

THE FIRST

WOMBAT

NEWSLETTER

Volume 1, Issue 1
August 2006

The WOMBAT (WOMen and Babies Wellbeing: Action through Trials) Collaboration aims to promote and support high quality randomised clinical trials in the perinatal area in order to improve the health and wellbeing of women and their children. It is funded through NHMRC Enabling Grant 349570.

WOMBAT WORKSHOPS

SYDNEY Thursday 23 November 2006, University of Sydney 9.00 to 12.30

Improving the health of mothers and babies through clinical trials.

The workshop is free and will cover an introduction to clinical trials, why randomisation is fundamental and recruitment to perinatal trials. The workshop leader will be Professor David Henderson-Smart. Contact Samantha Lain to register: email: slain@perinatal.usyd.edu.au or phone: (02) 9351 7739

Workshops and meetings before PSANZ 2007

We will again be holding workshops before the PSANZ conference in Melbourne next April. Here are some details to help with your travel planning:

Friday 30 March 2007 (from midmorning to 5pm) and Saturday 31 March (morning): How to write a protocol for a clinical trial

Saturday morning 31 March 2007: meeting/workshop for Trial Coordinators

Saturday afternoon 31 March 2007 (as part of the IMPACT Network) – workshop on recruitment.

The IMPACT Network meeting will continue on Sunday morning (and the IMPACT dinner will be on Saturday night).

There will also be a Cochrane work-in on Sunday afternoon.

Further details will become available from the WOMBAT website over the next few months.

WOMBAT REQUEST FOR ASSISTANCE

We have developed a form to assist you in requesting help from the WOMBAT Collaboration. This form is available from the WOMBAT website (www.wombatcollaboration.net). You can also request help by email or phone (see list of contacts below).

WOMBAT FACT #1

The young wombat will stay in the pouch for between 7 and 10 months.

NATIONAL ETHICS APPLICATION FORM (NEAF)

The National Ethics Application Form is now available from www.neaf.gov.au. It is a web-based tool that has been developed to assist researchers to complete research ethics proposals for submission to Human Research Ethics Committees.



Wombat courtesy of David Henderson Smart

ACTR

Australian Clinical Trials Registry (www.actr.org.au)

The Australian Clinical Trials Registry (ACTR) is a national on-line register of clinical trials being undertaken in Australia. It is funded for 5 years by a [National Health and Medical Research Council \(NHMRC\) Enabling Grant](#).

- The ACTR includes trials from the full spectrum of therapeutic areas trials of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies. It has nationwide coverage of all clinical trials involving Australian researchers or Australian participants.

- All data submitted is made publicly available

- Registration is voluntary, but if a Sponsor chooses to register a trial, certain fields are mandatory

- Registration is free of charge

- Responsibility for registration lies with the Sponsor

- o A Sponsor is defined by the [NHMRC and TGA](#) as "an individual, company or institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial".

It is the Sponsors responsibility to ensure that the information submitted is accurate and up-to-date.

The ACTR contains all the mandatory data fields specified by the ICMJE, is publicly owned and publicly accessible. Before allowing trial registration, the ACTR staff check each trial submission to ensure that each field contains meaningful information. **The ACTR has met the requirements of the ICMJE's trials registration policy and is now an ICMJE acceptable registry** (<http://www.icmje.org/faq.pdf>).

AUSTRALIAN PERINATAL TRIALS

The WOMBAT Collaboration encourages all those involved in Australian perinatal trials to register their trials on ACTR. Most of the trials from the existing IMPACT perinatal register are being transferred to ACTR. WOMBAT will not duplicate the work of ACTR but will maintain a listing of current Australian trials (defined as ongoing, in development, recently completed, or completed but still following up or awaiting publication of full results) on the WOMBAT website.

99 perinatal trials are currently included in the WOMBAT list (www.wombatcollaboration.net) – 56 of these have completed accrual but follow-up is continuing and/or the trial was not before September 2005; and 43 trials are ongoing or in development.



Prof Jeffrey Robinson and Wombat.

Congratulations to Jeffrey on his CBE awarded in the UK Queen's Birthday Honours (June 2006)

WOMBAT FACT #2

A wombat can reproduce after it reaches two years of age. Usually only one offspring is born after 30 days gestation.

ADDITIONAL FUNDING FOR AUSTRALIAN HEALTH AND MEDICAL RESEARCH

-excerpts from NHMRC website: www.nhmrc.gov.au

There will be an additional \$500 million over four years for NHMRC grants and an additional \$170 million over nine years for the Australian Health and Medical Research Fellowship scheme.

The Australian Government has more than doubled investment in health and medical research since 1999. Funding for 2004-05 was more than \$420 million. In 2004, NHMRC provided more than \$23.8 million for research into maternal health.

The NHMRC will provide up to \$5 million over 5 years to support innovative research that has an interdisciplinary and inter sectoral approach to child health, through the Healthy Start to Life for All Australians Strategic Award. Applications closed 10 July 2006 for funding to start in 2007.

NOTES FROM WOMBAT SESSION at IMPACT Network Meeting, PERTH, April 2006

The following notes summarise the small group brainstorming at the WOMBAT Session

EDUCATION

Topics suggested:

- Reporting adverse events
- Setting up data safety monitoring committee
- Questionnaire design – generating data sheets
- Grant writing, submitting grants for funding – workshop needed around October
- Recruitment process workshop: literature review, how to do it, how it is done elsewhere, training tools
- How to gain consent (perhaps video training) – key do's and don'ts, debriefing post-consent
- Wider understanding of the principles of randomisation and consent for consumers. Provide training and support for all health professionals.
- Postgraduate certificate in clinical trials
- Data monitoring committee – give examples of terms of reference on website.

NOTES FROM WOMBAT SESSION at IMPACT Network Meeting, PERTH, April 2006

STANDARDISED OUTCOMES

- Maternal, neonatal and childhood standardised outcomes were needed and working on this was considered to be useful.
- Need the involvement of all professional groups when generating outcome definitions
- Need to include psychological outcomes, cost effectiveness and comfort outcomes, for mother and baby
- Suggested resources for starting to generate outcomes include demographic indices, perinatal data collections and Cochrane reviews
- We should seek endorsement of standardised outcomes from relevant bodies such as RANZCOG and PSANZ.
- Place standardised outcomes on the WOMBAT website

Products suggested:

- Sample size calculator or information on products to use
- Patient information leaflet about trials (cf NSW document which has a section on trials for mothers of preterm infants) – consider national evaluation.
- Profiling of trials and why they are needed – for health professionals
- Answers to questions from parents

Other

- List current and proposed activities, relevant trials
- Develop newsletters to get to the shop floor
- List materials on the website
- Develop materials for training (powerpoint presentations that can be used locally) – evaluate this before and after as change in knowledge, attitudes and practices
- Monitor upskilling of individuals
- Audit research
- Set up mentoring and apprenticeships with existing data monitoring committees
- Link in with other groups for training e.g. Data Managers Association.

BARRIERS TO RESEARCH

- Process of going to ethics committees takes too long (can be one year which might represent 1/3 of the funding period)
- Need standardised measures for secondary outcomes
- Increase training for people sitting on ethics committees
- Increase the number of triallists sitting on ethics committees
- State/national single committees were suggested
- Unified forms were suggested
- Need greater knowledge of legal responsibilities

RESEARCH GAPS

- concentrate on systematic identification
- Individuals will apply their own ranking – using issues of common problem, seriousness, expensive, important for whom (health professional, patient, society, family)?
- Clinical areas of importance include: preterm birth, chronic lung disease, progesterone, caesarean section
- Methodological research – how to do trials e.g. recruitment strategies

What other resources apart from Cochrane reviews should be used to identify research gaps?

- Linking with basic scientists
- Consider running focus groups with key researchers around the country on ‘their’ priority research questions
- Use NHMRC priorities
- Use indigenous health priorities
- Practice variations identified through the ANNZ network
- Clinical indicators from Victoria
- Other audits
- CATS
- Basic science areas

What should we be doing with the research gaps identified?

- Put on WOMBAT website
- Ask if people want to be sent an alert for research gap updates
- ?Chat room
- web CT
- gaps to be discussed at national workshops
- Attempt to grade research into doable and not doable.

PSANZ 2006 WOMBAT SURVEY RESULTS

A short survey on Clinical Trials was carried out at PSANZ in April 2006. Summary points are set out below:

110 people responded (45% nursing, 35% medical, 15% research, 5% other)

- 66% had enrolled women or babies in RCTs
- 33% had enrolled 1 to 10 women or babies in RCTs in the last year (19% did not enrol any)
- 37% would like to offer RCT entry to most eligible women/babies
- 83% said a trial is better than an intervention when there is uncertainty
- 34% said that they had moderate encouragement for RCT participation at their workplace (37% for high/fairly high combined)
- Main barrier preventing RCT participation is not enough funding (24%)
- However not enough time (18%) and no support staff (16%) – 34% combined – are also major barriers
- The main encouragement (31%) would be from resources (funding, staffing, time)
- Financial support (18%) and knowledge and skills development (18%) were identified as the most helpful types of support
- Only half the respondents specified education/training topics – 33% research skills and 16% practical knowledge in trial development and management

RESEARCH GAPS

We are preparing ‘umbrellas’ of research gaps identified from Cochrane reviews and these will be progressively added to the WOMBAT website as they are completed. ‘Maternal infections’ and ‘Breech birth’ are among the first umbrellas.

WOMBAT FACT #3

The newborn wombat, weighs only 1 g and is less than 3 cm long, has to crawl from the birth canal into the mother's pouch.

RESULTS OF RECENT PERINATAL TRIALS RECRUITING IN AUSTRALIA – 2006 CITATIONS

- Campbell, E, Walsh, RA et al *A group randomised trial of two methods for disseminating a smoking cessation programme to public antenatal clinics: effects on patient outcomes* Tobacco Control 15: 97-102
- Crowther, CA, Haslam, RR et al *Neonatal respiratory distress syndrome after repeat exposure to antenatal corticosteroids: a randomised controlled trial* Lancet 367 (9526): 1913-9
- Dodd, JM, Crowther, CA et al *Oral misoprostol for induction of labour at term: randomised controlled trial* BMJ 332 (7540): 509-13
- Dodd, JM, Crowther, CA et al *Morning compared with evening induction of labor: a nested randomised controlled trial* Obstet Gynecol 108(2): 350-60
- Doyle, LW, Davis, PG et al *Low-dose dexamethasone facilitates extubation among chronically ventilator-dependent infants: a multicenter, international, randomized controlled trial* Pediatrics 117(1): 75-83
- East, CE, Brennecke, SP et al *The effect of intrapartum fetal pulse oximetry, in the presence of a nonreassuring fetal heart rate pattern, on operative delivery rates: a multicenter, randomized controlled trial (the FOREMOST trial)* AJOG 194(3): 606 1-16

(Continued on page 4)

(Continued from page 3)

- Hawkes, JS, Gibson, RA et al *Effect of dietary nucleotide supplementation on growth and immune function in term infants: a randomized controlled trial* Eur J Clin Nutr 60(2): 254-64
- Jordan, B, Heine RG et al *Effect of antireflux medication, placebo and infant mental health intervention on persistent crying: a randomized clinical trial* J Paediatr Child Health 42(1-2): 49-58
- Klimek, J, Morley CJ et al *Does measuring respiratory function improve neonatal ventilation?* J Paediatr Child Health 42(3): 140-2
- Lumley, J, Watson, L et al *PRISM (Program of Resources, Information and Support for Mothers): a community-randomised trial to reduce depression and improve women's physical health six months after birth* BMC Public Health 6: 37
- Paech, MJ, Magann, EF et al *Does magnesium sulfate reduce the short and long-term requirements for pain relief after caesarean delivery? A double-blind placebo-controlled trial* AJOG 194(6): 1596-602
- Rumbold, A, Crowther, CA et al *Vitamins C and E and the risks of preeclampsia and perinatal complications* N Engl J Med 354(17):1796-806
- Schmidt, B, Roberts, RS et al *Caffeine therapy for apnea of prematurity* N Engl J Med 354(20): 2112-21

