

TIPS on 2 Year Follow Up Questionnaires



- Make the 6 monthly phone calls to keep in contact.
- Don't forget to schedule an appointment with the parent as close to the 24month CGA as possible
- Ensure that all of the questions on both Paediatrician and Psychologist forms are completed before mailing them to us. Any unanswered or incomplete questions will be queried back to site.

In Other News....

An unpublished Cochrane review suggests in children less than 37 weeks, delay of cord clamping or an autologous placental transfusion could result in reduced Intraventricular hemorrhage, fewer blood transfusions and less Necrotising Enterocolitis. However, long term outcomes are not known, particularly in infants less than 30 weeks gestation.

In 2010 the APTS trial will start recruiting 1440 babies less than 30 weeks gestation to answer this question. The aim of the trial is to evaluate differences in mortality and morbidity between current standard practice and an autologous transfusion of placental blood. Follow up will be at 18 months of age, corrected for gestation.

To find out more please contact Lucille Sebastian at apts@ctc.usyd.edu.au.

Parent Information Consent (PIC) Forms

- After the SUPPORT Trial, the BOOSTII Parent Information Consent Forms have been updated.
- They now include the increased risk of retinopathy with the higher target and possible risk of death with either target.
- The new PIC (version 3) with tracked changes, have been emailed to all sites. A copy of the updated PIC, along with the Data and Safety Monitoring Committee report, must be submitted to your local HREC as soon as possible.
- We encourage each site to discuss these findings with parents of babies who are still on the masked study oximeters.

QUESTIONS, FEEDBACK, IDEAS, SUGGESTIONS CONTACT US AT: Phone: 02-9562 5000
Email: boost2@ctc.usyd.edu.au ; BOOSTII Team: Alpana Ghadge; Nick Muljadi
Principal Investigator: Prof. William Tarnow-Mordi

"I will give you a talisman... Whenever you are in doubt... recall the face of the poorest and the weakest whom you may have seen, and ask yourself, if the step you contemplate is going to be of any use to him" MK Gandhi

BOOSTII

BENEFITS OF OXYGEN SATURATION TARGETING

JULY 2010
Australian
Update 9.0



NHMRC Clinical Trials
Centre



SPECIAL EDITION—JULY 2010

IT'S OFFICIAL - KEEP ON RECRUITING!

An unexpected difference in mortality in the SUPPORT Study (New England Journal of Medicine, May 2010) led the BOOST II Data and Safety Monitoring Committee to review all infants enrolled so far. It found no evidence of a difference in mortality and recommended continuing recruitment. Our target is 1200 — just 167 more babies.

Letters have gone to Ethics Committees and the New England Journal of Medicine reporting the decision of the DSMC, which has been welcomed by US SUPPORT Principal Investigators, Drs Wally Carlo and Neil Finer.

Table of Contents

Welcome	1
Summary of SUPPORT trial	1
Review	2
DSMC Outcome	2
Recruitment	3
Misc	4

NEJM



US SUPPORT TRIAL

New England Journal of Medicine 2010 May 27;362: 1959-69

- SUPPORT is the first of 5 neonatal oxygen RCTs in infants <28 weeks gestation allocated saturation targets of 85—89% versus 91—95% shortly after birth.
- The high target doubled severe retinopathy (17.9% vs 8.6%, $p < 0.001$).
- But the low target increased death before discharge (19.9% vs 16.2%, $p = 0.04$).
- There were no significant differences in other short term adverse events.
- In a commentary in the same issue of the Journal, Professor Colin Morley wrote that the increased rate of death before discharge was 'weak evidence' and called for more research to clarify this finding.
- The unmasked trial data showed that the median saturation in the low target group was 91% - well above the target range of 85—89%. Because caregivers tended to overshoot both targets, SUPPORT actually compared saturations of about 89% to 97% in the low target with about 91% to 97% in the high target.
- Longer term follow-up into early childhood is vital



Extract From a letter to the New England Journal of Medicine on behalf of BOOST II and BOOST NZ

To the Editor

"The Data and Safety Monitoring Committee (DSMC) in the Australian BOOST-II and New Zealand BOOST-NZ trials, whose protocols are similar to SUPPORT, reviewed short term outcomes in 1,352 patients. The DSMC reported that there was not a clear difference between the two oxygen targets in deaths before hospital discharge. When considering the Australian BOOST-II and New Zealand BOOST-NZ trials combined with SUPPORT, there remained sufficient uncertainty about the effects of treatment on mortality that the DSMC recommended continuing recruitment."

"No RCT has reported survival free of disability in childhood, the major endpoint of all current oxygen-targeting trials. Until this is known it would be premature to adopt either the higher or lower oxygen targets for routine care."



Recommendations of the ANZ and Canadian Data and Safety Monitoring Committees

The BOOST II DSMC recommends continuing recruitment.

The DSMC of the Canadian Oxygen Trial (COT), with a similar protocol, reviewed over 1,300 infants and reached the same conclusion.

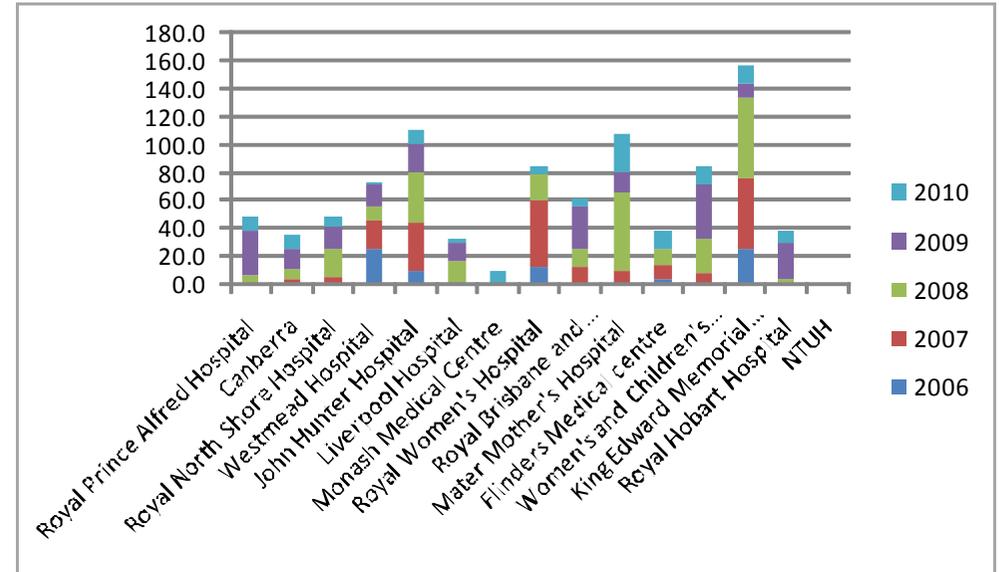
Yearly Summaries

AUS—1033 ; NZ—340

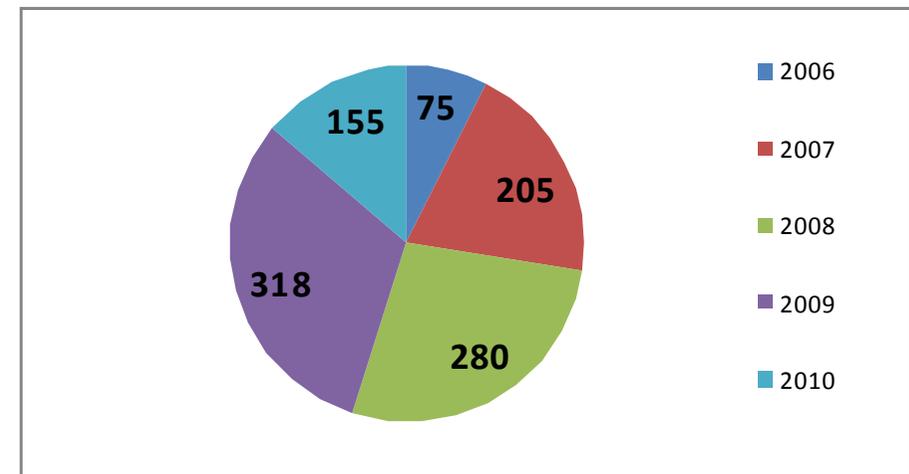


Our current target is 30 babies per month to finish recruitment in December 2010!

Yearly Summaries—2006-2010



Recruitment Yearly Summary



WE ONLY HAVE 167 BABIES TO GO BEFORE THE END OF THE YEAR!!!