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Multi-site implementation of a promising innovation in low income communities: support for childbearing women

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Multi-site implementation of a promising innovation in low income communities: support for childbearing women

1. Aims/Objectives:

Aims and objectives

The project aims to answer four broad questions:
What are:
Q1: the implications for the NHS of a volunteer doula service for disadvantaged childbearing women?
Q2: the health and psychosocial impacts for women?
Q3: the impacts on doulas?
Q4: the processes of implementing and sustaining a volunteer doula service for disadvantaged childbearing women?

Specific objectives within these are:
Q1: Implications for the NHS

1. To determine clinical and public health impacts for women and their babies, including type of delivery, low birth weight, admission to Neonatal Unit; method of infant feeding planned during pregnancy; infant feeding initiated at birth and baby's feeding method at 6 weeks of age; impact on mothers' smoking behaviour and to compare these for women who have received the volunteer doula service with data for the general Hull PCT population, a designated statistical neighbour and England averages
2. To identify the impacts on and experiences of NHS maternity care services and providers (midwives and Heads of Midwifery)
3. To identify impacts on other NHS services including referral to and uptake of smoking cessation services
4. To determine the actual and potential impacts on NHS maternity resource use of roll-out of doula support at scale
5. To determine potential savings to the NHS through clinical events averted by the service

Q2: Health and psychosocial impacts on women

6. To identify underlying beliefs and theories about how the service works and the contexts in which it has more or less impact
7. Based on this, to identify key outcomes which will allow the theories to be tested
8. To identify the views, experiences and psychosocial impacts on women who have been recipients of the service
9. To examine the characteristics and reasons of women who disengage from the service

Q3: Impact on volunteer doulas

10. To identify the views and experiences of the volunteer doulas and the impacts on their life course

Q4: Implementing and sustaining the service

11. To provide an independent assessment of the costs of providing a volunteer doula service, including training
12. To identify the challenges, facilitators and barriers experienced by the manager and staff (Locality Development Workers) of the Goodwin volunteer doula initiative in

establishing and maintaining the service
13. To identify the process of agreeing funding for service costs and the main factors responsible for the positive decision
14. To examine facilitators and barriers to implementation in the roll out sites and the extent to which these differ between sites and compared to the original service
15. To investigate the experiences of the replication package at the roll out sites

2. Background and contribution of existing research:

The maternal mortality rate for disadvantaged women is higher than for the general population(1). Similarly, for babies born to disadvantaged women, the chances of dying around birth or within the first month of life are higher than for babies of women who are not in adverse circumstances(2). Disadvantaged women have higher rates of smoking and formula feeding than other population sub-groups and are less likely to access routine services for themselves and their babies. Barriers include a lack of access to appropriate services (e.g. for very young women and their partners), lack of staff training in culturally-appropriate care, and a lack of knowledge among health professionals about relevant interventions and services that they could refer to. Recently published guidance for service provision for pregnant women with complex social factors recommends that such barriers are addressed; multi-agency working should be supported and the care provided by different agencies integrated(3).

Support and care in pregnancy, labour and postpartum have a positive impact on women's wellbeing and outcomes including reduced operative birth and increased breastfeeding rates. In the UK, the provision of intra-partum support has traditionally been the role of the midwife. However, current midwifery staffing levels are low and it is challenging to provide women with the ongoing support they need in these vulnerable and formative months. There is evidence that a significant proportion of women are worried by feeling unsupported by healthcare professionals during at least part of their labour(4). This lack of support is often due to high workloads on busy labour wards and is unlikely to improve in the medium term, given the demographic profile of the midwifery workforce with a high number of retirements anticipated in the next ten years. It is also recognised that services can offer care that is somewhat fragmented, with little coordination between midwives, health visitors, GPs, and social services, all of whom are likely to be involved in the care of families during pregnancy, birth and the early postpartum weeks. Such support and coordinated care is likely to be especially important in low income communities and for young women, as women in these circumstances have lower rates of breastfeeding, increased rates of infant mortality, and problems with emotional and psychological wellbeing(2).

The proposed research aims to examine an award-winning innovative social enterprise service that has been established in one city, Hull, and that is now rolling out to other sites. Based on principles derived from controlled studies conducted in other countries, the Hull Goodwin Doula Project offers lay support to women in vulnerable circumstances with the aim of enhancing support and improving the uptake of existing health and social services.

