Perinatal Research Activity Document 2011

(Obstetrics, Midwifery and Neonatology)

Royal Hospital for Women
INDEX

Foreword: Page 3

Listed Output from RHW 2011:
- Peer Reviewed Publications: Page 5
- Books and Book Chapters: Page 9
- Abstracts and Presentations: Page 11

List of Internally-based Obstetric and Midwifery Research Projects – RHW 2011
- A: Recruitment Finished in 2011: Page 14
- B: Recruitment Ongoing for 2012: Page 16
- C: PhD Projects: Page 19

Project Summaries:
- A: Recruitment Finished in 2011: Page 21
- B: Recruitment Ongoing in 2012: Page 29
- C: PhD Projects (ongoing): Page 35


Foreword

We present a summary of the internal research activity at the Royal Hospital for Women for 2011.

As can be seen, the Royal is now a highly active research institution, in all areas of Perinatal care. A large number of staff, from midwifery, obstetrics, neonatal nursing and neonatology have contributed to this research activity.

Recruitment of key staff has allowed development of a research and academic group and has allowed oversight of the work that is being undertaken and the published output that is resulting. In particular we are grateful to Dr Maryam Sana who has been responsible for collating this information over the last months, and for maintaining a database of all current internal trials. We are grateful to the Royal Hospital for Women Foundation for their support for Maryam’s role and for their recognition of the importance of coordination of research output.

The last months of 2011 also saw the development of a Maternity Academic Group to review new trial applications, discuss resource implications and oversee a research strategy for the future. Early 2012 has seen the implementation of lunchtime academic meetings, for which we again thank the Foundation for support. These meetings aim to provide a forum for multidisciplinary discussion of evidence based clinical practice, dissemination of new information, presentation of research findings and discussion of current hot topics and controversies.

Our apologies if we have overlooked any researchers or their projects in our attempts at an exhaustive list. Please contact us directly if you have projects or papers that you would like to have included in this summary. We thank all those involved for their input and look forward to further ongoing research collaboration and further improvement in the output from RHW.

Sally K Tracy

Professor Alec Welsh
Professor in Maternal-Fetal Medicine
University of New South Wales
Royal Hospital for Women

Professor Sally Tracy
Professor of Midwifery
University of Sydney
Royal Hospital for Women
Peer-Reviewed Publications 2011


Books and Book Chapters
Books and Book Chapters

Textbooks

Tracy SK, Martin M, White J. Head Heart and Hands, a Textbook for Midwives in Viet Nam, UNFPA, University of Sydney and Ministry of Health, Viet Nam 2011

Midwifery Book Chapters


Abstracts and Presentations
Abstracts and Presentations 2011


5. Collins S, Stevenson G, Noble A, Impey LW, Welsh AW. The need to standardise Virtual Organ Computer-aided AnaLysis (VOCAL) power Doppler indices to the sub-bloom gain (SBG) level. Accepted for oral poster presentation at the International Society of Ultrasound in Obstetrics & Gynaecology. 21st World Congress. Los Angeles. September 2011.

6. Meriki N, Welsh AW. Reference values for the right Mod-MPI (Modified Myocardial Performance Index) in normal fetuses within an Australian population. Accepted for poster presentation at the International Society of Ultrasound in Obstetrics & Gynaecology. 21st World Congress. Los Angeles. September 2011.


11. Hartz DL, Tracy SK. The M@ngo trial; a randomised controlled trial of caseload midwifery care. Oral presentation at the University Of Sydney, Faculty of Nursing and Midwifery, GOSSIP- Generation of Scholarship and Scholarship in Practice. 31 March 2011.

12. Hartz DL. Thinking outside the uterus: does a pregnant woman’s Attachment prototype influence physiological birth. University of Sydney, Faculty of Nursing and Midwifery Research Week. 21 July 2011.


Internally-based Obstetric & Midwifery Projects
List of Internal Medical and Midwifery Research Projects-RHW 2011

A. Recruitment Finished in 2011:

1. FOG
A Comparison of Outpatient Foley Catheter and Inpatient Prostaglandin Gel for Cervical Ripening for Induction of Labour
FOG aims to provide evidence of the clinical outcomes, cost effectiveness and patient acceptability of these two methods of induction of labour.
For details of the FOG trial please contact Amanda Henry Amanda. Henry @unsw.edu.au

2. Multiple Pregnancy Referral, Care and Outcomes at Royal Hospital for Women
To assess the effectiveness of the introduction of the Multiple Pregnancy Clinic at the Royal Hospital for Women (RHW) and to audit safety and quality of care of multiple pregnancy referrals to RHW’s Maternal Fetal Medicine service, focusing on demographic characteristics, reason for referral versus final diagnosis, and outcome.
For details please contact Amanda Henry Amanda.Henry@unsw.edu.au Emma Tetstall Emma.Tetstall@sesiahs.health.nsw.gov.au

3. The RHW Student Midwives Study 2011
The Royal has been at the forefront in offering student midwives the opportunity to experience continuity of midwifery care through the Midwifery Group Practice model of care. This Study evaluates the student experiences within this innovative clinical midwifery education model.
For details please contact Donna Hartz Donna.Hartz@sydney.edu.au Annette Wright Annette.Wright@sesiahs.health.nsw.gov.au

