Neonatal Pulmonary Hypertension Core Outcome Set (NeoPH COS)

Parent/Guardian Information Sheet

We would like to invite you to take part in our research study

You are being invited to participate in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives, and child's medical team if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

- We are conducting a study to look at the outcomes in babies with pulmonary hypertension. Pulmonary hypertension occurs when the pressure in the vessels in the lung is abnormally high.
- We would like to invite you to take part in one interview to see what you think are important outcomes in babies and children who were looked after in a neonatal unit for pulmonary hypertension. An outcome is a measure of a response to a particular treatment or intervention for a disease. For example, for babies with pulmonary hypertension this could be a blood test result or the reduction in need for support with their breathing.
- This will help to create a 'core outcome set', a list of outcomes that have been agreed to be the most important when studying babies with pulmonary hypertension.

How to contact us

If you have any questions and/or would like to take part in a focus group or interview, please contact:
Dr Cara Morgan **Or** investigator Dr Kerry Woolfall either by

- **Telephone:** 0151 702 4346 or
- **Email:** info@rephyneregistry.com

Why are we doing this study?

We are interested in studying why some newborn babies have high pressure in the blood vessels that supply the lungs. Having high pressure in your lungs is called pulmonary (= lung) hypertension (= high pressure). Pulmonary hypertension (sometimes also called persistent pulmonary hypertension of the newborn, PPHN) is usually diagnosed by an ultrasound scan of the heart performed at the cot side called an echocardiogram.

About one in every 500 babies develop pulmonary hypertension and it can happen for lots of different reasons. The lung blood vessels can be underdeveloped or fail to open properly after birth because of complications during pregnancy and labour, infections, and lung malformations. It is also common in babies born prematurely, especially those who need extra support with their breathing for a long time. Unfortunately, pulmonary hypertension is a serious condition, and some babies may have long-term problems with their breathing or circulation. There are very few treatments approved for the treatment of pulmonary hypertension in newborns and more research needs to be done to find medicines that can be used to treat these babies.

To decide if a new treatment is safe and effective, researchers need to be able to decide whether treatment with the new medicine is better than with the current medicine. This is done by comparing 'outcomes' of babies treated with and without the new medicine. An outcome can be something in the short term (before discharge home from the neonatal unit) such as how long a baby needs help with their breathing, or in the long-term (after they have been discharged home) such as how many times they are re-admitted into hospital. Researchers need to know which short- and long-term outcomes are the most important to study.

What is a core outcome set?

A core outcome set is a list of outcomes that parents/guardians and professionals have decided are the most important for researchers to study in future clinical trials. The view of parents/guardians with experience of babies with pulmonary hypertension is essential to make sure we are studying the right outcomes that matter most to them. They are developed using an established process (a series of steps) to reach agreement between various members of the panel. Core outcome sets have been developed for several conditions, but not yet for babies with pulmonary hypertension.

Who can take part?

Parents/guardians with experience of a newborn baby diagnosed with pulmonary hypertension, including those in whom pulmonary hypertension has resolved. We advise that parents/guardians of babies who are currently critically unwell do not participate in this study due to the potential unintended distress that may be caused surrounding discussion of their care.

How can I take part and what is involved?

If you would like to take part in an interview, please contact the study by email or telephone (contact details are on the first page). If two parents/guardians in the same family wish to take part then the interviews will be conducted separately, one at a time. The interview will be conducted online using vide-teleconference software or over the telephone and will last about 45 minutes.

Before the interview, we will send you an information sheet (like this one) about the outcomes that have been identified in a review of literature. During the interview, a member of the NeoPH-COS study team will ask you what you think about the outcomes, what improvements you think we could make and any additional outcomes we should include. We would also like your views on what you think are most important outcomes as a parent/guardian with a baby with pulmonary hypertension. With your permission we would like to record the interviews (to be able to analyse them in more detail) but all names and identifying information will be removed. Interviews will be digitally recorded and then written down by the researcher or a transcription service. After the interview, all participants will be sent a debrief letter a £25 gift voucher to thank you for your time.

Taking part is completely optional and you can change your mind about being part of the study at any time by contacting the study team.

Following the interview, we will ask you to register interest in taking part in the next study phase, which involves an online survey. The survey will form part of the decision-making process to help decide on the final core outcome set for babies with pulmonary hypertension. Taking part in this is completely optional and we will provide further information sheet such as this one on what is involved.

If you have any questions before deciding to take part, please do not hesitate to contact us.

Who is involved in this study?