The lay support is offered by volunteer 'doulas', a term to denote a woman who supports other women during pregnancy, birth and breastfeeding. The role is not one of a clinical professional, but of a trained lay supporter and does not include the support provided by female members of the woman's own family. Doulas offer emotional and physical support and companionship, and facilitate communications between the woman, her partner and healthcare professionals and services(5). In some situations, doula support may also include guidance with parenting. There

is a substantial evidence base, derived from randomised controlled trials and other studies conducted in a diverse range of settings and systems, in countries including South America, the US, Sweden, Finland and Belgium, that have demonstrated the benefits of doula support for childbearing women and their families. However there is no contemporary evidence derived from UK settings.

Existing evidence base

In preparation for this proposal, we conducted a rapid review of studies of 'doula support' including systematic searches on the following databases: Medline, Embase, Cochrane and CINAHL. The search was not limited by country, date, methodology or language.

Support during labour from trained doulas is associated with reduced length of labour(6), less pharmacological pain relief and oxytocin augmentation and fewer instrumental or operative births(7). All of these are important outcomes for women and their babies and reflect the QIPP Quality Metrics. In particular, instrumental and operative births are associated with increases in the risk of morbidity for women or their babies. This morbidity includes postpartum haemorrhage(8), genital tract trauma for the mother(9) and increased risk of intracranial haemorrhage for babies(10).

In addition to positive impacts on labour outcomes, there is also evidence of positive impacts on breastfeeding(11), including increases in the proportion of women initiating breastfeeding and continuing with exclusive breastfeeding(12). It is particularly noteworthy that these positive impacts have been achieved in groups where rates are frequently lower than national figures, including low income, first time mothers. These findings reflect the wider evidence base of breastfeeding support by peers(13) and resonate with contemporary policies that encourage the implementation of peer support for breastfeeding(14).

Positive benefits on women's psychosocial well-being include more positive feelings about labour and less anxiety(12), increased feelings of control(15) and confidence as a mother and fewer women experiencing postpartum depression and anxiety(16). Evidence suggests that doula support during labour may also have potential positive effects on parenting behaviours and the relationship between a woman and her child(17); including increased acceptance of a baby immediately after birth and an increase in behaviours such as stroking, smiling and talking to their babies(18) and more positive parenting when babies are two months old(19).

All of these findings resonate with important aspects of the policy context and many also offer potential benefits to the NHS from reduced resource use, including shorter inpatient stay following normal birth compared to assisted birth and fewer referrals to specialist services, including mental healthcare. Evidence of benefit from doula care is particularly striking for women in situations of social or economic disadvantage, those with lower educational attainment and where supportive contact starts during pregnancy. There are also suggestions that the provision of doula support is associated with increased use of *required* health care services(20).

The UK NHS spent £1.6bn on maternity services during the year 2008. Part of this cost is attributable to the high rate of caesarean sections that increased from 12% in 1990 to 24% of all births in 2008, each costing between £1,197 and £3,194(21). It was further estimated that the cost to the NHS for maternal care due to smoking in pregnancy is between £8m and £64m per year (depending on the costing approach)(22); a further £12 to £23.5m per year is spent treating

infant conditions attributable to smoking during pregnancy. Another study estimated that the cost of neonatal care for low birth weight babies was between £12,344 and £18,495 per child in English hospitals(23). These items reflect those in the QIPP Productivity Metrics.

The impacts of doula care described above are derived from quantitative data generated by randomised controlled trials and included in systematic reviews. There is a relative dearth of qualitative evidence to enable understanding of the experience of receiving doula support. The evidence that is available from women who received doula support indicates a greater sense of participation during labour(24). A recent study of the experience of receiving doula support in Sweden identified continuity; the 'natural' nature of the support provided and of a human dimension to the birth experience as the key characteristics of doula support. Private doulas are available in the UK(25); these are usually accessed by women from higher income groups who can afford to pay for their services. The potential to perpetuate inequalities in health and social support persists if mechanisms are not identified to allow doula support to be available, at scale and in particular, without cost to disadvantaged women.

