Guy's and St Thomas'
NHS Foundation Trust

Participant Information Sheet

Study title:

Prospective study to identify risk factors predictive of death, requiring Extracorporeal Membrane Oxygenation (ECMO) or cardiac disease in neonates referred to UK neonatal and paediatric transport services with respiratory failure

Chief Investigator: Jonathan Lillie

Summary: please read this first

- We know this leaflet may reach you at a very difficult time. You do not need to read it now, or do anything at all. Decisions resulting from the below information can be made at any time in the coming weeks.
- Your baby was moved between hospitals by a specialist transport team because of serious breathing problems. We would like to include information about babies like yours in a national research database.
- Your baby's care does not change. We only use information that is already recorded as part of normal care. There are no extra tests, visits or questionnaires.
- You do not need to do anything. Your baby's information will be included unless you tell us you do not want it to be.
- You can say no (opt out) at any time, without giving a reason, and it will not affect your baby's care. Tell any member of the team caring for your baby, use the online form at Choose if data from your health records is shared for research and planning - NHS or use the QR link below.
- This study is non-commercial and for NHS benefit only. Information is never shared with companies.

Research Background and Goal

Newborns with breathing problems often need to move to another hospital for more specialist care in a neonatal intensive care unit (NICU). A small number of these babies do not respond to this care and may need further transfer so they can receive a higher level of care, including **ECMO**. **ECMO** stands for **E**xtra**C**orporeal (out of the body) **M**embrane **O**xygenation and involves blood being taken out of the body and having oxygen added to it by a machine and then returning this blood to the patient. Results from an early study across London suggest a significant number of babies (27 out of 149) require a second transfer between intensive cares or become more unwell.

Our study aims to look at babies very early in their journey- when they are referred from the local hospital to the specialist neonatal transport team. By looking at key numbers and information on their treatment, we aim to identify if there are risk factors that suggest which babies are the most unwell, need ECMO or have an undiagnosed heart condition.

If we can find these risk factors, then in the future these could be used to decide at an earlier stage where these babies are best cared for (either an ECMO centre or a neonatal intensive care). We aim to make sure that the right babies are going to the right centre, improving outcomes and avoiding additional moves between hospitals.

What taking part involves

Babies will receive the normal care and all data used in the study is routinely collected already. After the baby is transported, the data about their clinical condition and the treatment that they received will be uploaded into a secure online database. The baby's NHS number will be used to link this data to data already collected in large databases looking at neonatal and paediatric intensive care across the UK: NHS spine, PICANet (audits paediatric intensive care)

and Badgernet (records care delivered by NICUs). This is important so that we can understand what happened to every baby.

Because this information is already collected as part of your baby's care, we do not ask parents for separate consent. We did not want to add to an overwhelming and stressful time. You can still say no at any time. This leaflet and the posters on the unit explain how.

Why would your child's information be helpful?

We are looking at information describing the way that newborns with respiratory illness become unwell and what their care journey is. If your child has needed to be moved between hospitals because of respiratory illness around the time of birth then looking at the routinely recorded care information may help other babies in the future.

Do you have to take part?

No. It is up to you to decide if your baby's data will be used. You can ask for your child's data to be deleted at any time and without giving a reason. Deciding not to take part in the database submission will not affect the healthcare that your child receives, or your legal rights.

Possible benefits of taking part.

There are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of babies in the future.

Further supporting information

How will we use information about you?

We will need to use information from your baby's medical records for this research project.

This information will include your baby's NHS number and details of their condition, treatment and recovery, taken from their medical records. We do not store your baby's name, address or date of birth in the study database.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

Only people who need to know who you are will be able to see your details. Your data will have a code number instead.

Guy's and St Thomas' NHS Foundation Trust is responsible for looking after your baby's information and is the data controller for this study. We use it because the research is a task in the public interest. Only the NHS number is stored with your baby's medical details, and the study team works with a code number instead. Information is kept on secure NHS systems in the UK and never shared with companies.

International transfers

Your data will not be shared outside the UK.

We will keep your study data for the minimum period required. The study data will be securely archived for 25 years and thereafter destroyed.

Your choices about how your information is used

- **You have the right to opt out from your data being used** (at this link Choose if data from your health records is shared for research and planning - NHS)

- You can stop being part of the study at any time, without giving a reason and ask us to remove your data from the REDCap data base and for the purposes of the study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At the QR code above
- by asking the study team (contact details below)
- at www.hra.nhs.uk/information-about-patients
- at www.guysandstthomas.nhs.uk/research/research-and-development/data-and-research
- by contacting the Guy's and St Thomas' Data Protection Officer at gstt.dpo@nhs.net

If you have a concern about any part of this study, you should ask to speak to the researchers who will do their best to answer your questions

If you remain unhappy and still want to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on phone: 020 7188 8801, email: gstt.pals-gstt@nhs.net. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

Who is organising the study?

This study has been organised by the Evelina Paediatric Intensive Care department and sponsored at Guy's and St Thomas' NHS Foundation Trust. The study is funded by the Evelina Paediatric Intensive Care department.

Who has reviewed the study?

This study has been reviewed by a Research Ethics Committee, the Confidentiality Advisory Group, GSTT Research & Development, and parents with experience of neonatal transfer.

Researcher contact details:

For further information please contact a member of the study team at the details below.

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