A neonatal discharge package to increase parental confidence in caring for their infant

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Aims and objectives.
The aim of the study is to assess whether the introduction of a parent-centred neonatal discharge package, known as a 'parent pack**',** can increase parental confidence in caring for their infant, reduce the length of stay (LOS) of infants in neonatal care and reduce health care resource use.

The primary objective is to compare maternal and paternal confidence when caring for a premature baby just after birth, at discharge and at home 8 weeks after discharge both before and after the introduction of the parent pack in 4 Local Neonatal Units (formerly known as level II units)(DH 2009).
The secondary objectives are to:
i) Measure the length of stay (LOS) of infants before and after the introduction of the parent pack and assess whether discharge is brought forward.

ii) Estimate the costs and cost savings associated with the parent pack intervention in terms of the NHS and other health care resources consumed by parents and infants in the 8 weeks after discharge in the period before and after the introduction of the parent pack.

iii) Use a nested qualitative approach to explore parents' and staff views of the intervention and its delivery in greater detail and to assess how easy the intervention was to deliver and any improvements that could be made.

Background
The survival of preterm infants has improved significantly over recent years, with survival rates of 91% for infants born at 28 weeks gestation and 98% at 33 weeks (UK Office for National Statistics 2011). This improved survival has resulted in more infants requiring intensive or high dependency care for a longer period, and increasing pressure on the scarce resources of neonatal care. The average LOS for infants in

Local Neonatal Units (LNU) in the South West during 2010 was 38 days (audit figures from the Badger System).

Neonatal care is an expensive and limited health resource with prematurely born infants occupying the majority of neonatal hospital bed-days (Rose 2008). Approximately 70,000 babies born in England (10% of all births) each year require additional medical care after delivery and are admitted to neonatal units (BLISS, 2010). Infants requiring neonatal unit admission can be categorised as needing intensive care, high dependency care or special care. The categories of care depend on the therapeutic and monitoring needs of the baby, and have been defined by the British Association of Perinatal Medicine (BAPM, 2001). Of the 70,000 infants admitted for neonatal care annually 19,500 are admitted to intensive care (BLISS 2010). According to the 2010 BAPM standards one nurse can provide care to one infant in intensive care, two infants in high dependency care, or four infants in Special care (BAPM 2010). The cost of care is determined mainly by the nursing staff requirements, with Intensive Care thus costing much more than High Dependency or Special Care. For most infants of less than 34 weeks gestation a relatively short period in intensive care is followed by a much longer period in High Dependency and then Special Care.

In the UK neonatal care is delivered in three types of neonatal unit which work together in managed clinical networks. Neonatal Intensive Care Units (NICUs) provide the full range of intensive care for infants from a wide geographical area with complex problems including extreme prematurity, in addition to providing high dependency and special care to their local population. LNUs provide limited intensive care, high dependency care and special care, for their own catchment population, and generally provide the majority of care for such infants born at 27 or more weeks of gestation. Special Care Units (SCUs) provide only special care for their local population (DH, 2009).

Preterm infants in the range of gestational ages (27-33 weeks inclusive) have more than a 90% probability of survival, but spend a relatively prolonged period in hospital. The progress of this group is relatively predictable and thus suitable for a discharge planning process where outcomes are anticipated and parents informed ahead of time about many of the expected events and changes over time. Infants born more prematurely will commonly be cared for over prolonged periods in the Regional Neonatal Intensive Care units (NICU) rather than LNUs, and those born closer to term will be transferred to the Regional NICU for care of complex anomalies or conditions (e.g. severe intrapartum asphyxia). The range of conditions and the very wide range of possible outcomes (in terms of in-hospital clinical course) make infants outside the 27-33 weeks range much less suitable for anticipatory care planning as a group.

The average LNU cost for each very low birth weight baby (birthweight less than 1500g, which is the mean birthweight at 30 weeks gestation) is over £13,000 and any increase in parental confidence to care for their infant at this early stage could reduce their LOS, reduce health care resource use, and result in significant health care savings (Petrou 2010).

There is growing evidence that early discharge programmes and integrated health care approaches in neonatal units substantially shorten the length of hospitalisation and need not increase utilisation of public health resources. This approach complements strategies employed in the adult setting where the discharge process is a key part of the patient experience. Evidence suggests that involving carers of patients in the patient's treatment and setting provisional discharge dates early in the hospital stay motivates them towards and prepares them for discharge (Rose 2008).

The major limitation in capacity for care of low birthweight infants is the lack of intensive care cots, both in NICUs and LNUs. Experience from several neonatal networks suggests that a major limitation to appropriate use of intensive care facilities is inability to move infants from intensive care to high dependency or special care cots because of delays in discharge of infants from these cots. A relatively small reduction in LOS in special care or high dependency care, which on its own would result in a relatively small potential cost saving, would thus have a disproportionate effect in improving availability of intensive care cots and allowing the most effective use of scarce resources.

An important component of routine health care for preterm infants after discharge from hospital in the UK has for many years been the support, advice and monitoring role of the generic health visitor (HV), who would routinely be allocated to all infants soon after birth. Changes to NHS workforce planning and commissioning processes have resulted in altered HV workload patterns and changes to their involvement with mothers and preterm babies (Craig & Adams 2007; RCN 2011). Consequently the role of the HV has shifted substantially, from a generic service role for all infants to a focused role providing less input to many families and concentrating on those deemed to be at highest risk. The role has also shifted from a predominantly health based role to one much more focused on the monitoring, prevention and identification of child neglect and abuse. This change in role has been accompanied in many areas by a significant reduction in HV numbers, and a loss of expertise in the care and support of preterm infants – both as a consequence of the change in health visiting practice and from experienced health visitors leaving the profession. This substantial reduction in the availability of experienced HV input in the care of ex-preterm infants after discharge from hospital has led many LNUs and NICUs to develop hospital based outreach teams that provide support, advice and monitoring to families of preterm infants for several weeks after discharge. They also address some of the parents' psychological and practical needs with individualised support, and care programmes. Our survey of UK neonatal units in 2010 showed the importance that staff attached to having post-discharge care of preterm infants coordinated by a team with knowledge and experience of hospital neonatal care.

Parents with babies in a neonatal care unit have particular psychological and practical needs which studies have addressed with individualised developmental and behavioural care programmes (Glazebrook 2007, Melnyk 2006, Van der Pal 2007, Wielenga 2006). Discharge home needs to be planned and families supported by preparation, overnight stays, health visitor contact details, and any home visiting/outreach in place. Discharge planning and the way in which discharge and adjustment to home takes place are key elements in supporting this transition, especially when vulnerable babies have been very sick. In 2010, we contacted neonatal units across England, Northern Ireland, Scotland and Wales to gain insights into their existing discharge practices and this demonstrated that all participating units had solely nurse-led documentation and described existing discharge processes as rarely planned and primarily reactive in nature These findings reflect Redshaw and Hamilton (2010) who report that family-centred care is inconsistent.

The POPPY (Parents of Premature Babies project) systematic review and report of parental experience (2009), described the key elements of family-centred care in neonatal units and found that in relation to the transition to home, families valued consistent communication, support in developing readiness for home and improved discharge information. Possible cost benefits, in addition to improving parental confidence and reduced LOS, may be reduction in re-admittance to hospital; reduction in non-scheduled attendance at emergency departments; an increase in attendance at scheduled outpatient appointments after discharge; and reduction in unscheduled use of community health resources.

One particular area of difficulty is in giving parents an idea of when their infant might be expected to be ready for discharge in the uncertain environment of the neonatal unit where unforeseen complications are common, and may lead to delayed discharge. From the experience of the POPPY review it is important that as far as possible information about the day to day vicissitudes of infant condition does not lead to similar ups and downs in parents' perceptions of how their baby is progressing overall. This must be achieved without being dishonest or giving them an unduly optimistic or pessimistic view, or one that is too much influenced by short term variations in infant conditions. To achieve this requires a highly disciplined approach to how we inform parents of events, and requires that information is as far as possible presented to parents by relatively senior staff, well trained in the use of the patient pathway approach. Recent work in US and Canada involving educational interventions for parents that started early in the neonatal unit stay have shown that parent-infant interactions are enhanced and hospital LOS reduced (Melnyk at al 2006).

This developing pattern of focussed hospital based outreach care rather than generic community based care, which is new to the UK, is similar to that which has been developed over a period of many years in Canada. One of our team (SM) was successfully awarded funding (Sir Halley Stewart Trust) to investigate the

benefits of an 'interactive discharge planning tool' developed at McMaster Neonatal Unit in Canada to achieve 'timely transfers to the next step-down level of care'. The use of this tool in the unit gave the family "implied permission to speak" (Gaal et al 2008) and with this tool, parents asked more questions than previously and the tool served to open up dialogue. The Canadian project prepared the family for transfer from an intensive care unit to a local unit nearer to their home; however, the processes, philosophy and thinking that underpin their work are as valid for the transition from intensive care to high dependency or special care within the same neonatal unit, or for discharge to home. The Canadian tool emphasises the importance of communications with parents that are focussed on the parents' needs and understanding rather than being driven by the infant's needs as perceived by the clinical staff. Other features include recognition that for families with infants in a neonatal unit the concept of 'the family' includes the neonatal unit for a brief time in their lives, reinforcing the transitional aspect of their experience; that parents should be shown how to continue to read the changing cues of their baby; to consider and identify areas that require anticipatory guidance and ensure that the drive to reduce LOS in the unit is driven by the appropriate criteria and that practice in the unit remains led by baby and parental readiness.

We have adapted the McMaster discharge tool creating a 'parent pack' which has two parts; the first is a template 'train to home' which operates a Red, Amber, Green system of capturing the health of the baby and which helps the parent monitor the progress of the infant whilst in the neonatal unit; the second part is two gestational age-appropriate care pathways (27- 30 weeks GA and 31-33 weeks GA) for family and staff working towards discharge. The parent pathways comprise a series of topic areas (breathing, feeding, growth, temperature, sleeping) for the parents to discuss with the nurses and doctors caring for their baby to help them understand what is being said to them and to facilitate completion of the coloured windows in the neonatal train, which may change each day and show the progress of their baby in the unit. Any clinical details about their baby will be relayed verbally to the parents and we will use all the currently existing resources available for translation at each unit for parents with language difficulties. This will include staff and family interpreters, the use of community link workers and the use of "Language Line". Adding extra facilities for translation or cultural interpretation of information would complicate the nature and potential effects of the planned intervention and make interpretation of the results difficult.

The parent pack has been developed with input from current and ex- NICU parents (our Parent Advisory Group) and nursing and medical staff to develop a pack that is culturally and linguistically relevant and reflects differences of culture, the use of language, and healthcare systems between the UK and Canada.

Our discharge pack is parent-focused as opposed to nurse-led and this project aims to investigate whether this approach will increase parents' confidence in caring for their babies once they get home and reduce babies' LOS in hospital. If we educate families better and they have increased confidence, we may also improve the appropriate use of hospital and community health services after discharge, with a reduction in numbers of readmissions of babies to hospital.

Self-efficacy tools (based on Bandura's Social Learning Theory), indicate belief and confidence about one's perceived ability to plan and carry out specific tasks (Bandura 1977). Behaviour-specific scales have been developed to identify those with high or low confidence and we will measure maternal and paternal confidence in caring for their baby using the validated Perceived Maternal Parenting Self-Efficacy tool (PMP S-E) (Barnes and Adamson-Macedo 2007) at three time points.

The 'parent pack' care pathways differ from the commonly used approach to care in most neonatal units as identified in our 2010 survey outlined above, in that soon after admission, a provisional discharge date will be marked on the pathway and by working towards that date to go home the parents and staff can focus the parental education needed to ensure that parents are ready. The health of the baby will be central in decision making and referring to the pathway will provide affirmation that the baby is moving along.

A search of current NIHR research has not revealed any current projects in this area. Discharge planning and patient/parent empowerment are high priority areas for both the NHS and NICE. "Care of the baby and

family experience" was one of eight principles highlighted by the Department of Health in the Toolkit for High quality Neonatal Services (DH, 2009). Strategies employed to improve the patient/parent experience and timely discharge need to be evidence based. In many neonatal units no discharge process initiatives are in place and there is potential for a UK wide initiative to manage the journey from hospital to home with a focus on the process being 'parent-led' rather than 'nurse-managed'. This project will add to current evidence in the neonatal setting to improve practice.

The proposed intervention study will collect parent reported self-efficacy measures at three time points from parents in 4 LNUs in the Southwest (Bath, Swindon, Taunton, Exeter), and compare outcome measures for all infants of born between 27 and 33 weeks completed gestation before and after the introduction of the parent-centred package.

Methods

1. The parent-centred neonatal discharge package: **the Parent Pack**

The parent pack is designed as a response to the reactive and poorly planned nature of existing discharge planning identified in our 2010 study outlined above. It provides a focal point around which planning for discharge to home can be discussed, and consists of a teaching aide in the form of a parent-focused neonatal train-to-home and gestational age appropriate pathway. The pack is parent friendly, uses simple language and supports teaching parents about 5 aspects of infant care to facilitate their progression to home (see Appendix I).

The neonatal train-to-home has been developed with agreement from a model used in McMaster Neonatal Unit, Hamilton, Canada and is a washable plastic, 2-dimensional image (Appendix I). The train is designed to be kept up to date by the parents, and is a device to ensure that staff have a continuing awareness of the parents' perceptions of their baby's progress. There are three stations marked on the train track representing the journey to home: ICU/high dependency, special care and home. It is a representation of a train with five windows relating to key areas of health necessary for babies to be able to 'manage' before they might move to areas of the unit where the care might be reduced or leave to go home. These 5 windows are breathing, feeding, growth, temperature and sleeping. Soon after admission, in the first week of their stay, a provisional discharge date will be marked on the train and by working towards that date to go home, the parents and staff can focus the parental education needed to ensure that parents are ready for that date.

Parents will be encouraged to mark each window with washable/wipe-clean red, orange or green marker pen depending on their baby's care needs on a daily basis or whenever they visit. For those babies who need intensive or high dependency care, the windows are marked using red marker pen i.e. 'stop'. As the baby's condition improves with decreasing dependency in each area, the relevant windows will be marked in orange pen i.e. 'proceed with care'. As the baby's required level of support in any area reaches that suitable for transition to the next level of care or to home, the appropriate windows can be marked with green marker pens i.e. 'go'. The colour coding of windows provide an at-a-glance reminder for the healthcare team and families of the baby's wellness and/or readiness to go home. Both discrepancies and agreements between the parents' perceptions and those of the clinical staff will be rapidly identified and will form the background to regular structured and informal communications between staff and parents to ensure they are fully informed, understand the baby's progress, and have the opportunity to ask questions about all aspects of the baby's care and needs.

It is vital that the families know that the health of the baby will be central in decision making and that there will at times be 'good' or 'bad' days; however, more broadly, reference to the pathway will allow parents to recognise the underlying pattern of progress despite these variations, and that home is now, for example, 4 weeks away if all continues well.

The gestational age-appropriate care pathways have been developed with agreement from models used in the Children's Hospital Eastern Ontario and the IWK Health Centre, Halifax in Nova Scotia and provide the multi-disciplinary neonatal team with a focus for the education of parents. There are two pathways to home:

27-30 weeks gestational age and 31-33 weeks gestational age. These pathways will be used by parents and staff in facilitating parents' care of the baby whilst in hospital, and as for the "train" will be the basis for improving parental understanding of the baby's progress and proactively acquiring the necessary knowledge and skills to deal with the baby's changing needs as or before those needs arise. The pathway will then become an important part of the parent-held infant record after discharge. A copy of the completed pathway will also be placed in the hospital record at the time of discharge. Each pathway orientates the parents to what they can expect of their stay in the neonatal unit. The pathway has 5 headings which mirror the windows of the discharge train and uses simple language to support the education of parents from a varying population in terms of literacy, education and language skills.

As these pathways are designed to be used by all professionals who interact with the family, LNU-Nurse Champions (who will be recruited in each of the intervention units – see below) will encourage all professionals to focus the education of the parents through the pathway tool where appropriate. Parents and professionals can then update the tool where needed. However, it is not intended that the pathway captures each encounter at each teaching opportunity as this can then become too mechanistic. The pathways have pre-determined headings that have been identified by clinical and nursing staff as central to support the family moving towards home and these will serve as opportunities for engagement and to promote confidence.

2. The proposed intervention study.

Study Design
We will use a before and after design for two 11-month periods with an intervening 1 month 'washout' period and staff training to investigate the effects of introducing a **parent-centred neonatal discharge pack** in four LNUs in the Southwest region (Bath, Taunton, Exeter and Swindon) on the self-efficacy of parents in caring for their infant

Study population
Parents with infants of gestational ages 27wk 0days to 33 wks 6 days inclusive admitted to 4 LNUs during two 11-month periods.

Primary Outcome
The primary outcome will be the change in maternal and paternal confidence from admission to discharge, as measured by the Perceived Maternal Parenting Self-Efficacy tool (PMP S-E) (Barnes and Adamson-Macedo 2007). The PMPS-E tool is a psychometrically robust, reliable and valid measure of parenting self-efficacy for mothers of relatively healthy preterm neonates and the developers have also agreed that it is appropriate to use it with fathers (Chris Barnes personal communication). (Appendix II). Parents will be asked to complete an assessment of their confidence to care for their infant within 14 days of their infant being admitted to the LNU, at the time of discharge and by postal questionnaire 8 weeks later.

Secondary outcomes
i) LOS of infants from birth to discharge from the LNU, collected directly from the units.

ii) Healthcare resource utilisation in the 8 week period after discharge. Parents of the infants discharged from the intervention units, during the initial (non-intervention) period and the subsequent (intervention) period will have additional sheets inserted into their parent-held Personal Child Health Record ("red book"), on which parents will be encouraged to record all contacts (planned and unplanned) with health care services weekly over the 8 week period from when their infant is discharged. This will include unplanned contacts – e.g. NHS direct, GP appointments, calls to out of hours services, unplanned contacts with hospitals (particularly A & E), as well as planned contacts – e.g. outpatient follow up appointments, GP appointments, HV contacts both in person and by phone. A resource use tool has been developed to identify and quantify the key components of health care utilisation by families of preterm infants. (See Appendix III). In addition, it is intended to elicit essential resource use data fortnightly using mobile phone text messages to validate the written record and to fill gaps in the data that might arise from parents being unable to complete the

written record in the additional sheets in the babies' red books, which will be collected at the end of the 8 week post discharge follow up period (see Economic Analysis below). Because of the strong seasonal influence on post-discharge hospital contacts (e.g. seasonal viral infections) multivariable comparisons of post-discharge health resource utilisation between the two time periods will include month of discharge as a mandatory variable. The two periods of study will also be seasonally matched.

iii) Assess how easy the intervention was to deliver and any improvements that could be made using qualitative methods with both the staff (focus groups and process data) and parents (semi-structured interviews).

Recruitment

Prior to the introduction of the parent pack we will recruit two 'nurse champions' from within the staff in each intervention unit. The eight nurse champions will each be part-funded from service support costs, and will work closely with the research team in identifying and recruiting families to the study in both the initial (pre-intervention) 11 month period and the subsequent (intervention) 11 month period. Posters in the parents room will describe the study and encourage them to ask the nurses about it. At the end of the pre-intervention study period a "wash out" and staff training period of 1 month will ensure that almost all infants born during the study period have been discharged before implementation of the intervention parent pack commences. Infants born within the 11 month period of recruitment who have not been discharged by the end of the twelfth month will be few but in both the pre - intervention and intervention periods will be removed from the primary analysis and dealt with separately. The training and familiarisation process for the staff in the intervention LNUs will take place during this two month period, during which time the nurse champions will help to ensure that all members of the LNU staff are trained and familiar with the pack and its use. Recruitment to the second (intervention) 11 month period will commence 12 months after the first to ensure no seasonal discrepancy between the two periods of data collection. In order to ensure all families receive equal care, the parent pack will be used for all babies born at less than 34 weeks gestation who are admitted to the intervention units during the study period, regardless of whether the baby meets the study inclusion criteria or parents have given consent for inclusion in the study.

Inclusion criteria

Parents eligible for inclusion in the study will be those whose infants are:

a) Born in the study LNU or transferred into the units within one week of birth at gestational ages between 27 weeks 0 days and 33 weeks 6 days inclusive during the initial 11 month control period and the subsequent 11 month intervention period, and

b) Have a home address within the primary catchment area of the LNU

Exclusion criteria

Parents with:

a) Infants who are born in another neonatal unit and not transferred into the LNU within the first week after delivery,
b) Infants born in the study LNU who have a home address outside the primary catchment area of the LNU
c) Triplets or higher order multiple births
d) Infants with major congenital anomalies i.e. those likely to require transfer to and/or treatment in a regional tertiary medical or surgical centre within early infancy.
e) Infants who would otherwise be eligible, but who are transferred to another neonatal unit and discharged to home from there rather than from the study LNU.

Parents whose infants otherwise meeting the inclusion criteria, but who have spent part of their hospital stay in another neonatal unit (e.g. a NICU) for any reason will be included, but will be identified separately for purposes of analysis.

Data collection.

Written informed consent will be sought from all eligible parents in the LNUs when their infant is aged 4-7 days. At this point, data on background family characteristics, pregnancy history and current pregnancy details, and baseline PMPS-E will be collected. At discharge from the unit a further PMPS-E score will be taken and a record of the amount of time the parents have spent in the LNU. Parents will be given four diary sheets to keep in their infants' red book to record their use of health services over the following 8 weeks. These will be returned by post to the research team at 8 weeks with a final PMPS-E. Fortnightly phone or text message reminders from the researchers will encourage parents to record this information.

A "washout" period to allow discharge of almost all infants born within the initial control study period, will avoid contamination of the data from this initial control period, and for training of all staff members in the use of the intervention. The parent pack will be introduced for all newly admitted infants of less than 34 weeks gestation. At the end of the training period we will repeat the information gathering process as outlined above for a further 11 month period (which will occur at the same time of year as the initial control period).

To encourage completion of the self-efficacy tool, parents will be given a £5 voucher on completion of the PMPS-E at discharge and another 8 weeks later on completion of the PMPS-E and health care resource use data sheets.

The final 5 months of the study will be used to complete follow-up, data analysis and writing-up of results and dissemination activities. Data cleaning will be a continuous process throughout the data collection period.