Although existing evidence from a range of countries identifies important benefits to the provision of lay support in labour, key questions remain. There is a dearth of UK evidence, and doula support is rare in the UK, especially for disadvantaged women. Existing studies have as their major focus lay support in labour, yet there may be advantage in providing such support throughout the childbearing episode.

The current innovative service: the Hull Goodwin Doula Project

The Goodwin volunteer doula project in Hull, established as a social enterprise initiative, has provided support to over four hundred women in situations of social disadvantage since 2005. The project developed in an area of Hull with high levels of social and economic deprivation, poor education, housing difficulties and with health states lower than the general population. Women are referred to the Goodwin service by health professionals, interpreters, social services workers and the Teenage Pregnancy Support Services. Support can be offered at any stage but commonly starts around the sixth month of pregnancy and continues through the postpartum weeks. Following an initial facilitated meeting, subsequent contact occurs approximately fortnightly during pregnancy until the last month when contact occurs weekly. This project therefore differs from many of the studies of doula support identified, several of which were limited to care in labour and immediate postpartum.

The Goodwin project also differs in what the doulas are trained to do. Women who volunteer to provide the doula service, who are themselves usually women from the local area with children, receive training for the role, accredited by the Open College Network. Topics included in the training are preparation for birth and the birthing process, breastfeeding, child protection, domestic abuse awareness training, cultural diversity and communication skills. The doulas are expected to work closely with existing services, and to optimise women's use of both health and social services; for example, attending smoking cessation clinics, accessing Healthy Start, and attending clinic appointments. A Signposting woman to other services (e.g. smoking cessation) is another key part of the doula's role. Women referred to the service are matched with doulas according to personality, background, locations and availability. Volunteer doulas receive reimbursement of expenses, for example, travel and childcare during training sessions. There are systems in place to provide ongoing support for the doulas, through, for example, Locality Development Workers.

Although a full scale evaluation of this service has not been conducted, descriptive data are available. These data indicate a range of positive benefit when compared with the whole population of the city; under normal circumstances, women with the deprivation profile of those cared for would expect substantially worse outcomes. Data collected from the series of 111 women who accepted support in the year 2009-2010 show a caesarean section rate of 20% (vs. local rates 24.5%) and higher rates of breastfeeding initiation (79%) than that of the local population (55%). 39% of women supported came from black and minority ethnic communities, and 22% were under age 20. Testimonies from women who accepted the service indicate their appreciation; positive features described include companionship and support and practical advice in the postpartum. There are also suggestions that experience as a volunteer doula has enabled subsequent access to employment and higher education, indicating a community development aspect to this work(26). The scheme has received positive endorsement within the maternity profession with acknowledgement of a 'best practice' award from the previous Health Minister (Johnson). Confirmed funding is available for the Goodwin initiative until 2013 from NHS Hull and Hull City Council, where there is established support for the service and established multi-agency working. Information available to date has been collated by the Goodwin project management team, who welcome a comprehensive, independent evaluation of the impacts of their service, including the identification of factors that contribute to successful implementation in the UK setting.

Descriptive data such as those above, informed the Department of Health's decision in March 2009, to provide 3 years funding (£267,000) to support roll-out and replication in up to eight additional sites. This funding supports the provision of a comprehensive portfolio that informs every aspect of establishing and running a volunteer doula service, including: consultancy expertise for one year, support with issues related to human resources, volunteer recruitment and induction; 'training the trainer'; promotional material and support; training for the first cohort in each roll-out site and access to accredited training materials. Sites have to provide and fund their own staff. Identification of replication sites has been slower than expected. By February 2011, four sites had confirmed service funding for replication (Leeds, Thurrock, Bradford and Tower Hamlets), which have substantially different service and demographic contexts from Hull. The initiative has been presented at the W*orkforce challenges facing maternity services* meeting held at the King's Fund (April 2010) and interested sites around England. Several of the latter are seeking to identify funding to enable roll-out into their maternity services. It is timely, therefore, that maximum information is gained from the experiences of the Goodwin initiative and from the first four identified replication sites, where it can be anticipated that new challenges to the adoption of this innovation will emerge(27).

