



Frequently Asked Questions:

Q: What do I need to do when the Oximetry use was interrupted during the trial period?

A: If the interruption is significant (several days) but the Oximeter was replaced on the baby, you need to fill and submit the Interruption Of Oximetry Form in the InForm database.

Q: What if I put on the wrong Oximeter to the randomised baby?

A: Notify the BOOSTII team immediately. We will give you instructions on what actions to take. A File Note must be filed, signed by the Principal Investigator and sent to us by mail.

Oxygen trials recruitment tally around the world...

Study	Start Date	Target	Actual*
BOOSTII - AUS	Mar'06	1200	1000
BOOSTNZ	Sept'07	320	340
BOOSTIIUK	Oct'07	705	738
SUPPORT - USA	Feb'05	1320	1316
COT - Canada	Jan'07	1200	1063

Staff Changes to the BOOSTII Team

You would have already know that there has been a change to the BOOSTII team in the last few months with the departure of Ilka Kolodziej. Ilka has been an amazing part of the team at BOOSTII and is currently working in the Oncology Group at NHMRC. Ilka has been replaced by Nick Muljadi. We welcome Nick to the BOOSTII team and wish Ilka all the best in her next career adventure.

QUESTIONS, FEEDBACK, IDEAS, SUGGESTIONS
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Welcome... To the team at the National Taiwan University on enrolling the 1st BOOSTII baby this March 2010



Do you have an idea for the newsletter? If there is something you would like to see in the newsletter, please tell your local research nurse and they will pass your ideas or requests on to us. This is your newsletter, so we welcome your feedback and suggestions.

House-keeping

Please do not forget to send us...

- Medicare consent approvals from ethics
- Annual progress report approvals from ethics
- Neonatal Screening logs on a regular monthly basis
- Patient Cables when you return the oximeter — these are very expensive and add to the cost of the study
- Reason for return of oximeters forms and Oximeter Tracking Logs
- Follow-up appointment schedule

"We are what we repeatedly do. Excellence, therefore, is not an act but a habit"

Aristotle

BOOSTII

BENEFITS OF OXYGEN SATURATION TARGETING

May 2010
Australian
Update 8.0
Autumn Issue



NHMRC Clinical Trials
Centre

1000 Babies... Only 200 to go!

We have reached another milestone: our 1000th Baby!

Thanks to all the centres for the great recruitment & special mention to King Edward Memorial for recruiting BOOSTII Millennium Baby.

Our final target is 1200....Not long to go now!!

With your help we can reach our target by Christmas 2010.

Targeting - how is your centre doing?

Percent of displayed SpO₂ values in

Restricted to times when baby was on supplementary oxygen. Only values of SpO₂ between 50 and 100 were considered as valid.

Hospital	< 85	85 - 95	88 - 92	>= 96
Royal Hobart	19.07	63.05	42.85	17.88
RNSH	24.18	61.49	37.79	14.33
RPA	22.26	60.48	39.59	17.26
Women's & Children's	21.3	59.69	36.64	19.02
Canberra	26.6	58.86	36.36	14.54
Mater Mothers	20.01	57.93	36.71	22.06
Liverpool	19.31	57.04	35.35	23.66
Royal Womens	21.49	56.61	35.02	21.9
KEMH	21.22	55.41	34.76	23.37
Flinders Medical	23.76	55.07	34.51	21.17
Royal Brisbane and Womens	31.09	54.22	33.56	14.69
John Hunter	26.8	54.14	34.50	19.05
Monash Medical	31.16	53.72	32.05	15.11
Westmead	27.89	51.9	33.14	20.21



Welcome to another update of the BOOSTII Trial.

Well done to the team at Flinders Medical Centre for recruiting our first BOOSTII quadruplets!



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Recruitment

AUS—1000 ; NZ—340



Our current overall target is 40 babies per month!

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

Your centre's BOOSTII recruitment 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 (as of 10th May 2010)

	Site	Monthly Target	Actual Monthly Average	Feb	Mar	Apr	Total (inc May)
61102	Canberra	1.0	0.9	2	2	0	30
61201	RPAH	3.0	1.6	3	2	1	31
61202	RNSH	2.0	1.7	1	3	0	55
61203	Westmead	4.0	1.4	0	1	0	70
61205	JHH	3.0	2.8	0	3	2	127
61213	Liverpool	1.0	1.0	0	1	0	27
61331	Monash	4.0	2.6	2	3	1	18
61341	RWH, Melb	5.0	2.6	2	0	3	114
61401	RBWH	5.0	1.3	1	3	1	46
61436	MMH	4.0	3.8	4	8	7	125
61504	Flinders	2.0	1.1	2	5	4	47
61515	WCH	4.0	2.2	4	3	2	69
61615	KEMH	6.0	4.3	2	2	5	208
61701	Royal Hobart	1.0	1.2	2	2	1	26
88603	NTUH	2.0	0.4	0	1	2	3
TOTAL				32	52	36	1000



Tips On 2 Year Follow Up:

- Please start thinking ahead and make sure the parents are contacted for the appointment. The Follow Up questionnaires are vital to the objectives of the study (see below for a reminder)
- The Paediatrician Form should be completed **as close as possible to 2 years corrected age**, and **within 1 month** of their 2 yrs corrected age. However we still prefer to have a late questionnaire than none at all.
- The BSIDIII form should also be completed **as close as possible to 2 years corrected age**, however it could be completed **up to 3 months either side** if necessary. The Bayley Scales are adjusted for corrected age so exact timing is not as crucial for this form compared to the Paediatrician form.



Endpoints: A reminder of the BOOSTII objectives

Primary outcome measure

- Death or major disability at two years, corrected for gestational age.
- The PRIMARY OUTCOME is derived from the data collected at our 2 year corrected follow-up so accurate completion of the Paediatric questionnaire and the Bayley III assessments is vital to provide reliable evidence on the study intervention.

Secondary outcomes

- Retinopathy of prematurity, duration of oxygen therapy, duration of respiratory support, patent ductus arteriosus, proven infection, necrotising enterocolitis, chronic lung disease, growth, re-admissions to hospital up to 2 years old, cerebral palsy and unable to walk at 2 years corrected gestational age, blindness, deaf using hearing aid, Bayley III scores, death before hospital discharge .

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

