ISRCTN62718241 https://doi.org/10.1186/ISRCTN62718241

Better Use of (electronic patient record infant) Data to improve parent Satisfaction with neonatal care (BUDS)

Submission date
07/03/2019

Recruitment status
No longer recruiting

Registration date
09/04/2019

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
One in eight babies born in the UK are too unwell to go home and need to stay in hospital on a neonatal unit. This is stressful for parents, who rely on neonatal staff for updates about their baby, and often feel they aren't involved in their baby's care. Parents usually receive written information at the beginning of their baby's stay and at the end, but are hardly ever given written information about their baby during the neonatal stay. All neonatal units in the UK use an electronic patient record system (EPR): a form of computerised medical notes. Doctors and nurses use this to record a lot of information about babies each day, such as their weight, amount of milk they took and any breathing support they needed. The researchers want to improve how parents receive information, and how involved they feel in their baby's care, by regularly sharing some of this information with them in a way that is easy to understand. They want to give every parent a daily printed summary of their baby's information, taken from the electronic system. They have designed this with parents of babies that needed neonatal care and now want to test it on a neonatal unit.

Who can participate?
Parents of babies who are receiving care on the neonatal unit

What does the study involve?
Parents are asked some basic details about themselves and their baby. Then they are given a printed summary sheet containing updates about their baby ('My Baby's Summary Report') every morning on the unit on weekdays (Monday to Friday). Parents are asked to complete an anonymous questionnaire before they start receiving the summaries and then twice a week until their baby is discharged. This includes questions on how they feel about how they receive their baby's information and how involved they feel in their baby's neonatal care. It also includes questions on how to further improve the content, layout and wording of the summaries. The summaries are tested on the neonatal unit over 2 months, moving from the lower intensity unit area to the highest. The number of times parents are asked to complete the questionnaire depends on how long their baby is likely to stay on the unit and which unit area their baby is in at the time of recruitment. Parent involvement ends when babies are discharged from the unit. At

the same time points of distributing the parent questionnaire (twice weekly) the researchers distribute a three-question staff survey to all neonatal staff on duty in the respective unit areas (to assess staff workload). Data completeness and accuracy is also assessed at the start of the study and every day by comparing EPR-recorded data to handwritten nursing documentation. Finally, one-on-one interviews are conducted with staff members and parents before the researchers start sharing the summaries with parents and after the piloting stage of the project has finished.

What are the possible benefits and risks of participating?
It is not thought that there are any risks or disadvantages of taking part in this study. It is hoped that the written summaries will improve parents' understanding of their baby's condition and their neonatal experience in general. Parent involvement will also help improve the summaries for use by future parents.

Where is the study run from?
Chelsea and Westminster Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2018 to March 2019

Who is funding the study?
1. National Institute for Health Research (NIHR) (UK)
2. Rosetrees Trust (UK)

Who is the main contact?
Dr Susanna Sakonidou
s.sakonidou@imperial.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Susanna Sakonidou

ORCID ID
https://orcid.org/0000-0003-1639-8669

Contact details
Imperial College London Academic Neonatal Medicine
Chelsea and Westminster hospital Campus
Floor 4, lift bank D
369 Fulham road
London
United Kingdom
SW10 9NH
+44 (0)2033153510
s.sakonidou@imperial.ac.uk

Type(s)

Scientific

Contact name
Dr Susanna Sakonidou

Contact details
Imperial College London Academic Neonatal Medicine
Chelsea and Westminster hospital Campus
Floor 4, lift bank D
369 Fulham road
London
United Kingdom
SW10 9NH
+44 (0)2033153510
s.sakonidou@imperial.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
232205

Protocol serial number
Protocol v1.3/ Sponsor ref 18HH4522

Study information

Scientific Title
Better Use of Data to improve parent Satisfaction (BUDS): a mixed method project using qualitative and improvement science methodology to improve parent experience of neonatal care

Acronym
BUDS

Study objectives
Having a baby that requires neonatal care is stressful and traumatic for parents, who often report dissatisfaction with communication of clinical infant information. A large percentage of parents in neonatal care experience post traumatic stress disorder, anxiety and depression, which interferes with parent-child bonding and affects infant outcomes. Doctors and nurses routinely record neonatal daily data onto an electronic patient record system (EPR) in the UK, from which de-identified data form a research database: the National Neonatal Research Database (NNRD). The aim of this study to evaluate the impact of sharing neonatal EPR data with parents in neonatal care, on parent–reported satisfaction, parent interactions with staff, staff workload and NNRD data completeness.

