npeu

National Perinatal Epidemiology Unit

Annual Report 2011–12

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npeu
National Perinatal
Epidemiology Unit

Front Cover

This stunning smile belongs to a little boy who was born with neonatal encephalopathy as a result of perinatal asphyxia (lack of oxygen during birth).

He was treated with therapeutic hypothermia and enrolled on the UK TOBY Cooling Register (2006–12).

The Cooling Register was set up at the NPEU to monitor the introduction of hypothermia for neonatal encephalopathy into routine UK neonatal practice following successful clinical trials, one of which was the MRC-funded TOBY Study (Whole body hypothermia for the treatment of perinatal asphyxia encephalopathy). The TOBY Study was co-ordinated by NPEU in collaboration with Imperial College London, 2002–08.

Citation for this report:

National Perinatal Epidemiology Unit, Annual Report 2011–12. Oxford: NPEU, 2013

ISSN 1757-5907

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Design and layout by: Andy Kirk

Cover design by: Sarah Chamberlain

Printed by: Joshua Horgan Print Partnership, Oxford

Contents

Introduction

Welcome to the annual report for the National Perinatal Epidemiology Unit 2011–12. We report here on two highly productive years during which the Unit has expanded in both size and scope of work. Our outputs in terms of publications and effects on clinical practice and health policy continue to be considerable. This is all made possible by the commitment and dedication of the NPEU staff who continue to be successful in competing for research funding to answer clinically important questions, address issues of importance to women and families, and ensure research projects are carried out to the highest national and international research standards.

The first of the many highlights of 2011–12 was the publication of the findings of the Birthplace Programme of work. The culmination of five years' work, the results were presented at the launch meeting at the Royal Society of Medicine simultaneously with publication in the BMJ followed shortly by publication of the economic evaluation. In summary, the team concluded that giving birth is generally very safe and midwifery units appear to be safe for the baby and offer benefits for the mother. For women having their second and subsequent birth, home birth also appears safe for the baby and offers benefits for the mother, whereas for women having their first baby a planned home birth increases the risk for babies, although adverse perinatal event rates are low. Women having their first baby in a midwifery unit or at home have a fairly high probability of transfer to an obstetric unit of 36% to 45%, whereas for women having their second or subsequent baby the transfer rate is about 10%.

These two years also saw the completion and publication of findings from several important trials run by the NPEU Clinical Trials Unit. In 2011 we saw the culmination of over 10 years' work with the publication in the New England Journal of Medicine of the INIS trial of intravenous immunoglobulin for the treatment of neonatal sepsis. This high profile publication underlines the increasing recognition of the importance of 'negative' trial findings, that is, we need to know which treatments are effective but it is also important to know which are not. In this case, the trial showed that IV immunoglobulin is no more effective than placebo in the treatment of proven or suspected neonatal sepsis. The results of the ADEPT trial of early versus delayed oral feeding for preterm growth-restricted infants was published in Pediatrics in 2012 and demonstrated that early introduction of feeding in these infants resulted in earlier achievement of full oral feeds and did not appear to increase the risk of nectrotising enterocolitis.

The Department of Health (DH) funded Policy Research Unit in Maternal Health and Care (PRUMHC) was established at the NPEU in January 2011. In 2011 and 2012 we published six papers reporting results of PRUMHC studies notably including findings relating to women's experience of support for breast feeding and other aspects of their experience of antenatal and postnatal care.

The UK Obstetric Surveillance System continues to make an important contribution to knowledge and clinical management of uncommon obstetric conditions and near-miss maternal morbidities with 12 UKOSS papers published in this period. This is exemplified by the UKOSS study of uterine rupture published in PLoS Medicine which highlighted the rarity of uterine rupture even among women who have had a previous caesarean delivery and are planning vaginal birth. The important contribution to clinical decision making comes from the quantification of the increasing risk of rupture with the increase in number of previous caesarean sections, with a short inter-pregnancy interval and with induction of labour.

The formation of the MBRRACE-UK collaboration naturally emerged from the work carried out by the UKOSS team and the NIHR funded UK Near-miss Surveillance programme. Together with colleagues working in the perinatal area from the Universities of Leicester, Birmingham and Liverpool, University College London and Sands – the stillbirth and neonatal death charity, we were successful in 2012 in bidding for the national Maternal, Newborn and Infant Clinical Outcome Programme. Through this programme of work the MBRRACE-UK collaboration is running the national surveillance of maternal and perinatal deaths, the national confidential enquiry into maternal deaths, a rolling programme of confidential enquiries into severe maternal morbidity, and a rolling programme of confidential enquiries into stillbirths, infant deaths and infant morbidity. We are in the early stages of this programme of work, but anticipate publication of the first reports in 2014.

Finally, I would like to take this opportunity to thank all the staff in the NPEU for their personal support for my role as Director particularly during the early period of my tenure in 2011. During 2013 we mark the 35th anniversary of the NPEU with a celebratory meeting taking a 35-year perspective on what has been achieved in maternal and neonatal care by ourselves and others during this period, bearing in mind that whilst there is much to celebrate there is still much work to do to achieve our mission:

"…to produce methodologically rigorous research evidence to improve the care provided to women and their families during pregnancy, childbirth, the newborn period and early childhood as well as promoting the effective use of resources by perinatal health services."

NPEU Director,
Professor Jenny Kurinczuk

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NPEU Staff

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Jenny Kurinczuk (Director),
Marian Knight, Rachel Rowe,
Maria Quigley, Maggie Redshaw,
Brenda Strohm

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Lizzy Schroeder, Emma Haines,
Melanie Workman, Lesley Merritt,
Cath Rounding, Sarah Chamberlain,
Laura Oakley, Denise Jennings,
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Helen Davenport, Anna Hobson,
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Tricia Boyd, Ed Gosden,
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Jane Forrester-Barker.
Pauline Rushby, Reem Malouf.
Lynn Hryhorsky, Oya Eddama.
Ameeta Roy, Linda Mottram.
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Ursula Bowler, Dimitrios Rovithis.
Jane Henderson

Row 6:
Demetris Pillas, Angela Garrett.
Marketa Laubeova,
Jennifer Hollowell, Haiyan Gao,
Ron Gray, Patsy Spark,
David Murray, Sue Bellenger,
Lynne Roberts

Row 7:
Charlotte McClymont,
Anthea Lindquist, James Griffiths,
Barbara Farrell, Ed Juszczak,
Patsy Spark, Vicki Barber

Absent from photo

Ben Allin
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Clare Barker
Beth Bosiak
Stella Botchway
Peter Brocklehurst
Friederike Buchallik
Claire Carson
Evelyn Chan
Lorna Coyle
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Anjali Shah
Peter Smith
David Thomson
John Townend
Pamela White
Sam Williamson
Yoshiko Yamamoto
Lawal Yusef

Website: 2013 Re-launch

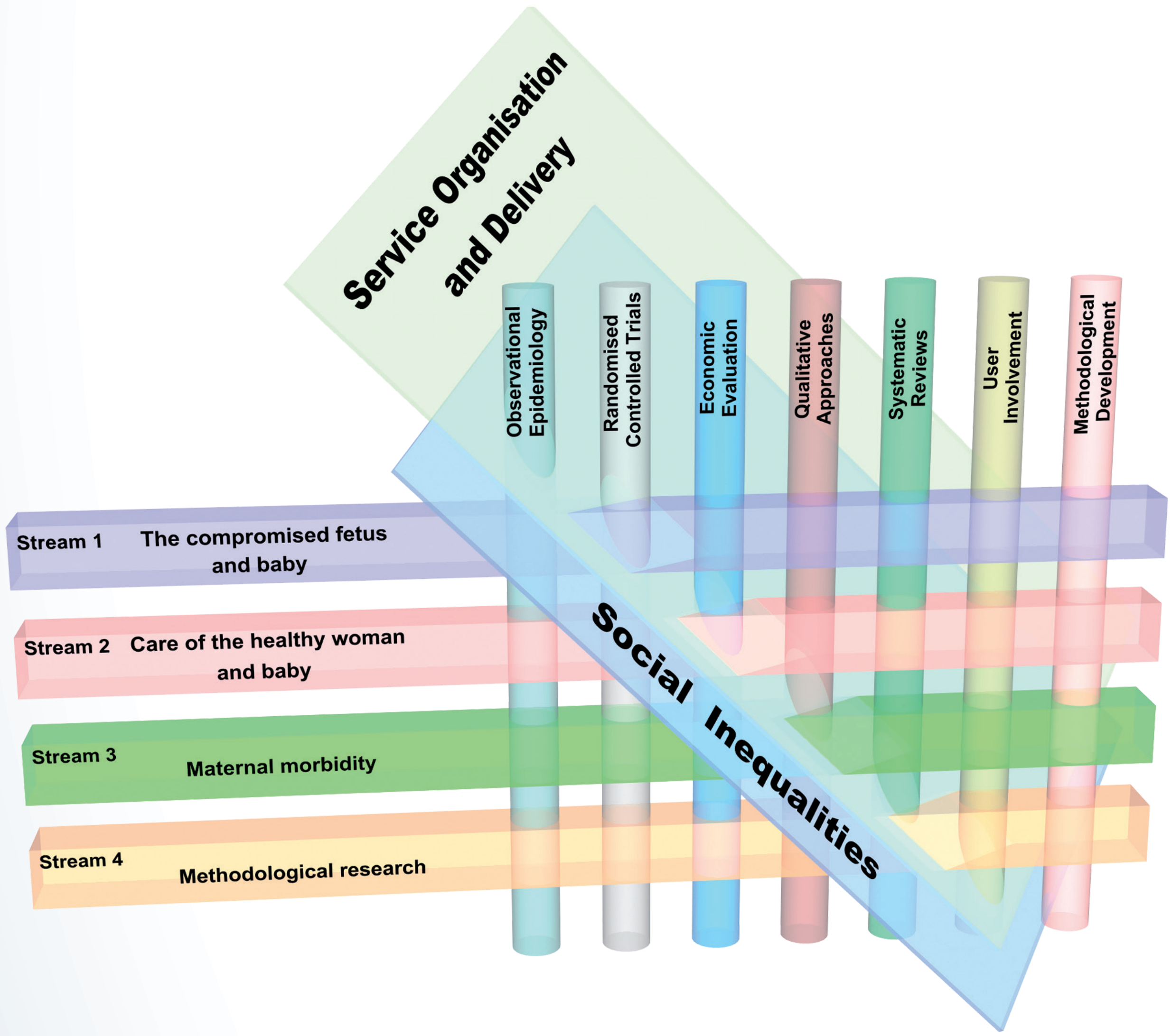
www.npeu.ox.ac.uk

The NPEU website has been undergoing a huge transformation behind the scenes over the last few years, and is due to be re-launched in late 2013. This will be the fifth version of the NPEU website since it was first launched in 1998.

The website has undergone some substantial changes to reflect the changing nature of the web and our work.

Here's a pre-release preview to give you a taste of what's to come:

Programme of Work



Introduction

The NPEU programme of work for the period 2011 to 2012 is described in this section of the report. The programme of work is conceptualised and illustrated above using the framework of four streams of work with two cross-cutting themes and the rods denoting the different research methodologies used. A summary of all the work in progress and work completed during 2011 and 2012 is given in the following two tables which separate work in progress, listed in the first table, from completed studies which are given in the second table. Following the summary tables and to avoid the repetition from year to year we have included the full details of only new projects which started in 2011–12. These are described after the summary table under the headings of the four streams of work. Further information can be found on our website: *www.npeu.ox.ac.uk*

Programme of Work – Ongoing Studies

NPEU Table of Work Key

NPEU contact: Most projects involve an NPEU team and often outside collaborators. The postscript (a) means that the grant holder or chief investigator for the project is from outside the NPEU.

The initials of the NPEU researchers are used in the table for brevity and represent the chief investigator or the researcher who is taking the lead for the project at the NPEU:

PB	Peter Brocklehurst*	EJ	Ed Juszczak	MR	Maggie Redshaw
OE	Oya Eddama	MK	Marian Knight	RR	Rachel Rowe
BF	Barbara Farrell	JK	Jenny Kurinczuk	LS	Liz Schroeder
RG	Ron Gray	SP	Stavros Petrou**	BS	Brenda Strohm
JH	Jennifer Hollowell	MQ	Maria Quigley	MV	Mara Violato

* Peter Brocklehurst left the Unit in April 2011

** Stavros Petrou left the Unit in August 2010.

Stream 1: The compromised fetus and baby	Duration	NPEU Contact
1.1 Neonatal encephalopathy, cerebral palsy and other childhood impairments		
Economic evaluation alongside INFANT trial - cost-effectiveness of an intelligent decision support system	2009–14	LS
Economic evaluation alongside TOBY trial - cost-effectiveness of total body cooling	2006–13	OE(a)
TOBY Children Study – School age outcomes following a newborn cooling trial	2009–14	BS(a)
TOBY Xenon: Neuroprotective effects of hypothermia combined with inhaled xenon following perinatal asphyxia	2009–14	EJ(a)
1.2 Child health outcomes following assisted reproductive technologies (ART) and related fertility issues		
International collaborative work using record linkage methods to investigate the risks of cerebral palsy, intellectual disability, hospitalisation and congenital anomalies associated with ART	2003–13	JK(a)
1.3 Congenital anomalies		
CAROBB – Monitoring rates of congenital anomalies for surveillance purposes and research	2003–14	JK
1.4 Preterm birth		

Stream 1: The compromised fetus and baby	Duration	NPEU Contact
The experience of women whose babies are admitted to a neonatal unit	2012–13	MR
BOOST-II UK trial – targeting oxygen saturation levels in preterm babies	2006–14	EJ(a)
PiPS – Probiotics in Preterm babies Study	2009–14	EJ(a)
I2S2 – Iodine supplementation trial - iodine supplementation for premature babies	2009–15	EJ(a)
ePrime – Evaluation of MR imaging to predict neurodevelopmental impairment in preterm infants	2009–15	MR(a)
SIFT – Speed of Increasing milk Feeds Trial	2013–19	EJ(a)
ELFIN trial – a multi-centre randomised placebo-controlled trial of prophylactic enteral lactoferrin supplementation to prevent late-onset invasive infection in very preterm infants	2013–17	EJ(a)
1.5 Fetal and infant effects of rare disorders of pregnancy (see Stream 3)		
Development of the British Association of Paediatric Surgeons Congenital Anomalies Surveillance System (BAPS-CASS)	2006–17	MK
BAPS-CASS: A population-based national study of the surgical outcomes of infants born with Hirschsprung's disease	2010–13	MK(a)
BAPS-CASS: Surveillance of the surgical outcomes of infants with Meconium Ileus	2012–15	MK(a)
BAPS-CASS: Surveillance of the surgical outcomes of infants with necrotising enterocolitis	2013–16	MK(a)
1.6 Infant mortality		
Nothing currently in progress under this heading - see table of completed studies for work in this area		

Stream 2: Care of the healthy woman, baby and child	Duration	NPEU Contact
2.1 Attitudes towards pregnancy and childbirth		
Nothing currently in progress under this heading - see table of completed studies for work in this area		

Stream 2: Care of the healthy woman, baby and child	Duration	NPEU Contact
2.2 Recent users' views and experience of maternity care		
Nothing currently in progress under this heading - see table of completed studies for work in this area		
2.3 Antenatal screening		
Nothing currently in progress under this heading - see table of completed studies for work in this area		
2.4 Minor problems in pregnancy		
Nothing currently in progress under this heading - see table of completed studies for work in this area		
2.5 Care in labour and delivery		
Changes in maternity care over time	2009–15	MR
An international comparison of maternity care	2011–14	MR
BUMPES - Upright maternal position in second stage labour in women with epidural analgesia; a randomised controlled trial	2009–13	PB
CORONIS Follow-up Study (Caesarean section surgical techniques randomised fractional factorial trial: three-year follow-up)	2011–15	BF(a)
Impact of maternal age on intrapartum interventions and outcomes (Birthplace)	2012–13	JH
2.6 Postnatal health and care		
Maternal health and wellbeing in the perinatal period	2010–13	MR
Factors associated with breastfeeding: an area-based analysis (FAB)	2011–13	MQ
Maternity care: womens' experience and outcomes	2011–13	MR(a)
2.7 Organisation of maternity care		
Modelling efficiency and cost-effectiveness in maternity care in the UK	2007–13	LS
Birthplace follow-on analysis to enhance policy and service delivery decision-making for planned place of birth	2012–14	JH
2.8 The healthy child		

Stream 2: Care of the healthy woman, baby and child	Duration	NPEU Contact
What makes children resilient? Investigating the mechanisms of resilience in children whose mothers were postnatally depressed	2011–15	RG

Stream 3: Maternal morbidity and mortality	Duration	NPEU Contact
3.1 Maternal mental illness		
Nothing currently in progress under this heading - see table of completed studies for work in this area		
3.2 Obesity and outcome of pregnancy		
Nothing currently in progress under this heading - see table of completed studies for work in this area		
3.3 Smoking, alcohol and drug misuse in pregnancy		
Nothing currently in progress under this heading - see table of completed studies for work in this area		
3.4 Surveillance of rare disorders of pregnancy		
Continued development of the UK Obstetric Surveillance System (UKOSS)	2005–14	MK
Surveillance of amniotic fluid embolism	2005–14	MK
Surveillance of pituitary tumours in pregnancy	2009–13	MK(a)
Surveillance of myeloproliferative disorders in pregnancy	2010–13	MK(a)
Surveillance of severe maternal sepsis	2011–14	MK
Surveillance of adrenal tumours in pregnancy	2011–14	MK(a)
Surveillance of cardiac arrest in pregnancy	2011–14	MK(a)
Surveillance of pregnancy after gastric band surgery	2011–14	MK(a)
Surveillance of stage 5 chronic kidney disease in pregnancy	2012–15	MK(a)
Surveillance of massive transfusion in major obstetric haemorrhage	2012–14	MK(a)
Surveillance of severe primary immune thrombocytopenia (ITP) in pregnancy	2013–15	MK(a)
Surveillance of maternal aspiration in pregnancy	2013–16	MK

Stream 3: Maternal morbidity and mortality	Duration	NPEU Contact
3.5 Pregnancy complications		
Long-term follow-up of women and their infants affected by near-miss morbidity	2010–13	MK
Investigating differences in the incidence of near-miss maternal morbidity between women from different age, socioeconomic and ethnic groups	2011–14	MK
Working with hospitals to maximise the benefits of studies of near-miss maternal morbidity	2012–14	MK
Economic evaluation of different second-line therapies for peripartum haemorrhage	2010–14	MK
UKNeS - Beyond maternal death: Improving the quality of maternity care through national studies of 'near-miss' maternal morbidity	2010–14	MK
Maternal sepsis in Denmark	2012–13	MK
3.6 Pregnancy, disability and chronic illness		
Improving outcomes for pregnant women with disability and their families	2011–15	RG
3.7 Serious Maternal Morbidity and Mortality		
National Maternal, Newborn and Infant Clinical Outcome Review Programme	2012–17	JK

Programme of Work – Studies Completed in 2011–12

Stream 1: The compromised fetus and baby	Duration	NPEU Contact
Secondary analysis of Western Australian case control data to further investigate the relationship between intrapartum events, neonatal encephalopathy and cerebral palsy	2005–12	JK(a)
NEST trial – Whole body cooling for neonates undergoing extracorporeal membrane oxygenation (ECMO)	2005–12	EJ(a)
A population-based study of the effect of infertility and its treatment on child health and development	2008–11	MQ
PROGRAMS trial – GM-CSF for sepsis prophylaxis in preterm growth-restricted babies	2001–12	PB(a)
BAPS-CASS – Before, during and after birth - how does care affect the future health prospects of infants with congenital diaphragmatic hernia?	2009–12	JK
Inequalities in Infant Mortality work programme - barriers to the early initiation of antenatal care by BME women	2010–12	JH

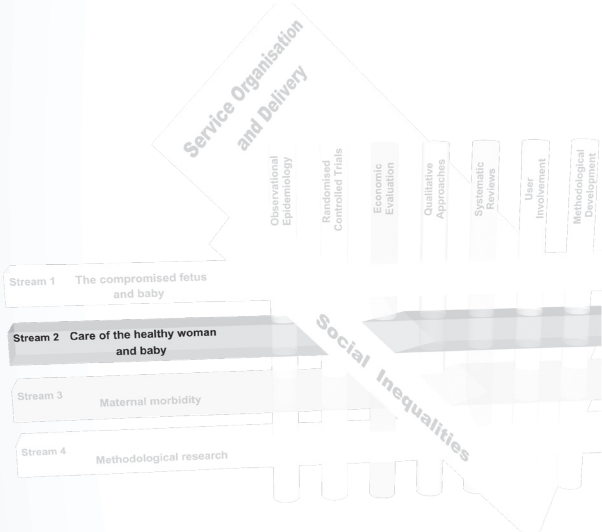
Stream 2: Care of the healthy woman, baby and child	Duration	NPEU Contact
Women's experience of support for breastfeeding	2009–11	MR
CORONIS Trial – a fractional factorial unmasked randomised controlled trial of caesarean section surgical techniques in developing countries	2006–11	BF(a)
The impact of family income on child cognitive and behavioural outcomes in the United Kingdom	2007–11	RG
Birthplace in England Research Programme	2006–12	JH
Birth at Home Study	2006–11	JH
Transfer from midwifery unit to obstetric unit during labour: rates, process, outcomes and women's experience	2007–11	RR

Stream 3: Maternal morbidity and mortality	Duration	NPEU Contact
The impact of maternal BMI on intrapartum outcomes: secondary analysis of the Birthplace national prospective cohort study	2011–12	JH
Surveillance of myocardial infarction in pregnancy	2006–11	MK

Stream 3: Maternal morbidity and mortality	Duration	NPEU Contact
Surveillance of pregnancy in women following non-renal solid organ transplant	2007–12	MK
Surveillance of uterine rupture	2009–11	MK
Surveillance of failed intubation	2008–11	MK(a)
Surveillance of aortic dissection/dissecting aortic aneurysm in pregnancy	2009–12	MK(a)
Before, during and after birth - how does care affect the future health prospects of infants with congenital diaphragmatic hernia? (UKOSS study)	2009–12	MK
Surveillance of sickle cell disease in pregnancy	2010–12	MK(a)
Surveillance of placenta accreta	2010–11	MK
Surveillance of HELLP syndrome	2011–12	MK
Surveillance of severe obstetric cholestasis	2010–12	MK(a)
Factors associated with progression from near-miss maternal morbidity to fatality	2010–11	MK
Incidence, risk factors and outcomes of maternal sepsis in a Scottish region over 23 years	2010–11	MK

Methodology	Duration	NPEU Contact
Dealing with childhood deaths in randomised trials (BRACELET)	2008–12	PB(a)
Health, medicines and self-care choices made by children, young people and their families: information to support decision making	2006–11	PB
Evidence into practice: evaluating a child-centred intervention for diabetes medicine management	2008–11	PB

Projects started in 2011



Stream 2: Care of the healthy woman, baby and child

2.5 Care in labour and delivery

An international comparison of maternity care

Chief investigators:

NPEU:
Maggie Redshaw.

Other investigators:

External:
Yvette Miller (*University of Queensland, Australia*).

Analyses will be carried out using the data from the National Maternity Surveys carried out by NPEU in 2010. In an international collaboration comparisons will be made with data collected in other countries including the USA and Australia, focusing on the type of care provided during labour and delivery in the context of different types of healthcare system and organisation.

Contact person: Maggie Redshaw
Status of project: Ongoing

CORONIS
International study of caesarean section surgical techniques: the follow-up study

CORONIS Follow-up Study (Caesarean section surgical techniques randomised fractional factorial trial: three-year follow-up)

Chief investigators:

NPEU:
Peter Brocklehurst.

Other investigators:
(Listed alphabetically)

External:
Edgardo Abalos (*Centro Rosarino de Studios Perinatales, Argentina*), Victor Addo (*Komfo Anokye Teaching Hospital, Ghana*), Mohamed ElSheikh (*University of Khartoum, Sudan*), Shabeen Naz Masood (*Fatima Bai Hospital, Karachi, Pakistan*), Jiji Elizabeth Mathews (*Christian Medical College and Hospital, India*), Enrique Oyarzun (*Depto. Obstetricia y Ginecología, Santiago, Chile*), James Oyieke (*Kenyatta National Hospital, Kenya*), Jai Sharma (*All India Institute of Medical Sciences, India*).

NPEU:
Ed Juszczak.

Other NPEU staff involved:
(Listed alphabetically)
Nina Armstrong, Barbara Farrell, Shan Gray, Pollyanna Hardy, Patsy Spark.

The CORONIS Follow-up Study is funded by the UK Medical Research Council and is following up women recruited to the CORONIS Trial (a multicentre international fractional factorial unmasked randomised controlled trial). The trial recruited 15,936 women between 2007 and 2010. The Follow-up Study aims to measure and compare the incidence of outcomes at 'three years' and is being conducted in hospitals in the following seven countries where recruitment to the CORONIS Trial was carried out: Argentina, Chile, Ghana, India, Kenya, Pakistan and Sudan. These countries have experience in detailed follow-up of large numbers of women.

Women will have a face-to-face interview at least three years post-discharge to assess long-term maternal morbidity and infant mortality outcomes including: the proportion of women with no subsequent pregnancy (both voluntary and involuntary); pelvic pain, dyspareunia, laparoscopy, hysterectomy (not related to pregnancy), incisional hernia; infant mortality. And for women having any subsequent pregnancy: the inter-pregnancy interval; miscarriage; multiple pregnancy; gestation at delivery; vaginal birth after caesarean; other pregnancy complications including uterine rupture, uterine scar dehiscence, placenta praevia, placenta accreta, postpartum endometritis, caesarean or postpartum hysterectomy, manual removal of placenta.

The long-term assessment of women began in September 2011 and is planned to end in August 2015.

Contact person: Barbara Farrell
Funding: MRC
Status of project: Ongoing

2.6 Postnatal health and care

PRUMHC
POLICY RESEARCH UNIT - MATERNAL HEALTH & CARE

Factors associated with breastfeeding: an area-based analysis (FAB)

Chief investigators:

NPEU:
Maria Quigley.

Other investigators:
(Listed alphabetically)

External:
Mary Renfrew (*University of York*).

NPEU:
Jenny Kurinczuk.

Other NPEU staff involved:
Laura Oakley.

Babies who are not breastfed have poorer health in infancy and childhood. One of the PSA indicators is to increase the breastfeeding rates at 6-8 weeks. Breastfeeding promotion and support is now an important component of local and national health service delivery.

The aim of this study is to measure the effects of breastfeeding interventions and socio-demographic factors on area-based breastfeeding rates. The specific objectives are to:

1. Collate area-based data on breastfeeding prevalence at 6-8 weeks, socio-demographic factors and breastfeeding interventions

2. Use these data to identify predictors of variation between areas in breastfeeding prevalence at 6-8 weeks

3. Use individual level data to measure the demand for breastfeeding services

4. Monitor changes over time in breastfeeding prevalence and interventions, and evaluate the implementation of any subsequent changes in service.