Dr Kerry Woolfall (Reader in Health Research Methodology, University of Liverpool) is the NeoPH COS Principal Investigator. Dr Nim Subhedar (Consultant Neonatologist at Liverpool Women's Hospital and University of Liverpool) and Dr Cara Morgan (Neonatal Research Fellow at Liverpool Women's Hospital and University of Liverpool) are co-investigators and leading on the development of the core outcome set. The NeoPH COS study team are qualified to do this study because they have all the specialties and skills needed. Members of team have a lot of experience in caring for babies and children with pulmonary hypertension and are very active in health research. The study is being funded by a commercial partner, Beyond Air.

Are there any risks in taking part?

This is a low-risk study. Most questions will be about proposed core outcomes in neonatal pulmonary hypertension. However, at the beginning of the interview we will be inviting you to discuss your child's experiences, such as when was your child's condition was first diagnosed. We acknowledge that your child may have been very sick and so such personal questions about your child's experience may be upsetting. If you would rather not answer such questions, or specific topics surrounding your child's care please let the interviewer know. You can decide not to answer a question at any time. The interview can also be paused or stopped at any time you wish. Details of additional support such as recommended paediatric and neonatal support groups for parents are provided on the last page of this information sheet. Following the interview, you will be offered a follow-up call to should you wish to discuss any topics that may have caused distress. If this is the case you will also be offered an optional debrief session with the research team to talk through your experience of the interview.

Are there any benefits in taking part?

There a no intended benefits to participation in the NeoPH COS study to the participant.

What will happen to the results of the study?

The study results will be made available on the study website when the study is finished. We anticipate that the NeoPH COS methodology and results will be published in a peer reviewed journal. By contributing to the study, you will not be identifiable from the results of the study.

How will my data be used?

A summary on how your data will be used can be found in the table below.

How will my data be collected?	Digital recording of interviews.
How will my data be stored?	Password protected data files.
How long will my data be stored for?	10 years
What measures are in place to protect the security and confidentiality of my data?	Any identifiable information will be taken out of the interviews when transcribed and each participant will be assigned a number. Consent forms will be securely stored.
Will my data be anonymised?	All identifiable information will be removed, and a number assigned to each participant.
How will my data be used?	Findings will be written up for the funders Beyond Air. Publication will be sought with peer reviewed journals.
Who will have access to my data?	Delegated members of the study team only.
Will my data be archived for use in other research projects in the future?	No
How will my data be destroyed?	Shredded or deleted after 10 years

We will be using the information you provide us with during interviews to perform this study and we will act on behalf of the university as the data controller. This means that we are responsible for looking after your information and using it properly. The research team will keep anonymised information about you for 10 years after the study has finished.

The University processes personal data as part of its research and teaching activities in accordance with the lawful basis of “public task“ and in accordance with the University’s purpose of “advancing education, learning and research for the public benefit.” Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University’s research.

If you have any queries relating to the handling of your personal data, please contact us on the details provided at the end of this information sheet.

What will happen if I want to stop taking part in the study?

Participation in the study is voluntary and you are free to withdraw without explanation prior to the interview. Once the interview has been conducted you may withdraw from the study up until your data has been anonymised, which will approximately be a week after the interview. Following this your rights to access, change, or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate.

What if there is a problem?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting the **NeoPH COS research team** by email info@rephyneregistry.com or calling **0151 702 4346** and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Ethics and Integrity Office at ***ethics@liv.ac.uk***. When contacting the Research Ethics and Integrity Office, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make. The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling **0303 123 1113**.

For NHS service advice or support please contact: Patient Advice and Liaison Services (PALS) services. Go to ***www.nhs.uk*** to find your local PALS contact details.

There are also the recommended support group for parents of affected babies and children:
Bliss, for babies born premature or sick, www.bliss.org.uk
Pulmonary Hypertension Association UK, www.phauk.org
The Rainbow Trust, supporting families with a seriously ill child, www.rainbowtrust.org.uk

Who has reviewed the study?

The study has been reviewed by the University of Liverpool Research Ethics Committee (REC Ref. 13458) who have agreed that the study is being conducted in a correct and appropriate manner.

How to contact us if you have further questions

If you have any questions and/or would like to take part in an interview, please contact the NeoPH COS study team:
Telephone: 0151 702 4346
Email: info@rephyneregistry.com
Address: Liverpool Women's NHS Foundation Trust, Crown Street, Liverpool, L8 7SS

Further information can be found on our website: **rephyneregistry.com.**

Thank you for your time.
We are very grateful that you are considering taking part in this study.

RePHyNe Registry of Pulmonary Hypertension in Neonates
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