Barriers and facilitators to smoking cessation in pregnancy and following childbirth: literature review and qualitative study

Study Protocol
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Research Summary

Maternal smoking in pregnancy causes substantial harm and, while many women in the UK stop smoking before or soon after becoming pregnant, one in four women smoke for part of pregnancy and one in eight smoke continually (NHS Information Centre, 2011). This study will explore barriers and facilitators to smoking cessation in pregnancy by reviewing relevant literature, conducting qualitative research and developing proposals for future interventions.

A qualitative study design will combine three systematic reviews and three exploratory studies conducted over a two year period, with data from a rapid mapping exercise to identify existing and in-development interventions for cessation in pregnancy.

Firstly, a set of three reviews of barriers and facilitators to cessation in pregnancy and following childbirth will be undertaken. The first will focus on pregnant women, updating and extending a recent systematic review conducted by members of the study team for the Department of Health (Graham et al, 2011), which was based on 25 qualitative studies on smoking and cessation in pregnancy published since the 1970s. The second and third reviews will focus on partners/household members and professionals.

Secondly, a set of three exploratory studies will be undertaken. These will focus on pregnant women, partners/family members and health professionals/lay advisors. The three studies will be undertaken in one study site in Scotland (NHS Lothian) and one in England (NHS North Yorkshire and York) including a mix of urban and rural areas and more affluent and deprived communities. The sample will comprise:

- 20 pregnant women who are continuing to smoke during pregnancy (10 in each site)
- 20 to 25 household members residing with these pregnant women (10 to 12 in each site)
- 20 pregnant women who have recently stopped smoking (10 in each site)
- 20 to 25 household members residing with these pregnant women (10 to 12 in each site)
- 20 professionals in each site including midwives and midwifery managers, consultant obstetricians, health visitors and cessation advisors.

A subsample of 10 of the women originally interviewed will also be followed up post-partum to identify their longer term experiences.

Findings from the interviews will identify barriers and facilitators to cessation in pregnancy from the perspective of each group of interviewees. These will be compared and contrasted and brought together with the evidence from the systematic reviews to produce a narrative synthesis of key themes and issues. These findings will inform recommendations for practice and lead to the development of proposals for interventions to address smoking in pregnancy that can be tested in future research.

Abstract in Plain English

Smoking while pregnant causes substantial harm and, while many women in the UK stop smoking before becoming pregnant or soon after becoming pregnant, one in four women smoke for part of pregnancy and one in eight smoke continually. In the UK, there are NHS services available to pregnant women that are known to help them stop smoking, however, less than one in seven pregnant smokers use these services.

This study will explore barriers and facilitators to smoking cessation in pregnancy and following childbirth involving pregnant women, their partners/household members and health professionals who have a role to play in supporting women to stop smoking. The study will examine why women do not use existing services, how these services and other forms of support could be improved and whether there are new forms of support that should be developed and tested in future research.

The study has two main components. Firstly, a set of three literature reviews will be undertaken focusing on the views of pregnant women, their partners/other household members and health professionals who support women to quit smoking. The findings from studies included in each review will be compared and combined to build an overview of common barriers and facilitators for each of the three groups.

Secondly, a set of three exploratory studies will be undertaken with pregnant women, partners/family members and health professionals/lay advisors. We will interview 20 pregnant women who have stopped smoking and 20-25 household members living with these women, and 20 pregnant women continuing to smoke and 20-25 of their household members. 10 women will be interviewed a second time after they have given birth. In the interviews we will examine the views of the women and their partners/other household members regarding smoking, smoking cessation and interventions to support cessation. We will also interview up to 40 health professionals who have a role to play in supporting women to stop smoking to explore their views of structural, organisational or cultural barriers that women face in the NHS or other services in accessing effective support to stop smoking.

The study will use findings from the reviews and the interviews to explore the current make-up of interventions and services to support women to quit smoking and to develop proposals for interventions that could be tested to improve current provision.

Background

Maternal smoking in pregnancy causes substantial harm, increasing the risk of miscarriage, stillbirth, prematurity, low birth weight, perinatal morbidity and mortality, neo-natal or sudden infant death, asthma, attention deficit disorder, learning difficulties, obesity and diabetes. Self-reported smoking status is known to underestimate prevalence and over-estimate quit rates in pregnancy (Owen & McNeill, 2001; Shipton et al, 2009); while evidence is limited, it suggests rates of under-reporting are similar across socioeconomic groups (Vartiainen et al, 2002).

While many women in the UK report that they stop smoking before or soon after becoming pregnant, one in four women smoke for at least part of their pregnancy and one in eight continue to smoke throughout (NHS Information Centre, 2011). The smoking status of partners and other household members is a predictor of maternal smoking habits, before and during pregnancy (Hiscock et al 2011, Lu et al 2001) and of post-partum relapse (Letourneau et al 2007, Ratner et al, 2007, Prady et al, 2011). Analyses of women who smoked in pregnancy in the Millennium Cohort Study indicates that, among those with partners, 70% had partners who also smoked – and over 70% of these partners neither cut down nor quit (Prady et al, 2011). Underscoring the role of partners, maternal smoking in pregnancy is associated with an unplanned pregnancy and difficulties in the partner relationship (Pickett et al, 2009).

Social disadvantage is a common factor in familial smoking habits. Compared to women in advantaged circumstances, women in disadvantaged circumstances are four times more likely to smoke prior to pregnancy and half as likely to quit in pregnancy; disadvantaged women are also more likely to resume smoking after birth (NHS Information Centre, 2011). Disadvantage is also predictive of partner's smoking status in pregnancy (Prady et al, 2012).

To enhance understanding of women's experiences of smoking in pregnancy, members of the study team undertook a systematic review of qualitative studies as part of the DH-funded Public Health Research Consortium (Graham et al, 2011). The review included studies published up to 2010, with the majority conducted in the US or the UK. The review indicated that pregnant smokers are aware of the health risks to their baby, and the strong social disapproval, of smoking in pregnancy; however, perceptions that these risks are low can combine with difficult domestic circumstances to undermine the motivation to quit. Perceptions that healthcare professionals offered inconsistent advice on, and support for, quitting in pregnancy also emerged as a potential barrier.

There are, however, interventions known to be effective in promoting cessation in pregnancy. The most recent Cochrane review of smoking cessation interventions pooled results from 72 trials and concluded that cessation interventions in early pregnancy can reduce smoking in later pregnancy by around 6% and reduce the incidence of low birth weight and pre-term births (Lumley et al, 2009). This evidence was included in the effectiveness review that members of the study team authored to inform the 2010 NICE guidance on smoking cessation in pregnancy (Bauld and Coleman, 2009, NICE, 2010). Interventions employing cognitive behavioural approaches to cessation are effective; those using a 'stages of change' approach showed borderline effectiveness. Financial incentives for smoking cessation during pregnancy were the single most effective intervention in both reviews and members of the study team are now conducting a phase II trial – the **C**essation in **P**regnancy **I**ncentives **T**rial (CPIT) in Glasgow to provide UK-based evidence of effectiveness (Tappin et al 2012). Much less is known about effective interventions to prevent post-partum relapse (Hajek et al 2009); however the smoking habits of partners, family and friends are recognised as important barriers to sustained quitting (Letourneau et al 2007, Van't Hof et al 2000, Prady et al 2011).

There is a wide range of information and support available to pregnant women who want to stop smoking. This ranges from self-help materials (available online and from health professionals) and brief advice from GPs and midwives, to specialist support offered by NHS stop smoking services (Bauld, 2009). These services were developed as part of England's 1998 tobacco control strategy, informed by evidence from effective interventions and rolled out across the UK from 2000. The services provide behavioural support delivered by trained advisors along with access to smoking cessation medications for smokers motivated to quit. From 2001, services in all parts of the UK began providing tailored support for pregnant women in clinic settings, in the home and by telephone, and results from national monitoring and recent research suggest that these interventions are successful in pregnancy, with between one third and one half of women stopping smoking at least in the short term. However, fewer than one in seven pregnant smokers access these services (Information Centre, 2011); the majority of those making quit attempts therefore do so without professional assistance – and most will not succeed (Graham et al, 2010). In addition, the quality and delivery of these services varies across the country and recent studies in Scotland and England have identified a number of limitations to smokers being identified and referred and then supported to stop (Tappin et al, 2010, Fahy et al, 2012). Health professionals themselves may fail to facilitate smoking cessation through, for example, midwives' reluctance to ask about smoking, lack of training in smoking cessation,

organisational factors and health professional's own smoking behaviour (Conliffe et al 2006). Taken together, this evidence suggests that there are likely to be important service-related barriers to cessation in pregnancy. It is for this reason that the proposed research includes perspectives from professionals as well as women and household members.

Smoking in pregnancy rates remain high in the UK despite the fact that free at the point of use smoking cessation services for pregnant women have been in place for more than a decade. The Department of Health's Tobacco Control Plan for England includes a national target to reduce smoking during pregnancy to 11% or less by the end of 2015 from a baseline measure of 14.1% in 2009/10. Similar commitments (without explicit targets) have been made in Scotland and Wales.

Aims and Objectives

This study aims to enhance understanding of the barriers and facilitators to smoking cessation in pregnancy and the feasibility and acceptability of improved interventions to reach and support pregnant women to quit. It will build on what is already known and explore in more depth than in previous studies what prevents women from quitting and how these factors can be modified. The specific objectives of the study are to:

- Examine existing qualitative literature on the barriers and facilitators to smoking cessation in pregnancy and postpartum, building on a recently-completed systematic review conducted by members of the study team.
- Explore the views of pregnant women and women who have recently given birth regarding smoking, smoking cessation and interventions to support cessation. This will include women who have accessed support to stop and those who have not accessed such support.
- Explore the views of partners and other household members of pregnant women regarding smoking, smoking cessation and interventions to support cessation. This will explore, where relevant, their smoking as well as that of the pregnant woman.
- Explore the views of health professionals and advisors who have a role to play in supporting women to stop smoking including: midwives and midwifery managers, health visitors, consultant obstetricians, GPs, smoking cessation managers and advisors.
- Examine the current configuration of interventions and services to support women to quit smoking, building on existing and recent research conducted by members of the study team, to develop proposals for interventions that could be tested to improve current provision.

In particular, this will be the first study in the UK to take into account the household and family context of smoking in pregnancy and compare and contrast the views of women and their household members with those of professionals involved in maternity and smoking cessation services. By taking this more comprehensive approach, the study will inform both the delivery of existing interventions and serve as the foundation for the development of a proposal to test promising future interventions.

Outcome measures

The study outcomes will include barriers and facilitators to cessation in pregnancy. As the research is qualitative, primary outcomes cannot be specified in advance. Instead, it is

anticipated that factors (i.e. barriers and facilitators) that can contribute to changes in smoking behaviour during and immediately following pregnancy will be identified through the study. Combining findings from previous research with predictions from the Theory of Planned Behaviour (TPB), it is anticipated that the barriers and facilitators may relate to at least four main categories:

- Characteristics and experiences of pregnant women (e.g. nicotine addiction, beliefs about smoking)
- Attitudes and behaviour of household members/significant others (smoking status, extent of support for pregnant women's quit attempt)
- Attitudes and behaviour of health professionals and advisors
- Availability, structure and content of aids and services for smoking cessation

It is anticipated that a matrix of facilitators and barriers from each of the participant groups in the study will be able to be developed. This can then be compared and contrasted with the barriers and facilitators identified through the three systematic reviews in a narrative synthesis that will inform recommendations for changes to practice and proposals for future interventions.

Research Design

Theoretical framework

The research is informed by the TPB (Ajzen, 1991), a theoretical approach used in a number of studies of women's smoking behaviour during pregnancy (e.g. Godin et al. 1992, De Vries & Backbier 1994, Moore et al. 1996, Bennett & Clatworthy 1999, Taylor 2010, Natan et al 2010). The model maintains that behaviour (in this instance quitting smoking) is determined by an individual's intention to engage in that behaviour and their perceived behavioural control, with behavioural intentions in turn shaped by attitudes, subjective norms and perceived behavioural control. Attitudes are conceptualised as the overall evaluation of the behaviour (e.g. a negative evaluation of smoking and a positive evaluation of quitting); subjective norms are the perceived preferences of significant others about whether behaviour should or should not be engaged in, and perceived behavioural control relates to factors seen to facilitate, or create barriers to, the behaviour, including those relating to psychological/chemical dependence and to the behaviour of others.

While there is a lack of high quality research to inform whether the TPB is a good predictive model for smoking cessation in pregnancy, the theory specifies key behavioural determinants which make both valuable investigative focal points and potential intervention targets. Further strengths of the TPB in relation to this research are its sensitivity to the contextual influences (subjective norms and perceived behavioural control) on behavioural intentions and, in consequence, its recognition that these can be modified through influencing an individual's social and physical environment (Ogden 2012). It is this foregrounding of contextual factors that led the team to use TPB as the theoretical framework for this research.

Research Methods

The research will involve an observational study comprising of three elements:

- Element 1 - systematic reviews of the evidence
- Element 2 - qualitative research (interviews) with pregnant women, their partners and healthcare professionals
- Element 3 - development of proposals for interventions that can be tested in future research

A flow diagram of the key study components is provided in Appendix 1. The setting for the study will be one study site in Scotland and a second in England. The first will be NHS Lothian, covering Edinburgh and surrounding areas, including areas of deprivation where smoking in pregnancy is particularly high. The second will be NHS North Yorkshire and York. Serving a population more scattered and rural than that of England as a whole (ONS, 2012), it provides a study site where access to services, including smoking cessation services, may be an additional barrier to cessation.

Before conducting the main elements of the study, a brief, rapid mapping exercise will be conducted to review and describe available cessation interventions for pregnant women in England and Scotland (including what is available in each site). The study team already have much of this information to hand given their 1) current involvement in a range of on-going research projects on smoking cessation in pregnancy (including an NIHR programme grant), 2) membership of key committees (including the working party to develop a national action plan for smoking in pregnancy, and the Scottish Government working group developing a new tobacco control strategy for Scotland, both of which the PI chairs) and networks (including the NIHR CLARHC for Leeds, York and Bradford where maternal and child health is a R&D theme) and 3) extensive knowledge of the field. The information the study team already have will be supplemented with local details of services from the NHS colleagues who are co-applicants on this study, and updates from relevant organisations such as ASH and ASH Scotland, the National Centre for Smoking Cessation and Training, the Department of Health and the Scottish Government. This will be supplemented by a brief appraisal of studies already underway testing new interventions for smoking cessation in pregnancy in the UK. The mapping exercise will produce a checklist of available interventions and services that will be used in the qualitative elements of the study and to inform the development of proposals for interventions that can be tested in future research.

