



NHMRC CLINICAL TRIALS CENTRE



The University of Sydney
AUSTRALIA

BOOST II
BENEFITS OF OXYGEN SATURATION TARGETING

To All BOOST II Investigators and ANZNN Directors

April 2011

Dear Colleague

N Engl J Med, 28 April 2011: Publication of interim findings in the BOOST II and SUPPORT Trials

As you know, recruitment to the Australian and UK BOOST II trials closed early on December 25th 2010 after the Data Monitoring Committees revealed the results of a combined analysis of survival to 36 weeks to the Trial Management Committees. This showed higher survival in infants on the high target using a new calibration algorithm, installed in Australian and UK study oximeters in 2009.

The Data Monitoring Committees asked for these interim data to be published quickly. A Letter was accepted by the New England Journal on 22 March, 2011. A copy will be sent to you on 28th April.

The DMCs requested early publication to explain to all who care for extremely preterm infant why both trials closed to recruitment early. **The Trial Management Committees consider it prudent not to target an SpO₂ of 85 to 89% in infants born earlier than 28 weeks of gestation when treated with oxygen, pending full results on the primary outcome of disability-free survival at two years, which are expected by 2014.**

What does this mean in practice? The data are insufficient to recommend a specific target range at present. Some TMC members continue to target 88 – 92%, while others target 91-95%, or a similar range.

No media release is planned, as the Letter's intended audience is professionals. However, professionals may be contacted by the media. To assist with media enquiries a Factsheet and Study Update for Parents approved by the University of Sydney Central Ethics Committee will go on the website on 27 or 28 April at http://www.ctc.usyd.edu.au/trials/other_trials/boost.htm, and copies are attached.

Please email a copy of this letter and attachments to the Chair of your ethics committee for information.

Parents seeking more information will be encouraged to contact a specialist who cared for their baby. If the baby was in BOOST II, please thank them for supporting a study likely to improve the outlook for preterm babies worldwide. For those whose babies experienced an adverse outcome, it may help to explain that we will never be able to work out exactly why an individual baby had a particular outcome, and that the difference in oxygen targets only explains part of the risks. The attached Study Update may also be of help.

An update on the trial for parents will be included in the next parent newsletter to be distributed via local hospitals in due course, after endorsement by local ethics committees.

If you would like, any further information or to discuss any aspects in more detail, please do not hesitate to contact Dr Alpana Ghadge at 02 9562 5341 or alpana.ghadge@ctc.usyd.edu.au in the first instance.

Thank you for all your support for this important study, whose final results will provide the most important evidence in the management of oxygen targeting in preterm infants for more than five decades.

Yours sincerely

William Tarnow-Mordi
on behalf of the BOOST II Trial Management Committee