

# 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

<b>Submission date</b> 21/06/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/08/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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-clinicians) 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  
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## Contact information

**Type(s)**

Public

**Contact name**

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**Type(s)**

Scientific

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

289144

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**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

**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

**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?
<a href="#">Results article</a>		21/04/2024	22/05/2024	Yes	No
<a href="#">Protocol article</a>		29/03/2022	15/09/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Influence of national guidance on preterm birth care in England	20/01/2023	12/08/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes