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Using the NNRD to evaluate the implementation of standard parenteral nutrition

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Background

- The use of standardised parenteral nutrition (sPN), prepared to a consistent formulation and delivered to a standard regimen, is not in widespread use in very preterm babies, one of highest PN users of all NHS patient groups.
- Use of individualised PN (iPN) contributes to variation in NHS costs and outcomes, and is a risk to patient safety because there is opportunity at multiple points for errors in prescription, formulation and delivery.
- Some neonatal Operational Delivery Networks (ODN) have decided to introduce sPN.

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Background

- Three standard PN products in use in London and South East
  - Nutritional Evaluation and Optimisation in Neonates (NEON)
  - Standardised, Concentrated Additional Macro-nutrients Parenteral (SCAMP)
  - East of England (EoE)
- Evidence of comparative effectiveness is limited

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Proposal

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Aim

- Use this natural experiment to evaluate the impact of introducing sPN in the NHS on preterm safety, effectiveness and cost-effectiveness.
- An ODN that is continuing with iPN will be the comparator.
- The aim is to fill an important knowledge gap in the care of very preterm babies by addressing the research question:

"In very preterm infants born below 31 weeks gestational age (Population), which of three sPN products (Interventions), compared to iPN (Comparator) has the best safety, clinical effectiveness and cost-effectiveness profile (Outcomes)?"

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Objectives

- The primary objective is to compare clinical safety and effectiveness outcomes for three sPN formulations for very preterm infants
- Secondary objectives are to compare i) health resource utilisation; and ii) compliance with the use of sPN

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Methods

- This is an opportunistic whole-population, observational, cluster comparison
- The decision to introduce sPN has already been made in the relevant ODN, providing an excellent opportunity to conduct an evaluation of a health technology being introduced into routine use in very preterm babies
- The study will include all babies within geographically defined populations and will thus be generalisable to the total eligible population

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Methods

- Additional items on Badgernet to capture items relating to PN
- Use the National Neonatal Research Database that holds routinely recorded data on all NHS neonatal unit admissions for demographic and baseline clinical data
- **Primary outcome** will be a composite safety and effectiveness measure (proportion of babies in whom either the aqueous or lipid component of PN is discontinued or reduced for metabolic disturbance in any 24-hour period or insulin therapy is initiated during PN use)
- **Secondary outcomes** will include measures of safety, clinical effectiveness and cost-effectiveness

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Additional items: Daily data

1. Type of PN (sPN or iPN)
2. Name of PN (NEON start up, NEON maintenance, SCAMP, EoE or iPN
3. Aqueous PN stopped or rate of infusion reduced in 24 h period for metabolic derangement derangements (hyperglycaemia, hypoglycaemia, hypertriglyceridaemia, hypernatraemia, hyponatraemia, hypokalaemia, hyperkalaemia)? (Yes/No)
4. Lipid emulsion stopped or rate of infusion reduced in 24 h period for hypertriglyceridaemia? (Yes/No)
5. Use of insulin in previous 24 h: (Yes/No)

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Additional items recorded at discharge

1. Highest level of conjugated hyperbilirubinaemia during admission
2. Highest level of serum triglycerides during admission
3. Highest serum cholesterol during admission
4. Highest level of alanine aminotransferase during admission
5. Highest serum calcium in the first two weeks.
6. Lowest serum phosphate in the first two weeks