative beliefs, and items, 3, 5, 8, 10 & 13 were control beliefs. Eleven items (1, 2, 3, 5, 6, 7, 9, 10, 11, 13 & 14) were positively worded statements with respect to the target behaviour and three items (4, 8 & 12) were negatively worded statements. For each statement, respondents were asked to tick the box which best described their opinion about the probability of the statement being true. The 7-point response format used in Study Three was retained with the available options being: 'very unlikely', 'unlikely', 'somewhat unlikely', 'uncertain', 'somewhat likely', 'likely' and 'very likely'.

7.3.2.2 Intention item

Given that Study Three had demonstrated very high Cronbach's alpha values in relation to the three intention measures used (i.e. 'I expect to...', 'I want to...' & 'I intend to...'), only the 'I intend to use NRT while I am pregnant' statement was retained in the NRTP-SF, appearing as item 15 beneath the belief items and scored in an identical manner to these.

7.3.2.3 Demographic measures

On the reverse side of the questionnaire, eight questions were included to elicit demographic characteristics and information about the smoking behaviour of the respondent. Firstly, the respondent was asked about her age, ethnic group, highest educational qualification (as a proxy for SES), marital status, number of weeks pregnant, and if she had any other children. Secondly, the respondent was asked about her current daily cigarette consumption, and whether she had previously used NRT (see Appendix 45 for questionnaire).

7.3.3 PROCEDURE

7.3.3.1 Recruiting Nottingham sample

Questionnaires were distributed in antenatal clinics at City Hospital and Queen's Medical Centre (QMC), Nottingham between October and December 2008. The researcher (SL[2]) was present at the three busiest weekly clinics at each hospital to approach those pregnant women clinic staff had first identified as smokers. All

[2] Third year medical student assisted with data collection in Nottingham

potential respondents were reminded of their right to refuse to complete the questionnaire and were reassured that any answers they gave would remain confidential. Due to each hospital running their clinics differently, the procedure for data collection differed at each site.

At QMC, the researcher approached pregnant smokers after they had undergone a blood pressure check as part of their routine antenatal visit. Willing respondents were taken into a clinic side room by the researcher to complete the questionnaire at which time they were given the opportunity to ask any questions about the study or questionnaire. As the researcher was not permitted to be present in the scan section of the clinic, the receptionist in this section encouraged eligible patients to complete the questionnaire on the researcher's behalf. At City Hospital, questionnaires were handed to all eligible women on their return from the scan section of the clinic as part of their routine antenatal visit. Willing respondents completed the questionnaire in a clinic side room at which point they could ask the researcher any questions about the research. Patients who were attending the clinic for a blood pressure check but not a scan were handed questionnaires by clinic staff to ensure that no eligible participants were missed. Willing participants filled in the questionnaire after their blood pressure had been taken. At the antenatal clinics at QMC and City Hospital not attended by the researcher, clinic staff distributed questionnaires to potential participants on the researcher's behalf. Although the pregnant smokers were encouraged to complete the questionnaire in the clinic, they were given the option to take it home and return it themselves in the Freepost envelopes provided.

7.3.3.2 Recruiting Leicester sample

The researcher (JT) sent batches of numbered questionnaires to a designated member of staff at the Maternity Units at Leicester Royal Infirmary and Leicester General Hospital for distribution. Questionnaires, accompanied by an invitation letter (see Appendix 46) explaining the study, were given to pregnant smokers attending for an antenatal clinic visit between November 2008 and May 2009. Although respondents were encouraged to complete and return the questionnaire in the clinic for the staff to return to the researcher, they were given the option to take it home and return it themselves in the Freepost envelope provided. The researcher (JT) sent batches of numbered questionnaires to the Manager of the Stop Smoking Services in Leicester City PCT for distribution to three Stop Smoking advisors working specifically with pregnant women. Data collection took place between December 2008 and May 2009 using an identical procedure to that

adopted in Study Three (see Section 6.3.4.1). Upon notification of a new referral to their service, each advisor would send a questionnaire to this client with a covering letter explaining the study (see Appendix 47), and that if the client was willing to complete the questionnaire, the advisor would collect it from her at the first home visit. If the questionnaire had not been completed by the time the advisor visited, she would give the client another opportunity to do so at the beginning of the session, and then return any completed questionnaires to the researcher in the Freepost envelopes provided. As in Study Three, it was important that the client completed the questionnaire before the advisor started to talk to her about NRT in order to capture her beliefs prior to any advisor influence.

7.3.3.3 Behavioural outcome

At the time of data collection, a randomised controlled 'Smoking, Nicotine and Pregnancy' (SNAP) trial was being conducted in the Nottingham hospitals to test the safety and efficacy of NRT use in pregnancy (Coleman et al., 2007). This ultimately involved randomising pregnant smokers to either NRT patches or placebo patches as well as providing counselling and support. When attending for their antenatal visit, pregnant women were handed a SNAP questionnaire to assess their eligibility for participation in this trial (see Appendix 48). If they were eligible and were interested in finding out more information about the trial from the SNAP midwife, they were asked to provide their name and contact details on the reverse of the form. Given the difficulties associated with acquiring actual behavioural follow-up data from the sample in Study Three, it was decided to use interest in the SNAP trial as a proxy for NRT behaviour in the Nottingham sub sample. For this reason, the Nottingham version of the NRTP-SF had a space for the respondent to record her name to enable the researcher (SL) to subsequently check against returned SNAP questionnaires for interest (or not) in the SNAP trial.

7.3.3.4 Ethical considerations

This study received ethical approval from the University Hospitals of Leicester NHS Trust on 25 April 2008 (see Appendix 49). Participants' consent to participate in the study was considered to be their willingness to complete the questionnaire.

7.3.4 DATA MANIPULATION AND ANALYSES

In total, 204 questionnaires were returned in the study period, comprising 68 from QMC, 14 from City Hospital, 59 from Leicester Royal Infirmary, 39 from

Leicester General Hospital, and 24 from Leicester City PCT. Data were entered into SPSS for Windows (Version 15.0) with the exclusion criteria being any questionnaire where the intention item was not completed. Data were entered using values from 1 to 7 as the responses were a measure of probability and as such were considered to be unidirectional (see Section 6.3.5.4). Before conducting the main analyses, it was necessary to screen for missing values and non-valid responses, impute missing values, and calculate overall scores for the behavioural, normative and control belief items.

7.3.4.1 Missing values analysis

SPSS Missing Value Analysis was conducted on the 204 cases for the 15 TPB items, revealing 36 missing values: 1 (0.5%) value was missing on 3 variables, 2 (1%) values were missing on 6 variables, 3 (1.5%) values were missing on 4 variables, and 9 (4.4%) values were missing on 1 variable, totalling 1.18% missing values. No values were missing on the intention variable. From SPSS Missing Values Analysis, Little's MCAR test, χ^2 (242) = 304.70, p = .004, showed that the missing data could not be assumed to be missing completely at random (MCAR). As no item was missing more than 5% of its values, it was not essential to test whether missingness was related to any of the other variables (Tabachnick & Fidell, 2007). Nevertheless, Mann-Whitney U tests revealed no differences in scores on TPB items 1-14 (independent variables), TPB item 15 (dependent variable) or in age, weeks of pregnancy and number of cigarettes smoked between those cases with missing data and those without. Furthermore, Chi-square or Fisher's Exact Probability tests (where cells had an expected frequency of less than 5) showed that missingness was not related to being White or from another ethnic group, having qualifications or not, being in a relationship or not, living with a partner or not, having children or not, having used NRT before or not, or city of recruitment. Given that missingness was not significant across the DV, the data were not considered to be missing not at random (MNAR). The data were therefore treated as missing at random (MAR) and imputation was deemed appropriate. For each missing value, the median score for that item was imputed. The median was chosen in preference to the mean in order to retain the whole number format of the existing TPB scores.

7.3.4.2 Response validity

The 15 TPB items were checked for non-valid responses by ensuring that all values were whole numbers between 1 and 7 inclusive.

7.3.4.3 Scoring of behavioural, normative and control belief items

Firstly, the three negatively worded belief statements (items 4, 8 & 12) were reverse coded so that higher numbers on the response scale always reflected a positive influence on the target behaviour. Then, incorporating the recoded scales, the six behavioural belief scores were summed to create a composite, indirect score for attitude, the three normative belief scores were summed to create a composite, indirect score for subjective norm, and the five control belief scores were summed to create a composite, indirect score for PBC.

7.3.4.4 Distribution properties

As good scales and items should produce variability of answers and minimal floor and ceiling effects (Etter et al., 2000), the three composite scales, the intention variable, and the 14 belief items were examined for these features.

7.3.4.5 Demographic measures and intention

As the test for normality for a sample size greater than 50 (Kolmogorov-Smirnov) showed non-normal distributions, Mann-Whitney U tests or Spearman correlations were conducted to assess for any relationships with age, ethnicity, educational qualifications, marital status, weeks gestation, parity, cigarette consumption and previous use of NRT on intention to use NRT in pregnancy. Preliminary analyses of the scatterplots were carried out to ensure that none of the potential correlations violated the assumptions of linearity and homocedasticity (see Appendix 43).

7.3.4.6 Assessing ability of indirect measures to predict intention

Multiple regression ('enter' method) was used to assess the ability of the three composite, indirect measures (attitude, subjective norm and PBC) to predict intention to use NRT. Preliminary analyses were conducted to ensure no violation of the assumptions of sample size, multicollinearity, normality, linearity, homoscedasticity, outliers in the solution and independence of errors as defined by Tabachnick & Fidell (2007) (see Appendix 43).

7.3.4.7 Assessing ability of indirect measure of perceived behavioural control and intention to predict interest in SNAP trial

Of the 82 potential follow-ups from the Nottingham hospitals (68 from QMC and 14 from City Hospital), 13 had not provided their name on the questionnaire. Therefore only 69 (57 from QMC and 12 from City Hospital) could be checked against the information provided on the SNAP questionnaire. Of these, 20 (29%)

indicated interest in SNAP and 49 (71%) did not. Binary logistic regression was conducted on these 69 cases to assess the impact of indirect PBC and intention (independent variables) on the likelihood that respondents would report interest in the SNAP trial (dependent variable). Preliminary analyses were conducted to ensure no violation of the assumptions of linearity of the logit, multicollinearity and outliers in the solution as defined by Tabachnick & Fidell (2007) (see Appendix 43).

7.3.4.8 Assessing ability of indirect measures to discriminate between low and high intenders

To assess the ability to discriminate between those who had low or high intentions to use NRT, the intention variable was firstly dichotomised into low and high intenders using a mean split procedure. Ordinarily, this would entail assigning all cases scoring below the mean on this variable to the low intender group and all cases scoring above the mean to the high intender group. As the mean score for intention was the same as the midpoint response option (4.00), it was considered more appropriate to assign a score of 4 to the low intender group as this category had been labelled 'uncertain' on the questionnaire. Kolmogorov-Smirnov tests showed that all three indirect measures were not normally distributed. Hence, Mann-Whitney U tests were conducted to assess for differences in indirect measure scores between the low and high intender groups.

7.3.4.9 Influence of specific beliefs on intention

Due to the larger sample size and smaller number of individual belief items than in Study Three, it was possible to conduct a multiple regression ('enter' method) to assess the predictive power of each belief item over and above that of the other 13 items in terms of how much unique variance in intention each explained. Preliminary analyses were conducted to ensure no violation of the assumptions of sample size, multicollinearity, normality, linearity, homoscedasticity, outliers in the solution and independence of errors (see Appendix 43).

7.3.4.10 Readability of NRTP-SF

The readability level of the NRTP-SF was assessed using Flesch Reading Ease and the Flesch-Kincaid Grade Level tests accessed through Microsoft Word 2003.

7.3.4.11 Sensitivity analysis

In an attempt to justify that the median imputation method used had not introduced bias, the following analyses were rerun excluding the cases where

values had been imputed for the TPB items: multiple regression to assess the ability of the three composite indirect measures to predict intention and to identify the most influential belief items, and logistic regression to assess the ability of the composite indirect measure of PBC and intention to predict interest in the SNAP trial.

7.4 STUDY FOUR RESULTS

7.4.1 RESPONDENT CHARACTERISTICS

The demographics for the NRTP-SF analysed cases are shown in Table 7.1.

Table 7.1 Respondent characteristics from NRTP-SF

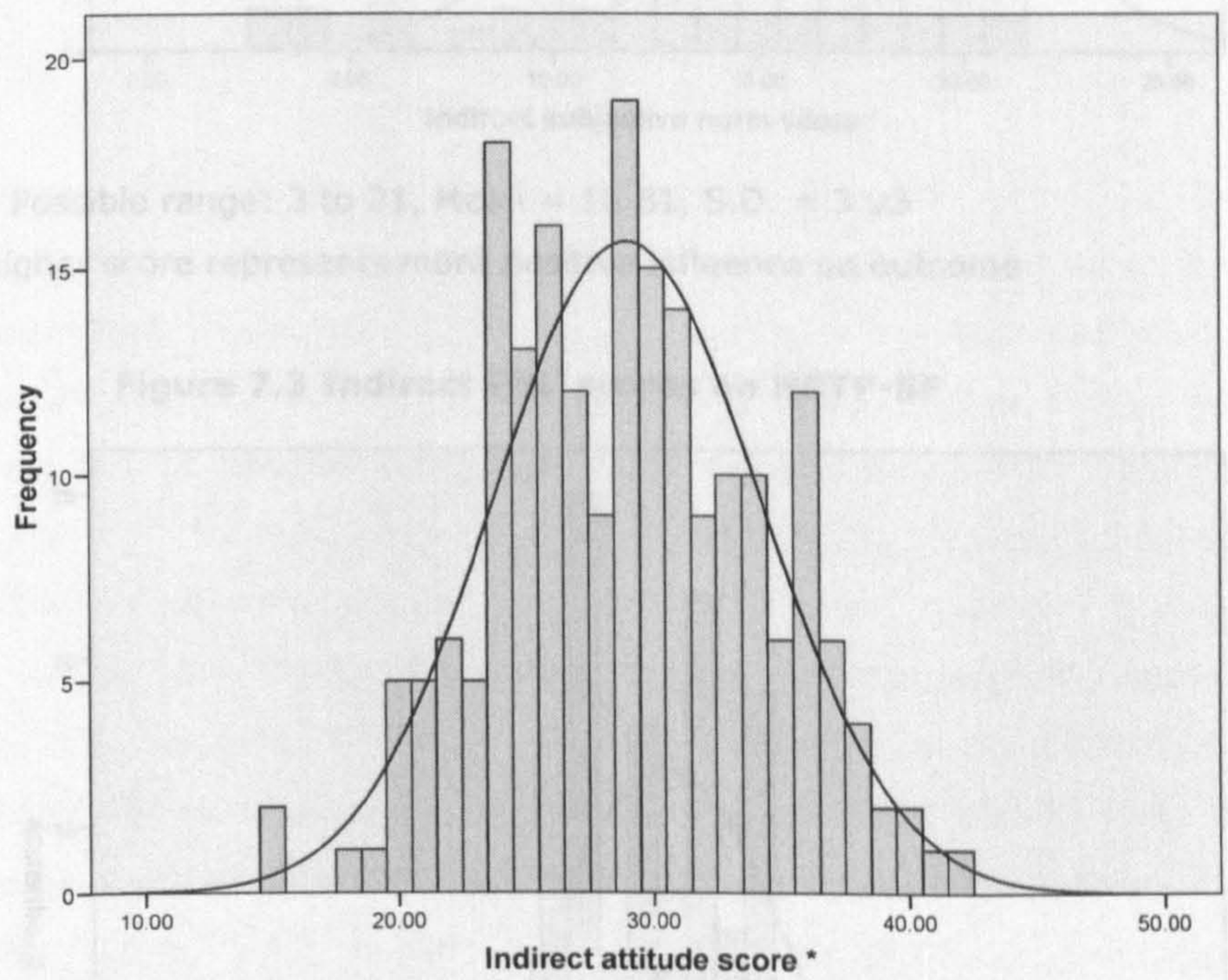
Characteristic	Category	Count	%	N
Ethnic group [b]	White	190	94.5	201
	Black-Caribbean	1	.5	
	Black-other	1	.5	
	Indian	1	.5	
	Pakistani	1	.5	
	Other/Mixed	7	3.5	
Highest educational qualification [a]	None	60	29.7	202
	NVQ/GCSE	114	56.4	
	BTEC/A level	15	7.4	
	Diploma/HND	7	3.5	
	Degree	4	2.0	
	Postgraduate degree	2	1.0	
Marital status [b]	Married/Living with partner	105	52.2	201
	In relationship but not living with partner	44	21.9	
	Single	46	22.9	
	Separated/Divorced	6	3.0	
Already have children [b]	Yes	134	66.7	201
	No	67	33.3	
Ever used NRT [a]	Yes	81	40.1	202
	No	121	59.9	
Characteristic	**Mean**	**S.D.**	**Range**	**N**
Age [b]	25.13	5.68	15-41	201
No. of weeks pregnant [c]	20.14	8.23	8-41	195
No. of cigarettes smoked per day currently [a]	10.73	6.35	1-30	202

Missing values: a = 2, b = 3, c = 9

7.4.2 DESCRIPTIVE STATISTICS

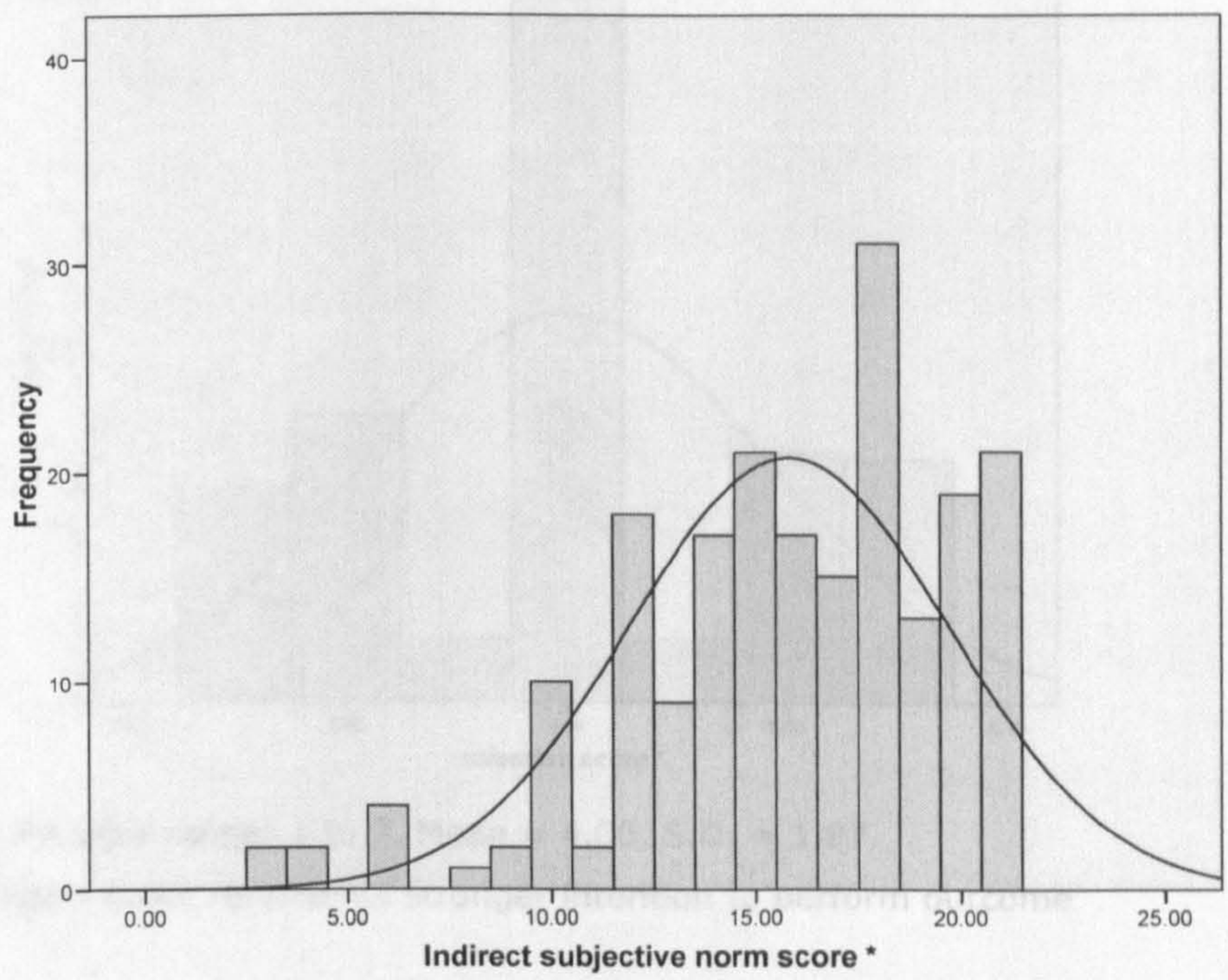
The distributions for the indirect measures and the intention outcome variable are shown in Figures 7.1 to 7.4, and all demonstrate variability in scores for the 204 cases with no obvious floor or ceiling effects. The distributions indicate that the majority of respondents had weak to moderate positive attitudes to NRT (Figure 7.1), felt positive social pressure to use NRT (Figure 7.2), perceived weak to moderate positive control over using NRT (Figure 7.3), and were uncertain about their intentions to use NRT (Figure 7.4).

Figure 7.1 Indirect attitude scores on NRTP-SF



* Possible range: 6 to 42, Mean = 29.01, S.D. = 5.21
Higher score represents more positive influence on outcome

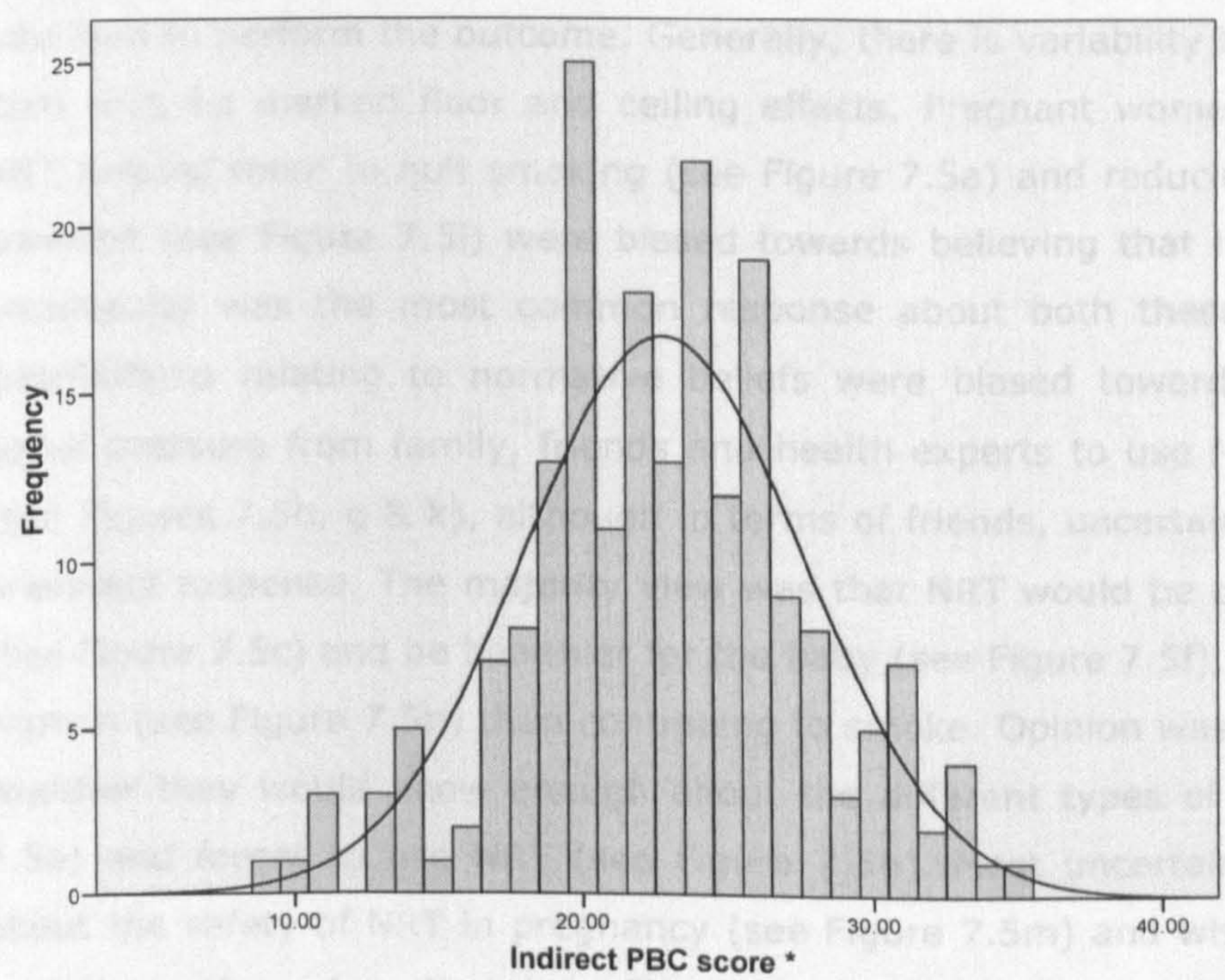
Figure 7.2 Indirect subjective norm scores on NRTP-SF



* Possible range: 3 to 21, Mean = 15.81, S.D. = 3.93

Higher score represents more positive influence on outcome

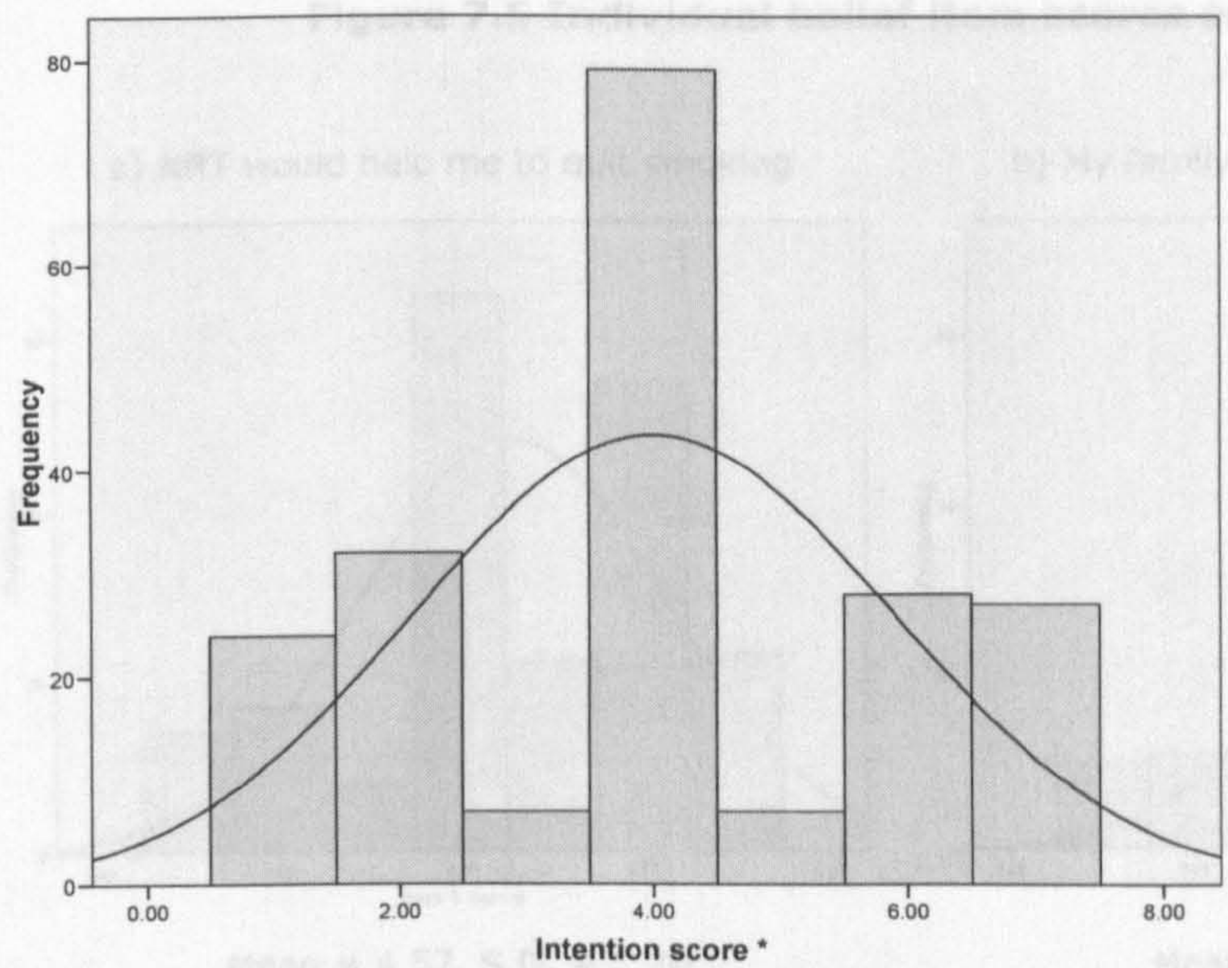
Figure 7.3 Indirect PBC scores on NRTP-SF



* Possible range: 5 to 35, Mean = 22.80, S.D. = 4.87

Higher score represents more positive influence on outcome

Figure 7.4 Intention to use NRT scores on NRTP-SF



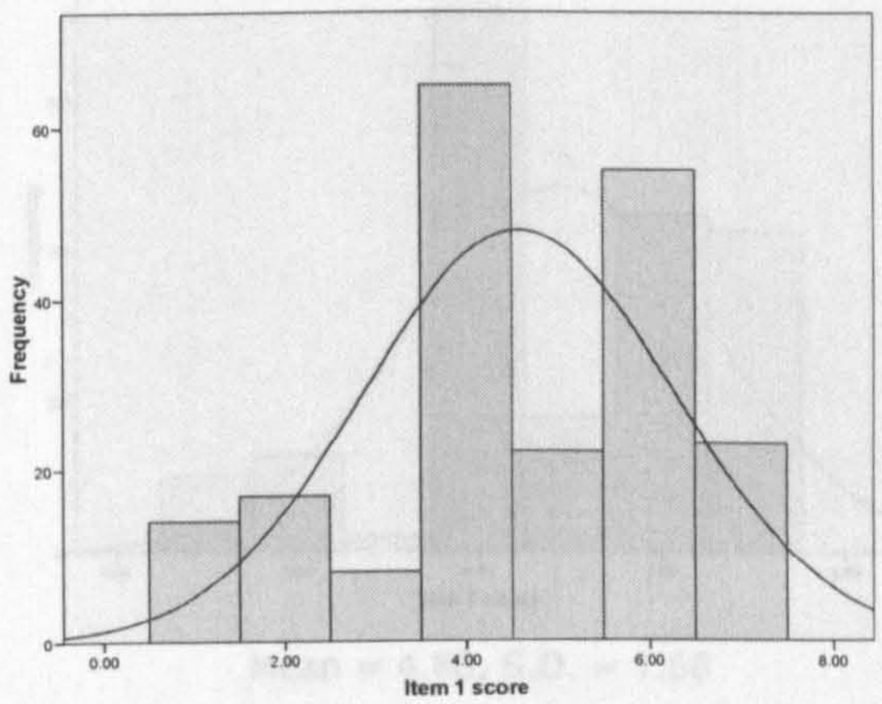
* Possible range: 1 to 7, Mean = 4.00, S.D. = 1.87

Higher score represents stronger intention to perform outcome

Figure 7.5 show the distributions for the 14 individual belief items, with participants being able to score between 1 and 7 inclusive on each. Higher scores represent a stronger intention to perform the outcome except for the three negatively worded items (see d, h & l) where higher scores represent a weaker intention to perform the outcome. Generally, there is variability in scores for each item with no marked floor and ceiling effects. Pregnant women's beliefs about NRT helping them to quit smoking (see Figure 7.5a) and reducing their cigarette cravings (see Figure 7.5i) were biased towards believing that it would although uncertainty was the most common response about both these outcomes. The distributions relating to normative beliefs were biased towards perceptions of social pressure from family, friends and health experts to use NRT in pregnancy (see Figures 7.5b, g & k), although in terms of friends, uncertainty was the most prevalent response. The majority view was that NRT would be convenient to use (see Figure 7.5c) and be healthier for the baby (see Figure 7.5f) and the pregnant woman (see Figure 7.5n) than continuing to smoke. Opinion was more divided on whether they would know enough about the different types of NRT (see Figure 7.5e) and forget to use NRT (see Figure 7.5h). Most uncertainty was reported about the safety of NRT in pregnancy (see Figure 7.5m) and whether NRT would cost more than cigarettes (see Figure 7.5l). There was also a high degree of uncertainty about easy accessibility to NRT (see Figure 7.5j) and whether NRT would exacerbate pregnancy sickness (see Figure 7.5d).

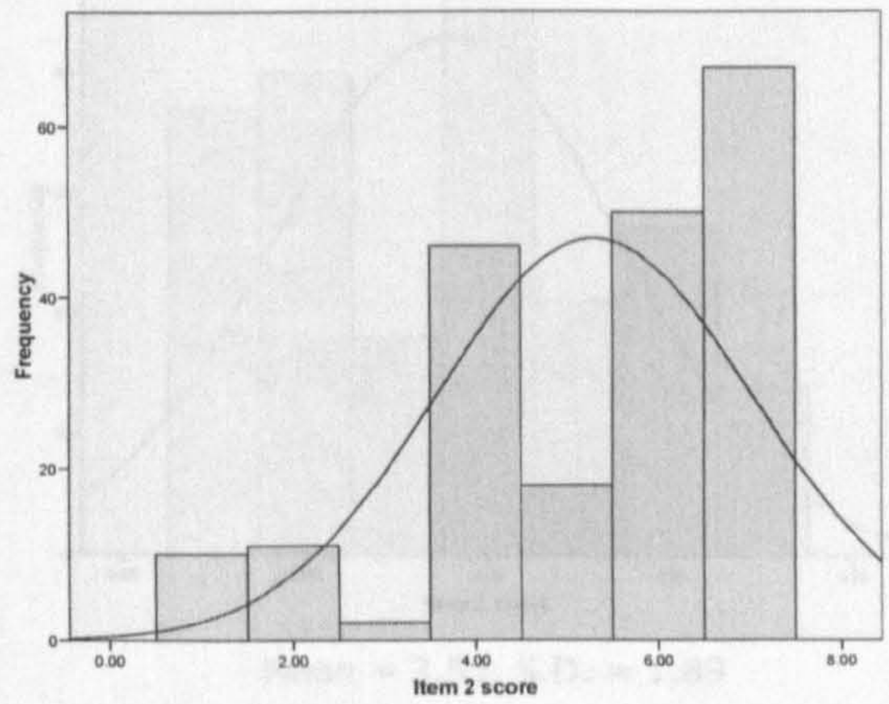
Figure 7.5 Individual belief item scores on NRTP-SF

a) NRT would help me to quit smoking



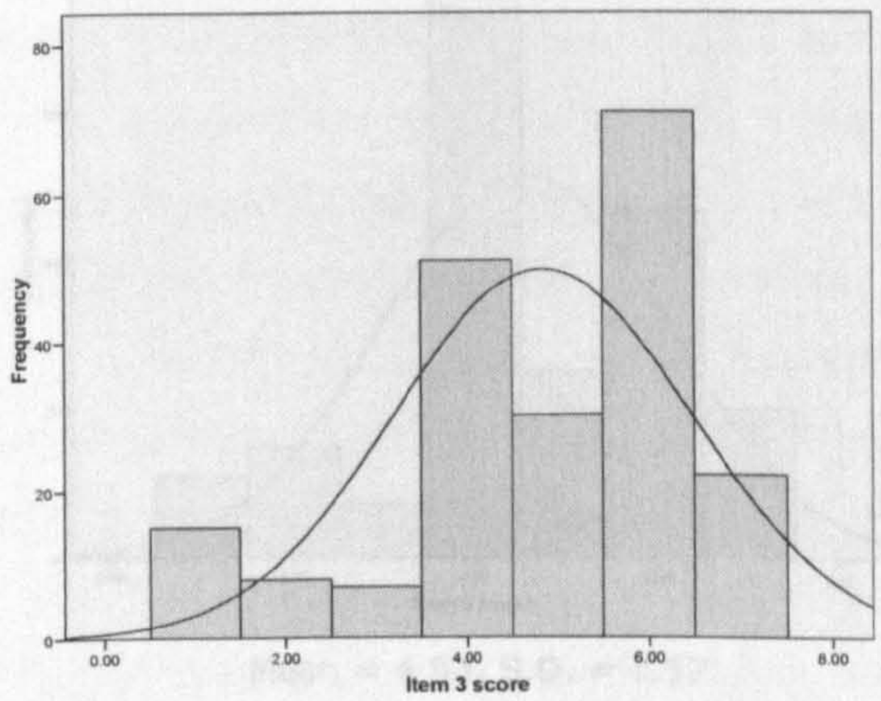
Mean = 4.57, S.D. = 1.70

b) My family would want me to use NRT



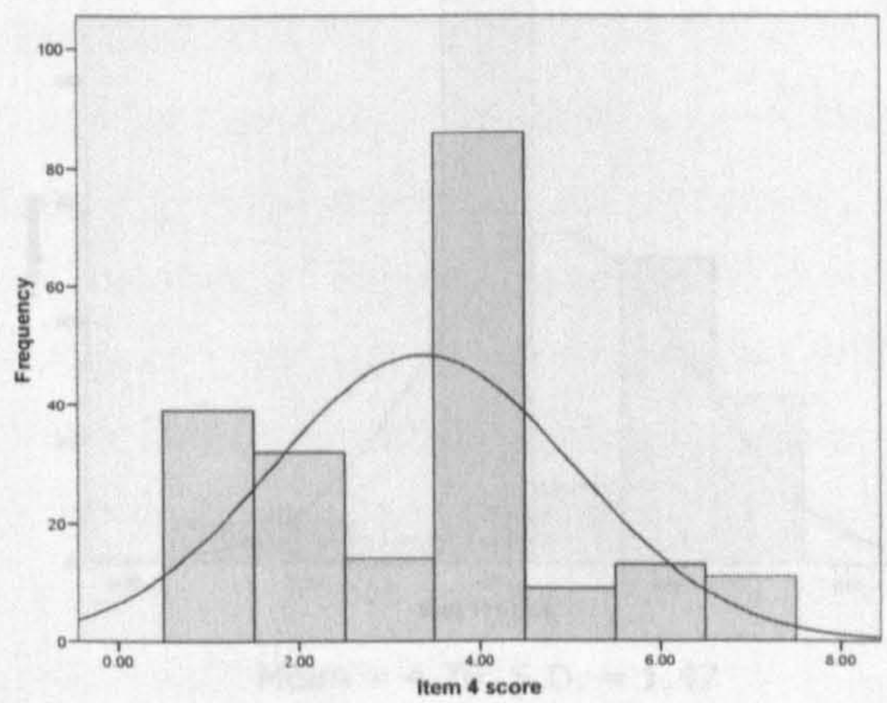
Mean = 5.30, S.D. = 1.74

c) I would find NRT convenient to use



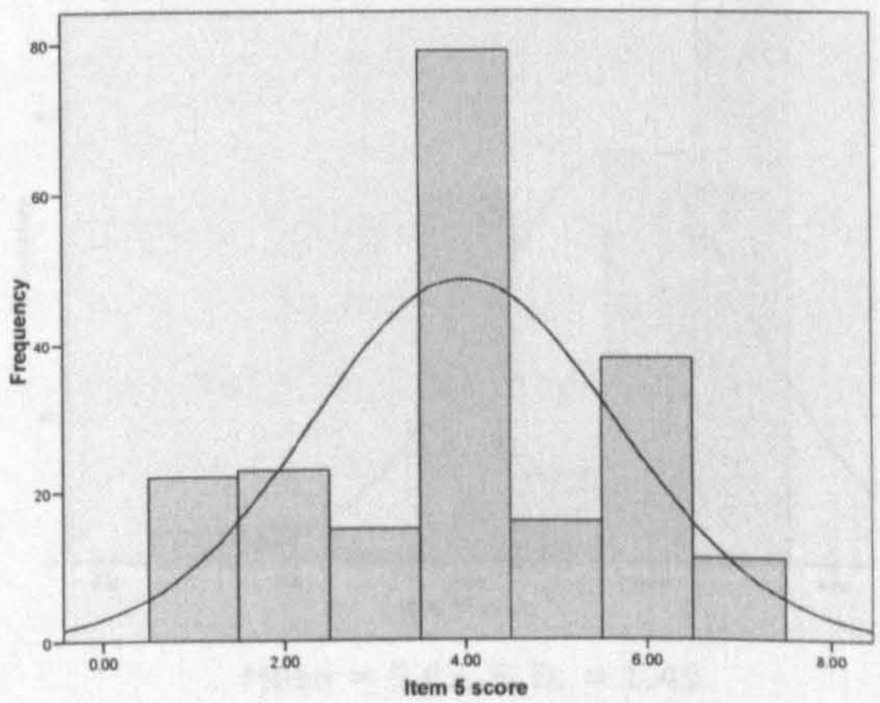
Mean = 4.83, S.D. = 1.64

d) NRT would make my sickness worse



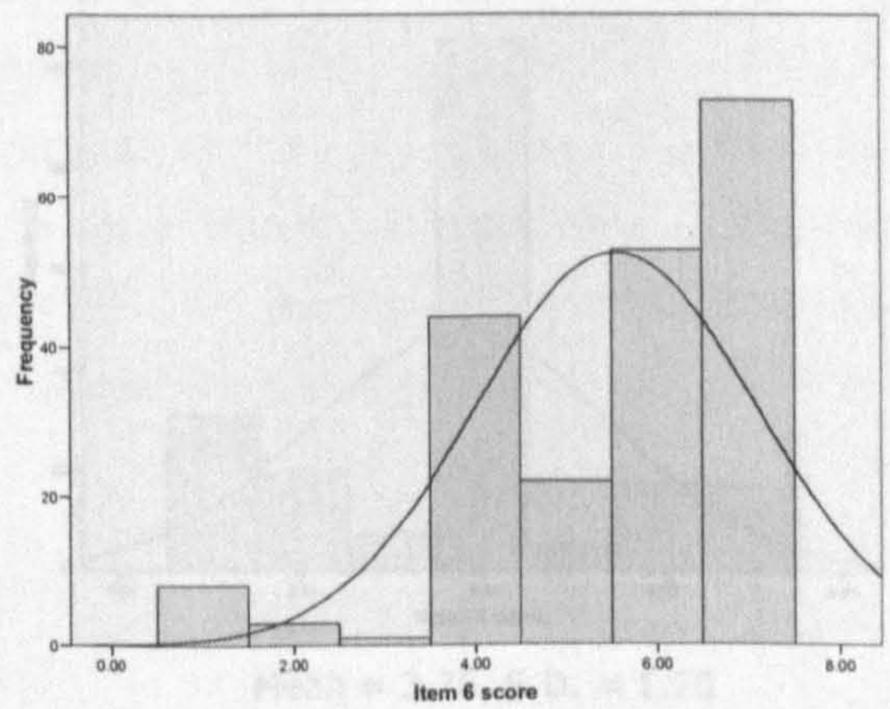
Mean = 3.38, S.D. = 1.68

e) I would know enough about NRT types



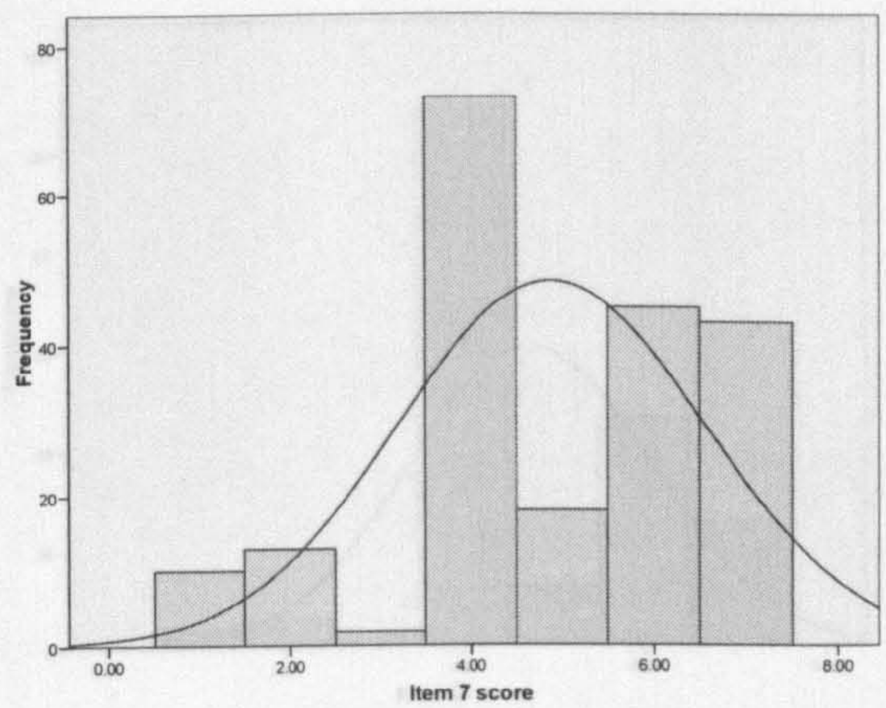
Mean = 3.99, S.D. = 1.68

f) NRT would be healthier for my baby



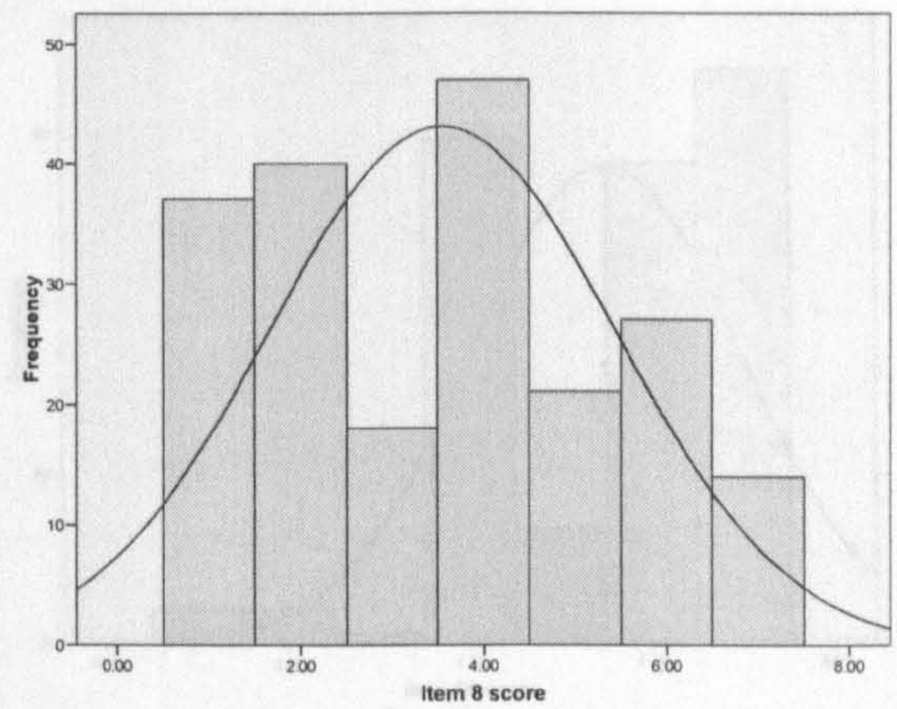
Mean = 5.55, S.D. = 1.55

g) My friends would want me to use NRT



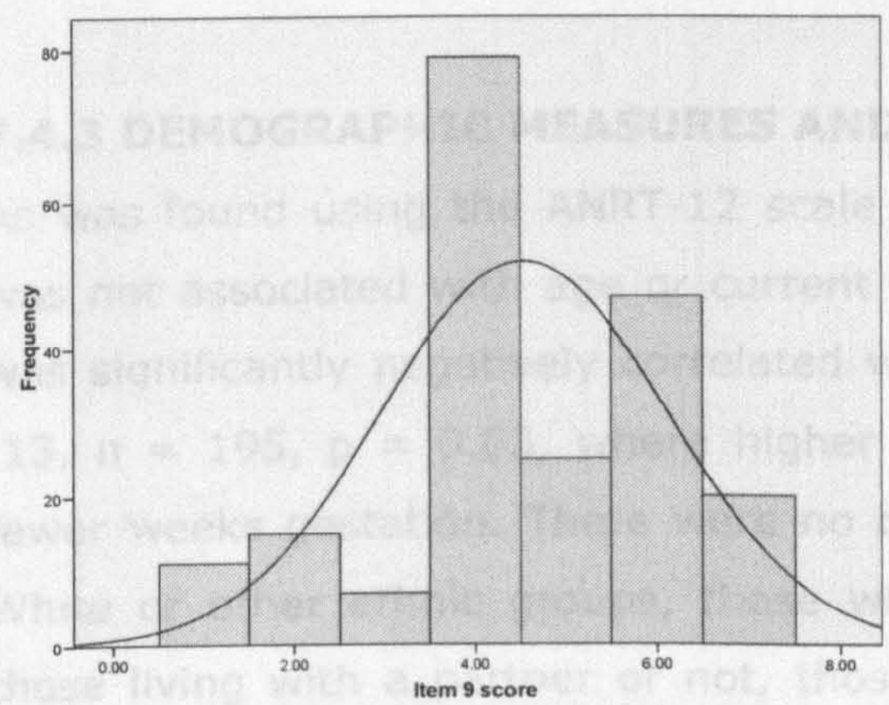
Mean = 4.88, S.D. = 1.68

h) I would forget to use NRT



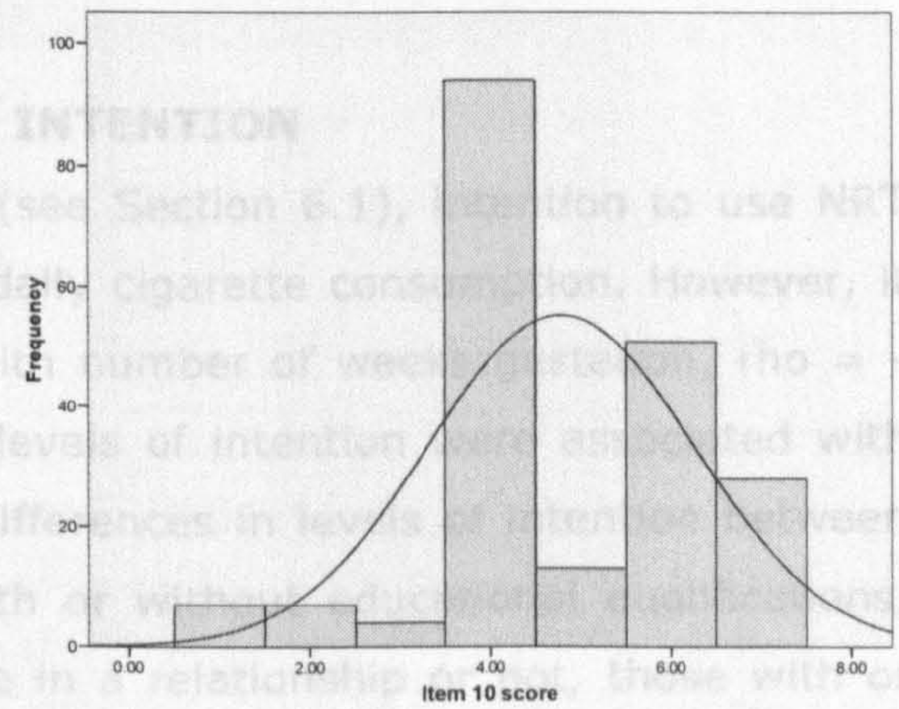
Mean = 3.55, S.D. = 1.89

i) NRT would reduce my cigarette cravings



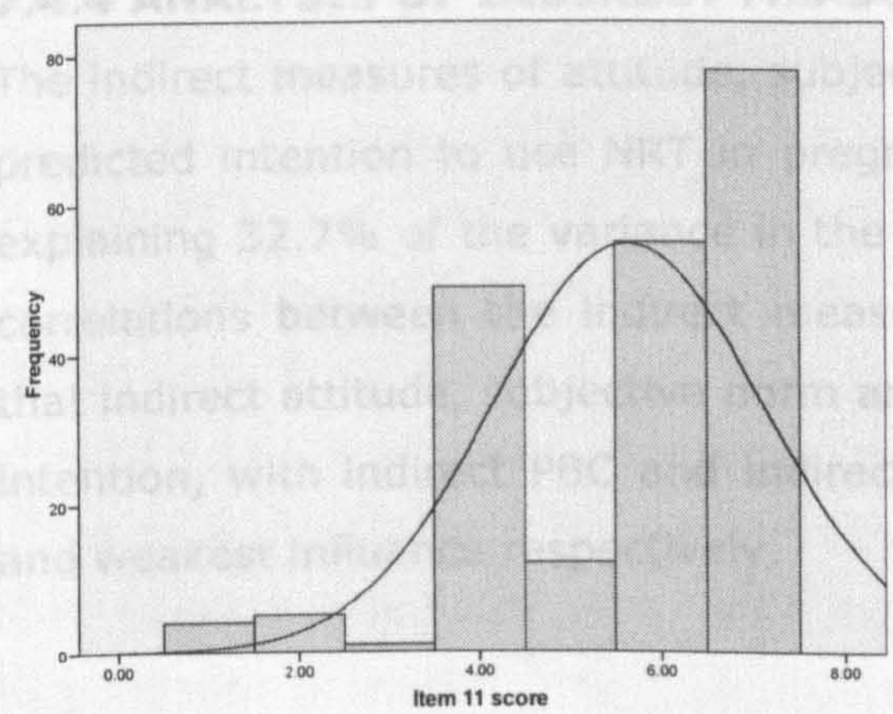
Mean = 4.53, S.D. = 1.57

j) I would be able to get NRT easily



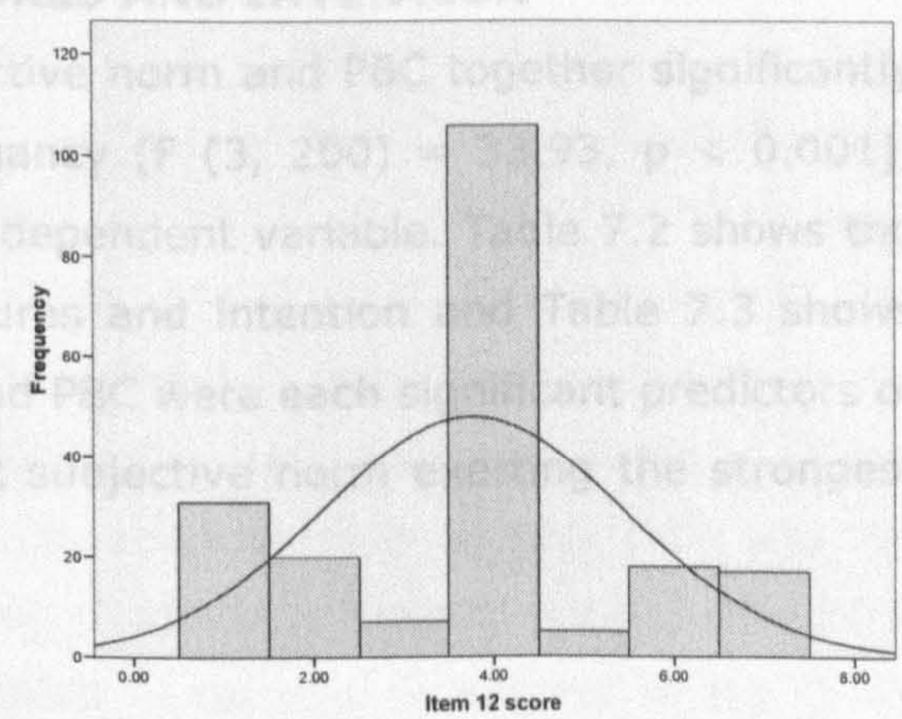
Mean = 4.78, S.D. = 1.47

k) Health experts would want me to use NRT



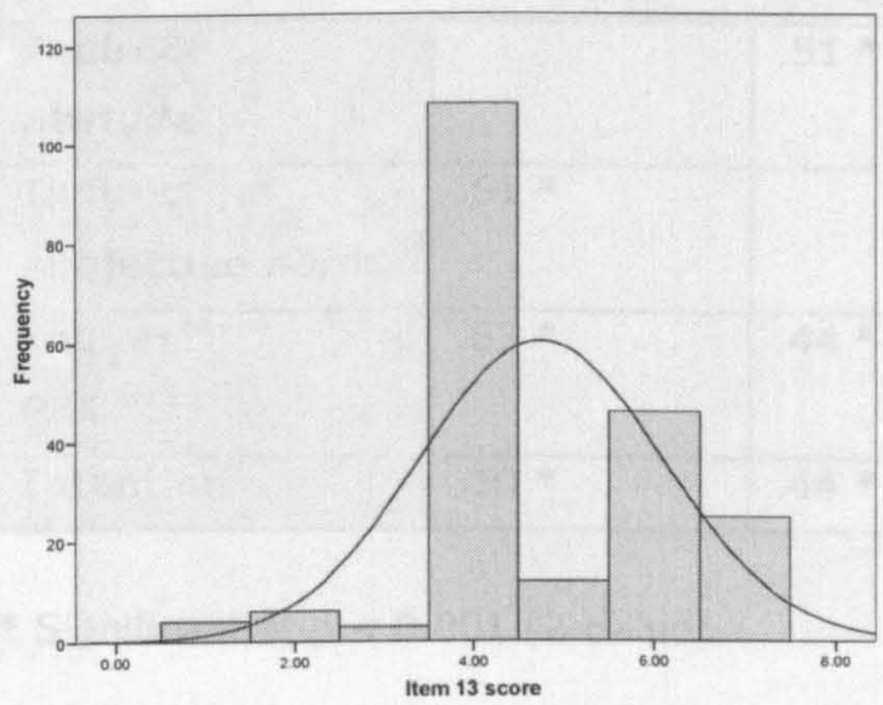
Mean = 5.63, S.D. = 1.49

l) NRT would cost more than cigarettes



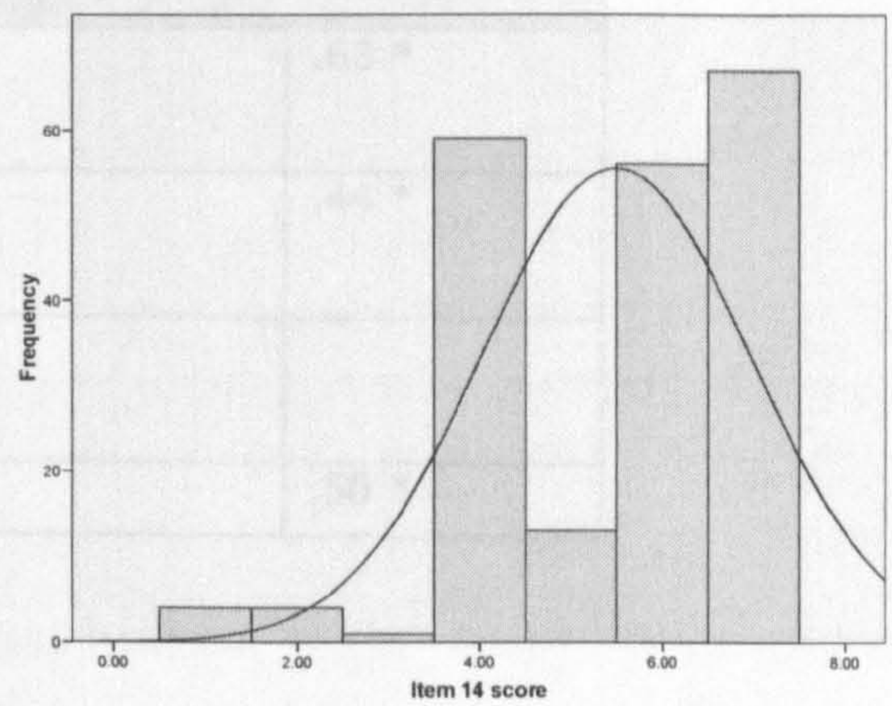
Mean = 3.76, S.D. = 1.70

m) NRT would be safe to use in pregnancy



Mean = 4.75, S.D. = 1.35

n) NRT would be healthier for me



Mean = 5.50, S.D. = 1.47

7.4.3 DEMOGRAPHIC MEASURES AND INTENTION

As was found using the ANRT-12 scale (see Section 6.1), intention to use NRT was not associated with age or current daily cigarette consumption. However, it was significantly negatively correlated with number of weeks gestation, rho = -.13, n = 195, p = 0.03, where higher levels of intention were associated with fewer weeks gestation. There were no differences in levels of intention between White or other ethnic groups, those with or without educational qualifications, those living with a partner or not, those in a relationship or not, those with or without children, or those who had or had not used NRT before.

7.4.4 ANALYSIS OF INDIRECT MEASURES AND INTENTION

The indirect measures of attitude, subjective norm and PBC together significantly predicted intention to use NRT in pregnancy ($F(3, 200) = 33.93$, $p < 0.001$), explaining 32.7% of the variance in the dependent variable. Table 7.2 shows the correlations between the indirect measures and intention and Table 7.3 shows that indirect attitude, subjective norm and PBC were each significant predictors of intention, with indirect PBC and indirect subjective norm exerting the strongest and weakest influence respectively.

