

### Updates

**Time of consent**— We have noticed a number of discrepancies between the time of consent on the consent form and the time of randomisation. In some cases where consent was taken very soon before randomisation the time of consent has been “rounded up” which can make it look as though consent was taken after randomisation,. E.g. Consent taken 10.54 and baby randomised 10.57 but time on consent form rounded up to 11.00. Please be as accurate as possible when recording the time of consent. This should always be completed at the time the form was signed by the parent and the researcher, not added retrospectively.

**Amendments**— Protocol V4.0 has now received REC & HTA approval and we have begun to receive trust approvals for the amendment. As the deadline for trust acknowledgement has now lapsed we will be sending V4.0 to all sites this week; please supersede V3.0.

**Microbiology**—As per Issue 6 we really need as many PICC tips to be cultured and positive cultures (PICC, blood or CSF) to be e-tested as possible. We are emailing laboratories where the e-testing rate is low but we know many sites have taken additional steps to improve their culture and testing rates so thank you for your hard work.

**Christmas Cover**—The CTRC will close 23/12/2016 and reopen on 04/01/2016. Each year one day of office cover is provided for urgent safety queries—this year I will be providing the cover so may also be able to respond to non-urgent PREVAIL emails depending on the workload from other trials. I will be available via email, telephone and fax on 29th December 2016.

## Star Site: Queen's Medical Centre



*Research Officer Helen Navarra (3rd from left) and the neonatal & research team at Queen's Medical Centre*

**QMC saw a huge surge in recruitment over October and November and their weekly recruitment rate increased by 13%, the biggest change of any site since the last newsletter.**

**Well done QMC!**

### Data Management Issues

**Data Protection**—a gentle reminder to please be vigilant against potential data protection breaches as we have had a few incidents lately. The most common problems are sending consent forms back in the same envelope as CRFs and sending consent forms via unsecure email. As the trial email is not on an NHS server it is not automatically encrypted. Fax remains the preferred method for returning consent forms but if you wish to return via secure email and have not done so for PREVAIL before please get in touch with us first so we can check that the system works.

**Eligibility Form 1**—V2.0 now asks you to confirm that eligibility decisions were undertaken under wider supervision of a medical practitioner. We believe there is always medical oversight of neonatal care but if the answer to this question is ever ‘no’ this baby should not be randomised. This is because it is a requirement of GCP that eligibility be **confirmed** by a physician, but does **not** mean that nurses cannot complete Form 1 or **assess** eligibility for PREVAIL—they still can.

## Recruitment Progress

Site	Opening Date	Recruitment to 28/11/2016	Recruitment rate per week
Bradford Royal Infirmary	10/08/2015	88	1.32
Leicester Royal Infirmary	11/08/2015	85	1.27
The Jessop Wing	01/09/2015	52	0.81
Birmingham Women's Hospital	07/09/2015	63	1.00
Nottingham City Hospital	07/09/2015	30	0.48
Queen's Medical Centre	08/09/2015	38	0.60
The Royal London Hospital	18/09/2015	45	0.73
Royal Oldham Hospital	23/09/2015	45	0.74
Homerton Hospital	02/10/2015	56	0.94
Liverpool Women's Hospital	12/10/2015	56	0.97
Queen's Hospital, Romford	10/11/2015	23	0.43
Royal Preston Hospital	11/11/2015	40	0.74
St Michael's Hospital	01/12/2015	24	0.47
Royal Bolton Hospital	03/12/2015	37	0.73
Leeds General Infirmary	04/12/2015	34	0.67
Newham University Hospital	04/01/2016	8	Closed as of 04/11/2016
St Mary's Hospital, Manchester	20/01/2016	56	1.27
John Radcliffe Hospital, Oxford	08/02/2016	38	0.92
<b>Totals</b>	<b>Sites: 18</b>	<b>Recruitment: 818</b>	<b>Average: 0.79</b>

The weekly recruitment rates are a good way of viewing your successes, and a rate of 0.6 babies per week would see you comfortably reaching the target of 30 per year. Several sites have achieved this milestone early and 3 have even doubled it which is phenomenal– well done! We are currently recruiting over 4 months ahead of target which is a brilliant achievement, so thank you. Please keep up all the hard work and if there is anything affecting your recruitment rate that you would like support with do not hesitate to let us know.

## Closure to Recruitment

As many of you have worked out we are incredibly close to reaching our planned recruitment target of 858 babies, well before the planned end of recruitment date of 31/05/2017.

**We can now announce that we will not be continuing recruitment once the planned target is met. We expect to hit target in mid-late December 2016.**

### *Why are we closing early?*

Discussions were held with the Trial Oversight Committees about the possibility of continuing until the planned closure date but the IDSMC, who are the only committee to have seen the Interim Analysis, did not feel it was necessary to increase our sample size. Based on their recommendations we are therefore planning to close once the sample size target has been met.

### *How will the close of recruitment be managed?*

We will not be closing the randomisation system as soon as the 858th baby is randomised because that does not allow for parents who have been approached (and potentially consented) to have their child entered into the study which the TSC did not think was appropriate. I will be contacting sites once we are closer to target to find out how many parents you have approached and consented and will ask you at this point to stop approaching parents for the trial. Those who have already been approached by this point will therefore still have the opportunity for their baby to participate if they wish.

I will be monitoring randomisations based on these numbers and will close each site individually once there are no further babies to be randomised who were approached prior to you being asked to stop approaching. Once closed to recruitment you will no longer have access to the randomisation system and we will ask for the back-up randomisation envelopes to be returned as a priority, but there will be more information about this at the time.

### *What next?*

Follow-up will of course carry on as usual for a maximum of 6 months after the last randomisation, so you can still expect to receive plenty of my newsletters which I know you all love..! Although it feels a bit sad to be closing early it is a fantastic achievement to have recruited so well and this is due to the hard work and energy site teams have put into the study. It's been fantastic to see the level of engagement and excitement about the study from sites and you should all be proud to have recruited so well.

**Thank you.**



***This will be the last newsletter of 2016 so all that remains is to wish you a very Merry Christmas & a Happy New Year from the PREVAIL team!***