Statistical considerations:

The primary outcome measure will be the Perceived Maternal Parenting Self-Efficacy Questionnaire (PMPS-E) measured in the first few days after birth (baseline) and at discharge (on average 6-7 weeks later). As a secondary outcome the PMPS-E will also be measured 8 weeks after discharge. This psychometric measure of parenting uses 20 statements and a 4 point Likert scale (ranging from strongly agree to strongly disagree) with a minimum score of 20 and a maximum score of 80. It has been validated using mothers (N=165) of hospitalized preterm neonates (average gestation 31.9 weeks) with a mean score of just under 60 and SD of around 10 measured 10 days after birth (Barnes and Adamson-Macedo 2007). A preliminary controlled study conducted by Barnes (2007) on potential changes in score over a 10 day period (using an intervention such as encouraging the mother to hold and stroke the baby) yielded a 10 point improvement compared to a higher than expected 5 point improvement amongst the controls (placebo effect). This suggests a potential medium effect size of 0.5. Assuming a more moderate effect size of 0.4SD (equivalent to a 4 point improvement more than the controls) and 80% power with a 5% significance level and 2-sided test we would need 100 parents in each group (200 in total). In 2010, 181 singletons and 81 twins were born between 27 weeks and less than 34 weeks and admitted to our 4 intervention units within the first week of life over an 11 month period (audit data from the Badger system). This suggests we will have in excess of 220 mothers to invite into the study for each arm of the trial over each of the 11 month recruitment periods, of which at least 80% (n=176) would be eligible for the study. If we recruit 70% of mothers with 20% loss to follow-up we will recruit around 100 mothers per group. Our experience in previous similar work suggests very high uptake and few families lost to attrition. If we achieve higher recruitment rates and lower loss to follow-up rates (i.e.90% and 5% respectively) we could recruit 150 mothers per arm which would increase the power of the study to 93%.

The analysis will include multivariable regression modelling to assess the influence of different covariates on the PMPS-E measure including family factors (socio-economic status, distance from family home to LNU etc) maternal factors (maternal age, parity, previous experience of premature birth, pregnancy complications, amount of time spent with the baby etc) and infant factors (gender, gestational age, birthweight, multiple births, medical conditions etc).

The baseline measures of the PMPS-E will be taken into account by both investigating the change in score between time-points in the two groups and including the baseline distribution in the modelling process, if there are any differences between the two groups. Univariable analysis, ANCOVA and multivariable regression modelling (primarily logistic regression) will be used to assess the primary outcome including the initial baseline values and potential covariates (demographic and clinical variables pertaining to the family, mother and infant) that may have some bearing on the relationship we are trying to assess. Multiple Imputation techniques may also be used depending on the amount of missing values.

Qualitative interviews: A nested qualitative study will explore parents' and staff views of the intervention and its delivery in greater detail. A purposive sample of up to 20 parents will be selected from those in the study in the initial (non-intervention) period and 20 in the subsequent intervention period to include a range of ethnic and socioeconomic groups, gestational age of infant and multiple births (maximum variation sampling). Parents will be invited to be interviewed by a qualitative researcher before they are discharged home with their baby and the sample will be selected from those who have agreed. These parents will be telephoned about 6-8 weeks after going home and the interview conducted at their home, by telephone or in a place of their choosing. A topic guide for the interviews will be developed in conjunction with our Parent Advisory Group, relevant literature and discussions within the management team and will include their experiences of having a baby in the LNU, their perceptions of communication with staff about their baby's condition, preparation for discharge and contact with health services since discharge. Interviews will be transcribed and analysed using NVivo software. The use of constant comparative technique will be used to facilitate an iterative analysis of the interviews so that emerging themes may be tested in subsequent interviews.

Process data will be collected by the nurse champions on the numbers of parents offered the intervention in each unit and its uptake. In addition we will use routinely collected data from each unit to document the numbers of babies, dependency levels and staffing levels during the two study periods.
Focus groups for staff in all units will be held before and after the intervention to explore current discharge processes; details of the training provided and any changes necessary; changes made after the intervention was introduced, their views on how easy it was to deliver and any changes that could be made, and their views on parents' reception of the intervention; and practical issues around the time involved in helping parents understand and use the train and pathways. Questions will also be asked about the climate on the unit, whether there are any issues about staffing levels or operational critical incidents that may have a bearing on the project. In addition to this, methods common in ethnographic projects will be used i.e. through semi-structured informal interviews/field notes with the Nurse Champions in their ongoing contact with the research team. This allows for contemporaneous data to be collated and analysed and used to inform the final analysis. This would also add contextual data to inform the analysis of the interviews with mothers. A formal semi-structured interview with the Lead Senior NICU Nurse for each unit will be conducted to generate coherent stories that illuminate the organizational issues playing out during the study. Thematic analysis of the focus groups and interviews will contribute to any changes required to the training manual and delivery procedures for the intervention as a result of using it in 4 different settings. This will facilitate a future roll out across the SW Region and the UK.

Economic analysis
The Toolkit for High-Quality Neonatal Services identified the difficulties in costing neonatal care. Economic analysis will identify measure and value the before-after costs and cost-savings that arise for parents in the non-intervention and the intervention periods during the hospital stay and up to eight weeks after discharge of the infant. It will estimate the differences in these costs and cost savings between the control and intervention periods. Resource use volumes and price/cost values will be estimated separately. This is because more accurate estimations can be obtained using this approach. A resource use tool has been developed (Appendix III). Unlike patient-reported measures of health outcome, tools for collecting resource use data are often designed by developing new questionnaires for each study or modifying questionnaires from a previous study, so they are not necessarily validated in their current form (Ridyard & Hughes, 2010).

Unlike outcome tools they do not have psychometric properties, but need to be appropriate, study specific and written in a way that is easily understood to aid accuracy of participant recall and self-report.

