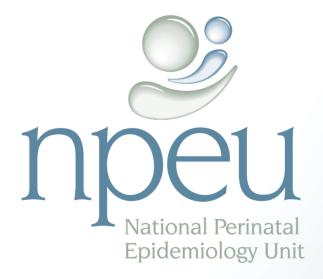


**Recruitment** period

# **Annual Report 2008**

# National Perinatal Epidemiology Unit

**Annual Report 2008** 



### **Front Cover**

The front cover shows the projected and actual recruitment to the TOBY trial of whole body cooling for the treatment of perinatal asphyxial encephalopathy. Recruitment ended in autumn 2006 and the 18 months follow-up was completed in autumn 2008. The results of the trial are reported in the forthcoming publication 17\* the details of which can be found on page 29.

#### Legend

The grey line indicates the projected recruitment. The blue line indicates the actual trial recruitment

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# Introduction

Welcome to the NPEU's annual report for 2008. This was another eventful year for the unit, with a number of major successes. The first is in relation to personal recognition of the efforts of some of the senior members of staff. Jenny Kurinczuk, Maria Quigley and Stavros Petrou were all awarded personal Readerships by the University of Oxford. These were in recognition of the major contribution each of these individuals has made to perinatal medicine and care over a number of years and are well deserved in all cases. In addition, Jenny Kurinczuk accepted the position of Deputy Director of the NPEU in January 2008, and her role has expanded as the NPEU has continued to grow in size. I am extremely grateful to her for taking this on.

A number of new projects were also funded in 2008. The largest of these is the INFANT trial, which should start recruiting in 2009. This is a randomised controlled trial of 46,000 women in labour who are undergoing continuous electronic fetal monitoring. The trial aims to find out whether the addition of an intelligent decision-support system to interpret the intrapartum CTG can result in improved outcomes for these babies. The trial has been funded by the NIHR Health Technology Assessment Programme for £5.9m. We are very grateful to the NIHR HTA for funding this project and now have the Herculean task of making sure we deliver the trial on time and to budget.

2008 was also a good year for publications from the NPEU. We published a total of 38 articles in peer reviewed journals and notable examples include a number of papers emerging from UK Obstetric Surveillance System including papers reporting the data on caesarean hysterectomy, acute fatty liver of pregnancy and antenatal pulmonary embolism. The results of two longstanding collaborations with researchers at the University of Leicester also bore fruit in 2008. The first was the paper reporting the association between recreational drug use in pregnancy and gastroschisis with Professor Liz Draper and colleagues, which showed that first trimester use of any recreational drugs

and specific vasoconstrictive recreational drugs increased the risk of gastroschisis. Other risky exposures included aspirin use, cigarette smoking and genitourinary infections or disease. The second was the 7-year follow-up of the ORACLE trial cohort of children with Dr Sara Kenvon and colleagues. This revealed an unanticipated association between the use of antibiotics for the management of women presenting in spontaneous preterm labour with intact membranes and developmental impairment and cerebral palsy. This is an important finding as it demonstrates that in pregnancy, even widely used and apparently 'safe' drugs may be less benign than we assume. It also highlights the need to investigate outcomes of therapies in pregnancy well beyond the traditional perinatal period.

Jorlahn



NPEU Director: Professor Peter Brocklehurst

# Website

### www.npeu.ox.ac.uk

The website continues to grow and attract more and more visitors. It has also been further enhanced by the development of a secure local intranet and content management system for members of the NPEU, enabling them to modify web pages connected to their projects.

#### **Website Statistics**

- The website currently receives an average of over 1000 page requests per day.
- The website has been visited by people from all over the world, including India, Argentina and Ghana.

- Currently, the top 10 most frequently visited areas of the website, in order, are:
  - 1. UKOSS
  - 2. National Maternity Surveys
  - 3. N3R
  - 4. TOBY (pictured below)
  - 5. Birthplace
  - 6. CORONIS
  - 7. 4Child
  - 8. BOOST
  - 9. NEST
  - 10. PROGRAMS

	Conference - The Safety of Birth rity of presentations are now available. More photos coming soon. Click to read more
Home   Contact NPEU	Find Us   Accessibility & Help Search: Type Here Go
What We Do by Methodology Trials TOBY	ТОВҮ
Protocol & Handbook	
Leaflets, Information & Letters	Whole Body Hypothermia for the Treatment of Perinatal Asphyxial Encephalopathy.
Consent	Recruitment to TOBY ended on 30th November 2006.
Data Collection Forms	
Newsletters, Posters & Presentations	18 month Follow up will be complete in autumn 2008.
Contact Details Logged in as Webmaster Logout	UK Cooling Tegister This link will take you to the UK TOBY Cooling Register pages, where you will find
Areas of Access User Controls	information on current treatment options: TOBY Register and an information leaflet for parents General Summary
	Perinatal asphyxia causing moderate or severe encephalopathy occurs in approximately 2/1000 births. In full term newborn infants, perinatal asphyxia may account for up to 30% of cases of cerebral palsy, and results in a significant health care and financial burden to the NHS. At present there is no specific treatment for asphyxia other than stabilisation with treatment to reduce seizures.
	This study aims to determine whether the use of whole body cooling following perinatal asphyxia is a safe treatment that will improve survival and reduce neurological and neurodevelopmental impairments. Babies who have experienced moderate or severe asphyxia are randomly allocated to receive either standard intensive care, or intensive care with cooling.
	Randomisation must take place before the baby is 6 hours of age, and the allocated treatment is commenced immediately. Cooled babies have their body temperature reduced to 33-34°C for 72 hours, followed by gradual rewarming.
	Primary outcome is the combined rate of mortality and severe neurodevelopmental impairment in survivors at 18 months of age.
	This randomised controlled trial is funded by the Medical Research Council.
	Top 👔 Print 🚔   Email 🖂   Full Page 📄   Text Only T   Edit 📓   Last Modified: March 20, 2008, 10:09 arr
	Home Contact NPEU Sitemap Accessibility & Help Email the Webmaster © 2009 npeu