This study will provide systematically-derived evidence that will be carefully analysed and synthesised. The findings will inform the decisions and practices of healthcare commissioners, provide answers to commissioners' questions related to providing support for disadvantaged women, inform maternity service provision and multi-agency working, inform future volunteer doula programmes, and provide evidence for optimal implementation and sustainability of volunteer doula programmes and similar non-professional roles. It will help to address inequalities in health and care. It will augment the evidence base related to the adoption of innovation in health services, and it will quantify health gain and economic impact of roll-out at scale.

3. Need:

This research addresses a number of key health policy areas including the need to reduce infant mortality and inequalities in health and care, improving the physical and emotional well-being of childbearing women, promoting normality in childbearing, improving the quality and productivity of maternity services, developing the workforce and examining large scale workforce change, reducing smoking, increasing breastfeeding rates and improving child health and development. The outcomes in the proposed research relate closely to the Quality, Innovation, Productivity and Prevention framework. Examples of this include perinatal mortality, improving women's and families' experiences of maternity services and the admission of full-term babies to neonatal care, listed in the Maternity and Newborn-related Improvement Areas included in the NHS Outcome Indicators for Maternity, at the current state of development. In addition, breastfeeding (a key prevention strategy) outcomes are included as examples of *Better for Less* activity in the NHS Yorkshire and the Humber Monthly QIPP Resource Pack for October 2010. Caesarean section rates and length of stay data provide examples of productivity activity for which calculations of financial savings can be derived using the Outcome and Expenditure toolkits (ChiMat www.chimat.org.uk) using data available at the level of the individual PCTs. Additional items that are available through the toolkit include rates of low and very low birthweight babies and the proportion of women who are still smoking by the time they deliver, Caesarean section and normal birth and breastfeeding initiation rates. Data related to women's experiences of care and their psychosocial outcomes are key indicators of the quality of clinical services.

4. Methods & Plan of Investigation:

a. Setting

We will be working with five Volunteer Doula Services; all run by Third Sector organisations, the original Hull Volunteer Doula Project and four roll out sites (Thurrock, Leeds, Tower Hamlets and Bradford). All are focused on providing a service for disadvantaged childbearing women. Two are restricted to women from minority ethnic groups and a third serves an area with a very large minority ethnic population.

b. Design

Conceptual framework: This study takes a Realistic Evaluation perspective(28), in recognition of the complex intervention being investigated in a real-life setting. The focus is therefore not so much on addressing the question 'does it work?' but rather the subtler question of 'what works for whom in what context'. Use of this framework is built upon theorised mechanisms of how and why the intervention is effective which are derived both from the literature and from key informants. The study will therefore start with an update of the literature based on the rapid review that we have already carried out and interviews with key informants.

Sampling: There will be no sampling. All individuals meeting the criteria of the constituencies of research informants identified will be asked to participate.

c. Data collection

Data addressing the four main research questions will be collected from the following sources and is described in greater detail in the following pages:

Q1: What are the implications for the NHS of a volunteer doula service for disadvantaged childbearing women?

1. The records of the Hull Goodwin Doula Project. Records of obstetric and other health outcomes for women, as well as some process data, have been gathered over the years by the Hull Goodwin Doula Project in a bespoke database. Anonymised data will be compared with selected population reference groups allowing an estimate of the impact for the NHS at scale, including a health economic analysis.

2. One- off telephone interviews with Heads of Midwifery in each site.

3. Focus groups with midwives in each site.

Q2: What are the health and psychosocial impacts for disadvantaged childbearing women?

4. A retrospective survey of all women who have been referred to the service (all sites, women to be accessed via the services records).

5. The records of the Hull Goodwin Doula Project and the four roll out sites, as above. The database is part of the roll out package, so the expectation is that the roll out sites will be collecting the same data.

Q3: What are the impacts on volunteer doulas?

6. A focus group with 6-10 experienced volunteer doulas in Hull early in the project.

7. A survey of all volunteers who have been trained by the service (all sites, to be accessed via the services records).

Q4: What are the processes of implementing and sustaining a volunteer doula service for disadvantaged childbearing women?

8. Focus groups with Locality Development Workers (or equivalent) in each site. These are the social enterprise employees who facilitate the service, e.g. by matching doulas with referrals. In the roll out sites, these will be repeated after 11months to assess change.

9. Interviews with project managers in each site. In the roll out sites, these will be repeated after 11 months to assess change.

10. Interviews with local champions, i.e. the people who have been instrumental in championing the service in the roll out sites.

