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NEONATAL EXCHANGE BLOOD TRANSFUSION IN INFANTS ≤28 DAYS

(Short Study Name: Exchange Blood Transfusion)

Abstract

Exchange Blood Transfusion (EBT) is now rare but remains an emergency treatment mainly for very high or rapid rising serum bilirubin levels that are not responding to treatment with phototherapy. There is very little known about how often the procedure is performed currently in the UK & Ireland, or the complication rate. This information would be useful to inform medical practice and for counselling parents in the future.

The study aims to ascertain the current incidence and complication rates (including death) of EBT, as well as the practical difficulties of performing an EBT. There is insufficient understanding of the effect of current EBT procedures on the baby's clotting and platelet count, and therefore uncertainty about when the baby should have additional blood component support. Systematic collection of routinely available laboratory data will enable better recommendations for future practice and neonatal exchange red cell component development. A better understanding of the current incidence of adverse metabolic outcomes as a result of EBT, as well as incidence of morbidity and mortality, will be invaluable to guide future practice.

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Background

Many babies develop a mild or moderate degree of physiological jaundice in the neonatal period, which if it requires treatment with phototherapy, usually responds to this and is harmless. Some babies, however, develop severe or rapidly increasing bilirubin levels e.g. in the presence of Haemolytic Disease of the Newborn or other pathologies. Bilirubin encephalopathy, which can result in cerebral palsy and / or deafness, can ensue. It therefore necessitates prompt treatment with phototherapy but occasionally EBT is required.

Coverage United Kingdom and the Republic of Ireland

Duration October 2014 – October 2015 (13 months surveillance)

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Research Questions

- What is the current incidence rate of EBT being performed in the first 28 days of life?
- What is the complication rate (including death)?
- What do the results of laboratory tests routinely collected around the time of the procedure indicate?
- What is the frequency of other therapeutic options (e.g. immunoglobulin)?
- What is the frequency of practical difficulties of performing an EBT?

Case definition

Any infant up to and including the age of 28 days undergoing an EBT during the past month

Reporting instructions

Please report any infant who has undergone an exchange blood transfusion in the preceding month

Methods

Surveillance

Active national surveillance of all infants who fulfil the case definition will be undertaken through the BPSU in the UK and Republic of Ireland. The details captured in the study questionnaire will be used to link the surveillance records with the blood transfusion product issued. Linking the reported cases in this way will allow us to evaluate the completeness of data and also the type of red cell product used.

Questionnaires

Reporting clinicians will be sent a questionnaire for completion with a stamped address return envelope. Data will be returned to the audit department at the NHS Blood & Transplant where it will be inputted onto a secure database by key members of the NHSBT Audit staff. The data will be quality checked.

The questionnaire will collect demographic data including NHS and hospital numbers, date and time of birth, date of death (if applicable), sex and ethnicity, gestational age and birth weight. In addition geographic identifiers of postcode of the hospital where the EBT was performed will be collected. Clinical data will include diagnosis, previous clinical management and therapies, laboratory investigations and clinical outcomes.

Funding

NHS Blood and Transplant Trustees Fund Grant & NICU Endowment Fund, St. Mary's Hospital, Manchester

Support Group

St Mary's Hospital NICU Parents' Research Group

Ethics approval

This study has been approved by NRES Committee – North West – Greater Manchester Central (REC reference: 13/NW/0063; IRAS project ID: 115143) and has been granted Section 251 HRA-CAG permission (CAG Reference: 14/CAG/1010).

For further information about the study, please contact:

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