

PADDINGTON - a study working with healthcare professionals and parents/carers to co-design resources for use in the UK and Ireland, aimed at improving medication safety for those giving medications to neonates in the home environment.

Submission date 28/05/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/11/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Over 100,000 babies are cared for in neonatal units in the UK and Ireland annually, either because they have been born prematurely, or born full term but require supportive care: this figure represents 1 in 7 babies born in the UK and Ireland each year. Premature neonates are often prescribed medications which require small volumes to be administered. Current practice on most neonatal units in the UK and Ireland is for nursing staff to give medicines. There have been recent moves towards parents/carers giving medicines in hospital to prepare them to give medicines to their baby at home. However, in many hospitals they are trained how to measure doses and administer medications only immediately prior to discharge. This can cause high levels of anxiety and concern for parents/carers as they worry about making a mistake measuring doses.

The aim of this project is to work with parents/carers to co-design resources aimed at improving medication safety for those giving medications to neonates in the home environment.

Who can participate?

Staff on neonatal units including: nurses, ANNPs, doctors, pharmacists and pharmacy technicians and parents/carers groups both in the UK and Ireland .

What does the study involve?

Participants will be sent an electronic survey to identify resources currently available for parents /carers.

Engagement with individual parents/carers of premature babies from five hospitals will be conducted through on-line or face to face focus groups to establish the problems or issues

related to medicines, their relative importance to parents and carers and what types of information and educational resources or interventions they think would be helpful. These parents/carers will be invited to help design new targeted medicine support resources and then, once the resources have been produced, a separate group of parents will be asked to provide feedback on these resources in the home setting.

What are the possible benefits and risks of participating?

We do not expect there to be either any risks or benefits to you. We will not be collecting any participant identifiable information. The information collected will be used to explore the needs for medication safety resources in more detail. We hope that the resources developed will help parents/carers on the neonatal unit in the future.

Where is the study run from?

Alder Hey Children's NHS Foundation Trust

When is the study starting and how long is it expected to run for?

January 2021 to May 2023

Who is funding the study?

Neonatal and Paediatric Pharmacists Group (NPPG Limited) (UK)

Who is the main contact?

Dr Louise Bracken, louise.bracken@alderhey.nhs.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

294675

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 49192, IRAS 294675

Study information

Scientific Title

Parent Co-designed Drug Information for Parents and Guardians taking Neonates Home

Acronym

PADDINGToN Version 1.0

Study objectives

The aim of this project is to work with parents/carers to co-design resources aimed at improving medication safety for those giving medications to neonates in the home environment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/07/2021, London - Bloomsbury Research Ethics Committee (MSE Meeting Rooms, Tottenham Court Road, London, W1T 1BB, UK; +44 (0)207 104 8063; bloomsbury.rec@hra.nhs.uk), ref: 21/LO/0351

Study design

Observational qualitative

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Medication safety for those giving medications to neonates in the home environment

Interventions

Work package 1 - Project management and coordination: including oversight of Study Management Group (SMG) and Research Delivery Group (RDG), protocol development, regulatory approvals (REC, HRA), site/investigator coordination, ongoing family communication, monitoring participant recruitment, risk management and budget management.

Work package 2 - Stakeholder mapping, development of e-surveys and focus groups: Healthcare Professionals (HCPs) in national and international sites and parent/carer networks will be identified and contacted via an e-survey to identify issues faced by parents/carers of neonates and currently available or effective practices. On-line interviews or face to face focus groups with parents/carers of premature babies with experience of transitions of care will explore these themes.

Work package 3 - Co-design of resources, evaluation and final dissemination: Caregivers willing to co-design educational and informative resources will be recruited, ensuring that content specificity, relevance and appropriate language are used in the new resources. A mixed methods evaluation with a different group of parent/carers will explore the utility (qualitative exploration), efficacy (quantitative evaluation of knowledge acquisition) and ease of implementation (including feedback on training needs) of the educational resources developed.

HCPs will also be asked to evaluate the ease of implementation of resources. Effect size of outcomes may inform a larger effectiveness study. A multi-modal dissemination programme will ensure results are made available to stakeholders, including peer-reviewed publications.

Intervention Type

Behavioural

Primary outcome(s)

1. Qualitative assessment of the usability and accessibility of resources available for parents /cares and healthcare professionals measured using e-surveys in July and focus groups in August 2021
2. Quantitative assessment of efficacy of the co-designed resources measured using a questionnaire circulated to a small group of HCPs to obtain feedback on training and support required to implement the resources Jan/Feb 2022
3. Ease of implementation – a questionnaire will be circulated to a small group of HCPs to obtain feedback on training and support required to implement the resources Jan/Feb 2022
4. An evaluation of the resource with a new group of parents/carers (approximately 10-15) to estimate:
 - a. Utility - qualitative exploration (short semi-structured interviews) of usability, accessibility, language, detail, size, complexity, etc.
 - b. Initial efficacy – Quantitative evaluation of knowledge acquisition Jan/Feb 2022

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/05/2023

Eligibility

Key inclusion criteria

Parents/Carers (focus groups, co-designing resources, evaluation of resources):

1. Parents/Carers of babies receiving care on a neonatal unit in one of the 5 study sites who will require medication to be continued after discharge from hospital
2. Parents/Carers whose baby has recently been discharged from the neonatal unit at one of the 5 study sites and whose medication has continued after discharge
3. Arrangements will be made for Parents/Carers who do not have access to a smart phone or

the internet to be able to contribute (eg face to face focus group may be offered where possible or phone credit will be provided)

Health Care Professionals

4. Nurses, doctors, ANNPs or pharmacy staff providing neonatal care in any of the five study sites
5. Other HCPs identified from the staff stakeholder map identified in 7.2.1 (eg NPPG, Irish Neonatal Health Alliance)

Neonatal parent support groups

6. Parents/Carers of babies who required medicines following discharge and are part of a neonatal parent support group identified in 7.2.1 (eg BLISS)
7. Parents/Carers of neonates whose babies were discharged from hospital within the last 5 years

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

369

Key exclusion criteria

Parents/Carers

1. Parents/Carers who do not speak English (the resources will initially be developed in English and then we will apply for further funding to allow them to be translated into other languages)
2. Parents/Carers whose baby's medication is likely to stop prior to discharge
3. Parents/Carers whose baby has a terminal diagnosis, a severe congenital abnormality or critical illness (unlikely to survive).
4. Parents/Carers unwilling to have audio-visual recording of focus group/interviews
5. Parents/Carers less than 16 years of age (the resources will initially be developed for parents /carers able to consent themselves, however, once the co-designed resources are available, we would like to explore utility in this group of parents)

Health Care Professionals

6. HCPs not providing care to neonates requiring medicines

Date of first enrolment

01/06/2021

Date of final enrolment

31/05/2022

Locations

Countries of recruitment

United Kingdom

England

Ireland

Study participating centre**Alder Hey Children's Hospital**

Alder Hey Children's NHS Foundation Trust

Eaton Road

Liverpool

United Kingdom

L12 2AP

Study participating centre**Arrowe Park Hospital**

Wirral University Teaching Hospital NHS Foundation Trust

Arrowe Park Road

Wirral

United Kingdom

CH49 5PE

Study participating centre**Rotunda Hospital**

Parnell Square

Dublin

Ireland

DO1 P5W9

Study participating centre**Liverpool Women's Hospital**

Liverpool Women's NHS Foundation Trust

Crown Street

Liverpool

United Kingdom

L8 7SS

Study participating centre

St James University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation

Alder Hey Children's NHS Foundation Trust

ROR

<https://ror.org/00p18zw56>

Funder(s)

Funder type

Research organisation

Funder Name

Neonatal and Paediatric Pharmacists Group (NPPG Limited)

Results and Publications

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 23/05/2023:

The datasets generated during and/or analysed during the current study are not expected to be made available because the sharing of datasets was not a provision within the protocol and the consent forms for the study's different work packages. The provision states that data collected will only be included, after analysis, in study reports or publications.

Previous IPD sharing statement:

The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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HRA research summary			28/06/2023	No	No
Interim results article	Parents' experiences of administering medication to neonates at home	27/10/2023	09/11/2023	Yes	No
Protocol (preprint)		10/07/2022	13/07/2022	No	No