11. Interviews with commissioners in each of the roll out sites.

In addition, it is expected that the interviews and focus groups with all other staff and doulas in the roll out sites (sources 2-8 above) will also contribute towards addressing this question.

Further information summarising primary data sources is given in Table 1. All data collection instruments will be piloted to ensure relevance and clarity. Because our pool of potential participants is small and unique, piloting will be undertaken with the help of project advisors and an additional non-participating site with experience of commissioning support for disadvantaged childbearing women.

Table 1. Summary of planned primary data collection

Data source	Telephone Interviews	Questionnaires	Focus groups
Heads of Midwifery	N=5		
Midwives			N=5
Women, retrospective		600 max	
Volunteer doulas	max. 10 to follow up questionnaire responses	160 with possibility of follow up telephone interview	one early on in Hull
Doula Service managers	10 (2 in Hull because of change of manager and one year follow up in each roll out site)		
Locality Development workers or equivalent			max 9 (early in each site and then repeated 11 months later in roll out sites
Local champions	4 (roll out sites only)		
Commissioners	4 roll out sites		
TOTAL	**33**	**760**	**15**

Data collection from key informants in the Hull Goodwin Doula Project

Fundamental to all subsequent data collection are interviews with the current and former manager of the Hull Goodwin Doula Project and with the Locality workers whose role is key in matching each woman referred with a suitable doula. Not only will these individuals give us valuable information about how the service works in practice and what the enablers, barriers and impacts have been, they will also be key informants in allowing us to map the theories and underlying beliefs about "how the intervention works, and for who in which circumstances" (28). This is an essential underpinning to other data collection tools and thus needs to be conducted at the start of the project. Accordingly interviews with the current and former manager of the Hull Goodwin Doula Project and a focus group with their project workers will take place in months 2 and 3 (Nov-Dec 2011). Similarly, it will important to hear the views of at least some of the doulas at an early stage, since they are the individuals who actually deliver the intervention and develop relationships with the women. We will therefore conduct a focus group with approx. 6 present or past experienced Goodwin doulas in month 2 or 3 (Nov-Dec 2011). Ethical clearance for this initial data collection will not be required since the individuals concerned are not NHS employees, although the work will of course still be conducted to the highest ethical standards.

Data collection from women

Data collection from women is an important part of our study in order that service users are given a voice. This is particularly important in this situation where the users are, by definition, disadvantaged and are least likely to have their voices heard through other means.

The relatively small number of women involved (circa 100 per year in Hull, fewer in the roll out sites), had led us to plan a mixed methods study in order to maximise what can be learnt. However, due to budgetary constraints, we are obliged to limit data collection from women to a retrospective quantitative study which will incorporate all five sites. We will take a Realistic Evaluation perspective(28) to address the question of 'what works for whom in what context' based on theorised mechanisms of how and why the intervention is effective. At this level the analysis is therefore within the sample, rather than comparison with a control group. However, a number of data sources are available to us which will allow us to contextualise our quantitative findings against relevant reference groups as well (see below).

Involving disadvantaged women in research

This project will involve some extremely vulnerable women including teenage mothers, and women who are separated from their families and speak no English (e.g. asylum seekers). They may well be suspicious of strangers asking them questions and worry about the possible unseen implications of their answers, for example with regard to benefit entitlements or their applications to stay in the UK. Some topics will be particularly sensitive to some of these sub-groups, such as obstetric details and depression. It will be important that women are approached to take part by someone that they trust, and that they are reassured of anonymity and confidentiality. The initial information and request to take part will come from the Doula service itself, although no-one from the service will be directly involved in data collection. It will be emphasised that the researchers are independent of the service and that nothing that women tell us will be shared with anyone outside the research team in a way that allows them to be recognised (except in extreme circumstances such as risk of harm to the woman or her child).

We recognise that response rates are likely to be low for a variety of reasons: this is a mobile population so we will have difficulty locating some women; many women will be non-English speaking since at least two of the roll out sites are focusing on women from Black and Minority Ethnic (BME) communities; some women will not be able to read and write either in English or in their own language. Nonetheless, we will do whatever we can to encourage women to take part since their views and experiences are central to evaluation of the service. Specific steps are described in the following sections.

