Births and their outcome: analysing the daily, weekly and yearly cycles and their implications for the NHS

Protocol Version 3, as at March 31 2017

Introduction

Analyses since the 1970s have shown that maternity outcomes have differed by day of the year, day of the week and time of day. It is unclear to what extent this reflects differences in characteristics of women giving birth, efforts made to intervene selectively in the onset of labour or in delivery, or in health services' workforce factors, notably numbers or seniority.[1,2] Previous analyses of data for England and Wales for the years 1970-76[3] and 1979-96[4] were based on aggregated counts and mortality was not disaggregated by cause. Analyses by time of day, method of onset of labour and gestational age were not possible in those analyses, as the relevant data items were not available at a national level for England and Wales.

Recent developments in data recording and linkage have changed this. As a by-product of the change to allocation of babies' NHS Numbers at birth in 2002, the time of day of birth is now recorded in a national dataset. As a result of a project led by City University London to link birth registration data with this NHS Numbers for Babies birth notification dataset, the Office for National Statistics (ONS) now has national data on gestational age and time of day of birth for years from 2005 onwards.[5] Linkage with Maternity Hospital Episode Statistics (HES), and National Community Child Health Database / Patient Episode Database Wales (NCCHD / PEDW) data for Wales in a project funded by the Medical Research Council, means that data are available about the onset of labour and mode of birth for most, although not all, maternities in the years from 2005 to 2007. The techniques developed during that project can be used to link these data for subsequent years.[6, 7] As morbidity in mothers and babies is also a matter of concern, it will be useful to extend this database by linking births to data about subsequent hospital admissions and readmissions of mothers and babies recorded in HES and PEDW.

Background and Rationale

Analyses of the outcome of births by day of week and time of day from Scotland[8] and the Netherlands[9] attracted considerable media attention and raised questions about the safety of 'out of hours' care. Both reported raised mortality rates among babies born outside usual

weekday working hours. The analysis of Scottish singleton birth and neonatal mortality data for the years 1985-2004 showed raised neonatal mortality attributed to asphyxia at weekends and on weekdays outside the hours of 9am to 5pm.[8] The authors found no changes over time and suggested that the findings were also true in other countries of the United Kingdom.

A ‘rapid response’ based on data from the West Midlands from 1995-2009 showed, however, that while similar patterns were found in the Region in the late 1990s, these had subsequently disappeared and there was no evidence of a raised mortality rate ‘out of hours’ in the years 2005-09.[10]

An earlier analysis of data for 1993-95 from the All Wales Perinatal Survey had pointed to higher rates of mortality related to intrapartum asphyxia in the holiday months of July and August and suggested a possible association with the rotation of junior doctors to new posts in August, but this was based on relatively small numbers of deaths.[11] A similar analysis of intrapartum related deaths in Scotland in the same years showed results which were in the same direction as those in Wales, but the differences observed were small and were not statistically significant.[12]

Previous analyses of data for England and Wales covered the years 1970-76[3] and 1979-96.[4] The first showed that rising induction rates in the 1970s were accompanied by a reduction in numbers of births at weekends and on Mondays and a corresponding increase from Tuesdays to Fridays.[3] Perinatal mortality showed a weekly cycle, with higher rates at weekends.

The next analysis covered the years 1979-1996.[4] It used more advanced statistical modelling techniques and found that stillbirth and early neonatal mortality rates tended to be higher on Saturdays and Sundays respectively, compared with other days. All the mortality rates varied according to the time of year.

Analyses by time of day, method of onset of labour and gestational age were not possible at that time, as the relevant data items were not recorded at a national level for England and Wales, even though they have long been recorded locally. Recent developments in data recording and linkage in England and Wales mean these analyses are now possible, along with analyses of data about any subsequent hospital care for mothers and babies.

The Scottish analysis[8] was restricted to neonatal deaths among singleton live births at term, defined as from 37 to 43 completed weeks of gestation. Although a key group, they form a relatively small proportion of neonatal deaths. As analyses elsewhere found differences by time of day and day of the week in other categories of births, this proposal aims to include births in other categories, but to analyse them separately.

The analyses of birth outcomes by day of week and time of day from Scotland[8] and the Netherlands[9] have contributed to the continuing debate and press publicity about workforce provision in terms of numbers of doctors and midwives and their seniority, as have two more recent analyses. One of these analyses used data from the Maternity Hospital Episode Statistics for records of births from April 1 2010 to March 31 2012 to analyse associations between days of the week of mothers' admissions and births of babies, and levels of consultant cover with perinatal mortality, infections, emergency readmissions and injuries to mothers and babies.[13] Its conclusion that mortality was higher at the weekends, met with considerable criticism, for including antepartum stillbirths in the analysis, for example.[14] This underlined the need for further research on this subject. It found no association between mortality and levels of consultant cover. The other study used data directly downloaded from 19 maternity units. It found no differences in outcomes at times of day when duty rotas for each hospital indicated that consultants would be on duty compared with those at other times.[15]

These questions about a possible 'weekend effect' are not peculiar to maternity care, as analyses of hospital care in other specialties have suggested that there is higher mortality among patients admitted at weekends.[16] This led to questions about relationships between the grade and specialty of key personnel,[17] and challenges to the assumptions behind the research.[18] There is now a considerable body of research on this subject and it is being reviewed as part of the research on the 24 hour health service commissioned by NIHR. [19]

As in other areas of health care, some earlier analyses of daily, weekly and yearly patterns of birth in other countries have produced differing results.[1, 8] In addition, a report by the NHS Litigation Authority on claims against the NHS for injury showed no difference between the rates of errors in and out of 'hours', although it pointed out that time recorded on claims will

often be the time of birth and so may not have been the time when the errors leading to claims occurred.[20]

The research described here will benefit patients and the NHS by describing current variation in the timing of births and their outcome in England and Wales as a whole and variations between maternity services in relation to their size, overall midwifery and obstetric staffing ratios and levels of intervention in the onset of labour and in delivery. This should inform local decisions about midwifery and obstetric staffing needs, the deployment of available staff as well as decisions about service configuration.

Retrospective analyses of routine data will provide important descriptive evidence about the issues raised here. In addition, although by their very nature they will not be able to provide answers to questions about causality, they will provide a key baseline and give rise to questions which could subsequently be tackled using other methods.

This proposal has the support of the Chief Executive of the Royal College of Midwives and of the Royal College of Obstetricians and Gynaecologists, both of which provided letters of support.

Aims and objectives

Aims

To build on work done in a previous project to link data from civil registration, notification of birth to allocate NHS Numbers to Babies and data about care during delivery to analyse linked maternity and neonatal data for England and Wales about births in the years 2005 to 2014 to compare daily, weekly and yearly variations in numbers of spontaneous and other births by time, day and season of birth and to compare variations in rates of adverse outcome.

Objectives

To achieve these aims, the objectives of the project are to answer the following questions:

1. How do numbers of births vary according to time of day, day of the week and time of year of birth and how does this relate to methods of onset of labour and delivery and multiplicity?

2. Subject to the availability of data, how do patterns of birth vary between maternity services in relation to variations in medical and midwifery staffing, patterns of intervention and size of unit?

3. How does the outcome of pregnancy in terms of rates of cause-specific intrapartum stillbirth and neonatal and infant mortality rates and rates of morbidity recorded at birth and at hospital admission in the first year of life vary according to time of day, day of the week and time of year in relation to gestational age, and intervention in the onset of labour and delivery?

4. Have the patterns observed changed over the years 2005 to 2014?

The project aims to inform decision making by providing information about how numbers of births in England and Wales vary by time of day, day of week and day of the year. It will analyse separately births before term and those after full term pregnancies. In addition, it will take account of whether labour and birth occurred spontaneously or whether their timing was affected by inducing labour, or by undertaking either a planned caesarean section or an emergency caesarean section during labour. The rates of death and severe problems in babies or their mothers will be analysed in relation to these factors.

The results will be related to aggregated information about midwifery and obstetric staffing in maternity units and NHS trusts and to their overall rates of induction and caesarean section. This information can be used by the NHS in planning both levels of staffing in terms of midwives and obstetricians and in detailed rostering, with the aim of trying to match the numbers of women in labour and giving birth and the numbers of midwives available and the availability of obstetric support should complications arise.

Research Plan and Methods

Design and setting

The design is a retrospective analysis of linked routinely collected data about births, maternity care in labour and at birth and any subsequent hospital admissions of mothers or babies after birth. All 7,013,804 births registered in England and Wales in the years 2005 to 2014 will be included.