Element 1 - Systematic reviews of the evidence

Three brief systematic reviews of the evidence relating to barriers and facilitators to smoking cessation in pregnancy will be conducted, building on the recent review for the Department of Health on using qualitative research to inform interventions to reduce smoking in pregnancy in England (Graham et al, 2011). The reviews will cover three populations relevant to this research and findings will then be synthesised. The groups will include: 1) pregnant women; 2) their partners and other household members; 3) health professionals with a role in the support of women to stop smoking.

Searching for studies

Relevant studies will be identified through (i) searches of electronic databases, (ii) scanning references of included papers, and (iii) consulting experts in the field. All electronic resources will be searched from 1990 onwards to ensure the papers included in the review have contemporary relevance.

For each review, relevant sets of search terms relating to: pregnant women; partners/household/family members; healthcare professionals and advisors will be combined with qualitative terms, pregnancy/early motherhood terms and smoking terms. A draft strategy will be developed in MEDLINE and, following testing against a sample of papers, will be finalised and adapted to run in CINAHL, PsycINFO, Social Sciences Citation Index (SSCI) and the Economic and Social Research Council (ESRC) database. These additional sources will facilitate inclusion of grey literature, book chapters, PhD theses, sociological literature and smaller qualitative research studies.

Citations from the literature search will be downloaded into a reference library. Two reviewers will independently screen all titles and abstracts. Any discrepancies will be resolved by discussion, or by referral to a third reviewer when necessary.

Inclusion criteria

Published and unpublished studies reported in English and conducted in a high-income country matching the stage of the cigarette smoking epidemic reached in the UK (i.e. a strong association between social disadvantage and cigarette smoking among women and men) will be eligible for inclusion if they use qualitative methods to investigate the barriers to, and facilitators of, quitting in pregnancy and following childbirth.

- Review One: qualitative studies that include pregnant women and women who have recently given birth who have experience of smoking during pregnancy

- Review Two: qualitative studies that include partners and other household/family members of pregnant women and women who have recently given birth and have experience of smoking during pregnancy
- Review Three: qualitative studies that include healthcare professionals and advisors supporting pregnant women and women following childbirth

Data extraction, quality assessment and synthesis

Data extracted will include: study aim, type and number of participants, methodology, methods of data collection, methods of analysis, and results. Data will be extracted by one researcher and checked by a second. Papers will be appraised for quality by one researcher and checked by a second using a quality appraisal checklist (Hawker et al 2002). All papers will be discussed by the review team prior to inclusion and any disagreements resolved by consensus.

The synthesis will be conducted using meta-ethnography (Noblit & Hare 1988), an approach to research synthesis widely used for the synthesis of qualitative studies (Campbell et al 2003, Flemming et al 2012). There will be four iterative phases to the meta-ethnography for each review, with the interpretative process guided by the TPB. Firstly, the studies' social contexts and findings will be mapped. Secondly, data relating to barriers and facilitators (taken from verbatim accounts and authors' interpretations) will be transcribed verbatim from the papers into text files, and imported into Atlas-Ti. Codes will be assigned line-by-line to authors' interpretation of findings and participants' accounts within the text files, an approach consistent with qualitative analysis of primary data (Alvesson 2009, Silverman 2009). The third phase involves the cross-reading of studies' findings; identified codes relating to barriers and facilitators will be compared to establish whether they can be merged into broader analytic categories, a technique known as Reciprocal Translation Analysis (RTA) (Noblit & Hare 1988). The aim is to protect the characteristics of each study, whilst, at the same time, identifying points of convergence and divergence in their evidence. Note will be taken of where the emergent categories align with or diverge from the components of the TPB model (behavioural intentions, attitudes, subjective norms, perceived behavioural control). In the fourth phase, these 'translations' will be compared to identify overarching 'lines of argument' (Noblit & Hare 1988). These 'lines of argument' will enable comparison of the similarities and differences running through the studies in each review regarding the barriers and facilitators to smoking in pregnancy and following childbirth.

Element Two - Qualitative research

This element of the research will involve interviews with a) pregnant women/women who have recently given birth, b) their partners and/or other household members/significant others, and c) health professionals and advisors.

Inclusion and exclusion criteria

The inclusion and exclusion criteria for participants in each group is given in Table 1 below.

Table 1: Inclusion and exclusion criteria

Pregnant Women	Household members of pregnant women	Health professionals/ advisors
Age 16 years or more	Aged 16 years or more	Aged 16 years or more
English speaking	English speaking	English speaking
Referred to Lothian/North Yorkshire & York obstetrics services	Lives in same household as pregnant women or close friend/relative that spends at least one hour per week with pregnant woman	Significant role in the provision of care or smoking cessation support to pregnant women referred to Lothian/North Yorkshire & York obstetric services
6-15 weeks gestation at maternity booking		
Self-reported smoker at maternity booking	Smoker or non-smoker	Smoker or non-smoker

Sampling strategy

The qualitative sample for interview will include up to:

- 20 pregnant women who were self-reported smokers at maternity booking and, at c20 weeks gestation are smokers (10 in each site – described in more detail below under 'Continuing Smokers')
- 20 to 25 household members living with these pregnant women (10 to 12 in each site)
- 20 pregnant women who were self-reported smokers at maternity booking and, at c20 weeks gestation have stopped smoking (10 in each site, described in more detail below under 'Quitters')
- 20 to 25 household members living with these pregnant women (10 to 12 in each site)
- 10 women will be interviewed for a second time in the post-partum period (up to six weeks after giving birth) to assess longer term experiences (5 in each site)

- 20 professionals in each site including midwives, health visitors, cessation advisors and others

Purposive sampling will be used to achieve maximum diversity within the recruited sample of pregnant women, household members and health professionals. Recruiting 40 pregnant smokers, up to 50 household members and 40 professionals will provide a significant sample for a qualitative study and result in the collection of detailed qualitative data that will allow the research questions in the proposal to be addressed, while also keeping the time and costs of the study within reasonable limits.

In terms of number of pregnant smokers in each study site, data obtained from NHS colleagues at each study centre suggests that the number of women who self-report as smokers at maternity booking annually is around 820 in NHS North Yorkshire & York, and 970 in NHS Lothian (2011 figures). Previous experience of qualitative studies of smoking in pregnancy suggests that, even with a thank-you payment being offered for the participant's time (£15 in this study), many pregnant smokers will choose not to participate in the research. However if recruitment takes place over a five month period the proposed sample size should be achieved in each area.

Sampling frame

A sampling frame will be used to ensure that the sample recruited for interview takes into account maternal age and deprivation and includes women who fall into two groups – Continuing smokers and Quitters.

Continuing smokers will be women who smoke in early pregnancy (as reported at booking appointment) and who are continuing to smoke, even occasionally, when contacted for interview at 20 weeks gestation. This group will, in practice, consist of women with varying experiences of smoking and smoking cessation. It is likely to include: women who refused a referral to NHS stop smoking services at maternity booking but who have smoked continually between booking and when they are interviewed by a member of the research team; women who are still smoking occasionally at 20 weeks gestation but may have made self-directed quit attempts in between and even have stopped completely for short periods; and women who have been referred to NHS stop smoking services and made a quit attempt with the services but not been successful. This type of heterogeneity within the group is inevitable as most pregnant smokers attempt some form of cutting down, temporary abstinence or longer quit attempts during pregnancy (Pickett et al, 2009) and

will add to the ability of the study to identify barriers and facilitators for women with a range of experiences.

Quitters will be women who smoke in early pregnancy (as reported at booking appointment) but who identify themselves as not smoking when contacted for interview at around 20 weeks gestation. Again these women are likely to have varied experiences of smoking and cessation. This group will, for example, include women who have been referred to NHS stop smoking services and been successful in stopping with the support of these services. It will also include women who have managed to quit without accessing NHS support.

Approximately 10 participants will also be followed up after they have given birth. Through telephone contact with study participants' post-partum, a mixture of women will be purposively selected who are a) abstinent post-partum and b) have continued to smoke or relapsed back to smoking in late pregnancy or post-partum. Studies have found that around half of those who relapse in the first 6 months after delivery do so by 4-6 weeks after delivery. Therefore, the study team will aim to interview these participants around this time period.

The group that will not be reached via the planned recruitment method is those who stopped smoking spontaneously before maternity booking. However this is not a priority group for the NHS and is not a particular concern that missing them will detract from the study. This group are estimated to represent between one in four and one in seven women smokers who smoked prior to their pregnancy. As part of the aim of the qualitative work is to explore pregnant women's views on available or alternative support to quit, the study team consider it key to focus on women who are likely to need assistance to quit. Whilst it is anticipated that some of these pregnant smokers may quit subsequently without assistance, this group is much more likely to relapse later in pregnancy compared to 'spontaneous' quitters (Hajek et al, 2001).

Women less likely to quit or more likely to relapse are a priority for interventions and hence for this study. As these women tend to be younger and more disadvantaged, the sampling frame will aim to take into account these characteristics: maternal age – aim to recruit 25% of the sample from women aged under 25 years (including at least two teenage mothers in each site); and deprivation – aim to recruit 75% of the sample (approx. 30 women) from disadvantaged groups as measured by the woman's educational attainment/(S)IMD score of woman's postcode of residence or GP practice.

The professional sample is intended to reflect a range of perspectives on smoking cessation in pregnancy and the various intervention options and opportunities available. The professionals approached to take part will depend in part on the outcomes of the proposed mapping exercise and systematic reviews. This may therefore include: pregnancy smoking cessation advisors and managers working within the stop smoking services, midwives and midwifery managers, health visitors, consultant obstetricians and GPs, for instance. Professionals will be interviewed by phone or face to face or will participate in a focus group.

Interviews

Interviews with pregnant women and household members/significant others

This component of the research will aim to enhance understanding of barriers and facilitators to cessation and the feasibility and acceptability of improved interventions to reach and support pregnant women to quit by examining the views of pregnant women and those who have recently given birth, and their partners/other household members regarding smoking, smoking cessation and interventions to support cessation.

These views will be sought through semi-structured interviews, building on, rather than duplicating, what is already known from existing literature and including the views of participants in two study sites.

The interviews with pregnant women will be quite relaxed, last up to 45 minutes and will take place either in the participants' homes or at another place of their choice. The topic guides will be informed by the TPB and by the mapping of cessation interventions and on-going work by members of the study team. Not only will smoking behaviour, quit attempts and views on available or alternative support to quit amongst pregnant women/women who have recently given birth be explored but also the smoking and quitting behaviour of the women's partners and other household members/significant others (see Interview Topic Guide Appendix 2). Participants will be free to contribute as much or as little to the interview as they wish and to stop the interview at any time without giving a reason.

Participants will be interviewed face-to-face by members of the research team; telephone interviews may be conducted for participants who prefer this. With the participants' consent, all interviews will be recorded as digital audio files, which will then be transcribed in full for thematic analysis.

Women and household members will be interviewed separately (pregnant women first, and household members subsequently) as some of the barriers and facilitators identified are likely to involve family and community norms and support, and participants may be more forthcoming on these matters if the interviews are conducted on a one-to-one basis with the researcher.

The study team are particularly interested in the views of partners but recognise the need for women who do not have partners to have an opportunity to nominate other household members/significant others as appropriate. The selection of significant others will be determined by the women who will be asked to pass on a brief study information sheet to those they view as the most significant individuals in their lives and with whom they have regular contact. Those individuals interested in taking part can then contact the researcher directly.

Interviews with health professionals and advisors

This element of the study will explore the views of health professionals and advisors who have a role to play in supporting women to stop smoking including: midwives and midwifery managers, health visitors, consultant obstetricians, GPs, smoking cessation managers and advisors.

Findings from the existing systematic review (described previously) and other recent research suggests that many of the problems that women face in accessing effective support to stop smoking involve structural, organisational or cultural barriers in the NHS or other services rather than reluctance or lack of knowledge amongst pregnant women. Furthermore, some health professional and advisor groups may deliver information and advice in ways that dilute the effectiveness of cessation interventions. For example, evidence indicates that midwives seldom advise pregnant smokers to abstain completely and are equally or more likely to recommend cutting down the quantity smoked instead (Owen & Penn, 1999; Glover et al, 2008). If the reach of existing services and more effective interventions are to be developed in the future these need to take into account the views of health professionals and advisors and the barriers they may face.

As stated above, up to 20 health professionals and advisors in each study site will be interviewed following a brief mapping exercise of local service configuration conducted by the NHS staff that are co-applicants on this proposal and supported by other members of the research team. Depending upon the outcomes of the mapping exercise and systematic reviews, the majority of research contact may focus on specific professional groups. It is

anticipated that midwives, health visitors and smoking cessation advisors may be the subject of this focus given their greater contact time with pregnant and recently delivered smokers. Interviews with some professionals will be on a one-to-one basis but, where possible, focus groups (e.g. with midwives) will be conducted to maximise efficient use of resources as well as minimising any impact on services from participation in the research.

Interviews with professionals will cover a number of themes, some of which are similar to those explored with pregnant women and their partners, family & friends. Themes will include: their own experience of smoking and their role in promoting smoking cessation; views on current practice (interviewees come from a range of professions relevant to smoking and smoking cessation in pregnancy); perceived barriers and facilitators to cessation in pregnancy; and views on available and in development interventions (see Appendix 2 Interview Topic Guides for details of content).

Data Analysis

Analysis will be undertaken in accordance with ethnographic principles. The qualitative data collected from interviews with pregnant smokers, their partners and household members/significant others and the interviews/focus groups with health professionals and advisors will each be analysed separately using the TPB as a framework for the thematic analysis (Braun &Clarke, 2006), an analytic approach consistent with that proposed for the qualitative systematic review (meta-ethnography). The process of analysis will proceed through the development of a coding framework, after which the data transcripts will be systematically coded into categories or groups related to barriers and facilitators. Codes and categories generated through the data analysis will be flagged where these align with components of the TPB model (behavioural intentions, attitudes, subjective norms, perceived behavioural control). Using the constant comparative method, similarities and differences between categories will be identified (Hammersley & Atkinson 2007). Analysis will continue until a coherent set of themes have been formulated. Coding and analysis will be aided by the qualitative analysis software NVivo http://www.qsrinternational.com/products_nvivo.aspx). This analysis process will be undertaken for each of the three groups of participants, staggered over the duration of the project as specified in the timeline. In addition to the interpretation of these themes within their groups, they will also be compared and contrasted between groups at a secondary level of analysis and interpretation.

Element Three - Development of proposals for future research

The study will use findings from the systematic reviews and the interviews to explore the current configuration of interventions and services to support women to quit smoking and to develop proposals for interventions that could be tested to improve current provision. Findings from the existing systematic review carried out by the study team and recent pilot work in England suggest that particularly promising areas for future interventions would be: better provision of information and advice regarding the use of NRT; tailored cut down to quit interventions and family or household based interventions.

Of these three, family or household/social network interventions are likely to be the focus for the development of proposals for future research from this study. This judgement is based on the findings of the NIHR HTA funded SNAP trial (led by Professor Tim Coleman, chair of the advisory group for this study and member of UKCTAS) that suggest standard dose NRT is not effective in pregnancy (Coleman et al, 2012). The results of the trial identify some future research questions on NRT but these are complex and likely to require the two year follow-up data from the trial before full consideration can be given. Cut down to quit options may be worth further research but in pregnancy the evidence for this is weak (NICE, 2011) and this may not be as fruitful a route for future research – although it will not be ruled out if findings from this study suggest it is an important route forward.

In contrast, there is increasing interest in piloting and trialling family or social network interventions for cessation in pregnancy. The smoking status of the partner during pregnancy and after birth, including whether they quit in pregnancy and relapse post-partum, has been identified as a predictor of maternal quitting in pregnancy and post-partum resumption of smoking (Lu et al, 2001; Letourneau et al, 2007; Prady et al, 2011); other studies also suggest that smokers quit with their partners and/or with other family members and friends (Hargreaves et al, 2010). Findings from a) the recent systematic review by study team members (where partner's smoking status as well as the wider dynamics of the couple's relationship emerged as important factors) and b) the study team's knowledge of existing services in the UK suggest that this is a promising avenue for future intervention development that to date has not been explored in any detail, particularly in the context of the NHS. Some trials of couples-based interventions exist, as well as a single trial in the USA that examined the support of one female friend for cessation in pregnancy (Hennrikus et al, 2010) but no definitive trial has been conducted of an intervention that involves the pregnant woman's wider household/significant others (such as female relatives who have a key role to play in determining smoking behaviour and supporting or undermining quit attempts). The proposed study – with its linked set of brief systematic reviews and qualitative studies locating pregnant women within their primary

social relationships – could lay the groundwork for the development of detailed proposals for future research on this issue.

A key output from this research, therefore, will be the development of a proposal that follows MRC guidance on the evaluation of complex interventions. The proposal will be for a pilot study that will establish the parameters of the intervention followed by a feasibility (phase II) trial. As far as possible, in developing the proposal the MRC's five questions for consideration in developing a new intervention (MRC, 2006) will be addressed:

- Are you clear about what you are trying to do?
- Is there a clear theoretical basis for the intervention (i.e. is there an identified need)
- What outcomes are you aiming for?
- How will you bring about change?
- Can you describe the intervention so it can be implemented, evaluated and replicated by others?

This proposal will form part of the final report from the study.

Research Governance

Sponsorship

The University of Stirling has agreed sponsorship of this research.

Indemnity

The University of Stirling will provide the relevant cover for all study participants & staff.

Ethical Arrangements

Approval by REC

Ethical approval will be obtained from the South East Scotland Research Ethics Committee (REC) for all three groups of participants in the study (pregnant women, their partners/other family members or friends and health professionals). This study should be straightforward from an ethical perspective provided appropriate consent is obtained from all participants. Pregnant women and their partners/other family members & friends will receive a £15 shopping voucher that can be used in many high street shops to cover their time for participating in the research. Reasonable travel expenses will be paid if incurred by these participants. Health professionals will not receive any payment for their participation.

Risks and anticipated benefits for study participants and society

The burden of involvement and risk for all participants will be minimised. The explicit wishes of the participant will be respected throughout the study including their right to withdraw from the study at any time. More generally, the interests of the participant will prevail over those of science and society.

Pregnant women – The study team acknowledge that care must be taken to avoid contacting any women who may have suffered from an adverse event in the time period between initial agreement to pass their contact details to the study team, contact to obtain verbal consent to take part and subsequent interview contact at around 20 weeks gestation and, where appropriate, after giving birth. Mechanisms will be established e.g. via woman's named midwife, at each centre to alert the study team to any adverse events, such as pregnancy loss, to ensure that women will not be approached who may be distressed by any involvement in the research.

Pregnant women and their partners/family & friends - Some people may find talking about smoking and pregnancy difficult and feel vulnerable discussing particular topic areas. Minimal risks for participants are anticipated in this respect however, as experienced

qualitative interviewers will be employed who have NHS research passports and who have experience in dealing with sensitive and distressing situations that may arise whilst conducting interviews. Whilst conducting similar studies with pregnant women and also with disadvantaged groups, many individuals report benefits from participating, which include having an opportunity to be listened to and to contribute their experiences which might help others in the future.

The study team also acknowledge that talking about smoking may make people feel guilty or ashamed and that some participants may perceive pressure to give up smoking at a time that is particularly emotionally demanding for them. It is therefore planned to stress that the aim of the study is to explore views and experiences of what helps women and what hinders women from stopping smoking during pregnancy, and not to persuade participants to give up smoking. A non-judgemental approach in relation to smoking and decisions about smoking cessation will be adopted, and will emphasise respect for the autonomy of individual participants.

Health professionals - Written informed consent will also be obtained from health professionals prior to any research interviews taking place. The study team are aware that issues surrounding questions about working practices may be particularly sensitive. The researchers conducting the interviews will be aware of this, and will have previous experience/skills to handle questions of this nature appropriately.

Informing potential study participants of possible benefits and known risks

An approved information leaflet (see Appendix 3) that clearly highlights the risks and benefits as outlined above will be given to all interview participants (pregnant women, nominated household members/significant others and health professionals) at least 48 hours prior to recruitment to allow participants time to consider these risks and benefits and ultimately whether to take part in the study. In addition, all participants will have the opportunity to ask questions and further discuss the possible risks and benefits during the initial contact with the research team to ascertain consent.

Process of recruitment & obtaining informed consent

Pregnant women/women who have recently given birth

Pregnant women will be recruited with the support of maternity service and/or stop smoking service colleagues in each study site. Maternity booking data include self-reported smoking status and information on whether those who are smokers agree to or decline referral to NHS stop smoking services. Recruitment and consent processes will fit around

the structure of existing services and thus will differ between sites. The planned processes at each site are given below.

In NHS Lothian, where pregnant smokers are routinely identified at maternity booking and referred to the NHS Lothian Stop Smoking Service, recruitment of women will be initiated by smoking cessation facilitators. Women who attend a face-to-face appointment with a smoking cessation facilitator will be informed during this appointment that the study is taking place. The smoking cessation facilitator will give a brief explanation of the study to all women interested in finding out more, give these women a study information sheet (see Appendix 3 Information sheet for pregnant women) to take away, and seek permission for their contact details to be passed to the study team. Women who do not attend a face-to-face appointment will be told about the study during routine telephone contact by the smoking cessation facilitator and asked if they are interested in finding out more. Those who are interested in finding out more will be sent a study information sheet by post. All women whose contact details are passed to the study team will be called by a member of the research team at least 48 hours after receiving the information sheet. At this call the researcher will explain the study, answer any questions they have and seek verbal consent for participation. For those who consent, the research team will remain in contact with them, with their permission, via text to maintain interest in the study until they are around 20 weeks pregnant when they will be contacted by the researcher to arrange an interview. A letter confirming these details will be sent to the women. At the beginning of the interview the researcher will ask women to sign a consent form to say that they are happy to take part (see Appendix 4 Interview consent form for pregnant women).

At the York site self-reported smokers who have undertaken their maternity booking by 12 weeks will be given a personal copy of the information sheet and asked to consider taking part in the study and to discuss participation with other household members. At the dating or nuchal translucency scan which takes place at around 12 weeks gestation, they will be invited to meet with the research midwife, who will again explain the aims of the study and go through the information sheet with them. Clients will be invited to participate by the research midwife who will secure formal written consent from those who wish to be involved. Details of clients who have given written consent will be entered into the participant database by the research midwife. The women will be advised that they will be contacted around the time they are 20 weeks pregnant by the research team at the University of York to arrange a suitable interview date. A letter confirming these details will then be sent to the women together with another copy of the study information sheet.

At the end of the five month interview women will also be asked if they are willing for the researcher/research midwife to contact them again around 4-6 weeks after having their baby to find out if they are smoking or not and, where appropriate, ask them to participate in a second interview. Their estimated date of delivery (EDD) will be confirmed at this stage to allow the research team to contact them at the appropriate time. Not all women contacted at 4-6 weeks after giving birth will be asked to take part in a second interview as only a small number of post-partum interviews are planned and these will be purposively selected from women who are a) abstinent post-partum and b) have continued to smoke or relapsed back to smoking in late pregnancy or after giving birth. As with the first interview women will be asked to sign a consent form (see attached Interview consent form for pregnant women) to say that they are happy to take part. The format and content of the interview will follow that of the first interview.

Prior to any study follow up at around five months pregnancy and post-partum all pregnant women will be notified (via their information sheet) that a check to ensure the health of themselves and their baby will be made to prevent any unnecessary distress or upset. Health professionals will be asked to check the names/date of birth of consenting women to check whether there have been any adverse outcomes prior to follow-up contact being made that would make follow-up contact inappropriate.

Household members

The selection of household members/significant others will primarily be determined by the women who have already agreed to participate in the study. At the consent and/or five month interview stage, pregnant women will be asked to pass on a brief study information sheet (see Appendix 3 Tear-off Information sheet for partners, family & friends of pregnant women) to those they view as the most significant individuals in their lives with whom they have regular contact. In some instances the research midwife/smoking cessation facilitator may be able to hand this directly to these individuals where they are attending an appointment with the pregnant woman. Individuals who are interested in taking part in a separate interview are invited to contact the researcher/research midwife directly either by telephone or by using the SAE provided to ask for a full study information sheet (see Appendix 3 Information Sheet for partners, family & friends of pregnant women) to be sent to them by post.

In the event of problems in recruiting the target number (40) of significant others an additional approach will be used. The significant others of all pregnant women who smoke (i.e. not just those who have agreed to participate in the study) will be invited to take part

using the methods outlined above i.e. asking pregnant women to pass on the brief study information sheet to partners, family & friends or by being approached directly by the research midwife/smoking cessation facilitator where they are attending an appointment with the pregnant woman. In this instance the pregnant women herself will not be approached to participate.

The researcher/research midwife will contact these individuals, no earlier than 48 hours after distribution of the study information sheet, to explain the study, seek verbal consent and arrange an interview. A letter confirming these details will be sent to all participating individuals. Full written consent will be obtained at the beginning of each interview (see Appendix 4 Interview consent form for partners, family & friends of pregnant women).

Health professionals

Health professionals will be approached to participate in the research study through appropriate organisational structures, facilitated by study co-applicants. A multi-channel approach to recruitment of these participants will be applied e.g. via team leaders, attendance at team meetings and use of e-mail invitations. An approved information sheet (see Appendix 3 Information sheet for healthcare professionals supporting pregnant women) will be issued to potential participants expressing an interest in taking part. After having the opportunity to read the information sheet and ask questions the study team will confirm participation, and where appropriate arrange an interview. Full written consent to take part in the interview will be obtained at the start of the interview (see Appendix 4 Interview consent form for healthcare professionals supporting pregnant women). More detailed information on the profile of the sample is provided in Research Methods – Element 2 Qualitative Research - Sampling strategy.

R&D approval

R&D approval will be obtained for both participating centres, with the support of the Scottish Primary Care Research Network and the UK Centre for Tobacco Control Studies, prior to commencement of recruitment to the study. R&D approval will be obtained, as appropriate, for any subsequent protocol amendments.

Data access, protection and storage

Efforts to maintain participant confidentiality will be taken at all times. Participants will be given guarantees of anonymity in storage, preparation and presentation of data and in dissemination of findings. At no time will the research team identify an individual when presenting study findings.

Data will be stored in accordance with the Data Protection Act. All electronic data will be kept on secure servers at the Universities of Stirling and York, which are encrypted and password protected. All written material and project files will be kept in locked filing cabinets at the respective workplaces of the research team members. Names, contact details and consent forms will be held separately from other data. Participants will be given a unique study identification number and all written and electronic data will be labelled with these anonymised codes. Documents and files will be retained for ten years after the end of data collection.

Patient identifiable data will need to be transferred to the study team from each of the NHS centres approaching eligible women regarding potential participation in the study. Procedures for the secure transfer of this data to the study team will be agreed with the respective NHS security services. This data will be stored either in a locked filing cabinet at the University of York or electronically on a password protected database on a secure server at the University of Stirling, that can only be accessed by the research team.

Digital audio recordings of interviews will be immediately uploaded to secure university servers, all personal identifiers removed and any identifying information removed from the recordings prior to transfer (via secure electronic upload) to an external company to transcribe the contents. Anonymised transcribed data will be stored securely on a University of Stirling server and only accessible to researchers involved in the study. Audio files will be deleted once the recordings have been transcribed. Only the project manager and those team members responsible for interview of participants and data analysis will have access to electronic data and written material, such as transcripts, generated by the project.

Direct quotations from respondents will be anonymised in any written material generated by the study in order to protect the identity of individual participants and the organisations they represent.

Health & Safety

The study will adhere to the ethical guidelines provided by the Social Research Association (http://www.the-sra.org.uk). This provides a framework for ensuring the physical, personal and emotion safety of researchers and participants. The policies in place at each University/NHS site for the physical and emotional protection of research staff when on fieldwork will be adhered to. The local NHS lone working policies in place at each study site

will be followed to ensure the safety of researchers and the study team will liaise with relevant health professionals prior to interviewing woman and other household members at home.

Project expertise

This proposal brings together researchers and NHS colleagues who have considerable experience of conducting research on smoking in pregnancy. A number of the applicants (LB, LS, FN) are members of the UK Centre for Tobacco Control Studies (www.ukctcs.org), a UK Centre for Public Health Excellence part funded by the NIHR. The applicants are also members of the NIHR Faculty and the research will use the NIHR infrastructure of a Primary Care Research Network.

The study will be led by Professor Linda Bauld (LB) from UKCTCS at the University of Stirling, with Professor Hilary Graham (HG) at the University of York. LB is joint lead for smoking in pregnancy research within UKCTCS (with Tim Coleman, the study advisory group chair) and worked closely with NICE on the development of the 2010 guidance on smoking cessation in pregnancy. She is also a former scientific advisor to the Department of Health on tobacco control and in this capacity she coordinated the establishment of the National Centre for Smoking Cessation and Training in England. She recently led the development of a national training programme for cessation advisors working with pregnant women that was launched in March 2013 by NCSCT. LB will lead the Scottish element of the study with Professor David Tappin (DT, a paediatrician) in an advisory role.

HG will lead the English element of the study and take responsibility for the systematic review elements of the research with Kate Flemming (KF), an experienced systematic reviewer. HG has conducted research on maternal smoking and social disadvantage over a number of decades. She was Director of the DH Public Health Research Consortium (PHRC) until April 2011 and remains a main collaborator in its current programme (2011-16). She was PI of the systematic review of qualitative studies of smoking in pregnancy (2010-11, involving KF) and is PI of a study of multiple risk behaviours (including smoking) among parents and children (2011-14). She is also a CI on a NAEDI-funded project of help-seeking behaviour of smokers.

The study will be supported by an advisory group of senior academics and NHS colleagues chaired by Professor Tim Coleman, an academic GP who leads a current NIHR funded programme on smoking cessation in pregnancy. The Project Steering Group will offer independent advice on the conduct and progress of the research and will meet by

telephone conference every six months - a total of four times throughout the two year duration of the project. Each meeting will have an agenda and minutes will be taken.

Project Steering Group membership includes:

Independent Chair	Prof Tim Coleman, Professor of Primary Care, University of Nottingham, Nottingham
Independent Public Member	Ms Susanna Mountcastle, Bath
Independent Member	Ms Catherine Chamberlain, Monash University, Australia
Independent Member	Ms Carmel O'Gorman, Midwife/Smoking cessation in pregnancy lead, Heart of England NHS Foundation Trust, Birmingham
Independent Member	Ms Brenda Friel, Health Improvement Senior (Tobacco Control), NHS Greater Glasgow & Clyde, Glasgow
Non-Independent Member	Prof Linda Bauld, Professor of Health Policy, University of Stirling, Stirling
Non-Independent Member	Ms Lesley Sinclair, Research Officer, University of Stirling, Stirling

Project management

The study will be managed across the two sites by the academic leads in each (the PI, LB in Lothian and HG in York) but with day to day coordination by Lesley Sinclair (LS). She is an experienced trial and project manager who has worked in both NHS and University settings.

LB will take primary responsibility for the qualitative data collection and analysis with the project manager (LS, Stirling) and researchers (JM, Stirling and DM, York) and Felix Naughton (FN). Dermot Gorman (DG) Consultant in Public Health Medicine will serve as the main NHS contact for the Lothian study site. Elizabeth Ross (ER) Midwifery Matron from York Teaching Hospitals will serve as the main NHS contact for the Yorkshire study site.

Project Team Roles & Responsibilities (Version 1.2 11.04.2013)

Name	Role & Responsibilities
Professor Linda Bauld*	Liaison with funders; study design; study co-ordination across sites; lead for the Lothian centre; support for analysis of interviews, lead for the development of future proposals for cessation in pregnancy interventions that can be tested; interpretation, write-up and dissemination of findings
Professor Hilary Graham*	Lead for the York centre; study design; support for D.McCaughan in conducting interviews; support for systematic reviews; input into the development of future proposals for cessation in pregnancy interventions that can be tested; interpretation, write-up and dissemination of findings

Ms Lesley Sinclair*	Project management; day-to-day co-ordination of study; ethics & R&D approvals (supported by Graeme Docherty, UKCTCS); development of information sheets, consent forms and interview topic guides for women and family members; organisation and conduct of qualitative fieldwork in Lothian (including conducting interviews with Lothian professionals); qualitative analysis; progress monitoring & reporting; support for write-up and dissemination of findings
Dr Kate Flemming*	Lead for systematic review element of study; conduct (with support from a York researcher) reviews; interpretation, synthesis and write-up of review results; contribute to design of interview topic guides drawing on literature review findings
Dr Felix Naughton	Lead for health professionals interview element of study; design topic guides for health professionals interviews; analysis of health professionals interviews with assistance from other team members); write-up and dissemination of findings
Ms Dorothy McCaughan	Arrange and conduct interviews with women, family members and health professionals at York centre; input to interview analysis
Ms Sara Collier	Assist with recruitment of participants for interview
Ms Beverley Waterhouse	Assist with recruitment of participants for interview
Ms Jennifer McKell	Conduct interviews with women and family members in Lothian; assist with professional interviews in Lothian; interview analysis, interpretation and write-up for women and family members element; dissemination of findings
Ms Kathryn Angus	Literature searching for systematic reviews
Professor David Tappin	Advisory role; comment on literature review drafts and interpretation of study findings; assist with write-up of study findings and development of future proposals for cessation in pregnancy interventions that can be tested
Dr Dermot Gorman	Lead NHS contact for Lothian; assist with access, links with local services and recruitment for the study
Ms Elizabeth Ross	Lead NHS contact for York; assist with access, links with local services and recruitment for the study
Ms Carol Anne Greenan	Project admin support
Outsourced	Interview transcription

Key members (*) of The Project Management Group will meet at least monthly by telephone conference throughout the duration of the project to review progress, solve issues and discuss emerging findings. Other members of the Project Management Group will participate in these meetings as required for specific stages of the project. Each meeting will have an agenda and brief meeting notes will be taken.

Patient and public involvement

This study will involve significant input from service users as the main elements of the qualitative research proposed are with pregnant women who are accessing the NHS, either maternity services or maternity services and smoking cessation services. In addition, the PI is public engagement lead for the UK Centre for Tobacco Control Studies. She has established a panel of active smokers and those trying to quit that meet regularly in Bath.

The main aim of the panel is to discuss smoking cessation research and policy initiatives. Two members of the panel also attend centre advisory group meetings in London. Between meetings, Bauld and one of the centre administrative staff maintain contact with panel members and invite them to comment on research proposals and provide feedback on centre outputs as well as attend relevant events (such as public lectures and short courses). In March 2012 a panel meeting was held and this proposal was discussed with panel members. A member of the panel, Susanna Mountcastle, a smoker who has two young children, has agreed to join the advisory group that will be formed to guide the study. Susanna will be involved in guiding the conduct of the study, in particular in reviewing data collection instruments and commenting on interim results as appropriate. The results of the study will also be discussed with the panel as a whole and their help will be requested in dissemination of the findings and integration with policy.

In addition to engaging with the UKCTCS smoker's panel and involving one of its members in the study in more depth, this research will be linked with the public engagement elements of another NIHR HTA funded study on smoking in pregnancy. This is the BIBS study (looking at incentives for cessation and breastfeeding). Two of the applicants on this proposal (LB and DT) are also co-investigators in BIBS. The BIBS study has public involvement from mother and baby groups with whom emerging findings from the study will be shared.

Funding

Research funding has been secured from the NHS National Institute for Health Research Health Technology Assessment Programme. These costs support the salaries of the research team; travel and interview transcription costs; and a proportion of NHS administration and support costs. There are no additional NHS treatment costs associated with this study.

Timetable

The study will start in May 2013 and the final report will be submitted to the HTA in April 2015. Key milestones over the two year study duration are:

- Systematic review element one (pregnant women): May to September 2013
- Interviews with pregnant women (quitters and non-quitters): October 2013 to February 2014
- Post-partum interviews with subsample of women: March 2014 to June 2014
- Systematic review element two (partners and other household members): October 2013 to February 2014
- Interviews with household members: February to May 2014
- Systematic review element three (professionals): March to June 2014
- Interviews with professionals: June to September 2014
- Final interview analysis and synthesis: October 2014 to January 2015
- Development of proposals for future interventions and final report write up: February to April 2015

NRES & R&D Approvals required by:

- Interviews with pregnant women (quitters and non-quitters): July 2013
- Interviews with household members: October 2013
- Interviews with professionals: April 2014

Dissemination and Projected Outputs

Plans for disseminating the findings of this research

The project team has a proven track-record of dissemination to the scientific, practice and policy community. For each project component, findings will be communicated via peer-reviewed journals, including those with a significant clinical readership (e.g. Tobacco Control, BMJ, Addiction, Midwifery). The study team will also proactively engage with NHS and local authority stakeholders via local workshops and national conferences and via the NIHR-funded Leeds, York Bradford CLAHRC which has developed research communities of practice for midwives, health visitors and GPs. Additionally, summaries will be provided for study participants and NHS partners in the project, and, if appropriate, posters/support materials used for staff training/CPD.

The project team, project steering group and the smokers' panel (UKCTCS public engagement panel) convened by the PI will all play a key role in fine-tuning and guiding this dissemination strategy.

Project outputs

Systematic reviews: Three outputs are envisaged summarising findings relating to barriers and facilitators derived from studies of pregnant women (short report in peer-review journal updating earlier review), partners/significant others (original paper) and professionals (original paper). A unique strength of these outputs is that each will be informed by and cross-referenced to the findings of other reviews. Findings will be communicated via journals, major national conferences (UKNSCC, SSM, UKPHA for example) and the NIHR-funded CLAHRC.

Qualitative studies: A set of papers are planned based on the matrix (mapping facilitators and barriers identified through the linked studies of pregnant women, their partners/significant others and health professionals). Triangulating findings across the studies will inform two papers to deepen understanding of barriers and facilitators, one comparing lay accounts (women and partners/significant others) and the second comparing lay and professional accounts. Given the anticipated centrality of the couple relationship to cessation intentions and behaviour, it is envisaged the output linking studies of womens' and partners' perspectives will make a particularly significant contribution to the field.

Recommendations for policy and practice: The matrix of results (from the set of three systematic reviews and three qualitative studies) will provide a platform from which to

make informed recommendations for policy and practice to promote smoking cessation in pregnancy. It is envisaged these will relate both to current service configuration and delivery and to alternative/additional avenues for development (e.g. family-based interventions). An additional output will therefore be proposals for new interventions that could be tested in future research. Recommendations will be included where appropriate in all forms of project dissemination (journal papers, workshops etc).

Expected output of research/impact

This study requires a unique project design, namely a linked set of systematic reviews and primary studies thus yielding importance advances in understanding of smoking and smoking cessation in pregnancy with direct relevance to policy and practice. Emerging and final outputs will be fed into policy and practice via the following mechanisms:

- The working group tasked with developing an action plan for addressing smoking in pregnancy, convened by ASH and leading children's charities in response to a request from the DH and chaired by the proposed PI of this study
- The World Health Organisation's guidelines group on smoking cessation in pregnancy, formed in May 2012, in which the PI of this study is the only UK representative
- An update of NICE guidance on cessation in pregnancy planned for late 2013 /early 2014 (the study team was closely involved in developing the initial guidance in 2010)
- Content and updates of the National Centre for Smoking Cessation and Training's national training programme for cessation in pregnancy advisors (developed by a group that the PI chaired)
- The ongoing and positive working relationships with policy teams responsible for tobacco control and maternity services in England and Scotland
- Input from the NHS colleagues at each centre named as co-applicants on this study who will ensure that findings inform local and national practice developments in Scotland and England

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Appendices

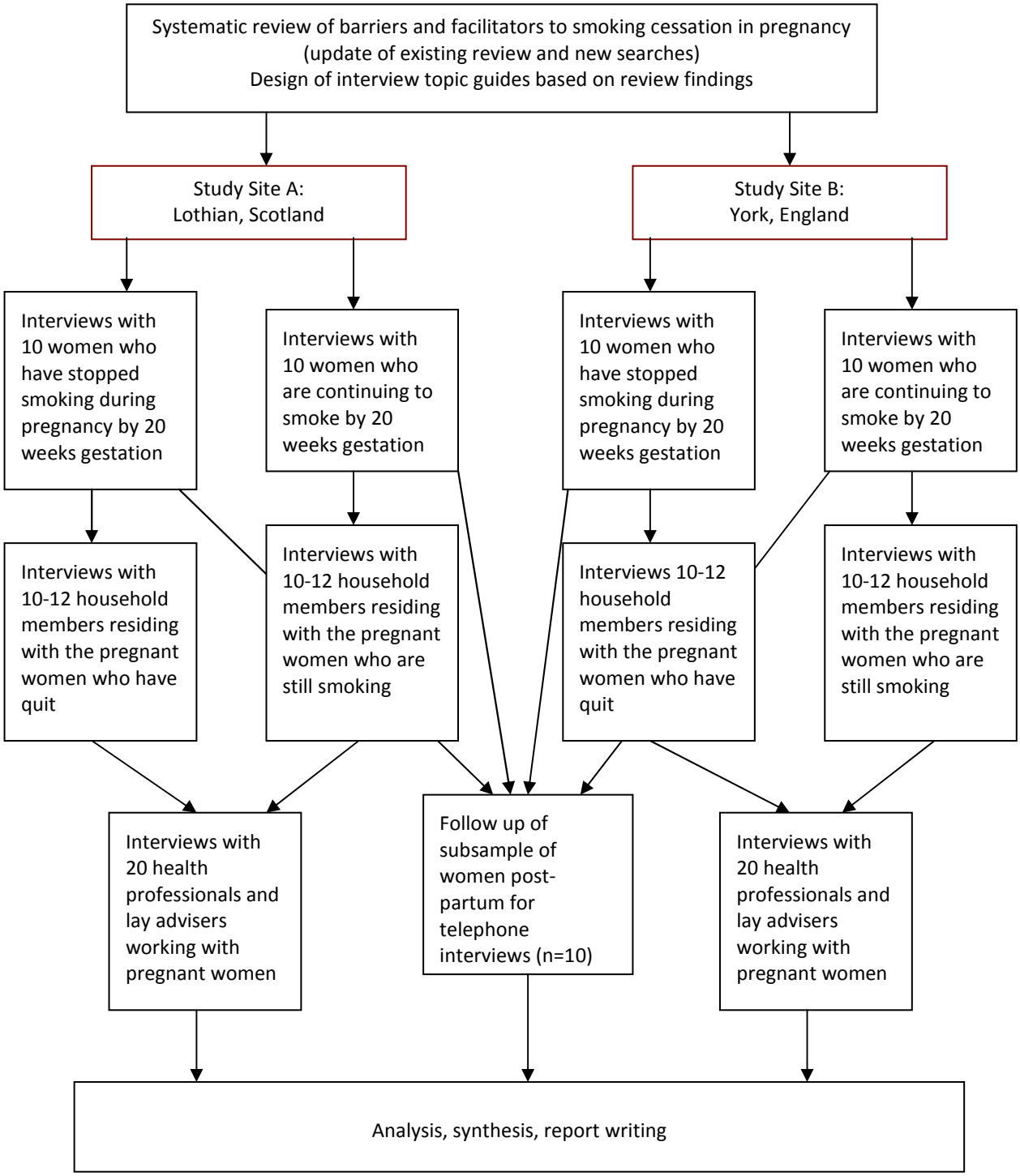
Appendix 1 Flow diagram of key study components

Appendix 2 Interview Topic Guides

Appendix 3 Participant Information Sheets

Appendix 4 Interview Consent Forms

Appendix 1 Flow diagram of key study components



Appendix 2 Interview Topic Guides

Pregnant women

Partners, family or friends of pregnant women

Healthcare professionals supporting pregnant women

DRAFT Interview schedule/topic guide for pregnant women and women who have recently given birth 21/08/2013

Generic introduction

- Introduction to the study
    1. Interviewer introduction
    2. Quick study summary
    3. Audio recording, anonymity, opportunity to ask questions etc.
    4. Consent

Warm up/context questions

- How has your pregnancy been? - when is your baby due/how many weeks are you now?
  OR
- How many weeks old is your baby now? - how have you been since giving birth?
  AND
- Are you currently smoking?

