

One never notices what has been done; one can only see what remains to be done *Marie Curie*

Boosting your knowledge ...

Compliance with alarm limits for pulse oximetry in very preterm infants.

Clucas L, Doyle LW, Dawson J, Donath S, Davis PG. *Pediatrics*. 2007 Jun;119(6):1195-6
"This study suggests that current guidelines regarding the upper pulse oximeter alarm limit for infants receiving oxygen might be commonly exceeded, although compliance might be better for infants at higher risk of adverse outcomes. However, there might be less variation from guidelines for the lower alarm limit."

QUESTIONS, FEEDBACK, IDEAS, SUGGESTIONS ... CONTACT US AT:
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In September the NHMRC Clinical Trials Centre is hosting the International Clinical Trials Symposium 2007. For more information, please visit the symposium website: www.clinicaltrials2007.com
 The Symposium will discuss issues ranging from clinical trials research to translating research into practice. We are sure you will find something here to interest you and we look forward to seeing you.

Featured Research Nurses

Brenda Argus, Bernice Mills & Connie Wong — RWH, Melbourne.

Brenda, Bernice and Connie have done an excellent job since RWH was activated in last September. They have added 47 BOOST II babies so far, meeting their monthly target with a recruitment rate of about >70% eligible babies! They have had a good share of challenges with oximeter breakdowns and trouble-shooting to add to their busy workload!! Thank you for the brilliant work and keeping up with the SpO2 charts, downloads, InForm and related paper work especially during the busiest months with monthly recruitment figures reaching 8s & 9s. We look forward to Brenda coming back this month from her maternity leave.



Brenda



Bernice



Connie

FAQ:

When do we stop using a trial oximeter?

All enrolled infants must use the allocated trial oximeter for a minimum of two weeks, even if not requiring supplemental oxygen.

The allocated oximeter will be used either until the infant reaches a corrected gestational age of 36 weeks, or until the SpO2 is more than 96% in air for >95% of the time over 3 days."

Thank you

A special thank you to Felicia at "Wazzup" for the screen printing for our baby singlet tops. This will allow us to send a singlet top to each baby on their first birthday.



A special thank you to "Cadbury" for donating Easter Eggs and the yummy BOOST chocolates for the great effort of the hospital staff in their contribution to this trial.



BOOST II

BENEFITS OF OXYGEN SATURATION TARGETING

September 2007
 Australian



NHMRC Clinical Trials Centre

Update 3.0
 Spring Issue



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As we head into spring, here is an update on BOOST II. A BIG THANK YOU for recruitment moving steadily to our target !!

We now have **193 babies from 10 active Australian sites**, with others about to join.

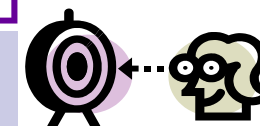
Another 108 babies have been enrolled from New Zealand, making a total of **306 in Australia and New Zealand combined**.

Good targeting is crucial!

- Good targeting is critical to the success of the study.
- The more time with SpO₂ outside 85—95% while in oxygen, the less separation between high and low study oximeters and the less the study's power to show a difference.
- Perfect targeting is impossible in babies who swing wildly, but it's important to achieve the best you can.
- Please share your ideas with us about what seems to help—prone position? changing the FiO₂ by a little but often? reducing the upper alarm limits?

Good targeting - how are we doing?

Percent of displayed SpO₂ values in various ranges



Restricted to times where the baby is breathing supplementary O₂. All values of SpO₂ between 0 and 100 are used
 Data from the first 100 trial babies. More analyses in progress....

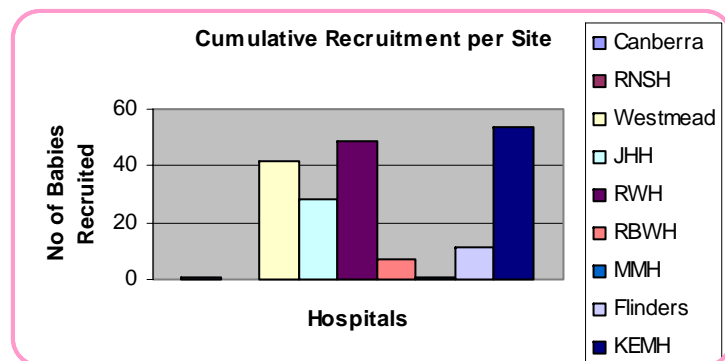
Site	>= 96	85 - 95	88 - 92	< 85
Royal Women's Hospital	24.23	56.10	36.56	19.66
Westmead Hospital	18.06	50.09	32.50	31.85
John Hunter Hospital	19.25	48.81	31.97	31.94
Royal Brisbane and Women's Hospital				
King Edward Memorial Hospital	30.05	48.47	30.28	21.49
Flinders Medical Centre	27.06	48.35	30.24	24.59
The Canberra Hospital				