Area-based data on breastfeeding rates at 6-8 weeks and socio-demographic factors (e.g. maternal age, ethnicity, deprivation) are routinely available; currently these are PCT-based but it is envisaged that these will become available for local authority areas. Data on breastfeeding interventions (e.g. Baby Friendly accreditation, number of breastfeeding counsellors, weekly opening hours of clinics/cafes) will be obtained from the relevant data sources or organisations as appropriate.

Data on local area-based breastfeeding initiatives will be obtained from the appropriate bodies. Data on other relevant interventions will be obtained e.g. Family Nurse Partnership sites. An Advisory Group with representatives from the NHS and breastfeeding organisations will ensure that all key data on breastfeeding support are collected. Area-level data will be summarised using descriptive statistics, graphs, and if appropriate using an atlas. Predictors of variation by area will be identified using regression models. The demand for breastfeeding services will be assessed using data from the Infant Feeding Surveys (2005, 2010) and the National Maternity Survey 2010.

Contact person: Maria Quigley
Funding: DH-PRP
Status of project: Ongoing

PRUMHC
POLICY RESEARCH UNIT - MATERNAL HEALTH & CARE

Maternity care: womens' experience and outcomes

Chief investigators:

NPEU:
Maggie Redshaw.

Other investigators:

External:
Julie Jomeen (*University of Hull*).

Other NPEU staff involved:
Jane Henderson.

The objective is to describe the outcomes and diversity of experience of women receiving maternity care and to identify factors associated with having positive and less satisfactory experiences of pregnancy, childbirth and the postnatal period.

Using the national surveys carried out in 2006 and 2010, based on random samples of women selected from birth registration from all over England data are being analysed to identify key individual and experiential factors contributing to different outcomes. Using the samples of nearly 3,000 and over 5,000 women, work has been undertaken in several areas: ethnic minority women's experiences and factors associated with positive and other outcomes.

A range of analyses have been completed: a study of antenatal, intrapartum and postnatal factors associated with being well and having no problems at three months after childbirth has been published in Birth. Working with a collaborator at the University of Hull, qualitative analysis of Black and Minority Ethnic women's experience of maternity care utilised the open text responses of more than 350 women from a wide range of ethnic groups and a paper was published in Ethnicity and Health. A quantitative paper using the Care Quality Commission survey 2010 data on more than 20,000 women comparing the perceptions and experience of care of those from different ethnic groups has been submitted. More recent quantitative and qualitative analyses have focused on women's experience of medical induction of labour and a mixed methods paper has been published in Acta Obstetrica. Ongoing work concerns women's experience of antenatal admissions.

Contact person: Maggie Redshaw
Funding: DH-PRP
Status of project: Ongoing

2.8 The healthy child

PRUMHC
POLICY RESEARCH UNIT - MATERNAL HEALTH & CARE

What makes children resilient? Investigating the mechanisms of resilience in children whose mothers were postnatally depressed

Chief investigators:
(Listed alphabetically)

NPEU:
Ron Gray, Maria Quigley, Maggie Redshaw.

Other investigators:
(Listed alphabetically)

External:
Jonathan Evans (*University of Bristol*), Mina Fazel (*University of Oxford*), Paul Ramchandani (*University of Oxford*), Alan Stein (*University of Oxford*).

Other NPEU staff involved:
Emily Savage-McGlynn.

Children born to depressed mothers and to mothers who develop postnatal depression are at increased risk of adverse developmental outcomes in both the short- and long-term. Furthermore, early intervention aimed at improving the quality of maternal care in the early years is considered critical to improving later outcome. However, it remains unclear exactly when to intervene or in what way.

Some children born to depressed mothers achieve comparatively good outcomes, a phenomenon termed resilience. By investigating the mechanisms leading to resilience in the children of depressed mothers we may learn more about where to target interventions which can subsequently be evaluated in trials.

Objectives:

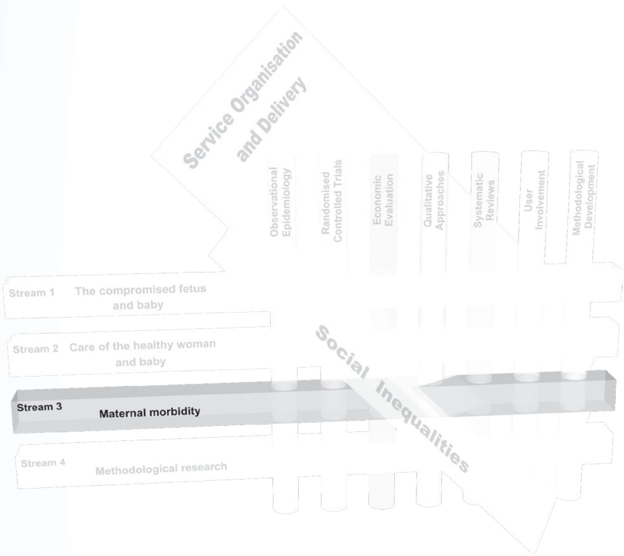
1. To specify and investigate the processes involved in childhood resilience at different ages with respect to different outcomes in health, education, family and social functioning.

2. To translate these findings into a policy-relevant framework of interventions which may help to build resilience.

Methods:

Using longitudinal data from the ALSPAC study we are investigating the factors (psychological, social, familial, environmental and biological) which are associated with good outcomes (resilience) as opposed to poor outcomes in children with various degrees of disadvantage.
In the first stage of the project we have identified some key factors involved in resilience; in the second stage we are investigating the role of fathers in more detail. We aim to translate these findings into a framework of potentially relevant interventions which could be used to inform or design interventions to help build resilience. This will be aided by a consensus process using an expert advisory group.

Contact person: Ron Gray
Funding: DH-PRP
Status of project: Ongoing



Stream 3: Maternal morbidity and mortality

3.2 Obesity and outcome of pregnancy

Birthplace
in England Research Programme

The impact of maternal BMI on intrapartum outcomes: secondary analysis of the Birthplace national prospective cohort study

Chief investigators:

NPEU:
Jennifer Hollowell.

Other investigators:
(Listed alphabetically)

NPEU:
Marian Knight, Louise Linsell, Maria Quigley, Rachel Rowe.

Other NPEU staff involved:
Demetris Pillas.

The aim of this study was to evaluate the impact of maternal BMI on intrapartum interventions and outcomes that may influence the choice of planned place of birth in women with singleton pregnancies of gestation ≥37 weeks planning a vaginal birth. The study focused on outcomes in otherwise healthy women without risk factors other than BMI of 35 of more.

The objectives were:

to describe the prevalence of medical and obstetric risk factors by maternal BMI

to evaluate the association between maternal BMI and intrapartum interventions and adverse maternal and perinatal outcomes both overall and in otherwise healthy women without known medical and obstetric risk factors immediately prior to the onset of labour

to explore whether the effects of BMI differ by parity

to explore the effect of BMI as a continuous variable on maternal and perinatal outcomes

to explore the relationships between maternal BMI and maternal and perinatal outcomes in planned home and midwifery unit births

Key findings:

Obesity is associated with increased risks of intrapartum outcomes requiring obstetric or neonatal care, but risks are not the same for all women who are obese. Otherwise healthy obese women have an increased risk of augmentation, intrapartum caesarean section and some adverse maternal outcomes, but when interventions and adverse outcomes are considered together, the size of the increased risk is modest (less than 15% for women with a BMI of >35kg/m^2 compared with women of normal weight). Multiparous obese women who do not have additional risk factors are at lower risk of requiring obstetric care during labour and birth than 'low risk' women of normal weight having a first baby. Risks to the baby (admission to a neonatal unit or stillbirth/early neonatal death) follow a similar pattern, with lower risks for babies of otherwise healthy multiparous obese women compared with babies of 'low risk' first time mothers of normal weight.

Contact person: Jennifer Hollowell
Status of project: Completed

3.4 Surveillance of rare disorders of pregnancy

Surveillance of HELLP syndrome

Chief investigators:

NPEU:
Marian Knight.

Other investigators:
(Listed alphabetically)

External:
Susan Sellers (*St Michael's Hospital, Bristol*).

NPEU:
Peter Brocklehurst, Kate Fitzpatrick, Jenny Kurinczuk.

Other NPEU staff involved:
(Listed alphabetically)
Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Melanie Workman.

HELLP is an important complication of pregnancy, characterised by haemolysis, elevated liver enzymes and low platelets. Women may be managed with expedited delivery or expectant management, but it is not clear to what extent expectant management is used in the UK and what the outcomes are for mothers and babies. The aim of this study, using the UK Obstetric Surveillance System (UKOSS) was to describe the current management and outcomes of HELLP syndrome in the UK.

One hundred and nine women were identified with HELLP syndrome. 69 women (63%) were diagnosed with HELLP syndrome antenatally at a median gestation of 35 weeks (range 21–41). 54%(37/68) of antenatally diagnosed women had a planned management of immediate delivery and delivered a median of 3h 37min after diagnosis (range 53min-21h 26min); 43%(29/68) had a planned management of delivery within 48h and delivered a median of 11h 40min after diagnosis (range 1h 28min–74h 43min); only 2/68 had a planned attempt at expectant management, with one delivering 3 days and the other 12 days after diagnosis. Severe morbidity was noted in 15%(16/109) of the women and one woman died (case fatality 0.9%, 95%CI 0.02-5.0%). Major complications were reported in 9%(10/108) of infants and there were two perinatal deaths (perinatal mortality rate 18 per 1,000 total births, 95%CI 2-62). All cases associated with major maternal or perinatal complication occurred in women delivered within 48h of diagnosis or in women diagnosed postpartum.

This study shows that HELLP syndrome is associated with severe maternal and perinatal morbidity. Expectant management is rarely used in the UK.

Contact person: Marian Knight
Funding: NIHR
Status of project: Completed

Surveillance of severe maternal sepsis

Chief investigators:

NPEU:
Marian Knight.

Other investigators:
(Listed alphabetically)

External:
Susan Sellers (*St Michael's Hospital, Bristol*).

NPEU:
Colleen Acosta-Nielsen, Peter Brocklehurst, Jenny Kurinczuk.

Other NPEU staff involved:

(Listed alphabetically)
Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Melanie Workman.

Maternal sepsis can be a severe complication of pregnancy or birth, which if untreated, can rapidly progress along a continuum of severity to septicaemic shock and eventually death. In the UK, the incidence of fatal maternal sepsis has increased over the last two decades. In the late 1980's the maternal mortality rate (MMR) due to sepsis was 0.4/100,000 maternities, while in the period from 2006–08 the MMR increased to 1.13/100,000. This places sepsis as the leading cause of direct maternal death, surpassing hypertensive disorders. Underlying each maternal death is a much larger number of cases of morbidity during pregnancy and puerperium. Given the recent increase in maternal deaths and morbidity incidence in the general population due to sepsis, an understanding of the risk factors in the UK of obstetric sepsis morbidity before death occurs is needed to better target potential points of clinical intervention. Establishing this epidemiology is vital to the prevention of poor outcomes for mothers and their infants.

While there are several well-established risk factors for maternal sepsis including caesarean section and anaemia, there has been no national-level study of the incidence or risk factors for this complication in the UK. The aim of this study, therefore, is to carry out a population-based case-control study using UKOSS to estimate the incidence of severe maternal sepsis in the UK, to investigate and quantify the associated risk factors, causative organisms, management and outcomes and to explore whether any factors are associated with poor outcomes.

Contact person: Marian Knight
Funding: NIHR
Status of project: Ongoing

Surveillance of adrenal tumours in pregnancy

Chief investigators:

External:
Catherine Williamson (*Imperial College, London*).

Other investigators:

(Listed alphabetically)

External:
Kimberley Lambert (*Imperial College, London*), David McCance (*Royal Victoria Hospital, Belfast*).

NPEU:
Marian Knight.

Other NPEU staff involved:

(Listed alphabetically)
Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Melanie Workman.

Tumours of the adrenal glands are very rare and information in the medical literature on the incidence, their management and maternal, fetal and neonatal outcomes is limited. Phaeochromocytomas, tumours associated with Conn's Syndrome, and adrenal or pituitary tumours linked to Cushing's Syndrome produce excess steroid hormones which are associated with major pregnancy complications, including major maternal and fetal morbidity and mortality. Adrenal tumours are linked to higher rates of hypertension, diabetes and pre-eclampsia, as well as fetal death, intrauterine growth restriction, fetal hypoxia, fetal distress, spontaneous abortion, stillbirth and prematurity. Currently, there are no data on the incidence of adrenal tumours in pregnancy in the UK and the associated maternal, fetal and neonatal morbidity and mortality.

In addition, there are few guidelines on the appropriate pharmacological or surgical management of these tumours. Therefore, this study will examine the effects of the drugs used to treat these in relation to maternal or fetal and neonatal complications and whether the timing of the surgery to remove the tumours is important. This will allow for development of guidelines on the management of adrenal tumours in pregnancy with the ultimate aim of improving maternal and infant outcomes.

Contact person: Marian Knight
Funding: SPARKS
Status of project: Ongoing

Surveillance of Cardiac Arrest in Pregnancy

Chief investigators:

External:
Virginia Beckett (*Bradford Royal Infirmary*).

Other investigators:

External:
Paul Sharpe.

NPEU:
Marian Knight.

Other NPEU staff involved:
(Listed alphabetically)
Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Melanie Workman.

Cardiac arrest in pregnancy affects around 1 in 30,000 women; incidence is thought to be rising due to the increasing age and morbidity of the antenatal population in the UK. The risk of death for mother and child is extremely high but some causes of cardiac arrest are reversible. Aggressive resuscitation is required, including caesarean section in most cases over 20 weeks' gestation. The importance of rapid delivery after cardiac arrest for maternal benefit is becoming a widely accepted practice and there is evidence to suggest that MOET (Managing Obstetric Emergencies & Trauma) training in obstetric resuscitation is leading to an increase in the use of peri-mortem caesarean section (PMCS) in maternal cardiac arrest in the UK and in Europe. In the UK 52 cases of PMCS were recorded between 2003–05 amongst women who subsequently died. There is, however, minimal information on survivors of cardiac arrest or PMCS. This study will investigate the incidence, management (including PMCS) and outcomes of maternal cardiac arrest including both women who survive and women who die. This information will be used to establish optimal management guidelines to improve survival of mother and infant.

Contact person: Marian Knight
Funding: Wellbeing of Women
Status of project: Ongoing

Surveillance of pregnancy after gastric band surgery

Chief investigators:

External:
Tim Draycott (*North Bristol NHS Trust*).

Other investigators:
(Listed alphabetically)

External:
Judith Hyde (*North Bristol NHS Trust*), Amanda Jefferys, Andrew Johnson (*North Bristol NHS Trust*), Mary Lynch (*North Bristol NHS Trust*), Elinor Medd (*North Bristol NHS Trust*), Dimitrios Siassakos (*North Bristol NHS Trust*).

NPEU:
Marian Knight.

Other NPEU staff involved:
(Listed alphabetically)
Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Melanie Workman.

The impact of obesity on pregnancy is well established; obesity negatively impacts on maternal, fetal and neonatal wellbeing. Laparoscopic Adjustable Gastric Band (LAGB) insertion is the primary surgical method of surgical weight reduction in the UK. It involves application of an adjustable silicone balloon around the upper portion of the stomach, resulting in a small upper stomach pouch and a narrowed outlet, which limits the stomach's capacity to intake food and increases the feeling of fullness. These two effects assist subsequent weight loss. LAGB insertion is increasing rapidly both in the private sector and in the NHS, with an estimated 1,700 bands inserted in women under the age of 40 years in 2007. The increase in gastric banding in women of reproductive age has resulted in increasing numbers of pregnancies following gastric banding.

Nevertheless, management of pregnancy following gastric band surgery has not been well defined. In most reports, women who conceive following LAGB have the band deflated for the duration of the pregnancy because of concerns regarding hyperemesis and poor nutritional intake. Deflating the gastric band has the adverse effect of excessive weight gain and subsequent pregnancy complications. However, pregnancy following LAGB has been shown to be well tolerated and studies have also demonstrated a reduction in incidence of gestational diabetes, maternal hypertension and caesarean delivery when compared to obese controls.

The aims of this study are to use the UK Obstetric Surveillance System to describe the epidemiology and management of gastric banding in pregnancy in the UK and to use this information to assess current practice and develop future guidelines for optimal management.

Contact person: Marian Knight
Status of project: Ongoing

3.5 Pregnancy complications

UKOSS
UK Obstetric Surveillance System

Investigating differences in the incidence of near-miss maternal morbidity between women from different age, socioeconomic and ethnic groups

Chief investigators:

NPEU:
Marian Knight.

Other investigators:
(Listed alphabetically)

External:
Anthea Lindquist (*NPEU student*).

NPEU:
Peter Brocklehurst, Jenny Kurinczuk.

Other NPEU staff involved:
(Listed alphabetically)
Jane Forrester-Barker, Charlotte McClymont, Amy Richardson, Melanie Workman.

The characteristics of women giving birth are changing, such that women are, on average, older, more likely to have been born outside the UK and more likely to suffer from pre-existing medical conditions than in the past. In addition, the impact of technologies such as in vitro fertilisation with ovum donation may contribute to an increasing incidence of pregnancies in women outside of the normal reproductive age. Addressing inequalities in health is an important aspect of public health policy in the UK. Identifying and describing such inequalities is an important first step in developing strategies to address them. A recent analysis of rates of selected near-miss morbidities identified through UKOSS has shown important inequalities in the occurrence of these disorders in ethnic minority women. However, this study, because of its relatively small size, was not able to investigate in depth potential causes for the observed differences between individual minority groups. Recent work has also suggested poorer outcomes of pregnancy in older women and an overrepresentation of socially disadvantaged women among mothers who died. Infant mortality is known to be much higher among routine and manual socioeconomic groups but social inequalities in near-miss maternal morbidity have not been investigated on a national basis in the UK.

This project will investigate inequalities in maternal morbidity in three specific groups: the older mother, women from routine and manual socioeconomic groups and ethnic minority women. Information about the entire cohort of women with near-miss morbidity identified through UKOSS will be analysed to determine rates of near-miss morbidity and the outcomes within subgroups.

The results of this study will allow targeting of services for high risk groups, and will alert us to specific morbidities occurring within population subgroups and hence help direct preventive clinical interventions. It will also allow us to develop strategies to address potentially modifiable risk factors associated with near-miss morbidity in these groups, such as poor attendance for antenatal care.

Contact person: Marian Knight
Funding: NIHR
Status of project: Ongoing

Incidence and risk factors of maternal sepsis in California

Chief investigators:

NPEU:
Marian Knight.

Other investigators:
(Listed alphabetically)

External:
Jeffery Gould (*Stanford University, Palo Alto, California, USA*), Henry Lees (*Stanford University, Palo Alto, California, USA*), Audrey Lyndon (*University of California San Francisco, San Francisco, USA*).

NPEU:
Colleen Acosta-Nielsen, Jenny Kurinczuk.

In countries with developed healthcare systems, sepsis remains a leading cause of preventable maternal morbidity and mortality. The objective of this study was to investigate the incidence and risk factors associated with maternal sepsis and progression to severe sepsis in a large population-based birth cohort from California.

The study showed that the incidence of severe sepsis was 4.7/10,000 births (95% CI=4.4-5.1). Women had significantly increased adjusted odds of progressing to severe sepsis if they were Black (OR=2.09), Asian (OR=1.59), Hispanic (OR=1.42), had public or no health insurance (OR=1.52), delivered in hospitals with an annual delivery rate of <1,000 births (OR=1.93), were primiparous (OR=2.03), had a multiple birth (OR=3.5), diabetes (OR=1.47), or chronic hypertension (OR=8.51). Pre-eclampsia and postpartum haemorrhage were also significantly associated with progression to severe sepsis (OR=3.72; OR=4.18). Factors had a significantly cumulative effect on risk of progression to severe sepsis.

This study suggested that the rate of severe sepsis was greater than that of the 1991–2003 national estimate. Risk factors identified are relevant to obstetric practice given the apparent increase in severe maternal sepsis.

Contact person: Marian Knight
Funding: NIHR
Status of project: Completed

3.6 Pregnancy, disability and chronic illness

Improving outcomes for pregnant women with disability and their families

Chief investigators:
(Listed alphabetically)

NPEU:
Ron Gray, Jenny Kurinczuk, Maggie Redshaw.

Other investigators:

External:
Crispin Jenkinson (*University of Oxford*).

Other NPEU staff involved:
(Listed alphabetically)
Haiyan Gao, Reem Malouf, Dana Sumilo.

The aim of this work programme is to help improve health outcomes for women with disability by (a) providing some estimates of the number of disabled women using maternity services in England, along with data on their characteristics, experiences of the healthcare system and outcomes; (b) conducting a systematic review on effectiveness of interventions to improve outcomes for disabled women and their families; (c) conducting a qualitative study to examine in detail the experiences of maternity services for women with learning disability.

The specific objectives address the following research questions:

1. What proportion of women giving birth in England are disabled?

2. Which particular disabilities are commonest?

3. To what extent is disability associated with other disadvantage in pregnant women? For example are there associations with poverty, domestic abuse, substance misuse living in areas with poor amenities and high crime?

4. Are there any particular (groups of) disabilities which are associated with either particularly poor birth outcomes or with patient safety issues (involving communication problems, for example)?

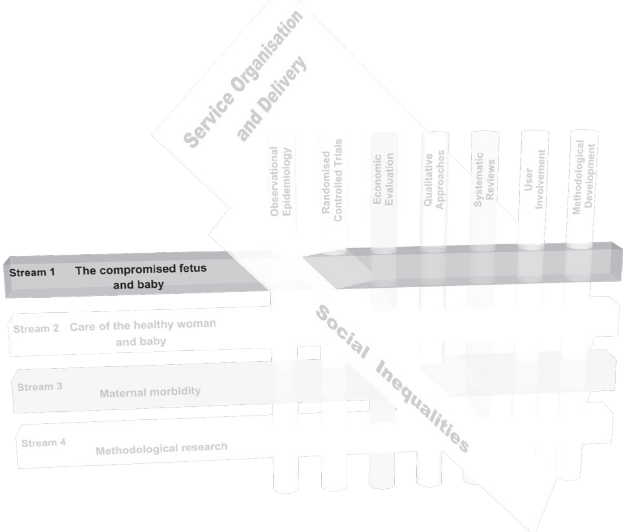
5. How do disabled women compare with those not disabled on the following: *Pregnancy outcome, mental health during pregnancy and the postnatal period, accessibility of services, information needs being met by clinicians, empowerment, involvement in decision making, inclusive, positive attitudes from staff, 'quality and choice of services'*.

6. Which health service interventions are effective in improving outcomes in disabled pregnant women and their families?

The work commenced with an analysis of data from the Millennium Cohort Study mothers and a systematic review of the effectiveness of health service interventions to improve outcome in this group as well as an analysis of data from the National Maternity Survey 2010. We are now going on to start a qualitative study in women with learning disability.

Contact person: Ron Gray
Funding: DH-PRP
Status of project: Ongoing

Projects started in 2012



Stream 1: The compromised fetus and baby

1.4 Preterm birth

The experience of women whose babies are admitted to a neonatal unit

Chief investigators:

NPEU:
Maggie Redshaw.

Other investigators:
(Listed alphabetically)

External:
Karen Hamilton, Merryl Harvey (*Imperial College, London*).

Other NPEU staff involved:
Jane Henderson.

The experiences of women whose babies were admitted to neonatal care are being explored using the data from the 2010 National Maternity Survey. Their care during pregnancy/labour and birth care and the postnatal period and views about that care are compared with that of women whose babies were not admitted to a neonatal unit.

Contact person: Maggie Redshaw
Funding: DH (part-funded)
Status of project: Ongoing

1.5 Fetal and infant effects of rare disorders of pregnancy (see Stream 3)

BAPS-CASS: Surveillance of the surgical outcomes of infants with Meconium Ileus

Chief investigators:

External:
Janet McNally (*Bristol Children's Hospital*).

Other investigators:
(Listed alphabetically)

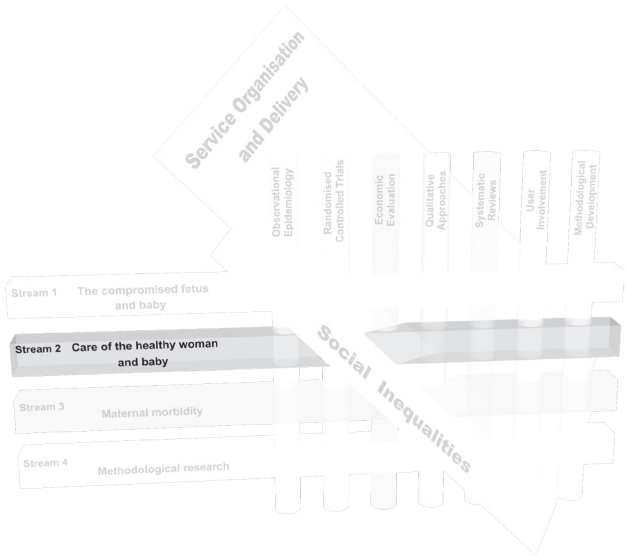
External:
Paul Johnson (*Oxford Children's Hospital*).

NPEU:
Marian Knight, Jenny Kurinczuk.

Other NPEU staff involved:
(Listed alphabetically)
Alex Bellenger, Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Patsy Spark, Melanie Workman.

Meconium Ileus (MI) is defined as small bowel obstruction in the newborn period caused by inspissated meconium within the terminal ileum. There is a well-recognised association of MI with cystic fibrosis (CF); 10% - 15% of infants with CF will present with MI. There is currently limited information about the incidence and mode of presentation of MI in the UK and Ireland. The British Association of Paediatric Surgeons Congenital Anomalies Surveillance System (BAPS-CASS) was established in 2006 to address such issues and has improved case ascertainment to up to 95% in specific anomaly review. However, MI is not a congenital anomaly and as such is not reported in any UK registry; however, by limiting the study to CF patients with MI we will be able to utilise CF registries to cross reference the cases and ensure high levels of case ascertainment. This study will collect accurate data on the incidence, mode of presentation, genotypes, clinical characteristics and outcomes for this group of infants and will provide valuable information which will aid in the counselling of parents with infants diagnosed with MI and CF.

Contact person: Marian Knight
Funding: BAPS and NIHR
Status of project: Ongoing



Stream 2: Care of the healthy woman, baby and child

2.5 Care in labour and delivery

Birthplace in England Research Programme

Impact of maternal age on intrapartum interventions and outcomes (Birthplace)

Chief investigators:

NPEU:
Jennifer Hollowell.

Other investigators:
(Listed alphabetically)

NPEU:
Marian Knight, Louise Linsell, Rachel Rowe.