A. Smoking behaviour and history

Core interview questions or sections are marked with an *. All others remaining can be skipped depending upon time available.

If interviewee is currently smoking ask the *current smoking behaviour* questions below. If not, proceed to *Recent quit attempt* (for current non-smokers)

*Current smoking behaviour (for current smokers)**

- How would you describe your smoking? (conversation opener)
    - P Heavy or light smoker; occasional or regular; a weekend/social smoker?
- On average, how many cigarettes do you smoke per day?
    - P 5 or less; 6-10; 11-20; 21-30; more than 30
- How soon after waking do you usually smoke your first cigarette?
    - P within 5 mins; 6-30 mins; 31-60 mins, over 60 mins
- Triggers for smoking e.g. spending time with family/friends; stressful situations; boredom
- Any changes in smoking habits post pregnancy
- Motivation to quit in pregnancy
    - P [If planning to quit during pregnancy] When they plan to quit
    - P [If planning to quit during pregnancy] Whether they plan to quit/stay quit beyond pregnancy

*Recent quit attempt (for current non-smokers)**

- How would you describe your smoking prior to quitting? (conversation opener)
  - P Heavy or light smoker; occasional or regular; a weekend/social smoker?
- On average, how many cigarettes did you smoke per day?
  - P 5 or less; 6-10; 11-20; 21-30; more than 30
- How soon after waking did you usually smoke your first cigarette?
  - P within 5 mins; 6-30 mins; 31-60 mins, over 60 mins
- Triggers for smoking e.g. spending time with family/friends; stressful situations; boredom
- Any changes in smoking levels post discovery of pregnancy and prior to quit attempt
- Motivation for recent quit
  - P Length of time between decision and making quit attempt (e.g. "How long between making decision and quit")
  - P Motivation to stay quit throughout pregnancy
  - P Motivation to stay quit beyond pregnancy
- General experience of quitting [skip if time limited]
  - P Easy/difficult; variation depending upon point in time

Previous quit attempts

- Ever attempted to quit smoking
- How many times; duration of previous quits;
  - P Any previous quits in pregnancy
- Motivation for previous quit attempts
- Feelings/thoughts about previous quit attempts
- How were previous quits attempted
  - P Any previous use of NRT
  - P Any previous use of behavioural support

*Beliefs/feelings about smoking**

- General beliefs/feelings about smoking
- Thoughts on quitting smoking in pregnancy i.e. negative/positive evaluation (if not already discussed)
  - P [negative] Beliefs about the harms of smoking during pregnancy and likelihood of them/their baby experiencing those harms (e.g. "What is your take on whether smoking during pregnancy is harmful for babies?/Do you think the risks associated with smoking in pregnancy are exaggerated?" and [if currently smoking] "Do you think your baby is at risk of harm from your smoking?")
  - P Perceived disadvantages of quitting smoking (e.g. Whether or not enjoys/enjoyed smoking)
  - P Perceived advantages of quitting smoking

*Smoking behaviour within household and among family and friends**

- Number of smokers in household
- Number of smokers amongst close family
- Number of friends that smoke
- Extent to which smoke with partner, family or friends – importance within relationships

[Ask interviewee to recommend a significant other who they feel would be important for us to speak to regarding the interviewee's smoking behaviour in pregnancy.]

- Any current attempts by partner/family member/friend (focus on significant other) to provide support for stopping smoking
- Any attempts in previous pregnancies by partner/family member/friend (focus on significant other) to provide support for stopping smoking

B, Perceived barriers and facilitators to cessation in pregnancy

*Confidence in quitting/staying quit during pregnancy**

- Control beliefs, considering internal (e.g. skills, emotions, information) and external (e.g. opportunities, barriers etc.) control factors
    - P "Do you feel your ability to quit/stay quit is within your control"

*Relationships with significant others inc. partner, family and friends**

- Feelings and thoughts about partner's/other household members' smoking (if applicable)
- Attitude of significant other to smoking in pregnancy and quitting (if not already discussed)
    - P [if currently smoking] attitudes of significant other on participant's smoking behaviour (e.g. "What do you think your [significant other] thinks about you currently smoking?")
    - P [if not currently smoking] attitudes of significant other on participant's smoking behaviour (e.g. "What do you think [significant other] would think if you had continued to smoke during pregnancy?")
- Partner/family/friends' attitudes to smoking in pregnancy and quitting
    - P [if currently smoking] attitudes of partner/family/friends on participant's smoking behaviour (e.g. "What do you think [partner/family/friends'] think about you currently smoking?")
    - P [if not currently smoking] attitudes of partner/family member/friends on participant's smoking behaviour (e.g. "What do you think [partner/family/friends] would think if you had continued to smoke during pregnancy?")

- Others' smoking in pregnancy behaviour (e.g. "What have other smokers that you know done when they became pregnant?")
- Any changes to where smoking takes place within household since discovery of pregnancy [skip if time limited]
    - P Smoking outside; smoking in particular rooms; at open doorways or windows.
    - P Feelings on ability to introduce smoking restrictions in home/around her
- Impact of changes in smoking behaviour on relationships
    - P [if currently smoking] spending time with smoking/non-smoking partner, family and friends (focus on significant other)
    - P [if not currently smoking] spending time with smoking/non-smoking partner, family and friends (focus on significant other)

*Accessing cessation support as a pregnant smoker**

- Experience of discussion of smoking in pregnancy with health care professionals e.g. midwife, smoking cessation adviser, GP, pharmacist, other health care professional
    - P Aspects which felt helpful/unhelpful
    - P Extent to which support received appeared consistent among different health professionals
    - P Extent to which felt in control of/felt responsible for quit attempt (e.g 'After agreeing to support from the cessation advisor, did you still feel in control of your quit?'
- Other aspects of health care which liked/disliked or found helpful/ unhelpful e.g. CO monitoring, NRT, group support
- Previous awareness of smoking cessation support available to pregnant smokers
    - P Thoughts on seeking support prior to contact with health care professionals
- Awareness of smoking cessation campaigns
    - P Feelings/thoughts about campaigns
    - P Influence of campaigns on own behaviour

Willpower

- Importance of willpower*
    - P [if currently smoking] Reasons why willpower wasn't sustained (e.g. 'It sounded like you had a plan to quit but it didn't work out – why do you think that was? What would do differently if you tried again?)
    - P [if not currently smoking] Level of influence of willpower on recent quit attempt

Other perceived barriers or facilitators

- Influence of work environment (if applicable)
    - P Opportunities for work breaks associated with smoking
    - P Spending time with colleagues who smoke

    - P Attitude of employer to smoking
- Costs of smoking/savings discovered from quitting or cutting back on smoking
- Extent to which smoking is used as a mechanism for relaxation/coping
    - P Availability of alternative strategies for leisure or dealing with stress
- Extent to which smoking is part of daily routine
    - P Availability of alternative strategies for leisure or dealing with stress
- Influence of unexpected consequences e.g. positive and negative
    - P Improved health or appearance; improved home atmosphere and appearance; increased appetite; substitution with food (weight-gain)
- Other unanticipated barriers and facilitators

C, Views on available and in development interventions

*Current smoking cessation interventions**

- Thoughts on brief interventions delivered by GPs or midwives
    - P Views on appropriateness of discussion of smoking in pregnancy with generic health professionals and associated support
- Thoughts on availability of smoking cessation support services
    - P Importance of specialist support services especially those designed specifically for pregnant smokers
- Thoughts on self help intervention (e.g. leaflets, websites, text message support, apps for smartphones)
    - P Views on availability of information and resources enabling self-supported quit
- Thoughts on using financial incentives to encourage cessation
    - P Views on types of possible incentives for supporting smoking cessation

*Future interventions**

- Preferred types of support for stopping smoking (in an ideal world)
    - P Characteristics of preferred type of support e.g. timing, nature of approach, people involved; nature and level of ogoing contact
- Thoughts on interventions involving partner, family and friends
    - P Perceptions of significant other's potential willingness to take part in an intervention involving them as well as self (e.g. "Do you think [significant other] would be willing to join you in a scheme to assist in stopping smoking during pregnancy?"]
    - P Perceptions of partner/family/friends' potential willingness to take part in an intervention involving them as well as self (e.g. "Do you think [partner/family/friends] would be willing to join you in a scheme to assist in stopping smoking during pregnancy?"]

DRAFT Interview schedule/topic guide for household members/significant others 21/08/2013

Generic introduction

- Introduction to the study
    1. Interviewer introduction
    2. Quick study summary
    3. Audio recording, anonymity, opportunity to ask questions etc.
    4. Consent

Warm up/context questions

- How long is it before the baby arrives now?
  OR
- How many weeks old is the baby now? - How has it been since the baby arrived?

A. Smoking behaviour and history

Determine if interviewee is a smoker. Do you smoke at all? If interviewee has smoked within the last year, ask the smoking questions below. If not, proceed to *beliefs/feelings about smoking* (smokers and non smokers) questions.

Core interview questions or sections are marked with an *. All others remaining can be skipped depending upon time available.

Current smoking behaviour (for current or recent smokers)

- How would you describe your smoking? (conversation opener)
    - P Heavy or light smoker; occasional or regular; a weekend/social smoker?
- On average, how many cigarettes do/did you smoke per day?*
    - P 5 or less; 6-10; 11-20; 21-30; more than 30
- How soon after waking do/did you usually smoke your first cigarette?*
    - P within 5 mins; 6-30 mins; 31-60 mins, over 60 mins
- Triggers for smoking e.g. spending time with family/friends; stressful situations; boredom
- Any changes in smoking habits post discovery of pregnancy*
- Motivation to quit during pregnancy (if not already quit)
    - P [If planning to quit during pregnancy] When they plan to quit
    - P [If planning to quit during pregnancy] Whether they plan to quit/stay quit beyond pregnancy

*Beliefs/feelings about smoking**

- General beliefs/feelings about smoking
- Thoughts on quitting smoking in pregnancy i.e positive/negative evaluation
    - P [negative] Beliefs about the harms of smoking during pregnancy and likelihood of them/their baby experiencing those harms (e.g. "What is your take on whether smoking during pregnancy is harmful for babies?/Do you think the risks associated with smoking in pregnancy are exaggerated?" and [if woman still smoking] "Do you think [woman's name]'s baby is at risk of harm from smoking?")
    - P Perceived disadvantages of woman quitting smoking in pregnancy
    - P Perceived advantages of woman quitting smoking in pregnancy

*Smoking behaviour within household and among family and friends of pregnant woman**

- Number of smokers in household
- Number of smokers amongst close family
- Number of friends that smoke
- Extent to which smoke with woman – importance within relationships
- Any current attempts at providing support to woman to stop smoking (if not already discussed)
- Any attempts in previous pregnancies at providing support to woman to stop smoking
    - P [if significant other participant currently smoking] Any changes in personal smoking habits in previous pregnancies

B. Perceived barriers and facilitators to cessation in pregnancy

*Confidence in woman's ability to quit/staying quit during pregnancy**

- Control beliefs, considering internal (e.g. skills, emotions, information) and external (e.g. opportunities, barriers etc.) control factors
    - P "Do you you think it's within [woman's name]'s control to quit/stay quit during her pregnancy"

*Relationships with close others**

- Knowledge of woman's views on smoking in pregnancy and quitting
- Attitude of significant other to smoking in pregnancy and quitting (if not already discussed)
    - P [if woman currently smoking] attitude of significant other on woman's smoking behaviour (e.g. "What do you think about [woman's name] currently smoking?")
    - P [if woman not currently smoking] attitudes of significant other on woman's smoking (e.g. "What do you think you would have thought if [woman's name] had continued to smoke during pregnancy?")
- Partner/family/friends' attitudes to smoking in pregnancy and quitting

  - [if woman currently smoking] attitudes of partner/family/friends' on woman's smoking behaviour (e.g. "What do you think [partner/family/friends'] think about [woman's name] currently smoking?")
  - [if woman not currently smoking] attitudes of partner/family/friends on woman's smoking behaviour (e.g. "What do you think [partner/family/friends] would think if [woman's name] had continued to smoke during pregnancy?")
- Other's smoking in pregnancy behaviour (e.g "What have other smokers that you have known done when they became pregnant?")
- Changes in smoking behaviour within household since discovery of pregnancy (if not already discussed) [skip if time limited]
  - Smoking outside; smoking in particular rooms; at open doorways or windows.
  - Perceptions of extent to which woman feels able to introduce restrictions in home/around her
- Impact of changes in smoking behaviour on relationships
  - Spending time with woman
  - Spending time with woman and others

*Pregnant smokers accessing cessation support**

- Knowledge or experience of woman's discussion of smoking in pregnancy with health care professionals e.g. midwife, smoking cessation adviser, GP, pharmacist, other health care professional
  - Any aspects that felt were helpful/unhelpful
  - Extent to which support received appeared consistent amongst different professionals
  - Extent to which significant other perceived woman to have felt in control of/responsible for quit attempt after involvement of health professionals (e.g. "After agreeing to cessation support, do you think she still felt in control of her quit")
- Other aspects of health care which liked/disliked or were helpful/ unhelpful e.g. CO monitoring, NRT, group support
- Previous awareness of smoking cessation support available to pregnant smokers
  - Thoughts on seeking support prior to contact with health care professionals
- Awareness of smoking cessation campaigns
  - Feelings/thoughts about campaigns
  - Influence of campaigns on woman's behaviour

*Personal motivations and willpower**

- Knowledge of woman's motivations for quitting and perceived importance
- Importance of willpower
    - P [if woman currently smoking] Reasons why willpower wasn't sustained (e.g. 'It sounded like [woman's name] had a plan to quit but it didn't work out – why do you think that was? What do you think they could do differently if they tried again?)
    - P [if woman not smoking] e.g. How important was [woman's name]'s level of willpower within their recent quit attempt

Other perceived barriers or facilitators

- Influence of work environment on woman's quit attempt (if applicable)
- Costs of smoking/savings discovered from quitting or cutting back on smoking
- Extent to which smoking is used as a mechanism by woman for relaxation/coping
- Extent to which smoking is part of woman's daily routine
- Perception of influence of unexpected consequences for woman e.g. positive and negative
    - P Improved health or appearance; improved home atmosphere and appearance; increased appetite; substitution with food (weight-gain)
- Other unanticipated barriers and facilitators

C. Views on available and in development interventions

*Current smoking cessation interventions**

- Thoughts on brief interventions delivered by GPs or midwives
    - P Views on appropriateness of discussion of smoking in pregnancy with generic health professionals and associated support
- Thoughts on availability of smoking cessation support services
    - P Importance of specialist support services especially those designed specifically for pregnant smokers
- Thoughts on self help intervention (e.g. leaflets, websites, text message support, apps for smartphones)
    - P Views on availability of information and resources enabling self-supported quit
- Thoughts on using financial incentives to encourage cessation
    - P Views on types of possible incentives for supporting smoking cessation

*Future interventions**

- Types of support for stopping smoking most beneficial to pregnant smokers (in an ideal world)
    - P Characteristics of preferred type of support e.g. timing, nature of approach, people involved; nature and level of ongoing contact

- Thoughts on interventions involving partner, family and friends as well as woman
    - P Significant other's willingness to take part in an intervention involving them as well as pregnant woman (e.g. "What do you think of the idea of partners/significant others taking part in a scheme to help pregnant women to stop smoking" followed by "Do you think this is something you could see yourself participating in with [woman's name]?"]
    - P Perceptions of partner/family/friends' potential willingness to take part in an intervention involving them as well as self (e.g. "Do you think [partner/family/friends] would be willing to take part in a scheme with [woman's name] to assist her in stopping smoking during pregnancy?"]