We will pilot our resource use data collection tool with our Parent Advisory Group to check for ease of completion and understanding before we submit it for ethical approval.

Part of the complexity of costing the care provided in the LNU is the different tariffs or prices attached to each level of care. To ensure that this is captured with clarity, we will implement a standardised approach to recording data on levels of dependency (based on the BAPM guidelines 2001) for all infants in the study.

In addition to an analysis from an NHS perspective, sensitivity analyses will be undertaken to explore other relevant economic evaluation perspectives including a societal perspective given the potential importance of the parent pack to parents and other public sector stakeholders. A societal perspective will include parental travel costs, time off work and the cost of arrangements to look after other siblings. Our resource use tool will also capture time off work and the cost of arrangements to look after other children alongside parental travel costs. These adjustments are judged to fall within the boundaries of data collection burden among parents given the nature of this study.

Economic analyses will provide a robust estimate of the costs associated with delivery of the parent pack and cost-savings based on participant reporting of resource use from the resource use tool. Resource use data in volume units will be combined with price and unit cost information from published sources to estimate mean differences in costs per hospital. Confidence intervals will be calculated using bootstrap sampling at the hospital level. Results will be presented in a disaggregated tabular format for decision makers from each perspective.

Contribution to collective research effort and research utilisation.
Knowledge mobilisation activities: We will submit annual interim reports to HS&DR and a final report at the end of the study containing details of study progress and dissemination activities completed and any subsequent suggestions for implementation of the findings in neonatal units in the UK.

Dissemination: We will present and discuss the findings of the study with the South West Neonatal Forum which meets twice a year and is attended by clinicians, managers and nurses from across the Western and Peninsula networks. We will also present the findings and discuss them with the newly formed National Neonatal Alliance (with representatives from the British Association of Perinatal Medicine (BAPM), BLISS, Royal Colleges of Obstetrics and Gynaecology, Royal College of Nursing, Royal College of Midwives, and the Neonatal Nurses Association). This alliance has been formed to explore QIPP opportunities and to support national initiatives and so could very rapidly disseminate the findings and support incorporation into practice and delivery of neonatal services.

Research outputs will be published in peer-reviewed journals and presented at national and international conferences. Members of the research team (PJF, JI, PSB, HB) have extensive experience in developing and implementing changes in clinical service provision and running multi-professional training and education activities to effect such changes successfully. We will produce additional guidance for units to facilitate the implementation of the 'parent package', based on feedback from our intervention units. A key component in the implementation of the results of this study if shown to be effective will be local, regional and national parents' networks and we will actively involve BLISS and our Parent Advisory Group in this part of the dissemination.

Patient and Public involvement.
The discharge pack has been developed with input at every stage from current and past parents of preterm infants, and our Parent Advisory Group (PAG) has been involved in the development and design of the present study. The PAG will continue to meet regularly and will help in the study implementation, information sheets for parents, and topic guides for qualitative interviews. The chair of the PAG, Joanne Ferguson (JF) who has commented on the proposal and lay summary, will be a member of the Project

Steering Committee (see below). If the pack is successful in increasing parental confidence for our study population the PAG will play an important supporting role in helping with widespread dissemination and implementation of the discharge pack.

Summary: 33 months duration
April -July 2012 (before start of project): obtain MREC and R&D approvals for study. Recruit staff
August 2012: Start date of project: Set up. Recruit and train nurse champions in each unit. Nurse champions to establish communication networks within each of the units for training and dissemination of information on the project.
Oct 2012 – August 2013 inclusive: Initial study period. Recruit parents for data collection. Questionnaires on parental self-efficacy at baseline and discharge from neonatal unit and 8 weeks later; data on LOS, health service costs and on use of health service resources in the 8 week period after discharge. Interview maximum of 20 parents in the four units to explore parents' views of neonatal stay and discharge home in greater detail. Interviews with staff on current discharge processes.
September 2013: "Wash out" period and staff training on the parent pack. Continue data collection as above for infants still in hospital or in first 2 months after discharge.
Oct 2013 – August 2014 inclusive. Implementation of the parent pack in the LNUs. Recruit parents for data collection. Same data collection as for the first period. . Interview maximum of 20 parents to explore parents' views of the intervention and its delivery in greater detail and on the process of discharge home.
Sept - Nov 2014 inclusive. Completion of data collection for infants born during the intervention period. Conduct focus groups with nursing staff to review the intervention package.
Dec 2014-January 2015 inclusive. Data analysis and writing up of results.
Feb – April 2015. Presentation of results to professional (SW Regional Forum, National Neonatal Alliance, conferences) and parent groups (BLISS). Submission of results for publication.
Study end date 30th April 2015

Ethics and R&D approvals.
The study will be performed subject to Research Ethics Committee (REC) approval, including any provisions of Site Specific Assessment (SSA), and local Research and Development (R&D) approval. The collection of data with informed consent on parental perceptions, parental self efficacy, LOS and healthcare utilisation after discharge will require research ethics approval, which will be sought before the project commences as noted above. As the intervention being investigated does not involve any risk to the infants, and has been developed and piloted as a way of improving communication with and education of the parents, as an extension to existing approaches, we do not consider that the intervention itself requires research ethics approval. During the intervention period we propose implementing the package for all infants of gestation less than 34 weeks in the intervention units, but only collecting data on parental self efficacy, parental perceptions and healthcare utilisation after discharge for those families that have given informed consent.