Methods

Data acquisition and linkage

The research will be carried out using data routinely collected at a national level in England and Wales. No single dataset contains all the information required, so we will use data from several sources linked together, using techniques we have developed in previous projects. Following a pilot study we did using data for 2005, the Office for National Statistics (ONS) now routinely links together data recorded in England and Wales when parents register their babies' births with those recorded when the births are notified to the NHS and babies' NHS numbers are allocated. Births are now notified directly to the Personal Demographics Service, a component of the NHS spine and this informs child health services, the NHS Newborn Hearing Screening Service and the ONS about the birth, but during the period covered by this project, an interim system, known as NHS Numbers for Babies (NN4B) was used.

In our previous linkage project, a nine step algorithm, made up of a combination of patient identifiers such as mother's and baby's NHS number, dates of birth and postcode, was used to link the linked birth registration/NHS Numbers for Babies records for births occurring in 2005 to 2007, to Maternity HES records.[6] Similarly, records for babies of mothers resident in Wales were linked by the NHS Wales Informatics Service (NWIS) to the NCCHD / PEDW.[7]

The techniques developed for births in 2005 to 2007 will be reviewed and compared with those which can be achieved with the standard algorithm used by the Health and Social Care Information Centre, now known as NHS Digital. This will be piloted using data for 2005 and compared with those achieved in the earlier study. The selected algorithm will then be used to link all the data about births in England in the years 2005 to 2014. ONS will provide a subset of data items from the birth registration and notification linked file to the HSCIC / NHS Digital to enable linkage to Maternity HES records. Similarly, a subset of data items for babies of mothers who gave birth in Wales will be provided to NWIS to be linked to NCCHD/PEDW. When the linked records are returned to ONS, the full set of data items from the birth registration and NHS Numbers for babies linked file will be reinstated.

Records of neonatal care and other postnatal hospital episodes of mothers and babies in England will then be linked to birth registration / notification records using HESID, a unique encrypted patient identifier used in HES. Similar linkage will be undertaken for Wales. Previous work in this area has shown that there are issues in linking HES re-admission and

transfer records for some of the hospital trusts as data quality is variable. There may also be similar issues in PEDW. The dataset will therefore have to be assessed for quality and cleaned before it is used for analysis.

A member of our Study Advisory Group highlighted to us that the Wigglesworth classification used by ONS to classify causes of stillbirth and neonatal death is unable to differentiate reliably between antepartum and intrapartum stillbirth and that the classification used by the Centre for Maternal and Child Enquiries CMACE), which had been responsible for national confidential enquiries made a much better distinction. We will therefore use these data, which are available for 2005 to 2009, to analyse intrapartum stillbirths. The national confidential enquiries are now the responsibility of Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK). MBRRACE introduced a new classification of causes of stillbirths and neonatal deaths but initially there were problems in ascertaining whether about 15 per cent of stillbirths were intrapartum or antepartum so we shall be unable to extend analyses of intrapartum stillbirths to the latter part of the study period.

The data provided to us by ONS will include infant deaths linked to births. We have also requested deaths of children at ages over the age of one year, which ONS routinely links to their birth records. To investigate the deaths of mothers, we have also requested the data about deaths of women during childbirth or within a year after giving birth, which ONS routinely links to the corresponding birth

The linked files will be held in the secure environment of the VML facilities at ONS. The quality of linkage will be assessed and records with inconsistent data and duplicate records will be deleted before the data files are analysed. The quality assured data will be held in a purpose-built relational database in the VML. Outputs will be released by ONS in the form of disclosure controlled tables, graphs and analyses.

The personally identifiable demographic and clinical data, described above, are held as individual records which have to be stored and processed in a secure environment. In contrast, aggregated data about the NHS workforce are openly available for downloading from the web sites of NHS Digital, Health Statistics Wales and the Royal College of Obstetricians. We will access and organise these before transferring them to the VML for analysis in conjunction with confidential record-based data. The workforce data available for

the years up to 2009 come from the annual censuses of the medical and non-medical NHS workforce. These censuses were taken in England and in Wales on September 30 each year before being replaced in 2009 by a new system with monthly reporting In England these data are available only for NHS trusts as a whole rather than for each maternity unit within a Trust. There are no routinely collected data about numbers of staff on duty by time of day and day of the year and the only way such data could be obtained would be by doing an extensive and costly prospective data collection exercise. We will therefore use these aggregated routinely collected to try to assess the overall average level of staffing. We will also use data collated by professional organisations, such as the Royal College of Obstetricians and Gynaecologists, where available.

Preparing the data for analysis

The project team is expecting to receive a large quantity of digital data. For 10 years there will be over seven million ONS records of birth registrations linked to notifications of births in England and Wales. For births in England, there will be over 6.5 million HES delivery records, and a similar number of HES birth records. There are likely to be approximately 10 million records of subsequent admissions of mothers and slightly fewer for the babies. There will be similar records for over 300,000 births in Wales. This means that, along with ONS mortality records, there will be nearly 40 million records, each of which can be 200 or more fields wide.

There are numerous one-to-many links between these records. A mother may have several delivery episodes each one of which can potentially result in several babies each with their own birth records. Both mother and baby can potentially have multiple subsequent admissions. The large number of records, along with the inherent connection between the records, mean that, to hold them, a relational database will have to be built as part of the project.

New variables will be derived for both the ONS and HES data, based on standardising formats across all years and between datasets, or combining original values in the data, so as to create better quality or more useful variables. This will be done using methods and background IP developed jointly by BirthchoiceUK held by Rod Gibson Associates, and Kings College London in a previous NIHR-funded project (10.1011/94). This IP will be retained by Rod Gibson Associates but made available to City University London for use in the project

Although HES data are known to be consistently formatted across all years, using standardised formats, ONS data are not. Examples of standardising include putting all dates into a form recognisable as a date field suitable for the target software, putting postcodes into a standard format and harmonising the format of variables like baby's sex across years and between ONS and HES.

Where a number of data fields replicate information, data from these sources will be combined to replace missing values and discard erroneous entries. For instance, birthweight and baby's date of birth appear in both birth notification and birth registration, and date and method of delivery in HES.

A variable will also be derived to flag inappropriate records, notably miscarriages and induced abortions, that should not be treated as deliveries by interrogating the ICD-10 codes that accompany each record. Invalid baby tails in HES, which can occur when trusts complete as many as either six or nine baby tails, even for a singleton delivery, will be flagged.

An estimation of parity will be derived, to provide a more robust parity variable than is available on HES or ONS data. Parity is poorly recorded in the Hospital Episode Statistics. Until 2012, it was recorded at birth registration only for births within marriage and the questions asked have been problematic, both before and after this change, although the problems are being resolved. Parity, along with or previous caesarean section, is an example of a derived variable for which complex algorithms are required to assess all of a woman's delivery records to make good estimates. These algorithms will have to be written in the scripting language of the database.

Gestational age, birthweight and place of delivery will not be derived in any way from HES because the ONS data are a more reliable source for these variables.

The storage and data format of missing values will be made consistent between years and datasets to avoid software errors.

The prime motivation for the creation of this database is to facilitate analysis by the project team, but it will also provide a legacy as the linked data will be in a standard industrial format suitable for other maternity research teams to use.

Duplicate HES delivery records will be dealt with in the quality assurance of the linked dataset, described below. HES records that have no link to ONS records will not be checked for duplicates in this way.

Quality assurance of linked data

All linkage of birth registration/NHS Numbers for Babies to Maternity HES and NCCHD/PEDW undertaken by NHS Digital and NWIS respectively, will be quality assured by the project team. This will ensure that each birth registration is linked to only one correct hospital delivery or birth record to maintain a one-to-one relationship and facilitate analysis.

Priority will be given to quality assuring the linked birth registration and hospital delivery data. This is to provide information on onset of labour and method of delivery. The linked data will be held in the secure environment of the VML facilities at the ONS, and where all quality assurance and analysis has to be undertaken.

For linked birth registration and hospital delivery data for births in England in 2005-2014, a step-wise procedure, will be used to categorise types of linkage to identify which should be preserved and which should be broken. These categories include invalid delivery records, duplicate delivery records, and 'same mother different birth' delivery records. Comparison of common baby data items will inform this.

This will enable the creation of a final file for analysis containing all the relevant information from across birth registration, NHS Numbers for Babies and HES delivery for each birth.

Singleton and multiple births will be processed separately due to the increased complexity of multiple birth linkage using a similar but adapted methodology.

For Wales, birth registration/NHS Numbers for Babies records first linked to NCCHD and then to PEDW will be assessed to ensure that the correct delivery record from PEDW is linked in by comparing data items obtained from the NCCHD with birth registration and remove invalid or duplicate delivery records from PEDW.