Interview schedule/topic guide for health professional interviews V2.0 30/05/2013
(P=example probe)

Generic introduction

Introduction to the study

1. Interviewer introduction
2. Quick study summary
3. Audio recording, anonymity, opportunity to ask questions etc.
4. Consent
5. Ask what their role is and involves – to describe in their own words

A. Health professionals with clinical contact with pregnant smokers

Topic - Support routinely provided to pregnant smokers

- Example question: What advice or support would you routinely provide when you see a [pregnant/recently delivered] women who smokes?
  - P Seeing the provision of advice or support to quit smoking as part of role
  - P Local support options to help [pregnant/recently delivered] smokers to quit smoking

Topic - Perceived barriers to quitting

- Example question: What do you think are the main barriers to quitting smoking for [pregnant/recently delivered] smokers?
  - P Barriers that women experience in their environment
  - P Barriers relating to them accessing support services (e.g. Stop Smoking Services)
  - P Barriers at a service level i.e. organisational factors that might make it harder for health professionals/services to be supportive of [pregnant/recently delivered] women quitting smoking

Topic - Perceived facilitators of quitting

- Example question: What do you think are the main facilitators to quitting smoking for [pregnant/recently delivered] smokers i.e. things which make it easier to quit?
  - P Facilitators in the women's environment
  - P Facilitators relating to support services (e.g. Stop Smoking Services)
  - P Facilitators at a service level i.e. aspects of routine care which can be helpful for [pregnant/recently delivered] women quitting smoking

Topic – Perceived behavioural control regarding provision of advice and support

- Example question: How confident do you feel talking to [pregnant/recently delivered] smokers about smoking and advising them to stop/referring them to support?
  - P Main issues involved as a midwife to do this

- P Have necessary resources to do this (e.g. internal – confidence, skills, etc.; external – facilities, time, etc.)?

Topic – Women's expectations regarding discussion on smoking

- Example question: What do you think [pregnant/recently delivered] smokers expect in terms of a discussion on smoking or offer of support?
  - P Experience of reactions to bringing up the issue of smoking or offering support

Topic – Effectiveness of smoking cessation support

- Example question: How effective do you think the smoking cessation support offered by your (local) service is?
  - P Brief advice to quit, behavioural support or pharmacological support e.g. nicotine replacement therapy etc.
  - P Chances of quitting if woman is referred/recommend to see a Stop Smoking Service advisor

Topic – Support needed for pregnant smokers

- Example question: Are there some kinds of smoking cessation interventions which [pregnant/recently delivered] smokers would benefit from which are not currently available?
  - P Family/social network interventions
  - P *Of any support mentioned:* Main aspects of support which would make it acceptable, feasible and effective (possible additional probes: timing, nature of approach, people involved, nature of continued contact etc.)

Topic – Clinical importance of smoking cessation in pregnancy (relative to other modifiable risks)

- Example question: How important is quitting smoking in pregnancy?
  - P In relation to other risk factors or unhealthy behaviours e.g. overweight, alcohol consumption
  - P Relative importance in relation to obese women losing weight in pregnancy

- Example question: What would you say are the main health effects of smoking in pregnancy?
  - P Experience of treating people with smoking-related complications

- Example question: How important is quitting smoking or staying quit after delivery?
  - P Relative importance in relation to other postnatal risks or unhealthy behaviours

Topic – Background – smoking status and training in smoking cessation

- Example question: Have you ever smoked?
  - P *If yes: The* effects of this on the way smoking is approached with [pregnant/recently delivered] smokers

- Example question: What training have you received on smoking cessation?
  - P Pre-registration training, CPD etc.
  - P Training needs regarding smoking cessation in [pregnancy/after delivery]?
  - P Discussion on smoking in team meetings or with colleagues

B. Stop Smoking Service advisors

Topic - Support routinely provided to pregnant smokers

- Example question: What advice or support would you routinely provide when you see a pregnant woman who smokes?

Topic – Women's expectations regarding discussion on smoking

- Example question: What do you think pregnant smokers expect before they attend the support you provide?
  - P Reaction of pregnant smokers when they have received support from you or your service

Topic - Perceived barriers to quitting

- Example question: What do you think are the main barriers to quitting smoking for pregnant smokers?
  - P Barriers that women experience in their environment
  - P Barriers relating to them accessing support services (e.g. Stop Smoking Services)
  - P Barriers within antenatal care i.e. organisational factors that might make it harder for health professionals/services to be supportive of pregnant women quitting smoking

Topic - Perceived facilitators of quitting

- Example question: What do you think are the main facilitators to quitting smoking for pregnant smokers i.e. things which make it easier to quit?
  - P Facilitators in the women's environment
  - P Facilitators relating to support services (e.g. Stop Smoking Services)
  - P Facilitators within antenatal care i.e. aspects of routine care which can be helpful for [pregnant/recently delivered] women quitting smoking

Topic – Effectiveness of smoking cessation support

- Example question: How effective do you think the smoking cessation support offered by your service is?
  - P Relative effectiveness of different forms of support e.g. behavioural support/counselling, pharmacological support e.g. nicotine replacement therapy etc.
  - P Chances of quitting if woman is seen by service

Topic – Support needed for pregnant smokers

- Example question: Are there some kinds of smoking cessation interventions which [pregnant/recently delivered] smokers would benefit from which are not currently available?
    - P Family/social network interventions
    - P *Of any support mentioned:* Main aspects of support which would make it acceptable, feasible and effective (possible additional probes: timing, nature of approach, people involved, nature of continued contact etc.)

Topic – Clinical importance of smoking cessation in pregnancy (relative to other modifiable risks)

- Example question: How important is quitting smoking in pregnancy?
    - P In relation to other risk factors or unhealthy behaviours e.g. overweight, alcohol consumption
    - P Relative importance in relation to obese women losing weight in pregnancy

- Example question: What would you say are the main health effects of smoking in pregnancy?
    - P Experience of treating people with smoking-related complications

- Example question: How important is quitting smoking or staying quit after delivery?
    - P Relative importance in relation to other postnatal risks or unhealthy behaviours

Topic – Background – smoking status and training in smoking cessation

- Example question: Have you ever smoked?
    - P *If yes: The* effects of this on the way smoking is approached with [pregnant/recently delivered] smokers

- Example question: What training have you received on smoking cessation?
    - P Training needs regarding smoking cessation in pregnancy or after delivery

C. Managers and commissioners

Topic - Perceived barriers to quitting

- Example question: What do you think are the main barriers to quitting smoking for [pregnant/recently delivered] smokers?
  - P Barriers that women experience in their environment
  - P Barriers relating to them accessing support services (e.g. Stop Smoking Services)
  - P Barriers at a service level i.e. organisational factors that might make it harder for health professionals/services to be supportive of [pregnant/recently delivered] women quitting smoking

Topic - Perceived facilitators of quitting

- Example question: What do you think are the main facilitators to quitting smoking for [pregnant/recently delivered] smokers i.e. things which make it easier to quit?
  - P Facilitators in the women's environment
  - P Facilitators relating to support services (e.g. Stop Smoking Services)
  - P Facilitators at a service level i.e. aspects of routine care which can be helpful for [pregnant/recently delivered] women quitting smoking

Topic – Effectiveness of smoking cessation support

- Example question: How effective do you think the smoking cessation support offered by your (local) service is?
  - P Brief advice to quit, behavioural support or pharmacological support e.g. nicotine replacement therapy etc.
  - P Chances of quitting if woman is referred/recommend to see a Stop Smoking Service advisor

Topic – How smoking cessation support be improved in service

- Example question: From a [management/commissioning] perspective, in what ways could the provision of support for pregnant smokers be improved within your service?

- Example question: What recent developments in national guidance related to smoking in pregnancy do you think are most significant in terms of their potential to benefit maternal and infant health?
  - P Changes or developments, if any, in national guidance that are needed

Topic – Support needed for pregnant smokers

- Example question: Are there some kinds of smoking cessation interventions which [pregnant/recently delivered] smokers would benefit from which are not currently available?
  - P Family/social network interventions

- P *Of any support mentioned:* Main aspects of support which would make it acceptable, feasible and effective (possible additional probes: timing, nature of approach, people involved, nature of continued contact etc.)

Topic – Clinical importance of smoking cessation in pregnancy (relative to other modifiable risks)

- Example question: How important is quitting smoking in pregnancy?
  - P In relation to other risk factors or unhealthy behaviours e.g. overweight, alcohol consumption
  - P Relative importance in relation to obese women losing weight in pregnancy

- Example question: How important is quitting smoking or staying quit after delivery?
  - P Relative importance in relation to other postnatal risks or unhealthy behaviours

Appendix 3 Participant Information Sheets:

Pregnant women in Lothian

Pregnant women at York

Partners, family or friends of pregnant women

Healthcare professionals supporting pregnant women

Tear-off sheet for partners, family or friends of pregnant women

UNIVERSITY OF STIRLING
THE UNIVERSITY of York
NHS Lothian
York Teaching Hospital NHS NHS Foundation Trust

What helps women and what holds women back from stopping smoking during pregnancy

Information sheet for pregnant women in Lothian
Version 2.0 31.05.2013

You are being invited to take part in a research study. Before you decide whether or not to take part, we would like you to understand why the study is being done and what it would involve for you.

Please take time to read this information carefully and talk about it with others if you want. Feel free to ask us about anything that is not clear. Our contact details are at the end of this sheet. We will do our best to explain and to provide any further information you may ask for.

If you think that you would like to take part in the study there are two ways that you can let us know:

1. You can contact Lesley Sinclair (one of the study researchers) on 0141 201 0804 who will give you a brief explanation of the study, answer any questions that you have and then ask you to confirm if you still want to take part.

2. You can let your stop smoking facilitator know at your next appointment that you would like to take part. Your stop smoking facilitator will then give you a brief explanation of the study and, with your permission, pass on your contact details to the study research team. Lesley Sinclair (one of the study researchers) will then phone you, answer any questions that you have and ask you to confirm if you still want to take part in the study.

Thank you for taking the time to read this.

What is the study about?

We want to find out what you think about smoking and pregnancy. We know that some women keep smoking during their pregnancy and others do not. We would like to know more about why that is. We would also like to know what you think about the help and advice that is available to pregnant women about smoking and whether there is anything that healthcare staff could improve on to help pregnant women with their choices about smoking.

We would like to speak to 40 pregnant women who smoke or have recently stopped smoking. We would also like to speak to their partners or other family members and to healthcare staff. We are doing this in order to learn more about the best ways to help pregnant smokers who want to stop smoking. We do not expect that you will change your smoking habits as a result of talking to us. However, if you or anyone you know is interested in stopping smoking please see contact details at the end of this information sheet.

Why have I been invited to take part?

You have been invited to take part because you are a pregnant woman who smokes or has recently stopped smoking and we are interested in your views. We are aiming to speak to women with a range of views.

Do I have to take part?

No, taking part in this study is entirely up to you. You are free to say that you do not want to take part in the study without giving a reason. Your choice will not affect your pregnancy care or any help that you may wish to receive from the stop smoking services.

What will happen to me if I agree to take part?

If you agree to take part the research team will keep in contact with you (by text) until you are around five months pregnant. At this time a member of the research team will contact you to arrange to come and speak with you and you will receive a letter confirming these arrangements. The researcher will come to your own home or to another place of your choice, e.g. GP Surgery, Hospital, at a time that suits you. Reasonable travel expenses will be paid if you choose to meet with the researcher at a place away from your own home.

The interviewer that you meet will be an experienced researcher from the University of Stirling who is used to talking with pregnant women about smoking. When you meet the researcher you will be asked to sign a consent form to say that you are happy to take part. You will also be asked if you are happy for your conversation to be recorded. This is to make sure that we can listen carefully and don't miss anything that you say. Your name and anything that could lead to anyone being able to identify you will be removed from the recording.

The conversation will be quite relaxed and will last up to 45 minutes. During the conversation the researcher will ask you questions about your views and experience of smoking and pregnancy and if these have changed since you became pregnant. The researcher will also ask you what you think about the help and advice that is available to pregnant women about smoking and what kind of things you think could help pregnant women who want to stop smoking to really stop. You are free to contribute as much or as little as you wish. You can stop the conversation with the researcher at any time without giving a reason.

At the end of the conversation with the researcher you will be given a sheet with a tear-off paper slip that has brief details of the study and the researchers' contact details to pass on to your partner/ another family member. If your partner/ family member wishes to find out more about the study, they can contact the researcher. Their participation will be entirely voluntary. We will be talking to them about their views on smoking and what does or does not help pregnant women quit.

You will also be asked at the end of the conversation if the research team can contact you again about 4-6 weeks after you have had your baby to find out if you are smoking or not and ask you if you are willing to take part in a second interview. If you agree to this, the research team will arrange a time and place to come and speak with you and you will receive a letter confirming these arrangements. As with the first interview you will be asked to sign a consent form when you meet the researcher to say that you are happy to take part. The interview itself will be similar to the first one.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the study will be kept strictly confidential. We will not share what you tell us with your partner, other family members or NHS staff. The researchers you speak to are not part of the NHS. We will however inform your GP that you are taking part in the study unless you tell us not to. Also, if you tell us something, which we believe places you or others at serious risk, we are obliged to pass this information on to the relevant persons.

What you tell us will be looked at along with those of others taking part in the study. No-one will be able to recognise you from any report about the study as you will not be named in any study reports.

The audio recordings of your conversation with the researcher will be listened to and written down in full. Your name and anything that could lead to anyone being able to identify you will be removed from these audio recordings and written notes. Only members of the research team will have access to these audio recordings and written notes and these will be kept in offices at the University of Stirling at all times (in locked filing cabinets and password protected computers). At the end of the study the audio recordings will be wiped out. The written notes will be stored for ten years and then they will be destroyed, according to University policy.

What are the possible benefits of taking part?

Taking part in this research may not help you personally, although you may like having a chance to talk about your experiences and to know that what you tell us may help others in the future.

What are the disadvantages of taking part in the study?

Taking part in the study will use up some of your own time. Also, some people find talking about smoking and pregnancy difficult. The researcher will be sensitive to all the issues raised but if you find talking to the researcher makes you anxious or upset, you can stop the conversation at any time.

What if there is a problem?

If you have cause to complain about the way in which you have been treated by a member of the research team during the study you can contact Ms Diane Dixon at the University of Stirling or the NHS Lothian Complaints team. Contact details are at the end of this sheet. You are free to pull out of the study at any time without affecting your future health care and without giving a reason.

What will happen to the results of the study?
At the end of study we will send you a summary of the results that we hope will help the NHS to improve choices for pregnant smokers who want to stop smoking.

The study findings will be presented in a report for the people who are paying for the study to take place. They will also be printed in educational magazines, NHS staff newsletters, patient support services and will be presented at local, health board, national and international meetings.

Will I receive money for taking part?
Yes, you will receive a £15 shopping voucher that can be used in many high street shops at the end of the interview as a thank-you for taking part. You will be required to sign a receipt for this payment.

Who is carrying out the study?
This study is being carried out by researchers at the Universities of Stirling and York. NHS Lothian and NHS North Yorkshire and York are involved in the research too. The study is being funded by the NHS National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. HTA Project Number: 11/93/01.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the South East Scotland Research Ethics Committee 01.

Contact for further information
If you would like further information about any part of the study, please contact Carol Anne Greenan, Research Secretary, School of Management, University of Stirling, Stirling FK9 4LA, Tel: 01786 467347, Email: carol.anne.greenan@stir.ac.uk

Contact for concern or complaint
If you have a concern or complaint and would like to speak to someone independent who is not involved in the study, please contact:

Diane Dixon, School of Management, University of Stirling, Stirling FK9 4LA
Tel: 01786 467390, Email: d.m.dixon@stir.ac.uk

NHS Lothian Complaints Team, Waverley Gate, 2–4 Waterloo Place, Edinburgh, EH1 3EG
Telephone: 0131 536 3370, Email: complaints.team@nhslothian.scot.nhs.uk

Interested in stopping smoking?
If you or anyone you know is interested in stopping smoking you can find information on how to stop smoking and details of stop smoking support services in your area at www.nhslothian.scot.nhs.uk or you can phone Smokeline on 0800 84 84 84 and they will put you in touch with your nearest stop smoking support service.

THANK YOU for taking the time to read this information sheet

We are grateful to you for thinking about taking part in the study

UNIVERSITY OF STIRLING THE UNIVERSITY of York NHS Lothian York Teaching Hospital NHS NHS Foundation Trust

What helps women and what holds women back from stopping smoking during pregnancy

Information sheet for pregnant women at York
Version 2.1 12.06.2013

You are being invited to take part in a research study. Before you decide whether or not to take part, we would like you to understand why the study is being done and what it would involve for you.

Please take time to read this information carefully and talk about it with others if you want. Feel free to ask us about anything that is not clear. Our contact details are at the end of this sheet. We will do our best to explain and to provide any further information you may ask for.

When you come for your 12 week scan *(Dating or Nuchal Transluency Scan),* you will be contacted by the research midwife, Beverley Stark. She will take you through this Information Sheet and can answer any questions that you have. She will then ask you to confirm if you want to take part in the study.

Thank you for taking the time to read this

What is the study about?

We know that some women keep smoking during their pregnancy and others do not. By talking directly to pregnant women, we would like to understand more about why that is. We would also like to know what you think about the help and advice that is available to pregnant women about smoking and whether there is anything that healthcare staff could do to improve the support they give to pregnant women with their choices about smoking.

We would like to speak to 40 pregnant women who smoke or have recently stopped smoking. We also would like to speak to their partners or other family members and to healthcare staff. We are doing this in order to learn more about the best ways to help pregnant smokers who want to stop smoking. We do not expect that you will change your smoking habits as a result of talking to us. However, if you or anyone you know is interested in stopping smoking please see contact details at the end of this information sheet.

Why have I been invited to take part?

You have been invited to take part because you are a pregnant woman who smokes or has recently stopped smoking and we are interested in your views. We are aiming to speak to women with a range of views.

Do I have to take part?

No, taking part in this study is entirely up to you. The research midwife will contact you at your 12 week scan *(Dating or Nuchal Transluency Scan)* to ask you if you would like to take part in the study. You are free to say no without giving a reason. Your choice will not affect your pregnancy care or any help that you may wish to receive from the stop smoking services.

What will happen to me if I agree to take part?

When you meet the research midwife you will be asked to sign a consent form to say that you are happy to meet a researcher to talk about smoking. You will also be asked if you are happy for your conversation to be recorded. This is to make sure that we can listen carefully and don't miss anything that you say. Your name and anything that could lead to anyone being able to identify you will be removed from the recording. At this time, you will also be given a sheet with a tear-off paper slip that has brief details of the study and the researcher's contact details to pass on to your partner/another family member. If your partner/ family member wishes to find out more about the study, they can contact the researcher.

You will be contacted by a researcher around the time you are five months pregnant and possibly again after you have had your baby. The researcher will come to your own home or to another place of your choice e.g. GP Surgery, Hospital, at a time that suits you. Reasonable travel expenses will be paid if you choose to meet with the researcher at a place away from your own home. The interviewer that you meet will be an experienced researcher from the University of York who is used to talking with pregnant women about smoking.

The conversation will be quite relaxed and will last up to 45 minutes. During the conversation the researcher will ask you questions about your views and experience of smoking and pregnancy and if these have changed since you became pregnant. The researcher will also ask you what you think about the help and advice that is available to pregnant women about smoking and what kind of things you think could help pregnant women who want to stop smoking to really stop. You can stop the conversation with the researcher at any time without giving a reason.

At the end of the conversation with the researcher, you will be given a sheet with a tear-off paper slip that has brief details of the study and the researcher's contact details to pass on to your partner/another family member (if you haven't already done so at the 12 week scan). If your partner/ family member wishes to find out more about the study, they can contact the researcher. Their participation will be entirely voluntary. We will be talking to them about their views on smoking and what does or does not help pregnant women quit.

You will also be asked at the end of the conversation if the research team can contact you again about 4-6 weeks after you have had your baby to find out if you are smoking or not and ask you if you are willing to take part in a second interview. If you agree to this, the research team will arrange a time and place to come and speak with you and you will receive a letter confirming these arrangements. As with the first interview, you will be asked to sign a consent form when you meet the researcher to say that you are happy to take part. The interview will be similar to the first one.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the study will be kept strictly confidential. We will not share what you tell us with your partner, other family members or NHS staff. The researchers you speak to are not part of the NHS. We will however inform your GP that you are taking part in the study unless you tell us not to. Also, if you tell us something, which we believe places you or others at serious risk, we are obliged to pass this information on to the relevant persons.

The audio recordings of your conversation with the researcher will be listened to and written down in full. Your name and anything that could lead to anyone being able to identify you will be removed from these audio recordings and written notes. Only members of the research team will have access to these audio recordings and written notes and these will be kept in offices at the Universities of York and Stirling at all times (in locked filing cabinets and password protected computers).

At the end of the study the audio recordings will be destroyed. The written notes will be stored for ten years and then they will be destroyed, according to University policy. No-one will be able to recognise you from any report about the study as you will not be named in any study reports.

What are the possible benefits of taking part?

Taking part in this research may not help you personally, although you may like having a chance to talk about your experiences and to know that what you tell us may help others in the future.

What are the disadvantages of taking part in the study?

Taking part in the study will use up some of your own time. Also, some people find talking about smoking and pregnancy difficult. The researcher will be sensitive to all the issues raised but if you find talking to the researcher makes you anxious or upset, you can stop the conversation at any time.

What if there is a problem?

If you have cause to complain about the way in which you have been treated by a member of the research team during the study you can contact Prof Ian Watt at the University of York or the NHS North Yorkshire & York Complaints team (details below). You are free to pull out of the study at any time without affecting your future health care and without giving a reason.

What will happen to the results of the study?
At the end of study we will send you a summary of the results that we hope will help the NHS to improve choices for pregnant smokers who want to stop smoking.

The study findings will be presented in a report for the people who are paying for the study to take place. They will also be printed in educational magazines, NHS staff newsletters, patient support services and will be presented at local, health board, national and international meetings.

Will I receive money for taking part?
Yes, you will receive a £15 shopping voucher that can be used in many high street shops at the end of the interview as a thank-you for taking part. You will be required to sign a receipt for this payment.

Who is carrying out the study?
This study is being carried out by researchers at the Universities of Stirling and York. NHS Lothian and NHS North Yorkshire and York are involved in the research too. The study is being funded by the NHS National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. HTA Project Number: 11/93/01.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the South East Scotland Research Ethics Commitee 01 as NHS North Yorkshire and York and NHS Lothian are working together on the study.

Contact for further information?
If you would like any further information about any part of the study, please contact Carol Anne Greenan, Research Secretary, School of Management, University of Stirling, Stirling FK9 4LA, Tel: 01786 467347, Email: carol.anne.greenan@stir.ac.uk

Contact for concern or complaint
If you have a concern or complaint and would like to speak to someone independent who is not involved in the study, please contact:

Professor Ian Watt, Professor of Primary and Community Care, Department of Health Sciences, University of York, York YO10 5DD (email ian.watt@york.ac.uk, tel 01904 321341)

York Teaching Hospital NHS Foundation Trust, Patient Advice and Liaison Service (PALS), Email: pals.york@york.nhs.uk, Telephone: 01904 726262 Or, write to: PALS, York Teaching Hospital NHS Trust, Freepost, NEA 11112, York, YO30 7ZZ

Interested in stopping smoking?
If you or anyone you know is interested in stopping smoking you can find information on how to stop smoking and details of smoking support services in your area at www.nyypct.nhs.uk/stayinghealthy/**StopSmoking**/ or you can phone North Yorkshire NHS Stop Smoking Service on 0300 303 1603.

THANK YOU for taking the time to read this information sheet
We are grateful to you for thinking about taking part in the study

What helps women and what holds women back from stopping smoking during pregnancy

Information sheet for partners, family & friends of pregnant women
Version 2.0 31.05.2013

You are being invited to take part in a research study. Before you decide whether or not to take part, we would like you to understand why the study is being done and what it would involve for you.

Please take time to read this information carefully and talk about it with others if you want. Feel free to ask us about anything that is not clear. Our contact details are at the end of this sheet. We will do our best to explain and to provide any further information you may ask for.

You will be phoned in a few days by a researcher who can answer any questions that you have. The researcher will then ask you to confirm if you want to take part in the study.

Thank you for taking the time to read this.

What is the study about?

We want to find out what you think about smoking and pregnancy. We know that the smoking habits of partners, family and friends of pregnant women and what they think about smoking and pregnancy can affect a pregnant woman's choice about smoking. We know that some pregnant women keep smoking during their pregnancy and others do not. We would like to know more about why that is. We would also like to know what you think about the help and advice that is available to pregnant women about smoking and whether there is anything that healthcare staff could improve on to help pregnant women with their choices about smoking.

We plan to speak to up to 50 partners, family members and friends of pregnant women who smoke or have recently stopped smoking. We also plan to speak to pregnant women themselves and to healthcare staff. We are doing this in order to learn more about the best ways to help pregnant smokers who want to stop smoking. We do not expect that you will change your smoking habits as a result of talking to us. However, if you or anyone you know is interested in stopping smoking please see contact details at the end of this information sheet.

Why have I been invited to take part?

You have been invited to take part because you are a partner, family member or friend of a pregnant woman who smokes or has recently stopped smoking and we are interested in your views. We are aiming to speak to people with a range of views.

Do I have to take part?

No, taking part in this study is entirely up to you. A researcher will contact you in a few days time to ask you if you would like to take part in the study. You are free to say no without giving a reason. Your choice will not affect your partner/relative/friend's pregnancy care or any help that she may wish to receive from the stop smoking services.

What will I have to do if I agree to take part?

If you agree to take part a member of the research team will contact you to arrange to come and speak with you around the time your partner/relative/friend is five months pregnant. We can come and chat with you at your own home or at another place of your choice e.g. GP Surgery, Hospital, at a time that suits you. Reasonable travel expenses will be paid if you choose to meet with the researcher at a place away from your own home.

The interviewer that you meet will be an experienced researcher from the University of Stirling or York who is used to talking about pregnancy and smoking. When you meet the researcher you will be asked to sign a consent form to say that you are happy to take part. You will also be asked if you are happy for your conversation to be recorded. This is to make sure that we can listen carefully and don't miss anything that you say. Your name and anything that could lead to anyone being able to identify you will be removed from the recording.

This conversation will be quite relaxed and will last up to 45 minutes. During the conversation the researcher will ask you questions about your experience of smoking and your views about smoking and pregnancy and if these have changed since your partner/relative/friend became pregnant. The researcher will also ask you what you think about the help and advice that is available to pregnant women about smoking and what kind of things you think could help pregnant women who want to stop smoking to really

stop. You are free to contribute as much or as little as you wish. You can stop the conversation with the researcher at any time without giving a reason.

Will my taking part in this study be kept confidential?
Yes. All information collected about you during the study will remain anonymous and strictly confidential. We will not share what you tell us with your partner, family or friends, or NHS staff. The researchers you speak to are not part of the NHS. However, if you tell us something, which we believe places you or others at serious risk, we are obliged to pass this information on to the relevant persons.

What you tell us will be looked at along with those of others taking part in the study. No-one will be able to recognise you from any report about the study as you will not be named in any study reports.

The audio recordings of your conversation with the researcher will be listened to and written down in full. Your name and anything that could lead to anyone being able to identify you will be removed from these audio recordings and written notes. Only members of the research team will have access to these audio recordings and written notes and these will be kept in offices at the University of Stirling or York at all times (in locked filing cabinets and password protected computers). At the end of the study the audio recordings will be wiped out. The written notes will be stored for ten years and then they will be destroyed, according to University policy.

What are the possible benefits of taking part?
Taking part in this research may not help you personally, although you may like having a chance to talk about your experiences and to know that what you tell us may help others in the future.

What are the disadvantages of taking part in the study?
Taking part in the study will use up some of your own time. Also, some people find talking about smoking and pregnancy difficult. The researcher will be sensitive to all the issues raised but if you find talking to the researcher makes you anxious or upset, you can stop the conversation at any time.

What if there is a problem?
If you have cause to complain about the way in which you have been treated by a member of the research team during the study please contact Diane Dixon at the University of Stirling or Prof Ian Watt at the University of York. Their contact details are at the end of this sheet. You are free to pull out of the study at any time without affecting your partner/relative/friend's future health care and without giving a reason.

What will happen to the results of the study?
At the end of study we will send you a summary of the results that we hope will help the NHS to improve choices for pregnant smokers who want to stop smoking.

The study findings will be presented in a report for the people who are paying for the study to take place. They will also be printed in educational magazines, NHS staff newsletters, patient support services and will be talked about at local, health board, national and international meetings.

Will I receive money for taking part?
Yes, you will receive a £15 shopping voucher that can be used in many high street shops at the end of the interview as a thank-you for taking part. You will be required to sign a receipt for this payment.

Who is carrying out the study?
This study is being carried out by researchers at the Universities of Stirling and York. NHS Lothian and NHS North Yorkshire and York are involved in the research too. The study is being funded by the NHS National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. HTA Project Number: 11/93/01.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the South East Scotland Research Ethics Committee 01.

Contact for further information
If you would like further information about any part of the study, please contact Carol Anne Greenan, Research Secretary, School of Management, University of Stirling, Stirling FK9 4LA, Tel: 01786 467347, Email: carol.anne.greenan@stir.ac.uk

Contact for concern or complaint
If you have a concern or complaint and would like to speak to someone independent who is not involved in the study, please contact either of the people below:

(If you took part in Scotland) Diane Dixon, School of Management, University of Stirling, Stirling FK9 4LA, Tel: 01786 467390, Email: d.m.dixon@stir.ac.uk

(If you took part in England) Prof Ian Watt, Department of Health Sciences, Area 2, Seebohm Rowntree Building, University of York, YO10 5DD, Tel: 01904 32 1341, Email: ian.watt@york.ac.uk

Interested in stopping smoking?
If you or someone you know is interested in stopping smoking you will find information on how to stop smoking and details of stop smoking support services in your area at : www.nhslothian.scot.nhs.uk or you can phone Smokeline on 0800 84 84 84 and they will put you in touch with your nearest stop smoking support service

www.nyypct.nhs.uk/stayinghealthy/StopSmoking/ or you can phone North Yorkshire NHS Stop Smoking Service on 0300 303 1603

THANK YOU for taking the time to read this information sheet

We are grateful to you for thinking about taking part in the study

What helps women and what holds women back from stopping smoking during pregnancy

Information sheet for healthcare professionals supporting pregnant women
Version 2.0 31.05.2013

You are being invited to take part in a research study. Before you decide whether or not to take part, we would like you to understand why the study is being done and what it would involve for you.

Please take time to read this information carefully and talk about it with others if you want. Feel free to ask us about anything that is not clear. Our contact details are at the end of this sheet. We will do our best to explain and to provide any further information you may ask for.

You will be phoned in a few days by a researcher who can answer any questions that you have. The researcher will then ask you to confirm if you want to take part in the study.

Thank you for taking the time to read this.

What is the study about?

The purpose of this study is to find out what you think about smoking and pregnancy and the support available to pregnant women who want to stop smoking. From 2001, the NHS began providing tailored support for pregnant women in clinic settings, in the home and by telephone. Feedback suggests that these services are successful in pregnancy with between one third and one half of women stopping smoking at least in the short term. However, less than one in seven pregnant smokers access these services. In addition we know access to services, and quality and delivery of services throughout the UK varies and can affect a pregnant woman's choice about smoking. We would like to know what you think about the help and advice that is available to pregnant women about smoking and whether there is anything that healthcare professionals could improve on to help pregnant women with their choices about smoking.

We plan to speak to up to 40 healthcare professionals, including midwives, health visitors and smoking cessation advisors, who have a role to play in supporting pregnant women who smoke or have recently stopped smoking. We also plan to speak to pregnant women themselves and to their partners, other family members and friends. We are doing this in order to learn more about the best ways to help pregnant smokers who want to stop smoking. We do not expect that you will change your smoking habits as a result of talking to us. However, if you or anyone you know is interested in stopping smoking please see contact details at the end of this information sheet.

Why have I been invited to take part?

You have been invited to take part because you have a key role in supporting pregnant women to stop smoking or encouraging them to access support and we are interested in your views. We are aiming to speak to health care professionals with a range of views.

Do I have to take part?

No, taking part in this study is entirely up to you. A researcher will contact you in a few days time to ask you if you would like to take part in the study. You are free to say no without giving a reason.

What will I have to do if I take part?

You will take part in a one-off interview (either by yourself or with a group of colleagues as appropriate). The format will be quite relaxed and will last up to 60 minutes and take place at a time and place that suits you. The interviewer that you meet will be an experienced researcher from the University of Stirling or York who is used to talking about pregnancy and smoking. When you meet the researcher you will be asked to sign a consent form to say that you are happy to take part. The interview will be recorded. This is to make sure that we can listen carefully and don't miss anything that you say. Your name and anything that could lead to anyone being able to identify you will be removed from the recording.

During the interview the researcher will ask you what you think about the help and advice that is available to pregnant women about smoking and what kind of things you think could help pregnant women who want to stop smoking to really stop. The researcher will also ask you about your own experience of smoking and your role in promoting smoking cessation.

You are free to contribute as much or a little to the interview as you wish. You can stop the conversation with the researcher at any time without giving a reason.

Will my taking part in this study be kept confidential?
Yes. All information collected from you during the study will remain anonymous and strictly confidential. We will not share what you tell us with your colleagues. The researchers you speak to are not part of the NHS. However, if you tell us something, which we believe places you or others at serious risk, we are obliged to pass this information on to the relevant persons.

What you tell us will be looked at along with those of others taking part in the study. No-one will be able to recognise you from any report about the study as you will not be named in any study reports.

The audio recordings of your conversation with the researcher will be listened to and written down in full. Your name and anything that could lead to anyone being able to identify you will be removed from these audio recordings and written notes. Only members of the research team will have access to these audio recordings and written notes and these will be kept in offices at the University of Stirling or York at all times (in locked filing cabinets and password protected computers). At the end of the study the audio recordings will be wiped out. The written notes will be stored for ten years and then they will be destroyed, according to University policy.

What are the possible benefits of taking part?
Taking part in the study may not help you personally, although you may like having a chance to express your views. Your help with the research is very important to obtain a better understanding about how pregnant women who smoke and wish to stop can be supported.

What are the disadvantages of taking part in the study?
Taking part in the study will use up some of your time.

What if there is a problem?
If you have cause to complain about the way in which you have been treated by a member of the research team during the study please contact Diane Dixon at the University of Stirling or Prof Ian Watt at the University of York. Their contact details are at the end of this sheet. You are free to pull out of the study at any time without giving a reason.

What will happen to the results of the study?
At the end of study we will send you a summary of the results that we hope will help the NHS to improve choices for pregnant smokers who want to stop smoking.

The study findings will be presented in a report for the people who are paying for the study to take place. They will also be printed in academic journals, NHS staff newsletters, patient support services and will be talked about at local, health board, national and international meetings.

Will I receive money for taking part?
No, you will not receive any payment for taking part.

Who is carrying out the study?
This study is being carried out by researchers at the Universities of Stirling and York. NHS Lothian and NHS North Yorkshire and York are involved in the research too. The study is being funded by the NHS National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. HTA Project Number: 11/93/01.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the South East Scotland Research Ethics Committee 01.

Contact for further information
If you would like further information about any part of the study, please contact Carol Anne Greenan, Research Secretary, School of Management, University of Stirling, Stirling FK9 4LA, Tel: 01786 467347, Email: carol.anne.greenan@stir.ac.uk

Contact for concern or complaint
If you have a concern or complaint and would like to speak to someone independent who is not involved in the study, please contact either of the people below:

(If you took part in Scotland)
Diane Dixon, School of Management, University of Stirling, Stirling FK9 4LA, Tel: 01786 467390, Email: d.m.dixon@stir.ac.uk

(If you took part in England)
Prof Ian Watt, Department of Health Sciences, Area 2, Seebohm Rowntree Building, University of York, YO10 5DD, Tel: 01904 32 1341, Email: ian.watt@york.ac.uk

Interested in stopping smoking
If you or someone you know is interested in stopping smoking you will find information on how to stop smoking and details of stop smoking support services in your area at:

www.nhslothian.scot.nhs.uk or you can phone Smokeline on 0800 84 84 84 and they will put you in touch with your nearest stop smoking support service

www.nyypct.nhs.uk/stayinghealthy/**StopSmoking**/or you can phone North Yorkshire NHS Stop Smoking Service on 0300 303 1603

THANK YOU for taking the time to read this information sheet

We are grateful to you for thinking about taking part in the study

UNIVERSITY OF STIRLING | THE UNIVERSITY of York | NHS Lothian | York Teaching Hospital NHS Foundation Trust

What helps women and what holds women back from stopping smoking during pregnancy

You are being invited to take part in a research study that is being carried out to find out more about the best ways to help pregnant smokers who want to stop smoking. We would like to talk to partners, family members and friends of pregnant women who smoke or have recently stopped smoking as we are interested in your views. You can help us by volunteering to take part.

Taking part in the study will involve no more than an hour of your time and everyone who completes an interview will receive a £15 voucher that can be used in many high street shops as a thank-you for taking part.

If you would like to find out more about the study you can request a Study Information Sheet by returning the slip below in the reply paid envelope provided OR by contacting Lesley Sinclair (Researcher) on 0141 201 0408 or l.a.sinclair@stir.ac.uk.

Thank you for taking the time to read this

What helps women and what holds women back from stopping smoking during pregnancy

Please send a Study Information Sheet to:

NAME: _____

ADDRESS: _____

_____

_____

POSTCODE: _____ - _____

TEL NO: _____

Please provide best contact no. for us to reach you on so that we can contact you once you've had a chance to read the Study Information Sheet

Appendix 4 Interview Consent Forms:

Pregnant women in Lothian

Pregnant women at York

Partners, family or friends of pregnant women

Healthcare professionals supporting pregnant women

What helps women and what holds women back from stopping smoking during pregnancy

Interview consent form for pregnant women (Lothian)
Version 3.0 12.06.2013

Name of Researcher/Research Midwife: _____

Please initial box

1. I have read and understood the study Information Sheet for Pregnant Women (V2.0 dated 31.05.2013) ☐
2. I have had a chance to discuss the study and ask questions. All my questions have been answered to my satisfaction ☐
3. I understand that taking part in the study is voluntary and I am free to leave the study at any time without giving a reason and this will not affect my pregnancy care or legal rights in any way ☐
4. I confirm that I am happy for my GP to be informed of my participation in this study ☐
5. I agree to take part in a face-to-face interview with a study researcher ☐
6. I agree for my interview session to be audio-recorded ☐
7. I agree to anonymised quotes from my interview being used when reporting the study findings ☐
8. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records ☐
9. I would like to receive a summary of the results when the study is finished ☐

Name of Participant	Date	Signature
Researcher	Date	Signature

1 copy for participant and 1 copy for researcher/research midwife

Thank you. We are grateful to you for taking part in the study

What helps women and what holds women back from stopping smoking during pregnancy

Interview consent form for pregnant women (York)
Version 3.0 12.06.2013

Name of Researcher/Research Midwife: _____

Please initial box

1. I have read and understood the study Information Sheet for Pregnant Women (V2.1 dated 12.06.2013) ☐
2. I have had a chance to discuss the study and ask questions. All my questions have been answered to my satisfaction ☐
3. I understand that taking part in the study is voluntary and I am free to leave the study at any time without giving a reason and this will not affect my pregnancy care or legal rights in any way ☐
4. I confirm that I am happy for my GP to be informed of my participation in this study ☐
5. I agree to take part in a face-to-face interview with a study researcher ☐
6. I agree for my interview session to be audio-recorded ☐
7. I agree to anonymised quotes from my interview being used when reporting the study findings ☐
8. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records ☐
9. I would like to receive a summary of the results when the study is finished ☐

Name of Participant	Date	Signature
Researcher	Date	Signature

1 copy for participant and 1 copy for researcher/research midwife

Thank you. We are grateful to you for taking part in the study

UNIVERSITY OF STIRLING | THE UNIVERSITY of York | NHS Lothian | York Teaching Hospital NHS Foundation Trust

What helps women and what holds women back from stopping smoking during pregnancy

Interview consent form for partners, family & friends of pregnant women
Version 1.0 16.04.2013

Name of Researcher/Research Midwife: _____

Please initial box

1. I have read and understood the study information sheet for partners, family & friends of pregnant women (V 2.0 dated 31.05. 2013) ☐

2. I have had a chance to discuss the study and ask questions. All my questions have been answered to my satisfaction ☐

3. I understand that taking part in the study is voluntary and I am free to leave the study at any time without giving a reason and this will not affect my partner/relative/friend's pregnancy care or any help that she may wish to receive from stop smoking services ☐

4. I agree to take part in a face-to-face interview with a study researcher ☐

5. I agree for my interview session to be audio-recorded ☐

6. I agree to anonymised quotes from my interview being used when reporting the study findings ☐

7. I would like to receive a summary of the results when the study is finished ☐

Name of Participant	Date	Signature
Researcher	Date	Signature

1 copy for participant and 1 copy for researcher/research midwife

Thank you. We are grateful to you for taking part in the study

What helps women and what holds women back from stopping smoking during pregnancy

Interview consent form for healthcare professionals supporting pregnant women
Version 1.0 16.04.2013

Name of Researcher/Research Midwife: _____

Please initial box

1. I have read and understood the study information sheet for health care professionals supporting pregnant women (V 2.0 dated 31.05.2013) ☐
2. I have had a chance to discuss the study and ask questions. All my questions have been answered to my satisfaction ☐
3. I understand that taking part in the study is voluntary and I am free to leave the study at any time without giving a reason ☐
4. I agree to take part in a face-to-face or group interview with a study researcher ☐
5. I agree for the interview session to be audio-recorded ☐
6. I agree to anonymised quotes from the interview being used when reporting the study findings ☐
7. I would like to receive a summary of the results when the study is finished ☐

Name of Participant	Date	Signature
Researcher	Date	Signature

1 copy for participant and 1 copy for researcher/research midwife

Thank you. We are grateful to you for taking part in the study