Table 7.2 Correlations between indirect measures and intention

	Indirect attitude	Indirect subjective norm	Indirect PBC
Indirect attitude		.51 *	.63 *
Indirect subjective norm	.51 *		.44 *
Indirect PBC	.63 *	.44 *	
Intention	.50 *	.44 *	.50 *

* Significant at $p < 0.001$ (2-tailed)

Table 7.3 Beta coefficients and t values for indirect predictor variables with intention as dependent variable

	B	SE B	β	t
Constant	- 2.28	0.64		- 3.54
Indirect attitude	0.09	0.03	.24	3.02 *
Indirect subjective norm	0.10	0.03	.21	3.07 *
Indirect PBC	0.10	0.03	.26	3.41 *

$R^2 = .34$, $R^2_{adj} = .33$ ($p < 0.001$), * Significant at $p < 0.01$ (1-tailed)

7.4.5 ANALYSIS OF INDIRECT PERCEIVED BEHAVIOURAL CONTROL MEASURE, INTENTION AND BEHAVIOURAL OUTCOME

The logistic regression model containing the two predictors (indirect PBC and intention) was statistically significant, χ^2 (2, N = 69) = 14.03, p = 0.001, indicating that the model was able to distinguish between respondents who expressed interest and who did not express interest in the SNAP trial. The model as a whole explained between 18.4% (Cox and Snell R square) and 26.3% (Nagelkerke R squared) of the variance in interest in SNAP status, and correctly classified 73.9% of cases. As shown in Table 7.4, only intention made a unique statistically significant contribution to the model, recording an odds ratio of 1.98. This indicated that for every one point increase in intentions to use NRT, respondents showed nearly double the odds of expressing interest in the SNAP trial, controlling for the other factor in the model. There was no interaction between PBC and intention on this behavioural outcome.

Table 7.4 Logistic regression predicting likelihood of showing interest in SNAP trial

	β	S.E.	Wald	df	Sig	Odds Ratio	95% CI for Odds Ratio	
							Lower	Upper
Indirect PBC	-.08	.07	1.22	1	.27	.92	.80	1.06
Intention	.68	.22	10.16	1	.001	1.98	1.30	3.02
Constant	-1.86	1.46	1.63	1	.20	.16		

7.4.6 ANALYSIS OF INDIRECT MEASURES AND LOW AND HIGH INTENDERS

Dichotomising the intention variable resulted in 142 low and 62 high intenders and Table 7.5 shows that each of the composite indirect measures significantly discriminated between low and high intenders. Inspection of the medians for low and high intenders show that the direction of the difference in scores was as would be expected for the groups. That is, low intenders had significantly lower scores for each indirect measure than high intenders, indicating that they had a more negative attitude, a weaker subjective norm and a lower PBC towards the behaviour than high intenders.

Table 7.5 Differences in scores for indirect measures between low and high intenders

Indirect measure	z	Median Low (n = 142)	Median High (n = 62)
Indirect attitude	- 6.23	28.00	33.00
Indirect subjective norm	- 5.45	15.00	18.00
Indirect PBC	- 6.42	21.00	26.00

* Significant at $p < 0.001$ (2-tailed)

7.4.7 INFLUENCE OF SPECIFIC BELIEFS ON INTENTION

The 14 belief items together significantly predicted intention to use NRT in pregnancy ($F(14, 189) = 10.69$, $p < 0.001$), explaining 40.1% of the variance in the dependent variable. Table 7.6 shows that belief items 1, 7, 8, 9 & 13 significantly predicted intention to use NRT in pregnancy.

Table 7.6 Beta coefficients and t values for belief items with intention as dependent variable

	B	SE B	β	t
Constant	- 0.16	0.64		- 0.25
Behavioural Beliefs				
Item 1 - NRT would help me to quit smoking (+)	0.21	0.09	.19	2.34 *
Item 4 – NRT would make my pregnancy sickness worse (-)	- 0.07	0.07	- .06	- 0.99
Item 6 – NRT would be healthier for my baby than if I smoke (+)	- 0.07	0.09	- .05	- 0.76
Item 9 - NRT would reduce my cravings for a cigarette (+)	0.19	0.08	.16	2.34 *
Item 12 – NRT would cost me more than cigarettes do (-)	0.08	0.06	.07	1.24
Item 14 - NRT would be healthier for me than if I smoke (+)	0.17	0.10	.13	1.64
Normative Beliefs				
Item 2 – My family would want me to use NRT while I am pregnant (+)	0.03	0.08	.03	0.42
Item 7 - My friends would want me to use NRT while I am pregnant (+)	0.24	0.09	.21	2.76 **
Item 11 – Health experts would want me to use NRT while I am pregnant (+)	- 0.04	0.09	- .03	- 0.39
Control Beliefs				
Item 3 – I would find NRT convenient to use (+)	0.12	0.10	.10	1.16
Item 5 – I would know enough about the different types of NRT (+)	0.01	0.07	.01	0.11
Item 8 - I would forget to use NRT (-)	- 0.16	0.06	- .16	- 2.44 *
Item 10 – I would be able to get a supply of NRT easily (+)	- 0.09	0 08	- .07	- 1.07
Item 13 - I would think that NRT is safe to use in pregnancy (+)	0.21	0.10	.15	2.19 *

$R^2 = .44$, $R^2_{adj} = .40$ ($p < 0.001$)

** Significant at $p < 0.01$ (1-tailed), * Significant at $p < 0.05$ (1-tailed)

(+) = positively worded belief, (-) = negatively worded belief

7.4.8 READABILITY OF NRTP-SF

Flesch Reading Ease was calculated to be 92% which classifies the NRTP-SF as 'easily understandable by an average 11 year old student'. Flesh-Kincaid Grade level was 2.7, so given that Grade 3 equates to ages 8-9, under this criterion the NRTP-SF was deemed to have readability suitable for an 8 year old.

7.4.9 SENSITIVITY ANALYSIS

The sensitivity analysis, excluding the 26 cases where data had been imputed on the TPB items, was run on 178 cases. Using multiple regression, the three indirect measures together predicted 35.3% of the variance in intention, much the same proportion as in the original analysis. As before, each measure significantly contributed to the variance in intention with similar standardised beta weights of .23, .24 & .26 for indirect attitude, subjective norm and PBC respectively. Multiple regression showed that belief items 1, 7, 8, 9 were again significant predictors of intention, but item 14 (NRT would be healthier for me than if I smoke) emerged as a different significant predictor to that found originally ($\beta = .22$, $t = 2.62$, $p < 0.05$) and item 13 (I would think that NRT is safe to use in pregnancy) was no longer significant. Excluding the cases where data had been imputed on the TPB items reduced the SNAP data by 6 cases. The logistic regression model using the 63 cases was again statistically significant, explaining between 17.6% and 26.0% of the variance in interest in SNAP, a very similar range to that found in the original analysis. As previously, only intention made a unique statistically significant contribution to the model, recording an identical odds ratio of 1.98. The similarity between the findings from the imputed and the unimputed datasets thus provides justification for the median imputation method used.

7.5 STUDY FOUR DISCUSSION

This study used a short form belief-based questionnaire informed by the TPB (NRTP-SF) to further explore factors associated with intention to use NRT in pregnancy. The composite indirect measures of attitude, subjective norm and PBC together significantly predicted intention to use NRT in pregnancy, explaining 32.7% of the variance. All three predictors independently significantly predicted intention with indirect PBC exerting the strongest influence ($\beta = 0.26$) followed by indirect attitude ($\beta = 0.24$) and indirect subjective norm ($\beta = 0.21$). This indicates that beliefs about outcomes of using NRT, social pressure to use NRT and control over using NRT are all important factors in predicting intention to use

NRT in pregnancy. Although explaining less variance in intention than the direct measures in NRTP-LF, the contributions made by these measures are not dissimilar to the indirect measures in the NRTP-LF (see Chapter Six) which highlights that the predictive validity of the NRTP-SF has not been unduly compromised by its shortened form. Indirect PBC and intention together significantly predicted interest in participating in the SNAP trial, but only intention made a uniquely statistically significant contribution to the model. Given that expressing interest in SNAP could be argued to be a behaviour with volitional control, as was expressing interest in participation in a smoking cessation programme (Babrow et al., 1991), these findings are in line with the TPB which states that PBC will only exert independent influence for nonvolitional behaviours (Armitage & Conner, 2001). These findings provide further evidence for the ability of the TPB to predict intention to use NRT in pregnancy, and the fact that the indirect measures proved to be good predictors has important implications for any intervention work given that it is modifications of beliefs which are expected facilitate behaviour change (see Section 3.5). The NRTP-SF was also able to discriminate between low and high intenders, as respondents with higher intention to use NRT in pregnancy had a significantly more positive attitudes, stronger subjective norms and higher PBC with regard to NRT use than those with lower intention to use it. Furthermore, its readability level was likely to be more than acceptable for the majority of those who would be completing it.

The fact that there was a spread of scores on each of the 14 NRTP-SF items with no apparent floor or ceiling effects indicates that they were selected appropriately. The very similar distributions in Figures 7.5a and 7.5i suggest that respondents tended to view NRT as being helpful for quitting because they believed it reduces cigarette cravings. However, the high numbers who were uncertain about this reflect the evidence-base where the success of NRT in pregnancy remains inconclusive (see Section 2.1.1.2). The social pressure felt from family (see Figure 7.5b), friends (see Figure 7.5g) and health experts (see Figure 7.5k) to use NRT in pregnancy is likely to be due to the strong societal expectations that pregnant women should not be smoking (Bull et al., 2007). Although the majority reported that they would feel a social pressure to use NRT in pregnancy, a number were unsure, which might be indicative of the degree of uncertainty that exists about whether or not NRT should be used by this group (e.g. Price et al., 2006b; see Section 2.3.6). Even though most felt that using NRT would be a healthier option than smoking both for themselves (see Figure 7.5n) and their baby (see Figure 7.5f), there was much uncertainty about the

safety of the products per se. This is consistent with other studies (e.g. Herbert et al., 2005; see Section 2.3.6) and is a legitimate concern given the lack of definitive evidence for the safety of NRT in pregnancy (see Section 2.1.2). Given that so many reported being uncertain about whether NRT would cost more than cigarettes highlights the need to promote the fact that it is available free in pregnancy, especially as knowing this can provide an incentive to quit (see Sections 4.4.2.1.1 & 4.4.3.1.5). Furthermore, many were unsure whether they could acquire NRT easily which provides further evidence that information about its availability though Stop Smoking Services is not being routinely given to pregnant women (e.g. Abatemarco et al., 2007; see Section 2.2.4.2). The only significant relationship between the demographic measures and intention to use NRT during pregnancy was a negative correlation between number of weeks of pregnancy and intention. The fact that higher levels of intention to use NRT were associated with fewer weeks gestation is consistent with reports that most pregnant smokers are most receptive to quitting early in their pregnancy (Owen & Penn, 1999) and supports the construct validity of the measure.

Table 7.6 and the sensitivity analysis (see Section 7.4.9) show that 6 of the individual belief items were significant predictors of intention to use NRT. These were 'NRT would help me to quit smoking', 'NRT would reduce my cravings for a cigarette', 'NRT would be healthier for me than if I smoke', 'My friends would want me to use NRT while I am pregnant', I would forget to use NRT, 'I would think that NRT is safe to use in pregnancy'. It could be that these are beliefs worthy of targeting in any interventions designed to increase uptake of NRT use in pregnancy as it is important for health professionals to focus on the beliefs pregnant women see as most important.

Although it is likely that promoting NRT as being helpful for quitting and safe to use in pregnancy would encourage its use, it would be important for health professionals to only provide information that is consistent with the evidence base which shows that the efficacy and safety of NRT use in pregnancy is far from conclusive (see Sections 2.1.1.2 & 2.1.2). The fact that the social pressure exerted from friends appears to be highly influential in the decision-making process about NRT use in pregnancy suggests that it would be beneficial if those working in smoking cessation could encourage friends who also smoke to consider quitting alongside the pregnant women. This could present a challenge given that smoking is very much embedded in the culture of many pregnant smokers but is very much in line with other studies which have stressed the need to involve and

account for social context in quitting (e.g. Bull et al., 2007). Much research points to quitting smoking in pregnancy as being a suspended behaviour purely undertaken to protect the health of the unborn child and many women do return to smoking following the birth (e.g. Stotts et al., 2000). It is therefore of interest that a belief that using NRT would protect their own health was found to be an influential factor in predicting NRT use in pregnancy and suggests that this issue should be given greater prominence by health professionals dispensing smoking cessation advice to this group. Helping women to develop positive beliefs about their own health could provide a motivation for them to remain abstinent postpartum (Lendahls et al., 2002) which would not only improve their own health but protect their child and others in their social network from the detrimental effects of environmental tobacco exposure (Rogers, 2008). The fact that issues around forgetting to use NRT were predictive of its use indicates that it might be beneficial for health professionals to promote the nicotine patch as a product the pregnant women could put on each morning and then forget about for the rest of the day. This positive aspect of patch use was raised in the elicitation study (Chapter Four). Furthermore, pregnant women could be reminded to use oral NRT products at the times when they would have had a cigarette.

7.5.1 STUDY STRENGTHS AND LIMITATIONS

7.5.1.1 Content validity

The fact that the items selected for the NRTP-SF were derived from an earlier elicitation study to ascertain the views of 'experts' in the field (see Chapter Four), suggests that the NRTP-SF had content validity, i.e. the ability to represent adequately the concept being investigated (Kerlinger, 1973).

7.5.1.2 Data collection

Data collection in this study was still a slow process which is likely to be indicative of research with a hard to reach group. However, the shortened questionnaire did enable double the number of questionnaires to be collected within a similar time period compared to the NRTP-LF, and its relative simplicity resulted in much less missing data and thus more usable cases for analysis. As in Study Three, the sensitivity analysis provided justification for the imputation method used on those questionnaires which had minimal missing data.

7.5.1.3 Sample

As for the NRTP-LF sample, the majority (86%) who completed the NRTP-SF were not educated beyond NVQ/GSCE level so the sample was in keeping with the educational level expected for this population (see Section 1.2.2). Again, women with differing marital status, parity and experience of NRT were present in the sample and there was a range of ages, stages of pregnancy and levels of cigarette consumption. Therefore, apart from the under representation of ethnic minority groups, the sample included women with varying demographic characteristics which suggests that a diverse set of views was likely to be captured. As was the case with the NRTP-LF sample, respondents were recruited via antenatal clinics and NHS Stop Smoking Services which means that the results might not be representative of pregnant women who do not attend these services. Also, those who completed the questionnaire might have held different views to those who declined to participate.

7.5.1.4 Proxy behaviour

As discussed in Section 6.5.1.6, a limitation of TPB research is that behaviour is rarely measured longitudinally. Attempts were made to partially address this by utilising interest in participation in the SNAP trial as a proxy for NRT use because of the lack of time available to follow-up women to the end of their pregnancies and the difficulties experienced in acquiring this data in Study Three (see Section 6.4.10). Although it could be argued that interest in SNAP represented a stage beyond intention to use NRT, it is recognised that this proxy might have been measuring interest in participating in clinical trials rather than using NRT. Therefore, it remains uncertain whether the NRTP-SF would predict actual NRT use in pregnancy and this would need to be tested by further research.

7.6 STUDY FOUR CONCLUSION

The NRTP-SF displayed content and predictive validity and identified specific beliefs which were particularly influential in forming an intention to use or not use NRT in pregnancy. The questionnaire also significantly predicted interest in participating in a clinical trial investigating the efficacy and safety of NRT in pregnancy. Although a proxy behaviour for actual NRT use, it was considered that this represented a stage beyond intention to use NRT in pregnancy. It is possible that the NRTP-SF could be of use to clinicians as a screening tool to enable them to tailor their advice about NRT use to pregnant women. It could also have utility for identifying appropriate targets for an intervention to improve the uptake of NRT in pregnancy and assessing the effectiveness of such interventions.

CHAPTER EIGHT: DISCUSSION

The content of each of the thesis chapters will be briefly restated followed by more detailed discussion about the findings and issues related to the thesis studies. The implications for future research and practice will then be considered.

8.1 SUMMARY OF CHAPTERS

Guided by a social cognition theory-based approach, this thesis systematically investigated the beliefs pregnant smokers have about NHS Stop Smoking Services and Nicotine Replacement Therapy (NRT). Chapter One outlined the range of harms that can result from smoking in pregnancy, the prevalence of smoking amongst pregnant women and the characteristics of this population. Chapter Two reported on the effectiveness of smoking cessation interventions in pregnancy, the safety of NRT for use by pregnant women and the current guidelines for smoking cessation support for this group. This chapter also summarised the attitudes pregnant women have towards smoking cessation support delivered as part of routine care and outside routine care, and their views about NRT. This was followed by pregnant women's experience of the provision of such support and health professionals' attitudes towards delivering this. Finally, this chapter provided justification for adopting a theory-based approach to inform the thesis studies. Chapter Three described the Theory of Planned Behaviour (TPB), covering the conceptual and operationalisation issues associated with this theory and its ability to predict behaviour and inform interventions relevant to the thesis. Chapter Four was a qualitative study designed to elicit the beliefs pregnant smokers have about NHS Stop Smoking Services and NRT, the information from which was used to inform later studies in the thesis. In Chapter Five, a theory-based resource to facilitate the communication of smoking cessation information to pregnant women was developed and tested. Chapter Six reported on the development and testing of a TPB questionnaire designed to predict NRT use in pregnancy and Chapter Seven tested the validity of a short form version of this.

8.2 STUDY ONE

The elicitation study reported in Chapter Four revealed a wide range of behavioural, normative and control beliefs in relation to use of NHS Stop Smoking Services and Nicotine Replacement Therapy, thus demonstrating that the TPB was a useful framework for this investigation. A criticism of much TPB research is

the lack of an initial elicitation study (Conner & Sparks, 2005; see Section 3.4.1) and the fact that this was conducted meant that the subsequent quantitative measures which were developed could be considered to have content validity. The standard elicitation questions as stipulated by Aizen (2002b) were used in this study, but it is acknowledged that these might have resulted in the generation of beliefs which were more cognitive than affective in nature (see Section 3.4.1). Although it is possible that the methodology used meant that the individual beliefs of respondents in the subsequent studies were not adequately represented, eliciting modal beliefs in this way has been found to be predictive of behaviour (Conner & Armitage, 1998). Furthermore, it is a much more time effective method than eliciting beliefs individually. Much deliberation took place when assigning coding units to the TPB constructs, and email communication with Jill Francis confirmed the view of Conner & Sparks (2005) that deciding whether an item constitutes a behavioural, normative or control belief can be a difficult decision. Although the use of the second coder demonstrated that the quotes had been reliably allocated on the basis of the codebooks, it should be noted that different themes might have emerged had a different researcher analysed the data. Furthermore, even though efforts were made to elicit beliefs from a representative sample, it is recognised that a different set of interviewees may have produced different findings.

8.3 STUDY TWO

A resource to facilitate the communication of smoking cessation information to pregnant women was developed because high quality smoking cessation advice as part of routine care in pregnancy is patchy (see Section 2.2.4) and health professionals working with pregnant women report lacking the confidence and skills to deliver such advice and have requested training for this (e.g. Clasper & White, 1995). Theory-based interventions are uncommon but considered necessary in health care settings (e.g. Jones & Donovan, 2004; see Section 3.5.3). Also, many theory-based intervention studies are poorly designed (Hardeman et al., 2002) with a lack of randomised controlled trials, appropriate control groups and blinding of participants (Norman & Conner, 2005). As such there has been a call for increased rigour in this regard (Michie & Abraham, 2004). This study represented an attempt to address these issues in the research by employing a RCT design incorporating exacting criteria.

Although use of the theory-based resource did not significantly improve the medical students' ability to elicit the salient beliefs of the simulated patient compared to those who used the standard information resource, there was a trend towards significance for this outcome. Furthermore, there was evidence to suggest that those who used the theory-based resource probed more deeply about the beliefs of the patient, utilised the subjective norm element of the TPB and believed more strongly that the resource helped them to elicit the patient views than the control group. Based on the study findings, there is reason to believe that the theory-based resource has the potential to facilitate a more patient centred exchange without compromising other important general communication skills and as such is worthy of further testing. As the trial was underpowered to detect small differences between the conditions if they existed, it would be necessary to repeat the study using a larger sample of health professionals or trainee health professionals. It would also be important to evaluate the impact of the intervention in a real world setting with pregnant patients rather than simulated patients as is recognised that the latter may not display the idiosyncrasies of the former (Wallace et al., 2002). As the main criticism levelled at the study by the trainee health professionals was the lack of time given to assimilate the information provided in the resources, it would be of interest to see if there was any effect of giving additional preparation time. As specified by Norman & Conner (2005) if an intervention is to translate successfully into a health-care setting, it has to be acceptable to the health professionals using it. According to Bhattacharya et al. (2006), evidence of the effectiveness of theory-based interventions via pragmatic trials is needed before they are routinely used in health care settings. It would be crucial in further research to assess health professionals' views about the viability of this resource especially as it would likely have to be accommodated into already busy work schedules and training would be needed on its theoretical underpinnings. As allocating time for training is often problematic in health care settings (Hajek et al., 2001), the perceived complexity of the intervention would also need to be ascertained.

The fact that the TPB has good predictive validity, describes the relationships between its constructs, provides clear guidelines for assessing these constructs and it is possible to manipulate the variables in the model makes it a potentially promising theory upon which to base an intervention (Norman & Conner, 2005). However, its main limitation in this regard is that it does not specify how to change behaviour (Taylor et al., 2006), and it possible that the persuasive

communication strategy selected for the theory-based resource was not an appropriate one for the purpose.

By acknowledging the difficulties associated with designing and conducting a RCT within a social setting, it was it is recognised that this was very much a pragmatic trial. Particular challenges were deciding what represented an acceptable control condition and attempting to train the simulated patients to respond in accordance with the stipulated guidelines. As it was clear from the findings that the simulated patients had responded differently, this issue would need to be given further consideration in future trials involving simulated patients. However, this would not be a concern if the resource was to be used in a health-care setting where its effectiveness would likely be judged on pregnant patients' intention to engage or actual engagement with Stop Smoking Services.

8.4 STUDY THREE

The NRTP-LF significantly predicted intention to use NRT in pregnancy, explaining an identical amount of variance in the intention variable as the study by Thomson et al. (2006) which used the theory to predict intention to use NRT in female smokers (see Section 3.2.4). The statistical tests employed indicated that the questionnaire was well designed using appropriate direct and indirect measures and that the TPB was a useful theory for investigating this behaviour. Conceptually, it was challenging to ascertain whether the negatively worded belief composites needed to be reverse coded and email communication with Icek Aizen took place on several occasions to discuss this and other issues in the researcher's attempt to operationalise the theory as rigorously and correctly as possible. Of particular concern was the decision-making about how to scale the multiple composites given that different combinations of unipolar and bipolar scales can produce very disparate findings (see Section 3.4.3). For the reasons stated in Section 6.3.5.4, it was decided to follow the recommendations of Francis et al. (2004) for this. As mentioned in Section 6.5.1.6, a criticism of TPB research is often the failure to measure behaviour longitudinally and attempts to do this in terms of actual NRT use yielded insufficient responses for meaningful statistical analysis. Therefore, the study had to rely on correlational data where causation cannot be inferred and whether the TPB is able to predict this behaviour remains an unanswered question which would need to be addressed by further research. The fact that the TPB is a relatively weaker predictor of actual behaviour suggests that other strategies, such as implementation intentions (Gollwitzer, 1993; see

Section 3.3.3) might need to be put into place to reliably translate intention into action. Thomson et al. (2006) found that effort and planning were successful strategies for NRT adoption in non-pregnant female smokers so perhaps these would also be applicable to pregnant women. The problems obtaining follow-up data and the slow rate of response to the NRTP-LF highlighted the challenges associated with conducting research with a hard to reach group and relying on data collection at remote sites.

Although in the strictest sense of the TPB, it is the direct measures which directly predict intention, the model only has practical utility for intervention work to the extent that the belief based measures are able to predict intention (Sutton, 2002). In the NRTP-LF, the indirect measures predicted nearly as well as the direct measures, calling into question the need for the latter given that they do not provide information about the specific underlying beliefs which could be amenable to change in an intervention. Aside from the theoretical and scaling issues surrounding the use of multiple composites, it was felt that the some of the evaluative items compromised the face validity of the questionnaire and these were only included for completeness sake. For instance, a pregnant women having to rate whether her baby being healthy was good or bad was clearly an item which would elicit an obvious response and thus generate little extra variance.

Even though both the direct and indirect measures predicted intention to use NRT in pregnancy, a large proportion of the variance remained unexplained and there is always room for improvement. As described in Section 3.1.4, multiple reasons have been put forward for this why this might be so. Although a decision was made to operationalise the TPB in its pure form in this study, it has been suggested that the model may be too parsimonious and perhaps neglects wider factors (e.g. Norman & Conner, 2005). Studies reported in Section 3.2.2 revealed that factors other than the TPB constructs, e.g. habit strength (Moore et al., 1996) and craving (Bennett & Clatworthy, 1999) predicted quitting behaviours in pregnancy. It has been argued that more attempt needs to be made to account for the social and environmental context (Sutton, 2002) and this could be particularly pertinent in the case of the pregnant smokers who tend to be of lower socio-economic status and whose behaviour is very much embedded in their societal culture. Indeed, changing individual cognitions might have a limited effect given that health equalities are functions of material and socio-cultural differences (Taylor et al., 2006).

8.5 STUDY FOUR

The NRTP-SF significantly predicted intention to use NRT, explaining a respectable proportion of the variance, and was able to discriminate between low and high intenders, despite its much shorter form. It is interesting to note that the composite indirect measures explained less variance than the collection of the individual belief items as, according to the principles of the TPB one might have expected these to equate. The reduced length and relative simplicity of the questionnaire likely made people more receptive to completing it, and using indirect measures offers potential practical utility for intervention work. Furthermore, not including multiple composites means that the expectancy-value relationship does not need unpicking and makes interpreting findings easier.

As the SNAP trial was being conducted in the Nottingham hospitals at the time of data collection for the thesis, it was considered that interest in participating in this would provide some indication of pregnant women's receptivity to using NRT. However, it is acknowledged that this might not have been an accurate predictor of actual NRT use but perhaps more of an interest in participating in clinical trials. However, because of the difficulties associated with ascertaining actual NRT use in Study Three and the time constraints on data collection in this study, it was considered that using the local available SNAP data might give more of an indication about interest in using NRT in pregnancy beyond the intention variable specified by the questionnaire. Further research is needed to assess the ability of the NRTP-SF to predict actual use of NRT in pregnancy.

According to the Aizen (2002b), it is not appropriate to assess for the reliability of indirect measures of the theory. However, in the future, the ANRT-12 scale mentioned in Section 6.1, could be used to test the concurrent validity NRTP-SF, as some of the attitudes towards NRT will be generic for pregnant and non-pregnant populations.

8.6 IMPLICATIONS FOR RESEARCH & PRACTICE

8.6.1 Pregnant smokers and health professionals

A major difficulty in conducting research with pregnant women was recruiting participants. Although pregnancy is an ideal opportunity for health professionals to discuss smoking, the fact that pregnant women are accessing health services for pregnancy related reasons, means that smokers in this group may not be very

interested in quitting (Ebert et al., 2009). This is a potential reason why recruitment via the antenatal clinic to participate in research investigating smoking cessation in pregnancy was very slow. Although recruitment via NHS Stop Smoking Services proved more fruitful, this meant that it was not possible to conduct a quantitative study to predict use of Stop Smoking Services using this sample. Given the poor attendance of these services by pregnant women, this is an investigation that warrants further attention. However, future studies of this nature would need to be adequately funded and supported in order to recruit sufficient numbers and acquire behavioural follow-up data. Antenatal clinic recruitment tended to depend on the attitudes of the health professionals in the clinic and whether they considered it to be an important use of their time. Therefore, such research may also benefit from a period of rapport building between researchers and health professional staff at the outset.

Smoking cessation interventions very often do not take sufficient account of pregnant smokers' needs, especially in terms of the stressors in their lives, their low self esteem and lack of control over their life circumstances. Furthermore, although many of these women smoke to control their mood, midwives tend to only address smoking habits via closed-questions (Ebert et al., 2009). As reported by Zhu & Valbo (2002), depression is not uncommon amongst pregnant smokers and this presents a major obstacle in their attempts to quit smoking (Blalock et al., 2005). Pregnant women need to be more involved in the decision-making process about quitting and have their beliefs and concerns addressed. To achieve this, it may be that a theory-based resource designed to help facilitate a more patient centred approach would be useful for midwives and other health professionals. This could help to make pregnant women feel more responsible and accountable for their actions and to take ownership of their smoking habit (Petersen et al., 2009). Use of such a resource would also be a good opportunity to make health professionals more aware of behavioural theories as they need more training in the use of these (Jones & Donovan, 2004). Community pharmacy-based smoking cessation has been shown to be effective and cost effective (Cramp et al., 2007) and using a computer system to structure delivery of smoking cessation advice was feasible and acceptable in a community pharmacy setting (Hodges et al., 2009). In line with the views of Lawrence & Haslam (2007) and Ebert et al. (2009), this thesis supports the need for the introduction of effective training programmes within educational settings and the recognition of smoking cessation as a routine clinical activity in medicine, nursing and midwifery.

8.6.2 Use of theoretical models

It is considered that the TPB has provided a useful framework for the thesis studies. A particular strength of this approach is the use of qualitative findings to inform subsequent questionnaire development (Young et al., 1991). Using the TPB has enabled salient beliefs of pregnant women with respect to NHS Stop Smoking Services and NRT to be identified. This information could be useful for health professionals when discussing smoking cessation with pregnant women. It could also help to inform the development of appropriate materials advertising the available aids to smoking cessation in pregnancy. However, like any theory, the TPB has conceptual and operational limitations which need to be considered.

Many models of health beliefs (including the TPB) have been criticised as assuming that behaviour is a consequence of a series of rational stages (Ogden, 2004). As behaviour such as smoking can be pleasurable, automatic and addictive (Lawrence & Haslam, 2007), it might be that a model which proposes a rational process is not the most appropriate for this investigation. However, as Lawrence & Haslam (2007) state, it is unlikely that any one model can account for the complexities of human behaviour change. It is also possible that the elicitation of behavioural, normative and control beliefs is merely an artefact of asking specific questions about these factors, and that interview and questionnaire questions actually create these cognitions (Ogden, 2004). Furthermore, such models are not specified to adequately incorporate and interpret social, economic and/or environmental factors as predictors and determinants of health behaviour (Taylor et al., 2006). Given that social context appears to be an important factor in the smoking behaviour of pregnant women, it could be argued that this is a particular shortcoming of utilising the TPB in this research area.

Fully specified TPB questionnaires which contain both direct and indirect measures including multiple composites are lengthy and complicated to complete. Young et al. (1991) identified a number of flaws in operationalising the TPB which could compromise questionnaire reliability: 1) how a respondent is expected to evaluate a belief that they do not hold 2) the difficulties associated with evaluating a belief out of context 3) the perceived similarity of the expectancy and value items leading to frustration and response set and 4) the potential for socially desirable responding, especially if recruited by a health professional. The authors noted that these issues can be minimised by the researcher providing thorough explanations and instructions, adequate time for questionnaire completion, a relaxed and accepting environment, and assurances about

anonymity, confidentiality and aggregation of data analysis. These are strategies that would need to be given particular attention in any future TPB research into smoking cessation in pregnancy. In a 'Think Aloud' study (French et al., 2007) to ascertain what people think about when answering TPB questionnaires, some additional concerns were raised. For example, certain respondents experienced difficulty in answering questions involving hypothetical scenarios. Others struggled with the single questions relating to the views of categories of people, stating that different people within these categories would hold different views. Participants also tended to answer normative belief questions with reference to the associated evaluative item, i.e. motivation to comply, and in a way that was not always consistent with their verbal response.

Taking account of some of these reasons and those specified in Section 8.4, it seems acceptable to have devised a TPB-based questionnaire with only belief items, particularly as the purpose of it is to inform behaviour change rather than test the predictive validity of the TPB per se. However, if developing a TPB questionnaire in this format, pilot work should be conducted to check that the indirect measures adequately capture the breadth of the direct measures. Following TPB guidelines, it is recommended that a new TPB questionnaire is developed every time a new behaviour is studied or the same behaviour is studied with a new population (Aizen, 2002b). Given the fact that the NRTP-SF questionnaire is grounded in the qualitative findings of a population of pregnant women and health professionals, there does not seem to be any logical reason why is cannot be used repeatedly with other samples of pregnant smokers. Indeed, the ANRT-12 (see Section 6.1) was similarly informed by qualitative data and is considered to have practical utility as screening tool in health settings. There appears to be no reason to assume that the NRTP-SF could not serve an equivalent function. However, it might be necessary to conduct additional psychometric analysis on the NRTP-SF to further confirm its validity or review its use if the status of NRT use in pregnancy changes as a result of new evidence.

Although the TPB was largely shown to have predictive validity in this research, a considerable amount of the variance nevertheless remains unexplained when using this (or any other) theory. The possible reasons for this were outlined in Section 3.1.4, and Sutton (1998) proposed that measuring intention after someone has made a real decision, and making all response categories compatible with each other would increase predictive power. Although the intention in this thesis was to use the TPB model in its pure form, it is possible

that adding further variables to the model could have improved its predictive power. The TPB has been criticised for lacking an emotional element (e.g. Van der Pligt & de Vries, 1998) and given the amount of guilt felt by pregnant smokers, it might be that additional factors which tap into this would improve the predictive validity of the model. Moral norm (e.g. Godin et al., 2005) and anticipated regret (e.g. Richard et al., 1996), which have both been shown to add to the prediction of the TPB, might be worthy of consideration as additional variables in this context. Moral norm should have an important influence on the performance of behaviours with a moral or ethical dimension (Conner & Armitage, 1998) which one could argue smoking in pregnancy has. These two variables could be potentially important additional variables especially as the elicitation procedures may not lend themselves to the affective and moral beliefs which are more difficult to articulate (Conner & Armitage, 1998). Alternatively, given that the elicitation study in Chapter Four might have produced beliefs that were more cognitive than affective, perhaps questions that help to redress this potential imbalance should be considered for future studies of this nature. Norman et al. (1999) found that perceived susceptibility was an important predictor for smoking cessation in a non-pregnant population and this might also increase the amount of variance explained by the TPB given that risk perception seems to be an influential factor for pregnant smokers and quitters (see Section 1.3.4). It might be that the Theory of Interpersonal Behaviour (Triandis, 1980), which also has strong predictive validity (Norman & Conner, 2005), could be a useful alternative to the TPB in this context as this model includes an affective component, a wider range of normative influences, moral considerations and habit as predictors.

As already stated, the TPB has mainly been used to predict behaviour and does not explain how to change it, which is a shortcoming when trying to devise an effective intervention based on the theory. It could be that models of attitude change such as the Elaboration Likelihood Model (Petty & Cacioppo, 1986) might more beneficial for informing intervention work or Social Cognitive Theory (Bandura, 1982) where ways of changing self-efficacy are specified (Norman & Conner, 2005). This latter model could be of particular use given that self-efficacy appears to be an important determinant of smoking cessation behaviours in pregnancy (e.g. Godin et al., 1992; see Section 3.2.2). A study by Vogt et al. (2009) actually showed that providing physicians with information about the effectiveness and cost effectiveness of smoking cessation services based on social cognitive theory increased their recommendations of these services. Alternatively,

it may be that approaches which seek to integrate various social cognition models are the way forward.

8.6.3 Adherence to medication

Adherence to NRT in pregnancy has been found to be a predictor of cessation (Fish et al., 2009) but adherence to this medication is known to be low in this group (see Section 2.1.1.2.1). It is therefore of use to refer to the adherence to medication literature as this might provide further insights into the potential reasons for this. The information might also help to explain why pregnant women often fail to adhere to the sequence of sessions offered by NHS Stop Smoking Services.

Patient beliefs have been reported as the most influential set of factors associated with patient adherence behaviour (Veazie & Cai, 2007) and social cognition models have been utilised in this field in an attempt to predict adherence behaviour. Farquharson et al. (2004) reported that adherence has been found to increase when a doctor initiates discussion about it and gives the patient permission to disclose non-adherence. Furthermore, encouraging patients to express views and concerns has been associated with increased adherence. This approach could well be a profitable one in terms of smoking cessation support and the training resource developed in Study Two might help to facilitate this process. The TPB has been applied to adherence to oral anticoagulant therapy (Burns, 2009) and this study recommended emphasising the positives of taking the medication, e.g. improved health, involving significant others in the education process, e.g. explaining the advantages of the medication, and devising strategies to increase adherence, e.g. reminders. As forgetting to use NRT was found to have a strong influence on intention to use NRT in pregnancy, reminder systems might be a useful way forward for pregnant women who forget to take their NRT or who don't remember that they have an appointment at a Stop Smoking Service. Involving significant others in the smoking cessation process could also benefit pregnant women.

Munro et al. (2007) argued that cognitive theories do not adequately address the behavioural skills needed to ensure adherence, nor do they give sufficient attention to the origin of beliefs and how these beliefs may influence other behaviours. Furthermore, they ignore other factors that may impact on adherence behaviour, such as power relationships. However, the authors did state that helping patients to overcome cognitive factors, lack of motivation and unrealistic

expectations about adherence were effective in improving adherence. Farmer et al. (2005) stated that whilst the TPB did not indicate what type of intervention might be effective for hypoglycaemic medication adherence for Type 2 diabetes, it did inform the content of an intervention. The theory had helped to identify those positive beliefs which needed reinforcement and the negative beliefs which needed to be addressed by problem solving. Intentional (ambivalence about the pros and cons) and non-intentional (forgetting) lapses in adherence have been identified as two important elements contributing to overall non-adherence (Farmer et al., 2008). The approaches the authors developed to address these two elements could be applied to smoking cessation in pregnancy, i.e. increasing patients' motivation by targeting underlying beliefs and to help them develop action plans. Rains et al. (2006) described a set of cognitive and behavioural adherence-enhancing strategies which could also be transferable to the smoking cessation field. These include scheduling and recalling appointments, providing patients with clear understanding of their treatment, simplifying the treatment regimen, involving patients in treatment planning, using reminder systems and cueing devices, and assessing and tracking adherence. The provider must also create a collaborative environment and be able to elicit the patient's concerns and enhance self-efficacy. The theory-based training resource in Study Two could be useful to assist with this.

The NRTP-SF could also be used as a scale to identify patients who are more or less likely to use NRT in pregnancy. Other social cognition models have informed the development of such tools. For example, Dolder et al. (2004) devised a measure based on the Health Belief Model (Becker et al. 1977) to monitor adherence to antipsychotic medication.

8.6.4 Informed choice

Although the goal of the thesis studies was to see if the TPB could have the potential to promote uptake of smoking cessation support, it is extremely important that the individual makes an informed choice about this. This is particularly pertinent in the case of NRT use where its efficacy and safety in pregnancy remains unclear. Informed choice is increasingly recognised as important for supporting patient autonomy and ensuring that people are not deceived or coerced (Jepson et al., 2005). Informed choices can be considered to comprise of two theoretical characteristics: (1) they should be informed by best current evidence and (2) they should reflect the decision maker's values (Mann et al., 2009). Decision aids, such as written information, are designed to help people

understand the options, consider the personal importance of possible benefits and harms and participate in decision making (O'Connor et al., 2009). The recent updated Cochrane review of trials found that decision aids improve people's knowledge of the options, create accurate risk perceptions of their benefits and harms, reduce difficulty with decision making and increase participation in the process (O'Connor et al., 2009). Evidence shows that NRT needs to be discussed more thoroughly between antenatal care providers, tobacco cessation specialists and pregnant smokers (Baha & Le Faou, 2009). Such a decision aid about NRT use in pregnancy would be a useful tool to help guide a pregnant woman to an informed decision about whether or not to use it. As cognitive factors determine whether or not an individual practices health behaviours and knowledge is an essential factor for an informed choice (Conner & Norman, 2005), the NRTP-SF could potentially be utilised to help develop a decision aid about NRT use in pregnancy. The TPB has been used to inform the development of a decision aid on cardiovascular risk prevention (Krones et al., 2010), where steps of the decision aid included links to the theory's components, e.g. exploring attitudes or reviewing the decision with significant others. As the authors concluded, most decision aids are developed and tested without reference to a theoretical model of psychosocial processes and the TPB may serve as a useful framework for these.

8.7 CONCLUSION

The Theory of Planned Behaviour (TPB) has proved to be a useful model for eliciting pregnant women's beliefs about NHS Stop Smoking Services and Nicotine Replacement Therapy (NRT). The salient beliefs about Stop Smoking Services were incorporated into the development of a theory-based resource to facilitate the communication of smoking cessation information in pregnancy. By helping health professionals to address the issues that pregnant women have about engagement with these services, this resource showed potential to guide them towards a more patient centred interview which might ultimately improve service uptake. The salient beliefs about NRT informed the development of a TPB questionnaire (NRTP-LF) that successfully predicted intention to use NRT in pregnancy and a short form version of this (NRTP-SF) which also had predictive validity. On the whole, these questionnaires showed that measures of attitude, subjective norm and perceived behavioural control were each independent predictors of intention to use NRT in pregnancy, and as such it would be appropriate to target beliefs relating to these constructs in interventions designed to increase uptake of NRT in pregnancy. The NRTP-SF might be of use to identify

the salient beliefs to target in an intervention where the outcome was smoking cessation or be used as a before and after measure to assess the effectiveness of a TPB intervention. It could also help clinicians to tailor their discussions about NRT with pregnant women more appropriately or inform the development of a decision aid to facilitate informed choice with respect to NRT use in this group. As the TPB holds promise in cross cultural research as reported by Young et al. (1991), the NRTP-SF could also be used in a cross-cultural study, for example, in countries where there are higher rates of smoking. Future research would need to test the practical utility and acceptability of the theory-based communication resource and the short form NRT questionnaire in health-care settings, and to assess whether they increase engagement with Stop Smoking Services and assist in the decision making process regarding NRT use respectively. If successful, these theory-based materials have the potential to reduce the rates of smoking in pregnancy and improve the health of women and their babies.

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INTERVIEW SCHEDULE - CLINIC

Introduction

- My name is John Taylor, I'm a PhD student based at the University of Nottingham
- You agreed to be interviewed when you were last in the antenatal clinic
- Is now convenient?
- Thank you for giving up your time to talk to me today

Just to remind you – the reason for the interview:

- To ask you what you think about the Stop Smoking Services the NHS offer for pregnant women
- The reason we are interested in your views is because although these services have been shown to be effective in helping people to stop smoking, very few people use them
- We hope that by finding out what pregnant women think about the services will help to improve Stop Smoking services in the future

Anonymity

- The interview is being audio taped, so that I can listen fully to your answers without having to write anything down. But I assure you that the discussion will be completely confidential. Are you happy with this?
- After the interview, the tape recording will be transcribed
- At this stage your name will be replaced by a code so that your identity is completely anonymous
- The transcriptions and original tapes will be retained securely in a locked filing cabinet

Ground Rules

- I will be asking a series of questions although I would like you to feel free to express any opinion that you have at any time during the interview
- Please be assured that there are no right or wrong answers
- Please remember that you are free to stop the interview at any time, without giving a reason
- Do you have any questions?
- OK, let's begin

First of all:
How many weeks pregnant are you? How's it going?

Are you smoking regularly at the moment or have you given up during your pregnancy?

Just a few questions about your smoking:

QUESTIONS FOR PREGNANT SMOKERS:

- About how many cigarettes a day would you say you are smoking at the moment?
- About how many cigarettes a day would you say you were smoking before you were pregnant?
- How long have you been smoking?
- Have you considered or tried to quit during this pregnancy?
- Would you like to quit?
- How do you feel about smoking in pregnancy?
- Have you been encouraged to stop smoking during pregnancy (by family, friends, health professionals)?
- What sort of advice have you received?

QUESTIONS FOR RECENT QUITTERS:

- When did you stop smoking?
- How many cigarettes were you smoking per day?
- What factors influenced your decision to stop smoking?
- Were you encouraged to stop smoking (by family, friends, health professionals)?
- If so, what sort of advice did you receive?
- What strategies did you use to stop smoking? Did you use NHS Stop Smoking services? What? What did you think of them?

NHS Stop Smoking Services

- Are you aware of the Stop Smoking services that the NHS offers free of charge to pregnant women?

- **If yes:** What do you know about them? How did you find out about them? Did a health professional tell you about them? Who? When? Were you referred to Stop Smoking Services? By whom? When? Have you ever used them? **If so**: what did you use? What did you think about it?

- **If no:** Explain NHS Stop Smoking Services

- **Vary from place to place but generally offer:**

- NHS Stop Smoking Service – specially trained advisor – 6 weekly appointments (40 mins each) either individual or group sessions. Referred by GP, midwife or pharmacist.

- Listen to your needs, discuss lapses & your concerns about smoking, explain possible harms to your baby, suggest different ways of giving up smoking, help you set a quit date, sometimes offer rewards for attendance, monitor your carbon monoxide levels

- Range of self-help materials with further info and advice on stopping smoking
- NHS Pregnancy Smoking Helpline

Would you consider using them?

Individual or group appointments? Reasons for choice?

TPB – Stop Smoking services

- What do you believe are the advantages of using Stop Smoking Services in pregnancy? (positive outcomes that would result from using Stop Smoking Services)
- What do you believe are the disadvantages of using Stop Smoking Services in pregnancy (negative outcomes of using Stop Smoking Services)?
- Do you have any other views about Stop Smoking Services in pregnancy? Would you consider using them? Why / why not?

- Are there any individuals or groups who would approve of you using Stop Smoking Services in pregnancy?
- Are there any individuals or groups who would disapprove of you using Stop Smoking Services in pregnancy?
- Are there any other individuals or groups who would have views about you using / or not using Stop Smoking Services in pregnancy? Has anyone else's opinion of the services influenced your decision to use / not use them? Do you feel pressure from others? Do you mind this?

- What factors or circumstances would enable you to use Stop Smoking Services in pregnancy? (Anything about Stop Smoking Services that would make it easy for you to use them) (Anything about your situation that would make it easy to use Stop Smoking Services) e.g. resources, opportunities. What would encourage you to use them? What things would help you to use them?
- What factors or circumstances would make it difficult or impossible for you to use Stop Smoking Services in pregnancy? (Anything about Stop Smoking Services that would make it hard for you to use them) (Anything about your situation that would make it hard to use Stop Smoking Services) e.g. obstacles, impediments. What would stop you using them? What things hinder/prevent you from using them?
- Is there anything else that comes to mind when you think about how easy or difficult it would be to use Stop Smoking Services in pregnancy? Would you feel able to use them? Why / why not? Would you feel confident about using them. Why / why not?

NRT

- One of the options the Stop Smoking services might offer you is NRT.
- Are you familiar with this? Have you ever tried it? What did you use? What did you think of it?
- Did you know that pregnant women can get NRT free through Stop Smoking services? Would that make you more likely to use NRT? Would that make you more likely to attend a Stop Smoking clinic?
- Are you aware of all the different forms of NRT?

Explain different forms of NRT – patches, gum, nasal spray, microtab, lozenge, inhalator

TPB – NRT

- What do you believe are the advantages of using NRT in pregnancy (positive outcomes of using NRT)?
- What do you believe are the disadvantages of using NRT in pregnancy (negative outcomes of using NRT)?
- Do you have any other views about NRT in pregnancy? Would you consider using it? Why / why not? Which NRT product would you choose if you decided to use one? Any you wouldn't want to use? Why?

- Are there any individuals or groups who would approve of you using NRT in pregnancy?
- Are there any individuals or groups who would disapprove of you using NRT in pregnancy?
- Are there any other individuals or groups who would have views on you using / not using NRT in pregnancy? Has anyone else's opinion of NRT influenced your decision to use / not use it? Do you feel pressured by others? Do you mind this?

- What factors or circumstances would enable you to use NRT in pregnancy? (Anything about NRT that would make it easy for you to use it) (Anything about your situation that would make it easy to use NRT), e.g. resources, opportunities. What would encourage/help you to use it?
- What factors or circumstances would make it difficult or impossible for you to use NRT in pregnancy? (Anything about NRT that would make it hard for you to use it) (Anything about your situation that would make it hard to use NRT), e.g. obstacles, impediments. What would prevent you from/stop you using it?
- Is there anything else that comes to mind when you think about how easy or difficult it would be to use NRT in pregnancy? Would you feel able to use it? Why / Why not? Would you feel confident about using it? Why / why not?

I'd finally like to ask you a few questions about yourself:

- What is your age?
- What is your ethnic group?
- Are you married, cohabiting with a partner, single, divorced, widowed? **If have partner:** Does your partner smoke?
- What is your highest educational qualification?
- Do you work? **If so:** What is your job?
- **If not working and have partner:** is your partner working, what is his job?
- Do you already have any children? If so, how many?

Is there anything else you would like to discuss that we haven't covered so far?

Conclusion:

- Thank you for taking part, this has been a very successful interview
- Your views will be of great use for the research
- I would like to remind you that any comments in this report will be anonymous
- Finally, many thanks for your time and please do not hesitate to contact me if you have any questions regarding this session

INTERVIEW SCHEDULE – COMMUNITY SAMPLE

Introduction

- My name is John Taylor, I'm a PhD student based at the University of Nottingham
- Thank you for agreeing to talk to me
- Are you sure that now is a convenient time for the interview?

Just to remind you – the reason for the interview:

- To ask you what you think about the Stop Smoking Services the NHS offer for pregnant women
- The reason we are interested in your views is because although these services have been shown to be effective in helping people to stop smoking, very few people use them
- We hope that by finding out what pregnant women and recently pregnant women think about the services will help to improve Stop Smoking services in the future

Anonymity

- The interview is being audio taped, so that I can listen fully to your answers without having to write anything down. But I assure you that the discussion will be completely confidential. Are you happy with this?
- After the interview, the tape recording will be transcribed
- At this stage your name will be replaced by a code so that your identity is completely anonymous
- The transcriptions and original tapes will be retained securely in a locked filing cabinet

Ground Rules

- I will be asking a series of questions although I would like you to feel free to express any opinion that you have at any time during the interview
- Please be assured that there are no right or wrong answers
- Please remember that you are free to stop the interview at any time, without giving a reason
- Do you have any questions?
- OK, let's begin

First of all:
How old is your new baby now? How's it going?

Did you smoke through all your pregnancy or did you give up part way through?

Just a few questions about your smoking:

QUESTIONS FOR WOMEN WHO SMOKED THROUGHOUT THEIR PREGNANCY

- About how many cigarettes a day would you say you smoked while you were pregnant?
- About how many cigarettes a day would you say you were smoking before you were pregnant?
- At what age did you start smoking?
- Did you consider or try to quit during your pregnancy?
- Would you have liked to quit?
- How did you feel about smoking in pregnancy?
- Were you encouraged to stop smoking during pregnancy (by family, friends, health professionals)?
- What sort of advice did you receive?

QUESTIONS FOR WOMEN WHO STOPPED SMOKING DURING THEIR PREGNANCY

- At what point in your pregnancy did you stop smoking?
- How many cigarettes were you smoking per day before you were pregnant?
- What factors influenced your decision to stop smoking?
- Were you encouraged to stop smoking (by family, friends, health professionals)?
- If so, what sort of advice did you receive?
- What strategies did you use to stop smoking? Did you use NHS Stop Smoking services? What? What did you think of them?

NHS Stop Smoking Services

- Are you aware of the Stop Smoking services that the NHS offers free of charge to pregnant women?

- **If yes:** What do you know about them? How did you find out about them? Did a health professional tell you about them? Who? When? Were you referred to Stop Smoking Services? By whom? When? Have you ever used them? **If so**: what did you use? What did you think about it?

- **If no:** Explain NHS Stop Smoking Services

- **Vary from place to place but generally offer:**

- NHS Stop Smoking Service – specially trained advisor – 6 weekly appointments (40 mins each) either individual or group sessions. Referred by GP, midwife or pharmacist.

- Listen to your needs, discuss lapses & your concerns about smoking, explain possible harms to your baby, suggest different ways of giving up smoking, help you set a quit date, sometimes offer rewards for attendance, monitor your carbon monoxide levels

- Range of self-help materials with further info and advice on stopping smoking

- NHS Pregnancy Smoking Helpline

Would you have considered using them?

Individual or group appointments? Reasons for choice?

TPB – Stop Smoking services

- What do you believe are the advantages of using Stop Smoking Services in pregnancy? (positive outcomes that would result from using Stop Smoking Services)
- What do you believe are the disadvantages of using Stop Smoking Services in pregnancy (negative outcomes of using Stop Smoking Services)?
- Do you have any other views about Stop Smoking Services in pregnancy? Did you consider using them? Why / why not?

- Are there any individuals or groups who would approve of you using Stop Smoking Services in pregnancy?
- Are there any individuals or groups who would disapprove of you using Stop Smoking Services in pregnancy?
- Are there any other individuals or groups who would have views about you using / or not using Stop Smoking Services in pregnancy? Did anyone else's opinion of the services influenced your decision to use / not use them? Did you feel pressure from others? Did you mind this?

- What factors or circumstances would enable you to use Stop Smoking Services in pregnancy? (Anything about Stop Smoking Services that would make it easy for you to use them) (Anything about your situation that would make it easy to use Stop Smoking Services) e.g. resources, opportunities. What would encourage you to use them? What things would help you to use them?
- What factors or circumstances would make it difficult or impossible for you to use Stop Smoking Services in pregnancy? (Anything about Stop Smoking Services that would make it hard for you to use them) (Anything about your situation that would make it hard to use Stop Smoking Services) e.g. obstacles, impediments. What would stop you using them? What things might hinder/prevent you from using them?
- Is there anything else that comes to mind when you think about how easy or difficult it would be to use Stop Smoking Services in pregnancy? Would you feel able to use them? Why / why not? Would you feel confident about using them. Why / why not?

NRT

- One of the options the Stop Smoking services might offer you is NRT.
- Are you familiar with this? Have you ever tried it? What did you use? What did you think of it?
- Did you know that pregnant women can get NRT free through Stop Smoking services? Would that have made you more likely to use NRT? Would that have made you more likely to attend a Stop Smoking clinic while you were pregnant?
- Are you aware of all the different forms of NRT?

Explain different forms of NRT – patches, gum, nasal spray, microtab, lozenge, inhalator

TPB – NRT

- What do you believe are the advantages of using NRT in pregnancy (positive outcomes of using NRT)?
- What do you believe are the disadvantages of using NRT in pregnancy (negative outcomes of using NRT)?
- Do you have any other views about NRT? Did you consider using it in pregnancy? Why / why not? Which NRT product would you choose if you decided to use one? Any you wouldn't want to use? Why?

- Are there any individuals or groups who would approve of you using NRT in pregnancy?
- Are there any individuals or groups who would disapprove of you using NRT in pregnancy?
- Are there any other individuals or groups who would have views on you using / not using NRT in pregnancy? Did anyone else's opinion of NRT influence your decision to use / not use it? Did you feel pressured by others? Did you mind this?

- What factors or circumstances would enable you to use NRT in pregnancy? (Anything about NRT that would make it easy for you to use it) (Anything about your situation that would make it easy to use NRT), e.g. resources, opportunities. What would encourage/help you to use it?
- What factors or circumstances would make it difficult or impossible for you to use NRT in pregnancy? (Anything about NRT that would make it hard for you to use it) (Anything about your situation that would make it hard to use NRT), e.g. obstacles, impediments. What would prevent you from/stop you using it?
- Is there anything else that comes to mind when you think about how easy or difficult it would be to use NRT in pregnancy? Would you feel able to use it? Why / Why not? Would you feel confident about using it? Why / why not?

I'd finally like to ask you a few questions about yourself:

- What is your age?
- What is your ethnic group?
- Are you married, cohabiting with a partner, single, divorced, widowed? **If have partner:** Does your partner smoke?
- What is your highest educational qualification?
- Do you work? **If so:** What is your job?
- **If not working and have partner:** is your partner working, what is his job?
- Do you already have any children? If so, how many?

Is there anything else you would like to discuss that we haven't covered so far?

Conclusion:

- Thank you for taking part, this has been a very successful interview
- Your views will be of great use for the research
- I would like to remind you that any comments in this report will be anonymous
- Finally, many thanks for your time and please do not hesitate to contact me if you have any questions regarding this session

INTERVIEW SCHEDULE – HEALTH PROFESSIONALS

Introduction

- Hi, I'm John Taylor, a PhD student at the University of Nottingham researching pregnant women's perceptions of smoking cessation services.
- You agreed to be interviewed about this
- Is now convenient?
- Thank you for giving up your time to talk to me

Just to remind you – the reason for the interview:

- Wanting to find out what pregnant smokers or recent quitters think about the Stop Smoking Services the NHS offer for pregnant women.
- As well as interviewing the women themselves, it will be useful to gain the insights of the health professionals actually involved in providing the service.

Anonymity

- The interview is being audio taped, so that I can listen fully to your answers without having to write anything down. But I assure you that the discussion will be completely confidential. Are you happy with this?
- After the interview, the tape recording will be transcribed
- At this stage your name will be replaced by a code so that your identity is completely anonymous
- The transcriptions and original tapes will be retained securely in a locked filing cabinet

Ground Rules

- I will be asking a series of questions although feel free to express any opinion that you think is important at any time during the interview
- Any questions?

First of all:

What type of smoking cessation services do you offer pregnant women?
How successful are these? Any particular profile of success / lack of?

- NHS Stop Smoking Service – specially trained advisor – 6 weekly appointments (40 mins each) either individual or group sessions.
- Range of self-help materials with further info and advice on stopping smoking
- NHS Pregnancy Smoking Helpline

What is the referral process?

Do you offer NRT to pregnant women (patches, gum, nasal spray, microtab, lozenge, inhalator) Routinely? Under what circumstances? What type of NRT (in combination?) Who prescribes?
How successful is this? Any particular profile of success / lack of?

Partner smoking, level of smoking, length of time smoking, previous quit attempts, age, ethnicity, marital status, education, occupation, parity, motivation

This study is based on the **Theory of Planned Behaviour** which says that people's intentions to carry out a behaviour are based on their attitudes towards the behaviour, whether they feel other people think they should perform the behaviour, and how much control they feel they have to actually do it.

So the following questions are linked to these three components.

TPB – Stop Smoking services (not NRT as I will be asking separate questions about this later)

- What do pregnant women say are the advantages of using Stop Smoking Services? (positive outcomes that would result from using any aspect of your Stop Smoking Services)
- What do pregnant women say are the disadvantages of using Stop Smoking Services (negative outcomes of using any aspect of your Stop Smoking Services)?
- What other views do they express about Stop Smoking Services? What reasons do they give for using them / not using them?

- Are there any individuals or groups who they say would approve of them using Stop Smoking Services?
- Are there any individuals or groups who they say would disapprove of them using Stop Smoking Services?
- Are there any other individuals or groups who they mention as having a view about them using/not using Stop Smoking Services? Do they say that anyone else's opinion of the services influence their decision to use/not use them? Who? Do they mention feeling pressure from others to use / not use the services? Who? Do they mind this?

- What factors or circumstances do they say enable them to use Stop Smoking Services? (Anything about Stop Smoking Services that they say makes it easy to use them) (Anything about their situation that they say makes it easy to use Stop Smoking Services) e.g. resources, opportunities.
- What factors or circumstances do they say make it difficult or impossible for them to use Stop Smoking Services? (Anything about Stop Smoking Services that they say makes it hard to use them)(Anything about their situation that they say make it hard to use Stop Smoking Services) e.g. obstacles, impediments.
- Do they mention any other issues in terms of the ease or difficulty of using Stop Smoking Services? What makes them feel able/unable to use them? What makes them feel confident/not confident about using them?

NRT

TPB – NRT

- What do pregnant women say are the advantages of using NRT (positive outcomes of using NRT)?
- What do pregnant women say are the disadvantages of using NRT (negative outcomes of using NRT)?
- Do they express any other views about NRT? Do they say why they would consider or not consider using it? Do they have any specific views about using different types of NRT? Any type they prefer/don't prefer? Why?

- Are there any individuals or groups that pregnant women say would approve of them using NRT?
- Are there any individuals or groups that pregnant women say would disapprove of them using NRT?
- Are there any other individuals or groups who they say have views about them using / not using NRT? Do they say that anyone else's opinion of NRT has influenced their decision to use / not use it? Do they mention feeling pressured by others to use/not use NRT? Who? Do they mind this?

- What factors or circumstances do they say enable them to use NRT? (Anything about NRT that they say makes it easy to use it) (Anything about their situation that they say makes it easy to use NRT), e.g. resources, opportunities.
- What factors or circumstances do they say make it difficult or impossible for them to use NRT? (Anything about NRT that they say makes it hard for them to use it (Anything about their situation that they say makes it hard to use NRT), e.g. obstacles, impediments.
- Are there any other issues they mention in terms of the ease/difficulty of using NRT? What makes them feel able/unable to use it? What makes them feel confident/not confident about using it?

