

COPE



1ST CLASS DELIVERY

Newsletter Issue 4, October 2021

@CopeTrial

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SITE OPENING & RECRUITMENT

Site Name	Date Opened	Randomisations
Sunderland Royal Hospital	09/12/2020	120
Poole Hospital	18/12/2020	18
Queen Elizabeth Hospital, Gateshead	22/01/2021	55
Medway Maritime Hospital	12/02/2021	35
Liverpool Women's Hospital	14/05/2021	20
University Hospital of North Tees	14/05/2021	14
Burnley General Hospital	09/07/2021	14
King's College Hospital	21/07/2021	3
Princess Royal University Hospital	25/08/2021	2

9
SITES OPEN

281
RECRUITED
WOMEN

10
MONTHS
RECRUITING



NOTICES



New insulated shipping containers for kit deliveries
COPE team to be notified of all excursions outside of 2-8 °C



Approx. 2-3 weeks notice required for kit re-supplies
Site pharmacies to please let us know when CS or vaginal kit supplies reach min. of approx. 5 kits



6 Substantial Amendments to date
Current approved protocol: v5.0 dated 14/04/2021



How to COPE Drop in sessions
16:00 Every Wednesday
All sites welcome



NEWS FROM EGLE, COPE DATA MANAGER

Useful tips to help reduce the amount of data queries sent to your site:

- | | |
|--------|---|
| Form 1 | Ensure that just <u>one</u> individual completes the 'confirmation of eligibility' sign off and that they are delegated this duty on the delegation log |
| Form 3 | "Total number of pregnancies over 24 weeks duration including this birth"
Please include the pregnancy for this birth for which COPE treatment was given |
| Form 4 | <ul style="list-style-type: none">• Ensure IV injection is given over at least 2 mins• 'Was the placenta removed manually?' Please do not complete this question for women recruited following C-section |
| Form 6 | Please ensure N/A is ticked for all 'organ dysfunctions' if not applicable |



SITES UPDATE



Burnley General Hospital



Medway Maritime Hospital

Special thank you to Medway Maritime & Burnley General for their hard work setting up their COPE promotional days & sharing their pictures with us.

WELCOME

Well done to our newest sites who opened during the Summer & have hit the ground running with recruitment.

- Liverpool Women's Hospital
- University Hospital of North Tees
- Burnley General Hospital
- King's College Hospital
- Princess Royal University Hospital

LIVERPOOL WOMEN'S HOSPITAL

We're especially very happy to have **our lead site**, where COPE began, open and recruiting. Thank you to all of your support in setting up the study as a whole and in Liverpool.



Thank you so much to all COPE sites, whether recruiting/ in set-up. We really appreciate your continued hard work despite all of the challenges faced, and we look forward to continuing to work with you all.

NEWS FROM BETH & KERRY, COPE EMBEDDED STUDY RESEARCHERS



So far, feedback about recruitment & use of research without prior consent (RWPC) has been extremely positive, with 95.7% of parents who have completed a questionnaire 'Agreeing' or 'Neither agreeing nor disagreeing' that they are satisfied with the consent processes for COPE
– Beth/Kerry

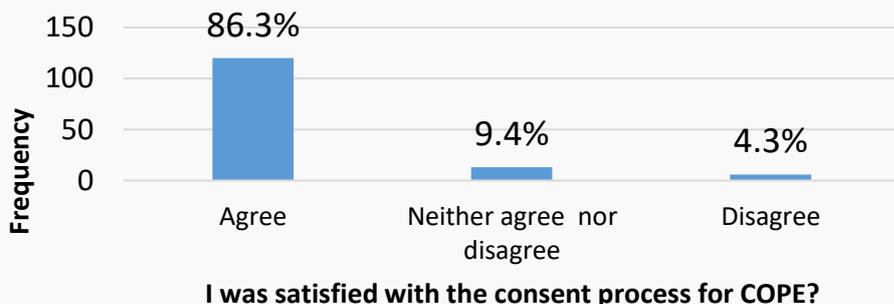
Staff who were initially unsure about the consent process have found that in practice RWPC in COPE worked well because:

- You would not normally receive formal consent for PPH drugs
- The medications aren't new
- Active treatment is being provided
- The women find it acceptable



REMINDER

People that choose to not to take part in COPE should also be asked to fill in an embedded study questionnaire/ if they would be interested in taking part in an interview – it is important that we receive decliners views.



SITE STAFF INTERVIEWS

We are holding telephone/ zoom interviews with site staff to explore their views on how COPE is going at your site. In particular, we would like to talk to staff at **Liverpool Women's, Medway, North tees & Burnley** sites. Interviews last about 45 mins and topics include:

- acceptability of the trial
- experience of recruitment and the approach to consent
- experience of giving the intervention
- potential barriers to recruitment and any potential solutions
- how information about the trial is communicated to women
- how women respond to trial information & any suggested improvements to trial information and consent processes.

If you would be interested in taking part in an interview please email Beth using the details below:

If you have any questions or comments about the embedded study please use the following contacts:



07392 285017



bdeja1@liverpool.ac.uk

CONSENT TOP TIPS

Due to the need to approach women when they are tired post labour the following have been commonly suggested by site staff and parents:

- Ensure that COPE posters are visible throughout wards/ clinics/ patient facing areas/ apps to increase general awareness of the study.
- Approach women when they are not alone so that their partners can help look after the baby / repeat back any information that they have had trouble taking in.
- Allow for a clinical debrief to happen first so that they are aware that they have had a PPH before they are approached by the research team.