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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/06/2021	**Overall study status** Completed	
Last Edited 09/11/2023	**Condition category** Other	

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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
294675

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Home

Study type(s)
Other

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

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
06/01/2021

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 185; UK Sample Size: 148

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
England

Ireland

United Kingdom

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

Sponsor details
Alder Hey Hospital
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West Derby
Liverpool
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United Kingdom
L12 2AP
+44 (0)1512525570
Lucy.Cooper@alderhey.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.alderhey.nhs.uk/

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Research organisation

Funder Name
Neonatal and Paediatric Pharmacists Group (NPPG Limited)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2023

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?
Protocol (preprint)		10/07/2022	13/07/2022	No	No
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