OTHER RELEVANT PUBLICATIONS 2006

- Ashwood, PJ, Crowther CA et al *Neonatal adrenal function after repeat dose prenatal corticosteroids: a randomized controlled trial* AJOG 194(3): 861-7
- Bancalari, E *Caffeine for apnea of prematurity – Editorial* N Engl J Med 354(20): 2179-81
- Cyna, AM, Andrew, MI et al *Hypnosis Antenatal Training for Childbirth (HATCH): a randomised controlled trial* BMC Pregnancy Childbirth 6:5
- East, CE, Chan, FY et al *Women's evaluations of their experience in a multicenter randomized controlled trial of intrapartum fetal pulse oximetry (The FOREMOST Trial)* Birth 33(2): 101-9
- East, CE, Brennecke, SP et al *Clinicians' evaluations of fetal oximetry sensor placement in a multicentre randomised trial (the FOREMOST trial)* Aust N Z J Obstet Gynaecol 47(3): 234-9
- Gill, A, Madsen, G et al *Neonatal neurodevelopmental outcomes following tocolysis with glycerol trinitrate patches* Am J Obstet Gynecol
- Morris, JM, Roberts, CL et al *Protocol for the immediate delivery versus expectant care of women with preterm prelabour rupture of the membranes close to term (PPROMT) Trial* BMC Pregnancy Childbirth 6: 9
- Nagle, C, Lewis, S et al *Evaluation of a decision aid for prenatal testing of fetal abnormalities: a cluster randomised trial study protocol* BMC Public Health 6: 96

- Paradisis, M, Evans, N et al *Pilot study of milrinone for low systemic blood flow in very preterm infants* J Pediatr 148(3): 306-13
- Paradisis, M, Jiang, X et al *Population pharmacokinetics and dosing regimen design of milrinone in preterm infants* Arch Dis Child Fetal Neonatal Ed
- Small, R, Lumley, J et al *Midwife-led debriefing after operative randomised trial* BMC Med 4: 3
- Watson, L, Small, R et al *Mounting a community randomised trial: sample size matching selection and randomization issues in PRISM* Control Clin Trials 25(3): 235-50
- Zhou, SJ, Gibson, RA et al *Effect of iron supplementation during pregnancy on the intelligence quotient and behaviour of children at 4 years of age: long-term follow-up of a randomized controlled trial* Am J Clin Nutr 83(5): 1112-7
- Zupancic, JA, Richardson, DK et al *Retrospective economic evaluation of a controlled trial of indomethacin prophylaxis for patented ductus arteriosus in premature infants: Early Hum Dev 82(2): 97-103*

WOMBACT FACT #4

Wombats grow to about 1.3 metres in length, and can weigh up to 36 kg.

WOMBAT PEOPLE

Chief Investigators: Prof Caroline Crowther
Prof Lex Doyle
Ms Vicki Flenady
Dr Christine Roberts
Prof Judith Lumley

Assoc Investigators: Prof David Henderson-Smart
Dr Jodie Dodd
Ms Philippa Middleton
Prof William Tarnow-Mordi
Prof Karen Simmer
Prof Jeffrey Robinson

National Coordinator: Philippa Middleton (SA/NT)

Regional Coordinators: Jo Blacker (WA)
Michelle Kealy (VIC/TAS)
Sam Lain (NSW/ACT)
Karen New (QLD)
Rachel Pearson (SA/NT)

Education Officer: Rebecca Tooher

Thanks to Sharon Egan and Yanlin Liu for all their help in designing and updating the WOMBAT website.

Contact Details: Discipline of Obstetrics and Gynaecology, The University of Adelaide, 1st floor, Queen Victoria Building, Women's and Children's Hospital, 72 King William Street, North Adelaide SA 5006. Phone: (08) 8161 7612; Fax: (08) 8161 7652; email: philippa.middleton@adelaide.edu.au

www.wombatcollaboration.net