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#### Missing

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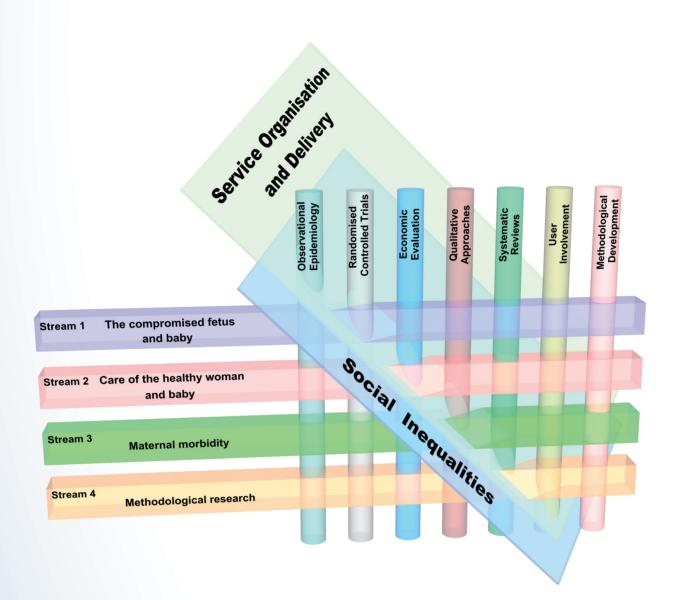
- 1. Maggie Redshaw
- 2. Carole Harris
- 3. Clare Shakeshaft
- 4. Bev Hoddell
- 5. Jenny Kurinczuk
- 6. Catherine Rounding
- 7. Rachel Rowe
- Felicity Allen
   Mara Violato
- 10. Marian Knight
- 11. Ann Kennedy
- 12. Patsy Spark

- 13. Geraldine Surman
- 14. Madalena Gallagher
- 15. Patricia Boyd
- 16. Rui Zhao
- 17. Karen Lindsay
- 18. Vicki Brock
- 19. Claire Carson
- Lyn Pilcher
   Jennifer Hollowell
- 22. Suzanne Williams
- 23. Maria Quigley
- 24. Barbara Farrell

- 25. Ed Juszczak
- 26. Vicki Barber
- 27. Sarah Ayers
- 28. Ursula Bowler
- 29. Jane Forrester-Barker
- 30. Peter Brocklehurst
- 31. Sara Lewis
- 32. Dimitrios Rovithis
- 33. Mary Stewart
- 34. Lydia Saroglou
- 35. Nicola Fitz-Simon
- 36. Gry Poulsen

- 37. Helen Davenport
- 38. Reija Klemetti
- 39. David Puddicombe
- 40. Sue Bellenger
- 41. Helen Newdick
- 42. Andy King
- 43. Mary Logan 44. Bob Gatten
- 45. Lynne Roberts
- NPEU Annual Report 2008

# **Programme of Work**



### Introduction

The NPEU programme of work for the period 2007 to 2010 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 2007 and 2008 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 2008. These are described after the summary tables under the headings of the four streams of work.

### **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	JK	Jenny Kurinczuk
ΤВ	Tricia Boyd	SP	Stavros Petrou
RG	Ron Gray	MQ	Maria Quigley
EJ	Ed Juszczak	MR	Maggie Redshaw
MK	Marian Knight	RR	Rachel Rowe

- GS Geraldine Surman
- LS Liz Schroeder
- MV Mara Violato

Stream 1: The compromised fetus and baby	Duration	NPEU Contact
1.1 Neonatal encephalopathy, cerebral palsy and other	childhood im	pairments
Reaching consensus on the definition of neonatal encephalopathy for surveillance purposes	2005-09	ЈК
Secondary analysis of Western Australian case control data to further investigate the relationship between intrapartum events, neonatal encephalopathy and cerebral palsy	2005-10	JK(a)
TOBY trial - whole body cooling for babies born with neonatal encephalopathy	2002-09	РВ
NEST trial - whole body cooling for neonates undergoing extracorporeal membrane oxygenation (ECMO)	2005-09	PB(a)
INFANT trial - recognition and management of intrapartum fetal compromise using an intelligent decision-support system	2009-14	PB
<i>4Child</i> - Monitoring rates of cerebral palsy, particularly in high risk subgroups	2003-10	ЈК
<i>4Child</i> - Monitoring rates of vision loss and hearing loss in children	2003-10	ЈК
UKCP Collaboration: Analysis of survival and regional variations in CP rates	2006-09	GS(a)
Economic evaluation alongside INFANT trial - cost- effectiveness of an intelligent decision support system	2009-14	РВ

Stream 1: The compromised fetus and baby	Duration	NPEU Contact
Economic evaluation alongside TOBY trial - cost- effectiveness of total body cooling	2006-09	SP
Economic evaluation of progesterone for the prevention of preterm birth in twins	2005-09	SP(a)
Experience of parents of children with cerebral palsy	2007-09	JK(a)
UK TOBY Register: register of the use of moderate hypothermia in neonates	2007-10	PB(a)
TOBY Trial - whole body cooling for babies born with neonatal encephalopathy 6-7 year follow-up study	2009-13	PB(a)
TOBY X: Neuroprotective effects of hypothermia combined with inhaled xenon following perinatal asphyxia	2009-12	EJ(a)
1.2 Child health outcomes following assisted reproducti and related fertility issues	ve technologi	ies (ART)
International collaborative work using record linkage methods to investigate the risks of cerebral palsy, intellectual disability, hospitalisation and congenital anomalies associated with ART	2003-10	JK(a)
The effects of psychosocial stress on time to conception	2005-09	RG(a)
Epidemiology of twinning and the effects of ART	2006-09	ЈК
A comparison of the early parenting experience of parents of multiples and singletons arising from natural conception and infertility treatment	2006-09	MR
A population-based study of the effect of infertility and its treatment on child health and development	2008-10	MQ
Experiences, information and support needs of women and men who go through treatment for infertility and sub-fertility	2006-10	JK(a)
Clinical and cost-effectiveness of elective single embryo versus double embryo transfer policy in assisted reproduction	2008-09	JK(a)
1.3 Congenital anomalies		
CAROBB - developing a system for monitoring rates of congenital anomalies for surveillance purposes	2003-10	ТВ

Stream 1: The compromised fetus and baby	Duration	NPEU Contact
FOCAL - feasibility of investigating the long-term outcomes of specific congenital anomalies using congenital diaphragmatic hernia as the examplar	2006-09	ЭК
EUROCAT - European Surveillance of Congenital Anomalies - Survey of prenatal diagnosis screening methods across Europe Perinatal screening for birth defects in Europe - a EUROCAT study of the impact of different national policies	2005-10	TB(a)
Cognitive and behavioural outcomes of children with an extra sex chromosome	2006-09	TB(a)
Prenatal diagnosis and outcome of pregnancy of sex chromosome trisomies in Europe	2007-09	ТВ
Terminations of pregnancy at >=24 weeks of gestation after prenatal diagnosis of fetal abnormality in Europe	2007-09	ТВ
To assess information availability on prevalence and prenatal detection rates of congenital anomalies in the South East Region to allow the monitoring of screening programmes	2009-10	TB(a)
1.4 Preterm birth		
Genetic association study of preterm birth	2006-10	RG(a)
Parent's experience of care following admission of their infant to a neonatal unit	2005-09	MR
ADEPT trial - early versus delayed enteral feeding for babies born with absent or reversed end-diastolic flow and growth restriction	2005-09	PB
INIS trial - International Neonatal Immunotherapy Study - intravenous immunoglobulin for babies with sepsis	2000-10	PB
PROGRAMS trial - GM-CSF for sepsis prophylaxis in preterm growth-restricted babies	2001-12	PB(a)
BOOST-II UK trial - targeting oxygen saturation levels in preterm babies	2006-11	РВ
PIPS - probiotics in preterm babies study	2008-12	PB(a)
Economic evaluation alongside PROGRAMS trial - the cost-effectiveness of GM-CSF for sepsis prophylaxis in preterm growth-restricted babies	2001-09	SP

Stream 1: The compromised fetus and baby	Duration	NPEU Contact	
Neonatal unit survey of communication, facilities and support for parents of preterm babies	2007-09	MR	
Evaluation of MR imaging to predict neurodevelopmental impairment in preterm infants	2009-14	MR(a)	
1.5 Fetal and infant effects of rare disorders of pregnar	ncy (see Strea	m 3)	
Development of the British Association of Paediatric Surgeons Congenital Anomalies Surveillance System (BAPS-CASS)	2006-10	МК	
BAPS-CASS - a population-based national study of surgical outcomes of infants born with gastroschisis	2006-09	МК	
BAPS-CASS - a population-based national study of surgical outcomes of infants born with oesophageal atresia	2008-09	МК	
BAPS-CASS - before, during and after birth - how does care affect the future health prospects of infants with congenital diaphragmatic hernia?	2009-12	ЈК	
1.6 Infant Mortality			
Inequalities in infant mortality work programme	2007-09	RG	
Stream 2: Care of the healthy woman and baby	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			
2.2 Recent users' views and experience of maternity ca	are		
Analysis of trust-based data from National Maternity Surveys on women's experience of care	2007-09	MR	
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			
Health and wellbeing in pregnancy	2008-09	MR	

Stream 2: Care of the healthy woman and baby	Duration	NPEU Contact
2.5 Care in labour and delivery		
CAESAR trial - factorial trial of caesarean section surgical techniques	2001-09	РВ
CORONIS International CAESAR trial - fractional factorial trial of caesarean section surgical techniques in developing countries	2006-11	PB
Women's experience of caesarean section: a qualitative study	2007-09	MR
Labour and delivery interventions in women from ethnic minorities	2005-09	MR
Changes in maternity care over time	2007-09	MR
An international comparison of maternity care	2007-09	MR
Women's worries about labour and birth: social and ethnic differences	2007-09	MR
Women's perceptions of maternity care	2007-09	MR
BUMPES - Upright maternal position in second stage labour in women with epidural analgesia; a randomised controlled trial	2009-13	PB
2.6 Postnatal health and care		
The protective effects of breastfeeding in a national UK survey	2005-09	MQ
Feeding twins, triplets and higher order multiples: a systematic review, secondary data analysis and development of evidence-based guidelines	2007-09	MQ
Cochrane review: Formula milk versus expressed maternal breast milk for feeding preterm or low birthweight infants	2006-09	MQ
The impact of family income on child cognitive and behavioural outcomes in the United Kingdom	2007-09	MV
2.7 Organisation of maternity care		
Birthplace in England Research Programme (incorporating the Evaluation of Maternity Units in England (EMU) research programme)	2006-10	PB
Birth at Home Study	2006-10	PB
Modelling efficiency and cost-effectiveness in maternity care in the UK	2007-11	LS

