

Boosting your knowledge ...

CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration

Hopewell et al and CONSORT Group
PLoS Medicine, Jan 2008, Vol 5, Issue 1
www.plosmedicine.org

"Clear, transparent, and sufficiently detailed abstracts of conferences and journal articles related to randomized controlled trials (RCTs) are important, because readers often base their assessment of a trial solely on information in the abstract. Here, we extend the CONSORT (Consolidated Standards of Reporting Trials) Statement to develop a minimum list of essential items, which authors should consider when reporting the results of a RCT in any journal or conference abstract."

QUESTIONS, FEEDBACK, IDEAS, SUGGESTIONS ... CONTACT US AT:

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At the PSANZ08 in April, we will be hosting the BOOSTII Collaborators' Meeting 2008.

Please note in your diaries the following schedule –

Meeting date: Monday, 23rd April
 Time: 12.45pm - 1.45pm

Venue: Meeting Room 5-6

We are sure you will find something here to interest you and we look forward to seeing you.

People do not decide to become extraordinary. They decide to accomplish extraordinary things

Featured Research Nurse

Jane Buchan — John Hunter Hospital.



Jane has done a brilliant job since JHH was activated in August 2006. JHH has added 56 BOOST II babies so far, meeting their monthly target with a recruitment rate of about >80% eligible babies! In the snapshot compliance analysis feedback, they have been shown as the site achieving the best targeting by spending more time in the recommended study SpO₂ ranges whilst the baby is in supplementary oxygen. Thank you for the fantastic work and keeping up with the SpO₂ charts, downloads, InForm and related paper work.

FAQ:

What is the definition for Total number of days in oxygen?

If the baby receives oxygen for ≥30 consecutive minutes in any one 24-hour period, this constitutes the use of supplemental oxygen or respiratory support on that day as one day. If supplemental oxygen is given intermittently within a 24 hour period, this counts as 1 day of oxygen therapy.

Thank you

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

A special thank you to Chris Albonico from "Baby Banz" for donating Hats and Sunglasses for our BOOSTII babies for their participation and contribution to this trial. These will be gifted to the children at the two year follow-up visit.

BOOSTII

BENEFITS OF OXYGEN SATURATION TARGETING

April 2008
 Australian
 Update 4.0
 Autumn Issue



NHMRC Clinical
 Trials Centre

Once again...Good targeting is crucial!

Good targeting is critical to the success of the study....

Over the coming months we will be encouraging NICUs to talk to each other and share ideas on achieving good targeting.

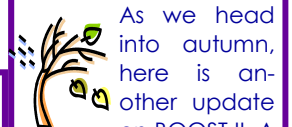
- Are differences in targeting between NICUs due to differences in clinical practice?
e.g. choice of alarm settings, positive feedback in ward rounds or team meetings?
- Remember- the more time SpO₂ is outside 85-95% while in oxygen, the less the study's power to show a difference!

Targeting - how are we doing?

Percent of displayed SpO₂ values in various ranges

Restricted to times where the baby is breathing supplementary O₂. Averages of the random compliance analyses performed for your site

| Hospital | | ≥ 96 | 85 - 95 | 88 - 92 | < 85 |
|--------------------------|------|------|---------|---------|------|
| John Hunter | n=9 | 11 | 70 | 51 | 19 |
| RWH, Melb | n=20 | 22 | 63 | 41 | 15 |
| Westmead | n=16 | 16 | 62 | 42 | 22 |
| Flinders | n=7 | 15 | 60 | 48 | 25 |
| Canberra | n=2 | 11 | 59 | 39 | 31 |
| King Edward Memorial | n=22 | 21 | 57 | 36 | 21 |
| Royal North Shore | n=2 | 20 | 52 | 24 | 28 |
| Women's & Children's | n=2 | 31 | 50 | 31 | 20 |
| Mater Mother's | n=2 | 36 | 50 | 27 | 14 |
| Royal Brisbane & Women's | n=2 | 43 | 40 | 25 | 17 |
| Liverpool | n=0 | | | | |



As we head into autumn, here is another update on BOOST II. A BIG THANK YOU for recruiting. We are moving steadily to our target. Welcome to all the new centres who have recently started or are about to start the trial. It's great to have you on board! We now have **347 babies from 11 active Australian sites** with others preparing to join. Another **173 babies** are enrolled in NZ.

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Recruitment

AUS—347 ; NZ—173



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.

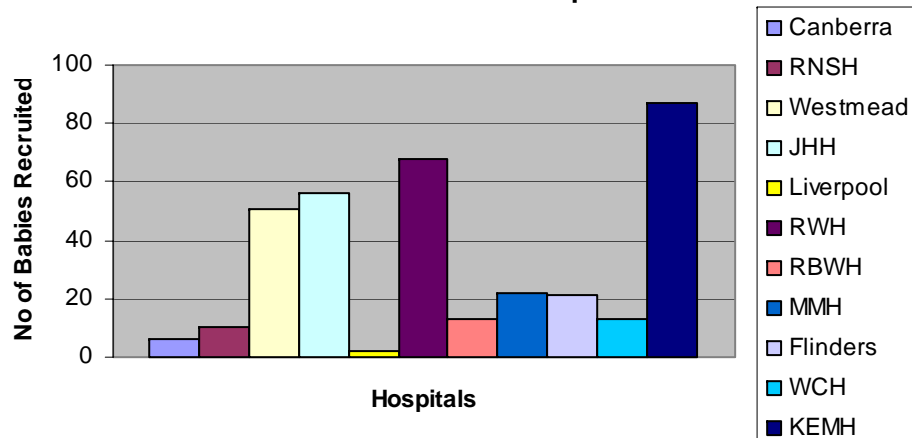
Approximate monthly recruitment targets are:

Large centres: 5+ infants; Medium centres: 3+ infants; Small centres: 1+ infant

Monthly Recruitment (as of 31st March 2008)

| | Site | Monthly Target | Actual Monthly Average | Jan | Feb | March | Total |
|-------|------------------------|----------------|------------------------|-----|-----|-------|-------|
| 61102 | Canberra | 1.0 | 0.7 | 0 | 0 | 2 | 6 |
| 61202 | RNSH | 2.0 | 1.3 | 1 | 3 | 1 | 10 |
| 61203 | Westmead | 4.0 | 2.0 | 1 | 3 | 1 | 51 |
| 61205 | JHH | 3.0 | 2.8 | 4 | 3 | 5 | 56 |
| 61213 | Liverpool Hospital | 4.0 | 2.0 | | | 2 | 2 |
| 61341 | RWH, Melb | 5.0 | 3.6 | 1 | 1 | 6 | 68 |
| 61401 | RBWH | 5.0 | 1.3 | 0 | 0 | 0 | 13 |
| 61436 | MMH | 4.0 | 2.8 | 7 | 0 | 5 | 22 |
| 61504 | Flinders | 2.0 | 1.2 | 1 | 3 | 3 | 21 |
| 61515 | Women's and Children's | 4.0 | 1.6 | 2 | 1 | 0 | 11 |
| 61615 | KEMH | 6.0 | 3.8 | 4 | 4 | 3 | 87 |
| | TOTAL | | | 21 | 18 | 28 | 347 |

Cumulative Recruitment per Site



Economic Evaluation

What is Economic Evaluation

Economic evaluation is the comparison of costs and benefits of two or more alternative therapies. It is increasingly used due to the problem of scarce health resources. Thus it has become very important to examine the relationship between the outcomes of a clinical trial and the costs of the medical therapy under study.

Medicare Consent Form

We have introduced a separate consent form which asks for permission to access PBS and Medicare data from Medicare Australia for the economic evaluation. Please note that this additional consent is designed to be obtained AFTER the child has been enrolled onto BOOSTII. It can be sought at an appropriate time before or after discharge, not necessarily at the time of trial entry. Please make sure that it has received ethics approval by your local hospital before you implement it.

Data Management

Upcoming first Two year follow-up

Our first two year follow-up is due in May. The two year questionnaire will be distributed to all the centres shortly.

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 adds to the cost of the study
- Reason for return of oximeters forms

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

