Boosting your knowledge ...

Issues of informed consent for intrapartum trials: a suggested consent pathway from the experience of the Release trial

Gillian Vernon1, Zarko Alfirevic2 and Andrew Weeks
Trials 2006, 7:13 doi:10.1186/1745-6215-7-13
Cochrane Database of Systematic Reviews

Service users within the NHS are increasingly being asked to participate in clinical research. In Liverpool Women's NHS Foundation Trust, approximately 35% of women take part in research during their pregnancy. For many studies the consent process is simple; information is provided and signed consent is given. There is a difficulty, however, with obtaining informed consent from women in pregnancy who become eligible only when they develop unforeseen complications, especially when they occur acutely. The problem is compounded with women in labour who may be frightened, vulnerable, in pain, under the effect of opiate analgesia, or all of the above. If research to improve the care of these women is to continue, then special consent procedures are needed. These procedures must ensure that the woman's autonomy is protected whilst recognising that women under these circumstances vary enormously, both in their desire for information and their ability to comprehend it. This paper will discuss the obtaining of consent in this situation, and describe an information and consent pathway for intrapartum research which has been developed in collaboration with consumer groups as a way in which these issues can be tackled.

Source Documentation Verification

What is Source Data Verification (SDV)?
Monitoring includes a review and comparison of a sample of patient data recorded in the case record against source documents

What are Source Documents?
All information in original records, certified copies of original records of clinical findings, observations, or other activities necessary for the reconstruction and evaluation of the trial
Reference ICH GCP section 1.51

QUESTIONS, FEEDBACK, IDEAS, SUGGESTIONS
CONTACT US AT: Phone: 02-9562 5000
Fax: 02-9565 1863
Email: boost2@ctc.usyd.edu.au
Alpana Ghadge; Ilka Kolodziej
Principal Investigator:
Prof. William Tarnow-Mordi

Welcome and Good Luck... to Kenneth Tan and his team at Monash, Melb. on joining BOOSTII

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.

Oxygen trials recruitment tally around the world...

* *figures correct as of the latest update from each study.*

Study	Start Date	Target	Actual*
BOOSTII - AUS	Mar'06	1200	747
BOOSTNZ	Sept'07	320	318
BOOSTIIUK	Oct'07	1200	411
SUPPORT - USA	Feb'05	1320	1317
COT - Canada	Jan'07	1200	684

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

I will not say I failed 1000 times, I will say that I discovered 1000 ways that can cause failure.
Thomas Alva Edison

BOOSTII
BENEFITS OF OXYGEN SATURATION TARGETING

Sept 2009
Australian
Update 7.0
Spring Issue

NHMRC Clinical Trials Centre

Update on Oximeter Software Upgrade

Thank you all for your hard work on BOOSTII. We thank all the centres for the fantastic recruitment. Some centres have already entered the follow-up phase of the trial which brings new challenges. The past 6 months have been busy for the BOOSTII team with the co-ordination of software upgrades on all BOOSTII Masimo oximeters. These software upgrades have been nearly completed with the exception of a few remaining monitors which are still attached to babies. Thank you for your co-operation.

Targeting - how is your centre doing?

Percent of displayed SpO_2 values in various ranges

Restricted to times where the baby is breathing supplementary O_2. Data from the first 500 babies in the study. More analysis in progress...

Hospital	>= 96	85 - 95	88 - 92	< 85
Royal Hobart	16.50	62.35	43.67	21.15
Liverpool	18.90	61.67	42.69	19.43
Women's & Children's	17.76	61.53	39.58	20.71
Royal North Shore	15.22	60.00	36.15	24.78
Mater Mothers, Brisbane	24.68	56.09	35.72	19.23
King Edward Memorial	23.64	54.53	34.37	21.83
Flinders Medical Centre	21.09	53.88	34.03	25.03
Royal Womens, Melbourne	24.06	53.52	32.38	24.06
John Hunter	18.33	53.44	34.64	28.23
Westmead	19.09	52.55	34.33	28.36
Canberra	20.75	49.55	25.88	29.70
Royal Brisbane and Womens	19.22	48.01	28.07	32.77
Royal Prince Alfred				

Welcome to yet another update of the BOOSTII Trial. There are a number of significant events and achievements to report on since our previous posting.
Congratulations and Well done to all! We now have **757 babies from 13 active Australian sites**. Another **318** babies have been enrolled in NZ.

Table of Contents

Recruitment

AUS—757 ; NZ—318

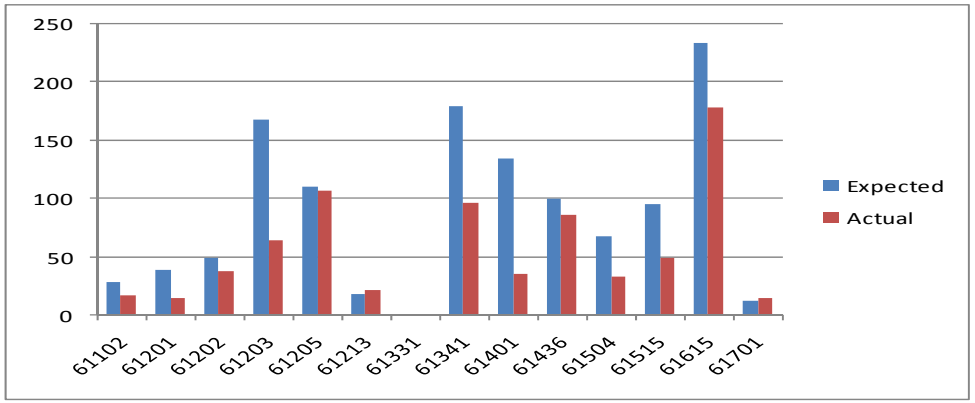
Our current overall target is 40 babies per month!

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 August 2009)*

	Site	Monthly Target	Actual Monthly Average	June	July	Aug	Total
61102	Canberra	1.0	**0.7**	0	0	0	17
61201	RPAH	3.0	**1.5**	2	0	0	15
61202	RNSH	2.0	**1.5**	1	2	2	38
61203	Westmead	4.0	**1.6**	0	1	0	64
61205	JHH	3.0	**2.9**	3	5	0	107
61213	Liverpool	1.0	**1.3**	0	0	2	22
61341	RWH, Melb	5.0	**2.7**	1	4	2	97
61401	RBWH	5.0	**1.3**	0	3	1	36
61436	MMH	4.0	**3.6**	2	2	1	86
61504	Flinders	2.0	**0.9**	1	1	2	33
61515	WCH	4.0	**2.1**	2	1	1	49
61615	KEMH	6.0	**4.4**	10	6	4	178
61701	Royal Hobart	1.0	**1.2**	4	1	1	15
			TOTAL	**26**	**26**	**16**	**757**



Recruitment tips

- Consider adding more Sub–investigators to your team to increase the number of people looking for and identifying potential BOOSTII babies.
- Consider inviting antenatal staff to BOOSTII in-services at your site.
- Liaise with antenatal clinics to ensure you are aware of all the potential pre-term babies less than 28 weeks.
- Publicise your study locally to increase awareness of BOOSTII

Endpoints: A reminder of the BOOSTII trial 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 arteriosis, 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!

SpO_2 charts

Please record the SpO2 charts regularly and accurately

- They provide immediate feedback and assist in achieving targets
- Commonest FiO_2 is vital information for compliance