Hypothesis: Sharing individualised, daily, clinical electronic patient record infant data with parents, in a parent-centred way, will lead to higher parent-reported satisfaction with communication of clinical information and involvement in neonatal care, and higher data completeness in the National Neonatal Research Database.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/06/2018, amendment submitted 23/11/2018 and approved 12/12/2018, West Midlands - South Birmingham REC, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS. Email: NRESCommittee.WestMidlands-SouthBirmingham@nhs.net, REC ref: 18/WM/0175, Protocol number: Sponsor ref 18HH4522

Primary study design
Observational

Study design
Prospective mixed method study using qualitative and improvement science methodology

Study type(s)
Other

Health condition(s) or problem(s) studied
Neonatal care

Interventions
Through qualitative work with parents of babies previously needing UK neonatal care, the researchers identified the type of infant information parents find important in neonatal care. They matched this information to the available EPR infant data items neonatal staff update daily throughout the UK and developed parent-friendly EPR data explanations. With parents, they co-designed a communication tool template for parents called “My Baby’s Summary Report”: a printed sheet of paper including individualised, daily infant updates for parents derived from EPR data, in parent-centred language. They will provide an individualised written summary report to each parent on weekdays. This will initially be offered to parents in the low-intensity neonatal unit area (Special Care Baby Unit) before expanding to approach all parents (High Dependency Unit and Intensive Care Unit). The communication tool’s impact will be measured and Plan-Do-Study-Act (PDSA) improvement science cycles will inform the tool’s continual improvement.

Intervention Type
Other

Primary outcome(s)
Parent satisfaction with communication of clinical information and involvement in care, assessed using validated self-administered parent questionnaire, the Parents' Experiences of Communication in Neonatal Care (PEC) questionnaire at baseline, twice weekly and at the end of piloting phase.

Key secondary outcome(s)
1. Parent interactions with staff, assessed with PEC questionnaire at baseline, twice weekly and at the end of piloting phase
2. Neonatal staff workload, assessed with self-administered staff questionnaire at baseline, twice weekly and at the end of piloting phase
3. Data completeness, assessed using historical completeness data from the National Neonatal Research Database and current completeness data from the live neonatal EPR at baseline, every

day and at the end of piloting phase
4. Parent/staff interaction and parental views on information communication assessed with one-on-one interviews with parents and staff at baseline and at end of piloting phase

Completion date
02/09/2019

Eligibility

Key inclusion criteria
1. Parents (male or female) of babies who are currently inpatients on the neonatal unit
2. The parental age lower limit will be 16 years
3. The researchers will start recruiting parents with babies in the lower intensity part of the unit (SCBU- Special Care Baby Unit) who are medically stable and not acutely unwell, in order to minimise the risk of causing anxiety to parents
4. They will recruit parents in SCBU only for 4 weeks, include High Dependency Unit parents in recruitment for 2 weeks and include Intensive Care Unit parents in the final 2 weeks

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Parents who cannot speak and/or read English will be excluded as the study's information documents and communication tool are in English
2. Parents younger than 16 years of age

Date of first enrolment
08/10/2018

Date of final enrolment
05/04/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
369 Fulham Road
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

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

Funder Name
Rosetrees Trust

Alternative Name(s)
Rosetrees, Teresa Rosenbaum Golden Charitable Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Chris Gale (christopher.gale@imperial.ac.uk). Type of data: anonymised, coded data (no free text). When the data will become available and for how long: After study results published and indefinitely. By what access criteria data will be shared including with whom: For research purposes and following review of individual requests. For what types of analyses and by what mechanism: Anonymised analyses reviewed on case by case basis. Whether consent from participants was obtained: Only anonymised data will be shared and consent was obtained for this. Extract from consent form: "I understand all data collected during the project, may be looked at by individuals from the sponsor (Imperial College London JRCO), NHS and regulatory authorities where it is relevant for regulatory purposes, as well as by approved researchers." Comments on data anonymisation: Only coded data, no free text.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/06/2019	26/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results			02/10/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes