NIHR Health Technology Assessment programme

NHS National Institute for Health Research

NETSCC, HTA

09 May 2012

The Health Technology Assessment programme is managed by NETSCC, HTA as part of the NIHR Evaluation, Trials and Studies Coordinating Centre at the University of Southampton.

Alpha House, University of Southampton Science Park
Southampton SO16 7NS
Suggest a topic for research via our online form at www.hta.ac.uk/suggest

tel: +44(0)23 8059 5586
fax: +44(0)23 8059 5639
email: hta@hta.ac.uk

www.hta.ac.uk

BIBS: Benefits of Incentives for Breastfeeding and Smoking cessation. *A platform study for a trial.*

Research Protocol –

Mother and baby/toddler group collaboration;
Stages 2A and 2B;
and Stage 3

Primary qualitative research (including interviews), web surveys and discrete choice experiment (DCE)

Agreed between University of Aberdeen, University of Central Lancashire, NHS Grampian and NHS Trusts for Blackpool, North Lancashire and Preston

Version 2: 10 April 2012
Protocol number: 2/024/12

Project Reference Number: HTA 10/31/02
(01 February 2012 – 30 September 2013)

1 PLAIN ENGLISH SUMMARY

This study is about the different types of encouragement (incentives such as vouchers, gifts, or services, free ironing and beauty treatments, for example) that have been used to a) help pregnant women to stop smoking and not relapse or give up and b) to help mothers to try and to continue breastfeeding up to six months in line with the World Health Organisation (WHO) guidelines. We want to see whether incentives work, which ones work, how much is needed, the timing and how it is given to women.

2 OVERVIEW

This project involves several stages and this protocol applies to ongoing co-applicant **mother and baby/toddler group collaboration, Stages 2A and 2B, and Stage 3**.

For information, **Stage 1** of the project (February-September 2012), which is already underway (and is covered under a separate protocol), involves finding research studies and reports about the different types of incentives that have been used to help women stop smoking during pregnancy and not relapse within six months of having given birth and to initiate breastfeeding and not give up within the first six months. We are looking in depth at these studies to see whether incentives work, which incentives work, how much incentive is needed, the timing and how it is delivered. Through this work, and ongoing co-applicant **mother and baby/toddler group collaboration**, a shortlist of incentives and a taxonomy of incentive characteristics and strategies will be developed which we will use to inform our topic guides and schedules for the ***group and individual interviews*** **(Stage 2A)**, as well as in the design of the ***web survey*** questions **(Stage 2B)** and the ***discrete choice experiment (DCE) questionnaire***, which forms **Stages 3** of this project.

2.1 Mother and baby/toddler group collaboration

This project involves ongoing **mother and baby/toddler group collaboration** with our respective co-applicant groups in Aberdeenshire and Lancashire. This will happen throughout the project to seek their input into all our research activities. Although they are collaborators, and are independent or Local Government rather than NHS groups, we will be seeking local ethics committee approval for us to attend a number of their meetings throughout the project (to be undertaken over May 2012-September 2013).

2.2 Stage 2 (Stages 2A and 2B)

In **Stage 2** of this project (to be undertaken over September 2012-July 2013), we want to use ***group and individual interviews*** to ask pregnant women and new mothers, their partners or significant others, care providers and policy and research decision makers, experts and advisers about their experiences and views on smoking around pregnancy, breastfeeding and the use of incentives **(Stage 2A)**. At the same time, we want to use a ***web survey*** of the general public (through MORI), and stakeholders and policy and research decision makers and advisers (through mailing list gatekeepers) to ask for feedback on a shortlist of incentives – which ones might be acceptable and which ones might be feasible to deliver **(Stage 2B)**.

2.3 Stage 3

In **Stage 3** (again, to be undertaken over September 2012-July 2013), we want to use a ***discrete choice experiment (DCE) questionnaire*** where those who complete it (some mothers and their partners/significant others where it will be administered through the

research team and some women of childbearing age through a commercially administered Research Now TM version) will be asked to choose between incentive schemes and to vote for the most acceptable and reasonable options that can be tested in a further research study.

The overall aim of this project is to identify feasible and acceptable incentives to use within a randomised controlled trial for smoking cessation and breastfeeding continuation.

3 BACKGROUND

3.1 Smoking cessation and breastfeeding

3.1.1 Smoking cessation, breastfeeding and health

Annual costs to the National Health Service (NHS) of adverse events related to smoking in pregnancy have been estimated at between £8 million and £64 million for maternal outcomes, and between £12 million and £24 million for infant outcomes.[1] Similar data on breastfeeding are now being compiled by the University of York. Smoking cessation and breastfeeding are often researched independently, but recent evidence suggests correlations, and furthermore the possibility of a causal relationship between stopping smoking and increased breastfeeding duration.[2]

The evidence that both smoking in pregnancy and choosing not to breastfeed are linked to adverse health outcomes for both the mother and the child is growing.[34] In the 2005 Infant Feeding Survey, pregnant mothers aged 20 or under are: three times more likely to smoke before or during pregnancy; less likely to quit compared to mothers aged 35 or over and more than five times less likely to be breastfeeding at 4 months.[5] The breastfeeding initiation rate was 88% for mothers in managerial and professional occupations, compared with 65% of mothers in routine and manual occupations, with a fourfold difference in smoking during pregnancy (29% and 7% respectively). Mothers in routine and manual occupations are also less likely to attend parent craft education classes or engage in health services which support behavioural change. In the UK, the health inequalities gap has been widening and this is currently a key priority for UK Governments. New evidence based approaches are recommended which are broader than the current focus on individual behaviour change interventions.[6]

3.1.2 Smoking cessation

Approximately 17% of mothers continue to smoke throughout pregnancy.[7] However, a recent Cochrane review found that smoking cessation interventions used in early pregnancy can reduce smoking in later pregnancy by around six percent, with cognitive behavioural approaches proving particularly effective.[8] All pregnant women who smoke should be offered support to quit and smoking cessation interventions in pregnancy have been shown to be effective.[9] NHS stop smoking services available to pregnant women employ cognitive behavioural approaches to cessation, in accordance with National Institute for Health and Clinical Excellence (NICE) guidance on smoking cessation interventions in pregnancy and following childbirth,[10] but there may be variation in uptake of these services among the targeted population.[11] In Scotland in 2006, for example, fewer than 10% of pregnant smokers set a quit date with NHS services.[12] Self-help interventions have also been shown to be effective, however, the UK evidence for this is limited and may not be directly applicable.[13] There is limited qualitative evidence for smoking cessation interventions in pregnancy, particularly in young mothers[14] and interventions can have unintended adverse consequences, particularly on maternal mental health and access to medical care.[15]