Recruitment

AUS—193 ; NZ—113



RECRUITMENT per SITE

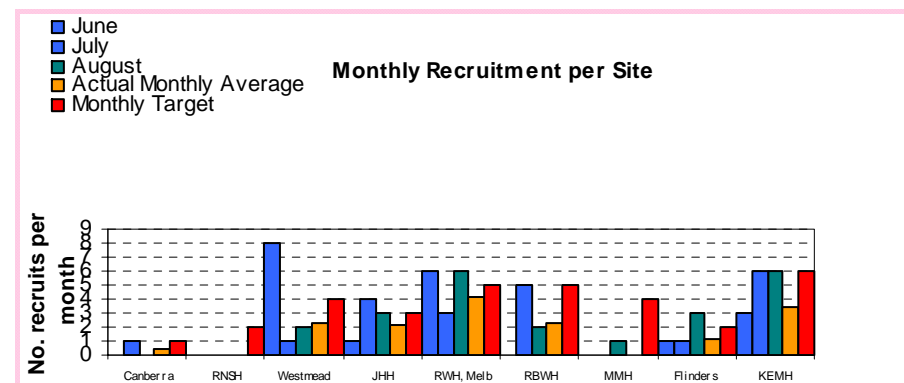


Your centre's BOOSTII re-
cruitment target is based on the size of your unit. Approximate monthly recruitment targets are:
Large centres: 5+ infants;
Medium centres: 3+ infants;
Small centres: 1+ infant

Monthly Recruitment

Is your unit meeting target? Is your unit approaching all parents with eligible babies?

Site	Monthly Target	Actual Monthly Average	June	July	August	Total
Canberra	1.0	0.5		1	0	1
RNSH	2.0	0.0			0	0
Westmead	4.0	2.3	8	1	2	42
JHH	3.0	2.2	1	4	3	28
RWH, Melb	5.0	4.1	6	3	6	49
RBWH	5.0	2.3	0	5	2	7
MMH	4.0	0.0			1	1
Flinders	2.0	1.1	1	1	3	11
KEMH	6.0	3.4	3	6	6	54
TOTAL			19	21	23	193



"Despite 50 years of research, there is not a shred of evidence to guide us regarding the appropriate limits of oxygenation in minimizing the four competing risks of retinal damage, chronic lung disease, neuro-developmental impairment and death."

Bill Silverman, Pediatrics 2004

Why is BOOST II important?

- Over 600 children born at 27⁶ weeks or less are discharged home in Australia each year
- Although oxygen is essential, they are highly sensitive to its toxic effects.
- Despite close to normal life expectancy, many have severe morbidity e.g. chronic lung disease, visual defects, cerebral palsy
- The risk of visual problems may be increasing.

The optimal range of arterial oxygen is unknown

- BOOST II aims to help answer this question
- Reducing morbidities in these children would greatly enhance quality of life
- Families and the community would benefit
- Costs and disability following NICU care would be substantially reduced

Data Management

Essential Information Follow-up Form—it's **ESSENTIAL!**

The primary outcome for BOOST II is death or major disability at 2 years

So we are aiming for excellent follow-up at 2 years of age. The Essential Information Follow-up form captures information to help us keep in touch with each family. Thank you for completing it as soon as possible after randomisation. We'll ask you to keep in touch with the parents every 6 months to update their contact details.

Oximeters

Please do not

- Clear or re-set the trend data
- press the 'dustbin' in the display
- reset the time

All of these steps will delete the data!

Please do

- check the 'Output' before downloading
√ Must be set at 'Binary'

Troubleshooting oximeters or downloading data — don't panic, just ask us!



SpO₂ charts

Please record the SpO₂ charts regularly and accurately



- They provide immediate feedback and assist in achieving targets
- Commonest FiO₂ is vital information for compliance analysis