Project Management.
The project management team (PMT) will comprise the PIs and co-applicants and will meet on a monthly basis initially and then bi-monthly throughout the study to monitor recruitment and data collection. The PI (PJF) will chair these meetings and take responsibility for the running of the project assisted by JI (co-PI) and SW as clinical lead and be responsible for submitting reports to NIHR. A project steering committee (PSC) will be formed with an independent chair, a neonatologist and nurse manager from one or more of the LNUs, representatives from the management team including PJF, JI, DP, MR and KP, and two members of the PAG (including JF). Dr Chris Barnes who developed the PMPS-E has also agreed to be part of the PSC. The PSC will meet 3 times throughout the study and the chair of the PSC will decide whether a data monitoring and ethics committee is required. The Parent Advisory Group will meet in advance of the PSC and their views will be fed back to the PSC.

Safety reporting.
Adverse events will be recorded in accordance with UH Bristol's Research Related Adverse Event Reporting Policy.

Monitoring and audit.
The study will be monitored and audited in accordance with Trust policy. All trial related documents will be made available on request for monitoring and audit by UH Bristol and the relevant Research Ethics Committee.

Data protection.
Data will be collected and retained in accordance with the Data Protection Act 1998.

Storage of records.
Study documents (paper and electronic) will be retained in a secure location during in the University of Bristol and after the trial has finished. All source documents will be retained for a period of five years following the end of the study. Where trial related information is documented in the medical records – those records will be identified by a 'Do not destroy before dd/mm/yyyy' label where date is five years after the last patient last visit.

Indemnity.
This is an NHS-sponsored research study. For NHS sponsored research HSG(96)48 reference no. 2 refers. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial.
NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm.
Ex-gratia payments may be considered in the case of a claim.

Research Governance statement.
This study will be conducted in accordance with the Research Governance Framework for Health and Social Care and Good Clinical Practice.

Expertise.
Professor P. Fleming (PI; UHBristol NHS Trust and University of Bristol): 5% (2hr/wk). PF brings expertise in paediatrics and treating premature infants, particular interest in neonatology, experience in successfully implementing changes in practice on a national basis and a continuing involvement in the development of patient related outcome measures for infants and children with complex needs. PI will lead the management group and provide overall guidance to the team.
Dr J Ingram (co-PI; University of Bristol and RDS-SW): 15%. JI brings trial design, project co-ordination, neonatal research experience, overseeing qualitative and self-efficacy aspects.
Dr P Blair (University of Bristol, RDS-SW, Bristol Randomised Trials Collaboration): 10%. PB brings trial design and overseeing data collection and statistical aspects of the project.
Dr C Rose (North Bristol NHS Trust): 2% CR is a neonatologist with detailed knowledge and research experience of the processes within neonatal care, patient pathways and discharge planning; particular interest in the development of parent-oriented approaches to discharge planning.
Dr S Wain (University Hospitals Bristol NHS Foundation Trust): 5% SW is a consultant neonatologist with expertise in the field of organisation of neonatal services and patient pathways; she will be the clinical lead for the project. Her role will be complementary to that of CR and she will be responsible for collating the routinely collected data from the Badger database.
Dr J Powell (University of the West of England): 8%. JP brings a public health perspective, experience in economic evaluation of national health programmes and interventions, overseeing and conducting the health economic analysis.

Dr M Redshaw (NPEU, University of Oxford): 4%. MR brings extensive experience of conducting research projects on the organisation and user experience of neonatal and maternity care; overseeing psychological theoretical aspects.
Dr D Pontin (University of Glamorgan): 3%. DP brings the community children's nursing and health visitor perspective to the project.
Dr S Manns (University of the West of England): 50%. SM will be one of the Research Fellows responsible for collecting, collating and analysing data, including the qualitative interviews and focus groups. She also has extensive research experience and knowledge of the long -term effects of prematurity on families.
Heather Burden (North Bristol NHS Trust and SW neonatal network lead): 2%. HB will provide the links into the Neonatal Units and liaison with and training of staff. She brings knowledge of developing, planning and standardising of the family experience during Neonatal care. She is also a member of the National Neonatal Alliance and SW Regional Forum.
Kay Pullen (costed within steering group expenses) is an NHS manager at University Hospitals Bristol NHS Foundation Trust. As the matron leading a tertiary NICU in Bristol she brings expertise in facilitating timely discharge planning.
A trial manager (40%) will co-ordinate the researchers and running of the trial with the management team and a second researcher (50%) will work alongside Dr Manns in data collection and analysis. The second researcher will collect, collate and analyse data alongside Dr Manns and carry out the statistical analysis under the supervision of Dr Blair.

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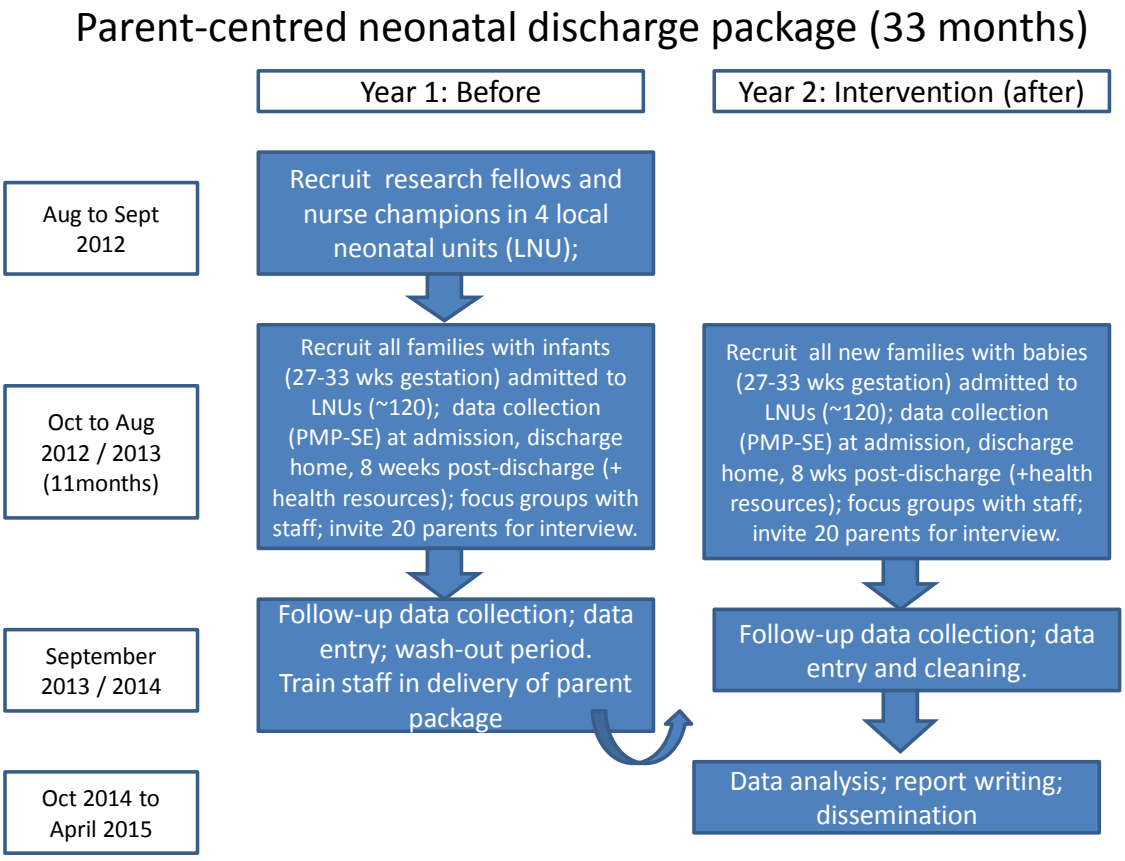
Flow Diagram.



Appendix I.

Neonatal train and pathways. (see separate 3 page pdf file)

Appendix II

The Perceived Maternal Parenting Self-Efficacy Questionnaire.

Barnes, C.R. & Adamson-Macedo (2007) **Instructions to parents**

Below are questions that relate to how you and your baby interact. When answering a question please **tick** the response you feel best describes how you feel about the statement.

i.e. Strongly Disagree; Disagree; Agree or Strongly Agree.

		Strongly disagree	Disagree	Agree	Strongly agree
1	I believe that I can tell when my baby is tired and needs to sleep.				
2	I believe that I have control over my baby's care.				
3	I can tell when my baby is sick.				
4	I can read my baby's cues.				
5	I can make my baby happy.				
6	I believe that my baby responds well to me.				
7	I believe that my baby and I have a good interaction with each other				
8	I can make my baby calm when he/ she has been crying.				
9	I am good at soothing my baby when he / she becomes upset.				
10	I am good at soothing my baby when he / she becomes fussy.				
11	I am good at soothing my baby when he / she continually cries.				
12	I am good at soothing my baby when he / she becomes more restless.				
13	I am good at understanding what my baby wants.				
14	I am good at getting my baby's attention.				
15	I am good at knowing what activities my baby does not enjoy.				
16	I am good at keeping my baby occupied.				
17	I am good at feeding my baby.				
18	I am good at changing my baby.				
19	I am good at bathing my baby.				
20	I can show affection to my baby.				

Appendix III. Health Resource use tool.

The Parent Pack

These questions are about how you use health services once your baby has come home from hospital. The information you tell us is confidential and we will not pass it anyone who is not on the research team.

1. Has your child gone to hospital in the last 2 weeks: Yes ❑ No ❑

If no, please go to Question 2

	Reason for attendance	Which hospital	No. of times in the last 2 weeks
Inpatient care: staying in hospital overnight			
Hospital Outpatient clinic: Baby clinic appointment			
A and E: Emergency Dept.			

If your child stayed overnight in hospital, please can you let us know the **number of nights** your child stayed in the last 2 weeks: _____

2**.** For each health service used by you for ***your baby*** in the last 2 weeks, approximately how much did it cost you and/or your family and relatives?

	Train £	Bus £	Taxi £	Car - total mileage	Parking £	Accommodation (Hotel/B&B) £	Number of days off work (both parents)
A hospital inpatient stay							
A hospital visit							
An A & E attendance							
A visit to the GP							

3. Please give details of any of the following services that you used for **your baby** outside of hospital in the last 2 weeks. This should include all telephone contact.

Appointment with or visit from	Did you see?	By phone?	Number of contacts in last 2 weeks	Typical length of each contact (minutes)	Was the contact at home?
General Practitioner (GP)	No/Yes	No/Yes			No/Yes
Practice nurse (at GP surgery)	No/Yes	No/Yes			No/Yes
Neonatal outreach nurse	No/Yes	No/Yes			No/Yes
Health Visitor or other nurse	No/Yes	No/Yes			No/Yes
Out of Hours doctor	No/Yes	No/Yes			No/Yes
Walk-in Centre	No/Yes	No/Yes			No/Yes
NHS Direct	No/Yes	No/Yes			No/Yes
Other therapist Type _____	No/Yes	No/Yes			No/Yes
'Complementary' medicine or therapy Specify _____	No/Yes	No/Yes			No/Yes
Social worker	No/Yes	No/Yes			No/Yes
Voluntary worker (including priest) Specify _____	No/Yes	No/Yes			No/Yes
Day centre/drop-in/baby group Name _____	No/Yes	No/Yes			No/Yes
Self-help group Name _____	No/Yes	No/Yes			No/Yes
Child minder to look after your other children					No/Yes

There are 4 of these sheets for your red book. Please start a new sheet after 2 weeks.

Thank you for taking the time to answer these questions. Your answers are very important in building a complete picture of how the parent pack might help parents, carers and their families and the use of NHS services