Thank you to all the units which have produced data so far. This has been invaluable to us in piloting both the oxygen log and the download software. So why do we need you to complete a pre-trial audit?

The study will only work if units are able to target the oxygen saturation levels (SpO₂) of the babies who they recruit between 88% and 92% (while the baby is on supplemental oxygen). Everyone recognises how difficult this is.

The SUPPORT trial in America is more than halfway through their recruitment phase and find that they can achieve SpO₂:

- 88% to 92% for 40% of the time
- 85% to 94% for 70% of the time

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when the baby is on supplemental oxygen. When the data from BOOST-II UK is analysed it must be possible to demonstrate that recruiting centres adhered to the protocol for similar amounts of time while the babies were in oxygen. This will ensure that separation between the two trial groups is maintained.

Targeting will prove an enormous challenge for everyone, but those running the American study report that it gets easier with practice. With this and the results from the AVIOX audit in mind we thought it best for our potential BOOST centres to have “practice” before the study begins.

As SpO₂ can rise above 94% when babies are in air we need to know when a baby was in oxygen and when the baby was in air. We want to know when a baby was in oxygen for a period of more than 20 minutes at any time, but are not concerned what the percentage of oxygen was. The first oxygen log which we piloted was badly received by many centres so we have redesigned it. A copy of the new oxygen log is attached to this newsletter. The feedback from those who are using it is positive so far, but we would welcome your comments.

Data gathered with the new oxygen log can be analysed to give units a real sense of how well they can adhere to the protocol. Many have found this valuable as an insight into their own practice as well as in preparation for the BOOST-II UK study.

Thank you to everyone who has provided data - we are using this to help us refine the download software so that we can provide you with clearer feedback. Those who have not received feedback, thank you for your patience; we will be in touch very soon.

If your centre has data to download please contact your Regional Research Nurse or the Co-ordinating Centre to arrange a visit.

*Remember* there is no need to continue the audit if the baby comes off oxygen permanently

*Remember* the audit does not necessarily need to be carried out on a trial eligible baby

*Remember* you should aim to keep saturations below 95% for more than 90% of the time while the baby is receiving supplemental oxygen.

What do I need to do next?

In order for the study to take place at your centre a few more approvals need to be obtained. Both your trust and your local ethics committee must consider any local issues before they can give the study local approval. Michelle, the study co-ordinator will complete the paperwork and submit it on your behalf. The Principal Investigator (PI) at each site need only review these forms and sign an agreement stating that they are willing to run the study in accordance with the protocol. To help this process along Michelle will need a signed CV from the PI and the local nurse. If you haven’t already done so please send your CV’s to the FREEPOST address below.

The Pre-trial Audit

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Which sensors are being used for BOOST-II UK?

The sensors which have been recommended for the babies in the various international studies looking at oxygen saturation targeting are the LNOP Neo Pt-L sensors. These sensors are recommended for babies of under 1kg but also work perfectly well in babies of up to 3kg or more.

All Masimo sensors use identical light sources and photo-detectors. The only thing that differs between sensors is the distance between the source and the detector. The LNOP Neo Pt-L has a specially designed velcro strap which is ideal for preventing damage to the skin of a preterm baby.

What is SatSharing and how does it work?

A few units have found it difficult to manage their smallest and sickest babies on stand-alone Masimo monitors for various reasons. This is usually because they either need to electronically collect data through their multichannel monitors or because they want an alarm to be triggered at a central console because of staffing levels and unit design. These units have elected to use “SatShare cables” and we can provide two to any unit which feels that it needs them as long as we know which multichannel monitor is being used.

When they are used data are collected, stored and can be downloaded from the Masimo monitor in the usual way. The SatShare cable connects the Masimo monitor to the multichannel (host) monitor through the same port as the patient cable in most cases. When the host monitor receives data from the Masimo it behaves exactly as it would if it received data from a patient. It takes many samples of these data and, rather than simply reproducing them, displays the “average” saturation over the period set, usually two seconds. This means, however, that there is a delay of approximately twelve seconds between data being displayed on the Masimo and the same data being displayed on the host monitor. The fact that the monitor has reprocessed the data means that the host monitor may not display identical numbers, but there should be a very strong correlation between what is displayed on both monitors.

As this delay and the reprocessing of the data is clinically insignificant, and having two saturation levels displayed at once is confusing, it is strongly advised that the number display is switched off on the Masimo monitor. This will not affect what the monitor stores or what is downloaded for the study in any way. It is possible to switch off the number display but continue to display the pleth wave on the Masimo, which is often helpful in assessing a clinical situation. The pleth wave seen on the host monitor is artefact and cannot be taken as an indication that the signal is good from the patient.

The BOOST nursing team and Jane Lovell, the Masimo Clinical Specialist, are available to give advice on any aspect of SatSharing, so please contact your Regional Research Nurse or the Co-ordinating Centre at any time.

International trial update

The SUPPORT trial which opened to recruitment in America in April 2005 is now half way to its target of recruiting 1,320 babies, and the New Zealand BOOST trial which opened to recruitment in October 2006 looks set to reach its target of 320 babies two years from now. The Australian BOOST trial which aims, like us, to recruit 1,200 babies got off to a slow start but will soon be recruiting in at least 15 centres while COT, a trial of similar size funded by Canada, which is also planning to recruit in a few large centres in Argentina and Europe, hopes to be recruiting everywhere within a few months.
Which units will be taking parting in BOOST-II UK?

Addenbrooke’s Hospital, Cambridge
Birmingham Heartlands Hospital
Birmingham Women’s Hospital
Bradford Royal Infirmary
City Hospital Birmingham
Derriford Hospital, Plymouth
Erinville Hospital, Cork
Forth Park Hospital, Kirkcaldy
Hope Hospital, Manchester
James Cook University Hospital, Middlesbrough
John Radcliffe Hospital, Oxford
Leeds General Infirmary
Liverpool Women’s Hospital
National Maternity Hospital, Dublin
New Cross Hospital, Wolverhampton
Ninewells Hospital & Medical School, Dundee
Nottingham City Hospital
Nottingham University Hospital, QMC
Princess Anne Hospital, Southampton
Royal Gwent Hospital, Newport
Royal Infirmary of Edinburgh - Little France
Royal Maternity Hospital, Belfast
Royal Shrewsbury Hospital
Royal Victoria Infirmary, Newcastle
Russells Hall Hospital, Dudley
Singleton Hospital, Swansea
Southmead Hospital, Bristol
St James’s University Hospital, Leeds
St Michael’s Hospital, Bristol
Stirling Royal Hospital
Sunderland Royal Hospital
The Jessop Wing, Sheffield
University Hospital of North Tees, Stockton-on-tees
University Hospital of Wales, Cardiff
University Hospitals Coventry & Warwickshire
Wishaw General Hospital

The Great Wall of Masimo
The offset monitors which will be used in the trial have been delivered and are ready to be shipped out to all of the units once R&D approval and LREC have been granted!!

Consent Workshops
We will be organising consent workshops for those involved with recruiting babies to BOOST. These will take place closer to the time that recruitment is due to begin at your centre. We will keep you updated about dates arranged for your region.
Who are we?

Co-ordinating Centre

Peter Brocklehurst
Chief Investigator

Breidge Boyle
Senior Research Nurse

Michelle Gabriel
Study Co-ordinator

Andy King
Programmer

Regional Research Nurses

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