ISRCTN70227207 https://doi.org/10.1186/ISRCTN70227207

# PINSA (Provision of Information about Newborn Screening Antenatally): the provision of antenatal information for the NHS Newborn Bloodspot Screening Programme (NBSP)

**Submission date**
05/03/2013

**Recruitment status**
No longer recruiting

**Registration date**
03/04/2013

**Overall study status**
Completed

**Last Edited**
14/11/2017

**Condition category**
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
This project looks at the best way of providing information to parents about the newborn blood spot screening programme (NBSP) via studies conducted both nationally and locally in the North West.
Study 1: A realist review. Information from expanded NBSPs about how they give parents NBSP information and publications about NBSP communication are reviewed. We will also contact NBSP researchers internationally to gather information about ongoing research. From this we create a range of ways of providing NBSP information to parents.
Study 2: Parents, midwives and screening professionals will be interviewed about their experiences of NBSPs and we will look at what factors affect parents' understanding. We will collect their views of the alternative ways of providing NBSP information we designed in study 1.
Study 3: A national survey of midwives will show us which resources midwives use when giving NBSP information. Also, 5-8 midwives locally will be watched when giving NBSP information. We can see how long midwifes takes to provide information and what resources they use. We can then calculate the current cost of providing NBS information and compare the alternatives to this.
Study 4: A national study with parents and midwives to examine which of the alternative ways of giving NBSP information is preferred.
Study 5: An expert panel will look at the impact of the alternative ways of giving NBSP information on midwife practice to enable us to calculate the cost of the alternatives.
Study 6: Focus groups (like group discussions) with parents and NBSP health professionals will discuss the study findings and recommendations. This will help us to ensure that guidance fits with parents and health professional's needs. We will conduct telephone interviews with parents who need interpreters.

Who can participate?
Study 2: All regional NBSP co-ordinators will be invited to participate (N=9); front-line professionals involved in communication of NBSP information: 18 hospital screening co-

ordinators, 14 community midwives and 4 hospital based midwives. 15 prospective parents after the initial time they should have received NBSP information, but prior to screening and birth of child; 15 parents following the heel prick test, but prior to results; 15 parents who receive normal results; 20 parents who receive a false positive result and 12 parents who receive a positive result for one of the metabolic disorders currently screened for.
Study 3: The survey aims to identify current practice in a national sample of midwives (N=300) recruited via the RCM register. 5-8 midwives in the North West SHA to be directly observed for one week each.
Study 4: 250 midwives and 500 parents
Study 5: Five NBSP experts
Study 6: Thus we plan to run one focus group with service providers (N=10-12) and two with parents (N=~20). Telephone interviews (N=~7) will augment this data, target negative cases or facilitate parents who need interpreters to participate.

What does the study involve?
Study 2: Interviews with service providers and parents regarding experiences and views of current newborn screening practice and potential alternative communication and consent models identified in study 1.
Study 3: This study involved two parts: (i) a national survey of midwives and (ii) direct observation of midwife practice.
Study 4: A discrete choice experiment (DCE). A DCE is a form of survey which identifies and measures what outcomes or aspects of service delivery service users or providers prefer and value the most and can be used to help policy makers decide which type of service is best. This DCE will test out the different alternative models discussed in study 2.
Study 5: A preliminary economic model of the proposed alternatives. Data from studies 2-3 will be used to create a model that compares current practice with the alternatives.
Study 6: Focus groups will provide a chance to check the studys conclusions with participants and gather suggestions for future research.

What are the possible benefits and risks of participating?
In any interview there is a chance that interviewees may become distressed. The questions asked in the interviews will be designed by team members experienced in collecting sensitive data, and training and support will be provided to the interviewers to ensure that data is collected professionally. Written records of the interviews will have any identifiable information removed to protect participants' identities. It is impossible to guarantee confidentiality of focus group data due to the group setting. Participants will be asked to respect others' views and maintain confidentiality of data, but will also be advised that as this cannot be guaranteed they should not discuss issues which they feel uncomfortable being disclosed outside the group. It is our experience that although parents may become distressed when participating in research about newborn screening, they value the opportunity to discuss their experiences. They do, occasionally, however require more support. It is our experience that when researching actual service provision health professionals may disclose that the service is not being provided in a way that fits with guidance. Thus, all data will either be collected anonymously or the identity of those observed will be protected. The sounding out of study findings with health professionals in study six will help the project team report any such findings in a sensitive manner. The project team includes a psychologist, lawyer, health economist, statistician, professor of midwifery, and neonatologist. All have experience of a conducting research with parents and health professionals and the person leading the research has expertise in research about NBSP communication and the ethical issues such research entails.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
May 2013 to October 2015

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 11/62/02

# Study information

### Scientific Title
The provision of antenatal information for the NHS Newborn Bloodspot Screening Programme (NBSP): a two phase sequential exploratory mixed methods project

### Acronym
PINSA

### Study objectives

The overall study aim is to determine service providers and users views about the feasibility, cost, efficiency, impact on understanding and consent of current practice, and preference of alternative methods of conveying Newborn Bloodspot Screening Programme information antenatally. There are nine objectives:

Phase one: generation of alternative models, establishing costs and implications of current best practice for parent understanding
1. Collate characteristics of alternative communication and consent models for NBSPs via a realist review of current NBSP communication models within the UK and countries operating extended NBSPs
2. Explore how providers and users envisage that information given antenatally can best meet the challenge of effectively and efficiently providing parents with sufficient understanding of an extended NBSP, including their reflections on the alternatives identified via the review
3. Examine parents understanding and experience of NBSP communication to draw inferences regarding best practice within an extended NBSP;
4. Establish the resource use and costs associated with the current practice(s) of providing NBSP information antenatally
5. Examine the preferences of midwives, parents and prospective parents, for different models of conveying NBSP information antenatally

Phase two: acceptability, preference, cost and broader impact of alternative communication models
6. Establish the key parameters affecting the cost effectiveness of new modes compared with the current practice(s) of providing NBSP information antenatally
7. Outline the key uncertainties in the current evidence base and what is the value of future research to evaluate the effectiveness and cost effectiveness of providing NBSP information antenatally
8. Explore provider and users views on the study suggestions, focusing on acceptability, broader impact, effectiveness, efficiency and parent understanding
9. Establish how generalisable the study findings are across conditions screened for in the UK NBSP

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/116202
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/81168/PRO-11-62-02.pdf

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Studies 2 & 6 involving parents only: NRES Committee West Midlands - Edgbaston, 24/10/2013, ref: 13/WM/0438
All other studies (including healthcare professional elements in studies 2 & 6): University of Manchester Research Ethics Committee, 02/10/2013, ref: 13198

## Study design
Two phase sequential exploratory mixed methods project using qualitative, quantitative, observational, survey and economic modelling studies in a complementarity style

