Improving Shared-Decision Making on the Neonatal Unit through Assessment of Parental Experiences: *The ShAPE Study*

Background

Having a baby who requires help on a neonatal unit is a stressful experience. One way to help to support families is to ensure there is open dialogue between clinicians and families. The *"Shared Decision Model"* has been highlighted by the British Association for Perinatal Medicine (BAPM) as being fundamental to how Neonatal Care is delivered.

What is ShAPE?

The ShAPE study aims to facilitate the development of an evidence-based information tool, which can be used by parents and clinicians as an aide when faced with clinical decisions on NICU. We want this tool to support parents with the Shared Decision Process, enabling parents to be more actively involved in the management of their infant on the neonatal unit.

To do this we want to investigate recent parental experience of clinical discussions surrounding three interventions;

1. ***Transfusion of Blood Products:*** *a transfusion of donated blood in order to correct anaemia (low red blood cell level) and improve oxygen supply to the body.*
2. ***Medications for Persistent Ductus Arteriosus (PDA):*** *a PDA is a blood vessel used to circulate blood around the body when the baby is still inside the womb. After birth this vessel is no longer needed and is programmed to close. In some babies the vessel remains open and diverts extra blood into the lungs. This can cause issues with breathing and blood supply to the rest of the body. Sometimes doctors use medicines (including; ibuprofen, indomethacin and paracetamol) to stimulate this vessel to close.*
3. ***Corticosteroid Therapy for Chronic Lung Disease****: Steroid medications that are given to babies who still require a ventilator or oxygen when they are over 1month of age or 36weeks corrected gestation*

Through hearing your experiences we hope to be able to gain a better understanding of factors which improve effective shared decision making and as such create a useful and informative information sharing tool, supporting future families with unwell infants.

How can I participate?

If you would like to participate in the project, we will first arrange a brief phone call to check that the study is suitable for you. There will be a consent form to sign, after which we will arrange a suitable time to conduct an interview. During this interview we will discuss your experiences of clinical discussions surrounding the three procedures stated above. **The interview will be conducted by the chief investigator, Dr Daniel Keen, over a virtual meeting platform. Once the study has been completed, we will complete a report—a copy of which will be sent to you.**

We appreciate having an infant who has required treatment on a neonatal unit is stressful and that recollecting these experiences may be distressing. If this is the case, we can re-schedule the interview to a different day and if necessary refer you to an appropriate agency if further support is needed. This may include your General Practitioner (GP) or a parent support charities such as Bliss.

Can I change my mind?

If at any stage during the process you feel you no longer wish to participate in the study, you are free to inform us without an explanation and withdraw. Any data collected will be deleted and will not be used in the analysis.

Your decision not to participate or withdraw from the study will not impact any future care received or interactions with healthcare professionals.

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Confidentiality

Interviews will be conducted over a virtual meeting platform and are strictly confidential. Information used for analysis and in the final written reports will be anonymised to protect confidentiality, such that it will not be possible to identify individual participants.

There are a few specific circumstances in which, by law, it would be necessary for the research team to breach the confidentially of the interview:

- Information is disclosed which raises safeguarding concerns around the parent or child
- Information is disclosed which raises concerns that clinicians have acted in an unprofessional or negligent manner

In the case that information needs to be shared with a third party, the researcher will inform you of the need to share information and only information pertinent to the concern raised will be shared.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, contact details and some information regarding your baby. We will use this information to undertake the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see you name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

This study will require the use of audio recordings taken during research interviews between the participant and the researcher. These audio recordings will be stored under password protection on the researchers computer. These files will be transcribed into an anonymised text format so that they can be analysed.

The audio recording of the interview will be transcribed into an anonymised written script with the assistance of commercially available transcription software. In order to facilitate transcription, the software stores the recording on an encrypted server within the United States and follows appropriate security and privacy policies, including GDPR principles. Further information can be found at https://otter.ai. If you would rather we did not use this software, you can opt out of its use and the research team will transcribe the audio recording manually.

Once we have finished the study, we will keep some of the data so we can check the results. Audio recordings will be stored securely for a maximum of 3years, before being deleted. When we finish the study, we will write our reports in a way that no-one can work out that you took part in 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 www.hra.nhs.uk/information-about-patients/
- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to ekhuft.dataprotectionofficer@nhs.net
- By ringing us on 01233 616204

Questions?

Feel free to contact us;

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