Stream 2: Care of the healthy woman and baby	Duration	NPEU Contact
Transfer from midwifery unit to obstetric unit during labour: rates, process, outcomes and women's experience	2007-11	RR
Birth and beyond: antenatal education and preparation for parenthood-a review of the literature and current service provision	2009	MR(a)
Stream 3: Maternal Morbidity	Duration	NPEU Contact
3.1 Maternal mental illness		
Nothing currently in progress under this heading - see ta studies for work in this area	able of comple	eted
3.2 Obesity and outcome of pregnancy		
Surveillance of extreme obesity in pregnancy	2007-09	МК
3.3 Smoking, alcohol and drug misuse in pregnancy		
Effects of prenatal alcohol consumption and alcohol metabolising genes on child growth and neurodevelopment in the ALSPAC study	2008-10	RG
The association between alcohol consumption in pregnancy and emotional and behavioural problems in childhood	2007-09	MQ(a)
3.4 Surveillance of rare disorders of pregnancy		
Continued development of the UK Obstetric Surveillance System (UKOSS)	2005-10	МК
Surveillance of amniotic fluid embolism	2005-12	MK
Surveillance of pulmonary vascular disease	2006-11	МК
Surveillance of myocardial infarction in pregnancy	2006-10	МК
Surveillance of different methods of treating obstetric haemorrhage	2007-09	MK
Surveillance of pregnancy in women with a renal transplant	2007-10	MK
Surveillance of pregnancy in women following non- renal solid organ transplant	2007-12	MK

2007-09

MK

Surveillance of antenatal stroke

Surveillance of failed intubation	2008-10	MK(a)
Surveillance of multiple repeat caesarean section	2009-10	MK(a)
Before, during and after birth - how does care affect the future health prospects of infants with congenital diaphragmatic hernia?	2009-12	МК
3.5 Pregnancy complications		

Antenatal detection of shoulder dystocia	2007-09	MQ(a)
--	---------	-------

Methodology	Duration	NPEU Contact
4.1 Methodological developments		
Investigation of the completeness of case ascertainment by UKOSS using FMAIT as one of the candidate conditions	2006-09	МК
Investigation of the completeness of case ascertainment by UKOSS using gastroschisis as one of the candidate conditions	2006-09	MK
Comparison of different sources of incidence data for rare disorders of pregnancy	2007-10	МК
INLET trial - cluster trial of newsletters and educational supplements to centres participating in INIS trial	2006-09	PB
Dealing with childhood deaths in randomised trials (BRACELET)	2008-12	PB(a)
Programme of methodological research on economic aspects of perinatal and paediatric health care	2006-11	SP
Health, medicines and self-care choices made by children, young people and their families: information to support decision making	2006-09	PB(a)
Evidence into practice: evaluating a child-centred intervention for diabetes medicine management	2008-11	PB(a)
Preference-based Health Utilities Index scores for childhood conditions	2007-09	SP
Development and validation of an instrument measuring aspects of the working environment in maternity and healthcare	2008-09	MR

### **Programme of Work – Studies Completed in 2007-08**

Stream 1: The compromised fetus and baby	Duration	NPEU Contact
4Child - Analysis of 15 year trends and causes of vision loss in children	2005-07	ЈК
UKCP Collaboration: regional variations in the relationship between cerebral palsy and socio-economic deprivation	2005-08	JK(a)
Health status and health-related quality of life preference- based outcomes of children aged 7-9 years with bilateral permanent childhood hearing impairment	2007	SP
Pregnancy of survivors of cancer: an epidemiological study (PISCES)	2006-07	JK(a)
Survey of fertility, reproductive choices and future plans (FINE study)	2006-08	JK(a)
Review of the perinatal outcomes of ART	2006-07	ЈК
Congenital hydrocephalus: a population based study on prevalence and outcome	2005-08	TB(a)
Effect of social deprivation and fetal gender on gestational age and size at birth	2005-07	RG(a)
Neonatal networks, admissions and transfers	2005-07	MR

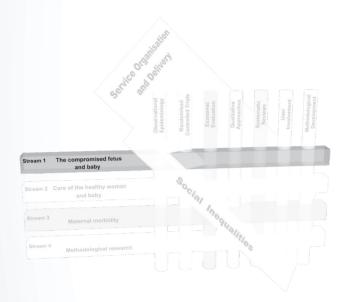
Stream 2: Care of the healthy woman and baby	Duration	NPEU Contact
The Oxford Worries about Labour Scale: maternal concerns about labour and birth	2008	MR
Feasibility study for a large national survey of women's views of maternity care	2006-07	MR(a)
Women's experience of antenatal screening and social inequalities in access to screening	2003-07	PB(a)
Antenatal screening for Group B Strep - protocol development	2005-07	PB
Infant feeding and neonatal/postnatal mortality	2005-07	MQ
Systematic review of effect of donor breast milk in preterm infants	2004-07	MQ
Socio-economic inequalities in maternal health	2005-07	SP

Stream 2: Care of the healthy woman and baby	Duration	NPEU Contact
Cochrane review: formula milk versus donor breast milk for feeding preterm or low birthweight infants	2006-07	MQ
A model for predicting behavioural sleep problems in pre- schoolers	2006-07	JK(a)

Stream 3: Maternal Morbidity	Duration	NPEU Contact
Systematic review of the use of the EPDS in screening for postnatal depression	2005-08	RG
Do children's sleep problems predispose mothers to depression?	2006-07	ЈК
Surveillance of fetomaternal alloimmune thrombocytopenia	2006-08	МК
Surveillance of gastroschisis	2006-08	МК

Methodology	Duration	NPEU Contact
Study of women's preferences for alternative management methods for first trimester miscarriage (MIST)	2006-08	SP
Using verbal autopsy to assign stillbirths and neonatal causes of death	2006-08	MQ(a)
Social capital and its relationship with preference-based measures of health status	2006-08	SP
Valuation of prenatal life in economic evaluations of perinatal interventions	2006-08	SP

### **Projects started in 2008**



#### Stream 1: The compromised fetus and baby

**1.2 Child health outcomes** following assisted reproductive technologies (ART) and related fertility issues

#### A population-based study of the effect of infertility and its treatment on child health and development

Chief investigator: NPEU: Maria Quigley.

#### **Other investigators:**

(Listed alphabetically) **External:** Yvonne Kelly, Amanda Sacker (University College London).

**NPEU:** Jenny Kurinczuk, Maggie Redshaw.

#### Other NPEU staff involved:

(Listed alphabetically) Claire Carson, Reija Klemetti.

The aim of this study is to elucidate the separate effects of infertility and its treatment on a range of child health and development outcomes measured at age 3 and 5 years in a national cohort study (the Millennium Cohort Study). We will compare three groups of children: those who resulted from a 'usual time to conception'; those who resulted from a "prolonged time to conception"; and those who were conceived following infertility treatment.

Contact Person:Maria QuigleyFunding:MRCStatus of Project:In progress

#### *Clinical and cost-effectiveness of elective single embryo versus double embryo transfer policy in assisted reproduction*

#### Chief investigator: External:

Siladitya Bhattacharya (University of Aberdeen).

#### Other investigators:

(Listed alphabetically) **External:** Kirsten Harrild (University of Aberdeen), Anthony Harrold (Ninewells Hospital, Dundee), Helen Lyall (Glasgow Royal Infirmary), M Rajkhowa (NHS Tayside), Graham Scotland (University of Aberdeen).

#### NPEU:

Jenny Kurinczuk.

In vitro fertilisation (IVF) involving the transfer or two embryos (DET) results in a twin rate of about 25%. This is in contrast to a natural incidence of 1.25% for twin births in the general population. Twin pregnancies result in significant morbidity and mortality for mother and infants, as well as increased costs. The Human Fertilisation and Embryology Authority (HFEA) are encouraging more liberal use of elective single embryo transfer (eSET) in women at risk of twins. However, a blanket policy of eSET in all women is likely to reduce success rates and hence the costeffectiveness of IVF. The solution is to develop a selective eSET policy based on the characteristics of women and embryos which is clinically and cost-effective. This project seeks to do this by means of analysis of existing anonymised Scottish data from three major Scottish IVF Units,

and the development of decision analytic models to assess cost-effectiveness across different sub-groups.

Contact Person:Jenny KurinczukFunding:CSO, ScotlandStatus of Project:In progress

#### **1.4 Preterm birth**

## PIPS - probiotics in preterm babies study

**Chief investigator: External:** Kate Costeloe (Homerton Hospital, London).

#### **Other investigators:**

(Listed alphabetically) **External:** Michael Miller, Mark Wilks (Homerton Hospital, London).

#### NPEU:

Peter Brocklehurst.

#### Other NPEU staff involved:

(Listed alphabetically) Ursula Bowler, Ed Juszczak.

Preterm babies are at increased risk of episodes of bacterial infection which may be fatal and are associated with chronic complications in survivors. This is largely because preterm babies have immature defences against infection. An important way in which the body is protected is through the 'friendly bacteria' that normally live in the gut. At birth there are no organisms in the gut but healthy babies who are nursed with their mothers quickly become colonised with their 'friendly' bacteria. Preterm babies who are separated from their mother at birth are more likely to become colonised with bacteria in the environment of the Neonatal Unit that may cause disease. It is possible that if these babies are given 'friendly bacteria' (probiotic), these will multiply in the gut, improve the general health of the intestine and reduce the chance of potentially pathogenic organisms becoming established. This should reduce infection. There is some evidence of the beneficial effects of probiotics in the published literature but they have not been adequately tested in a study involving more than one hospital and including

the babies at greatest risk. Probiotics do seem to be safe, but again more data are needed. This randomised trial will test whether giving preterm babies a single probiotic bacterium will improve their health and decrease their risk of infection. The main outcomes that will be measured are episodes of infection, episodes of necrotising enterocolitis, death, growth, use of antibiotics and length of stay.

Contact Person:Peter BrocklehurstFunding:NIHR HTAStatus of Project:In progress

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

BAPS-CASS - a populationbased national study of surgical outcomes of infants born with oesophageal atresia



#### **Chief investigators**

**External:** David Burge (*Southampton General Hospital*).

#### NPEU:

Marian Knight.

#### Other investigators:

(Listed alphabetically) **External:** Elizabeth Draper (University of Leicester), Paul Johnson (Oxford Children's Hospital), Sean Marven (Sheffield Children's Hospital).

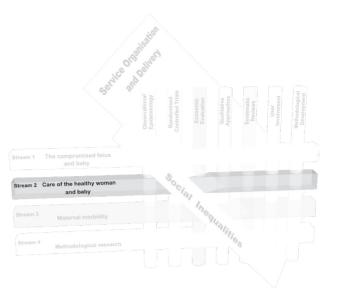
#### NPEU:

Jenny Kurinczuk.

#### Other NPEU staff involved:

(Listed alphabetically) Carole Harris, Patsy Spark. The aim of this project is to describe the incidence, management and outcomes of neonates with oesophageal atresia (OA) in the UK. OA is a congenital discontinuity in the oesophagus, often combined with a communication to the airways, and often found in association with other congenital anomalies. Five subtypes of OA are described, but as vet no national or population-based survey has been conducted to assess the incidence of each sub-type, success of antenatal diagnosis, national variation in management and outcomes. This will be a prospective, descriptive study using the routine monthly mailing of the British Association of Paediatric Surgeons Congenital Anomalies Surveillance System (BAPS-CASS) to identify cases. Clinicians reporting cases will then be asked to complete a questionnaire giving details of the type of OA, antenatal and postnatal management and outcomes. Immediate and medium term outcome data will be recorded, including complications, duration of inpatient stay and mortality. The findings will provide a benchmark of the current management of children with OA in the UK, describe the outcomes of specific subtypes and particular management techniques. This information is important for patient counselling, to highlight areas that require further research and to establish a "gold-standard" of practice.

Contact Person:Marian KnightFunding:BAPS, BDF Newlife and<br/>TOFSStatus of Project:In progress



# Stream 2: Care of the healthy woman and baby

#### 2.1 Attitudes towards pregnancy and childbirth

The Oxford Worries about Labour Scale: maternal concerns about labour and birth Chief investigator: NPEU: Maggie Redshaw.

#### Other investigators:

(Listed alphabetically) **External:** Colin Martin (School of Health, Nursing and Midwifery, University of Paisley).