4. The Nurses and Midwives Engagement Survey
This project was undertaken collaboratively with the Department of Organisation and Management at the Australian School of Business based at UNSW to undertake a rigorous assessment of RHW nurses and midwives performance, motivation, well-being and emotion management strategies. The ARC Grant was awarded in 2009 with the Royal Hospital for Women becoming an Industry partner.
For details please contact Donna Hartz Donna.Hartz@sydney.edu.au
5. PRAMS (Perinatal Regulation and Mood Study_NHMRC funded)
This study aims to focus on the different behaviour of babies in relation to the sleeping, feeding and settling more easily than others “why some babies love to explore while others prefer familiar faces and toys”?
For details of PRAMS study please contact
Helene Seddon-Glass prams@mq.edu.au

6. The Perinatal Journey: the Process and Impact of Psychosocial Assessment (ARC/UWS funded)
The above mentioned study aims to determine the relationship between perinatal mental health, use of health services, and outcomes in pregnancy at 6 weeks and 6 months after birth, for women and their infants. In addition, it also focuses on the process and impact of psychosocial assessment undertaken by midwives in the antenatal booking visit and by child and family health services (CFHN) in the postnatal universal home visit (UHHV).
For details of the PJ study please contact
Virginia Schmied v.schmied@uws.edu.au
Marie-Paule Austin m.austin@unsw.edu.au

7. V.I.G.R - Viral Infection in the Genetically at Risk of Type 1 Diabetes
V.I.G.R focuses on the association between Enterovirus infection and the development of islet autoimmunity and type 1 diabetes (T1DM) in a prospective cohort of infants and children who have a first degree relative with T1DM. It also includes the investigation of the molecular characteristics of Enterovirus isolated in this cohort and identify putative ‘diabetogenic’ Enterovirus genotypes in vivo and in vitro.
For details please contact
Maria Craig m craig@unsw.edu.au
Jackie Catteau Jackie.Catteau@sesiahs.health.nsw.gov.au

8. Physical Activity in Pregnancy
This study is based on five surveys which will be conducted throughout pregnancy to determine the correlation between physical activity and the progress in pregnancy.
- Pre-pregnancy
- Trimester 1, 2 and 3
- Post partum
For further details please contact
Justine Darling Justine.Darling@sesiahs.health.nsw.gov.au
B. Recruitment Continues in 2012:

1. The Pilot Amniotic Fluid Lactate Study
The Pilot Study aims to determine the feasibility of collecting and analysing samples of amniotic fluid lactate from labouring women. We will assess the suitability of the information, consent procedures and the validation of a commercially available meter (the Lactate Pro), before embarking on a larger study. We got the University of Sydney Bridging Support Grant $40,000 for this pilot study.
For details of the Pilot Amniotic Fluid Lactate Study please contact
Sally Tracy  sally.tracy@sydney.edu.au
Beverly Hall  Beverley.Hall@sesiahs.health.nsw.gov.au

2. Audit of Iron Infusion in Pregnancy
This audit focuses on the use of intravenous iron therapy in pregnant women at the Royal Hospital for Women. The indication for treatment, any complications from therapy, response to the treatment and pregnancy related outcomes such as post partum haemorrhage will also be examined.
For details please contact
Amanda Henry          Amanda. Henry @unsw.edu.au
Giselle Kidson-Gerber Giselle.Kidson-Gerber@sesiahs.health.nsw.gov.au

3. To Test the Model for the Impact of Routine Screening for Domestic Violence as Part of Antenatal Care, Among a Sample of Aboriginal and Non-Aboriginal Women (NHMRC funded)
This study aims for women’s decisions to disclose abuse in response to screening for intimate partner violence in accordance with model developed in the previous research.
For details please contact
Joanne Spangaro j.spangaro@unsw.edu.au

4. The Triple B Study: Bumps, Babies and Beyond.
The Impact of Parental Substance Use on Infant Development and Family Functioning
Triple B study aims to monitor prenatal alcohol, tobacco and other substance use patterns in a cohort of pregnant women and their partners, and identify characteristics associated with their substance use, such as demographics, psychological and physical health, a range of pregnancy-specific outcomes (e.g. birth weight), and subsequent early life wellbeing.
For details please contact
Laura Dewberry l.dewberry@unsw.edu.au
5. T.R.I.G.R - Trial to Reduce the Incidence of Type 1 Diabetes in the Genetically at Risk
TRIGR study aims to determine whether weaning a hydrolysed protein formula, compared with a standard intact cow’s milk protein formula, reduces the cumulative incidence of diabetes-predictive auto antibodies and/or clinical diabetes by 10 years of age.
For details please contact
Maria Craig mcraig@unsw.edu.au
Jackie Catteau Jackie.Catteau@sesiahs.health.nsw.gov.au

6. An Audit of Vaginal Breech Outcomes Over 12 years
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

7. Determinants of Perineal Trauma and Opportunities for Prevention
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

8. Teaching Assisted Vaginal Birth – The Use of a Model
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

9. Continuous Syntocinon vs. Cessation of Syntocinon at 5cm Dilatation, in Induction of Labour.
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

