BOOST II Questions and Answers for Parents - 10 February 2016

Improved survival at two years with a higher oxygen saturation target

Background:

- Air contains 21% oxygen.
- When we breathe air, this oxygen enters our bloodstream through our lungs.
- Most of the oxygen in our blood is carried by a molecule in the red blood cells called haemoglobin.
- When a healthy person breathes air (21% oxygen) the haemoglobin in their arteries carries between 95 - 100 % of its maximum possible volume of oxygen.

  i.e. the arterial haemoglobin is 95-100% saturated with oxygen.
- If the lungs aren't working well, the oxygen saturation in arterial blood falls below 90%.
- To compensate, patients with sick lungs are given a higher concentration of oxygen to breathe, between 22 - 100%.
- Doctors wrap a probe around the wrist or ankle of a baby which shines a bright light through the artery. This probe is attached to a machine called a pulse oximeter. The pulse oximeter measures the saturation of the haemoglobin in the arterial blood.
- The higher the concentration of oxygen the baby is given to breathe, the higher the arterial oxygen saturation will be.
- However, if babies are given too much oxygen to breathe for prolonged periods, their oxygen saturation will be close to 100% for long periods, which is associated with the risk of eye damage (retinopathy).
- In 2005, when these studies were set up, neonatal paediatricians aimed to give enough oxygen to babies to breathe to keep their haemoglobin saturation between 85-95%.
- We planned to compare the outcomes for babies allocated to a target oxygen saturation of 85-89% with the outcomes of babies allocated a target oxygen saturation of 91-95%.
- We reported the results of the hospital outcomes of over 2400 babies from Australia, NZ and the UK in the New England Journal of Medicine in 2013, and this showed increased survival for babies allocated to the higher target range.
- Now, results at two years in over 2000 babies in the Australian and UK trials confirm that babies allocated the higher target range had higher survival. Details are given below.

1. **What was the aim of the BOOST II and other oxygen targeting studies?**

Five oxygen targeting studies in babies born before 28 weeks gestation were begun in the US, Australia, New Zealand, UK and Canada in 2005-7. All five trials aimed to find out if targeting the higher (91-95%) or lower (85-89%) part of the accepted range was better long term. The BOOST II studies were undertaken in Australia, New Zealand and the UK.

2. **What did we know about how much oxygen preterm babies need?**

It was known that too much or too little oxygen for long periods might harm these babies' eyes, lungs and brain, in or out of the studies. However, it was not known if 91-95% was too much or 85-89% was too little or if aiming for the higher or lower target would increase or decrease survival.

3. **What are the latest results in the BOOST II trials?**

Just over 2,000 infants were recruited in the Australia and UK BOOST II studies. In the combined analysis, the death rate for very premature babies under 28 weeks gestation who were allocated to the lower target range was 21.2% compared with a death rate of 17.7% in those allocated the higher oxygen saturation target range. The difference is 3.5%, which means that for every 28 babies targeting the higher range there would be one extra survivor.

The rate of death or disability for babies allocated to the lower target range was 48.1% and for those allocated the higher target range it was 43.1%. The difference is 5% which means that for every 20 babies targeting the higher range there would be on extra survivor without disability.

4. **What do these results mean for babies in the future?**

Now, thanks to the many parents who took part, many more babies will survive. Without these results, we still would not know if the higher or lower part of the normal saturation range was safer.

5. **Can these results explain why my baby died or had a bad outcome?**

No. Of every 28 babies allocated the higher rather than lower target, there was only one extra survivor. So the difference in oxygen saturation only explains part of the risks these tiny babies have.

6. **If my baby died or had a bad outcome, was I wrong to join the study?**

No. Babies outside the study were at least as likely to have a bad outcome as those who took part. By joining the study, you have helped improve the outlook for other parents and babies.

7. **One of my twins or triplets died and the other survived. Was I wrong to join the study?**

No. Each twin or triplet had an equal chance of being allocated the high or low target.

8. **Can I talk to other parents who were in the study?**
   Yes. If you would like to get in touch with other parents whose babies were in BOOST II, please contact Miracle Babies Foundation via their Facebook page.
9. **Can I talk to a specialist who cared for my baby?**
   Yes. Please contact Dr Alpana Ghadge at 02 9562 5341 or 9562 5000 or alpana.ghadge@ctc.usyd.edu.au who can put you in touch with a specialist at the hospital where your baby was looked after.