- Are they surprised that they can get NRT free through Stop Smoking services? Do they say that this would make them more likely to use it? Do they say that this would make them more likely to attend a Stop Smoking Clinic?

Is there anything else that you think is relevant that we haven't covered so far?

Conclusion:

- Thank you for taking part, this has been a very successful interview
- Your views will be of great use for the research
- I would like to remind you that any comments in this report will be anonymous
- Finally, many thanks for your time and please do not hesitate to contact me if you have any questions regarding this session

INTERVIEW PROMPTS

Types of NRT

Patch – usually on upper arm

Gum

Nasal spray – sprayed directly into the nose

Tablet – which you put under your tongue

Lozenge – sweet that you suck

Inhalator – a plastic device shaped like a cigarette which you suck on

Smoking Cessation Clinics:

Advantages
Advice about managing cravings
Praise and encouragement
Advice about medications
Checking of progress
Sharing my concerns
Increased quit rates
Learning about harm to baby
Increased confidence
Structure
Obtain medications
Free
Trained personnel
Group support

Disadvantages
Lack of time
Need to plan
Rigid schedule of sessions
Focus on NRT
Fear of failure
Not wanting to discuss smoking with others / be questioned
Not wanting people to know I smoke
Lack of support from others
Don't want to stop smoking
Feeling judged / lectured
Finding out about harm to baby

Individuals or groups: partner, baby, family, friends, children, health professionals (GP, midwife, health visitor), government, NHS, anti-smoking groups (e.g. ASH – Action on Smoking & Health, Campaigning Public Health Charity), FOREST (Freedom Organisation for the Right to Enjoy Tobacco Smoke) Media and political lobbying group that opposes smoking bans and discrimination against smokers

Make it easy to attend
Home visits
Flexible timings
Child care
Availability – local service
Good support from family & friends
Motivated to quit
Think service will help
Knowing there is good support there

Make it difficult to attend
Lack of social support from family & friends
Lack of child care
Too far to travel
Lack of time
Not wanting to give up
Think service will not help
Not wanting to discuss with others
Lacking confidence to quit
Fear of failure / fear of wasting advisor's time
Attitudes towards stopping smoking
Attitudes towards stop smoking courses
Feeling judged
Embarrassment
Feeling weak
Not wanting find out about harm to baby

NRT

Advantages
Help people to feel less irritable when they quit smoking
Help people to feel less depressed when they quit smoking
Help people to cope with cravings / withdrawal
Help people to feel less anxious when they quit smoking
Reassuring to know that these products are available
Encourages quitting
NRT helps people in situations when smoking is not possible
Free in pregnancy
Decreases need to smoke
Patch is discreet
Can be used anywhere
Gum occupies the mouth
Inhalator occupies the hands
No smell of smoke
Improves concentration
Relaxing
Good taste

Disadvantages
Not knowing enough about them - concern about side effects / safety
Risk of becoming dependent on NRT
Dangerous to smoke at all when using them
Taste
Not as satisfying as smoking
Expense (Not knowing they are free)
Allergies, itching from patch
Inducing sickness, headache
Medical prescription needed for free product
Impractical, embarrassing to use

Make it easy to use
If used alongside other help
Confident that they are safe and effective
Free
Partner support
If it improved well-being
Discreet to use
Can use in places where smoking is banned

Make it hard to use
Not knowing anything about them
Having tried them before without success
Thinking they don't work
Disliking taste
Feeling sick
Partner smoking
Feeling stigma
Not liking to take medicines
Fear they give too much nicotine
Thinking they are effective without willpower
Do not impact on psychological dependence
Not wanting GP to know
Want to / can quit on own – do not need NRT
Forgot
Impractical, embarrassing to use

Nottingham City Hospital NHS
NHS Trust

Academic Division of Obstetrics
Gynaecology & Child Health
City Hospital
Hucknall Road
Nottingham
NG5 1PB

27 October 2006

An investigation of attitudes to smoking cessation in pregnancy

I would like to tell you about a research study which is being conducted in the antenatal clinic at City Hospital by John Taylor, who is a PhD student at the University of Nottingham.

John wants to find out why some women who smoke during pregnancy use smoking cessation services and others do not. If you are a smoker or have recently stopped, John would like to talk to you. This will help us improve smoking cessation services.

The enclosed information sheet explains the project in full. If you eligible for the study, I would be very grateful if you could consider participating.

At your first antenatal visit, John may approach you to ask if you would like to be interviewed. If you agree, the interview can be by telephone or in the clinic, according to your choice. It will last about 20 minutes.

Thank you for taking the time to read this letter. If you would like any further information, please contact John Taylor on 0115 823 0526, on mgxjt1@nottingham.ac.uk, or at Behavioural Sciences, A Floor South Block, Queen's Medical Centre, Nottingham, NG7 2UH.

Yours faithfully

Professor of Obstetrics & Gynaecology

Nottingham City Hospital NHS
NHS Trust

Attitudes of pregnant smokers and recent quitters to smoking cessation services

Participant Information Sheet

You are invited to take part in a student research project being conducted by John Taylor as part of his PhD. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

- Part 1 is a brief summary about the study
- Part 2 gives you more detailed information about the study

Please ask John Taylor (contact details below) if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

What is the purpose of the study?
Smoking during pregnancy is harmful to both the baby and the mother, but many women continue to smoke in pregnancy. Although the NHS offers ways to help smokers stop smoking, only a few smokers make use these services. It would help to know what advice and treatment pregnant smokers prefer. This study will investigate the attitudes of pregnant smokers and those who have recently stopped to the types of "stop smoking" services currently on offer. We would therefore like to invite pregnant women who smoke or have quit smoking during their current pregnancy to take part in an interview. The results will be used to improve services in future.

Why have I been chosen?
Because you have either given up smoking during this pregnancy or are still smoking.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. No one will be told whether or not you decide to take part.

What will the study involve?
Participation in this study involves taking part in a 20 minute interview to find out your attitudes to smoking cessation in pregnancy. You will also be asked some questions about yourself, for example your age, ethnicity and occupation. The interview will take place over the telephone at a time that is convenient for you.

Alternatively, you may prefer to be interviewed face-to-face in the antenatal clinic when you come for your appointment.

The interview will be audio-taped to allow the researcher to pay attention to what you are saying during the interview, rather than taking notes. It will also make it possible to accurately record and analyse the discussion. Once you have completed the interview, there will be no further involvement in the study.

What are the possible benefits of taking part?
There will be no direct benefit to you, although you may learn something which will encourage you to stop smoking.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks to taking part in this study other than the giving up of 20 minutes of your time.

What if there is a problem?
If you have a concern about any aspect of this study, you should contact the Chief Investigator, John Taylor, who will do his best to answer your questions (Tel: 0115 823 0526 or 0115 823 1898). If you remain unhappy, please contact the study supervisor, Professor Jim Thornton (Tel: 0115 823 1889). If you wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Will my taking part in this study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential. You will not be identified in any published report.

Contacts
If you would like further information about this study or have any concerns during the study, please contact John Taylor, Tel: 0115 823 0526 or 0115 823 1898, email: mgxjt1@nottingham.ac.uk. If you remain unhappy, please contact the study supervisor, Professor Jim Thornton, Tel: 0115 823 1889.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What if there is a problem?

Complaints:
If you have a concern about any aspect of this study, you should contact the Chief Investigator, John Taylor who will do his best to answer your questions (Tel: 0115 823 0526 or 0115 823 1898). If you remain unhappy, please contact the study supervisor, Professor Jim Thornton (Tel: 0115 823 1889). If you wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Harm:
In the event that something does go wrong and you suffer harm during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham or Nottingham City Hospital NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Although the interview will be transcribed word-for-word and the researcher may use direct quotations, your name and identifiable personal details will not be included in any reports of the study. It will therefore not be possible for the reader to identify any individual or their comments. The tapes and transcriptions will be stored in a locked filing cabinet, and only the researcher will hear the tape recordings. Participants' names and addresses will be securely stored in a separate place.

What will happen to the results of the research study?
The results of this study will be written up as part of a PhD by John Taylor and will be published as a scientific paper

Who is organising and funding the research?
The research is being organised by Mr John Taylor (Chief Investigator), Professor Jim Thornton, Dr Cris Glazebrook and Dr Tim Coleman from the University of Nottingham. The study is funded by the Medical Research Council.

Who has reviewed the study?
This study has been reviewed and approved by Nottingham Research Ethics Committee.

THANK YOU VERY MUCH FOR YOUR TIME

Nottingham City Hospital NHS
NHS Trust

An investigation of attitudes to smoking cessation in pregnancy

You many recall receiving a letter telling you about a research study which is being conducted in the antenatal clinic by a PhD student, John Taylor.

The aim of the study is to find out what women who smoke during pregnancy think about smoking cessation services.

To help John Taylor recruit participants to this study, it would be much appreciated if you could please answer the following questions.

	Please circle your answer
Are you a current smoker?	YES / NO
Have you quit smoking during your current pregnancy?	YES / NO
If you have answered 'YES' to either of these questions, would you be willing for John Taylor to tell you about the study?	YES / NO

If 'YES', please write your name below and return the form to the reception desk

NAME: _____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Nottingham City Hospital NHS
NHS Trust

CONSENT FORM

Title of project: Attitudes of pregnant smokers to smoking cessation in pregnancy

Site: City Hospital, Nottingham

Investigators: Mr John Taylor, Professor Jim Thornton, Dr Cris Glazebrook, Dr Tim Coleman

Please cross out as necessary

- Have you read & understood the patient information sheet (dated 090207, version 5.0)
  YES / NO

- Have you had opportunity to ask questions and discuss this study
  YES / NO

- Have all the questions been answered satisfactorily
  YES / NO

- Have you received enough information about the study
  YES / NO

- Who have you spoken to
  Dr/Mrs/Ms .....

- Do you understand that you are free to withdraw from the study:
  - at any time
    YES / NO
  - without having to give a reason
    YES / NO
  - without affecting your future medical care
    YES / NO

- Do you agree to your interview being audio-taped with possible use of anonymous direct quotations
  YES / NO

- Do you understand that relevant sections of your medical notes may be looked at by the Chief Investigator
  YES / NO

- Do you give permission for this access to your records
  YES / NO

- Do you agree to take part in this study
  YES / NO

_____	_____	_____
Name of Patient	Signature	Date

I have explained the study to the above patient and she has indicated her willingness to take part

_____	_____	_____
Research	Signature	Date

When completed, 1 for participant; 1 to be kept in medical notes; 1 (original) for researcher site file

The University of Nottingham

APPENDIX 9

CONTACT DETAILS

Title (please circle) Mrs / Ms / Miss / Other _____

First name: _____

Last name: _____

Address: _____

_____

_____ Postcode _____

Telephone Number: _____

Email Address: _____

How would you prefer to be contacted to arrange your interview?

Post ☐ Telephone ☐ Email ☐

Is there a particular time / date that would be convenient or inconvenient for me to contact you?

_____

_____

_____

Thank you very much

The University of Nottingham

APPENDIX 10

060606, Version 2.0

27 November 2006

Dear Madam

An investigation of attitudes to smoking cessation in pregnancy

I would like to tell you about a research study which I am conducting as part of my PhD at the University of Nottingham.

I want to find out why some women who smoke during pregnancy use smoking cessation services and others do not. If you are a smoker or have recently stopped, I would like to talk to you. This will help us improve smoking cessation services.

The enclosed information sheet explains the project in full. If you are a smoker or have recently stopped, I would be very grateful if you could consider participating.

In the next week or so, I may approach you and invite you to participate. If you agree, the interview will last no longer than 20 minutes. This can be in the community centre or over the telephone, according to your choice.

Thank you for taking the time to read this letter. If you would like any further information, please contact John Taylor on 0115 823 0526, on mgxjt1@nottingham.ac.uk, or at Behavioural Sciences, A Floor South Block, Queen's Medical Centre, Nottingham, NG7 2UH.

Yours faithfully

John Taylor

Attitudes of pregnant smokers and recent quitters to smoking cessation services

Healthy Volunteer's Information Sheet

You are invited to take part in a student research project being conducted by John Taylor as part of his PhD at the University of Nottingham. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Please contact John Taylor (contact details below) if there is anything that is not clear or if you would like more information. If you do decide to take part, please save this information sheet.

What is the purpose of the study?

Smoking during pregnancy is harmful to both the baby and the mother, but many women continue to smoke in pregnancy. Although the NHS offers ways to help smokers stop smoking, only a few smokers make use these services. It would help to know what advice and treatment pregnant smokers prefer. This study will investigate the attitudes of pregnant smokers and those who have recently stopped to the types of "stop smoking" services currently on offer. We would therefore like to invite pregnant women who smoke or have quit smoking during their current pregnancy to take part in a short interview. The results will be used to improve services in future.

Why have I been chosen?

Because you have either given up smoking during this pregnancy or are still smoking.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. No one will be told whether or not you decide to take part.

What will the study involve?

Participation in this study involves taking part in an interview lasting about 20 minutes to find out your attitudes to smoking cessation in pregnancy. You will also be asked some questions about yourself, for example your age, ethnicity and occupation. The interview will be take place at a time that is convenient for you, either face to face in the community centre or over the phone.

The interview will be audio-taped to allow the researcher to pay attention to what you are saying during the interview, rather than taking notes. It will also make it possible to accurately record and analyse the discussion. Once you have completed the interview, there will be no further involvement in the study.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks to taking part in this study other than the giving up of 30 minutes of your time.

What if something does wrong?
If you have a concern about any aspect of this study, you should first contact the Chief Investigator, John Taylor, who will do his best to answer your questions (Tel: 0115 823 0526 or 0115 823 1898). If you remain unhappy, please contact the study supervisor, Professor Jim Thornton (Tel: 0115 823 1889). If you are still unsatisfied, please then contact Louise Sabir, Secretary of the University of Nottingham Medical School Ethics Committee, c/o Division of Therapeutics and Molecular Medicine, D Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH.

Will my taking part in this study be kept confidential?
Although the interview will be transcribed word-for-word and the researcher may use direct quotations, your name and identifiable personal details will not be included in any reports of the study. It will therefore not be possible for the reader to identify any individual or their comments. Participants who choose to be interviewed as part of a group discussion are requested to maintain confidentiality of the views of other participants.

What will happen to the results of the research study?
The results of this study will be written up as part of a PhD by John Taylor and will be published as a scientific paper. If you would like to receive a copy of a report of this study, please contact John Taylor using the details below.

Who is organising and funding the research?
The research is being organised by Mr John Taylor (Chief Investigator), Professor Jim Thornton, Dr Cris Glazebrook and Dr Tim Coleman from the University of Nottingham. The study is funded by the Medical Research Council.

Who has reviewed the study?
This study has been reviewed and approved by the University of Nottingham Research Ethics Committee.

Contacts for further information
If you have any questions about this study or would like further information, please contact John Taylor, Tel: 0115 823 0526 or 0115 823 1898, email: mgxjt1@nottingham.ac.uk or at Behavioural Sciences, A Floor South Block, Queen's Medical Centre, Nottingham, NG7 2UH.

THANK YOU VERY MUCH FOR YOUR TIME

The University of Nottingham

SMOKING CESSATION STUDY

Are you pregnant and a current smoker?

OR

Are you pregnant but have recently quit smoking?

If either of these applies to you, can you spare around 20 minutes to tell me your views about smoking cessation?

I would like to invite you to take part in a study which I am conducting as part of my PhD at the University of Nottingham.

The study aims to find out what pregnant women who smoke think about the different types of smoking cessation support on offer.

If you are interested in finding out more about this research, I will be pleased to give you an information pack when I call in to the community centre in the next month.

Alternatively, I can send you an information pack if you contact me on 0115 823 0526, at mgxjt1@nottingham.ac.uk, or at Behavioural Sciences, A Floor South Block, Queen's Medical Centre, Nottingham, NG7 2UH.

Many thanks for your time and consideration.

John Taylor

University of Nottingham, School of Community Health Sciences

Title of Project: Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy

Name of Investigators: Mr John Taylor, Professor Jim Thornton, Dr Cris Glazebrook, Dr Tim Coleman

Healthy Volunteer's Consent Form

Please read this form and sign it once the above named or their designated representative, has explained fully the aims and procedures of the study to you

- I voluntarily agree to take part in this study.
- I confirm that I have been given a full explanation by the above named and that I have read and understand the information sheet given to me which is attached.
- I have been given the opportunity to ask questions and discuss the study with one of the above investigators or their deputies on all aspects of the study and have understood the advice and information given as a result.
- I agree to the above investigators contacting my general practitioner [and teaching or university authority if appropriate] to make known my participation in the study where relevant.
- I agree to comply with the reasonable instructions of the supervising investigator and will notify him immediately of any unexpected unusual symptoms or deterioration of health.
- I authorise the investigators to disclose the results of my participation in the study but not my name.
- I understand that information about me recorded during the study will be kept in a secure database. If data is transferred to others it will be made anonymous. Data will be kept for 7 years after the results of this study have been published.
- I understand that I can ask for further instructions or explanations at any time.
- I understand that I am free to withdraw from the study at any time, without having to give a reason for withdrawing.
- I confirm that I have disclosed relevant medical information before the study.
- I have not been a subject in any other research study in the last three months which involved : taking a drug; being paid a disturbance allowance; having an invasive procedure (eg venepuncture >50ml, endoscopy) or exposure to ionising radiation.

- I confirm that I have not been exposed to more than 5 mSv of ionising radiation in the last 12 months.

Name: .....

Address: .....

Telephone number: .....

Signature: ..... **Date:** .....

I confirm that I have fully explained the purpose of the study and what is involved to:

.....

I have given the above named a copy of this form together with the information sheet.

Investigators Signature: ..... **Name**: ...John Taylor

Study Volunteer Number: .....

Are you a health professional involved in giving smoking cessation advice or support to pregnant women?

If so, please can you spare 30 minutes to tell me your views?

Dear Colleague

I am conducting a research study to identify barriers to take-up of smoking cessation services in pregnancy and, if appropriate, I would like to interview you.

I will be telling you more about the study in this session.

If, after listening to me, you think you might be interested in participating, please could you complete the 'Contact Details' form on the other side of this sheet, and hand it to me at the end of the session.

Many thanks for your time and consideration.

Yours faithfully

John Taylor

The University of Nottingham

CONTACT DETAILS

Title (please circle) Prof / Dr / Mrs / Ms / Miss / Other _____

First name: _____

Last name: _____

Address: _____

_____

_____ Postcode _____

Telephone Number: _____

Email Address: _____

How would you prefer to be contacted to arrange your interview?

Post ☐ Telephone ☐ Email ☐

Is there a particular time / date that would be convenient or inconvenient for me to contact you?

_____

_____

_____

Thank you very much

Faculty of Medicine and Health Sciences

School of Community Health Sciences
Division of Psychiatry
Behavioural Sciences
A Floor, South Block
Queen's Medical Centre
Nottingham
NG7 2UH

30 June 2006

Dear

Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy

Many thanks for agreeing at the UK National Smoking Cessation Conference to take part in the above study, it is much appreciated.

Before being interviewed, I am required by the University of Nottingham Research Ethics Committee to obtain informed, written consent from you. To this end, please find enclosed a participant information sheet which explains the study in full and a consent form. If, after reading the participant information sheet, you are still happy to take part in the study, please could you sign the consent form and return it in the prepaid envelope provided. Alternatively, you may prefer to fax it to me on 0115 823 0433.

Once I have received your signed consent form, I will contact you soon to arrange a convenient time for the interview. If you have any queries, please don't hesitate to contact me on Tel: 0115 823 0526, Email: mgxjt1@nottingham.ac.uk or at the address above.

Thank you again for your help.

Yours sincerely

John Taylor

Attitudes of pregnant smokers and recent quitters to smoking cessation services

Healthy Volunteer's Information Sheet

You are invited to take part in a student research project being conducted by John Taylor as part of his PhD at the University of Nottingham. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Please contact John Taylor (contact details below) if there is anything that is not clear or if you would like more information. If you do decide to take part, please save this information sheet.

What is the purpose of the study?

Smoking during pregnancy is harmful to both the baby and the mother, but many women continue to smoke in pregnancy. Although the NHS offers ways to help smokers stop smoking, only a few smokers make use these services. It would therefore be beneficial to know what advice and treatment pregnant smokers prefer. As such, this study will investigate the attitudes of pregnant smokers and those who have recently stopped to the types of "stop smoking" services currently on offer. As well as interviewing the pregnant women themselves, we wish to examine health professionals' views of the attitudes of pregnant smokers and recent quitters to smoking cessation services. We would therefore like to invite health professionals involved in giving smoking cessation advice and support to pregnant women to take part in an interview. The results will be used to develop items from which, during future studies, a reliable and valid psychological scale measuring such attitudes can be developed.

Why have I been chosen?

Because you are involved in delivering smoking cessation advice or support to pregnant women, and, as such, will be able to provide useful insights into their views of smoking cessation services.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. No one will be told whether or not you decide to take part.

What will the study involve?

Participation in this study involves taking part in a 30 minute interview to find out what you perceive to be the attitudes of pregnant women towards smoking cessation services. The interview will be take place at a time that is convenient for you over the telephone.

The interview will be audio-taped to allow the researcher to pay attention to what you are saying during the interview, rather than taking notes. It will also make it possible to accurately record and analyse the discussion. Once you have completed the interview, there will be no further involvement in the study.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks to taking part in this study other than the giving up of 30 minutes of your time.

What if something does wrong?
If you have a concern about any aspect of this study, you should first contact the Chief Investigator, John Taylor, who will do his best to answer your questions (Tel: 0115 823 0526 or 0115 823 1898). If you remain unhappy, please contact the study supervisor, Professor Jim Thornton (Tel: 0115 823 1889). If you are still unsatisfied, please then contact Louise Sabir, Secretary of the University of Nottingham Medical School Ethics Committee, c/o Division of Therapeutics and Molecular Medicine, D Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH.

Will my taking part in this study be kept confidential?
Although the interview will be transcribed word-for-word and the researcher may use direct quotations, your name and identifiable personal details will not be included in any reports of the study. It will therefore not be possible for the reader to identify any individual or their comments.

What will happen to the results of the research study?
The results of this study will be written up as part of a PhD by John Taylor and will be published as a scientific paper. If you would like to receive a copy of a report of this study, please contact John Taylor using the details below.

Who is organising and funding the research?
The research is being organised by Mr John Taylor (Chief Investigator), Professor Jim Thornton, Dr Cris Glazebrook and Dr Tim Coleman from the University of Nottingham. The study is funded by the Medical Research Council.

Who has reviewed the study?
This study has been reviewed and approved by the University of Nottingham Research Ethics Committee.

Contacts for further information
If you have any questions about this study or would like further information, please contact John Taylor, Tel: 0115 823 0526 or 0115 823 1898, email: mgxjt1@nottingham.ac.uk or at Behavioural Sciences, A Floor South Block, Queen's Medical Centre, Nottingham, NG7 2UH.

THANK YOU VERY MUCH FOR YOUR TIME

NHS

Nottingham Research Ethics Committee 2
1 Standard Court
Park Row
Nottingham
NG1 6GN

Telephone: 01159123344
Facsimile: 01159123300

APPENDIX 18

09 June 2006

Mr John Taylor
PhD Student
University of Nottingham
School of Human Development
Academic Division of Obs & Gynae
City Hospital, Hucknall Road
Nottingham, NG5 1PB

Dear Mr Taylor,

Full title of study: **Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy**

REC reference number: **06/Q2404/48**

Thank you for your letter of 26 May 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	1	29 March 2006
Investigator CV		27 March 2006
Investigator CV		07 March 2006
Protocol	3	18 May 2006
Letter from Sponsor		27 March 2006
Peer Review		26 April 2006
Interview Schedules/Topic Guides	2	07 March 2006
Questionnaire	1	27 March 2006
Letter of invitation to participant	2	18 May 2006
Participant Information Sheet	4	18 May 2006

Participant Consent Form	3	18 May 2006
Response to Request for Further Information		26 May 2006
Flow Chart	3	18 May 2006
Letter from Rebecca Freeman		03 April 2006

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q2404/48	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr M Hewitt/Ms L Ellis
Chair/Co-ordinator

Email: linda.ellis@rushcliffe-pct.nhs.uk

Enclosures: *Standard approval conditions*
Site approval form

Copy to: Mr Paul Cartledge

R&D Department for NHS care organisation at lead site - NCH

APPENDIX 18

SF1 list of approved sites

APPENDIX 19

Nottingham University Hospitals NHS Trust
Research and Development Department
Hucknall Road
Nottingham
NG5 1PB

Direct Dial: 0115 9627913
Tel: 0115 969 1169 ext 46913
Minicom: 0115 962 7749
www.nuh.nhs.uk/nch/randd

Ref: 06MA001

Date: 21 June 2006

Mr J Taylor
PhD student
School of Human Development
University of Nottingham
City Hospital Campus
NUHT

Dear Mr Taylor

Re: Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy

R&D Reference: 06MA001

Ethics Reference: 06/Q2404/48

The R&D Department have considered the following documents:

- NHS REC application form
- R&D Application form
- Protocol version 3, dated 18/05/06
- Participant information sheet, version 4, dated 18/05/06
- Participant Consent form version 3, dated 18/05/06
- Letter of invitation, version 2, dated 18/05/06
- Interview schedule, version 2, dated 07/03/06
- Procedures flow-chart, version 3, dated 18/05/06
- Questionnaire version 1, dated 27/03/06

The study now has R&D approval subject to the conditions set out below:

That you:

- Abide by the Clinical Trial/Research agreement (as applicable)
- Abide by the terms of your substantive employment/honorary contract with the Trust (where applicable)

- Ensure that all study personnel, not employed by the Nottingham University Hospitals Trust, hold Honorary contracts with this Trust, before they have access to any facilities, patients, staff, their identifiable data, tissues or organs.

- Conduct all Clinical Trials under the jurisdiction of the EU Directive 2001/20/EC in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004

- Comply with the current Research Governance Framework for Health and Social Care. (Copies of the Research Governance Framework for Health and Social Care can be found at www.doh.gov.uk or via the R&D office)

- Report all research, which is discontinued temporarily or permanently, to the R&D Department in a timely manner

- Provide information for R&D reporting purposes including publications, Serious Adverse Events and progress reports as requested/required

- Request written approval from the R&D Department for any changes to the project protocol including amendments, study personnel and study documentation you propose to implement

- Notify the R&D Department as soon as you are made aware of any study inspection/audit by an external organisation

- Must not start your project until you have received all relevant written regulatory approvals/authorisations

In addition:

- All projects are liable to be monitored by the Trust

- Unless you have indicated otherwise on the R&D application form the project details will be uploaded to the National Research Register (NRR) database (The NRR can be accessed on www.nrr.nhs.uk)

Yours sincerely

pp G. Dockery

Dr B Thomson
Research & Development Director

cc NHS Research Ethics Committee

APPENDIX 20

Direct line/e-mail
+44 (0) 115 8231063
Louise.Sabir@nottingham.ac.uk

Faculty of Medicine and Health Sciences

Medical School Research Ethics Committee
Division of Therapeutics & Molecular Medicine
D Floor, South Block
Queen's Medical Centre
Nottingham
NG7 2UH

Tel: +44 (0) 115 8231063
Fax: +44 (0) 115 8231059

Mr John Taylor
PhD Student
Behavioural Sciences
A Floor, South Block
Queen's Medical Centre
Nottingham
NG7 2UH

19 June 2006

Dear Mr Taylor

Ethics Reference No: D/5/2006 - *Please quote this number on all correspondence*
Study Title: Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy.
Lead Investigator: Mr John Taylor, PhD Student
Co Investigators: Professor Jim Thornton, Professor of Obstetrics & Gynaecology, Human Development, Dr Cris Glazebrook, Reader in Health Psychology, Behavioural Sciences, Dr Tim Coleman, Director of General Practice Undergraduate Education Unit, Senior Lecturer in Primary Health Care.

Thank you for your letter dated 5th June 2006 and enclosing revised version of:

- Application form dated 06/06/06
- Protocol version 4.0, dated 06/06/06
- Volunteer Information sheet version 4.0, dated 06/06/06
- Invite Letter to volunteers version 2.0 06/06/06

Thank you for clarifying the points raised which on review are satisfactory and the study is approved.

Approval is given on the understanding that the Conditions of Approval set out below are followed.

Conditions of Approval

You must follow the protocol agreed and any changes to the protocol will require prior Ethic's Committee approval.

You promptly inform the Chairman of the Ethic's Committee of

(i) Deviations from or changes to the protocol which are made to eliminate immediate hazards to the research subjects.

Please note that all correspondence and queries should be sent to my Ethics Committee Secretary Louise Sabir

(ii) Any changes that increase the risk to subjects and/or affect significantly the conduct of the research.

(iii) All adverse drug reactions that are both serious and unexpected.

(iv) New information that may affect adversely the safety of the subjects or the conduct of the study.

Statement of Compliance (from May 2004 only)

The University of Nottingham Medical Research Ethics Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

Professor R C Spiller
Chairman, Nottingham University Medical School Research Ethics Committee

APPENDIX 20

Please note that all correspondence and queries should be sent to my Ethics Committee Secretary Louise Sabir

CODEBOOK - NHS STOP SMOKING SERVICES THEMES

Label: **Practical support**

Definition: Pregnant smokers' beliefs about the practical support they would receive from a Stop Smoking service

How to know when theme occurs: Look for mention of practical strategies employed by the Stop Smoking service to aid a quit attempt, and where practical strategies are perceived to be lacking

Qualifications or exclusions: Does not include emotional support offered by Stop Smoking services or motivation

Example of positive coding: *They'll say 'it keeps me going because I know you're coming next week with your CO monitor' (Health professional 4)*

Example of negative coding: *The person who I actually spoke to was really understanding and really friendly ... that kind of put me at ease (Pregnant woman 14; smoker)*

Label: **Emotional support**

Definition: Pregnant smokers' beliefs about the emotional support they would receive from a Stop Smoking service

How to know when theme occurs: Look for mention of a Stop Smoking service easing feelings of guilt, showing understanding & offering encouragement. Also look for where emotional support is perceived to be lacking.

Qualifications or exclusions: Does not include practical support offered by Stop Smoking services

Example of positive coding: *They like the fact that, in their words, somebody understands what they're going through (Health professional 12)*

Example of negative coding: *Apparently now there are things what they can give you to help you stop (Pregnant women 4; smoker)*

Label: **Service effectiveness**

Definition: Pregnant smokers' beliefs about whether a Stop Smoking service would help them and others quit

How to know when theme occurs: Look for mention of services being helpful or unhelpful for quitting

Qualifications or exclusions: Does not include specific support offered by the service
Example of positive coding: *It [Stop Smoking service] has actually stopped quite a few of my friends from smoking (Pregnant woman, 4; smoker)*

Example of negative coding: *I mean obviously they can give you something [NRT] to help you stop smoking (Pregnant woman 4; smoker)*

Label: **Improving health**

Definition: Pregnant smokers' beliefs about how attending a Stop Smoking service would improve her health and that of her baby

How to know when theme occurs: Look for mention of health improvements that might be expected for mother and baby, health problems that might be avoided, and desire to create a smoke-free environment.

Qualifications or exclusions: Health must be specifically mentioned. Giving up smoking as a proxy for health improvement is not sufficient.

Example of positive coding: *I want the house to be fresh for when it [baby] comes (Pregnant woman 3; smoker)*

Example of negative coding: *Maybe [Stop Smoking services] give them that extra boost and kind of help them quit [Pregnant woman 14; smoker)*

Label: **Acquiring information**

Definition: Pregnant smokers' beliefs about the useful information they would gain from a Stop Smoking service

How to know when theme occurs: Look for mention of acquiring information about the harms of smoking, the benefits of quitting and Nicotine Replacement Therapy

Qualifications or exclusions: In terms of NRT, only refers to receiving information about it, not acquiring it.

Example of positive coding: *A lot of it is the information that they get because a lot of them may not be aware that they can use nicotine replacement (Health professional 8)*

Example of negative coding: *They [Stop Smoking service] can give you the patches (Pregnant woman 1; recent quitter)*

Label: **Social pressure**

Definition: Pregnant smokers' beliefs about the social pressure they would feel to engage or not engage with Stop Smoking services

How to know when theme occurs: Look for mention of family, health experts and friends as sources of social pressure to engage or not engage with Stop Smoking services

Qualifications or exclusions: Does not include stigma or fear of being judged

Example of positive coding: *They get pressured from members of the family that they should access the service (Health professional 12)*

Example of negative coding: *[I wouldn't feel uncomfortable going to a group] if you were with other pregnant people in the same situation. But if it was just normal people and then you're there pregnant, they'd think, you know (New mother 1; smoked throughout pregnancy)*

Label: **Access to services**

Definition: Pregnant women's beliefs about the ease or difficulty of accessing Stop Smoking services

How to know when theme occurs: Look for mention of practical issues considered to facilitate or impede access to services

Qualifications or exclusions: Includes considerations such as location and lifestyle pressures, but not motivation to quit

Example of positive coding: *'Don't have the time' is the answer for most of the reasons why they don't attend (Health professional 6)*

Example of negative coding: *I've never looked into it [Stop Smoking services] because I've never been interested in stopping [smoking] (Pregnant woman 9; smoker)*

Label: **Motivation**

Definition: Pregnant smokers' beliefs about their desire or their ability to quit smoking

How to know when theme occurs: Look for mention of pleasure of smoking, difficulties associated with quitting, not wanting to quit, or wanting to quit alone.

Qualifications or exclusions: Does not include stigma

Example of positive coding: *The ones who don't want to use it [Stop Smoking service] are normally the ones who just want to carry on smoking (Health professional 3)*

Example of negative coding: *I think in my head it's slightly stereotyped the fact that you go to a group and stand up and say well I'm a smoker. I don't think I'd be comfortable in that situation (Pregnant woman 5; smoker)*

Label: **Stigma**

Definition: Pregnant women's beliefs about how her smoking in pregnancy would be negatively received by others.

How to know when theme occurs: Look for mention of shame associated with smoking in pregnancy, concerns about being judged by others, and hiding smoking from others

Qualifications or exclusions: Does not include social pressure to quit or fear of failing to quit

Example of positive coding: *They [pregnant smokers] certainly don't like going to clinics in the community ... they feel embarrassed that people know that they are smoking (Health professional 8)*

Example of negative coding: *They can't do it [quit] and they feel that they don't want to tell me that they can't do it (Health professional 4)*

Label: **Knowledge about services**

Definition: Pregnant smokers' existing knowledge about Stop Smoking services

How to know when theme occurs: Look for mention of pregnant women's existing knowledge or lack of knowledge about services

Qualifications or exclusions: Does not include beliefs about information they would acquire from a Stop smoking service

Example of positive coding: *No [I wasn't aware that the Stop Smoking services offer NRT], that's what I mean, I don't know anything about it (Pregnant woman 10; recent quitter)*

Example of negative coding: *Other women believe it or not are still not aware of the risks to the baby ... some women are quite surprised actually (Health professional 2)*

Label: **Fear of failure**

Definition: Pregnant smokers' beliefs about the negative impact a failed quit attempt would have on themselves and others

How to know when theme occurs: Look for mention of pregnant woman letting herself and her adviser down, and embarrassment about relapse

Qualifications or exclusions: Specifically relates to concerns about failing to quit. Does not include social pressure to quit or stigma associated with smoking in pregnancy

Example of positive coding: *Sometimes they absolutely dread telling you that they've had a slip up and you can see that it's just a relief when you say 'well that's alright, what are your plans now' (Health professional 1)*

Example of negative coding*: Nobody knows I smoke. My Mum would kill me. (Pregnant women 4; smoker)*

NHS STOP SMOKING SERVICES QUOTES

(Sequence randomised for use with codebook)

Practical support

I suppose that's a good part of it, because you get help with the nicotine patches (Pregnant woman 12; recent quitter) 1

They always say to me 'oh whenever I want a cigarette, I'll just think about that baby's bottle [with the tar in it]' (Health professional 4) 2

Every time you went she's get me to blow into this thing what read the carbon monoxide ... that was quite good because I used to think 'I wonder what it's going to be today'. And I was quite chuffed with myself when I knew I hadn't had a cigarette and I could see it coming down (Pregnant woman 4; smoker) 3

Emotional support

Probably it [using a Stop Smoking service] would make you not so ashamed and let you know that there is other people that do it and you're not on your own (Pregnant woman 7; smoker) 4

It [Stop Smoking service] is the face to face kind of contact of someone who's more understanding and can empathise with them (Health professional 7) 5

Other comments we've had are people just saying that the encouragement as well and the 'well done, keep it going' [are positive outcomes of attending a Stop Smoking service] (Health professional 10) 6

Service effectiveness

To help you stop. I do know a lot of people who have actually used [the Stop Smoking service] who have actually stopped. My friends and things. So it obviously does work (Pregnant woman 1; recent quitter) 7

And it [Stop Smoking service] helping you if you can't do it [quit] by yourself (Pregnant woman 7; smoker) 8

Some say it [meeting the Stop Smoking adviser] brings the memories back and that if they were feeling OK, sometimes they feel that they're craving terribly after I've gone (Health professional 1) 9

Improving health

Well it's going to improve my health, it's going to improve the baby, it's not going to make the small birth weight or any complications in the labour and stuff (Pregnant woman 8; smoker) 10

Obviously the health of your baby isn't it, number one, and it's better for you as well I think when they are born (New mother 1; smoked throughout pregnancy) 11

Well I know [using a Stop Smoking service] would be better for me and the baby (Pregnant woman 11; smoker) 12

Acquiring information

Ladies have wanted to know more information about certain things, 'why are the babies smaller?' and certain information that they want to know more about (Health professional 12) 13

Probably the advantages [of using a Stop Smoking service in pregnancy] would be making you aware of what it can do to the baby and things (Pregnant woman 7; smoker) 14

Some women do want to know about [NRT] studies and things that have been done (Health professional 10) 15

Social pressure

My Dad, my friends and family [would approve of me using a Stop Smoking service] (Pregnant woman 2; smoker) 16

Family members tend to encourage them to use the service because they want them to stop smoking (Health professional 12) 17

Because they get asked [about their smoking] so regularly [by health professionals], I think they feel 'well they keep asking me, maybe I ought to do something about it' (Health professional 13) 18

Probably just my mates [wouldn't want me to go to a Stop Smoking service], you know what they're like (Pregnant woman 3; smoker) 19

Well I suppose everyone at the surgery, you know at the clinic, hospital, they would encourage you wouldn't they? (New mother 2; quit during pregnancy) 20

My family would approve, definitely ... my GP probably would as well (Pregnant woman 12; recent quitter) 21

The consultants, the obstetricians and the health service personnel who obviously are much happier if they do use it [Stop Smoking service] because obviously it's better for them and their baby (Health professional 3) 22

Access to services

Why I wouldn't [attend a Stop Smoking service], would be time with work and the children (Pregnant woman 7; smoker) 23

I thought it was really good that the drop in centre was open in the evening. Because people go to work. My husband wanted to give up smoking as well and he said 'it's difficult for both of us to try and get there at the time one of us is at work (Pregnant woman 6; recent quitter) 24

It's far out most of these [Stop Smoking services] ... well out of my reach. And the green buses with a pushchair, you can't get on (New mother 3; smoked throughout pregnancy) 25

I actually had somebody come out and see me at home ... so it was really easy for me to see New Leaf [Stop Smoking service] (Pregnant woman 14; smoker) 26

It [Stop Smoking service] would have to be close to me. I wouldn't want to be travelling far (Pregnant woman 10; recent quitter) 27

If it was a home visit, that would be brilliant, that would fit round me very easily (Pregnant woman 5; smoker) 28

That would be easier if they came to me, because I've got 3 kids and I'm pregnant with my 4th (Pregnant woman 8; smoker) 29

Motivation

I just enjoy a fag too much. I like the one when you wake up first thing in the morning and last at night ((new mother 3; smoked throughout pregnancy) 30

I would've [liked to have been able to quit during the pregnancy] yes, the harm and everything but it is just too difficult ... a lot of stresses (new mother 3; smoked throughout pregnancy) 31

And she [smoking cessation advisor] told me I could go to the clinic but I never went because I decided I could do it on my own (Pregnant woman 6; recent quitter) 32

Stigma

It [smoking in pregnancy] makes them feel guilty and they don't want the world to know ... so in some ways I think that's one of the reasons why they quite like me to go to the house (Health professional 16) 33

I hide it as well, I don't let anyone see me at work or anything like that, I don't smoke where people can see me, and my parents don't know or anything like that. Even my son who's six doesn't think I smoke (Pregnant woman 7; smoker) 34

I guess at first I was a little bit [awkward] because there is the whole stigma that goes with it, so I was a little bit like, yeah they probably do think I'm sort of horrible (Pregnant woman 14; smoker) 35

Knowledge about services

Unless you want to give up and you seek the information out yourself ... then you don't really hear about it, you don't see it (Pregnant woman 6; recent quitter) 36

I never see adverts for the place [Stop Smoking service] where you go to. You don't know anything about it (Pregnant woman 10; recent quitter) 37

Not really knowing fully what the service can actually offer, and being a little bit unsure of what is going to be expected of them when they come [would put some pregnant women off making an appointment] (Health professional 17) 38

Fear of failure

I'd probably just think 'oh god if I don't do it' and maybe feeling under pressure to do it, once you've decided to go ahead and try and if you didn't then ... I probably would feel like I was letting myself and the advisor down if I didn't do it (Pregnant woman 7; smoker) 39

And then I'll not see them again then, because they're embarrassed about going back to smoking (Health professional 16) 40

Sometimes it's the drive that keeps them giving up is the fact that they don't want to disappoint the advisor who's helping them (Health professional 14) 41

CODEBOOK – NICOTINE REPLACEMENT THERAPY THEMES

Label: **Effective for quitting**

Definition: Pregnant smokers' beliefs about whether or not NRT would help them quit smoking

How to know when theme occurs: Look for mention of NRT assisting or not assisting a quit attempt

Qualifications or exclusions: Does not include reduction of cravings or stress

Example of positive coding: *I've heard it [NRT] works (Pregnant woman 11; smoker)*

Example of negative coding: *'They're not getting a craving [using NRT]' (Pregnant woman 10; recent quitter)*

Label: **Side effects**

Definition: Pregnant smokers' beliefs about unwanted side effects when using NRT

How to know when theme occurs: Look for mention of unpleasant reactions to NRT

Qualifications or exclusions: Does not include exacerbation of pregnancy sickness

Example of positive coding: *'They can feel light headed, they can feel dizzy, they can get constipated, they can have flu like symptoms.' (Health professional 3)*

Example of negative coding: *If I'm getting girls early in pregnancy and they're still feeling a bit nauseous, they can't tolerate the taste of the oral preparations (Health professional 14)*

Label: **Reduction of cravings**

Definition: Pregnant smokers' beliefs about NRT reducing their cigarette cravings

How to know when theme occurs: Look for specific mention of NRT helping to reduce cravings or taking the edge off withdrawal symptoms

Qualifications or exclusions: Does not include NRT generally helping to aid a quit attempt or NRT reducing stress or improving mood

Example of positive coding: *They say it helps take the edge off the withdrawal symptoms (Health professional 10)*

Example of negative coding: *It [NRT] would stop you getting niggly and ratty wouldn't it? (Pregnant woman 2; smoker)*

Label: **Exacerbated sickness**

Definition: Pregnant smokers' beliefs about NRT exacerbating pregnancy sickness

How to know when theme occurs: Look for mention of pregnancy sickness being made worse by using NRT and certain products not being tolerated well due to nausea.

Qualifications or exclusions: Only includes side effects associated with pregnancy sickness

Example of positive coding: *The taste of the other products, especially if they're feeling a bit sickly themselves (Health professional 10)*

Example of negative coding: *I've tried the chewing gum, the nicotine chewing gum, that was too chalky. It was like chewing on chalk. (Pregnant woman 8; smoker)*

Label: **Financial cost**

Definition: Pregnant smokers' beliefs about how using NRT would impact on them financially

How to know when theme occurs: Look for mention of NRT being free or expensive and cost issues associated with NRT.

Qualifications or exclusions: Does not include knowledge about specific types of NRT

Example of positive coding: *'If it was free, that would be an incentive [to use NRT].' (Pregnant woman 6; recent quitter)*

Example of negative coding: *'I didn't know about that one [microtab].' (New mother 3; smoked throughout pregnancy)*

Label: **Stress reduction**

Definition: Pregnant smokers' beliefs about NRT reducing stress and improving mood

How to know when theme occurs: Look for mention of NRT relieving stress or lightening mood

Qualifications or exclusions: Does not include NRT helping with quitting or reducing cravings

Example of positive coding: *It helps them with the irritableness (Health professional 15)*

Example of negative coding: *It's the fact that they are having something to help them with the cravings (Health professional 4)*

Label: **Improved health**

Definition: Pregnant women's beliefs about NRT being better for their health and that of their baby than smoking

How to know when theme occurs: Look for mention of NRT being a healthier option than smoking and the resultant benefits to mother and baby

Qualifications or exclusions: Does not include NRT helping with a quit attempt

Example of positive coding: *'It [NRT} has got to be better than smoking hasn't it? ... you're not going to get the rubbish you get with cigarettes' (New mother 4; smoked throughout pregnancy)*

Example of negative coding: 'Well they say they couldn't have managed to stop without it [NRT]' (Health professional 1)

Label: **Not the same as quitting**

Definition: Pregnant smokers' beliefs about using NRT not representing properly quitting smoking

How to know when theme occurs: Look for mention of using NRT not being like quitting smoking because nicotine is still being used

Qualifications or exclusions: Does not include concerns about becoming addicted to NRT or wanting to quit without NRT

Example of positive coding: *'It [NRT] is like something replacing it [smoking], and you're not quite giving up' (New mother 2; quit during pregnancy)*

Example of negative coding: *Occasionally people are strongly against NRT ... even after I've said it's none addictive they're still against it' (Health professional 11)*

Label: **Satisfaction**

Definition: Pregnant smokers' beliefs about NRT replacing or not replacing the satisfaction derived from smoking

How to know when theme occurs: Look for mention of NRT being able or unable to replace the sensation derived from smoking

Qualifications or exclusions: Only includes direct comparisons between NRT and cigarettes, not the effectiveness of NRT

Example of positive coding: *'It [the inhalator] is so strong ... choking to death ... it's like having 10 fags at one go (New mother 3; smoked throughout pregnancy)*

Example of negative coding: *'[NRT] makes you stop ... I suppose it just gives you the nicotine doesn't it that you need' (Pregnant woman 1; recent quitter)*

Label: **Becoming addicted**

Definition: Pregnant smokers' beliefs about NRT being addictive

How to know when theme occurs: Look for mention of concerns about not being able to come off NRT

Qualifications or exclusions: Does not include NRT not being the same as quitting or wanting to quit without NRT

Example of positive coding: *Occasionally people are strongly against NRT ... even after I've said it's none addictive they're still against it' (Health professional 11)*

Example of negative coding: *'I felt this time that I shouldn't bother with anything else [NRT] and just try and stop.' (New mother 2; quit during pregnancy)*

Label: **Social pressure from family**

Definition: Pregnant smokers' beliefs about social pressure from family to use or not use NRT

How to know when theme occurs: Look for mention of family members approving or not approving of NRT use in pregnancy

Qualifications or exclusions: Does not include social pressure from friends or health experts, or pregnant women reporting concerns about NRT not being allowed in pregnancy

Example of positive coding: *'I think the negative views [about NRT] probably are from family members and maybe the fact that they've tried it and it hasn't worked.' (Health professional 1)*

Example of negative coding: *'Occasionally some of the women say, 'I don't think my doctor would prescribe that [NRT].' (Health professional 10)*

Label: **Social pressure from health experts**

Definition: Pregnant smokers' beliefs about social pressure from health experts to use or not use NRT

How to know when theme occurs: Look for mention of health experts approving or not approving of NRT use in pregnancy

Qualifications or exclusions: Does not include social pressure from family or friends, or pregnant women reporting concerns about NRT not being allowed in pregnancy

Example of positive coding: *The medical side of things would all approve [of me using NRT] because obviously I'm attempting to stop smoking, and I think they'd be grateful for anything if I'm trying to stop' (Pregnant woman 5; smoker)*

Example of negative coding: *I was told you're not allowed to use them [inhalators] during pregnancy (Pregnant women 14; smoker)*

Label: **Social pressure from friends**

Definition: Pregnant smokers' beliefs about social pressure from friends to use or not use NRT

How to know when theme occurs: Look for mention of friends approving or not approving of NRT use in pregnancy

Qualifications or exclusions: Does not include social pressure from family or health experts, or pregnant women reporting concerns about NRT not being allowed in pregnancy

Example of positive coding: *'Friends [would approve of NRT use]' (Pregnant woman 1; recent quitter)*

Example of negative coding: *'I have had cases where women have had the patch and the GP has told them they shouldn't be wearing it, and they've taken it off (Health professional 12)*

Label: **Safety**

Definition: Pregnant smokers' beliefs about the safety of NRT use in pregnancy

How to know when theme occurs: Look for mention of concerns about NRT being harmful and worries about the effect on the baby

Qualifications or exclusions: Does not include concerns about NRT not being allowed or social pressure

Example of positive coding: *They worry of course about the effect it [NRT] has on the unborn baby (Health professional 6)*

Example of negative coding: *'Occasionally some of the women say 'I don't think my doctor would prescribe that [NRT]' (Health professional 10)*

Label: **Unsure if allowed**

Definition: Pregnant smokers' beliefs about NRT not being allowed in pregnancy

How to know when theme occurs: Look for mention of being unaware that or unsure whether NRT has been sanctioned for use in pregnancy

Qualifications or exclusions: Does not include concerns about safety or social pressure

Example of positive coding: *'Sometimes they don't think that they can have it [NRT]' (Health professional 17)*

Example of negative coding: *'But with the patch you would wear it all day and there's going to be a constant kind of supply of nicotine going to the body, and I just don't like the thought of that' (Pregnant woman 14, smoker)*

Label: **Convenience of use**

Definition: Pregnant smokers' beliefs about how convenient NRT would be to use

How to know when theme occurs: Look for mention of ease or difficulty of use once obtained

Qualifications or exclusions: Does not include ease or difficulty of obtaining NRT or unpleasant side effects

Example of positive coding: *'With the patch, they like the convenience that they can just put it on and forget about it' (Health professional 12)*

Example of negative coding: *'The fact that we [Stop Smoking service] are in town so it's convenient. They don't have to do a lot of work in order to get it [NRT], I think that's probably the main reason [why they use NRT].' (Health professional 6)*

Label: **Ease of acquisition**

Definition: Pregnant smokers' beliefs about how easy it would be to acquire NRT

How to know when theme occurs: Look for mention of ease or difficulty in obtaining NRT

Qualifications or exclusions: Does not include convenience of use once obtained

Example of positive coding: *'[It would be easier to use NRT] if there's plenty of locations around where I lived where you can be supplied with it.' (Pregnant woman 12; recent quitter)*

Example of negative coding: *'If I've got a patch on, then I can do things with my hands.' (Pregnant woman 9; smoker)*

Label: **Self consciousness / embarrassment**

Definition: Pregnant smokers' beliefs about whether or not using NRT would cause self consciousness or embarrassment

How to know when theme occurs: Look for mention of feeling awkward about using NRT and how it might appear to others or not being concerned what others might think

Qualifications or exclusions: Does not include social pressure or being unsure that NRT is allowed

Example of positive coding: *'I used that [inhalator] and I don't particularly like it, I think you look a bit weird with it.' (New mother 4; smoked throughout pregnancy)*

Example of negative coding: *'Once or twice they've said 'my Mum said you shouldn't really be wearing that [patch] because you're pregnant.' (Health professional 13)*

Label: **Knowledge about products**

Definition: Pregnant smokers' existing knowledge about the range of NRT products

How to know when theme occurs: Look for mention of awareness or lack of awareness of the range of products available

Qualifications or exclusions: Does not include beliefs about NRT generally

Example of positive coding: *'Clear information, unbiased information. I'm sure that helps them, a lot of them. 'Oh, I didn't know that, OK I'll try that.' (Health professional 11)*

Example of negative coding: *'They [Stop Smoking services] give you the support and they give you the stuff [NRT] free' (Pregnant woman 8; smoker)*

Label: **Smoking addiction**

Definition: Pregnant smokers' desire or perceived ability to quit smoking and its impact on NRT use

How to know when theme occurs: Look for mention of degree of motivation to quit or beliefs about ability to quit

Qualifications or exclusions: Does not include wanting to quit without using NRT or beliefs that NRT is addictive or is not the same as quitting

Example of positive coding: *'[I would] probably not [be more likely to try NRT if I knew it was free] because I'm not ready to quit myself.' (Pregnant woman 11; smoker)*

Example of negative coding: *'I kind of feel that I'd be using the patches and stuff as a crutch ... I feel if I can do it without using the patches, I'd prefer to.' (Pregnant woman 14; smoker)*

Label: **Wanting to quit without**

Definition: Pregnant smokers' beliefs about wanting or feeling able to quit smoking without using NRT

Qualifications or exclusions: Does not include concerns about NRT being addictive or beliefs that using NRT is not the same as quitting

Example of positive coding: *'Some of the pregnant ladies that I have don't complete the 12 week course [of NRT] because they don't need to.' (Health professional 17)*

Example of negative coding: *'I think you're still doing the same thing as smoking. Obviously maybe not as nearly as harmful but you're still putting nicotine into your body' (Pregnant woman 6; recent quitter)*

Label: **Forgetting to use**

Definition: Pregnant smokers' beliefs about their ability to remember to use NRT

How to know when theme occurs: Look for mention of memory influencing NRT use

Qualifications or exclusions: Does not include convenience of use

Example of positive coding: *'If they forget to put the patch on, they recognise the difference very quickly.' (Health professional 18)*

Example of negative coding: *'They prefer to put a patch on ... they just put it on and it's there for the rest of the day' (Health professional 10)*

NICOTINE REPLACEMENT THERAPY QUOTES

(Sequence randomised for use with codebook)

Effective for quitting

Everyone I know's had them [NRT patches] ... and they say they're quite effective anyway (New mother 1; smoked throughout pregnancy) 1

I mean last time I was pregnant they prescribed them [NRT patches] and it didn't work at all (Pregnant woman 3; smoker) 2

I've tried it [NRT] in the past and it's not worked for me ... I'm up against a bit of a brick wall on the replacement therapy kind of thing (Pregnant woman 5; smoker) 3

If it hasn't worked for some people, then they think it's not going to work for them. So it's really word of mouth (Health professional 3) 4

Side effects

I suffered quite a lot of headaches as well with them (NRT patches] ... I've had migraines a lot (Pregnant woman 13; smoker) 5

[I wouldn't want to use NRT] from stories that I've heard off other people ... nightmares and hot sweats and things like that (Pregnant woman 1; recent quitter) 6

She [a friend] used the patches but she couldn't get to sleep because she was hallucinating and she got very paranoid (Pregnant woman 10; recent quitter) 7

I've tried patches before and I come out in a rash with the patch (Pregnant woman 5; smoker) 8

Reduction of cravings

I would imagine that it [NRT] would make life that little bit easier, the withdrawal from it [smoking] (Pregnant woman 5; smoker) 9

Well only that it [NRT] helps stop the cravings, that's about it really (Pregnant woman 7; smoker) 10

Well, they feel it [NRT] does help their cravings (Health professional 12) 11

Exacerbated sickness

I think morning sickness if they come within the first few weeks, you know if they're using an oral product, they tend to feel sick and they don't want to use it (Health professional 9) 12

Your taste in pregnancy is different ... and you're feeling a bit sick so a lot of the oral products aren't going to work anyway (Health professional, 15) 13

Sometimes what I find is that if it's very early in pregnancy, obviously the nausea and vomiting can be a particular problem with the oral products (Health professional 17) 14

Financial cost

I've always thought you'd have to pay for NRT things and they are quite expensive (Pregnant woman 12; recent quitter) 15

If I had to pay for it [NRT], I'll just have a fag rather than go and get them sort of thing (Pregnant woman 2; smoker) 16

The fact that it [NRT] is free makes them want to use it (Health professional 4) 17

Stress reduction

One of the other problems that I have with quitting smoking during pregnancy is kind of the stress levels that you get to when you go without a cigarette ... and so I can see how maybe a nicotine patch or some sort of NRT could kind of take the edge off that' (Pregnant woman 14; smoker) 18

They're still getting the sense of having a fag ... and they won't get as stressed (Pregnant woman 10; recent quitter) 19

They might have the inhalator or something, and they just have the odd puff in a day you know, just if the toddler's playing up and they're stressed or whatever (Health professional 4) 20

Improved health

It's not like smoking is it? I don't think there's anyway near the amount of toxins that you're taking in ... so I imagine that is healthier (New mother 2; quit during pregnancy) 21

If I used anything like that [NRT] it'd make me a lot healthier. I wouldn't be getting out of breath all the time (Pregnant woman 9; smoker) 22

You're not inhaling the smoke so therefore it's not hurting your baby is it ... it /NRT] is better for you. It's probably better for the whole pregnancy isn't it? (New mother 1; smoked throughout pregnancy) 23

Not the same as quitting

If you're stopping smoking, you don't want nicotine inside you, but that [NRT] is putting nicotine in you and I've never got that (Pregnant woman 7; smoker) 24

It's still the same as having a fag, you're still getting the nicotine aren't you? (Pregnant woman 8; smoker) 25

You're not cutting the nicotine out and you're not actually quitting smoking, you're just kind of replacing it with something else (Pregnant woman 14; smoker) 26

Satisfaction

I can't see it's like having a cigarette. I can't imagine it's the same (Pregnant woman 2; quit during pregnancy) 27

One woman [using NRT] very recently said that she doesn't get to blow smoke out, so that was really important (Health professional 2) 28

It [the inhalator] didn't really stop me wanting to hold a cigarette ... really it didn't replace that hand to mouth thing (New mother 2; quit during pregnancy) 29

Becoming addicted

Becoming addicted to something else [would be a disadvantage of using NRT] because I think if you have a bit of an addictive type of mindset, again that's something else you'd have to quit (New mother 2; quit during pregnancy) 30

Because you're getting a sense of having a fag, you might not be able to stop on the thing that you're using [NRT]. And then if you stop [using NRT] you're just going to want a fag aren't you? (Pregnant woman 10; recent quitter) 31

Social pressure from family

Yes, my family would approve [of me using NRT], definitely (Pregnant woman 12; recent quitter) 32

I think some of the family discourage them from using the oral products ... and that's just if they've tried them before (Health professional 10) 33

We do get the odd person that will come back and say 'my Nan said I shouldn't be on that or my Mum said I'm pregnant and I shouldn't be taking that' (Health professional 2) 34

Social pressure from health experts

I think then everybody should approve [of NRT use] in a health [setting], health visitors, midwives and hospital because it's a step in the right direction (New mother 2; quit during pregnancy) 35

Well I suppose anyone in the medical profession [would approve of me using NRT] because they'd say to do that rather than smoke (Pregnant woman 6; recent quitter) 36

My midwife [has encouraged me to use NRT] (Pregnant woman 4; smoker) 37

Social pressure from friends

Anyone close to you would be supportive if you wanted to do it [use NRT] ... your closest friends (Pregnant woman 10; recent quitter) 38

I would say 5 out of 10 people say well 'my friend [has put me off using NRT]' (Health professional 16) 39

Probably friends, their peers, I would say more than anything [influence them to use NRT] ... maybe friends that have been pregnant and have had experience of using it (Health professional 13) 40

Safety

They worry about using it in pregnancy ... with what effect it'll have on the pregnancy, on the baby (Health professional 17) 41

At the beginning of this year there was something in the newspapers about NRT being linked to birth defects ... I did actually have one lady who was already on treatment and doing very well and unfortunately stopped the treatment after reading this article (Health professional 17) 42

If it has been actually tested out and somebody could say to me, 'look this is 100% safe' ... then I think I would be a lot more willing to use them [patches]' (Pregnant woman 14, smoker) 43

Unsure if allowed

I didn't think you could actually use nicotine replacement patches when you're pregnant (Pregnant woman 2; smoker) 44

I didn't know you could use them [NRT] when you were pregnant (Pregnant woman 7; smoker) 45

I don't know whether you're allowed to do it [use NRT] when you're pregnant (Pregnant woman 10; recent quitter) 46

Convenience of use

[The inhalator] was discreet as well because it fits into your bag or you could put it in your purse ... it's not like the chewing gum where you've got to mess around with the box to get it out and then put it away, it was just a lot easier ... you can just get it out of your bag or out of your pocket, stick it in your mouth, suck on it and then put it away (Pregnant woman 4; smoker) 47

Most women prefer the patch ... they just like the feeling of not having to take a piece of gum or use an inhalator, they like to be able to just get on which what they have to do (Health professional 12) 48

[I'd find NRT easier to use] if the patches stuck a bit better (New mother 3; smoked throughout pregnancy) 49

Ease of acquisition

A disadvantage is trying to get hold of it [NRT] ... they have to come in and see someone or someone has to go and see them, they don't want to see anybody really if they can help it (Health professional 18) 50

'Maybe if you could access it directly when you visit your midwife at the clinic [it would be easier to use NRT] ... I don't know if you can.' (New mother 2; quit during pregnancy) 51

Knowing that they're not going to run out and it's not going to be difficult [to access NRT], and that once they've got it it's going to be an ongoing supply for as long as necessary, rather than having to go and see the GP every time. So I think ease of access to it is important (Health professional 13) 52

Self consciousness / embarrassment

And the inhalator, some of them like it, but they wouldn't want to be seen out using it (Health professional 10) 53

I've got one lady who goes all week without a cigarette, she's on the inhalator and she's doing fine. She goes out [at the weekend] and is too embarrassed to hold the inhalator so she has a fag ... she tells me about it every Monday (Health professional 16) 54

They see you walking street and you've got that thing in your mouth [inhalator], they'll think, 'hold on a minute, that's not good, she's not allowed to do that', you'd proper get some weird looks ... I don't care what people think (Pregnant woman 4; smoker) 55

Knowledge about products

I've never used it [NRT], it's just something I don't really know anything about (Pregnant woman 7; smoker) 56

I don't know all of them [NRT products] ... I don't know a lot about it (Pregnant woman 11; smoker) 57

If I knew more about it [NRT], more awareness [it would make NRT use easier] (Pregnant woman 7; smoker) 58

Smoking addiction

You've got to have the will power I suppose, I just haven't got it at the moment ... I didn't think they [NRT] were working and it was just winding me up ... I wasn't in the right frame of mind at the time I don't think (Pregnant woman 13; smoker) 59

I just don't feel ready to give up smoking yet. When I feel ready then I will [try NRT] (New mother 1; smoked throughout pregnancy) 60

The patches are alright, I wouldn't use them ... I just enjoy a fag too much (New mother 3; smoked throughout pregnancy) 61

Wanting to quit without

That's why I decided not to do it [use NRT] personally because you're going to give it [smoking] up ... you have to believe you can cope without (Pregnant woman 6; recent quitter) 62

I don't really need it [NRT] (Pregnant woman 10; recent quitter) 63

If I wanted to try stop smoking, then I'd try it on my own without using any stuff [NRT] first (Pregnant woman 9; smoker) 64

Forgetting to use

It's memory [that makes it difficult for them to use NRT] (Health professional 3) 65

APPENDIX 23

A guide for giving smoking cessation information to pregnant women

APPENDIX 23

Aims of the guide

- There is evidence that health professionals lack the knowledge and confidence to give brief smoking cessation advice to pregnant women
- The following guide has been designed to help medical students give relevant information to pregnant women who smoke
- The aim of the guide is to encourage pregnant smokers to use NHS Stop Smoking services

APPENDIX 23

How smoking affects unborn babies

- Cigarette smoke contains over 4,000 chemicals
- One of these is a poisonous gas called carbon monoxide which cuts down the oxygen reaching the baby
- As oxygen helps babies grow, babies who don't get enough oxygen can be born smaller and weaker

APPENDIX 23

Risks of smoking in pregnancy

- Smoking during pregnancy has been linked to:
- Poor health for the mother:
  - Miscarriage
  - Bleeding
  - Nausea
- Poor health for the baby:
  - Slow growth of the foetus
  - Premature birth or stillbirth
  - Low birth weight
  - Cot death
  - Breathing problems
- A reduced birth weight will not necessarily make it easier for the mother to give birth – babies who don't grow well are more likely to be short of oxygen and need an emergency delivery

APPENDIX 23

Benefits of quitting in pregnancy

- Stopping smoking at any stage of pregnancy will benefit the baby immediately
- A pregnant woman who quits smoking during pregnancy will have:
  - Less morning sickness
  - Fewer complications during pregnancy and labour
  - A more content baby after birth
- Quitting smoking will also save the pregnant woman money

APPENDIX 23

What if partners, friends or family smoke?