The linked data will be held in the secure environment of the VML facilities at the ONS where the work described above will be done. Once quality assured, the linked records will be held in the relational database created for this purpose within the VML. The database will form a central repository which team members can either access by using ODBC (Open

Database Connectivity) drivers which can be called directly from their software package of choice, such as SAS, STATA or R. Alternatively, CSV files can be produced and distributed. Outputs of analyses undertaken in the VML will be released by ONS in the form of disclosure controlled tables for publication.

Analysis

The main analysis and statistical modelling will focus on singleton births in hospital.

Multiple births and births occurring at home will be analysed separately along with smaller numbers of other births outside NHS maternity units as more limited data are available.

Only a minority of births occurring at home are captured in the Maternity Hospital Episode Statistics but it is important to take account of them as they provide important information about the timing of spontaneous birth after spontaneous onset of labour. Multiple births are more likely to experience complications than singletons and are consequently subject to higher levels of obstetric intervention. This is likely to affect their distribution by time of day and day of the week and its association with outcome.

Outcome measures

We will use a number of outcome measures from the linked dataset to reflect the safety and quality of maternity care received by women. These will include significant harms such as intra-partum stillbirth, neonatal and infant mortality rates, morbidity in mothers and babies recorded by ICD code in HES records or in any subsequent hospital episodes of readmissions of mothers or babies to hospital or admissions to neonatal units and rates of medical intervention.

We will also investigate the use of positive outcome measures for baby and mother, such as the well-baby flag and bodily integrity, building on quality indicators developed for a maternity workforce project in which two of the project team were involved at King's College London (NIHR project number 10/1011/94).[21]

Outcomes may be stratified by maternal characteristics, gestational age and obstetric or medical risk factors, using ICD and procedure codes to identify women at increased risk of complications according to criteria set out in the NICE Intrapartum Care guideline.[22] The association with levels of midwife and obstetric staffing on outcomes will be analysed.

Descriptive statistics

We will create frequency tables to describe the distributions of numbers of live births and stillbirths in England and Wales as a whole from 2005 to 2014 by hour of day, day of the week, and day of the year. These tables will be produced by year and overall and will be a reference point to subsequent descriptive and modelling results. We will stratify the analyses by mode of onset of labour and of delivery and other relevant factors. We will then construct similar tables for outcome measures and construct rates.

Analyses by NHS trust

One aim of the analysis is to investigate how daily, weekly and yearly cycles in numbers of births vary between NHS trusts and to assess whether these differences are associated with characteristics of trusts, which will be grouped by size in relation to overall numbers of births and by levels of obstetric intervention. A further exploratory analysis will consider if it is possible to draw any conclusions about associations with staffing levels.

In order to analyse birth by trust, firstly each birth location will be identified. For each maternity unit there is a site code, known as the communal establishment code, allocated by the ONS. In HES, there is a three-digit NHS code for each trust and a five-digit code for each maternity unit within each trust. As not all registered births in England can be linked to HES records, the ONS communal establishment codes will be used as the basic identifier for analysis.

Because some maternity units will have opened or closed or have been administered by different trusts during the years covered by the analysis, 2005 to 2014, maternity services in a locality will be allocated to a fixed 'Assigned trust' for the duration of the study period. Mapping ONS codes communal establishment codes to 'Assigned trusts' will be aided by having access to information from the BirthChoiceUK historic maternity unit database which has tracked service reconfigurations and site code changes since 2001.

For all births in NHS hospitals, the numbers of births will be analysed by time of day, day of week and day of the year, and by whether labour or birth were elective or spontaneous. We will pay special attention to fixed and variable dates which are known to induce changes in birth frequencies, notably bank and public holidays, particularly the Christmas and Easter breaks.

Statistical modelling

The analysis of cyclical patterns requires specialised statistical modelling methodology to take into account latent periodic structures in the data.

Seasonally-adjusted measures of proportions of elective and spontaneous births occurring in and out of hours, and on weekdays and at weekends will be developed and modelled. Such measures will be analysed to establish clusters of NHS trusts with common patterns of births and to see if these correspond to variations in their units' rates of adverse outcome and staffing levels. Comparisons of rates of adverse outcomes will be made between units in relation to case mix, the levels of medical, midwifery and other relevant non-medical staffing and the overall number of births in the unit. Measures of case mix will include the mother's age, the mother's and baby's ethnicity, the mother's country of birth, the index of multiple deprivation scores derived from the mother's address, and parity.

Spectral analysis allows identification of the main cycles present in time series data and will be used to explore any secular trends in births frequencies and in incidence of birth outcomes. In particular, periodograms are a powerful graphical tool to characterise complex seasonal data containing cycles with different periods and intensities and to amount of variance explained by different cycles in the time series and to test for significant seasonality, and relevant cycles that may explain significant aspects of the overall variation.[23]

Functional data analysis (FDA) methods[24] consider trajectories as the units of analysis and fit smooth curves representing the underlying data-generating process. We will analyse daily trajectories of number of births and rates of birth outcomes within the FDA outcome, which is particularly appropriate for high-frequency datasets. Descriptive functional techniques will be used to produce graphical summaries of the smoothed trajectories, for example mean and variance curves. These plots will be helpful to characterise the main seasonal patterns present in the dataset. Nonparametric regression models based on spline curves representing birth outcome rates will be fitted to analyse the functional time series stratified by covariates of interest, such as cause of death, place of birth, and maternal age. Functional principal components decomposition will be applied to the smoothed curves to determine a small number of uncorrelated harmonic functions which will help to interpret latent aspects of cyclical variation.

Secular and cyclical mortality trends will be modelled using generalised linear models (GLM) with a Poisson or a negative binomial distribution, the latter being preferred if there is over dispersion in the data. Daily, weekly and yearly cycles will be modelled using GLMs incorporating spline and sine/cosine terms with different frequencies to account for different periods of seasonality.[25] Interaction terms among those cycles and secular trends will be fitted, to allow for changes in the seasonal patterns along time. Binary factors corresponding to public and bank holidays will be considered.[3, 4]

Dissemination and projected outputs

We plan an article on data linkage and one on quality assurance of the linkage for submission to peer reviewed journals plus three papers analysing the data, one describing patterns of births, one giving results of analyses of mortality and one giving results of analyses of morbidity. Work on describing patterns of births will be further subdivided into singleton births in NHS maternity units and home births and other births outside NHS maternity units, these will be the subject of separate articles. Analyses of multiple births in England will also be described separately. A further article will describe births in Wales.

We will submit a further article summarising our findings to Significance, the Royal Statistical Society's magazine which aims to popularise statistics and has a very wide international circulation. We will also present findings at data linkage and professional conferences.

NCT will disseminate the findings to parent representatives and 'patient' advocates serving on maternity services liaison committees and labour ward forums. This will also have the effect of highlighting research findings and service users' views and priorities to clinical managers and commissioners.

NCT will also post results on its website and on 'babble', its intranet for NCT practitioners and other workers. Articles will be published in NCT Matters magazine for parents, and in Perspective, its CPD journal for NCT practitioners (antenatal teachers, breastfeeding counsellor and postnatal leaders). A meeting will be convened for members of maternity services liaison committees and labour ward forums where the results will be presented and discussed. A short summary of findings can be disseminated via NCT local branch newsletters, of which there are about 300 in the UK, mostly in England. A telephone journal club meeting will be convened to discuss the published results and appraise them using CASP

appraisal questions. NCT will also incorporate the findings into conference presentations and talks to policy makers and professionals, such as the All Party Parliamentary Group on Maternity, which was set up with the support of NCT, and continues to be serviced by NCT. All output will be signposted using social media such as Facebook and Twitter.

The results will be disseminated via social media by BirthChoiceUK which had a substantial lay following on Twitter and published in an accessible form on the website of BirthchoiceUK.

Plan of investigation and timetable

As this protocol is being revised at a time when much of the work in it has been done but funding is not available to do the rest of it, it is not realistic to produce a new plan of investigation and timeline. When applying for funding to complete the outstanding work, we will do this for the work for which we will be seeking funding.

Project management

The project team will meet monthly either face to face or by Skype to review progress with the research and issues to be resolved. Alison Macfarlane, Nirupa Dattani, Mario Cortina-Borja, Rod Gibson and Miranda Dodwell and a full time researcher to be appointed will be members of the project team, along with the part time administrator to be appointed to organise meetings and support project management. An advisory group with an independent chair will be established, with members from midwifery and obstetrics, data providers and related researchers. Mary Newburn of NCT is involved as a co-applicant. As a member of the advisory group she will enable involvement of members of user groups in the discussion of results as they emerge and in plans for further analysis and will organise three meetings with service users for patient and public involvement (PPI) as well as other consultation activities.

The data cleaning and analytical work will all take place in the secure environment of ONS' VML in its London office in Pimlico. Nirupa Dattani will liaise with data suppliers in ONS at Newport, the Information Centre in Leeds and NHS Wales Informatics Service in Cardiff about arrangements for secure transfer of data files and for data linkage. All members of the project team will apply to the Office for National Statistics for Approved Researcher status, to enable them to derive and view interim analyses and discuss them before the selected outputs are released for dissemination.

Approval by ethics committees and other bodies

These linked data for the years 2005 to 2007 have already been further linked in a previous project to records about births in England in the Maternity HES and to records of births in Wales in NCCHD/PEDW using patient identifiable data items.[6, 7] For our original project, in 2005, we obtained ethics approval for this (05/Q0603/108) from East London and the City Local Research Ethics Committee and approval from the Patient Information Advisory Group under Section 60 of the Health and Social Care Act 2001 (PIAG 2-10(g) 2005).

To do the further linkage involving data for 2005 to 2007, we updated our previous approvals. This included successful applications for a substantial amendment to the ethics approval and to the National Information Governance Board for permission to process patient identifiable data without consent, now under Section 251 of the National Health Service Act 2006. Approval was also obtained from the Caldecott Guardian for Wales. Although we have access to the unique identifiers needed to link the records, we do not have access to parents' names and addresses and the data are held in a secure environment at the ONS, where the analyses will be done. ONS Approved Researcher Status was obtained for the project and for all the staff who would be accessing data in the VML. We had successfully applied for our approval to be extended to cover the years 2008 to 2012. We will now apply to the Confidentiality Advisory Group of the NHS Research Authority, NIGB's successor organisation, to renew this permission and to extend our permissions to include data for births in 2013, 2014 and beyond.

We will also apply for a substantial amendment to our ethics approval and for a Section 251 approval to extend the linkage to include records of any further hospital care after birth, including linking in records of admissions of babies to neonatal units and readmissions of mothers and babies and to hold the linked data as a database.

To complement this, we will also apply to amend our ethics and Section 251 approvals to include access to data about the deaths at ages of more than one year of children born in 2005 to 2014. From 1993 onwards, ONS has linked these deaths routinely to birth records. We will also apply for amendments to permit us to access data about deaths of mothers within a year of giving birth, which ONS links routinely to birth records.

To obtain stillbirth and neonatal death data from CMACE, which are now held by the MBRRACE-UK team at the National Perinatal Epidemiology Unit we shall apply for

permission to the Healthcare Quality Improvement Partnership (HQIP), which oversee the confidential enquiries as well as applying to extend to extend our ethics and Section 251 approvals.

Permissions will also be required from the Information Governance team in the Health and Social Care Information Centre to access individual records from HES and corresponding approval will be needed from the NHS Wales Informatics Service.

Patient and Public Involvement

Active user involvement is at the heart of our project. The chief investigator has developed strong links with service user groups and representatives over a number of years, which has enabled their views on the project to be sought at an early stage in the design. The aims of active involvement are to ensure that maternity services users have access to safe midwifery, obstetric and neonatal care twenty-fours hours a day, seven days a week and throughout the year and that their needs to do so are addressed throughout this research project.

We have two service user representatives as co-applicants to the project, and they were involved in designing this application. They will be actively involved at all stages of the project. Miranda Dodwell will attend regular meetings to discuss the direction of the research and the analysis and interpretation of results as they become available. In particular she has expertise in identifying outcome measures derived from routine data which assess quality of maternity care from a woman's perspective. Mary Newburn's role as co-investigator will enable involvement of members of user groups coordinated by NCT in the discussion of results as they emerge and plans for further analysis.

All written output from the project will be reviewed to ensure that a service user context is included. Both Mary and Miranda will play a key role in dissemination via NCT and BirthChoiceUK. BirthChoiceUK will provide a summary of the research and links to research output on their website. NCT will disseminate the findings to parent representatives and to 'patient' advocates serving on maternity services liaison committees and labour ward forums, as well as publishing in magazines and journals for parents and NCT practitioners. Detailed dissemination plans by NCT are described under 'Dissemination and Output'. Both NCT and BirthChoiceUK have social media presence on Facebook and Twitter to alert their followers to summaries of research on the BirthChoiceUK website, papers in peer-reviewed journals and NIHR published reports.

A blog will be written for #MatExp web site, a large facebook group for women and healthcare professionals.

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