10. Pregnancy Outcome following First Trimester Exposure to Lithium
It’s a multicentre prospective cohort follow-up study on pregnancy outcome following first trimester exposure to lithium. Collaboration with Israel and Canada.
For further details please contact
Debra Kennedy Debra.Kennedy@SESIAHS.HEALTH.NSW.GOV.AU

11. Medications in Pregnancy
It’s an international internet survey in collaboration with University of Oslo, Norway.
For further details please contact
Debra Kennedy Debra.Kennedy@SESIAHS.HEALTH.NSW.GOV.AU
12. Pregnancy Outcome following First Trimester Exposure to Duloxetine

It’s a multicentre prospective cohort follow-up study on pregnancy outcome following first trimester exposure to duloxetine. **Collaboration with Motherisk Canada.**

For further details please contact

Debra Kennedy [Debra.Kennedy@SESIAHS.HEALTH.NSW.GOV.AU](mailto:Debra.Kennedy@SESIAHS.HEALTH.NSW.GOV.AU)
C. PhD Projects:

1. M@NGO The Midwives @ New Group practice Options RCT
NHMRC funded three year randomised controlled trial of midwifery group practice.
PhD candidate Donna Hartz: donna.hartz@sydney.edu.au
Supervisor: Sally K Tracy Sally.tracy@sydney.edu.au

2. FETAL TEI INDEX (MYOCARDIAL PERFORMANCE INDEX) TRIAL
Fetal Doppler and the Tei Index for Evaluation of Normal and Pathological Pregnancy
As part of a UNSW PhD project, Dr Neama Meriki is evaluating the use of the Fetal Tei Index (myocardial performance index) to assess fetal cardiac function in health and disease.
For further details please contact
Alec Welsh alec.welsh@unsw.edu.au
Neama Meriki neamameriki@yahoo.com

3. Fractional Moving Blood Volume (FMBV) as a Measure of Cerebral Perfusion in the Human Neonate: Defining a Normal Range and its Measurement with Neonatal Pathology and Therapy
To investigate the use of power Doppler Ultrasound and the index FMBV to define a normal range for regional neonatal cerebral perfusion; and to determine the influence of pathology and intervention on perfusion.
For further details please contact
Alec Welsh alec.welsh@unsw.edu.au
Tim Schindler tschindl@med.usyd.edu.au

4. Perinatal Outcomes of Birth Centre Care in New South Wales
The study examines morbidity for women who intended to give birth in a NSW birth centre at the onset of labour compared with those who intended to give birth in the co-located hospital labour ward, and their babies, during the period 2001–2007.

For details please contact
Elizabeth Sullivan e.sullivan@unsw.edu.au
Sally K Tracy Sally.tracy@sydney.edu.au
Alec Welsh alec.welsh@unsw.edu.au
Paula Laws p.laws@unsw.edu.au
Project Summaries
Details of Internal Medical and Midwifery Research Projects RHW-2011

A. Recruitment Finished in 2011:

1. FOG
A Comparison of Outpatient Foley Catheter and Inpatient Prostaglandin Gel for Cervical Ripening for Induction of Labour

Aims:
- To compare the clinical effectiveness, patient acceptability, safety of the use of intracervical Foley catheter in the outpatient setting with intravaginal PGE2 (Prostin) gel in the inpatient setting for induction of labour.
- To assess the cost-effectiveness of intracervical Foley catheter in the outpatient setting to intravaginal PGE2 (Prostin) gel in the inpatient setting for use in induction of labour.

Study Population: Unblinded randomised controlled trial.
The Prostin group is acting as the control group as this is the usual mode of care for women requiring cervical ripening at RHW. 100 subjects in each arm (200 total).

Inclusion Criteria:
- Age 18 and over.
- Gestational age 37 weeks or greater.
- Informed consent to participate.
- Booked by treating clinician for an induction of labour, including a cervical ripening procedure.

Exclusion Criteria:
- Not suitable for outpatient management.
- Potentially unsuitable for randomisation to prostaglandin gel use e.g. presence of uterine scar, oligohydramnios, grand multiparity.
- Ruptured membranes, chorioamnionitis or suspected chorioamnionitis, multiple pregnancies, non-vertex presentation.
- Use of prior cervical ripening procedure.
- Regular uterine contractions at time of booked induction.
- Bishops score 7 or more, or cervical dilation 2cm or greater, at time of presentation for cervical ripening.
- Insufficient English for valid consent without assistance of interpreter.
- Allergy/hypersensitivity to Latex or Prostin gel.

Starting Date:
June 2009.

Expected Date of Completion:
- For the first part of the study the data entry has been completed, plan to write up. Abstract has been presented at RANZCOG ASM Nov 2011.
- Economic analysis part has being done by Kathryn Austin, Registrar RHW (Kathryn Austin@sesias.health.nsw.gov.au), aim to have data entry by the end of 2011, analysis and write up by mid 2012.

Contact Details:
Amanda Henry
Maternal Fetal Medicine Fellow, Royal Hospital for Women
Barker St, Randwick 2031.
Amanda.Henry@unsw.edu.au
2. Multiple Pregnancy Referral, Care and Outcomes at Royal Hospital for Women

Aims:

- To assess the effectiveness of the introduction of the Multiple Pregnancy Clinic at the Royal Hospital for Women (RHW) by examining demographic characteristics and outcomes of multiple pregnancies at RHW since the introduction of the Multiple Pregnancy Clinic (2009) compared to the two years prior to the clinic’s operation (2007-2008).
- To audit safety and quality of care of multiple pregnancy referrals to RHW’s Maternal Fetal Medicine service, focusing on demographic characteristics, reason for referral versus final diagnosis, and outcome.