- If anyone smokes near the pregnant woman she will breathe in harmful gases and chemicals
- Partners, family and friends could ideally try to stop smoking with the pregnant woman
- If they can't, they can help by not offering cigarettes to the pregnant woman or smoking near her

APPENDIX 23

Help with stopping smoking

- Pregnant women can get in touch with their local NHS Stop Smoking Service
- These services are free and run by health professionals who are specially trained to support smokers
- Many services offer special help for pregnant women, either in a group or one-to-one
- They offer individual help that's tailored to the pregnant woman's needs
- They enable the pregnant woman to monitor her progress using a breathalyser which measures the fall in carbon monoxide levels in her body
- Evidence shows that working with a trained Stop Smoking adviser can dramatically improve the chances of giving up

APPENDIX 23

Nicotine Replacement Therapy

- Nicotine Replacement Therapy (NRT) is the name given to products (e.g. gum or patches) which contain nicotine and help people give up smoking by reducing their cravings
- Pregnant women who are finding it difficult to stop smoking can try NRT after talking through the risks and benefits with a health professional
- Pregnant women who use Stop Smoking services can talk to their adviser about NRT
- NRT is considered safer than smoking. This is because it doesn't contain the toxic chemicals in cigarettes like tar or carbon monoxide, and does not cause cancer (NICE, 2002)
- NRT is not a magic cure, but women who use it are twice as likely to succeed in stopping when using it
- The pregnant woman's GP can advise her on the best option and give her a prescription for gum or patches so it doesn't have to cost a fortune

APPENDIX 24

A guide for giving smoking cessation information to pregnant women

APPENDIX 24

Aims of the guide

- There is evidence that health professionals lack the knowledge and confidence to give brief smoking cessation advice to pregnant women
- The following guide has been designed to help medical students give relevant information to pregnant women who smoke
- The aim of the guide is to encourage pregnant smokers to use NHS Stop Smoking services

Using the Theory of Planned Behaviour (Ajzen, 1991) to structure information about NHS Stop Smoking services

APPENDIX 24

- According to the Theory of Planned Behaviour, a pregnant smoker will be more likely to use an NHS Stop Smoking service if she believes that:
  - She will benefit from using the service
  - There is social pressure on her to use the service
  - She will be able to use the service
- Therefore, giving a pregnant smoker the following information is likely to encourage her to use an NHS Stop Smoking service:
  - What she can expect to gain from using the service
  - Which other people are likely to want her to use the service
  - What might make it easier for her to use the service
- The information in this guide is structured as above to help you explore the beliefs which influence the pregnant smoker in her decision-making about using an NHS Stop Smoking service
- You giving the pregnant smoker this information will help her challenge any negative beliefs she has about the service and create positive beliefs about it. This will make engagement with the service more likely

Gains from using a Stop Smoking Service

APPENDIX 24

1) Finding out about the risks of smoking in pregnancy

- Cigarette smoke contains over 4,000 chemicals. One of these is a poisonous gas called carbon monoxide which cuts down the oxygen reaching the baby
- As oxygen helps babies grow, babies who don't get enough oxygen can be born smaller and weaker
- Smoking during pregnancy has been linked to:
  - Poor health for the mother
    - Miscarriage, Bleeding, Nausea
  - Poor health for the baby
    - Slow growth of the foetus, Premature birth or stillbirth, Low birth weight, Cot death, Breathing problems
- A reduced birth weight will not necessarily make it easier for the mother to give birth – babies who don't grow well are more likely to be short of oxygen and need an emergency delivery

Gains from using a Stop Smoking Service

APPENDIX 24

2) Finding out about the benefits of quitting in pregnancy

- Stopping smoking at any stage of pregnancy will benefit the baby immediately
- A pregnant woman who quits smoking during pregnancy will have:
  - Less morning sickness
  - Fewer complications during pregnancy and labour
  - A more content baby after birth
- Quitting smoking will also save the pregnant woman money

Gains from using a Stop Smoking Service

APPENDIX 24

3) Receiving specialised support

- NHS Stop Smoking services are run by health professionals who are specially trained to support smokers
- Many services offer special help for pregnant women, and offer individual help that's tailored to the pregnant woman's needs
- The adviser will enable the pregnant woman to monitor her progress using a breathalyser which measures the fall in carbon monoxide levels in her body
- Stop Smoking advisers are friendly, understanding and non-judgemental in their approach
- Even if a pregnant woman is finding it difficult to quit, the adviser will continue to offer praise and encouragement

Gains from using a Stop Smoking Service

APPENDIX 24

4) Becoming a non-smoker

- Evidence shows that working with a trained Stop Smoking adviser can dramatically improve the chances of giving up
- This will enable the pregnant woman and her baby to have improved health by avoiding the risks of smoking and enjoying the benefits of quitting

5) Helping partners, friends and family to quit with the pregnant woman

- If anyone smokes near the pregnant woman, she will breathe in harmful gases and chemicals
- To make the pregnant woman's quit attempt easier, partners, family and friends could ideally try to stop smoking with the pregnant woman. The NHS Stop Smoking service will help them with this.
- Even if partners, family and friends can't do this, they can help by not offering cigarettes to the pregnant woman or smoking near her

Gains from using a Stop Smoking Service

APPENDIX 24

6) Nicotine Replacement Therapy

- Nicotine Replacement Therapy (NRT) is the name given to products (e.g. gum or patches) which contain nicotine and help people give up smoking by reducing their cravings
- Pregnant women who are finding it difficult to stop smoking can try NRT after talking through the risks and benefits with a health professional
- Pregnant women who use Stop smoking services will be able to get information about NRT from their adviser who will be able to advise on the best option
- Stop Smoking advisers can then give the pregnant woman access to free supplies of NRT
- NRT is considered safer than smoking. This is because it doesn't contain the toxic chemicals in cigarettes like tar or carbon monoxide, and does not cause cancer (NICE, 2002)
- NRT is not a magic cure, but women who use it are twice as likely to succeed in stopping when using it

Pressure from other people to use a Stop Smoking Service

- Many pregnant smokers feel a strong social pressure from others to quit smoking by whatever means, including using a Stop Smoking service

APPENDIX 24

1) From health experts

- Health professionals the pregnant smoker comes into contact with during the course of their pregnancy, e.g. midwives and hospital consultants, are likely to encourage her to use a Stop Smoking service
- This is because they are acutely aware of the risks of smoking in pregnancy and know that getting professional help will increase her chances of quitting and having a healthy pregnancy

2) From family and friends

- Although well meant, pressure from family and friends to give up smoking can be perceived by the pregnant woman as 'nagging' and be unhelpful
- NHS Stop Smoking advisers will not tell the pregnant woman to stop smoking. They offer specialist support that the pregnant woman cannot get from family and friends

Ease of using a Stop Smoking service

APPENDIX 24

1) Local services

- Pregnant women can get in touch with an NHS Stop Smoking service near to where they live

2) Free services

- All NHS Stop Smoking services are free of charge

3) Flexible appointments

- Every effort is made by the adviser to arrange appointments at times that suit the pregnant woman
- Sessions can take place in groups, or one-to-one with the adviser if this is preferred
- Many Stop Smoking services offer home visits to cater for women who have child care or transport issues
- Evening appointments can be available for women who work, or who want their partner who works to attend with them

APPENDIX 25

Study No:

Independent Assessor Checklist

Each scored as Yes (Y), No (N) or Partially (P)

(In SPSS Y=2, N=0, P=1)

1) Greets patient and introduces self to patient as a medical student	Y	N	P
2) Explains purpose of interview with patient	Y	N	P
3) Gets explicit consent	Y	N	P
4) Uses categorisation to structure interview / signposting	Y	N	P
5) Checks patient knowledge of Stop Smoking services and NRT	Y	N	P
6) Explains risks of smoking	Y	N	P
7) Explains benefits of quitting	Y	N	P
8) Explains what should happen if partner, friends or family smoke	Y	N	P
9) Explains help with stopping smoking	Y	N	P
10) Explains Nicotine Replacement Therapy	Y	N	P
Elicits patient's beliefs:			
11) She will find it difficult to quit because partner smokes	Y	N	P
12) Social pressure to quit (from parents, GP) is stopping her trying	Y	N	P
13) She doesn't think Stop Smoking services will help	Y	N	P
14) She is concerned about having to talk in front of a group	Y	N	P
15) She thinks advisor will make her feel more guilty	Y	N	P
16) She will not be able to attend regular clinics because of child	Y	N	P
17) If she can't quit she will be letting the adviser down	Y	N	P
18) She thinks NRT is not safe to use in pregnancy	Y	N	P
19) She thinks she will not be able to afford NRT	Y	N	P
20) Discusses and negotiates engagement with Stop Smoking services	Y	N	P
21) Checks patient understanding	Y	N	P
22) Encourages patient to ask questions	Y	N	P
23) Summarises information	Y	N	P
24) Closes interview effectively	Y	N	P
25) Uses appropriate non verbal communication	Y	N	P
26) Appropriate use of verbal communication	Y	N	P
27) Good rapport established and maintained	Y	N	P

EXPLANATION TASK CRITERIA

Checklist objectives	Done?	Comments
Greets patient		
Agrees purpose of consultation		
Gets explicit consent		
Uses categorisation to structure interview/signposting		
Check patient knowledge of condition		
Explains condition/test result/procedure		
Discuss and negotiate adherence to treatment/regime/lifestyle change		
Checks patient understanding		
Encourages patient to ask questions		
Uses appropriate language		
Uses appropriate non-verbal behaviour		
Closes interview effectively		

Study No:

OUTCOME MEASURES

SIMULATED PATIENT AND INDEPENDENT ASSESSOR VERSION

Please rate your satisfaction with the interview in terms of clarity, rapport and thoroughness

Clarity

Did the student do the following?
Structure the interview well, explain the information clearly, use words you could understand, pace the interview appropriately

Based on the above, how would you rate the **clarity** of the interview?

(low) 1 2 3 4 5 (high)

Rapport

Did the student do the following?
Greet you by name, introduce themselves, clarify their role, demonstrate interest and respect, use sympathy and empathy, understand your perspective and feelings

Based on the above, how would you rate the **rapport** the student established with you?

(low) 1 2 3 4 5 (high)

Thoroughness

Did the student do the following?
Tell you all you wanted to know, address all the concerns you had, answer your questions competently

Based on the above, how would you rate the **thoroughness** of the interview?

(low) 1 2 3 4 5 (high)

Study No:

OUTCOME MEASURES

STUDENT VERSION

Please rate your satisfaction with the interview in terms of clarity, rapport and thoroughness by circling the appropriate number on each scale.

Clarity

Did you feel you managed to do the following?
Structure the interview well, explain the information clearly, use words the patient could understand, pace the interview appropriately

Based on the above, how would you rate the **clarity** of the interview?

(low) 1 2 3 4 5 (high)

Rapport

Did you feel you managed to do the following?
Greet the patient by name, introduce yourself, clarify your role, demonstrate interest and respect, use sympathy and empathy, understand the patient's perspective and feelings

Based on the above, how would you rate the **rapport** you established with the patient?

(low) 1 2 3 4 5 (high)

Thoroughness

Did you feel you managed to do the following?
Tell the patient all she needed to know, address all the concerns she had, answer her questions competently

Based on the above, how would you rate the **thoroughness** of the interview?

(low) 1 2 3 4 5 (high)

Please answer the following questions about the presentation you viewed before conducting the interview by ticking the appropriate box.

	Strongly agree	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	Strongly disagree
1. The presentation gave me the knowledge I needed to conduct the interview	☐	☐	☐	☐	☐	☐	☐
2. The presentation helped me to structure the interview	☐	☐	☐	☐	☐	☐	☐
3. The presentation helped me to find out about the patient's views	☐	☐	☐	☐	☐	☐	☐
4. The presentation gave me confidence to conduct the interview	☐	☐	☐	☐	☐	☐	☐
5. Overall, the presentation prepared me well for the interview	☐	☐	☐	☐	☐	☐	☐

If you have any other comments to make about the presentation you viewed, please write them in the box below

Thank you again for your participation in this study

Explanation task: Explaining smoking cessation information to a pregnant smoker

SIMULATED PATIENT VERSION

You are Sarah Smith, aged 22, and are 12 weeks pregnant. You have been smoking about 20 cigarettes a day for 7 years and would like to be able to stop now that you are pregnant. You live with your partner, who is a mechanic, and already have a child, aged 2. You do not work outside the home.

You have just attended your first antenatal clinic appointment where your midwife has established that you are a smoker. The midwife has asked you if a 2nd year medical student in the clinic can give you some information about smoking cessation and NHS Stop Smoking services, which you have agreed to.

Although you know that smoking might harm your baby, you don't know what the specific risks are or the specific benefits of quitting. You think you will find it difficult to quit because your partner also smokes. Also, the fact that your parents and GP keep nagging you to stop smoking is actually putting you off trying.

You don't know anything about NHS Stop Smoking services, but can't see them being of any help. You are worried that, if you go to a Stop Smoking service, you would have to talk in front of a group, and the adviser would make you feel even more guilty about your smoking. Given your commitments to your 2 year old and the difficulties you have in arranging child care, you think it is unlikely that you would be able to attend a regular Stop Smoking clinic. Also, if you didn't manage to quit, you feel you would be letting the adviser down.

You have heard that Nicotine Replacement Therapy can help with quitting but you don't know much about it. You are concerned that it is not safe to use when pregnant and that you will find it too expensive.

If the student asks if you have any other questions you should ask:

If I have a smaller baby, won't it make the birth easier?

NOTES FOR SIMULATED PATIENT

You are playing the part of a pregnant smoker who has just attended her first antenatal clinic appointment. You have been asked if a student can interview you before you leave the clinic.

It is important to play the role as consistently and in as standardised a manner as possible although the direction of the interview will be guided by the student.

Try to memorise pertinent facts, but refer to the role sheet if necessary.

Enter into role as much as possible – put yourself 'in the patient's shoes' and think how they would be feeling.

If you are asked about anything that does not appear on the sheet then you can add minor detail consistent with your character's personality.

Amongst other things, the students have been asked to ascertain your **knowledge** and **beliefs / concerns.**

The information you give will depend on the questions asked. It is important that you give specific answers to specific questions, as outlined below.

Knowledge

If asked why you are attending the interview – only answer that you would like to be able to stop smoking because you are pregnant, and your midwife has passed you on to the student for further information

If asked what you know about smoking in pregnancy – only answer that you know it might be harming the baby

If asked what you know about Stop Smoking Services - answer that you don't know anything

If asked what you know about Nicotine Replacement Therapy – only answer that you have heard that it can help people stop smoking

If asked whether you have used Stop Smoking services or Nicotine Replacement Therapy before - answer no

Beliefs / Concerns

Only give the information about your beliefs / concerns if asked about them specifically.

If asked if there is anything stopping you from quitting / concerns about stopping smoking / beliefs about stopping smoking – only answer that you believe it will be difficult to quit because your partner smokes.

If you are probed further, say that your GP and parents' nagging is putting you off trying

If asked if there is anything stopping you from using Stop Smoking services / concerns about Stop Smoking services / beliefs about Stop Smoking services – only answer that you don't think they will be able to help.

If probed further, use the following answers in the order given (only give one answer per probe, i.e. only move on to the next statement if the student asks you again if you have anything else to add)
1) You worry about having to talk in front of a group at Stop Smoking services
2) You are concerned that the Stop Smoking adviser will make you feel more guilty about your smoking
3) You don't think you will be able to attend regular Stop Smoking clinics because of commitments to your 2 year old child and difficulties arranging child care
4) You think you will be letting the adviser down if you can't quit

If asked if there is anything putting you off using NRT / concerns about NRT / beliefs about NRT – only answer that you think it is not safe to use in pregnancy

If probed further, say that you don't think you will be able to afford it

Explanation task: Explaining smoking cessation information to a pregnant smoker

STUDENT VERSION

This is Sarah Smith. She is 22 years old and is 12 weeks pregnant. She has just attended her first appointment at the antenatal clinic where her midwife has established that she is a smoker. The midwife has asked you (as a 2nd year medical student) to see the pregnant woman before she leaves the clinic to explain some smoking cessation information to her and encourage her to seek help from NHS Stop Smoking services.

Based on the guide you have read, the following is a reminder of the information you should try to include in the interview:

How smoking affects unborn babies
Risks of smoking in pregnancy
Benefits of quitting in pregnancy
What if partners, friends or family smoke?
Help with stopping smoking
Nicotine Replacement Therapy

Remember to:

- Check patient knowledge of smoking cessation and Stop Smoking services
- Explain smoking cessation information and Stop Smoking services
- Obtain social background
- Elicit patient's beliefs about smoking cessation and Stop Smoking services
- Discuss and negotiate engagement with Stop Smoking services
- Check patient understanding
- Encourage patient to ask questions

Explanation task: Explaining smoking cessation information to a pregnant smoker

STUDENT VERSION

This is Sarah Smith. She is 22 years old and is 12 weeks pregnant. She has just attended her first appointment at the antenatal clinic where her midwife has established that she is a smoker. The midwife has asked you (as a 2nd year medical student) to see the pregnant woman before she leaves the clinic to explain some smoking cessation information to her and encourage her to seek help from NHS Stop Smoking services.

Based on the guide you have read, the following is a reminder of the information you should try to include in the interview:

Gains from using a Stop Smoking service:

1) Finding out about the risks of smoking in pregnancy
2) Finding out about the benefits of quitting in pregnancy
3) Receiving specialised support
4) Becoming a non-smoker
5) Helping partners, friends and family to quit with the pregnant woman
6) Nicotine Replacement Therapy

Pressure from other people to use a Stop Smoking Service:

1) From health experts
2) From family and friends

Ease of using a Stop Smoking service:

1) Local services
2) Free services
3) Flexible appointments

Remember to:

- Check patient knowledge of smoking cessation and Stop Smoking services
- Explain smoking cessation information and Stop Smoking services
- Obtain social background

- Elicit patient's beliefs about smoking cessation and Stop Smoking services
- Discuss and negotiate engagement with Stop Smoking services
- Check patient understanding
- Encourage patient to ask questions

Instructions for Students

Thank you for agreeing to take part in this study.

You will shortly be asked to explain some smoking cessation information to a simulated patient who will be playing the role of a pregnant smoker.

Before you do this, you will have 10 minutes to view a Powerpoint presentation which will provide you with the knowledge and skills you may need for the interview. You will control the pace of the presentation by moving the slides yourself using the up and down arrow keys or the mouse. As the presentation is on a continuous loop, you may browse it for as long as you feel is necessary in the 10 minutes available.

There will also be a paper copy of the presentation for you to look at if you find this easier than reading off the computer screen.

The explanation task is outlined on the sheet in front of you, which you must familiarise yourself with whilst viewing the presentation. You will be able to take this sheet into the interview with you for reference. Included on it is a list of the headings from the presentation to remind you what to talk about. Also included are the key aspects of Communication Skills (CS) which you should aim to cover. However, you should try to conduct the interview using all the CS criteria you have been taught to use for an explanation task.

After you have viewed the presentation and familiarised yourself with the task, you will have 10 minutes to conduct the interview. The interview will be filmed to enable it to be analysed at a later date.

After the interview, you will be asked to complete a couple of short questionnaires to give us some feedback on how you found the task.

Notes for Independent Assessor

Greets patient and introduced self to patient as a medical student
If only does one of these, mark as 'partially'

Explains purpose of interview with patient
Been asked by the patient's midwife to explain some smoking cessation information to her and encourage her to seek help from Stop Smoking services

Gets explicit consent
Asks patient if she is happy to receive this information

Uses categorisation to structure the interview / signposting
Tells the patient at the beginning of the interview what he/she is going to talk about. Alternatively, might signpost as he/she goes along, e.g. 'and now I'm going to tell you about...'

Checks patient knowledge of smoking cessation, Stop Smoking services, NRT
Asks patient what she already knows about these. If asks about two or more, mark as 'yes', if asks about one, mark as 'partially'.

Explains risks of smoking
Chemicals in cigarettes
Lack of oxygen to baby
Specific health risks to mother
Specific health risks to baby

Explains benefits of quitting
Quitting at any stage of pregnancy is beneficial
Pregnant woman will have healthier pregnancy and more content baby – reasons
Saving money

Explains what should happen if partner, friends or family smoke
Smoking near pregnant woman will be harmful and why
Partners etc should ideally try to stop smoking with pregnant woman
If they can't, they can help by not offering pregnant woman cigarettes or smoking near her

Explains help with stopping smoking
Pregnant woman can get in touch with local NHS Stop Smoking services
Services are free and run by health professionals trained to support smokers
Many services offer specific help to pregnant women
They offer individual help tailored to pregnant woman's needs
They help pregnant woman monitor her progress using a carbon monoxide monitor
Working with trained Stop Smoking adviser improves chances of quitting

Explains Nicotine Replacement Therapy
Tells pregnant woman what NRT is and how it can help
Pregnant women who are finding it difficult to stop can try it after discussing risks and benefits with a health professional
Pregnant women who use Stop Smoking services can talk to their adviser about NRT
NRT is considered safer than smoking and explanation why
NRT is not magic cure, but twice as likely to succeed in stopping when using it
Can get NRT on prescription, therefore not costly

Eliciting patient beliefs
Patient must volunteer each belief as a result of questions asked by the student (even if the 'belief' has already been covered in the explanation)

Discusses and negotiates engagement with Stop Smoking services
Asks patient if she thinks she is likely to be able to use Stop Smoking services

Checks patient understanding
If only asks if patient understands, mark as 'partially'. If also asks patient to repeat back, mark as 'yes'

Encourages patient to ask questions
Explicitly asks patient if there is anything else she would like to ask

Summarises information
Gives a brief summary of the main points at the end

Closes interview effectively
Thanks patient for their time, tells her what will happen next. If only does one of these, mark as 'partially'

Uses appropriate non verbal communication
e.g. posture and eye contact

Appropriate use of verbal communication
e.g. open, closed, probing questions, avoids jargon

Good rapport established and maintained
e.g. uses empathy/sympathy, enquires about social background

Study No: _____ Date: _____

The University of Nottingham

ATTITUDES OF PREGNANT SMOKERS TO NICOTINE REPLACEMENT THERAPY

For each question, please circle the number on the scale that best describes your opinion.

SECTION 1

This section asks questions about your attitude to using NRT while you are pregnant.

1) First, please answer this general question.

In my opinion, using NRT while I am pregnant would be:

a) Calming	1	2	3	4	5	6	7	Stressful
b) Helpful	1	2	3	4	5	6	7	Unhelpful
c) Harmful	1	2	3	4	5	6	7	Beneficial
d) Bad	1	2	3	4	5	6	7	Good
e) Useful	1	2	3	4	5	6	7	Useless
f) Unpleasant	1	2	3	4	5	6	7	Pleasant
g) Foolish	1	2	3	4	5	6	7	Sensible

2) Using NRT may have a number of outcomes. Now, please rate how likely each of the following outcomes would be if you were to use NRT while you are pregnant.

a) NRT would reduce my cravings for a cigarette

Very unlikely	1	2	3	4	5	6	7	Very likely

b) NRT would cost me more than cigarettes do
Very unlikely 1 2 3 4 5 6 7 Very likely

c) NRT would make quitting smoking less stressful
Very unlikely 1 2 3 4 5 6 7 Very likely

d) NRT would help me to quit smoking
Very unlikely 1 2 3 4 5 6 7 Very likely

e) I would become addicted to NRT
Very unlikely 1 2 3 4 5 6 7 Very likely

f) NRT would be as satisfying as smoking cigarettes
Very unlikely 1 2 3 4 5 6 7 Very likely

g) NRT would give me unwanted side effects
Very unlikely 1 2 3 4 5 6 7 Very likely

h) NRT would be healthier for my baby than if I smoke
Very unlikely 1 2 3 4 5 6 7 Very likely

i) NRT would make my pregnancy sickness worse
Very unlikely 1 2 3 4 5 6 7 Very likely

j) NRT would be healthier for me than if I smoke
Very unlikely 1 2 3 4 5 6 7 Very likely

k) Using NRT would make me feel like I haven't really quit smoking
Very unlikely 1 2 3 4 5 6 7 Very likely

3) Now, please rate how good or bad each of these outcomes would be for you.

a) Having fewer cravings for a cigarette
Bad 1 2 3 4 5 6 7 Good

b) Having less money
Bad 1 2 3 4 5 6 7 Good

c) Having less stress
Bad 1 2 3 4 5 6 7 Good

d) Quitting smoking
Bad 1 2 3 4 5 6 7 Good

e) Becoming addicted to NRT
Bad 1 2 3 4 5 6 7 Good

f) Getting the satisfaction that cigarettes give me
Bad 1 2 3 4 5 6 7 Good

g) Having unwanted side effects
Bad 1 2 3 4 5 6 7 Good

h) Baby being healthier
Bad 1 2 3 4 5 6 7 Good

i) Having pregnancy sickness made worse
Bad 1 2 3 4 5 6 7 Good

j) Me being healthier
Bad 1 2 3 4 5 6 7 Good

k) Feeling like I haven't really quit smoking
Bad 1 2 3 4 5 6 7 Good

SECTION 2

This section asks you about the opinions of other people regarding NRT use in pregnancy. They ask if you think these people would like you to use NRT while you are pregnant. If you are not sure, try to guess or imagine what you think their opinion would be.

1) First, please answer these general questions.

a) Most people who are important to me would want me to use NRT while I am pregnant
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

b) It is expected of me that I use NRT while I am pregnant
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

c) I feel under pressure from others to use NRT while I am pregnant
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

2) Now, please consider whether each of the following people would like you to use NRT while you are pregnant.

a) My family would want me to use NRT while I am pregnant
Very unlikely 1 2 3 4 5 6 7 Very likely

b) My friends would want me to use NRT while I am pregnant
Very unlikely 1 2 3 4 5 6 7 Very likely

c) Health experts would want me to use NRT while I am pregnant
Very unlikely 1 2 3 4 5 6 7 Very likely

3) Now, please rate how much you want to do what these people think you should do with regard to using NRT while you are pregnant.

a) I want to do what my family thinks I should do...
Not at all 1 2 3 4 5 6 7 Very much

b) I want to do what my friends think I should do...
Not at all 1 2 3 4 5 6 7 Very much

c) I want to do what health experts think I should do...
Not at all 1 2 3 4 5 6 7 Very much

SECTION 3

This section asks you about factors that might make it more likely or more unlikely for you to use NRT while you are pregnant.