Women's outcomes

The use of a Realistic Evaluation Framework(28) means that the choice of outcome measures is critical and that they will be chosen to test underlying beliefs and theories about how the intervention works. These theories are generated both from the literature and from the beliefs of key informants, in this case user representatives and the doulas, doula managers and Locality Development Workers in Hull, who will be interviewed at an early stage in order that outcome measures can be finalised and application for Ethical clearance for subsequent phases can proceed.

The following domains of outcomes are likely to be included in data collection from women:

- health behaviours
- emotional wellbeing including self-efficacy, postnatal depression, the extent to which the woman feels in control of her life

- social support
- adaptive functioning
- health status
- feelings about the baby
- parenting beliefs
- attitudes and practices (including breastfeeding)
- relationship with doula
- overall retrospective assessment of the benefits and disbenefits of the service.

In addition some demographic data will be gathered, e.g. education undertaken, employment status, partnership status, relationships with family with particular emphasis on changes over time. The choice of specific measures will be guided as far as is realistic by the desire to be able to compare with key reference groups (see below). Apart from those specific to the doula service, all of the outcomes listed here are available in the Millennium Cohort study.

The retrospective questionnaire study

A single questionnaire will be sent to all women who have ever been referred to the service (including women who subsequently failed to engage with the service but not those still in receipts of the service) in each of the five sites. Questionnaires and covering letters will be translated into up to 5 additional languages as required. The records of the doula service will indicate what language a particular woman needs to be approached in. It is expected that circa 600 questionnaires will be distributed assuming 400 from Hull (from 2007-12) and 50 from each roll out site (2011-12). Responses will be anonymous unless women wish to identify themselves. For some women contact will have been quite recent, for others it could be as much as 5 years previously. This could potentially allow us to look for trends in the data by taking this time lapse into account, although it should be noted that there will be inevitable confounding with the age of the child and number of subsequent children. It will also allow us some insights into how the service has developed. Given our concerns about a low response rate, we plan to include all women on the services' databases, rather than limiting to, say, the last 3 years, in order to maximise the data, even though we recognise that those whose contact was some years previously are likely to be harder to reach.

The questionnaires will be sent in two waves. The first wave will be sent in June-July 2012 to all women referred up to 1st September 2011. All these women should have ceased contact with the service by then. A second wave will be sent in November 2012 to women referred since 1st September 2011 (but not including those for whom the service is still ongoing). This approach will maximise the number of women we can approach while spreading the load of data entry and reducing the time interval for women who had early contact with the Hull Goodwin Doula Project.

All women will be sent a paper copy of the questionnaire in the appropriate language but will be invited to submit their responses via an online version if preferred. We will also offer the option of having a researcher (bilingual if necessary) telephone them to talk them through the questionnaire. Reminders will be sent to non-respondents after 3 weeks, followed by a telephone reminder. Each questionnaire will have a unique code number to allow non-responders to be identified, but names and personal details will be kept separately from questionnaire data and only the immediate project team will be able to link data to names. Women will be assured that nothing that they say will be passed on to the service or to anyone else, in a way that identifies them, unless they so wish.

Questionnaire data will be analysed using SPSS (Statistical Package for the Social Sciences) using both descriptive statistics (means, frequencies etc) and exploring similarities and differences within the sample (e.g. older and younger mothers, site, time since service use) as sample size allows.

Data collection from Doulas

A number of studies have indicated that volunteers often gain substantial personal benefit from volunteer involvement(26) and the data collected by the Hull Goodwin Doula Project support this. We will therefore be asking the doulas about the impact on themselves as well as their perceptions of the impact on the women that they have supported and the community more broadly. We will also address issues of process and doulas' suggestions for how the service could be improved. A questionnaire will be designed for distribution in month7 (April 2012) with a second wave in October 2012 for the more recently trained doulas. As with the women's questionnaires, responses will be anonymous to encourage openness but will have a unique code number to allow us to identify and follow-up non-responders. Respondents will be asked if they would be willing to be telephoned for further information, if required, and a maximum of 10 follow up interviews with doulas will be carried out if issues are raised beyond the scope of the questionnaires. The development of the questionnaire will be underpinned by the interviews with key informants, as described above, including a focus group of approx. 6 experienced doulas from the Hull Goodwin Doula Project at an early point in the project (month 2 or 3).

