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BMJ Open Protocol for the IMPART study: Implementation of the preterm birth surveillance Pathway – a Realist evaluation

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ABSTRACT

Introduction New guidance, from NHS England (Saving Babies Lives Care Bundle Version 2 Element 5 (SBLCBv2)) has recommended a best practice pathway for women at risk of preterm birth (the Preterm Birth Pathway). This is to help meet the Department of Health's aim to reduce preterm birth from 8% to 6% by 2025. Considering most hospitals do not currently have a preterm prevention clinic, implementing this pathway will require significant coordination.

Methods and analysis The study will aim to investigate key features of contexts, mechanisms and outcomes, and their interactions in the implementation of the asymptomatic prediction and prevention components of the SBLCBv2 Preterm Birth Surveillance Pathway. This will be through a theory driven realist evaluation, utilising mixed methods (interviews with staff and women, observational analysis and analysing routinely collected hospital and admin data) in three case sites in England. The study has a Project Advisory Group composed of five women who have recently given birth.

Ethics and dissemination The study has ethical approval (King's College London REC approval number: MRSP-20/21-20955, and, IRAS:289144). A dissemination plan will be fully created with the Project Advisory Group, and we anticipate this will include presenting at conferences, publications, webinars, alongside dissemination to the wider population through parent and baby groups, the media and charities.

Trial registration number ISRCTN57127874.

INTRODUCTION

What is the problem being addressed?

In the UK, approximately 60 000 babies are born preterm (before 37 weeks' gestation). Globally, prematurity is responsible for around 40% of neonatal deaths,¹ while babies who survive often have short and long-term sequelae.^{2,3} A decade ago, preterm birth was estimated at costing the National Health Service (NHS) one billion pounds annually.⁴

The Department of Health wants to reduce the UK preterm birth from 8% to 6% by 2025,⁵ which is reiterated in The NHS Long Term Plan.⁶ New guidance, Saving Babies

Strengths and limitations of this study

- The study uses a realist evaluation to understand implementation of the asymptomatic prediction and prevention components of the Saving Babies Lives Care Bundle Version 2 Preterm Birth Surveillance Pathway.
- The study has a Project Advisory Group comprising five women who have recently given birth.
- The study aims to produce a set of recommendations to implement the pathway in a range of hospitals.
- The ability to undertake observational analysis may be affected by COVID-19, and we will need to take steps to mitigate this with the recommendations that we produce.

Lives Care Bundle Version 2 (SBLCBv2) Element 5,⁷ has recommended a best practice pathway for women at risk of preterm birth (the Preterm Birth Pathway (PBP)), which is a complex service intervention. The PBP is incorporated into the NHS standard contract for 2019/2020.⁸

This new NHS guidance standardises the care for pregnant women and will be a significant change for many hospitals. As this NHS guidance has only recently been published, it means that there are currently wide variations in care.⁹ The implementation of this pathway will determine how successful it is.⁷ This study therefore aims to research how, why, for whom, to what extent and in what contexts the PBP is implemented through a realist evaluation (including a realist literature scope).

Implementing the preterm birth pathway

The new PBP recommends all women are assessed by a midwife at their booking (first) appointment using a standardised assessment tool based on her medical history. Women will be assessed as low, intermediate or high risk of preterm birth. Women deemed as intermediate or high risk should be referred

to a preterm prevention clinic. If referred to a preterm prevention clinic, women are usually offered screening tests. These can include predictive biomarker tests and transvaginal ultrasound scans to measure cervical length—both determine which women are more likely to deliver preterm, regardless of potential causes of preterm birth.^{10 11} Preventative medical interventions that are effective in preventing preterm birth can then be offered if necessary.

Currently only 33 consultant-led hospitals have a Preterm Prevention Clinic out of 187 hospitals offering obstetric care in the UK.⁹ Considering most hospitals do not currently have a preterm prevention clinic, implementing this pathway will require significant coordination.

Why is this research important?

Currently, there is variation in preterm birth care across England. The PBP aims to homogenise this care pathway, however a standardised pathway may not produce standardised results. Realist evaluation examines the processes that mediate the effects of an intervention on outcomes.¹² Instead of asking ‘what works?’, realist evaluation asks ‘what works, for whom, in what circumstances and why?’¹³

This study would investigate the PBP in different contexts to see ‘what works, for whom in what circumstances and why’, leading to theories of how PBP implementation in different contexts can be improved. A set of recommendations for implementing the pathway in a range of hospitals will be produced to improve delivery of the PBP, clinical outcomes and to reduce divergent care.

Why this research needed now?

A systematic review¹⁴ of specialist Preterm Prevention Clinics found that the more recent literature supports specialist clinics, however none of these studies were randomised control trials (RCT). The authors note that undertaking an RCT will become increasingly difficult as Preterm Prevention Clinics become more established, which is now compounded by the national recommendation of the PBP.⁷ It may not yield the most useful findings given the social and complex nature of the intervention, implemented across many different contexts (for example cultural norms, economic conditions, hospital ethos).

The perceived value of preterm prevention clinics appears to derive both from the opportunity to provide clinical knowledge, skills and interventions in a holistic and equitable way to all women, and also from theorised added value that arises through the approach to care taken within the clinics. For example, midwifery continuity of care is associated with a reduction in preterm birth and fetal loss (before and after 24 weeks’ gestation).¹⁵ Attending a regular Preterm Prevention Clinic with the same obstetric and midwifery staff may provide a relational continuity effect. For example, preterm prevention clinics provide coordinated and individualised care to women.¹⁴ This, along with consistent and evidence-based information provision may reduce maternal anxiety

which in itself has been associated with preterm birth.^{16 17} A realist literature scope will be undertaken during stage 1 of this project, which alongside evaluating the PBP using the proposed theory-driven approach will generate transferable lessons about outcomes (both positive and negative) and implementation.

Cochrane reviews concluded that awareness of successes and barriers is key to implementing a new guideline or pathway,¹⁸ and more research into implementation is required.¹⁹ However, as a PBP has not been recommended before, there is no information for hospitals on their potential facilitators or barriers. This proposed research would provide this information.

Guidance recommending the PBP was published in March 2019,⁷ and maternity providers should have implemented this by April 2020,⁶ which was in the middle of the first national COVID-19 lockdown. Undertaking this research now is timely as hospitals begin implementation. This proposed research ensures intended and unintended outcomes of pathway implementation are tracked, explores implementation facilitators and barriers so sustainability of the pathway is likely, and develops theories on how to improve implementation at different hospitals. A set of recommendations for implementing the pathway in a range of hospitals can then be produced which will give the best chance of successful implementation.

METHODS AND ANALYSIS

Aims and objectives

Aim

The study will aim to investigate key features of contexts, mechanisms and outcomes, and their interactions in the implementation of the asymptomatic prediction and prevention components of the SBLCBv2 PBP. It will identify and understand the features of successful and unsuccessful implementation of the prediction and prevention components of the PBP.

Research question

To understand how, why, for whom, to what extent and in what contexts the asymptomatic prediction and prevention components of the SBLCBv2 PBP is successfully (and unsuccessfully) implemented.

Objectives

- ▶ To develop and refine realist programme theories related to the implementation of the asymptomatic prediction and prevention components of the PBP.
- ▶ To identify contexts and mechanisms leading to both positive and negative outcomes in terms of implementation of the asymptomatic prediction and prevention components of the PBP.
- ▶ To understand the relationship between the contexts, mechanisms and outcomes in implementing the asymptomatic prediction and prevention components of the PBP.

- ▶ To identify and assess a range of implementation outcomes in implementing the asymptomatic prediction and prevention components of the PBP, and any unintended consequences.
- ▶ To determine optimal implementation programme theories for successful national uptake of asymptomatic prediction and prevention components of the PBP, to produce a set of recommendations to implement the pathway in a range of hospitals.

Secondary clinical objective (based on the SBLCBv2 Element 5 outcome indicator)

- ▶ Determine whether implementation of the asymptomatic prediction and prevention components PBP will reduce the incidence of women having a singleton pregnancy having a preterm birth (live-born and stillborn) as a percentage of all singleton births⁷:
 - From 16+0 to 23+6 weeks' gestation.
 - From 24+0 to 36+6 weeks' gestation.

Study design

The approach of this study is a realist evaluation, drawing on an Implementation Science theory, model or framework. Evaluating national programmes aiming to standardise care through a realist evaluation is suited to understanding complex service interventions, such as the PBP.^{20 21}

There are fundamental hypotheses on how complex service interventions will produce outcomes.^{22 23} The first step of a realist evaluation is to elicit and formulate these theories, known as (initial) programme theories. A programme provides a resource, an opportunity, or a constraint—all of which can affect the decision-making process of its intended target group.²⁰ It is this decision-making process that determines whether an outcome is attained. The interaction between what a programme provides, and the reasoning of its intended targets, is known as a mechanism. Understanding and explaining the (often implicit) mechanisms are essential to a realist evaluation.^{23 24} Mechanisms can be encouraged in specific favourable and unfavourable contexts, which leads to intended and unintended outcomes. A programme theory formulates a proposed relationship between a context (C), mechanism (M) and outcome (O)—also known as CMO configuration.²³

While realist evaluation is an iterative, non-linear process, Pawson and Tilley¹³ outline research stages which this proposal will use (see figure 1):

- ▶ Stage 1: Formulating initial programme theories about implementation of the PBP (using CMO statements for how each programme component works) through a realist informed scope of the literature, a national questionnaire of current practice, and interviews with national programme developers (who developed SBLCBv2 Element 5) (through King's College London REC approval number: MRSP-20/21-20955).

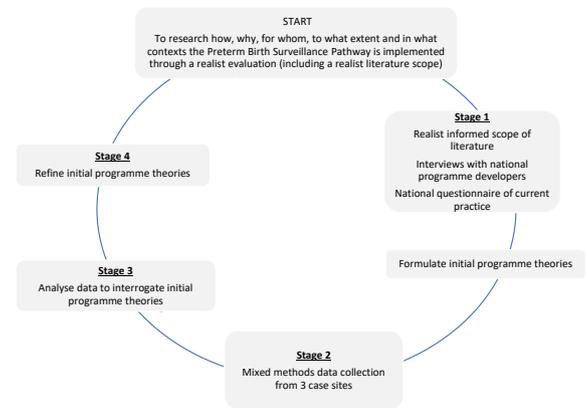


Figure 1 The realist research cycle for the IMPART study (adapted from Marchal *et al*).

- ▶ Stage 2 (through IRAS 289144): Collecting data from three case studies (guided by initial CMO statements) to ‘test’ the programme theories.
- ▶ Stage 3: Analysing data using a realist logic of analysis²⁵ to interrogate programme theories.
- ▶ Stage 4: Synthesising and interpreting to refine initial theories, leading to theories of how, for whom, in which circumstances and why implementation of the PBP works (and does not work). This will allow understanding of how PBP implementation can be improved and lead to the production of a set of recommendations for implementing the pathway in a range of hospitals.

Implementation Science literature and theory will be drawn on throughout to maximise the explanatory potential of data collected. Once stage 1 has been undertaken and initial programme theories have been formulated, several implementation science theories, models and frameworks will be sought and reviewed to find one which is suitably fits the data.^{26–28}

Study setting

Three case sites will be selected that vary in size, sociodemographic status, are in different local maternity system (LMS) areas and contain different local commissioners/different clinical commissioning groups (CCGs).^{29 30} LMS areas are important because the PBP specifies that women with very complex histories require referral to tertiary clinics.

Process and method of data collection

Data collection at this point has been informed by the models proposed by Proctor *et al*³¹ and Peters *et al*³² (see table 1) but will also be informed by stage 1 (initial programme theories).

The specific data to be analysed will be determined after the initial programme theories have been formulated in stage 1. It is likely to include the below (which incorporates the Preterm Birth Core Outcome Set³³):

- ▶ Demographics.

Table 1 Implementation outcomes and data collection method at each site (adapted from Proctor *et al*³¹ and Peters *et al*³²)

Implementation outcomes Adapted table from Proctor <i>et al</i> and Peters <i>et al</i> ^{31 32}		Data collection method from each site
Acceptability	Perception the pathway is agreeable	Realist interviews with women (pregnant women who are currently using maternity services) and staff (eg, managerial team, midwives who undertake bookings, clinical staff who work in the preterm prevention clinic and/or admin staff)
Adoption	Initial decision to implement the pathway	Realist interviews with staff Review of key documents (hospital guidelines, protocols, etc)
Appropriateness	Perceived fit or relevance of the pathway	Realist interviews with women and staff
Feasibility	Extent to which the pathway can be carried out	Realist interviews with staff Observational analysis
Fidelity	Degree to which the pathway was implemented as it was designed in the original guidance policy or protocol	Review of key documents (hospital guidelines, protocols, etc) Anonymised routine electronic hospital and admin data* Observational analysis
Implementation cost	Cost of implementation	Realist interviews with staff
Coverage	Degree to which the population that is eligible to benefit from the pathway actually receives it	Anonymised routine electronic hospital data
Sustainability	Extent to which the pathway is maintained or institutionalised in a given setting	Not collected. Rationale: Unlikely the project will be undertaken long enough to determine this

*Routine electronic hospital data from hospital maternity and neonatal databases, and administrative activity data, will be anonymised and downloaded with suitable support from an experienced data manager.

- ▶ Gestation at booking.
- ▶ Preterm birth risk at booking and if followed PBP.
- ▶ Antenatal care schedule (including any ultrasound assessments, preterm birth clinic appointments, care provider).
- ▶ Antenatal interventions.
- ▶ Antenatal admissions.
- ▶ Birth and neonatal outcomes.
- ▶ Length of hospital postnatal stay.
- ▶ Postnatal care schedule/readmissions.

Discovering unintended negative and positive consequences is an important aspect of both implementation²⁶ and realist research,¹³ and will be explored fully throughout the realist research cycle.

Sample size

Realist interviews will be conducted with:

- ▶ Staff members (clinicians and non-clinicians) from each site: n=5–10.³⁴ In these interviews, the implementation components outlined above will be covered.
- ▶ Women from each site: n=5–10.³⁴ Data collection from pregnant women will be conducted over 10 months across both sites, allowing for multiple interviews to be conducted across each woman's pregnancy. If this is not possible, different women at different pregnancy stages may be interviewed to ensure the programme theories are tested at different gestations.

Observational analysis: (COVID-19 permitting) Other realist reviews have undertaken 15–40 hours of observational analysis per site.^{21 35}

Anonymised routine electronic hospital data and admin activity data: Pseudonymised routine hospital and administrative data will be collected for a period before the PBP was implemented (eg, March 2019–March 2020), and a period after implementation at each site (eg, April 2020–April 2021).

Subject inclusion criteria

- ▶ Staff interviews: involved in the preterm birth pathway as staff (as clinicians and/or non-clinicians), are 18 years or older and English speaking.
- ▶ Women interviews: involved in the preterm birth pathway as service users, are 18 years or older and English speaking.
- ▶ Observations: involved in the preterm birth pathway as service users or staff and are 18 years or older.
- ▶ Anonymised routine electronic hospital data and admin activity data: all service users at that hospital, collected for a period before preterm birth pathway implementation, and for a period after preterm birth pathway implementation.

Subject recruitment

Women: Women at each site identified as eligible can be approached by the direct care team and offered a Participant Information Sheet. Women's demographic, medical and obstetric history details may be used to select a purposive realist sample, which 'tests' all of the relevant programme theories (Manzano, 2016). If the woman would like to take part, informed consent will be taken

by the researcher undertaking the interviews (NC). The interviews will take place via the telephone/video call at a convenient time for them.

Staff: Appropriate staff will be contacted (to create a purposive realist sample) via email, or approached in person by the direct care team (their colleagues) or the research team, to be informed about the study and offered a Participant Information Sheet. If they are interested in taking informed consent will be taken by the researcher undertaking the interviews (NC). The interviews will take place via the telephone/video call at a convenient time for them.

Women observations: Women at each site identified by staff as being 18 years or over and receiving antenatal care will be eligible to be approached and offered a participant information sheet by the direct care team. Women's demographic, medical and obstetric history details may be used to select a purposive realist sample, which 'tests' all of the relevant programme theories (Manzano, 2016). If, the woman would like to take part, informed consent will be taken by the researcher undertaking the observations (NC).

Staff observations: Appropriate staff will be contacted (to create a purposive realist sample) to be informed about the study and offered a participant information sheet by the direct care team (their colleagues) or the research team. If they want to take part, informed consent will be taken by the researcher undertaking the observations (NC).

Routine electronic hospital and admin activity data: Pseudonymised routine hospital and administrative data will be collected for all women who accessed maternity care for a period before the Preterm Birth Pathway was implemented (eg, March 2019–March 2020), and a period after implementation at each site (eg, April 2020–April 2021). This aspect of the study requires Confidentiality Advisory Group/Section 251 approval.

Patient and public involvement

During development of the proposal, NC engaged with two patient and public involvement and engagement groups were engaged with. NC delivered a short PowerPoint presentation was delivered at both PPI meetings, followed by an open discussion.

Both PPI groups alongside charities Twins Trust and Bliss provided feedback on how to make the Plain English summary of research clearer (eg, adding how many hospitals provide maternity care in the UK when explaining current preterm birth clinic numbers) and more accessible (eg, reducing the number of acronyms used). Bliss and Tommy's charities have also both written letters of support for the IMPART Study, believing that evaluation of the PBP is required.

The IMPART study will have a Project Advisory Group comprised of five women who have recently given birth. The group will meet regularly (at least two times a year) with NC. The role of the Project Advisory Group is to

provide strategic advice to contribute to the success of the project.

ETHICS AND DISSEMINATION

Withdrawal/dropout of subjects

Data can be withdrawn from the project up until 1 st July 2022, after which withdrawal is no longer possible as the data will have been anonymised and committed to the development and refinement of the programme theories.

Peer-review

This project has been through internal and external peer-review. The project is funded through a NIHR Clinical Doctoral Research Fellowship awarded to NC, and went through peer-review as part of receiving fellowship funding.

Data

Interviews and observational analysis

- ▶ Interviews and observational analysis will be undertaken by NC who is responsible for data collection, recording and quality.
- ▶ The transcripts and observational analysis field notes will be anonymised (participants will be referred to as a participant number), encrypted and will be kept on a secure online storage repository recommended by King's College London research storage (eg, SharePoint or OneDrive for Business), with a backup copy on a password secure King's College London laptop.
- ▶ Participants name and contact details will be kept securely and separately from the anonymised transcripts and field notes, and will be kept on a secure online storage repository recommended by King's College London research storage (eg, SharePoint or OneDrive for Business), with a backup copy on a password secure King's College London laptop. This will be deleted at the end of the study.
- ▶ From the end of the study, the consent forms and anonymised transcripts and field notes will be archived and kept for a further 10 years.

Routine electronic hospital data and admin activity data

- ▶ The password-protected pseudonymised data will be securely sent centrally to King's College London through an established NHS electronic network for analysis.
- ▶ Posters in antenatal clinical areas will highlight the study, allowing women to opt out. Each site holds an opt-out register within the site file, to record the details of women who request that their information is not shared with the research team. The details of these women will be removed by the local site team before the research team have local access to the data for the purpose of performing the linkage and pseudonymisation.
- ▶ No data that is not pseudonymised will be leaving the local site.

- ▶ The key connecting participant details to study identification number will be password-protected and kept locally at the individual sites on NHS networks.
- ▶ From the end of the study, the pseudonymised data will be archived and kept for a further 10 years.

Dissemination

A dissemination plan will be created with the Project Advisory Group to achieve visibility and disseminate effectively. The results will be presented at conferences and published in a combination of both peer-reviewed journals, and in magazines/journals read by clinicians to ensure the research is disseminated to both researchers and clinicians. A 'TRiP event' (Translation of Research into Practice) webinar is planned, which would be suitable for busy clinicians across the country.

After discussion with PPI, dissemination to the wider population may take place through parent and baby groups, antenatal groups, through the media and charities.

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Contributors NC conceived and designed the study, and the original fellowship/funding proposal. Once funded, NC developed the study protocol with input from JS, SMD and AS. JS, SMD and AS will provide methodological expertise throughout the study. NC will provide quotidian oversight of participant recruitment, data collection and liaison with the study sites. NC wrote the first draft of this manuscript and all authors critically reviewed and approved the final version of the manuscript.

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Competing interests AS is Principal Investigator on Hologic® funded science grants, which are paid directly to institute. NC received financial assistance from Hologic® covering expenses only, paid directly to institute, to provide educational talks on preterm birth. The other authors report no conflicts of interest

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval The study has ethical approval (King's College London REC approval number: MRSP-20/21-20955, and, IRAS:289144).

Provenance and peer review Not commissioned; externally peer reviewed.

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