3.1.3 Breastfeeding

With regard to breastfeeding, less than one percent of women in the UK adhere to the World Health Organisation (WHO) recommendation of exclusive breastfeeding (with no other liquids or solids) until the child reaches six months of age.[16] Data suggest that although breastfeeding is initiated by 76% of women, 22% have stopped doing so by two weeks and 37% have stopped doing so by six weeks. 90% of women report that they would have liked to have breastfed for longer.[17] The effectiveness of professional and lay support, particularly multifaceted interventions and those that continue through pregnancy and postnatal care, is recognised,[18] but there is a lack of evidence found within UK trials

and what little there is may not be generalisable to all populations as breastfeeding is a complex behaviour and practical skill that usually requires help to learn. Qualitative studies suggest that the barriers and facilitators for initiating and sustaining breastfeeding are complex and include: maternal confidence; self-efficacy; family and peer attitudes; health service support and systems; the environmental and cultural attributes of place, social and cultural norms and their interaction with psychological factors like embarrassment; physiological concomitants like pain, maternal well-being, infant weight loss and distress.[19]

3.2 Incentives

3.2.1 How do they work?

Little is known about how incentives work, how they might facilitate rather than erode informed choice and importantly how time and context modify effects.[2021] Incentives are not similarly effective across all types of behaviour. Moderators include: incentive size/value, with low income groups being more sensitive to price changes; the timing with immediate and periodic incentives more effective; the inclusion of social support and whether an incentive is delivered with praise, positive reinforcement and in a manner that improves confidence, skills and self-efficacy.[22] Individual behaviour change theories like Social Cognitive Theory and the Theory of Planned Behaviour hypothesise that people deliberately consider the balance of anticipated positive and negative consequences of their behaviour. From this perspective, incentives might tip the balance towards a desirable behaviour. Behavioural economic theory further acknowledges that people's preferences may depend on timing, with more immediate outcomes (e.g. the positive physical response to nicotine) valued more highly than future outcomes (e.g. distant health consequences). Associating incentives immediately with a desired behaviour might tip the balance. Learning theories assume that incentives delivered for a target behaviour will increase the behaviour and that withdrawing the incentives should result in the behaviour stopping, as demonstrated for smoking cessation.[23] Systems or ecological theory considers incentive interventions as occurring within a complex socio-cultural milieu, with multiple interactions at different levels. The wider economic climate, media influences as well as local cultures are likely to influence incentive outcomes. Incentive delivery usually includes a variety of associated activities for example; to establish behavioural targets; monitor performance and provide behaviour change techniques.[24] Changes to the "choice architecture" within an organisation or system can facilitate behaviour change.[25]

3.2.2 Can they work for health?

The potential of incentives to increase healthy behaviours is increasingly being recognised.[262728] However, such use of public funding requires to be well scrutinised, especially within the current financial climate. Incentive initiatives like NHS Scotland's "Give It Up For Baby" (Tayside) which provides £12.50 per week of grocery vouchers has generated media controversy and resistance from The Taxpayers Alliance. It is therefore important that resources spent on any health behaviour incentives are acceptable and justifiable. At a NICE Citizens' Council held in May 2010, 20/32 (62.5%) attendees voted in favour of the acceptability of incentives to change individuals' behaviours to improve health, but with conditions attached, including evidence being available on the effectiveness of such incentives.[2930]

There is strong evidence that negative incentives (e.g. increased taxes) change behaviour.[31] However, the evidence supporting positive incentives is more limited and mixed. With regard to paying the patient directly, evidence syntheses have found this to be most effective for clearly defined, simple, time-limited behaviours (e.g. to attend a clinic appointment),[32] but for more complex behaviours (e.g. smoking) behaviour change is not sustained.[33] The evidence for an alternative strategy of providing financial incentives to

providers or organisations to improve the quality of care or to meet targets is complex due to variation in individual responses to such incentives, given that health professionals are likely to be motivated by other factors. Nevertheless, there is UK evidence for this approach from evaluations of the primary care quality and outcomes framework[34] and a much broader international literature linking financial incentives and their direct and indirect impact on quality of care.[35] The individual behavioural response to financial incentives may be more complex than generally considered by most empirical economic analyses, as health professionals are motivated by more than financial incentives, including public sector incentives or intrinsic motivation.[36]

A more unusual strategy is to incentivise partnerships between service users, health and social care providers and the voluntary sector. Local community development incentive schemes can have benefits beyond individual behaviour change, by increasing social capital in disadvantaged communities, fitting with the current Government's vision of a "Big Society." Examples of partnership incentive strategies from the Breastfeeding Groups (BIG) trial led by the PI (Pat Hoddinott) included groups with fund raising partnerships of local mothers, providers and stakeholders to subsidise crèches, refreshments, or a free ironing service for breastfeeding women, thus creating local employment opportunities and social networks that extended benefit beyond the group. These incentives motivated women to attend whereas supportive, motivational or persuasive relationships with peers or health professionals were inconsistently perceived as either incentives or disincentives to attend.

The available international evidence on the effectiveness of smoking cessation initiatives suggests that financial incentives are the single most effective intervention in supporting women to quit,[37] although the results may not be generalisable to an NHS-based population. Further, there is limited literature on incentives for providers to improve the quality of breastfeeding services and we identified only one narrative review which includes pay for performance.[38] The Baby-Friendly Hospital Initiative (BFHI) increases breastfeeding initiation in the UK[39] and is being implemented in many countries. For a significant cost, hospitals receive a widely publicised non-financial but esteemed accreditation award for meeting 10 evidence based or good practice steps. For breastfeeding, no systematic reviews have been identified that evaluate incentives given to women. Internationally, several multifaceted intervention trials have been conducted including five which contributed to part of the Special Supplemental Food program for Women, Infants and Children (WIC) in the USA. From these trials there is some evidence looking at participation in education/support interventions and incentives to reward breastfeeding. A variety of incentives have been considered including gift certificates (value of less than $50.00), breast pumps, football tickets for partners/significant others, nappies, infant lotion, toys and raffle prizes. However, these trials are small and are also not without methodological weaknesses, rendering it difficult to see how effect sizes relate to the incentives being offered or the educational/support components of the intervention.

3.2.3 Evidence for the use of incentives for smoking cessation and breastfeeding

Given the uncertain knowledge and understanding of the use of incentives in relation to smoking cessation around pregnancy and breastfeeding initiation and continuation, there has been a need to systematically review the available literature on this subject to improve clarity and understanding of incentives for both behaviours. A systematic review of both quantitative and qualitative evidence is being carried out as part of this project (**Stage 1**, which is covered under a separate protocol) and considers the effectiveness of experimental interventions offering incentives for:

1. smoking cessation in pregnancy and up to six months after birth;
2. breastfeeding up to six months after birth.

In both cases, this is being done to determine the evidence for the effectiveness of incentive interventions delivered within or outside of the NHS to either/both:

1. individuals and/or their families;
2. organisations aiming to increase and sustain smoking cessation and/or breastfeeding.

A shortlist of candidate incentives will be developed along with a taxonomy of incentive characteristics and strategies, together with their associated theories of behavioural change, mechanisms of action and existing barriers, facilitators, motivators/de-motivators. These will be informed by our **mother and baby/toddler group collaboration**, **Stage 2**, which will involve primary qualitative research: ***group and individual interviews*** **(2A)**, in tandem with ***web surveys*** **(2B)**, and **Stage 3**, which will comprise a ***discrete choice experiment (DCE)***. These stages will allow us to assess the acceptability and feasibility of the shortlist of candidate incentives and will contribute to the final incentive classification, enabling us to build an holistic picture of how incentives might tip the balance to change behaviour, as well as acting as a platform for a trial.

4 AIMS AND OBJECTIVES

The overall aims of **mother and baby/toddler group collaboration, Stages 2A and 2B, and Stage 3** are:

- To gather qualitative data to inform the assessment of acceptability and feasibility of a shortlist of candidate incentives for smoking cessation and trying breastfeeding to stakeholders at an individual or social level, including participants, the public, stakeholders and policy makers;
- To investigate the attitudes of participants and clinicians to establish whether a trial will be feasible for our shortlisted incentive(s) and, if so, to identify the most appropriate trial outcomes and define how they would be measured.

The objectives of **mother and baby/toddler group collaboration, Stages 2A and 2B, and Stage 3** are:

1. To determine the evidence for the effectiveness of incentive interventions delivered within or outside the NHS, to a) individuals, families or b) organisations that aim to increase and sustain smoking cessation and trying and continuing breastfeeding.
2. To determine evidence for effective incentive delivery processes and how they work to increase and sustain smoking cessation and trying and continuing breastfeeding, including their acceptability and how they fit with existing barriers, facilitators and intrinsic and extrinsic motivators to behaviour change:
    a) To ascertain how incentives alter the balance of existing intrinsic and extrinsic motivators/de-motivators;
    b) To investigate how incentives interact with the environmental, organisational, social and cultural facilitators and barriers to behaviour change.
3. To establish the likely unintended consequences for the non-incentivised.
4. To determine the acceptability and feasibility of a shortlist of promising incentive strategies and potential harms or adverse consequences from the perspectives of a) women and partners/significant others b) health professionals, managers, policy makers, research funders, ethics committee members, academics and other relevant stakeholders c) the general public.
5. To develop the incentive taxonomy from objectives 1 – 4, building an holistic picture of how incentives might tip the balance to change behaviour.
6. To design a feasible trial: target population, the active components and mechanisms of action of the intervention, the control group, recruitment and delivery strategy, monitoring and outcome measurement, effect size.

5 RESEARCH DESIGN AND METHODS

The technologies being assessed are incentives. The settings for conducting this research include primary and secondary health services in Aberdeenshire and Lancashire including; Local Government community and voluntary sector services (e.g. children and family centres; mother and baby/toddler groups) and the commercial sector (e.g. pharmacies). The target populations are a) pregnant women, new mothers and their partners or significant others with follow up until six months after birth; b) other stakeholders who could receive incentives to support women to initiate or sustain smoking cessation or breastfeeding, for example: midwives, health visitors, primary or acute care organisations at local, regional or national level; local communities through baby café and crèche incentives; community pharmacies and c) policy and research decision makers, experts and advisers (UK wide).

The research design and methods covered by this protocol are: **mother and baby/toddler group collaboration, Stages 2A (*group and individual interviews*) and 2B (*web surveys)***, and **Stage 3 *(discrete choice experiment (DCE))***.

5.1 Stage 2A – *Group and individual interviews*

(**NB.** Sections 5.1.1, 5.1.2 and 5.1.5 also apply to our co-applicant **mother and baby/toddler group collaboration**)

5.1.1 Theory (mother and baby/toddler group collaboration and Stage 2A)

The underlying theoretical approach to our sampling strategy is informed by grounded theory.[40] This is appropriate as the outcome of this research will be a theoretically informed, acceptable and feasible intervention ready to pilot. At this stage we do not wish to make any assumptions about what our findings will be. Our sampling strategy is also informed by ecological theories of behavioural change,[41] which consider smoking, breastfeeding and incentives as part of dynamic complex adapting systems, where the micro, meso and macro context in which incentive delivery occurs is likely to be important and influence outcomes.

5.1.2 Settings (mother and baby/toddler group collaboration and Stage 2A)

The study settings have been purposively selected for their diverse socio-demographic characteristics and their different incentive cultures for smoking cessation in pregnancy and breastfeeding:

Aberdeenshire has a mixed urban/town/rural population, with partners absent for long spells working offshore in fishing and the oil industry and pockets of affluence and deprivation. In 2009, at antenatal booking 17.7% of women reported smoking and at hospital discharge 60% of babies were receiving some breast milk.[42]

Incentive culture: Aberdeenshire has the highest proportion in Scotland (71%) of smoking cessation services to pregnant women delivered through community pharmacists, who receive payments per person registering for smoking cessation support and for data collection.[43] In discussions between the PI (Pat Hoddinott) and providers in primary care and maternity services, many managers and practitioners are resistant to providing financial incentives to patients following adverse media publicity about a smoking cessation incentive scheme in neighbouring Tayside http://thensmc.com/resources/showcase/search-case-studies.html?view=single&id=72 which our collaborator Susan Macaskill evaluated. Our co-applicant mother and baby group is an example of a partnership community development project part funded by the Local Government, which has raised money from local businesses to provide non-financial incentives (a crèche and subsidised café).

Lancashire has a mixed urban, small town and rural population with a wide socio-demographic range. For 2007 Indices of Deprivation, six local districts (including Blackpool) are ranked within the top 50 in England and some towns have up to 35% of births to women of South Asian origin. Lancashire has the second lowest breastfeeding initiation rate (66% compared to 78% for England) and the equal lowest rate of babies still breastfed at six months (17% compared to 25% for England).[44] Whilst smoking rates vary across the region, Blackpool has the highest overall rate, with twice the national average of expectant mums smoking (data from the Association of Public Health Observatories, 2010).

Incentive culture: Lancashire is an innovative area for breastfeeding incentive schemes. The Be a Star http://www.beastar.org.uk/archives/tag/be-a-star-adverts-lancashire campaign started in Lancashire in 2008 and promotes breastfeeding amongst 16-25 year old mothers. It originated as a partnership between one of the Primary Care Trusts, Little Angels breastfeeding peer support organisation and The Hub social marketing agency. Be a Star transforms local breastfeeding mums to look like models, celebrities, singers and actresses, making breastfeeding glamorous, sexy and appealing in posters and provides breastfeeding support. Be a Star has been rolled out across fifteen Primary Care Trusts in England with encouraging results. The Local Government have recently provided funds to three areas in the North-West (one of which is NHS Blackpool Primary Care Trust) to run incentive schemes with the aim of increasing breastfeeding duration at 6-8 weeks in 2011 by 5%. The community Star Buddies Breastfeeding Peer Supporters who are delivering the incentive scheme in Blackpool operate out of the Local Government funded St Cuthbert's and Palatine Children's Centre (our co-applicant base).

Ensuring inclusion of ethnic diversity: Our sampling frame will include ethnic origin and we will purposively sample women from different ethnic groups. Through mother and baby/toddler groups, antenatal clinics, GPs and health visitors we will identify women to approach to ensure that participants from the main UK Census Level 1 Ethnic Groups (White, Mixed, Asian or Asian British, Black or Black British, Chinese or other ethnic groups) are represented. Aberdeenshire and Lancashire will provide access to considerable ethnic diversity.

Inclusion/exclusion criteria and processes:
We will ensure that interviewees have sufficient understanding of the English language before embarking on any interview. Health professionals and Children Centre staff will identify individuals where an interview is not appropriate, e.g. severe mental or physical health problems or following birth complications or stillbirth. We will not be accessing other individual health details as part of our research (other than those volunteered or self-reported, e.g. smoking behaviour). For participants recruited through health services, health professionals will either introduce participants or will be involved in participant recruitment. They will be asked to exclude any potential participants where group and/or individual interviews would be inappropriate (without disclosing the details or reasons). They will also be approached prior to researchers making subsequent post-natal contact with women in order for the researchers to re-establish the suitability of existing participants.

The sampling and recruitment strategy for the group and individual interviews is summarised in Table 1 below.

Table 1. Sampling and recruitment strategy for group and individual interviews

Sample	**Recruitment strategy**	**Data collection methods and estimated sample size (total across sites)**
Pregnant women and mothers/partners/ significant others from first trimester until six months after birth.	Pregnancy, mother and baby/toddler groups across Aberdeenshire and Lancashire Antenatal clinics, GP surgeries, hospitals, midwives across Aberdeenshire and Lancashire GPs and Health Visitors, midwives and voluntary workers across Aberdeenshire and Lancashire Partners/significant others through women already participating	Recorded meetings with our co-applicant mother and baby/toddler groups (n=12-15) Group interviews (n= 4-6) Individual or couple interviews (n=12-15) and follow-up interviews (estimate total of 80 participants in this group across Aberdeenshire and Lancashire)
Providers of care/stakeholders Midwives, health visitors, obstetricians, paediatricians, general practitioners, public health specialists, pharmacists, voluntary sector, children and family centre staff.	Purposive or theoretical sampling: individuals identified by NHS managers, primary care networks, antenatal clinics, baby clinics. Web survey question inviting volunteers for a 15 minute telephone interview/30 minute face to face interview	Group interviews (n=2-4). Face to face or telephone interviews (n=12-15) (estimate total of 20 volunteers across Aberdeenshire and Lancashire including the policy and research participants below)
Policy and research decision makers, experts and advisers UK government policy makers for maternal and child health and public health. Research ethics and research governance personnel. Expert advisers. Voluntary sector.	Purposive or theoretical sampling: individuals identified through key informants and our advisory panel. Web survey question inviting volunteers for a 15 minute telephone/30 minute face to face interview Conference delegates at the: Maternal and Infant Nutrition and Nurture conference; UK National Smoking Cessation conference; Public Health in Scotland conference	Face to face or telephone interviews (n=10-15) Group interviews (n=3) (estimate total of 20 volunteers across Aberdeenshire and Lancashire including the care provider participants above)

5.1.3 Sampling (Stage 2A)

Pregnant women, new mothers, their partners or significant others: a sampling frame will be used for a) smoking: no intention to quit; have cut down; have quit; have relapsed, never smoked b) breastfeeding: no intention; exclusive; non exclusive; different durations c) experience of incentive initiatives or no experience. We will aim for a sample with diverse characteristics: maternal age, rurality (first four digits of postcode), marital status, ethnicity, educational level, occupation and family size.

Providers of care/stakeholders (who may also deliver or receive incentives): e.g. midwives, health visitors, paediatricians, obstetricians, general practitioners, practice nurses, public health doctors and specialists, community pharmacists, Local Government children and family centres, NHS managers for maternity, child health, primary care and public health.

Policy and research decision makers, experts and advisers: national maternal and child health policy makers and advisors, including the voluntary sector: research funding board panels (e.g. NIHR HTA; MRC; CSO); ethics committee members; NHS research and development personnel.

This purposive and theoretical sampling method will be employed to achieve a maximum diversity sample of potential recipients and those involved in the delivery of incentives, both within and outside the NHS. We have estimated the number of group and individual interviews based on our extensive experience of conducting qualitative research in similar areas and would like to keep this flexible so that we can use purposive or theoretical sampling of information rich individuals to reach theoretical saturation for our final analysis.

5.1.4 Recruitment (Stage 2A)

Pregnant women, new mothers, their partners or significant others: we have identified several sources for recruiting participants, including NHS and non NHS mother and baby/toddler groups, antenatal clinics, GPs, health visitors, midwives and voluntary workers and we have well established working relationships with NHS colleagues. All initial approaches to NHS patients, either by letter or face to face, will be through a midwife, a health visitor, a member from a voluntary organisation or a GP. They will ensure that it is appropriate to discuss the study with the woman and in some cases (where the woman indicates) her partner/significant other. Where appropriate they will explain the study (face to face or by telephone) and give or send the woman an information leaflet to read. If the woman is interested in participating there will be two possible options: 1. A researcher may be present at the clinic, who can explain the study in more detail. 2. The health professional will ask permission for a member of the research team to contact them. Alternatively, the woman can return a form to the research team, expressing her interest, or can contact the research team herself via contact the details provided, or the study website. In all scenarios potential participants will be given at least 48 hours to read the information and to decide whether to participate or not before informed consent is sought for group/individual interview. Based on our previous experience of recruiting women around childbirth and health service staff for qualitative interviews in Aberdeenshire and Lancashire, we are confident that this sampling strategy is both feasible and theoretically robust.

Providers of care/stakeholders: will be recruited through purposive or theoretical sampling whereby individuals identified by NHS managers, primary care networks, antenatal clinics and baby clinics will be contacted. An information sheet will be issued initially by email with participants asked to respond directly to the researcher if they are willing to take part in the study. Again, the study settings, Aberdeenshire and Lancashire, have been purposively selected as above. In addition, within the web survey (Stage 2B as

described below), there will be a question inviting volunteer respondents to take part in a face to face or telephone interview.

Policy and research decision makers, experts and advisers: will be identified through our key informants and advisory panel. Again, within the web survey (described below), there will be a question for these respondents inviting them to volunteer to take part in a face to face or telephone interview. We will also approach conference delegates at the conferences named in Table 1. Depending on our shortlisted incentive strategies, we may also request to interview incentive organisers/researchers (but not NHS patients) in other parts of the UK where they have relevant expertise. We will seek informed consent to sound record interviews and data will contribute to the qualitative analysis.

5.1.5 Data collection and analysis (mother and baby/toddler group collaboration and Stage 2A)

Mother and baby/toddler group collaboration: The qualitative researchers will work in partnership with Local Government mother and baby/toddler group co-applicants from the outset, informed by participatory research methods which are considered to improve the relevance of research.[45] Qualitative sampling strategies, topic guide refinement, data collection and analysis will be iterative to address specific research questions. The two post-doctoral research fellows who will conduct early group discussions with the co-applicant mother and baby/toddler groups, but also with identified care providers/stakeholders and relevant conference delegates, which will inform initial topic guides and assist in piloting survey questions for the discrete choice experiment. Consent will be requested to sound record their meetings. The groups also run *Facebook* pages, which the researchers seek permission to use to engage with members (on group administration/members' terms). Messages posted would relate to the research only and would be posted by research staff using profiles identifying as themselves by name and explicitly as researchers.

Stage 2A – *Group and individual interviews*: Once participants have provided consent to participate, the type of interview (group or individual, face to face or telephone) will be negotiated, together with where the interview will take place (home, clinic health centre, Local Government venue). For follow-up interviews, consent will be re-established. The topic guide will change as the analysis progresses and more refined research questions will be generated to inform the incentive taxonomy and the shortlist of incentive intervention strategies. The sampling strategy will change to identify and recruit the most appropriate participants to answer these questions. This may involve recruiting incentive scheme organisers or researchers from other parts of the UK if we identify individuals who are information rich. We will not recruit any NHS patients or staff from sites other than those stated in our IRAS application. We will aim to reach theoretical saturation for our final analysis and make every attempt to search for disconfirming data through our sampling strategy and by triangulating between the different data sources in our study.

Mother and baby/toddler group collaboration and Stage 2A: Interviews will be open-ended, with a checklist of topics to ensure key issues are covered. They will explore issues relating to our incentive taxonomy and the shortlist of promising incentive strategies (a sample topic guide has been appended to this protocol, which has been developed for illustration at this stage). As the analysis progresses, the sampling strategy and topic guides will be modified to develop theory and refine the incentive taxonomy. Intervention vignettes, used by the Principal Investigator (Pat Hoddinott) in previous qualitative research to inform the design of an intervention,[46] and pilot trial information leaflets will be constructed for the promising incentive strategies. These will further refine the analysis, search for disconfirming data and inform a trial design (incentive characteristics, timing, presentation and delivery). They will provide data to compare and contrast with the real time experiences of participants of incentive interventions.

Analysis will be informed by the Framework method,[47] which is well established as a transparent, systematic and rigorous data management tool in applied policy research which summarises data into a thematic matrix. One of Framework's strengths is its potential to integrate mixed method data into matrices, to look for patterns or explanations. Initially, two researchers will identify key themes and categories independently by reading transcripts of and listening to the first four participant and provider interviews. Through wider research team discussion and reading of interview transcripts, a single tree structure coding index will be agreed and will be applied to the separate datasets using NVivo 9 software, with 2-4 weekly merges of datasets. The researchers will also undertake a detailed ethnographic analysis of data with discussion between sites to ensure consistency. The emerging analysis and the Framework matrices will inform and refine the incentive taxonomy developed from the evidence synthesis.

5.2 Stage 2B – *Web surveys*

5.2.1 Theory (Stage 2B)

The web survey will investigate the following research questions for the samples in Table 2 below:

a) Is our short-list of incentive strategies for initiating and sustaining smoking cessation in pregnancy and breastfeeding acceptable and feasible? In practice? For a research trial?
b) What are likely to be the unintended consequences for the non-incentivised?

5.2.2 Settings (Stage 2B)

The web surveys will be sent to members of the general public, providers of care/stakeholders and policy and research decision makers, experts and advisers. For the former (the general public), the setting will be UK wide, according to who is accessed through MORI's pool of survey respondents. For health professionals, the settings will be Strategic Health Authorities – for Scotland (co-ordinated through NES) and the North West of England. For policy and research decision makers, experts and advisers, recruitment will be UK wide. The sampling and recruitment strategy for the web surveys is summarised in Table 2 below.

Table 2. Web surveys sample characteristics and recruitment strategy

Sample	Recruitment strategy	Setting	Sample size
General Public	MORI Omnibus Survey – guaranteed response rate (administered independently)	UK	N=1000
Providers of care/stakeholders Midwives, health visitors, GPs, practice nurses paediatricians, obstetricians, public health specialists, managers, pharmacists.	Mailing list gatekeepers for two Strategic Health Authorities	Scotland and NW England	N=1000 (likely to send 2000 assuming 50% response rate, found in other UK health professional web surveys[48])
Policy and research decision makers, experts and advisers	Government maternity services, child and public health departments	UK	N= estimate 100

5.2.3 Sampling (Stage 2B)

The sampling strategy aims to meet the commissioning brief objectives a) to assess the acceptability and feasibility of incentives to stakeholders at an individual or social level, including patients, participants, the public and policy makers and b) to establish the perspectives of trial participants and whether clinicians are willing to include incentives in research and therapeutic interventions. To address these objectives we require the diverse sample described in Table 2 above. This includes the general public who will indirectly pay for publicly funded incentive initiatives through taxation and may have other health priorities; policy makers who will make the decisions about whether to support new incentive initiatives and evidence based incentives practice; research funders who will enable the evidence base for incentives to be strengthened and ethics committees who currently have different practices for approving the use of incentives in research.

5.2.4 Recruitment (Stage 2B)

Survey recruitment will start after initial qualitative data collection and analysis, which will enable us to refine and pilot the survey questions. We will commission MORI to add our survey questions to their fortnightly Omnibus survey of the general public http://www.ipsos-mori.com/omnibusservices.aspx, as this will ensure a UK wide representative sample with a guaranteed response rate. For the survey of stakeholders, we have taken advice from several colleagues, UK research networks, professional bodies, ISD Scotland and NHS Education Scotland (NES) about the most feasible method, as organisational protocols for using email lists for research vary. Our stakeholder sample will depend on the nature of our shortlisted incentive strategy, for example pharmacists may or may not be included. The web surveys will take place concurrently with the qualitative interviews and will be piloted with a sample of pregnant and recent mothers (recruited from antenatal clinics or mother and baby/toddler groups), health professionals and our advisory panel members. We will gain REC and NHS R&D approvals to use gatekeepers of email lists for Scotland (co-ordinated through NES) and the North West England Strategic Health Authority. This will provide us with a denominator to calculate response rates.

Ensuring inclusion of ethnic diversity: The MORI Omnibus survey includes participants from different ethnic groups and web surveys will collect data on ethnicity from respondents.

5.2.5 Data collection and analysis (Stage 2B)

The web survey will be administered in an independent commission by MORI, whereby our questions will be attached to their fortnightly omnibus survey of the general public. We will also use *Survey Monkey* linked to emails sent to health professionals to ask 6-8 Likert scale questions and socio-demographic characteristics and respondents will be eligible for a prize draw. By linking the survey questions to descriptions of the shortlisted incentives, the questions will be more realistic rather than abstract in nature.

Sample sizes of 1000 will allow us to estimate proportions to within 3% with 95% confidence and will be analysed using descriptive statistics such as percentages with associated confidence intervals. Likert based data will be summarised using means or medians as appropriate. The survey results will inform the final qualitative sampling strategy to refine the development of the trial.

NB. Since its design depends on earlier stages of the research study having been completed (reviews and initial qualitative research), details of the web survey (i.e. format and questions) will be included in a later version of this protocol, with a sample attached

in the relevant appendix, and will then be submitted for subsequent REC and NHS R&D approvals.

5.3 Stage 3 – *Discrete choice experiment (DCE) questionnaires*

5.3.1 Theory (Stage 3)

DCEs have increasingly been used in health to identify preferences for service attributes.. DCEs have also been used to assess responsiveness of health behaviours to policy changes. Hammar and Carlsson (2005) estimated the effectiveness of different tobacco control policies on smokers' expectations to quit smoking.[49] They included price (taxation) and subsidies for smoking cessation, both of which increased the probability of quitting, but no other incentive based policies. We propose to adapt this approach to consider a wider range of incentives based policies, derived from the literature, and effectiveness in pregnant smokers. We will also develop a DCE for the effectiveness of incentives and other policies to increase the take up and duration of breastfeeding.

The discrete choice experiment (DCE) is primarily concerned with identifying the possible effect size for different incentive proposals, as well as contributing to the assessment of feasibility and acceptability. In common with many DCE studies, the Haamar and Carlsson questionnaire[50] required respondents to choose one of the options presented (forced choice). In adapting the approach for this study, we would allow respondents to indicate whether or not they would participate in the incentive scheme offered (acceptability). It is likely that the existing literature will yield limited data on effect sizes and that the effect sizes will be restricted to comparisons of one or possibly two incentives versus no incentive. The DCE approach would enable respondents to consider different incentive characteristics and levels in a number of combinations. The characteristics and levels would be identified from the literature reviews and primary qualitative research but might include combinations of financial or non financial incentives, at different levels and for different durations, incentives to the women (and family) and changes in support arising from incentives to service providers.

5.3.2 Settings (Stage 3)

The DCE will be piloted with mother and baby/toddler group collaborators and participants in Stage 2A of this study (Aberdeenshire and Lancashire). The final DCE will then be open to new volunteer respondents in the study areas (Aberdeenshire and Lancashire) and will also be distributed commercially through Research Now TM's pool of respondents (target population – women of childbearing age/current or former smokers).

5.3.3 Sampling (Stage 3)

Our sampling strategy aims a) to have a minimum of 200 completed questionnaires and b) to sample women (and partners/significant others) who are pregnant, have recently had a baby, or are of childbearing age to ensure that respondents are able to relate to the behaviour changes being sought; women of childbearing age and their partners/significant others (breastfeeding) and those who are current or former smokers (smoking cessation). To achieve these aims, we propose questionnaires distributed to mother and baby/toddler groups at study sites and a commercial web-based survey. Our team has prior experience using web-based surveys successfully for DCEs and this has proved a better option than postal questionnaires for achieving a high response rate. We also chose a web version to minimise potential burden to participants. We will pilot the questionnaire with mother and baby/toddler group collaborators and then the commercial distribution will provide a more geographically diverse sample.

One drawback of DCE questionnaires can be achieving an adequate sample for analysis. Whilst it is not essential for the final sample to be fully representative, because individual characteristics are controlled for in the regression analysis, it should be large enough to ensure approximately 30 responses in each key sub group.

If the potential interventions identified do include an incentive for service providers, without a clear indication of effect size, then a separate DCE will be designed and mailed to the relevant providers to measure the responsiveness of their behaviour. The expected change in service provision characteristics will have been included in the DCE for women (and partners/significant others).

5.3.4 Recruitment (Stage 3)

We propose to employ three methods to recruit respondents: a) women who take part in the interviews will be asked to participate; b) a questionnaire distributed to pregnant and post partum women via services and groups that they attend/their voluntary response to adverts placed at service venues and in the local press and c) via the commercially conducted web surveys. The first two approaches have the advantage of targeting women who are or have recently been pregnant but will include those who have never smoked. However, response rates for such surveys are typically quite low (20%-30%) requiring a large number of questionnaires to be distributed to achieve sufficient responses. The commercial survey will recruit women (and partners/significant others) from an existing panel, using specified characteristics, and will charge based on the number of responses required. This guarantees a level of responses but to be viable the targeted women are of childbearing age rather than actually or recently pregnant. However, this group are relevant as potential recipients of any future incentive scheme.

5.3.5 Data collection and analysis (Stage 3)

The DCE will be administered to some of the women who have been participants in the mother and baby/toddler groups and/or who have taken part in the qualitative interviews. These women may complete the final questionnaire, but may also be involved in developing it through completing and feeding back on a pilot version(s). This will be undertaken with the research team using ‘think aloud’ techniques to go through the questionnaire. Data will also be collected through the commercial web-based survey under the administration of Research Now TM, who will host and manage the DCE and provide the raw data. Data on respondent characteristics will include information on ages, rurality (first four digits of postcode), marital statuses, ethnicities, educational levels and occupation, as well as their smoking and breastfeeding behaviours.

Respondents are usually presented with a computer generated series of paired alternatives for the characteristics of the service under consideration to choose between. The DCE choices are analysed using regression techniques to identify both absolute and relative preferences for service characteristics. The DCE methods allow for responses to be analysed in terms of relevant individual characteristics to establish whether the probabilities of behaviour change vary systematically across individuals. If this is the case, then a range of incentives may be more effective than a ‘one-size-fits-all’ approach.

NB. Since its design depends on earlier stages of the research study having been completed (reviews and initial qualitative research and a piloting process), details of the DCE (i.e. format and questions) will be included in a later version of this protocol, with a sample in the relevant appendix, and will then be submitted for subsequent REC and NHS R&D approvals.

5.4 Data reporting (mother and baby/toddler group collaboration, Stages 2A and 2B, and Stage 3)

Towards the end of our analysis, we will disseminate the study findings widely via the study website with links to *Facebook, Twitter, Netmums,* MIDIRS and the JISCmail.ac.uk group on health incentives and seek feedback. No patient identifiable data will be shared. We will send study findings to participants. We will publish findings in peer reviewed academic journals and present findings at international and national conferences.

A study website (https://w3.abdn.ac.uk/hsru/bibs/) linked to *Facebook, Twitter, Netmums and MIDwives* and *Information Resource Service* (MIDIRS) will disseminate information about the study and receive feedback via a web forum.

6 METHODOLOGICAL CONSIDERATIONS, RISKS AND ETHICS

The research involves a number of ethical and methodological issues, particularly in relation to pregnant women and new mothers (and their partners/significant others) taking part.

Pregnancy and childbirth are important life events and can be both enjoyable and/or stressful times for families. Consideration has been given to this issue in the proposed research design and the collaboration of our Local Government mother and baby/toddler groups across Aberdeenshire and Lancashire is central to the development of appropriate data collection strategies and techniques. These will require a sensitive approach by the research team and UK Research Ethics Committee and NHS Research and Development approvals will be required and the agreed protocols subsequently followed. In all cases, lest birth complications or stillbirth could occur, researchers will ensure that no follow-up contact is made with women unless the advice of the relevant NHS body/personnel has been sought and it is agreed that it is appropriate.

The researchers will follow the University of Aberdeen and University of Central Lancashire Health and Safety (http://www.abdn.ac.uk/safety/ and http://www.uclan.ac.uk/information/services/hr/4.Health_and_Safety_at_work_Policy.php), lone working (http://www.abdn.ac.uk/safety/resources/personal/lone_working/ and http://www.uclan.ac.uk/information/services/fm/safety_and_health/lone_working.php) and Fieldwork Safety policies (http://www.abdn.ac.uk/safety/resources/workplace/fieldwork and http://www.uclan.ac.uk/information/services/sds/procedural_guidance_for_the_management_of_health_safety_on_field_trips_fieldwork_educational_visits.php) to ensure the safety of researchers and liaise with relevant health professionals prior to interviewing families at home.