## Primary study design
Observational

## Secondary study design
Cohort study

## Study setting(s)
Other

## Study type(s)
Screening

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

## Health condition(s) or problem(s) studied
Expanded newborn screening programme

## Interventions
Study 1: Realist review (no patients so no further information provided)
Study 2: Interview study involving regional screening co-ordinators, midwives and parents. Each participant is involved for one interview only, lasting approximately one hour.
Study 3: Midwife survey and observation study. Each midwife is involved in completing a survey for approximately 20 minutes. A small number of midwives will have their practice observed for one week.
Study 4: Discrete choice experiment parents and midwives will complete one discrete choice experiment, lasting approximately 30 minutes.
Study 5: Economic modelling (some stakeholders may be approached to provide guidance on this, but not provided further information as we will not know nature of this till closer to conducting it)
Study 6: Qualitative feedback study: stakeholders, and health professionals and parents from study 2 will be invited to take part in one focus group or telephone interview. Their participation will last approximately 30 mins to 2 hours.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
This is a mixed methods project which will generate a range out outcomes. The qualitative work will provide an outline of parents' and health professionals' views of alternative communication and models grounded in their personal experience of the NBSP. In the final phase focus groups will seek a consensus view on the preference, feasibility and acceptability of nascent models of communication and consent. These data will also illustrate how such preferences are shaped by social group processes. Telephone interviews will permit the inclusion of views from participants who are unable to participate in focus groups. This will also enable an in-depth and personal reflection at the idiopathic case study level of the implications of the study findings. This final phase of the study will be conducted between 9-15 months after the parents were initially interviewed. It is our experience from previous work that returning to parents in this fashion enables them to reflect on their earlier accounts and also add to the depth of the data by reflecting on their current adaptation to NBSP information. This will be crucial as work suggests

that the mode in which parents are informed may be used by parents to in turn convey information to the wider family. Thus, whilst changes in communication models may be sufficient for individuals at the time of testing, it is important to look at the wider implications of this communication event which commonly occurs many months after initial screening.

The costing study will provide a description of the types of resources driving the total cost of current models of communication and consent. The primary outcome will be the mean costs (total, fixed, semi-fixed and variable) with a description of the variation and distribution of the mean costs. The DCE will provide a measure of stated preferences that reflect a quantitative description of the trade-offs that people make between service and outcome attributes when valuing preferences for a model of communication or consent. The economic model will provide a measure of the expected incremental costs and benefits of proposed new models of communication or consent compared with a standardised description of current practice. It will also provide a measure of the uncertainty and key parameters driving cost effectiveness and the value of future research.

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
01/05/2013

### Completion date
30/10/2015

## Eligibility

### Key inclusion criteria
Study 2:
1. Health professionals: All regional screening co-ordinators
2. Midwives with experience of providing NBSP information in the community or a hospital.
3. Parents: a sampling framework will be constructed to ensure maximum variation. Parents will be included from across the screening pathway (e.g. antenatally, screening conducted but results not received, post results) as research suggests that parents ability to process information during this time are reduced increasing the likelihood of recollection biases, making the use of whole pathway recollection designs problematic as they are likely to capture particularly salient recollections, rather than a realistic assessment of information needs. Using immediacy recall has been advocated in this setting. Parents will be sought with a range of results including negative, positive and false positives (for each disorder). Participation of parents who do not speak fluent English will be facilitated by offering study materials in their own language and providing interpreters. Specific attempts will also be made to ensure participation of fathers, young parents and those with lower education achievement as these are commonly underrepresented in the research or may have different communication needs.
Study 3: Practising midwives of any grade
Study 4: Practising midwives of any grade and adults of child bearing age (18+ years)
Study 5: A hypothetical cohort of parents and up to five NBSP experts
Study 6: Participants from study 2. Key stakeholders for cystic fibrosis and sickle cell NBSPs.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
1219

### Key exclusion criteria
Study 2: Parents whose child has died or their child was born prematurely; who had newborn screening performed >180 days, or where multiple abnormalities were identified. Parents who do not have the capacity to consent
Study 4: Parents who do not read English fluently due to the linguistic demands of the discrete choice experiment (DCE)
Study 6: Parents who require interpreters will be excluded from focus groups due to the fast paced discussion style of focus groups. Low participation rates of non-English speakers in research are likely to make it impractical to run language specific groups. These parents' views will be collected via interviews with translators

### Date of first enrolment
01/08/2013

### Date of final enrolment
01/12/2014

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Manchester**
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## Sponsor information

### Organisation

University of Manchester (UK)

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### Sponsor type
University/education

### Website
http://www.manchester.ac.uk/

### ROR
https://ror.org/027m9bs27

## Funder(s)

### Funder type
Government

### Funder Name
Health Technology Assessment Programme

### Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

## Intention to publish date
01/05/2016

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |