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Understanding how, why, for whom, to what extent and in what contexts the Preterm Birth Surveillance Pathway is successfully (and unsuccessfully) implemented in England through a realist evaluation

Submission date
21/06/2021

Recruitment status
No longer recruiting

Registration date
22/07/2021

Overall study status
Completed

Last Edited
29/07/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

In the UK, 1 in 13 babies are born early (before a woman reaches 37 weeks of pregnancy) – otherwise known as 'preterm'. This means that around 60,000 babies are born preterm every year. Many preterm babies do not survive. If they do survive, they often have long-term health problems. Because of these poor health outcomes, the Department of Health plans to reduce the preterm birth rate. This would also help the NHS save money as preterm birth currently costs the NHS one billion pounds a year.

Currently, women who are at risk of having a preterm birth receive different care depending on which hospital they receive treatment at. Some women are offered specialist care in a preterm birth prevention clinic, but many women do not receive any specialist care. At present, only 33 hospitals have a preterm birth prevention clinic out
of 187 hospitals offering maternity care across the UK.

NHS England has recently published some guidance on how to reduce preterm birth and help standardise care across the UK. This means that all women will receive the same care, even if they are at different hospitals. The new guidance has developed a pathway called the Preterm Birth Surveillance Pathway (PBP). This pathway says that midwives should assess every pregnant woman for her risk of having a preterm birth. This assessment will involve asking a woman questions about her medical history and deciding whether she is at high, intermediate or low risk of a preterm birth. If the midwife assesses the woman as being at high or intermediate risk of having her baby early, then they should refer her to a special preterm birth prevention clinic. Preterm birth prevention clinics are clinics where specialist doctors and midwives can offer the woman additional tests (such as scans and swab tests) alongside the normal care she receives when she is pregnant. These additional tests can help doctors and midwives decide which women may need further help, such as being admitted to hospital, to help stop them from having their baby early.

Now that this new guidance has been published, all hospitals are expected to follow the PBP for

pregnant women at risk of having their baby early by April 2020. This will be a big change for many hospitals. This is the first time guidance has recommended a PBP so it has never been reviewed or evaluated before. This study aims to research how, why, for whom, to what extent and in what contexts the Preterm Birth Surveillance Pathway is successfully (and unsuccessfully) implemented.

Who can participate?
1. Staff (clinicians and non-clinicans) aged 18 years and over who are involved in the preterm birth pathway
2. Women aged 18 years or older who are involved in the preterm birth pathway as service users
3. All service users at that hospital for a period before (e.g. 1 year) and a period after (e.g. 1 year) implementation of the preterm birth pathway

What does the study involve?
Staff take part in one interview of up to 60 minutes. Women take part in up to three interviews, lasting up to 60 minutes. Staff are observed in an antenatal setting and women are observed during an antenatal appointment. Anonymized routine electronic hospital data and admin activity data for all service users receiving maternity care at that hospital are collected for a period before (e.g. 1 year) and a period after (e.g. 1 year) implementation of the preterm birth pathway.

What are the possible benefits and risks of participating?
There will be no individual benefit from taking part in the study. However, the results will help to develop a set of recommendations for implementing the pathway in a range of hospitals. This will hopefully help to ensure that women at risk of preterm birth receive the care they require and help reduce the number of babies born preterm.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
April 2019 to March 2024

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Naomi Carlisle
naomi.h.carlisle@kcl.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Naomi Carlisle

ORCID ID
http://orcid.org/0000-0001-8943-8700

Contact details
Dpt Women And Children's Health
10th Floor, North Wing
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 (0)20 7836 5454
naomi.h.carlisle@kcl.ac.uk

Type(s)
Scientific

Contact name
Ms Naomi Carlisle

Contact details
Dpt Women And Children's Health
10th Floor, North Wing
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 (0)20 7836 5454
naomi.h.carlisle@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289144

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 289144

Study information

Scientific Title
IMplementation of the Preterm Birth Surveillance PAthway: a RealisT evaluation (including a realist literature scope)

Acronym
IMPART

Study objectives
To understand how, why, for whom, to what extent and in what contexts the Preterm Birth Surveillance Pathway is successfully (and unsuccessfully) implemented.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/06/2021, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8009; coventryandwarwick.rec@hra.nhs.uk), REC ref: 21/WM/0150

Study design
Multi-center observational study

Primary study design
Observational

Secondary study design
Multi-center observational study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Preterm birth

Interventions
Initial programme theories will be tested through interviews with women and staff, observational analysis and analysing routinely collected hospital and admin activity data. Staff members will be interviewed once. Women will be interviewed up to three times. Each site will have 15-40 hours of observational analysis undertaken.

Intervention Type
Other

Primary outcome measure
The contexts and mechanisms leading to both positive and negative outcomes in terms of implementation of the preterm birth pathway (PBP), assessed using interviews, observational analysis and routinely collected hospital and admin activity data for a period before and after implementation

Secondary outcome measures

The incidence of women having a singleton pregnancy having a preterm birth (liveborn and stillborn) as a % of all singleton births from 16+0 to 23+6 weeks' gestation, and from 24+0 to 36+6 weeks' gestation, assessed by analysing routinely collected hospital admin and activity data for a period before and after implementation

Overall study start date
30/04/2019

Completion date
01/03/2024

Eligibility

Key inclusion criteria
1. Staff: involved in the preterm birth pathway as staff
2. Women: involved in the preterm birth pathway as service users
3. Routine electronic hospital data and admin activity data: all service users at that hospital, collected for a period (e.g. 1 year) before preterm birth pathway implementation, and for a period (e.g. 1 year) after preterm birth pathway implementation

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
126

Key exclusion criteria
1. Staff interviews: not involved in the preterm birth pathway as staff (either clinical or non-clinical), are under 18 years old, and not English speaking
2. Women interviews: not involved in the preterm birth pathway as service users, are under 18 years old, and not English speaking
3. Observations: not involved in the preterm birth pathway as service users or staff, or are under 18 years old
4. Anonymized routine electronic hospital data and admin activity data: women who have specifically requested to opt out of the study after seeing the posters in antenatal clinical areas

Date of first enrolment
01/12/2021

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Homerton University Hospital
Homerton University Hospital NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Yeovil District Hospital
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Sponsor information

Organisation
King's College London

Sponsor details

8th Floor, Melbourne House
44-46 Aldwych
London
England
United Kingdom
WC2B 4LL
+44 (0)20 7848 332
EA-VPResearch@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Dissemination plans include:
1. Antenatal/postnatal groups with the Patient and Public Involvement (PPI) members of the project advisory group

2. The media and charities
3. A dissemination webinar 'TRiP (Translating Research into Practice) event' - planned date 01/03/2024
4. Publication(s) in peer-reviewed journals - planned date 31/08/2024
5. The study protocol is planned to be published in a peer-reviewed journal

Intention to publish date
31/08/2024

Individual participant data (IPD) sharing plan
The routinely collected hospital and admin activity data will not be shared as it was obtained through Confidentiality Advisory Group (CAG)/section 251 approval so the researchers are unable to share.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		29/03/2022	15/09/2023	Yes	No
Results article		21/04/2024	22/05/2024	Yes	No