1) First, please answer these general questions.

a) Whether I do or do not use NRT while I am pregnant is entirely up to me
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

b) How much control do you feel you have over using NRT while you are pregnant?
No control 1 2 3 4 5 6 7 Complete control

c) I am confident that I could use NRT while I am pregnant if I wanted to
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

d) For me to use NRT while I am pregnant would be...
Very difficult 1 2 3 4 5 6 7 Very easy

2) Now, please rate how likely it is that each of the following would occur while you are pregnant.

a) I would be able to get a supply of NRT easily
Very unlikely 1 2 3 4 5 6 7 Very likely

b) I would forget to use NRT
Very unlikely 1 2 3 4 5 6 7 Very likely

c) I would think that NRT is safe to use in pregnancy
Very unlikely 1 2 3 4 5 6 7 Very likely

d) I would think that NRT is not allowed in pregnancy
Very unlikely 1 2 3 4 5 6 7 Very likely

e) I would know enough about the different types of NRT
Very unlikely 1 2 3 4 5 6 7 Very likely

f) I would find NRT convenient to use
Very unlikely 1 2 3 4 5 6 7 Very likely

g) I would struggle to go without cigarettes
Very unlikely 1 2 3 4 5 6 7 Very likely

h) I would want to quit smoking without using NRT
Very unlikely 1 2 3 4 5 6 7 Very likely

i) I would feel self-conscious or embarrassed about using NRT
Very unlikely 1 2 3 4 5 6 7 Very likely

3) Now, please rate the extent to which each of these factors would make it more unlikely or more likely that you would use NRT while you are pregnant.

a) Being able to get a supply of NRT easily would make this...
More unlikely 1 2 3 4 5 6 7 More likely

b) Forgetting to use NRT would make this...
More unlikely 1 2 3 4 5 6 7 More likely

c) Thinking that NRT is safe to use in pregnancy would make this...
More unlikely 1 2 3 4 5 6 7 More likely

d) Thinking that NRT is not allowed in pregnancy would make this...
More unlikely 1 2 3 4 5 6 7 More likely

e) Knowing enough about the different types of NRT would make this...
More unlikely 1 2 3 4 5 6 7 More likely

f) Finding NRT convenient to use would make this...
More unlikely 1 2 3 4 5 6 7 More likely

g) Struggling to go without cigarettes would make this...
More unlikely 1 2 3 4 5 6 7 More likely

h) Wanting to quit smoking without using NRT would make this...
More unlikely 1 2 3 4 5 6 7 More likely

i) Feeling self-conscious or embarrassed about using NRT would make this...
More unlikely 1 2 3 4 5 6 7 More likely

SECTION 4

This section asks you about the likelihood of you using NRT while you are pregnant.

1) Please answer these general questions about using NRT while you are pregnant.

a) I expect to use NRT
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

b) I want to use NRT
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

c) I intend to use NRT
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

SECTION 5

This section asks you some questions about yourself, your smoking and your partner, if you have one.

1) First, please answer these questions about yourself.

a) How old are you? _____

b) What is your ethnic group?

White ☐ Black-Caribbean ☐ Black-African ☐ Black-other ☐ Indian ☐

Pakistani ☐ Bangladeshi ☐ Chinese ☐ Other/Mixed ☐

c) What is your highest educational qualification?

None ☐ NVQ/GCSE ☐ BTEC/A level ☐ Diploma/HND ☐ Degree ☐

Postgraduate degree ☐

d) Are you employed? Yes ☐ No ☐

e) If 'Yes', what is your current or most recent employment?

_____

f) What is your marital status?

Married/Cohabiting ☐ Single ☐ Separated/Divorced ☐ Widowed ☐

g) How many weeks pregnant are you? _____

h) Do you already have any children? Yes ☐ No ☐

i) If 'Yes', how many? _____

2) Now, please answer these questions about your partner, if you have one. If you do not have a partner, please go to section 3) below.

a) Does your partner smoke? Yes ☐ No ☐

b) What is your partner's highest educational qualification?

None ☐ NVQ/GCSE ☐ BTEC/A level ☐ Diploma/HND ☐ Degree ☐

Postgraduate degree ☐

c) Is your partner employed? Yes ☐ No ☐

d) If 'Yes', what is your partner's current or most recent employment?

_____

3) Now, please answer these questions about your smoking.

a) About how many cigarettes a day are you smoking at the moment? _____

b) About how many cigarettes a day were you smoking before you were pregnant? _____

c) How many years have you been smoking for? _____

d) Do you have any intention of giving up smoking during this pregnancy?

Yes, definitely	Yes, probably	Don't know	Probably not	Definitely not
1	2	3	4	5

e) Have you ever used NRT? Yes ☐ No ☐

f) If 'Yes', for how many days were you on NRT when you last used it? _____

SECTION 6

We would like to contact you in a few months to find out if you go on to use NRT or not during this pregnancy. Please indicate your willingness for this by ticking the appropriate box below.

I would be happy for the researchers to contact me again in a few months time

Yes ☐ No ☐

If you have answered 'Yes' to the above statement, please provide your contact details below.

Name _____

Address _____

_____ Postcode _____

Telephone number _____ Email _____

Thank you very much for completing this questionnaire

(ON PCT HEADED PAPER)

Address

Date

Dear Madam

Attitudes of Pregnant Smokers to Nicotine Replacement Therapy

As you will probably know, Nicotine Replacement Therapy (NRT) is the name given to products that release nicotine into the body, which some people choose to use when they are trying to quit smoking.

Researchers at the University of Nottingham are interested in finding out why some women smokers choose to use NRT in pregnancy while others do not. They have developed a questionnaire which will help to answer this question.

We would be very grateful if you could help with this research by completing the attached questionnaire. Although it looks quite long, it should only take you about 10 minutes. You can complete it now or take it home with you and post it back in the Freepost envelope provided.

Your answers will be totally confidential and seen only by the researchers at the University of Nottingham. You are under no obligation to take part and can withdraw at any time without this affecting your care in any way.

For further information about the research study, you may contact John Taylor at Behavioural Sciences, A Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH. Tel: 0115 823 0411, Email: mgxjt1@nottingham.ac.uk.

Many thanks for your time.

Yours faithfully

(Head of Service)

APPENDIX 37

The University of Nottingham

School of Community Health Sciences
Division of Psychiatry
Behavioural Sciences
A Floor, South Block
Queen's Medical Centre
Nottingham, NG7 2UH

Participant's Address

Study No:

Date

Dear (Name)

Thank you for completing the questionnaire about Nicotine Replacement Therapy (NRT) which you received from your NHS Stop Smoking adviser when you were recently pregnant.

As we are interested to find out whether or not you went on to use NRT during this pregnancy, I would be grateful if you could answer the two questions below. Then please return this form in the envelope provided, which does not need a stamp.

There are no right or wrong answers so please answer as honestly as you can. All the information you provide will be confidential and only seen by the research team in Nottingham. Also, you will not be identified by name in any reports about the study.

Thank you for your help with this research. It will be useful for finding out more about how women decide whether or not to use NRT in pregnancy.

Yours sincerely

John Taylor

1) Since you first met the Stop Smoking adviser during your recent pregnancy, how often did you use NRT while you were pregnant? (Please tick the appropriate box)

Every day ☐ Almost every day ☐ Most days ☐ On about half the days ☐

A number of times, but less than half ☐ A few times ☐ Never ☐

2) Since you first met the *Stop Smoking* adviser during your recent pregnancy, please estimate how often you *used NRT* while you were pregnant. (Please circle the number on the scale that best represents your estimate)

Never 1 2 3 4 5 6 7 8 9 10 Every day

APPENDIX 38

NHS

Nottingham Research Ethics Committee 2
1 Standard Court
Park Row
Nottingham
NG1 6GN

Tel: 0115 912 3344 ext 49435
Fax: 0115 9123300

26 February 2007

Mr J Taylor
PhD Student
School of Human Development
Academic Division of Obs & Gynae
City Hospital,
Hucknall Road
Nottingham
NG5 1PB

Dear Mr Taylor

Study title:	**Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy**
REC reference:	**06/Q2404/48**
Amendment number:	**1**
Amendment date:	**09 February 2007**

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 26 February 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Summary/Synopsis: Flowchart	4	09 February 2007
Questionnaire	3	09 February 2007
Protocol	4	09 February 2007
Participant Information Sheet	5	09 February 2007

Participant Consent Form	4	09 February 2007
Notice of Substantial Amendment (non-CTIMPs)	1	09 February 2007
Letter of invitation to participant	2	09 February 2007
Covering Letter		09 February 2007

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q2404/48:	**Please quote this number on all correspondence**

Yours sincerely

Ms Linda Ellis
Committee Co-ordinator

E-mail: linda.ellis@nottinghamshirecounty-tpct.nhs.uk

Enclosures List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: *Mr Paul Cartledge, University of Nottingham*
R&D office for NHS care organisation at lead site – NUH-C Campus

APPENDIX 38

APPENDIX 39

NHS
National Research Ethics Service

Nottingham Research Ethics Committee 2
1 Standard Court
Park Row
Nottingham
NG1 6GN

Tel: 0115 9123344 ext 39435
Fax: 0115 9123300

21st May 2007

Mr John Taylor
PhD Student
School of Human Development, Academic Division of Obs & Gynae
City Hospital, Hucknall Road
Nottingham
NG5 1PB

Dear Mr Taylor

Study title:	**Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy**
REC reference:	**06/Q2404/48**
Amendment number:	**Amendment number 2**
Amendment date:	**15th May 2007**

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 21st May 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Summary/Synopsis	5.0	15 May 2007
Questionnaire: Hospital Anxiety and Depression Scale (DRAFT)	1.0	15 May 2007
Questionnaire - Attitudes of Pregnant Smokers to Nicotine Replacement Therapy	9.0	04 May 2007
Protocol	5.0	04 May 2007

Notice of Substantial Amendment (non-CTIMPs)	Amendment number 2	
Letter of invitation to participant - Phase 1	1.0	04 May 2007
Letter of invitation to participant - Phase 2	1.0	04 May 2007

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q2404/48:	**Please quote this number on all correspondence**

Yours sincerely

Ms Linda Ellis
Committee Co-ordinator

E-mail: linda.ellis@nottinghamshirecounty-tpct.nhs.uk

Enclosures List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: Mr Paul Cartledge

R&D office for NHS care organisation at lead site – NUH City Campus

Nottingham University Hospitals NHS Trust

Please reply to: Research and Development
E11 Curie Court
Queen's Medical Centre Campus
Derby Road
Nottingham
NG7 2UH

Telephone: 0115 970 9049
Fax: 0115 849 3295
E-mail: alison.steel@nuh.nhs.uk

APPENDIX 40

Mr J Taylor
School of Human Development
University of Nottingham
School of Human Development
Academic Division of Obs & GYNae
City Hospital Campus, Nottingham

01 August 2007

Dear Mr Taylor

ID: 06MA001 **Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy**

Thank you for your letter dated 12 June 2007, informing R&D of the following amendments:

- Summary version 5.0 dated 15th May 2007
- Questionnaire: Hospital Anxiety and Depression Scale (DRAFT) version 1.0 dated 15th May 2007
- Questionnaire: Attitudes of Pregnant Smokers to Nicotine Replacment Therapy version 9.0 dated 4th May 2007
- Protocol version 5.0 dated 4th May 2007
- Notice of substantial amendment - amendment 2
- Letter of invitation to participant version 1.0 dated 4th May 2007
- Letter of invitation to participant - phase 2 version 1.0 dated 4th May 2007
- REC approval letter dated 21st May 2007

The amendment has been given R&D approval, however, you may be contacted in due course if we wish to re-visit the original costings attached to the study.

Please note that you may not implement the amendment until you have obtained BOTH R&D and REC approval.

Yours sincerely

Alison Steel
Research Governance Adviser

Nottingham University Hospitals NHS Trust

Please reply to: Research and Development
E11 Curie Court
Queen's Medical Centre Campus
Derby Road
Nottingham
NG7 2UH

Telephone: 0115 970 9049
Fax: 0115 849 3295
E-mail: ruth.doyle@nuh.nhs.uk

APPENDIX 41

Mr J Taylor
School of Human Development
University of Nottingham
School of Human Development
Academic Division of Obs & GYNae
City Hospital Campus, Nottingham

07 August 2007

Dear Mr Taylor

ID: 06MA001 Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy

Thank you for sending documents and informing R&D of the following amendments:

Rec amendment approval letter received dated 19/02/07
Notice of substantial amendment form v1 dated 9/02/07
Summary/Synopsis - flowchart v4 dated 09/02/07
Questionnaire : Draft 3 v3 dated 09/02/07
Protocol v4 dated 09/02/07
Participant information sheet v5 dated 09/02/07
Participant Consent form v4 dated 09/02/07
Letter of invitation to participant v2 dated 09/02/07

The amendment has been given R&D approval, however, you may be contacted in due course if we wish to re-visit the original costings attached to the study.

Please note that you may not implement the amendment until you have obtained BOTH R&D and REC approval.

Yours sincerely

Alison Steel

Research Governance Adviser

APPENDIX 42

Leicestershire, Northamptonshire and Rutland Primary Care Research Alliance

Third Floor
Enkalon House
92 Regent Road
Leicester
LE1 7PE

Telephone: 0116 295 4080
Fax: 0116 295 4177
Email: info@leics-research.nhs.uk
www.leics-research.nhs.uk

15/07/07

John Taylor
Division of Psychiatry
Behavioural Sciences
A Floor, South Block
Queen's Medical Centre
Nottingham
NG7 2UH

Dear Mr Taylor

Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy.

We are pleased to advise you that, under the authority delegated to us as the designated RM&G PCT (hosted by Leicester City PCT) for the three PCTs in Leicestershire, Northamptonshire and Rutland, PCT approval for the above research project is now in place. We therefore advise that approval from the Leicestershire, Northamptonshire and Rutland Primary Care Research Alliance to carry out your study within Leicester City PCT, Leicestershire County and Rutland PCT, and Northamptonshire Teaching PCT is now granted.

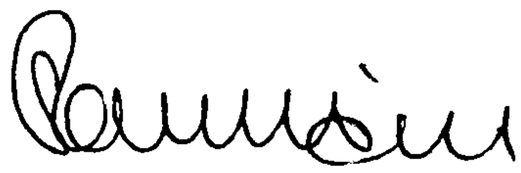
It is required, under the terms of the Research Governance Framework, that all researchers undertaking work within an NHS organisation which impacts upon patient care must have an NHS contract for the term of the research study. ***Therefore The Leicestershire Northamptonshire and Rutland Primary Care Research Alliance (LNR PCRA) will require study researchers to hold an honorary contract with the LNR PCRA in order for the study to take place in the Leicestershire, Northamptonshire and Rutland primary care sector.*** It is the responsibility of the Chief Investigator to ensure that all study staff have a valid contract in place with the LNR PCRA before they start work within the Primary Care Trusts of Leicestershire, Northamptonshire and Rutland. Please note that this applies when there is ***any*** change in the research staff working in the primary care sector for the duration of the study. Requests for honorary contracts need to be made to the LNR PCRA office, address as above.

Could you please ensure that any interim or final reports, protocol amendments or any documents that require submission to a REC are channelled through this office. In addition can any adverse event relating to this study be reported to us, please. We will undertake to forward any documentation to the REC as well as advise the relevant PCT/s in accordance with Research Governance requirements.

Please also be aware that, where required under NHS obligations, we will submit details of this study to the National Research Register to log PCT involvement in this study. The Alliance is also currently implementing new systems for research governance on behalf of local PCTs, so the study may be subject to some follow up and/or auditing during its field work stage.

May I take this opportunity to wish you the very best of luck with this study.

Yours sincerely



Sue Palmer-Hill
Research & Development Manager

APPENDIX 42

STATISTICAL ASSUMPTIONS

Assumptions for correlation

For each of the scatterplots a straight line better represented the cluster of points rather than a curved line, suggesting a linear relationship, and the shape of the clusters were roughly even from one end to the other, suggesting homoscedasticity.

Assumptions for multiple regression

Sample size

Using the rule of thumb $N \geq 50 + 8m$ (where m = the number of predictor variables) as recommended by Tabachnick and Fidell (2007), the sample size exceeds that required to look at the combined effects of the predictor variables.

Multicollinearity

The predictor variables must not be very highly correlated with each other.
The correlation between each IV is less than 0.7, and all tolerance values are greater than 0.10 and VIF values are less than 10. Therefore the multicollinearity assumption has not been violated.

Normality

The residuals should be normally distributed about the predicted DV scores
The points on the Normal P-P Plot of the Regression Standardised Residual lie in a reasonably straight line diagonal line from bottom left to top right, suggesting no major deviations from normality.

Linearity & Homoscedasticity

The residuals should have a straight-line relationship with predicted DV scores (linearity) and the variance of the residuals about predicted DV scores should be the same for all predicted scores (homoscedasticity). The scatterplot of the standardised residuals is roughly rectangularly distributed with most scores around the 0 point. A lack of a systematic curvilinear or funnelled pattern indicates linearity and homoscedasticity respectively.

Outliers in the solution

The scatterplot of the standardised residuals detected no outliers in the solution with all cases having a standardised residual of no more than 3.3 or no less than -3.3.

Independence of errors

The errors of prediction should be independent of one another, i.e. the residuals for each subject should not be related to each other. The Durbin-Watson score of autocorrelation suggests independence of errors. Also, the errors of prediction and the independent variables should be independent. The scatterplot of the standardised residuals shows no trend from lower left to upper right, indicating that errors of prediction and the independent variables are independent.

Assumptions for Logistic Regression

Linearity of the logit

All interactions between each predictor variable and the log of itself have significance values greater than .05 which indicates that the assumption of linearity of the logit has been met.

Multicollinearity

The predictor variables must not be very highly correlated with each other. The correlation between each IV is less than 0.7, and all tolerance values are greater than 0.10 and VIF values are less than 10. Therefore the multicollinearity assumption has not been violated.

Outliers in the solution

For standardized residuals, no more than 5% of cases have absolute values above 2, no more than about 1% have absolute values above 2.5, and there are no values above about 3. Therefore there appear to be no points for which the model fits poorly. There are no values for Cook's distance above 1, so there appear to be no points that exert an undue influence on the model.

INTERNAL CONSISTENCY STATISTICS FOR DIRECT MEASURES

(Sensitivity analysis in brackets)

	Corrected item-total correlation	Cronbach's alpha if item deleted
Attitude		
Calming-Stressful (reverse coded)	0.44 (0.43)	0.80 (0.78)
Helpful-Unhelpful (reverse coded)	0.57 (0.59)	0.78 (0.75)
Harmful-Benefical	0.64 (0.62)	0.77 (0.75)
Bad-Good	0.69 (0.68)	0.76 (0.74)
Useful-Useless (reverse coded)	0.43 (0.40)	0.81 (0.79)
Unpleasant-Pleasant	0.49 (0.42)	0.80 (0.79)
Foolish-Sensible	0.60 (0.51)	0.78 (0.77)
		α = 0.81 (0.79)
Subjective norm		
Most people who are important to me...	0.46 (0.45)	0.59 (0.61)
It is expected of me...	0.63 (0.62)	0.32 (0.33)
I feel under pressure from others...	0.36 (0.38)	0.73 (0.69)
		α = 0.66 (0.66)
Perceived behavioural control		
It is entirely up to me	0.16 (0.15)	0.55 (0.57)
How much control do you feel you have?	0.32 (0.39)	0.40 (0.37)
I am confident I could	0.34 (0.38)	0.38 (0.38)
How difficult / easy would it be?	0.36 (0.33)	0.37 (0.43)
		α = 0.50 (0.52)
Intention		
I expect to	0.92 (0.92)	0.97 (0.98)
I want to	0.94 (0.94)	0.96 (0.96)
I intend to	0.96 (0.97)	0.94 (0.94)
		α = 0.97 (0.97)

MRC Medical Research Council

APPENDIX 45

190908, Version 10.0

The University of Nottingham

Name: _____ **Date:** _____ **Study No:** _____

PREGNANT SMOKERS' VIEWS ABOUT NICOTINE REPLACEMENT THERAPY (NRT)

For each statement, please tick ☑ the box which best describes your opinion.

	Very unlikely	Unlikely	Somewhat unlikely	Uncertain	Somewhat likely	Likely	Very likely
1. NRT would help me to quit smoking	☐	☐	☐	☐	☐	☐	☐
2. My family would want me to use NRT while I am pregnant	☐	☐	☐	☐	☐	☐	☐
3. I would find NRT convenient to use	☐	☐	☐	☐	☐	☐	☐
4. NRT would make my pregnancy sickness worse	☐	☐	☐	☐	☐	☐	☐
5. I would know enough about the different types of NRT	☐	☐	☐	☐	☐	☐	☐
6. NRT would be healthier for my baby than if I smoke	☐	☐	☐	☐	☐	☐	☐
7. My friends would want me to use NRT while I am pregnant	☐	☐	☐	☐	☐	☐	☐
8. I would forget to use NRT	☐	☐	☐	☐	☐	☐	☐
9. NRT would reduce my cravings for a cigarette	☐	☐	☐	☐	☐	☐	☐
10. I would be able to get a supply of NRT easily	☐	☐	☐	☐	☐	☐	☐
11. Health experts would want me to use NRT while I am pregnant	☐	☐	☐	☐	☐	☐	☐
12. NRT would cost me more than cigarettes do	☐	☐	☐	☐	☐	☐	☐
13. I would think that NRT is safe to use in pregnancy	☐	☐	☐	☐	☐	☐	☐
14. NRT would be healthier for me than if I smoke	☐	☐	☐	☐	☐	☐	☐
15. I intend to use NRT while I am pregnant	☐	☐	☐	☐	☐	☐	☐

APPENDIX 45

190908, Version 10.0

Now please answer these questions about yourself and your smoking.

1) How old are you? _____

2) What is your ethnic group?

White ☐ Black–Caribbean ☐ Black-African ☐ Black-other ☐

Indian ☐

Pakistani ☐ Bangladeshi ☐ Chinese ☐ Other/Mixed ☐

3) What is your highest educational qualification?

None ☐ NVQ/GCSE ☐ BTEC/A level ☐ Diploma/HND ☐ Degree ☐ Postgraduate degree ☐

4) What is your marital status?

Married/Living with partner ☐ In relationship but not living with partner ☐ Single ☐ Separated/Divorced ☐ Widowed ☐

5) How many weeks pregnant are you? _____

6) Do you already have any children? Yes ☐ No ☐

7) How many cigarettes are you smoking a day at the moment?

_____

8) Have you ever used Nicotine Replacement Therapy?

Yes ☐ No ☐

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE

(ON UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST HEADED PAPER)

Address of hospital

Date

Dear Madam

Pregnant smokers' views about Nicotine Replacement Therapy

As you will probably know, Nicotine Replacement Therapy (NRT) is the name given to products that release nicotine into the body, which some people choose to use when they are trying to quit smoking.

Researchers at the University of Nottingham are interested in finding out why some women smokers choose to use NRT in pregnancy while others do not. They have developed a short questionnaire to help answer this question which they would be grateful if you could complete.

The questionnaire, which is enclosed, contains some questions about NRT on one side and a few questions about yourself and your smoking on the other. It will only take a couple of minutes of your time and your answers will be confidential.

We would appreciate it if you could complete the questionnaire while you are waiting in the clinic and hand it back to one of the staff. However, if you prefer, you can take it home with you and post it back in the Freepost envelope provided.

You are under no obligation to take part and can withdraw at any time without this affecting your care in any way.

If you want further information about the research study, you may contact John Taylor at Behavioural Sciences, A Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH. Tel: 0115 823 0411, Email: mgxjt1@nottingham.ac.uk.

Many thanks for your time.

Yours faithfully

(Name)
Head of Service

(ON PCT HEADED PAPER)

Address of service

Date

Dear Madam

Pregnant smokers' views about Nicotine Replacement Therapy

As you will probably know, Nicotine Replacement Therapy (NRT) is the name given to products that release nicotine into the body, which some people choose to use when they are trying to quit smoking.

Researchers at the University of Nottingham are interested in finding out why some women smokers choose to use NRT in pregnancy while others do not. They have developed a short questionnaire to help answer this question which they would be grateful if you could complete.

The questionnaire, which is enclosed, contains some questions about NRT on one side and a few questions about yourself and your smoking on the other. It will only take a couple of minutes of your time and your answers will be confidential.

We would appreciate it if you could complete the questionnaire and hand it back to your Stop Smoking adviser. However, if you prefer, you can take it home with you and post it back in the Freepost envelope provided.

You are under no obligation to take part and can withdraw at any time without this affecting your care in any way.

If you want further information about the research study, you may contact John Taylor at Behavioural Sciences, A Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH. Tel: 0115 823 0411, Email: mgxjt1@nottingham.ac.uk.

Many thanks for your time.

Yours faithfully

(Name)
Head of Service

Nottingham University Hospitals NHS
NHS Trust

Ante-natal Questionnaire

Dear Madam

We are looking at ways to improve the lifestyle and health of pregnant women and babies in the womb. As one part of this study we are asking all women attending for routine ultrasound examinations to fill in a 5-minute questionnaire.

We would like to invite you to participate in this study. If you are happy to complete this 6-question questionnaire then tick the box marked 'YES' and then complete the questionnaire, following the instructions on it. If you do not wish to complete the questionnaire then please hand it back.

YOUR ANSWERS WILL BE TOTALLY CONFIDENTIAL AND SEEN ONLY BY THE RESEARCH MIDWIVES AND RESEARCHERS AT THE UNIVERSITY OF NOTTINGHAM.

Many thanks for your help.
Best wishes

Fiona Bailey
SNAP Trial Research Midwife

For most questions, just tick the relevant box, like this ☑

I am happy to complete the Ante-natal Questionnaire. I understand that I am under no obligation to take part and can withdraw at any stage ***YES*** ☐

Signed:..... Date:.....

1. Have you smoked any cigarettes or tobacco in the last week?
   - *Yes* ☐
   - *No* ☐

2. Are you less than 25 weeks into your pregnancy?
   - *Yes* ☐
   - *No* ☐
   - *Don't Know* ☐

*If you have answered '**No**' to either of the two questions above, you have finished and can hand back the questionnaire. If you answered '**Yes**' or '**Don't Know**', please continue below*

Tick one box

3. How often do you usually smoke cigarettes or tobacco?
   - *Every day* ☐
   - *On most days* ☐
   - *Less than most days* ☐

*If you answered: '**less than most days**' to question 3 above you have finished and may hand the questionnaire back. If not, please continue.*

Tick one box

4. **Before you became pregnant**, how often did you usually smoke cigarettes or tobacco?

Every day ☐
On most days ☐
Less than most days ☐

*If you answered: '**less than most days**' to question 4 above you have finished and may hand the questionnaire back. If not, please continue.*

5. Are you interested in stopping smoking during this pregnancy?

Yes ☐
No ☐
Not sure ☐

*If you answered '**No**' to question 5 above, you have finished and can hand back the questionnaire. If you answered '**Yes**' or '**Not sure**', please read on and continue.*

Nicotine patches help smokers to stop smoking and smokers who use patches are twice as likely to manage to stop for good. Experts recommend that pregnant women who smoke should use patches to try to stop smoking because they believe that these are safer for expectant mothers and their babies than continuing to smoke.

Researchers from your hospital have teamed up with University of Nottingham and are running a research project to find out if nicotine patches help pregnant women to stop smoking.

6. Are you interested in taking part in this project?

Yes ☐
No ☐

***IF YOU ARE INTERESTED** and answered '**Yes**' to question 6 above, please COMPLETE YOUR CONTACT DETAILS BELOW AND TELL THE PERSON WHO IS COLLECTING THIS QUESTIONNAIRE.*

Name		
Address		
Telephone	Day:	Evening:
	Mobile:	
Best time to contact		

You have now finished.

THANK YOU FOR YOUR HELP

Office Use Only

Centre number: Date ...../..... /200.... ID:

University Hospitals of Leicester NHS
NHS Trust

DIRECTORATE OF RESEARCH AND DEVELOPMENT

Director: Professor D Rowbotham
Assistant Director: John Hampton
Co-ordinator: C Cannaby
Direct Dial: 0116 258 4614
Fax No: 0116 258 4226
EMail: chris.cannaby@uhl-tr.nhs.uk

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Tel: 0116 249 0490
Fax: 0116 258 4666
Minicom: 0116 258 8188

25 April 2008

APPENDIX 49

Mr John Taylor
University of Nottingham
Division of Psychiatry
Behavioural Sciences
A Floor South Block
Queens Medical Centre Nottingham
NG7 2UH

Dear Mr Taylor

ID: 10519 **Attitudes of pregnant smokers and recent quitters to smoking cessation services in pregnancy**

SSA Ref: NA **REC Ref: 06/Q2404/48**

Sponsor and Funder University of Nottingham

Please note that Trust Indemnity ceases on: 25/09/2008

As you are aware all research undertaken within the NHS requires both a favourable ethical opinion from an independent ethics committee, and R&D Approval from each NHS Trust it is taking place within. We have received confirmation that your study has gained a favourable opinion from the local Ethics Committee. All papers submitted have also been reviewed by University Hospitals of Leicester NHS Trust R&D Office and I am pleased to confirm NHS R&D Approval from the Trust, on the following conditions:

- All papers submitted to this office are followed to the letter; should any amendments or changes be required these must be submitted to this office.
- Only researchers detailed on the second page of this letter are to be involved in the study. If this changes, the changes must be submitted to this office as a non-substantial amendment.
- Your study is now covered by NHS Indemnity, as required, and excluding aspects covered by external indemnity, e.g. ABPI, University. This indemnity is in place to the above date – the end date you supplied. Should you wish your study to extend past this date you must notify the R&D Office, as not doing so would mean you are no longer covered to conduct your research. One method for this is through Annual Reports, see over page.
- Ongoing Pharmacovigilance and safety reporting is essential in all research studies. Serious Adverse Events (SAE), Serious Adverse Reactions (SAR) and Suspected Unexpected Serious Adverse Events (SUSAR) must be reported appropriately and timely. Please ensure you are aware of our SOP on Safety Reporting which is available on the UHL R&D web pages: http://www.uhl-tr.nhs.uk/our-services/research--development
- Your application detailed resources to be used in this study, you must ensure the budget detailed is followed as the Trust will not cover any additional costs associated to this research.
- If honorary research contracts have been issued it is your responsibility to ensure this/these are kept up to date.

Reporting Requirements
Within University Hospitals of Leicester we are keen to encourage well structured, good quality research; to ensure this high standard is achieved and maintained we are keen to make you aware of national and local reporting requirements:

- Annual & Final Reports on the progress are required each year, or final on completion. These reports are needed by both the R&D Office and local Ethics Committee. Templates for these reports are available on the R&D & NRES website, and we look forward to the receipt of these on the anniversary of your ethics approval, and on the completion of your study.
- Additionally Annual Safety Reports are required for CT-IMP (Clinical Trials of Investigational Medicinal Products) studies and should be submitted to the MHRA annually 60 days prior to the anniversary of MHRA Approval.

We are aware that undertaking research in the NHS comes with a range of regulatory responsibilities and have attached to this letter, forming part of your R&D approval, an information sheet to ensure you are aware of these responsibilities.

The R&D Office is keen to support research, researchers and facilitate approval. If you have any questions regarding this or other research you wish to undertake in the Trust please feel welcome to contact this office again. The Trust wishes you success with your research.

Below is a list of the Researchers Approved to work on this Application within UHL

Dr Tim Coleman

Mr John Taylor

Yours sincerely

John Hampton

Assistant Director for Research and Development