The University of Aberdeen and University of Central Lancashire hold and maintain insurance policies which will provide appropriate compensation for harm arising from the management, design or conduct of the research.

6.1 Risks (mother and baby/toddler group collaboration, Stages 2A and 2B, and Stage 3)

We anticipate very few risks for participants as we will be employing experienced qualitative interviewers (who will have NHS research passports, which involve criminal record and occupational health assessments) to meet with the **mother and baby/toddler group collaborators** and to conduct the group and individual interviews (**Stage 2A**). Web surveys will be carried out remotely and the general public who will participate will be protected by MORI standards and guidelines (**Stage 2B**). The discrete choice experiment (DCE) will be carried out both remotely (via the web) and through the researchers who will meet with participants to complete the questionnaire (**Stage 3**). Both the latter (web surveys and DCE) will be subject to stringent design and review processes to ensure that the questions are appropriate.

6.2 Ethics (mother and baby/toddler group collaboration, Stages 2A and 2B, and Stage 3)

6.2.1 Informed consent

The dates when a researcher intends to attend a **mother and baby/toddler group collaborator** meeting will be advertised at least 7 days in advance via the group leader and the *Facebook* page for the group.

No personal details of participants will be provided to the research team without individual/management consent. All participants (**mother and baby/toddler group collaborators** and **Stage 2A**) will be asked to sign a consent form at each data collection session (or to provide verbal consent if this is not possible, or to click to indicate their consent if **Stage 2B or Stage 3**). All participants will be asked whether they would like to receive a summary of the findings and how they would like this to be received (e.g. via email or post).

All **mother and baby/toddler group collaborators** and group and individual interview participants (**Stage 2A**) will be provided with a minimum of 48 hours prior to recruitment to enable participants to have time to consider the relevant project information sheets before deciding whether they wish to take part. Mothers and their partners/significant others recruited at **Stage 2A** will also be given a 'sign up' sheet for them to volunteer their participation if they wish.

All participants (mothers, partners/significant others, health professionals, policy makers, etc.) taking part will be provided with information sheets (or information screens for **Stages 2B and 3**), which provide full details about the project and what participation will involve for each category of participant. In addition, at the start of the group or individual interview (**Stage 2A**), the researcher will also provide a verbal summary of the project and participants will be asked if they have any questions. For those who are interviewed more than once, the researcher will provide a further summary of the project at the start of the interview, and provide a further information sheet if required.

6.2.2 Withdrawal

At the start of the group and individual interviews (**with mother and baby/toddler group collaborators** and at **Stage 2A**), all participants will be advised that they do not have to answer any questions and that they can end/leave the interview at any point. All participants (across all stages) will be aware that they will be able to withdraw their data from the study and that they will have up until final analysis has been completed to withdraw any data. Participants will be advised to contact the research team for further information about this issue.

6.2.3 Confidentiality and anonymity

All participants (across all stages) will be informed as to the confidentiality and anonymity procedures in place regarding data storage and reporting of data (detailed within the information sheets/screens, with additional information provided on a verbal basis).

Each participant will be given a unique Participant Identification number to ensure anonymity. All interview data (**mother and baby/toddler group collaborators** and **Stage 2A**) will, with consent, be sound recorded, transcribed and, together with e-mail, written and web correspondence, will be entered into the NVivo 9 qualitative data software package to facilitate data organisation and retrieval. Any contact or demographic details for a participant will be stored securely and separately from the interview data, following the University of Aberdeen Research Governance Guidelines (http://www.abdn.ac.uk/research/governance-framework.php) and the guidelines provided by the University of Central Lancashire ethics committee. All data will be stored securely on password protected University of Aberdeen and University of Central Lancashire computers with only members of the direct research team having access. Paper copies will be held in locked tambour units at the Universities of Aberdeen and Central Lancashire that only the research team have access to.

Direct quotes may be used in the publication of research findings, but these will not be attributed to named individuals and any identifiable information will be removed. Anonymised data will be archived according to the University of Aberdeen guidelines.

Access will only be with the consent of the chief investigator and the research funders and the research sponsor and for research purposes.

[1] Godfrey C, Pickett K, Parrott S, Mdege N, Eapen D. *Estimating the costs to the NHS of smoking in pregnancy for pregnant women and Infants [document on the internet].* Public Health Research Consortium; 2010 [accessed January 2012]. Available from URL: http://phrc.lshtm.ac.uk/PHRC_A3-06%20Revised%20Final%20Report.pdf.

[2] Higgins TM, Higgins ST, Heil SH, Badger GJ, Skelly JM, Bernstein IM et al. Effects of cigarette smoking cessation on breastfeeding duration. *Nicotine Tob Res* 2010;12:483-8.

[3] Lumley J, et.al. Interventions for promoting smoking cessation during pregnancy. Cochrane Database of Systematic Reviews 2009; Issue 3;CD001055. DOI: 10.1002/14651858.

[4] Hoddinott P, Tappin D, Wright C. Breast feeding. BMJ 2008 April 19;336(7649):881-887.

[5] Bolling K, Grant K, Hamlyn B, Thornton A. Infant Feeding Survey 2005. 2007. UK Information Centre, Government Statistical Service.

[6] Asthana S, Halliday J. Developing an Evidence Base for Policies and Interventions to Address Health Inequalities: The Analysis of Public Health Regimes. Milbank Q 2006;84(3):577-603.

[7] Bolling K, Grant C, Hamlyn B, Thornton A. *Infant feeding survey 2005 [document on the internet].* London: The NHS Information Centre; 2007 [accessed January 2012]. Available from URL: http://www.ic.nhs.uk/cmsincludes/_process_document.asp?sPublicationID=1177936850140&sDocID=3603.

[8] Lumley J, et.al. Interventions for promoting smoking cessation during pregnancy. *Cochrane Database of Systematic Reviews* 2009; Issue 3;CD001055. DOI: 10.1002/14651858.

[9] Bauld L, Coleman T. *The Effectiveness of Smoking Cessation Interventions during Pregnancy: A Briefing Paper. 2009. National Institute for Health and Clinical Excellence.* London.

[10] *PH26: How to stop smoking in pregnancy and following birth.* London: National Institute for Health and Clinical Excellence; 2010 [accessed January 2012]. Available from URL: http://www.nice.org.uk/nicemedia/live/13023/49345/49345.pdf.

[11] MacAskill S, Bauld L, Tappin D, Eadie D. *Smoking cessation support in pregnancy in Scotland [document on the internet].* Edinburgh: NHS Health Scotland; 2008 [accessed January 2012]. Available from URL: http://www.healthscotland.com/uploads/documents/7578-Smoking%20in%20Pregnancy.pdf.

[12] Macaskill S, Bauld L, Eadie D, Tappin D. Smoking Cessation Support in Pregnancy in Scotland. 2008.