Questionnaire data will be analysed using SPSS (Statistical Package for the Social Sciences) using both descriptive statistics (means, frequencies etc), and exploring similarities and differences within the sample (e.g. Site, amount of experience as a doula) as sample size allows.

Data collection from local champions, commissioners, project staff and managers in the roll out sites

Each roll out site will have had a local champion: an individual who championed the adoption of the project and saw it through to successful commissioning. Their perspectives will be an essential part of developing an understanding of this vital part of the process. To date only four sites have found funding to initiate the service. Others have expressed interest but have been unable to persuade commissioners to make the project a funding priority. This raises the question of what it is that has led these four sites to proceed with implementation of the roll out in an economic climate that has proved a barrier elsewhere. We will therefore also conduct telephone interviews with the key commissioner in each roll out site, who will be nominated by the local champion.

Other important informants will be the manager and project workers in each of the roll out services. As with their counterparts in the Hull Goodwin Doula Project, these individuals give us valuable information about how the service works in practice and what the enablers, barriers and impacts have been. Of particular interest will be a comparison of their underlying beliefs and attitudes about how the intervention works, with those in other sites. We will be seeking to understand more about how these beliefs and attitudes vary across the sites and how they relate to the reported experiences of doulas and women and their outcomes. Because the roll out sites will be at an early stage of their development, our study also affords the opportunity to study this development over time, by carrying out interviews with these key individuals both at the

start of the study (Nov-Dec 2011) and again eleven months later (Oct 2012). The first interview will ask not only about what has happened so far but also about aspirations for the coming year. The second interview will be able to revisit these and discover if these hopes were met.

Data collection from key individuals in the NHS

The data collection described above will tell us about the immediate impacts of those involved but also of importance are the perceptions of those involved in the delivery of maternity care. Telephone interviews will be carried out with Heads of Midwifery (HoMs) in each of the five sites. Both hospital and community midwives are likely to be directly affected by the introduction of doula support. We plan to ask each HoM to forward an email from us to midwives asking them if they have had experience of caring for a woman who has had support from the doula scheme and, if so, with the HoM's permission, whether they would be willing attend a focus group, during working hours and at their place of work to discuss their views and experiences. This will be supported by CLRN funding.

Data collected using interviews and focus groups will be analysed using content analysis to identify themes within the data, underpinned by the framework of Realistic Evaluation.

Data from the service database

Data from the bespoke database will give descriptive information on outcomes for the service since 2007. It will be possible to examine trends over time, for example of the numbers of women being referred and their characteristics as well as their outcomes. Although the study design precludes any direct comparison group (as explained above) we will be collecting data in a form that will allow multiple comparison reference groups. These will allow us to compare the results for women in our study with comparable data for certain clinical and psychosocial outcomes including health behaviours such as smoking and breastfeeding.

Reference Groups

Reference Group 1: Hospital Episode Statistics and PCT data

1) Detailed analysis of Hospital Episode Statistics and PCT data will be undertaken by analysts at the national Public Health Observatory for Children and Maternity (ChiMat , http://www.chimat.org.uk/) led by co-applicant Helen Duncan. These data sources will allow us to look at mode of birth, breastfeeding initiation, breastfeeding at 6-8weeks and smoking by a number of demographic factors, e.g. age of mother, ethnic group of mother, economic hardship of mother based on index of multiple deprivations. We will then be able to look at outcomes for demographically comparable subsamples within (i) the general Hull PCT population, (ii) the designated statistical neighbours for Hull and (iii) England averages. ('Designated statistical neighbours' are areas that have been identified as having similar key characteristics based on census data). These data, and Payment by Results tariffs, also hold utility for investigation of improved productivity and potential for cost savings.

Reference Group 2: Millennium Cohort Study

Many of the outcomes that we will assess were also used in the Millennium Cohort Study (MCS). The MCS has data concerning approx. 18,800 babies born in the UK in 2000-1, with oversampling in areas designated as 'ethnic' and 'disadvantaged'. Many of the outcomes being assessed in the FNP trial (and therefore in our study) were also used in the MCS. The size of the MCS dataset is such that it will be possible to look at outcomes for subgroups with demographic characteristics that match those of women in our study, thus providing an

additional reference group for a range of clinical and psychosocial outcomes. The Department of Health Sciences at the University of York has an active group of doctoral students and other researchers working on the MCS (including JMG) and it is anticipated that a member of the group will be willing to be employed to carry out the requisite analyses. This has been allowed for in the budget.