Other NPEU staff involved:
John Townend.

The aim of this project is to evaluate the impact of maternal age, in particular advanced maternal age, on intrapartum interventions and outcomes that may influence the choice of planned place of birth in women with singleton pregnancies of gestation ≥37 weeks planning a vaginal birth. The study will address the following questions:

1. How does the prevalence of maternal medical and obstetric risk factors vary by maternal age? How does this vary by parity?

2. What is the relationship between maternal age and intrapartum interventions and other maternal and neonatal outcomes that may influence the choice of planned place of birth? How does this vary by parity? How is the relationship influenced by the presence or absence of medical and obstetric risk factors

3. For healthy older women with straightforward pregnancies, is planned birth in a non-Obstetric Unit setting associated with a lower incidence of intrapartum interventions and other outcomes requiring obstetric care compared with planned birth in an Obstetric Unit?

Contact person: Jennifer Hollowell
Status of project: Ongoing

2.7 Organisation of maternity care

Birthplace in England Research Programme

Birthplace follow-on analysis to enhance policy and service delivery decision-making for planned place of birth

Chief investigators:

NPEU:
Jennifer Hollowell.

Other investigators:
(Listed alphabetically)

NPEU:
Peter Brocklehurst, Marian Knight, Louise Linsell, Maggie Redshaw, Rachel Rowe.

Other NPEU staff involved:
John Townend.

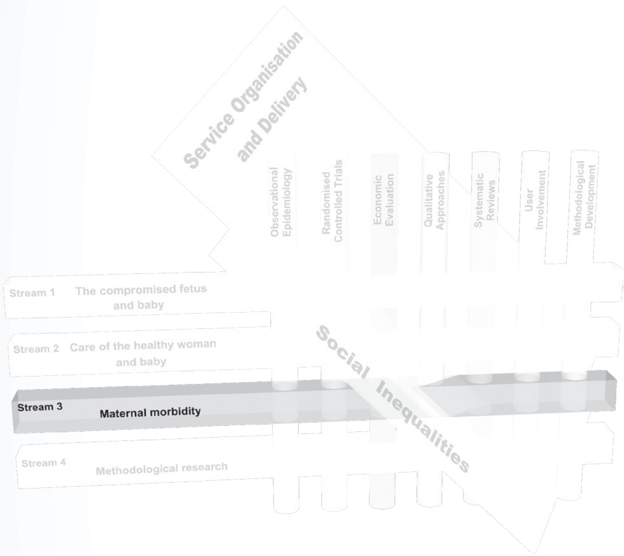
The aim of this follow-on project is to support the development and delivery of safe, equitable and effective maternity services by strengthening the evidence-base relating to planned place of birth. The project will:

Describe and explore the impact of service configuration, unit characteristics and other aspects of the organisation and delivery of services on birth outcomes, with a particular focus on maternal outcomes which impact on future pregnancies, such as caesarean section or complicated vaginal delivery.

Further describe intrapartum transfers (e.g. transfer rates, duration of transfer) and explore the possible impact on transfers of factors relating to the organisation and delivery of services, for example, staffing, time of day, distance from the nearest obstetric unit.

Explore the clinical characteristics, management and outcomes of 'higher' risk women who opt for a non-OU birth.

Contact person: Jennifer Hollowell
Funding: NIHR
Status of project: Ongoing



Stream 3: Maternal morbidity and mortality

3.4 Surveillance of rare disorders of pregnancy

UKOSS
UK Obstetric Surveillance System

Surveillance of Stage 5 Chronic Kidney Disease in pregnancy

Chief investigators:

External:
Catherine Nelson-Piercy (*St Thomas' Hospital, London*).

Other investigators:
(Listed alphabetically)

External:
Kate Bramham (*Guy's and St Thomas' Hospital, London*).

NPEU:
Marian Knight.

Other NPEU staff involved:
(Listed alphabetically)
Alex Bellenger, Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Patsy Spark, Melanie Workman.

Current pre-pregnancy advice given to women with Chronic Kidney Disease (CKD) Stage 5 is to delay conception until they receive a renal transplant, which is associated with restored fertility and improved pregnancy outcomes. Women ineligible for prospective transplantation are counselled regarding high rates of fetal loss, severe preterm delivery, fetal growth restriction and small for gestational age infants, and maternal complications including pre-eclampsia. Dialysis strategies are continually developing; however, more intensive dialysis regimes are likely to be associated with treatment related complications (e.g. infection, fluid volume shifts) which may have consequences for both mother and fetus. Furthermore, the dialysis dose (urea clearance) has not yet been shown to be predictive of fetal outcome. More information is needed about the intrauterine effects and neonatal consequences of changes in dialysis dose.

This project will prospectively collect information about pregnancy outcomes amongst women with CKD Stage 5 during pregnancy in the UK and assess the role of dialysis regimens and other factors in the outcomes of women and their infants. Outcomes will be compared with women with renal transplants matched for age, parity and ethnicity. This information is important to inform future management and counselling of these women; in particular to provide a direct comparison of pregnancy outcomes between different forms of renal replacement therapy i.e. dialysis and transplantation.

Contact person: Marian Knight
Status of project: Ongoing

Surveillance of massive transfusion in major obstetric haemorrhage

Chief investigators:
(Listed alphabetically)

External:
Laura Green (*Barts and the London NHS Trust*), Simon Stanworth (*National Blood Service, Oxford*).

Other investigators:

NPEU:
Marian Knight.

Other NPEU staff involved:
(Listed alphabetically)
Alex Bellenger, Jane Forrester-Barker, Jenny Kurinczuk, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Patsy Spark, Melanie Workman.

Major obstetric haemorrhage (MOH), resulting in massive transfusion (MT), accounts for 80% of all maternal morbidity. As there is no universally accepted definition for MOH, its incidence varies depending on how it is defined. The most critical feature of MOH is the development of disseminated intravascular coagulopathy (DIC) which, unlike DIC that follows major haemorrhage in trauma or surgery, occurs quite early on in the course of the haemorrhage. The situation is further complicated by the fact that during massive haemorrhage volume resuscitation with fluid and blood can lead to dilutional coagulopathy. In recent years, availability of rapid new diagnostic testing and the introduction of new haemostatic resuscitation strategies have challenged our thinking on optimal transfusion support for patients with massive haemorrhage. Much of the drive for new approaches to management of bleeding has come from studies of patients with trauma. In trauma-induced haemorrhage it is now believed that standard MT protocols are less effective in treating major bleeding.

Although studies from bleeding trauma patients have some limitations, they have raised some important questions on the optimum management of patients with massive bleeding. Increasingly, the high-ratio protocols are being adapted and applied to patients with other major bleeding (including MOH) with no supporting evidence. Clinical studies of massive bleeding in trauma have also raised concerns about the role and value of standard coagulation tests (PT, APTT). These are in vitro tests, largely developed and validated for patients with inherited bleeding disorders. Moreover, the time required to obtain their results limits their usefulness in the management of MT and increases its complexity resulting in suboptimal transfusion therapy and maybe contributing to poor outcome. Further investigation is required to enable the generation of evidence-based clinical guidance, as well as the identification of new avenues for research including, among others, interventional clinical trials.

Contact person:	Marian Knight
Funding:	NHS Blood and Transplant
Status of project:	Ongoing

Surveillance of anaphylaxis in pregnancy

Chief investigators:

NPEU:
Marian Knight.

Other investigators:
(Listed alphabetically)

External:
Rhiannon D'Arcy (*John Radcliffe Hospital, Oxford*), Kim Hinshaw, Nuala Lucas (*Northwick Park Hospital*), Ben Stenson (*Simpson Memorial Maternity Pavilion, Edinburgh*), Derek Tuffnell (*Bradford Royal Infirmary*).

NPEU:
Peter Brocklehurst, Jenny Kurinczuk.

Other NPEU staff involved:
(Listed alphabetically)
Alex Bellenger, Jane Forrester-Barker, Charlotte McClymont, Philippe Peirsegaele, Amy Richardson, Patsy Spark, Melanie Workman.

Anaphylaxis is severe and potentially fatal systemic hypersensitivity reaction. It is characterised by a combination of life-threatening airway, breathing or circulatory problems with skin or mucosal changes. There is always rapid onset and progression of symptoms. Current estimates of incidence suggest that maternal anaphylaxis occurs in approximately 1 in 30,000 pregnancies, although this is based on limited evidence. There is currently no published information relating to the incidence of anaphylaxis during pregnancy available for the UK and although this condition is rare, the importance of studying it is highlighted by a number of case studies showing that anaphylaxis during pregnancy can be associated with significant adverse outcomes for both mother and infant. Anaphylaxis can be caused by a wide variety of agents and it is unclear as to whether the risk factors for anaphylaxis in the general population such as age, concomitant co-morbidities and previously documented hypersensitivity can accurately predict risk of anaphylaxis in pregnancy. The recent proposed and actual policy changes with regard to antibiotic administration in pregnancy, including the use of prophylactic antibiotics up to one hour prior to delivery by caesarean section and the use of prophylactic antibiotics for maternal group B streptococcal carriage in labour have the potential to impact on the incidence and/or outcomes of anaphylaxis during pregnancy, making this study very timely. Beyond adhering to the best practice algorithm for management of anaphylaxis in an adult, there is little known about how anaphylactic shock in pregnancy should be managed in order to optimise the outcome for both mother and infant. This study will collect information about the incidence, management and outcomes of anaphylaxis in pregnancy in the UK.