[13] Naughton F, Prevost AT, Sutton S. Self-help smoking cessation interventions in pregnancy: a systematic review and meta-analysis. *Addiction* 2008;103(4):566-579.

[14] Ingall G, Cropley M. Exploring the barriers of quitting smoking during pregnancy: A systematic review of qualitative studies. *Women and Birth* 2010;23(2):45-52.

[15] Burgess DJ, Fu SS, Ryn M. Potential Unintended Consequences of Tobacco-Control Policies on Mothers Who Smoke: A Review of the Literature. *American Journal of Preventive Medicine* 2009;37(2):S151-S158.

[16] Bolling K, Grant K, Hamlyn B, Thornton A. Infant Feeding Survey 2005. 2007. UK Information Centre, Government Statistical Service.

[17] Bolling K, Grant C, Hamlyn B, Thornton A. *Infant feeding survey 2005 [document on the internet].* London: The NHS Information Centre; 2007 [accessed January 2012]. Available from URL: http://www.ic.nhs.uk/cmsincludes/_process_document.asp?sPublicationID=1177936850140&sDocID=3603.

[18] Chung M, Raman G, Trikalinos T, Lau J, Ip S. Interventions in primary care to promote breastfeeding: An evidence review for the U.S. preventive services task force. *Ann Intern Med* 2008;149:565-82.

[19] Hoddinott P, Craig L, Britten J, McInnes R. A prospective study exploring the early infant feeding experiences of parents and their significant others during the first 6 months of life: what would make a difference? 2010.NHS Health Scotland.

[20] Jochelson K. Paying the patient: improving health using financial incentives. December 2007; Kings Fund.

[21] Marteau TM, et al. Using financial incentives to achieve healthy behaviour. BMJ 2009 April 9;338:b1415.

[22] Jochelson K. Paying the patient: improving health using financial incentives. December 2007; Kings Fund.

[23] Cahill K, Perera R. Competitions and incentives for smoking cessation. Cochrane Database of Systematic Reviews. 2008; Issue 3;CD004307.

[24] Johnston M, Sniehotta F. Financial incentives to change patient behaviour. J Health Serv Res Policy 2010;15(3):131-132.

[25] Thaler RH, Sunstein CR. Nudge: improving decisions about health, wealth and happiness. New Haven: Yale University Press; 2008.

[26] *Applying behavioural insight to health [document on the internet].* London: Cabinet Office Behavioural Insights Team; 2010 [accessed January 2012]. Available from URL: http://www.cabinetoffice.gov.uk/sites/default/files/resources/403936_BehaviouralInsight_acc.pdf.

[27] *Healthy lives, healthy people: our strategy for public health in England [document on the internet].* London: UK Department of Health; 2010 [accessed January 2012]. Available from URL: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127424.pdf.

[28] The UK government recognises the potential of incentives to increase healthy behaviours. The Cabinet Office Behavioural Insight Unit, set up to consider how to encourage people to act in their own and society's longer term interests, has published a discussion paper on applying behaviour insights to health, including behavioural economics theory. The recent Public Health White Paper in England proposes a wider systems

approach than just incentivising individuals, by providing incentives to local communities to forge partnerships to deliver better health outcomes and reduce health inequalities.

[29] *The use of incentives to improve health [document on the internet].* London: NICE Citizens' Council Meeting 20th-22nd May; 2011 [accessed January 2012]. Available from URL: http://www.nice.org.uk/media/9AF/56/CCReportIncentives.pdf.

[30] Of 32 attendees, 12 voted against and 20 voted for incentives but with conditions such as: evidence that they work; why they sometimes fail and, cash incentives should be a last resort. Other concerns were: unfairness to those who make healthy choices; appearing to reward unhealthy behaviours; potential for abuse; cost; the need to monitor and safeguard particularly if private companies are involved; and becoming a ”nanny state”. Benefits of incentives included their potential to demonstrate to people that they are worthy of being helped, facilitating contacts between recipients and care providers and the benefits to child health.

[31] Sutherland K, Christianson JB, Leatherman S. Impact of Targeted Financial Incentives on Personal Health Behavior. *Medical Care Research and Review* 2008 December 01;65(6 suppl):36S-78S.

[32] Jochelson K. *Paying the patient: improving health using financial incentives [document on the internet].* London: The King's Fund; 2007 [accessed January 2012]. Available from URL: http://www.kingsfund.org.uk/document.rm?id=8274.

[33] Cahill K, Perera R. Competitions and incentives for smoking cessation. *Cochrane Database Syst Rev* 2008;Issue 3:Art. no. CD004307. DOI: 10.1002/14651858.CD004307.pub3.

[34] Petersen LA, Woodard LD, Urech T, Daw C, Sookanan S. Does Pay-for-Performance Improve the Quality of Health Care? *Annals of Internal Medicine* 2006 August 15;145(4):265-272.

[35] Christianson J, Leatherman S, Sutherland K. *Financial incentives, healthcare providers and quality improvements*. 2007. The Health Foundation. London.

[36] Frey B. *Not just for the money. An economic theory of personal motivation*. Brookfield VT: Edward Elgar Publishing; 1997.

[37] Heil SH, Higgins ST, Bernstein IM et al. Effects of voucher-based incentives on abstinence from cigarette smoking and fetal growth among pregnant women. *Addiction* 2008;103(6):1009-1018.

[38] Bartick M, Stuebe A, Shealy KR, Walker M, Grummer-Strawn LM. Closing the Quality Gap: Promoting Evidence-Based Breastfeeding Care in the Hospital. Pediatrics 2009 October 1;124(4):e793-802.

[39] Bartington S, et al. Are breastfeeding rates higher among mothers delivering in Baby Friendly accredited maternity units in the UK? Int J Epidemiol 2006;35(5):1178-1186.

[40] Strauss A, Corbin J. *Basics of qualitative research. Grounded Theory Procedures and Techniques.* London: Sage; 1990.

[41] McLeroy KR, Bibeau D, Steckler A, Glanz K. An Ecological Perspective on Health Promotion Programs. *Health Educ Behav* 1988; January 1;15(4):351-77.

[42] Information and Statistics Division, National Health Service Scotland. Information and Statistics. 2010; [accessed January 2011]. Available from URL: http://www.isdscotland.org/isd/3348.html.

[43] *Ibid.*

[44] Bolling K, Grant K, Hamlyn B, Thornton A. *Infant Feeding Survey 2005*. 2007. UK Information Centre, Government Statistical Service.

[45] Health Development Agency. *Participatory approaches in health promotion and planning*. 2000.

[46] Hoddinott P, Craig L, Britten J, McInnes R. *A prospective study exploring the early infant feeding experiences of parents and their significant others during the first 6 months of life: what would make a difference?* 2010. NHS Health Scotland.

[47] Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. *Analyzing qualitative data* London: Routledge; 1994. p. 173-94.

[48] Braithwaite D, Emery J, de Lusignan S, Sutton S. Using the Internet to conduct surveys of health professionals: a valid alternative? Family Practice 2003;20(5):545-551.

[49] Hammar H, Carlsson F. Smokers' expectations to quit smoking. Health Econ 2005;14(3):257-267.

[50] *Ibid.*