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Revised IRB for CRC

Study Background

Perinatal detection of congenital anomalies leads to identification of infants who are affected by life-limiting conditions leading to death in the postnatal period. Because of the early identification of these infants, the establishment of a proper plan of care focused on the infant's comfort is essential. However, an extensive literature review shows that there is no current evidence-based standard of care for this selected population. (1)

Moreover, there has been a greater recognition of the emotional and psychological effects on mothers delivering an infant affected by life-limiting condition. (2,3)

At Morgan Stanley Children's Hospital of New York-Presbyterian (MSCHONY) neonatal comfort care management is defined as an individualized medical plan of care focused on promoting patient's comfort, without the intent of shortening or prolonging life.

Guidelines for comfort care management have been developed from evidence-based data obtained in neonatal populations. (4-7) Specifically a state of comfort for a neonate is defined as a condition where the infant's basic needs are satisfied. These needs include family/infant bonding, warmth, hydration and pain/discomfort management.

Previously, a retrospective study of 45 infants with life-limiting diagnoses was performed to describe these guidelines, as well as the natural history of these infants after birth. However, the retrospective nature of this study did not allow for systematic evaluation of the families' grieving process with the experience.

Therefore, the present study will be a prospective observational study to evaluate parental grieving in a population of infants affected by life-limiting conditions.

Study Aim

1. To assess the parental grieving process of parents of infants affected by life-limiting conditions treated with comfort care.

Study Hypothesis

1. Neonatal comfort care management facilitates the parental grieving process.

Study Design

Patient Population

We will prospectively enroll newborns diagnosed with life-limiting conditions or terminally ill whose parents elect comfort care from August 1, 2013 through July 31, 2017 at MSCHONY. Expected number of infants=40.

In order to assess parental grieving, the Texas Revised Inventory of Grief (TRIG) will be administered to the parents of the infants at least 6 months after the infant's death. The aim of this questionnaire is to document how the parents experienced their baby's death at 2 specific moments: at the time of the infant's demise and at least 6 months after the event.

In order to obtain more robust data on parental assessment of infants' comfort and parental grieving, a second population will be enrolled. We will identify infants delivered at MSCHONY and treated with comfort care because they were affected by lethal or life-limiting conditions or

were terminally ill from January 1, 2008 to July 31, 2013. Expected number of infants=50. These infants will be identified by retrospective chart review and their parents will receive by mail questionnaires aimed to document parental perception of their baby's comfort during comfort care and parental grieving.

Data Analysis

Demographic data in the TRIG will provide patient population characteristics. Evaluation of the parents' answers will produce an index obtained by the sum of the scores and cluster analysis will be performed to identify subsets. These data will be analyzed by SPSS software.

These data will be then cross-compared to identify associations among variables. Parents' comments will be evaluated in a qualitative fashion and synthetic categories of common themes will be identified and assessed with atlas-ti software.

Study Subjects

Inclusion Criteria: Hospitalized infants of all gestational ages and birth weights diagnosed with life-limiting conditions or terminally ill are eligible for inclusion in this study.

Exclusion Criteria: Those infants neither affected by life-limiting conditions nor terminally ill.

Recruitment

For the first population, eligible infants will be identified before or after delivery by the PI Dr. Elvira Parravicini. At the identification, the PI Dr. Elvira Parravicini will present information regarding this study through an information sheet. The parents who elect to participate in the study will fill out the questionnaires and send them back via the pre-stamped envelope.

We will pay special attention in mailing the letters and the questionnaires, avoiding both the day of birth and the day of death of the infants.

Informed Consent Process

If the parents of these infants decide to participate in the survey, their consent is obtained by filling out the information sheet or the information letter and the questionnaires and mailing them back to the researchers via the pre-stamped envelop.

Confidentiality of Study Data

All study subjects will receive a unique study number that is only known to the study team. The link of the study number with the patients' names and medical records will be destroyed once the computerized medical records have been abstracted and the data analysis is completed. The list with the link will be kept on a secure, password protected computer.

Privacy Protections

All data obtained for this study will be kept confidential as stated above.

Potential Risks

None

Data and Safety Monitoring

Not Applicable

Potential Benefits

There is no direct benefit to this study population.

References

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