Contact person: Marian Knight
Status of project: Ongoing

3.5 Pregnancy complications

UKNeS
The National Maternal Near-miss Surveillance Programme

Working with hospitals to maximise the benefits of studies of near-miss maternal morbidity

Chief investigators:

NPEU:
Marian Knight.

Other investigators:
(Listed alphabetically)

External:
Shona Golightly (*CMACE*), Mervi Jokinnen (*Royal College of Midwives*), Susan Sellers (*St Michael's Hospital, Bristol*), James Walker (*University of Leeds*).

NPEU:
Peter Brocklehurst, Jenny Kurinczuk, Gwyneth Lewis.

Other NPEU staff involved:
(Listed alphabetically)
Olaa Mohamed-Ahmed, Anjali Shah, Melanie Workman.

Methodological and detailed case review is commonly used as a strategy to improve health professionals' care of women, not only through documenting the number and causes of morbidity and mortality, but also through identifying preventable factors. Two approaches have been taken nationally to learning from adverse incidents in maternity care: expert case review (Confidential Enquiries, as undertaken by CMACE), and peer review, using root cause analysis, as recommended by the National Patient Safety Agency for use at a local level. Neither of these approaches has been applied systematically to investigate cases of near-miss maternal morbidity or compared with each other to assess the impact on local learning from adverse events. There is currently no national strategy for local learning from near-miss maternal morbidity and we do not know what approaches are being used locally. This project will identify which approaches are currently in use locally and will conduct a pilot investigation of any added benefit of expert case review (confidential enquiry) over local peer review (root cause analysis) to determine whether additional evaluation of the two techniques should be conducted.

Contact person: Marian Knight
Funding: NIHR
Status of project: Ongoing

Maternal sepsis in Denmark

Chief investigators:
(Listed alphabetically)

NPEU:
Colleen Acosta-Nielsen, Marian Knight, Jenny Kurinczuk.

Other investigators:

External:
Jens Langhoff-Roos (*Rigshopitalet Dept of Obstetrics and Gynaecology, Copenhagen, Denmark*).

Denmark represents a unique country in which to undertake a population-level study of severe maternal sepsis, since all in-patient and out-patient diagnoses are maintained in a National Patient Register (Landspatientregistret), and all pregnancies are recorded in the Medical Birth Register. Merger of the data from these two registers will allow for the identification of all maternal sepsis cases, both intrapartum and postpartum. This study aims to carry out a population-based, case-control study using the Landspatientregistret and the Danish Medical Birth Register to estimate the incidence of severe maternal sepsis in Denmark, to investigate and quantify the associated risk factors, causative organisms, outcomes and to explore whether any factors are associated with poor outcomes. Establishing this epidemiology and comparison of the findings with ongoing studies in other countries, is vital to the prevention of poor outcomes for mothers and their infants.

Contact person: Marian Knight
Funding: NIHR
Status of project: Ongoing

3.7 Serious Maternal Morbidity and Mortality

MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

National Maternal, Newborn and Infant Clinical Outcome Review Programme

Chief investigators:

NPEU:
Jenny Kurinczuk.

Other investigators:
(Listed alphabetically)

External:
Elizabeth Draper (*University of Leicester*), David Field (*University of Leicester*), Sara Kenyon (*University of Birmingham*), Brad Manktelow (*University of Leicester*), Jim Neilson (*University of Liverpool*), Janet Scott (*Sands - the stillbirth and neonatal death charity, London, UK*), Lucy Smith (*University of Leicester*).

NPEU:
Peter Brocklehurst, Ron Gray, Marian Knight, Maggie Redshaw.

Other NPEU staff involved:
(Listed alphabetically)
Oliver Hewer, Sarah Lawson, Carl Marshall, Charlotte McClymont, Anjali Shah, Peter Smith.

The MBRRACE-UK collaboration has been commissioned by the Healthcare Quality Improvement Partnership to deliver the UK-wide Maternal, Newborn and Infant Clinical Outcome Review Programme. The aim of MBRRACE-UK is to provide robust information to support improvements in the delivery of safe, equitable, high quality, patient-centred maternal, newborn and infant health services.

To meet this aim MBRRACE-UK is carrying out:

Surveillance and confidential enquiries on all maternal deaths in the UK since 2009 together with a rolling programme of confidential enquiries of topic-based serious maternal morbidity.

Surveillance of all late fetal losses (22-23 weeks gestation), stillbirths and infant deaths in the UK from 2013 onwards together with a rolling programme of topic-based confidential enquires of stillbirths, infant deaths and serious infant morbidity.

Contact person: Jenny Kurinczuk
Funding: HQIP
Status of project: Ongoing

Publications 2011 – 2012

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FC-3 Zuccolo L, Smith GD, Lewis SJ, Sayal K, Draper ES, Fraser R, Barrow M, Alati R, Ring S, Macleod J, Golding J, Heron J, Gray R. Prenatal alcohol exposure influences offspring school performance. A "Mendelian randomization" natural experiment. Int J Epidemiol.

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NPEU Advisory Committee 2011 and 2012

Department of Health Liaison Officer

Alison Tingle	Research Liaison Officer, Policy Research Programme, Research and Development Directorate *Department of Health*

Royal College and Faculty Representatives

Anthony Falconer	President, Royal College of Obstetricians and Gynaecologists (from 24 September 2010 - 27 September 2013) *Royal College of Obstetricians and Gynaecologists Representative*
David Richmond	President, Royal College of Obstetricians and Gynaecologists (from 27 September 2013) *Royal College of Obstetricians and Gynaecologists Representative*
David James	Emeritus Professor of Fetomaternal Medicine, University of Nottingham and Clinical Co-Director National Collaborating Centre for Women's and Children's Health *Royal College of Obstetricians and Gynaecologists Representative (alternate)*
Paul Lewis	Board Member of the Royal College of Midwives (until 30 August 2013). Emeritus Professor of Midwifery Practice and Development, Bournemouth University. Supervisor of Midwives for NHS England (South West LSA & South Central LSA) *Royal College of Midwives Representative*
Mervi Jokinen	Practice and Standards Development Adviser, Royal College of Midwives *Royal College of Midwives Representative (alternate)*
Andrew R Wilkinson	Professor of Paediatrics and Perinatal Medicine, University of Oxford and Honorary Consultant Neonatologist, John Radcliffe Hospital, Oxford *Royal College of Paediatrics and Child Health Representative*
Sandra Calvert	Consultant Neonatologist, Department of Child Health, St George's Hospital, London *Royal College of Paediatrics and Child Health Representative (alternate)*
Nicholas Hicks (Chairman)	Chief Executive COBIC Ltd *Faculty of Public Health Representative*

Jean Chapple	Consultant in Perinatal Epidemiology/Public Health, NHS England, London Region *Faculty of Public Health Representative (alternate)*
Sarah Purdy	Reader in Primary Health Care, University of Bristol *Royal College of General Practitioners Representative*
	Alternate Representative of Royal College of General Practitioners (vacant)

General Advisory Group Members

Jane Abbott	Head of Programmes, Bliss, the special care baby charity
Jennifer Beecham	Professor of Health and Social Care Economics, PSSRU at the University of Kent and London School of Economics
Pat Doyle	Professor, Department of Non-communicable Disease Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine
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Mark Turner	Senior Lecturer in Neonatology University of Liverpool/Liverpool Women's NHS Foundation Trust, Chair MCRN/AMR Neonatal Clinical Studies Group and Associate Director for International Affairs, NIHR MCRN
Suzanne Tyler	Associate Director Maternity & Newborn, NHS South of England

Sources of funding

Summary of Income in 2011 and 2012

Funder	2011	2012
Action Medical Research	14,738.54	10,602.70
British Heart Foundation	14,788.10	27,341.89
British Association of Paediatric Surgeons	11,285.41	
BUPA Foundation	42,138.17	
Department for Education		25,000.00
Department of Health	974,006.06	923,223.04
European Commission	474.12	642.66
Healthcare Quality Improvement Partnership (HQIP)	121,025.01	425,278.68
Lauren Page Trust		1,464.72
Medical Research Council (MRC)	1,171,146.40	898,200.15
Newlife Foundation for Disabled Children	13,428.25	19,815.91
NHS Blood and Transplant Trust Fund		1,715.54
NIHR	2,051,771.54	1,291,709.88
SPARKS for Children's Health	2,801.12	21,198.88
TAMBA (Twins & Multiple Births Association)	5,308.39	
UNICEF (via York)	6,526.55	1,685.45
Waltham Forest PCT	10,585.33	
Wellbeing of Women	15,283.84	8,189.87
Wellcome Trust	38,591.44	
Total for Each year	**4,493,898.27**	**3,656,069.37**
Grand Total	**8,149,967.64**	

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