



Summary Protocol: Parents and Neonatal Decisions: A Research Study

AIMS: To explore the decision making processes, parental perceptions and the outcomes of treatment decisions for critically ill babies on the neonatal unit.

OBJECTIVES

1. To explore how parents are involved in making decisions for their babies
2. To explore parental perceptions of the decision making process
3. To determine how often life support decisions about a baby are made in the neonatal unit
4. To determine whether palliative/comfort care is offered to these very ill babies and families, and if so, how it is translated into clinical practice
5. To determine the short and long term outcomes of babies where life support decisions have been considered

SCIENTIFIC JUSTIFICATION

The decision making process

Having a baby cared for on the neonatal unit can involve an uncertain and very difficult time for the baby and their parents. For a variety of reasons, parents may be asked to participate in important decisions regarding the care of their baby. Although it is crucial that parents are involved, we know very little about how doctors and parents come to their choice of actions together or how parents are supported after these decisions have been made. Understanding how difficult decisions are made also provides important information for training and provision of palliative/comfort care in the neonatal unit.

Previous research has shown that most parents want some involvement in decision making, with the extent of this involvement varying depending on their cultural, religious and ethnic background. Ethical and legal guidance have been produced by professional and regulatory bodies to ensure that the core guiding principle is the professional's duty to act in the best interest of the baby. It is recognised that 'best interest' for the baby involves considerations of all aspects of the baby's life, including quality of life not only from a medical perspective, but also giving consideration to their family and social context. Recommendations from the Nuffield Council on Bioethics state that "parents have interests and that it is reasonable for those interests to be given some weight in any relevant deliberations about critical care decisions for a child who is, or who will become, severely ill", but how this is managed in clinical situations is currently unknown and the evidence suggests variable levels of involvement in practice. Disagreement around decision making has been reported within the literature, or as high profile cases in the media, but the actual frequency is not known.

There is no reported large multicentre study which follows families through their time on the unit to see how decisions around treatment are made. Little evidence exists around parental experience of these decisions. A recent study exploring how nurses assisted parents in the decision making process found that parents reported nurses played an important role in their understanding of information, providing emotional support and creating a supportive environment in which to make difficult decisions. Further exploration is required, however, around the actual decision making process itself and from the parents' perspective.

In extremely difficult cases of life-support decision making, where parents do not support a recommendation by the neonatal team to withhold or withdraw life sustaining treatment, their babies may survive. There are also a small number of babies who may survive following the discontinuation of treatment. Research is needed to determine how often this happens, and what the outcomes are for babies following continuation or discontinuation of life sustaining treatment, and following disagreement with parents. This information is required to give parents a balanced view of all potential outcomes.

The above highlights the requirement for a programme of research into how parents make difficult decisions for their fragile baby on the neonatal unit and which explores how families are supported by health care professionals.

SUMMARY OF DESIGN AND METHODOLOGY

Methodology: A mixed methods approach will be used, incorporating (1) case study analysis where individual families are studied in-depth, and (2) survey data to capture the extent and frequency of life support decision making.

1. Case Study analysis of parental decision making

Inclusion criteria

Approximately 20 families will be recruited who are receiving critical care on the neonatal unit.

Data collection

The study will be undertaken within two tertiary neonatal units (units which specialize in maximum intensive care) within London and over a 10 month period.

Data collection will consist of 3 different data sources:

- digital recordings of all formal conversations between parents and health care professionals away from the cot side
- 1 or 2 interviews with parents
- analysis of the baby's notes

Digital recordings of formal conversations

All formal interactions will be audio recorded to explore the skilful ways doctors communicate with parents when discussing treatment about their baby. Recordings will be offered to the parents on a personal MP3 player (provided by the study) as there is evidence that parents find these recordings helpful for information recall and relate to higher levels of satisfaction with their baby's care.

Healthcare professionals will also be given access to a password protected site, where they will be able to listen and reflect on their individual conversations (only those involved in the conversations will have access to these recordings).

Interview data

Parents will be invited to participate in 1 or 2 interviews throughout the study. The interviews will explore parents' perception of the information and support they have been given and the potential decisions presented to them. The interviews will last between 30 and 60 minutes and will be digitally recorded and added to the parents' MP3 player.

The babies' notes

In order to understand the context of the conversations being recorded, the babies' medical notes will be explored. Information will be documented surrounding the clinical wellbeing of the baby and parental support.

2. National survey

A pilot survey will be undertaken within 2 neonatal networks to explore the incidence and outcomes of neonatal life support decisions, as they occur, with a view to refine and roll out the survey across England and Wales following evaluation.

The survey has been designed to capture the following information:

- What is the incidence of life support decisions?
- Who is involved in life support decisions?
- What factors prompt life support decisions?
- What are the outcomes for all babies involved in a life support decision?
- How is parental support documented?
- Is palliative/comfort care offered to babies and families?
- How is palliative/comfort care documented?

Inclusion criteria

All babies who meet either of the following inclusion criteria will be eligible for the study:

- Any baby where a discussion has been had with the parents or between the health care team only, either antenatally or postnatally, around the discontinuation of full intensive treatment for the new born baby.
- Any baby who died after live birth, both in the neonatal unit and labour ward.

Data collection

Data collection will be prospective, as cases arise in the units, rather than after they have happened, and over a period of 9 months. The survey will collect non-identifiable, routine clinical data. All data will be securely stored by the research team. Health care professionals will be asked to identify babies that fit the inclusion criteria and then complete a secure online survey for each baby. The baby's hospital number will be used to generate a unique number which the health care team can then use to enter information about decision making and treatment throughout the baby's journey.

Data analysis

All data will be entered into a computer software package for analysis. We will use the data to determine the frequency of life support decisions, the documentation of palliative/comfort care, and the different outcomes. We will also try to determine the factors which may prompt discussions around life support decisions.

ETHICAL ISSUES

The study has been carefully designed and reviewed by neonatal clinicians and a parent advisory group to ensure that parents are approached in the most sensitive and yet informative way. Parents will only be approached after being introduced to the study by their consultant. All transcripts and audio recordings will be anonymised so that all identifying information is removed and the voices are unrecognizable in published material and presentations. All data will be stored securely by the research team.