Methodology:
Hospital databases, and where required for clarification, the patient Medical Record, will be used for the audit of multiple pregnancies in the years 2007-2009. The number of participants is expected to be approximately 300 based on hospital figures of 90-100 twin deliveries and 5 higher order multiples per year.

Starting Date: November 2009.

Expected Date of Completion:
Initial data collection April 2010: plan for ongoing yearly to second yearly data collection and review.

Progress of the Project:
Status: In progress
Work on the project is in two phases

1) Data collection for the audit of the multiple pregnancy clinic at the Royal Hospital for Women in its first year of operation (March 2009-March 2010) and data collection for multiple pregnancies seen at the Royal Hospital for Women 2007-2009 inclusive. The pregnancies have been identified from hospital databases and a study database constructed. Work on data collection is being undertaken by Dr Jennifer Nicole Lees, an SRMO at RHW & study investigator, and is continuing during 2011.

2) Data collection and analysis for the multiple pregnancy referrals to the RHW (NSW Fetal Therapy Centre) during the years 2007-2009. 176 twin referrals and 26 triplet referrals were identified. Data collection and analysis is partially complete for these referrals, and results have been accepted for presentation by Dr Emma Tetsell, SRMO at RHW & study investigator, at the Perinatal Society of Australia and New Zealand in March 2011 in Hobart, Tasmania.

Contact Details:
Amanda Henry
Maternal Fetal Medicine Fellow
Royal Hospital for Women
Barker St, Randwick 2031
amandahenry@unsw.edu.au
3. The RHW Student Midwives Study 2011

Aims:
- To evaluate the extension of the clinical rotation of graduate diploma student midwives within a Midwifery Group Practice to 12-14 weeks.
- To determine any differences in the Clinical Learning Environments between a Midwifery Group Practice and the non Midwifery Group Practice clinical rotations.
- To determine differences, if any, in opportunities to meet Australian Nursing & Midwifery Council National competency standards for the student midwives between a Midwifery Group Practice and the non Midwifery Group Practice clinical rotations.
- To analyse the impact of extended student rotations for MGP midwives, educators and midwifery managers.
- To analyse the driving and resistant forces impacting on students learning opportunities on clinical rotations within Midwifery Group Practice and the non Midwifery Group Practice clinical rotations.

Background:
Significant progress has been made in Australia midwifery education reform to ensure that curricula provide strategies to support students to meet the full scope of midwifery practice competencies by the completion of their training and hence registration as a midwife. Previously there has been limited or no opportunity for graduate student midwives to gain experience in a midwifery continuity of care model in the Australian context. This has meant that midwifery students have had limited experiential opportunity to observe and participate in models of midwifery care where continuity of care/utilising the full scope of midwifery practice is undertaken. A major clinical redesign of midwifery services at the Royal Hospital for Women has provided the opportunity for a cohort of 10 graduate diploma midwifery students to have an extended clinical rotation of 12-14 weeks with a Midwifery Group Practice.

Study Population and Inclusion Criteria:
2011 Postgraduate midwifery student employed at the RHW.
Caseload Midwives.
Midwifery managers and educators.

Starting Date:
November 2011.

Expected Date of Completion:
February 2012.

Contact Details:
Donna Hartz       Donna.Hartz@sydney.edu.au
Annette Wright    Annette.Wright@sesiahs.health.nsw.gov.au
4. The Nurses and Midwives Engagement Survey

This project was undertaken collaboratively with the Department of Organisation and Management at the Australian School of Business based at UNSW to undertake a rigorous assessment of RHW nurses and midwives performance, motivation, well-being and emotion management strategies. The ARC Grant was awarded in 2009 with the Royal Hospital for Women becoming an Industry partner.

Contact Details:
Sally K Tracy  
Professor of Midwifery  
University of Sydney  
Midwifery and Women’s Health Nursing Research Unit  
Level 1, Royal Hospital for Women  
Barker Street  
Randwick NSW 2031  
sally.tracy@sydney.edu.au

Donna Hartz  
Donna.Hartz@sydney.edu.au
5. PRAMS (Perinatal Regulation and Mood Study)  
(NHMRC funded)

Hypotheses:
- Why are babies all so different?
- Why some babies sleep, feed and settle more easily than others?
- Why do some babies love to explore while others prefer familiar faces and toys?

Study Population: Women receiving antenatal care at the Royal Hospital for Women.

Inclusion Criteria:
During pregnancy, the women are required to complete
- Questionnaires and an interview about their experience of pregnancy and the expectations of becoming a mother and caring for the baby.
- An interactive task that allows exploring individual differences in temperament.

After the baby is born, women are to
- Complete some further questionnaires and an interview about their experience of early parenthood and infant’s behaviour, sleeping and feeding patterns.
- Participate in a play task exploring the baby’s responses to a novel situation.

The mothers will receive:
- A report about the baby’s development and temperament.
- A copy of the booklet “Understanding and Supporting Your Baby’s Development”.

Starting Date:
August 2010.