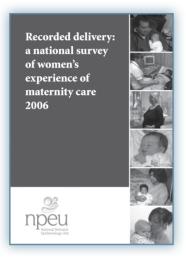
#### NPEU:

Christine Hockley, Rachel Rowe.

The study describes the measurement characteristics of a short (9-item) multidimensional measure of worry about labour and birth, the Oxford Worries about Labour Scale (OWLS-9), and its use in a large scale study of women's experience of care. Data utilised were from 2960 women who participated in a national survey of a random sample of women who had recently given birth in England (Recorded Delivery). Exploratory factor analysis revealed three sub-scales within the instrument assessing specific concerns about labour pain and distress, pre-labour uncertainty and interventions. However, the item asking about 'embarassment', may be of particular use in working with Black and Minority Ethnic groups of

women who were more likely to raise it as a concern. Used antenatally the scale will be a useful research instrument and a measure of worry about labour and birth that could be useful in planning antenatal education and support.

# Contact Person:Maggie RedshawFunding:DHStatus of Project:Completed



# 2.4 Minor problems in pregnancy

Health and wellbeing in pregnancy Chief investigator: NPEU: Reija Klemetti.

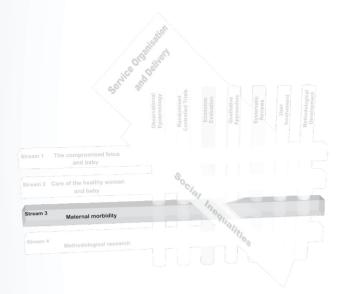
#### Other investigators:

(Listed alphabetically) **NPEU:** Jenny Kurinczuk, Maggie Redshaw.

Most developed countries are undergoing fertility postponement transition and men and women are becoming parents at an older age. Births over 35 and 40 are becoming increasingly common, and the age at first childbirth has increased notably. For example, in the United Kingdom the average age of the first birth was 23.7 years in 1977 and 27.6 in 2006. Previous literature has shown that older maternal age is associated with increasing risks for many pregnancy complications. The objective of this study is to describe the use of antenatal care and the health and wellbeing during the pregnancy, comparing the experience of older and younger mothers.

Data from the national survey of women's experience of maternity care (Recorded Delivery) in 2006 in England are being used for this study, with complete data on age and parity available on 2825 women. The prevalence of different symptoms, such as nausea and hyperemesis, varicose veins and stress incontinence, and the number of these experienced during the pregnancy, the extent to which GP and midwifery services were used and relationships with clinical and other factors will be investigated. The health and wellbeing, evidenced in common symptoms reported for pregnancy, of older mothers (aged 35 or more) will be compared with those of younger mothers (aged under 25 years and 25-34 years) adjusting for mother's ethnicity, marital status, and area level of deprivation and education. The analyses will be carried out separately for primiparous and multiparous mothers as previous pregnancies are likely to affect the way such symptoms are experienced and the extent to which help is sought from health professionals.

Contact Person: Maggie Redshaw Status of Project: In progress



#### Stream 3: Maternal Morbidity

# **3.3 Smoking, alcohol and drug** misuse in pregnancy

Effects of prenatal alcohol consumption and alcohol metabolising genes on child growth and neurodevelopment in the ALSPAC study

Chief investigator: NPEU: Ron Gray.

#### **Other investigators:**

(Listed alphabetically) External:

Rosa Alati (University of Queensland, Australia), Margaret Barrow (University of Leicester), George Davey Smith (University of Bristol), Elizabeth Draper (University of Leicester), Robert Fraser (University of Sheffield), Jean Golding, Sarah Lewis, David Nutt (University of Bristol).

#### Other NPEU staff involved:

Nicola Fitz-Simon.

This study, which commenced in March 2008 will examine the effect of prenatal alcohol consumption (and polymorphisms of several of the genes coding for enzymes involved in alcohol metabolism) on child growth and neurodevelopment. We will be using extended mendelian randomisation

to examine the unconfounded effects of alcohol consumption on the fetus. The study uses data from the well characterised ALSPAC cohort.

Contact Person:Ron GrayFunding:WellcomeStatus of Project:In progress

# **3.4 Surveillance of rare disorders of pregnancy**

#### Surveillance of failed intubation

 UK Obste	tric Surveilla	ance System	

#### Chief investigator:

**External:** David Milne (Leeds General Infirmary).

#### Other investigators:

(Listed alphabetically) **External:** Heather Gorton, Amanda Pinder, Audrey Quinn (*Leeds General Infirmary*).

**NPEU:** Marian Knight.

#### Other NPEU staff involved:

(Listed alphabetically) Carole Harris, Patsy Spark.

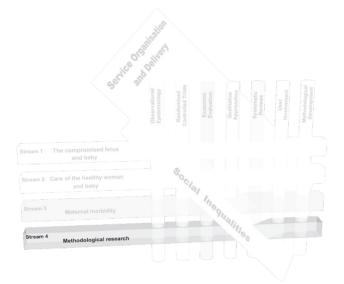
Reports from the Confidential Enquiries into Maternal Deaths have shown a decrease in the number of anaesthetic related deaths over recent years. However, a consistent cause of deaths is hypoxia relating to a failure to intubate and ventilate. The incidence of failed intubation among the pregnant population is estimated to be up to 8 times that of the non-pregnant population. The reasons for this higher incidence in the obstetric population are multiple. Anatomical changes in the airway due to physiological changes in pregnancy have been noted. These issues are compounded by the fact that obstetric surgical procedures are now less frequently performed under general anaesthesia, so that training opportunities for junior anaesthetists are becoming more rare. The procedures are also frequently required 'out of hours' when the trainee anaesthetist is likely not to be working under direct supervision. This new study

will elucidate the first national figures regarding failed intubation in obstetric anaesthesia, and with this bring new recommendations on methods of reducing its impact.

Contact Person:Marian KnightFunding:OAAStatus of Project:In progress



UKOSS Steering Group.



# Stream 4: Methodological research

#### Dealing with childhood deaths in randomised trials (BRACELET)



#### Chief investigator: External:

Diana Elbourne (London School of Hygiene and Tropical Medicine).

#### Other investigators:

#### (Listed alphabetically)

**External:** Claire Snowdon (London School of Hygiene and Tropical Medicine), Robert Tasker (Addenbrookes Hospital, Cambridge), Martin Ward-Platt (University of Newcastle).

#### NPEU:

Peter Brocklehurst.

The project will describe current policy and practice in relation to death in neonatal and paediatric intensive care trials. It will draw upon the views and experiences of bereaved parents, triallists and staff associated with a small number of such trials, to determine how parental bereavement is handled and what issues respondents feel it raises. The inclusion of paediatric as well as neonatal trials will highlight the common and the disparate needs which might arise in the two settings as well as widen the relevance of the research. Improved understanding of the perspectives of the various parties will assist triallists and clinicians to develop methods and strategies for new trials in the intensive care setting which would best serve the needs of clinicians and families at the centre of the research process.

Contact Person:Peter BrocklehurstFunding:NIHR HTAStatus of Project:In progress

#### **Evidence into practice:** evaluating a child-centred intervention for diabetes medicine management Chief investigator: External:

Anne Williams (University of Cardiff).

#### Other investigators:

(Listed alphabetically) **External:** Davina Allen, Cynthia Carter (University of Cardiff), Rhiannon Edwards (University of Wales, Bangor), Graham Edwards, John Gregory, Sheila Hunt (University of Cardiff), Carole Jackson (Royal United Hospital Bath NHS Trust), Mary Lewis (The Lifetime Service, Bath), Lesley Lowes (University of Cardiff), Jane Noyes, Ian Russell, Joanne Rycroft-Malone (University of Wales, Bangor), Mark Samuels (Roche Diagnostics (UK) Ltd), Jan Sharp (University Hospital of Wales).

#### NPEU:

Peter Brocklehurst.

Little scientific evidence exists concerning the effectiveness of the types and formats of information that could empower children to make decisions regarding medicines and self-care. For children with type-1 diabetes, intensive structured education programmes exist, however there is insufficient evidence about the effectiveness of information underpinning these programmes or routine clinical management.

The aim of this project is to develop and evaluate an individually-tailored, age-appropriate information resource to support decision-making and selfcare relating to insulin management and electronic blood glucose monitoring for children aged 6-18 years with type-1 diabetes, compared with available resources (if any) in routine clinical practice.

Contact Person:Peter BrocklehurstFunding:NIHR SDOStatus of Project:In progress

Development and validation of an instrument measuring aspects of the working environment in maternity and healthcare Chief investigator: NPEU: Maggie Redshaw.

#### **Other investigators:**

(Listed alphabetically) **External:** Colin Martin (School of Health, Nursing and Midwifery, University of Paisley), Julia Sonander (Healthcare Commission).

Collaborative and supportive working is an important feature of effective multidisciplinary team functioning and may have a significant impact on the

way that healthcare is provided, in this instance for women during pregnancy and the perinatal period. The goal of the study is to develop a measure of collaborative and supportive team working applied to staff from different professional groups providing maternity care and to describe the initial psychometric properties of the tool. The original instrument was developed jointly by the Healthcare Commission and NPEU as part of a staff survey that was a component of the 2007 review of maternity services in England, which individual staff completed online. To evaluate the initial instrument and the items included in the measure exploratory factor analysis (EFA) is being used followed by confirmatory factor analysis (CFA).

**Contact Person:** Maggie Redshaw **Status of Project:** In progress

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- NPEU 90 Redshaw M, Hamilton K. Networks, admissions and transfers: the perspectives of networks, neonatal units and parents. Oxford: NPEU, 2007.
- NPEU 91 National Perinatal Epidemiology Unit. Annual Report 2006. Oxford: NPEU, 2007
- NPEU 92 Knight M, Kurinczuk JJ, Spark P, Brocklehurst P. UKOSS Annual Report, 2007. Oxford: NPEU, 2007.
- NPEU 93 Surman G, Newdick H, King A, Gallagher M, Kurinczuk JJ. *4Child* Four Counties Database of Cerebral Palsy, Vision Loss and Hearing Loss in Children. Annual Report 2007. Oxford: NPEU 2007.
- NPEU 94 National Perinatal Epidemiology Unit, Annual Report 2007, Oxford: NPEU, 2008.
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### **Forthcoming publications**

- 1\* Eddama O, Petrou S, Schroeder E, Bollapragada S, MacKenzie F, Norrie J, Reid R, Norman JE. The cost effectiveness of outpatient (at home) cervical ripening with isosorbide mononitrate prior to induction of labour. Br J Obstet Gynaecol.
- 2\* Bollopragada SS, MacKenzie F, Norrie JD, Eddama O, Petrou S, Reid M, Norman JE. Randomised placebo controlled trial of outpatient (at home) cervical ripening with isosorbide mononitrate (IMN) prior to induction of labour - clinical trial with analyses of efficacy and acceptability. The IMOP Study. Br J Obstet Gynaecol.