Reference Group 3: The Family Nurse Partnership (FNP) Evaluation Trial
A randomised controlled trial of the Family Nurse Partnership (FNP) is currently ongoing in 19 sites in England, all of which have high levels of deprivation, including three of the sites in the proposed study. The intervention is targeted at women aged 19 or under having their first baby. We would therefore expect considerable overlap of the demographic characteristics of women in that trial and those who have been referred to the Doula service. Professor Kate Pickett from the Dept of Health Sciences at the University of York is an advisor to our project and has also been responsible for compiling the measures and assessments used in the FNP trial. Our psychosocial outcome measures will, as far as possible, be based on those used in the FNP trial to allow comparison once the FNP data are released. Professor Pickett has agreed to act as liaison between the two studies.

Health Economic analysis

The objective of the economic analysis is to compare the costs and consequences of the doula service with a reference group. The economic evaluation will take an incremental analysis approach and will compare the incremental costs and incremental effects of providing the doula service to pregnant women. The doula service will be assumed to be additional to the currently available services through the NHS.

Whilst it is common practice in the health economics literature to take the cost-effectiveness or cost-utility approach based on short or long-term outcomes(31, 32), these approaches rely on translating the process or intermediate outcomes into a common outcome denominator, which in most cases is the quality-adjusted life years (QALYs). However, for interventions that have diverse range of short-term outcomes, a cost-consequence analysis is also appropriate. This approach is defined as an analysis '... in which costs and effects are calculated but not aggregated into quality-adjusted life-years or cost-effectiveness ratios'(33). This method is used to display all the key costs and consequences associated with the intervention for the purpose of comparison; the consequences are expressed in the most appropriate natural units for each outcome measure. This approach is particularly relevant when a wide range of multidimensional process outcomes are of interest for a particular intervention(34). The information presented in this format is understandable and usable for non-health economists(35), and it also overcomes the need for complex economic modelling to estimate the long-term effects expressed in terms of a single common outcome. This approach has been used in many studies in the recent years(36-39).

The main outcomes to be evaluated in this economic analysis will be the clinical events that have been hypothesised to be influenced by the doula intervention, including mode of birth, use of epidural during labour, incidence of low birth weight, rates of breastfeeding initiation and smoking cessation. The data on these outcomes for the doula service recipients will come from the Hull Goodwin Doula project database, while the estimates for the reference group will be based on the data derived by Chimat (as discussed above). Resource use and unit costs associated with the clinical outcomes will be estimated based on the NHS reference costs database(21) and the Personal and Social Services Research database(40). The cost of providing the doula service will be estimated based on information from the Hull Goodwin

Doula project and the roll out sites. The economic analysis will identify any cost-savings associated with the doula service along with the benefits of the programme in terms of the outcomes outlined above. The analysis will also estimate uncertainty around cost savings.

d. Data analysis

5. Project Management:

Project management meetings of HS, JMG and the research fellows will be held, led by the PI, initially fortnightly and subsequently monthly, and other co-applicants will be invited to join these in person or by teleconference at appropriate stages. Excellent infrastructure resources are available on site, e.g. NHS Centre for Reviews and Dissemination; IT support; induction, mentorship and training for new staff. We anticipate a maximum of two Advisory Group meetings during the course of the research, as additional advice will be available to us between meetings by email and teleconference.

6. Service users/public involvement:

As explained under *Involving disadvantaged women in research* above, this project faces some particular challenges in involving service users. We have so far taken the following steps to overcome these. We have a co-applicant who is an experienced advocate for disadvantaged childbearing women and who will ensure that all possible steps are taken to access and respect women's voices. We also have the user Vice Chair of the Hull Maternity Services Liaison committee as an Adviser. A user of the Hull Goodwin Doula Service has also given helpful advice through telephone discussion which has informed this proposal and is willing to continue to advise on this basis. We hope to engage additional users of the doula service similarly by convening a user panel at the Hull site. The NCT (formerly National Childbirth Trust) are also supporting this proposal.

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