Parent priorities for outcomes in neonatal palliative and end-of-life care
A qualitative interview study with families to inform the development of a core outcome set
(the NeoPace Study)

UCL Research Ethics Committee Approval ID: 16059/012
UCL Data Protection Registration: Z6364106/2023/05/142
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Name of Co-Investigators: Professor Neil Marlow, Professor Myra Bluebond-Langner, Alex Mancini
Name of researcher: Dr Kathy Chant

Participant Information Sheet

Invitation paragraph
You have been invited to take part in a study. Before you decide whether to take part it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss with others if you wish to. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

Background
Death in the first 28 days of life, or 'neonatal death', represents the highest number of deaths in children under 5 in the UK. Each year 1,200 babies unfortunately die during this period, with most neonatal deaths happening on neonatal units, where babies receive treatment from specialist doctors and nurses. For many families, conversations will have taken place with their baby's healthcare team to decide whether to continue treatment, or whether to provide palliative, or end-of-life, care.

What constitutes good palliative and or end-of-life care, however, is unclear and professionals often provide different treatment to different families, reporting different outcomes in their research. This means we cannot compare whether one approach to neonatal end-of-life care is better than another. Creating a common, or 'core' set of outcomes from which to measure neonatal end-of-life care would allow us to develop measures of good practice and improve the care of families. These outcomes must reflect the needs of all families involved; this is particularly relevant for Black and Asian families whose infants are at higher risk of neonatal death, for reasons we do not yet fully understand. A core outcome set will identify care to be reported in all research exploring neonatal palliative and end-of-life care.

What does the study involve?
This is an observational study. That means that no interventions or treatments will take place. We would like to do a single 30-60 minute interview, conducted either over the phone or through video conferencing software (MSTeams). A researcher with previous experience of interviewing families will conduct the interviews. To ensure that we capture what you would like to tell us correctly, we will record the interview, with your consent. The physical recording will be deleted once we have downloaded the written transcript of the conversation. During the interview we will ask you about your personal experience with neonatal palliative, or end-of-life, care and what you think is important in the care of families facing similar situations.

Why have you been chosen?
We are asking you to consider taking part as a parent whose baby unfortunately died on the neonatal unit, whose baby died following discharge from neonatal care, or whose baby is living at home with specialist support from palliative care services.

Do you have to take part?
It is up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw at any time and without giving a reason. You may decline to answer any question you do not want to answer, or not answer an interview question by saying "pass". To take part, we ask you to consent to recording the interview and so it is worth considering whether you feel comfortable with this aspect of the study.

If you decide to take part, there will be a 'cooling off' period of 4 weeks following the interview, should you decide within this time that you no longer want to participate. In this time period, you will still be able to withdraw your data without having to give a reason. The recording will be pseudonymised for these 4 weeks and will then be deleted. Following this, we will be unable to remove your data and it will be included in the analysis.

You will not receive any direct benefit from being in this study, however information learned from this study may help other families whose baby requires palliative, or end-of-life, care in the future. There are no medical risks if you take part in this study.

What do I have to do?
If you are interested in taking part in the interview, we will ask you to contact one of our researchers; Dr Kathy Chant (neopace@ucl.ac.uk) to discuss further and find out whether you are eligible. If you would still like to take part, we will arrange a time for the interview which is convenient for you. You can decide whether you would like to do the interview on the telephone or over video chat. We will send you a link to an online consent form for you to complete before the interview. We will ask you if you are interested in being contacted about the next phase of the research; you can say no and still participate in the interview.

What if something goes wrong?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you have any complaints about the study, please contact the Chief Investigator at UCL:

Dr Katie Gallagher
EGA Institute for Women's Health
University College London
Medical School Building
London WC1E 6AU
Email: katie.gallagher@ucl.ac.uk Tel: 020 7679 2301

If you feel your complaint has not been dealt with to your satisfaction, you can contact the Chair of the UCL Research Ethics Committee (ethics@ucl.ac.uk)

How will we use information about you?

In this research study, alongside the interview, we will collect information about you and your baby including when (year) your baby was born, how many weeks pregnant you were when your baby was born (your baby's 'gestational age' at birth), when your baby died, where your baby died, or, if your baby is alive and receiving specialist support, how old your baby is and where they are receiving care. We will also ask your age, and your ethnicity, to ensure that we get a range of families from different backgrounds in our study. People will use this information to do the research or to check our 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 your name or contact details. Your data will have a code number instead. The fully anonymised interview data will be stored separately to your personal details in a secure research database at UCL.

We will keep all data about you safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it. We will write our reports in a way that no-one can work out that you took part in a study. You can stop being part of the study at any time, without giving a reason. If you withdraw from the study following the 4 week cooling off period, we will be unable to extract your data from the analysis and so this will be used in the study.

All information which is collected about you during the course of the research will be kept on a password protected database. All information will be confidentially archived by UCL for 10 years before it is destroyed in line with UCL data destruction policies. The data will not be shared with other researchers in future and will not be available in any repositories.

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 UCL website or https://www.ucl.ac.uk/legal-services/privacy or by sending an email to katie.gallagher@ucl.ac.uk or Sponsor Data Protection Officer data-protection@ucl.ac.uk

What will happen to the results of the research study?
The results will contribute to the development of a core outcome set for neonatal palliative care. Fully anonymised results will contribute towards publication in academic journals and conference presentations and will be shared on relevant social media pages (e.g University College London). We will ask you during consent if you would like to receive a copy of the results. If you would, we will contact you at the end of the study and share our findings.

Who has reviewed the study?
The study has been reviewed and approved by the UCL Research Ethics Committee (ID: 16059/012).

Local Data Protection Privacy Notice
The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk**.** This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in health and care research studies, click here or please see additional information from the researcher (available at: https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care- research-privacy-notice). The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:

- Infant: year of birth, gestational age at birth (i.e. how many weeks pregnant you were, when you gave birth), when and where your baby died, or, if your baby is alive and receiving specialist palliative care support, how old they are and where they are receiving care.
- Parent(s) / carer(s): age, ethnicity, gender, postcode, name, email address

The lawful basis that will be used to process your personal data are: 'Public task' for personal data and' Research purposes' for special category data. Your personal data will be processed so long as it is required for the research project. We will anonymise or pseudonymise the personal data you provide and will endeavour to minimise the processing of personal data wherever possible. Personal data will be stored separately to study data to ensure anonymity throughout this study.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

What do I do now?
If you are interested in taking part in the study, please email Dr Kathy Chant (neopace@ucl.ac.uk) a member of the research team to arrange a time for the interview which is convenient for you. Should you require any further information, either prior to your participation or following your participation, please contact Dr Katie Gallagher on the details above.

Thank you for reading this information sheet and for considering taking part in this study.

We would also like to make sure that you have details of Sands and Together for Short Lives, organisations that provide support to families experiencing neonatal death or palliative care. Help and support is there for you if you need it:

Sands	**Together for Short Lives**
Providing specialist advice and support for bereaved families	*Providing specialist advice and support for families caring for a child with life-limiting or life-threatening conditions*
The Sands helpline is for anyone who has been affected by the death of a baby and wants to talk to someone about their experience. Tel: 0808 164 3332 Email: helpline@sands.org.uk	The Together for Short Lives helpline is for parents or carers looking after a child or young person who has a life limiting or life threatening condition, offering support and someone to talk to about their experience. Tel: 0808 8088 100 Email: helpline@togetherforshortlives.org.uk