- 3\* O'Leary CM, Nassar N, Kurinczuk JJ, Bower C. Impact of maternal alcohol consumption on fetal growth and preterm birth. Br J Obstet Gynaecol.
- 4\* Petrou S, McIntosh E. Women's preferences for attributes of first-trimester miscarriage management: a stated preference discrete-choice experiment. Value Health.
- 5\* Schroeder L, Petrou S, Balfour G, Eddama O, Heath P. The economic costs of Group B streptococcus disease: prospective cohort study of infants with GBS disease in England. European Journal of Health Economics.
- 6\* Quigley M, Kelly Y, Sacker A. Breastfeeding, hospitalizations and the role of ethnicity authors' reply. Pediatrics.
- 7\* Williamson I, Benge S, Barton S, Stavros P, Letley L, Fasey N, Abvangma G, Dakin H, Little P. A double-blind randomised placebo controlled trial of topical intra-nasal corticosteroids in 4-11 year old children with persistent bilateral otitis media with effusion in primary care. [Report for NIHR HTA]. Health Technology Assessment.
- 8\* Surman G, Hemming K, Platt MJ, Parkes J, Green A, Hutton J, Kurinczuk JJ. Children with cerebral palsy: severity and trends over time. Paediatr Perinat Epidemiol.
- 9\* Gray R, Mukherjee RA, Rutter M. Analysis: Alcohol consumption during pregnancy and child development: what is known and what remains uncertain. Addiction.
- 10\* Dixon G, Badawi N, French D, Kurinczuk JJ. Can parents accurately screen children at risk of developmental delay? J Paed and Child Health.
- 11\* Petrou S, Kupek E. Estimating preference-based health utilities index mark 3 utility scores for childhood conditions in England and Scotland. Med Decis Making.
- 12\* Dolk H, Pattenden S, Bonellie S, Colver A, King A, Kurinczuk JJ, Parkes J, Platt MJ, Surman G. Socio-economic inequalities in cerebral palsy prevalence in the United Kingdom: a register based study. Paediatr Perinat Epidemiol.
- 13\* Garne E, Loane M, Addor M-C, Boyd PA, Barisic I, Dolk H. Congenital hydrocephalus prevalence, prenatal diagnosis and outcome of pregnancy in four European regions. Eur J Paed Neurol.
- 14\* Rowe RE. Local guidelines for the transfer of women from midwifery unit to obstetric unit during labour in England: A systematic appraisal of their quality. Qual Saf Health Care.
- 15\* Petrou S, Abangma G, Johnson S, Dieter W, Marlow N. Costs of health utilities associated with extremely preterm birth: evidence from the EPICure Study. Value Health.
- 16\* Sabet F, Richter LM, Ramchandani PG, Stein A, Quigley MA, Norris SA. Low birthweight and subsequent emotional and behavioural outcomes in 12-year-old children in Soweto, South Africa: findings from birth to twenty. Int J Epidemiol.
- 17\* Azzopardi D, Strohm B, Edwards DA, Dyet L, Halliday H, Juszczak E, Kapellou O, Levene M, Marlow N, Porter E, Thorensen M, Whitelaw A, Brocklehurst P. Moderate hypothermia to treat perinatal asphyxial encephalopathy. New Eng J. Med

# **NPEU Advisory Committee 2008**

### **Department of Health Liaison Officer**

Sandra Williams	Deputy Director, Policy Research Programme, Chief Research Officer - Child and Maternal Health and Sexual Health, Department of Health (until July 2008)
Zoltan Buzoky	Senior Principal Research Officer, Policy Research Programme, Department of Health (from July 2008)
<b>Royal Colle</b>	ge and Faculty Representatives
Sabaratnam Arulkumaran	President, Royal College of Obstetricians and Gynaecologists Royal College of Obstetricians and Gynaecologists Representative
David James	Professor of Fetomaternal Medicine, University of Nottingham Royal College of Obstetricians and Gynaecologists Representative (alternate)
Liz Stephens	President, Royal College of Midwives. Head of Midwifery, Ealing Hospital Trust 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, Honorary Consultant Paediatrician, 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, Milton Keynes Primary Care Trust and Director of Public Health Milton Keynes Primary Care Trust and Milton Keynes Council Faculty of Public Health Representative
Jean Chapple	Consultant in Perinatal Epidemiology/Public Health, Westminster Primary Care Trust Faculty of Public Health Representative (alternate)
Sarah Purdy	Consultant Senior Lecturer/MRC Clinician Scientist, Academic Unit of 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**

Doug Altman	Director, Centre for Statistics in Medicine, University of Oxford (until May 2008)
Jane Abbott	Head of Innovation, Bliss – for babies born too soon, too small, too sick
John Cairns	Professor of Health Economics, London School of Hygiene and Tropical Medicine
Pat Doyle	Professor, Non-communicable Disease Epidemiology Unit, Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine
Hilary Graham	Director, Department of Health Public Health Research Consortium and Professor of Health Sciences, Department of Health Sciences, University of York
Jenny Hewison	Professor of the Psychology of Healthcare, Leeds Institute of Health Sciences, School of Medicine, University of Leeds
Stuart Logan	Cerebra Professor of Paediatric Epidemiology and Director, Institute of Health Service Research, Director, NIHR PenCLAHRC, Peninsula College of Medicine and Dentistry, Peninsula Medical School, Exeter
Mary Newburn	Head of Policy Research, The National Childbirth Trust and Honorary Professor, Thames Valley University
Sandie Skinner	Consultant Neonatal Nurse and Advanced Neonatal Nurse Practitioner, Royal Hampshire County Hospital, Winchester (until May 2008)
Alan Stein	Professor of Child and Adolescent Psychiatry, University of Oxford, Warneford Hospital, Oxford
David J Taylor	Vice Dean and Professor of Obstetrics and Gynaecology, Leicester Medical School, University of Leicester

# **Sources of funding**

### **Summary of Income in 2008**

Funder	Total (£)
Action Medical Research	42,142
BDF Newlife	24,097
BLISS – for babies born too soon, too small, too sick	2,350
British Association of Paediatric Surgeons	5,881
British Heart Foundation	25,196
Chief Scientist Office, Scotland	1,679
Department of Health	1,841,445
Economic and Social Research Council	5,851
European Commission	5,518
Medical Research Council	1,046,994
Multiple Birth Foundation	40,110
National Childbirth Trust	1,243
National Institute for Health Research	12,103
Service Delivery and Organisation Programme	113,946
Wellbeing of Women	27,081
Wellcome Trust	27,869
World Health Organisation	36,775
Grand Total	3,260,280

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