Expected Date of Completion:
Aim to finish recruitment by February 2012 in the Royal hospital for Women (outpatients department), Royal North Shore Hospital and North Shore Private Hospital.

Recruitment:
200 targeted.

Contact Details:
Helen Seddon-Glass, University of Macquarie Centre for Emotional Health, 02 98506750.
prams@mq.edu.au
www.psy.mq.edu.au/prams

Aims:
1. To determine the relationship between perinatal mental health, use of health services, and outcomes in pregnancy and at 6 weeks and 6 months after birth, for women and their infants;
2. To describe the process and impact of psychosocial assessment undertaken by midwives in the antenatal booking visit and by child and family health services (CFHN) in the postnatal universal home visit (UHHV).

Study Population:
The sample will comprise 100 pregnant (both nulliparous and multiparous) women who are public patients booked to give birth at the Royal Hospital for Women and Liverpool Hospital. In addition, the sample will comprise approximately 40 midwives and 40 CFHN.

Inclusion/Exclusion Criteria:
Women ≥18 years, ≥12 week’s gestation at first interview. Women recruited for this study include who experienced a neonatal death, had an actually ill infant, had an infant removed from their care following birth or had a serious maternal illness. Women who were not sufficiently proficient in English were excluded from the study.

Starting Date:
September 2009.

Expected Date of Completion:
Finished Recruitment (50 women from the Royal Hospital for Women) in February 2011 and plans to do the follow up at 6-12 months, finalizing the results and publishing in mid 2012. The results from the observational part of the study (16 women) have been presented at the Australian College of Midwives Conference in 2010 and Mental Health Conference in 2011.

Contact Details:
Associate Professor Virginia Schmeid
School of Nursing and the Family Community Health Research Group,
University of Western Sydney.
v.schmied@uws.edu.au

Marie-Paule Austin
Consultant, Liaison, and Perinatal Psychiatry
Royal Hospital for Women, Sydney.
m.austin@unsw.edu.au
7. V.I.G.R - Viral Infection in the Genetically at Risk of Type 1 Diabetes

Aims:
- Describe the association between Enterovirus infection and the development of islet autoimmunity and type 1 diabetes (T1DM) in a prospective cohort of infants and children who have a first degree relative with T1DM.
- Examine the association between islet autoimmunity/T1DM, virus infections (particularly Enteroviruses), HLA genotype and disease modifying factors (including infant feeding, diet/nutrition, growth, and vitamin D status).
- Investigate the molecular characteristics of Enterovirus isolates in this cohort and identify putative ‘diabetogenic’ Enterovirus genotypes in vivo and in vitro.

Study Population:
This is an observational longitudinal study of children. Children will have a first degree relative with type 1 diabetes and be enrolled in the study at birth and followed up for 10 years. The target population is neonates who have a first degree relative with T1DM. Pregnant women who have T1DM themselves or have a partner/child with T1DM are recruited through antenatal clinics, obstetricians, paediatricians and endocrinologists associated with the three main study centres in Sydney, Australia (Children’s Hospital, Westmead; the Royal Hospital for Women, Randwick and St George Hospital, Kogarah).

Inclusion Criteria:
- The biological parent or sibling of the newborn infant has type 1 diabetes as defined by the World Health Organisation.
- The infant’s parent or legal guardians give signed consent to participate.

Exclusion Criteria:
- Other forms of diabetes (type 2, secondary diabetes)

Stage of the Project:
Recruitment till December 2011_254.

Expected Completion Timeframe:
2012.

Contact Details:
Dr. Maria Craig
Principal Investigator
St George Hospital Kogarah
Children’s Hospital at Westmead.
m craig @unsw.edu.au

Jacki Catteau
Study Coordinator
Centre for Women’s Health Nursing
Royal Hospital for Women.
Jackie.Catteau@sesiahs.health.nsw.gov.au
8. Physical Activity in Pregnancy

**Aim:**
To determine the correlation between physical activity and progress in pregnancy.

**Methodology:**
Five surveys will be conducted through pregnancy
- Pre-pregnancy
- Trimester 1, 2 and 3
- Post partum

**Stage of the Project:**
Finished recruitment.

**Starting Date:**
2011.

**Expected Date of Completion:**
April 2012.

**Contact Details:**
Justine Darling
Acute Care Nurse/ Research Assistant.
[Justine.Darling@SESIAHS.HEALTH.NSW.GOV.AU](mailto:Justine.Darling@SESIAHS.HEALTH.NSW.GOV.AU)
B. Recruitment Ongoing in 2012:

1. The Pilot Amniotic Fluid Lactate Study
A University of Sydney Bridging Support Grant $40,000 was recently awarded to continue this pilot study.

Hypothesis:
To determine the feasibility of collecting samples of amniotic fluid lactate from labouring women.

Aims:
1. Determine the feasibility of undertaking a large prospective cohort study of women in labour
2. Measure the concentration of amniotic fluid lactate at specific time intervals during labour and birth.
3. Determine the suitability of the information and consent procedure before embarking on a larger study.
4. Validate a commercially available meter (the Lactae Pro) against formal laboratory measures of lactate.

Study Population:
Women who book to give birth at the RHW between 17/10/2011 and 31/12/2012.

