TRANSFER

THREATENED PRETERM BIRTH, ASSESSMENT OF THE NEED FOR IN UTERO TRANSFER BETWEEN 22+0-23+6 WEEKS' GESTATION

Aim

To establish the incidence of women presenting with threatened preterm birth to obstetric units in England, Scotland and Wales and Northern Ireland between 22+0-23+6 weeks' gestation and determine the number requiring transfer to an obstetric unit with co-located neonatal intensive care unit (NICU) (level 3). This data is essential to facilitate adequate service provision and planning for obstetric and neonatal units throughout the UK.

Format

Multicentre prospective service evaluation.

Methods

Anonymised prospective data collection for a maximum period of 10 months plus follow up (all women will be followed up until delivery).

Eligibility: Pregnant women ≥16 years old admitted to an obstetric unit with threatened preterm birth between 22+0-23+6 weeks' gestation.

Threatened preterm birth is defined as: Any woman presenting with regular uterine activity but no cervical change and/or ruptured membranes and/or vaginal bleeding who in the opinion of the assessing medical team is in threatened preterm birth.

Data Collection Tool: REDCap secure web application.

Approval: Local trust site approval is needed. This project is not considered Research by the NHS according to the HRA decision tool (http://www.hra-decisiontools.org.uk/research/). Please register this project as a service evaluation.

TRANSFER project office: Birmingham Centre for Observational and Prospective Studies (BiCOPS) at the University of Birmingham.

Local Registration

Institutions providing data will be requested to register this project according to their local guidelines to adhere to clinical governance procedures. Identification of a lead clinician at each hospital is required.

Costs

No local costs should be incurred through the routine collection of data. This project has received funding from the South West Neonatal Network and the Bristol LMS.

REGISTRATON PROPOSAL

Your Details:

Name:	**Division:**
Position / Job Title:	**Specialty:**
Email:	**Tel: Bleep:**

Title: Assessing the incidence of threatened preterm birth in women presenting at 22+0-23+6 weeks' gestation, a service evaluation to inform the need for in utero transfer.

Short Title: TRANSFER

Project Team:

Name	Job Title	Specialty	Role within Project (data collection, Supervisor etc)
		Obstetrics	*Project lead*

Background

Preterm birth is a significant problem with 8-9% babies born preterm across the U.K (1, 2). The majority of these early births occur in women presenting beyond 27 weeks' gestation. Infants born before 27 weeks gestation require highly specialized care and are at significant risk of death or disability(3). In 2019 the British Association of Perinatal Medicine (BAPM) published their updated framework "Perinatal Management of Extreme Preterm Birth Before 27 weeks of Gestation". Of particular note is the risk-based approach to decisions about care pathways following delivery for the most extremely preterm infants born between 22+0 and 23+6 weeks. Babies at moderate risk of death or severe disability should receive active treatment; those at extremely high risk would normally be managed palliatively, whilst those babies at high risk should be managed in line with parental wishes following careful counselling.

However, the number of women presenting at risk of delivery between 22 and 24 weeks is unknown.

References:

1. Newnham JP, Dickinson JE, Hart RJ, Pennell CE, Arrese CA, Keelan JA. Strategies to Prevent Preterm Birth. Frontiers in Immunology. 2014;5.
2. Wagijo M-a, Sheikh A, Duijts L, Been JV. Reducing tobacco smoking and smoke exposure to prevent preterm birth and its complications. Paediatric Respiratory Reviews. 2017;22:3-10.
3. Marlow N, Bennett C, Draper ES, Hennessy EM, Morgan AS, Costeloe KL. Perinatal outcomes for extremely preterm babies in relation to place of birth in England: the EPICure 2 study. Arch Dis Child Fetal Neonatal Ed. 2014;99(3):F181-8.

Aims & Objectives

1. Calculate the incidence of women presenting with threatened preterm birth to obstetric units in England, Wales, Scotland and Northern Ireland between 22+0-23+6 weeks' gestation.
2. Determine the number of women who present outside an obstetric unit with a NICU.
3. Determine the number of in utero transfers of women presenting between 22+0 -23+6 weeks' gestation
4. Determine the number of women who deliver between 22+0 -23+6 weeks' gestation in a unit without a NICU.

Methodology

Data Collection Method:

Case note review		Prospective data collection	X	Data from existing database(s)	X	Patient/ staff questionnaire	

Pregnant women ≥16 years old admitted to an obstetric unit with threatened preterm birth between 22+0-23+6 weeks' gestation.

Capture data on all eligible women presenting to their unit within a maximum time frame of 10 months. All women will be followed up until delivery. Each site will have a local method of identifying women presenting with threatened preterm birth within the specified gestational window.

This includes notifying the site lead when regional units are contacted to discuss care pathways and possible transfer by the unit at which the woman presents. Weekly monitor the participants to ensure completion of follow-up data.

Deadlines:

- Start of data collection: 17-May-2021. ***Please note TRANSFER has a rolling registration so hospitals can sign up to participate after the launch data of 17-May-2021. As data collection is prospective centres should start to collect data when they have permission from their Trust.***
- Data collection duration: 20 weeks after ten month project enrolment duration
- End of participant inclusion: 31-Mar-2022
- Follow Up period: to outcome (maximum of 20 weeks after inclusion of the last patient - end August 2022)
- Proposed date for presentation of results: 31-Oct-2022