Inclusion Criteria:
Eligible women will include nulliparous (first time mothers) with either a spontaneous labour or induction of labour at 37 - 42 weeks gestation, with a live singleton fetus in a cephalic presentation and no recognised contraindication to vaginal birth.

Exclusion Criteria:
Women will be excluded at the onset of labour if they have a known fetal anomaly; a non reassuring CTG or the fetus is not in a cephalic (head down) presentation.

Starting Date:
October 17, 2011.

Expected Date of Completion:
December 31, 2012.

Contact Details:
Sally K Tracy
Professor of Midwifery
University of Sydney
Midwifery and Women's Health Nursing Research Unit
Level 1, Royal Hospital for Women
Barker Street
Randwick NSW 2031
Australia
sally.tracy@sydney.edu.au
sally.tracy@sesiahs.health.nsw.gov.au

Beverly Hall
Midwifery and Women's Health Nursing Research Unit
Royal Hospital for Women
Beverley.Hall@sesiahs.health.nsw.gov.au
2. Audit of Iron Infusion in Pregnancy

**Aims:**
- To audit the use of intravenous iron therapy in pregnant women at the Royal Hospital for Women.
- To determine the indication for treatment, any complications from therapy, response to the treatment and pregnancy related outcomes such as post partum haemorrhage.

**Study Population/Inclusion Criteria:**
- Hospital databases, and where required for clarification the patient Medical Record, will be used for the audit of Iron transfusion in pregnancy from February 2005 (when this hospital first commenced using Iron sucrose infusion) until 31/12/09.
- The number of records is expected to be approximately 50 based on preliminary advice from the Royal Hospital for Women pharmacy.
- Proposed databases to be used are: Obstetrix, Health information exchange (HIE), iPatient Manager (IPM), eMR, WRQ reflection (pathology results), Medical records.
- Data will be compared with hospital data for overall demographics for maternal age, parity, number of fetuses and gestational age at delivery and also specific hospital data for PPH and transfusion in order that the efficacy and acceptability of iron transfusion in pregnancy can be examined.

**Starting Date:**
February 2010.

**Expected Date of Completion:**
April 2012.

**Contact Details:**
Amanda Henry  
Maternal Fetal Medicine Fellow, Royal Hospital for Women  
Barker St, Randwick 2031.  
Amanda.Henry@unsw.edu.au
3. To Test the Model for the Impact of Routine Screening for Domestic
Violence as Part of Antenatal Care, Among a Sample of Aboriginal and
Non-Aboriginal Women (NHMRC funded).

**Hypothesis:**
Women’s decisions to disclose abuse in response to screening for intimate partner
violence in accordance with model developed in previous research.

**Study Population:**
Antenatal patients (Aboriginal and non-Aboriginal) who have been asked the NSW Health
Domestic Violation (DV) screening questions. Half of the sample will be recruited from
Aboriginal Maternal and Infant Health Strategy.

**Inclusion Criteria:**
The sample target is 120 pregnant women who have experienced abuse or fear of
partner in the past 12 months.

**Methodology:**
The research team will directly approach women in the antenatal clinic waiting areas.
Women who agree will be explained about the screening policy and will be offered a 20
minutes interview on the same day/subsequent appointment.

**Starting Date:**
Just funded – not yet commenced.
Data collection will be done from July 2012 to June 2013.
Aim to have the Recruitment rate of approximately 3 women per week (40 women from
Royal Hospital for Women).

**Expected Date of Completion:**
March 2014.

**Contact Details:**
Dr. Joanne Spangaro
Research Fellow
School of Public Health and Community Medicine
University of New South Wales
Sydney
j.spangaro@unsw.edu.au
4. The Triple B Study: Bumps, Babies and Beyond. 
The Impact of Parental Substance Use on Infant Development and Family Functioning

**Aims:**
1. To monitor prenatal alcohol, tobacco and other substance use patterns in a cohort of pregnant women and their partners, and identify characteristics associated with their substance use, such as demographics, psychological and physical health, a range of pregnancy-specific outcomes (e.g. birth weight), and subsequent early life wellbeing.
2. To examine the extent to which substance use is interrelated among couples during pregnancy and whether partners influence each other’s substance use over time.
3. To determine whether prenatal alcohol, tobacco and other substance use by pregnant women and their partners negatively impact on infant development and family functioning over time.

**Study Population:**
The study includes both biological and non-biological partners in an intimate relationship with a pregnant female participant. In cases where both the biological and non-biological partner are involved, the individual who
(a) Has been the mother’s main support during pregnancy, and
(b) Who intends to take the most significant role in infant care giving will be interviewed. If this is unclear, both partners will be invited to participate and data from the partner who reports having had greater responsibility for infant care will be used. Note: DNA will not be collected from non-biological partners as this information would not be informative.

**Inclusion Criteria:**
Women being identified as pregnant by a medical practitioner; parents being aged 16 years or older; the absence of any known major medical complications in the mother or the foetus; parent’s residential postcode must be for New South Wales (NSW) or Western Australia (WA); the mother or both parents intend to be the primary caregiver(s); parents being considered mentally able to complete the interview; being sufficiently literate in English (able to understand a standard English newspaper); and not having been previously enrolled in the study.

**Starting Date:**
Pilot study commenced in 2009. Main study commenced in 2010 (Outpatients RHW).

**Current Recruitment:**
The current recruitment is approximately 700 out of targeted 1800 from 3 hospitals across Sydney (RHW, RPAH and Liverpool) and one in Perth (King Georges Memorial Hospital).

**Expected Date of Completion:**

**Contact Details:**
Laura Dewberry, Research Officer
National Drug and Alcohol Research Centre
University of New South Wales, Sydney
Tel: 02 9385 0190
Email: l.dewberry@unsw.edu.au
Website: http://ndarc.med.unsw.edu.au/ndarc.nsf
5. T.R.I.G.R - Trial to Reduce the Incidence of type 1 Diabetes in the Genetically at Risk

Hypothesis:
To determine whether weaning a hydrolysed protein formula, compared with a standard intact cow’s milk protein formula, reduces the cumulative incidence of diabetes-predictive auto antibodies and/or clinical diabetes by 10 years of age.

Study Population:
There were 298 infants recruited from six states in Australia; 103 (40%) were eligible for TRIGR based on HLA genotypes. As of August 2011, 89 (91%) children remain in the study. Reasons for discontinuation include:
- Diagnosis of type 1 diabetes (n=5); these children are no longer followed in TRIGR
- Death (n=1), cerebral aneurysm at age 3
- The remaining 8 children (8%) have been lost to follow up At six years of age, an oral glucose tolerance test is performed. To date 32 (36%) of children have reached this milestone in the study and all OGTTs have been normal. At six years six months of age, islet antibody results from TRIGR are released (ICA, IAA, GAD and IA-2). Of the 15 children who have reached this time point, only 1 (7%) has multiple persistent positive antibodies (and is positive for all four). The remaining children are all antibody negative.

Inclusion Criteria:
TRIGR is an international primary prevention trial for T1DM, involving 77 centres in 15 countries across three continents. There are three study sites in Australia: The Children’s Hospital at Westmead (the co-ordinating site); the Royal Hospital for Women Randwick and John Hunter Children’s Hospital in Newcastle. Eligibility criteria for randomisation are:
- Newborn infant > 35 weeks gestation
- First degree relative with T1DM
- High risk HLA genotype confirmed on cord blood at the birth

Methodology:
Follow up:
Participants are seen at one of the three study sites, at their local doctor/paediatrician and pathology service, or in some cases at their home (this was encouraged by the international steering committee to maintain high retention rates). Clinical assessment, interviews and blood sampling is performed at the ages of 3, 6, 9, 12, 18, and 24 months and will continue annually until 10 years of age or onset of T1D. An oral glucose tolerance test is performed at 6 and 10 years. The blood sample for autoantibody analysis is kept at -80 degrees and shipped in batches 3 monthly to the core laboratory in Helsinki. HbA1c and random blood glucose are done locally. All information is recorded in a web based database and transmitted to the Data Management Unit in Florida, USA.

Stage of the Project:
At this phase in the TRIGR Trial, dropout rates are generally low across participating countries. Of the 2,160 children recruited to TRIGR worldwide, the overall retention rate is 86%. In Australia our retention rate is 91%.

Expected Completion Timeframe:
2016.

Contact Details:
Dr. Maria Craig
Principal Investigator
St George Hospital Kogarah
6. An Audit of Vaginal Breech Outcomes Over 12 years
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

7. Determinants of Perineal Trauma and Opportunities for Prevention
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

8. Teaching Assisted Vaginal Birth – The Use of a Model
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

9. Continuous Syntocinon vs. Cessation of Syntocinon at 5cm Dilatation, in Induction of Labour.
For details please contact
Andrew Bisits Andrew.Bisits@sesiahs.health.nsw.gov.au

10. Pregnancy Outcome following First Trimester Exposure to Lithium
It’s a multicentre prospective cohort follow-up study on pregnancy outcome following first trimester exposure to lithium. Collaboration with Israel and Canada.
For further details please contact
Debra Kennedy Debra.Kennedy@SESIAHS.HEALTH.NSW.GOV.AU

11. Medications in Pregnancy
It’s an international internet survey in collaboration with University of Oslo, Norway.
For further details please contact
Debra Kennedy Debra.Kennedy@SESIAHS.HEALTH.NSW.GOV.AU

12. Pregnancy Outcome following First Trimester Exposure to Duloxetine
It’s a multicentre prospective cohort follow-up study on pregnancy outcome following first trimester exposure to duloxetine. Collaboration with Motherisk Canada.
For further details please contact
Debra Kennedy Debra.Kennedy@SESIAHS.HEALTH.NSW.GOV.AU
C. PhD Projects 2011

1. M@NGO Midwives @ New Group practice Options
A randomised controlled trial of caseload midwifery practice
NHMRC Project Grant 510207 2008-2010

Aims:
- To compare the outcomes and costs of caseload midwifery care to standard or routine hospital care for childbearing women through a randomised controlled trial.
- To undertake a cost analysis to determine both the cost effectiveness of midwifery group practice care and an estimation of the cost of care in relation to the quality of the outcome for women and their families.

Study Population:
Women enrolled in the M@NGO trial fill out a 36 week, a 6 week postpartum and a 6 month postpartum questionnaire. This will provide detailed information regarding the difficulties and the benefits of all models of maternity care at the Royal Hospital for Women.

Inclusion Criteria:
- Women who have no prior preference to book with anybody else and who are not intending to have an elective caesarean section.
- Women who are unsure whether or not they want to try to have a vaginal birth after the previous caesarean section.

Exclusion Criteria:
Women who are quite sure that they want to book with a midwifery group practice or an obstetrician or a named GP or would prefer to go to midwives/ doctors clinics they are not invited into the trial.

Recruitment Rate and Future Plan:
Recruiting ceased on the 11th April 2011 with 1332 women recruited at the RHW. The last woman to be randomised is expected to give birth in early December 2011 and then the analysis will begin.

Starting Date:
8th December 2008

Expected Date of Completion:
February 2012

Contact Details:
Prof Sally K Tracy (Professor of Midwifery, University of Sydney)
sally.tracy@sydney.edu.au
Donna Hartz (PhD Student)
Donna.Hartz@SESIAHS.HEALTH.NSW.GOV.AU
2. FETAL MYOCARDIAL PERFORMANCE INDEX TRIAL

Fetal Doppler and the Tei Index for Evaluation of Normal and Pathological Pregnancy
As part of a UNSW PhD project, Dr Neama Meriki is evaluating the use of the Fetal Tei Index (myocardial performance index) to assess fetal cardiac function in health and disease.
For further details please contact
Alec Welsh  alec.welsh@unsw.edu.au
Neama Meriki neamameriki@yahoo.com
Amanda Henry Amanda.Henry@unsw.edu.au


Aims:
- To use power Doppler Ultrasound and the index FMBV to define a normal range for regional neonatal cerebral perfusion.
- To investigate the influence of pathology and intervention on perfusion.

Hypothesis:
- There are regional differences in neonatal cerebral perfusion.
- A normal range for regional cerebral perfusion can be defined for healthy preterm and term newborns.
- Pathology may alter these values for perfusion and that FMBV may be used to discriminate between normal and abnormal.
- The values for perfusion during the newborn period may correlate with neurodevelopment outcome.

Study Population:
Preterm and term neonates in the Newborn Care Centre at Royal Hospital for Women

Inclusion Criteria/Exclusion Criteria:
Newborns with known pathology and clinically unstable babies will not be enrolled in the initial studies investigating temporal variations in FMBV and establishing a normal range. Newborns enrolled in subsequent studies investigating how pathology and therapy affects FMBV will be included/excluded based on the opinion of an experienced neonatologist involved in the trial.

Starting Date:
November 2011.

Expected Date of Completion:
December 2013.

Stage of the Project:
The project has recently been granted ethics approval. Intending to start recruiting babies for the study after the SSA form is approved.

Contact Details:
Professor Alec Welsh  Tim Schindler
Royal Hospital for Women  Neonatal Advanced Trainee Registrar,
alec.welsh@unsw.edu.au  Royal Hospital for Women
tschindl@med.usyd.edu.au
4. Perinatal Outcomes of Birth Centre Care in New South Wales

Aim:
The study would examine morbidity for women who intended to give birth in a NSW birth centre at the onset of labour compared with those who intended to give birth in the co-located hospital labour ward, and their babies, during the period 2001–2007.

Methodology:
The project is a record linkage study using the NSW Midwives Data Collection (MDC), Admitted Patient Data Collection (APDC), Birth Defects Register (BDR), ABS perinatal mortality data, ABS (maternal) mortality data and Registrar of Births, Deaths and Marriages death registration data. Hospital data would provide additional information on medical conditions and complications not available from the perinatal data. Mortality data would indicate both maternal and perinatal deaths and the cause of death. The study would be a retrospective cohort study with matched pairs. The main study factor is place of birth. Outcome factors would include ICD10AM diagnosis and procedure codes (to examine outcomes such as postpartum haemorrhage, perineal trauma, major puerperal infection, retained placenta, uterine rupture, hysterectomy), and baby outcomes such as birth status, resuscitation measures, presence of congenital anomalies at birth and admission to Special Care Nursery or Neonatal Intensive Care Unit. Descriptive statistics, odds ratios and adjusted odds ratios would be calculated to compare mother and baby outcomes according to intended place of birth. A subanalysis would examine the characteristics and outcomes of birth centre women who were transferred to hospital in labour (ie. according to actual place of birth).

Starting Date:
01/09/2010.

Expected Date of Completion:
31/12/2012.

Contact Details:
A/Prof Elizabeth Sullivan
Perinatal & Reproductive Epidemiology Research Unit
Level 2, McNevin Dickson Building
Randwick Hospitals Campus
e.sullivan@unsw.edu.au

Sally K Tracy
Professor of Midwifery
University of Sydney
Midwifery and Women’s Health Nursing Research Unit
Level 1, Royal Hospital for Women
Barker Street
Randwick NSW 2031
Australia
sally.tracy@sydney.edu.au

Prof. Alec Welsh
Professor in Maternal-Fetal Medicine
School of Womens' & Childrens' Health
University of New South Wales
Level 1, Royal Hospital for Women
alec.welsh@unsw.edu.au

PhD Candidate: Ms Paula Laws
Perinatal & Reproductive Epidemiology Research Unit
Population Health Analyst
University of New South Wales
Australia
p.laws@unsw.edu.au