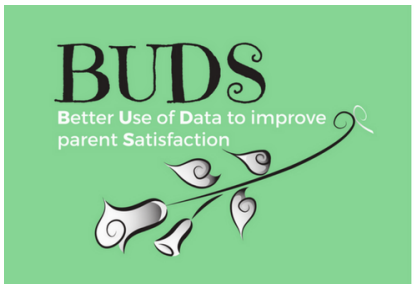


# **B**etter **U**se of **D**ata to improve parent **S**atisfaction (**BUDS**): A mixed method project using quality improvement methodology to improve parent experience of neonatal care

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A Thesis in the Field of Medicine
for the Degree of Doctor of Philosophy

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August 2023

## Abstract

### Background

Neonatal care is stressful for parents; national survey data show *'parent satisfaction with receiving clinical information'* is low in England. Neonatal data are not routinely shared with parents; this could improve satisfaction with neonatal care. There is a lack of interventions to improve neonatal data completeness.

### Aims

To use routinely-recorded data to co-develop, implement, and evaluate a neonatal communication tool with parents.

### Methods

I undertook a systematic review of interventions to improve parent satisfaction in neonatal care. I process-mapped parent/staff information exchange and parent information needs and co-created a communication tool using routinely-recorded data with parents. I adapted an existing survey and validated it for real-time feedback with cognitive interviews. I piloted the tool for 6 weeks on an NHS neonatal unit using quality improvement Plan-Do-Study-Act cycles, including quantitative and qualitative evaluation (parent satisfaction; staff workload; routinely-recorded data completeness/accuracy; parent/staff interviews).

### Results

In 32 studies (>2800 parents), 29 satisfaction surveys were used (six validated). 15% studies reported parent co-design; all had high risk of bias. I co-created *'My Baby's Summary Report'* (MBSR) with parents; a parent-centred, written, daily infant update derived from routinely-recorded data. I developed the *'Parent Experiences of Communication in Neonatal Care'* (PEC) survey, the first validated UK real-time neonatal survey. The MBSR increased parent satisfaction with *'amount of written information received'*, parents were highly satisfied with it and more likely to recommend the neonatal unit (*'NHS Friends and Family'* question); verbal communication

frequency needs unexpectedly increased. Data completeness improved and accuracy was high (>=90%) for most items.

**Conclusions**

Parent satisfaction in neonatal care is inconsistently measured, using unvalidated surveys in studies lacking parent involvement. The MBSR was co-created with parents and evaluated by a real-time validated survey. Parent satisfaction, routinely-recorded data completeness and verbal communication needs increased, supporting MBSR use as an adjunct to verbal communication.

**Keywords:** Parent satisfaction, systematic review, survey, routine data

## Statement of Originality

I, Susanna Sakonidou, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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**Acknowledgments**

I am delighted to have completed this work, with the help, guidance, and support from a diverse group of people. I am very grateful to my supervisors for giving me the opportunity to embark on this project and providing invaluable support along the way. Prof Chris Gale always ensured I kept a holistic overview in progressing all workstreams and has been a huge driving force in my academic learning on this journey. Prof Neena Modi and Prof Derek Bell have provided vital advice in ensuring this work's high standard, at all key project milestones. Thank you to Dr Kerry Woolfall, for supervising the qualitative element of my work. She was inspirational in making me truly enjoy a type of research I had previously had little involvement in.

I would like to thank all members of the Imperial College London neonatal research team, including some that have since moved on. James Webbe for being my PhD 'partner in crime', providing academic support and encouragement along the way. Emily Prior, Holly Jenkins, Robby Emsley and Suzan Jeffries were a fantastic team, ensuring this was a fun time to remember. Matthew Hyde, Cheryl Battersby and Sabita Uthaya gave valuable advice. Surbhi Shah provided excellent administrative support and Richard Colquhoun always ensured my project funding affairs were in order. Sandeepa Arora and Jena Sawad provided data support and advice, whilst Nick Longford gave statistical advice and endless entertainment.

A huge thank you to the core BUDS team; Izabela Andrzejewska and Wendy Carnegie, I am so grateful for your belief in the project, dedication and hard work which helped ensure the project's success. Sophia Kotzamanis was absolutely key in ensuring the parent voice transcended across the whole project and I am very grateful for her participation in honour of her late son, Monroe.

The NIHR CLAHRC NWL support was instrumental in setting up and progressing this project; thank you to leads Ganesh Sathyamoorthy and Rachel Matthews. A huge thank you to Thomas Woodcock and Mable

Nakubulwa for invaluable statistical support, as well as Catherine French for qualitative support.

I would like to thank Picker Institute Europe (Amy Tallett and Sarah-Ann Burger) for their support in survey design and development. A huge thank you to AJ Poots for providing statistical and quality improvement advice and support across successive roles within NIHR CLAHRC and Picker.

Thank you to all the managers, nurses, doctors, allied health professionals and non-clinical staff on the Chelsea and Westminster (C&W) Neonatal Unit for making this work possible. Sandra Howgate beautifully illustrated parent-friendly project materials and George Vasilopoulos from C&W Communications ensured these were disseminated to a high standard.

Thank you to neonatologist Mark Thomas and Innovation Business Partner Mike Wright, who have been instrumental in helping secure a contract for a live parent application and to Cambridge Digital Health, as we continue working together to further translate this research work into practice.

Thank you to my PhD funders for making this work possible: the National Institute for Health Research, NIHR CLARHC NWL, CW+ charity and Rosetrees Trust, as well as the Portland Hospital for initially funding my fees. The neonatal charity Bliss has been supportive throughout.

I want to extend a huge thank you to all parents that have participated throughout, in all working groups and project activities. This is for them, and it would not be possible without them.

Finally, thank you to my family, friends, and colleagues for supporting me on this journey. To my partner, Gemma, thank you for your patience and for keeping the rest of our life on track and to our son, George, thank you for making it all worth it.

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## List of abbreviations

| | |
|---|---|
| ANCOVA | Analysis of CoVariance |
| BMJ | British Medical Journal |
| CT | Communication Tool |
| CW | Chelsea and Westminster Hospital |
| EPR | Electronic Patient Record |
| FB | Facebook |
| HDU | High Dependency Unit |
| ITU | Intensive Therapy Unit |
| MBSR | My Baby's Summary Report |
| NHS | National Health Service |
| NICU | Neonatal Intensive Care Unit |
| NIHR CLAHRC NWL | National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care Northwest London |
| NNRD | National Neonatal Research Database |
| NNU | Neonatal Unit |
| PEC survey | Parents' Experiences of Communication survey |
| PDSA cycle | Plan-Do-Study-Act cycle |
| PM | Process Map |
| PPI | Patient and Public Involvement |
| PSG | Project Steering Group |
| RCT | Randomised Controlled Trial |
| SCBU | Special Care Baby Unit |
| SPC | Statistical Process Control |
| TPN | Total Parenteral Nutrition |
| UK | United Kingdom |

# Chapter 1
# Introduction

## 1.1 THESIS OVERVIEW

This thesis describes the co-development with parents, and subsequent evaluation of, a communication tool aimed at parents of babies receiving neonatal care. The communication tool, *'My Baby's Summary Report'* (MBSR), is a daily written update for parents about their baby's progress on a neonatal unit, derived from routinely recorded data in the neonatal electronic patient record system (EPR). I piloted the MBSR on a National Health Service (NHS) neonatal unit and evaluated its impact on parent satisfaction, neonatal staff workload, data completeness and data accuracy.

This is a mixed methods project, where I used parent co-design principles throughout and quality improvement methodology to conceive, develop and iteratively improve the communication tool with parents. I conducted separate quantitative and qualitative evaluations of the communication tool. These evaluations and parent feedback have been used to develop an electronic version of the MBSR in the form of a mobile phone application for parents in neonatal care.

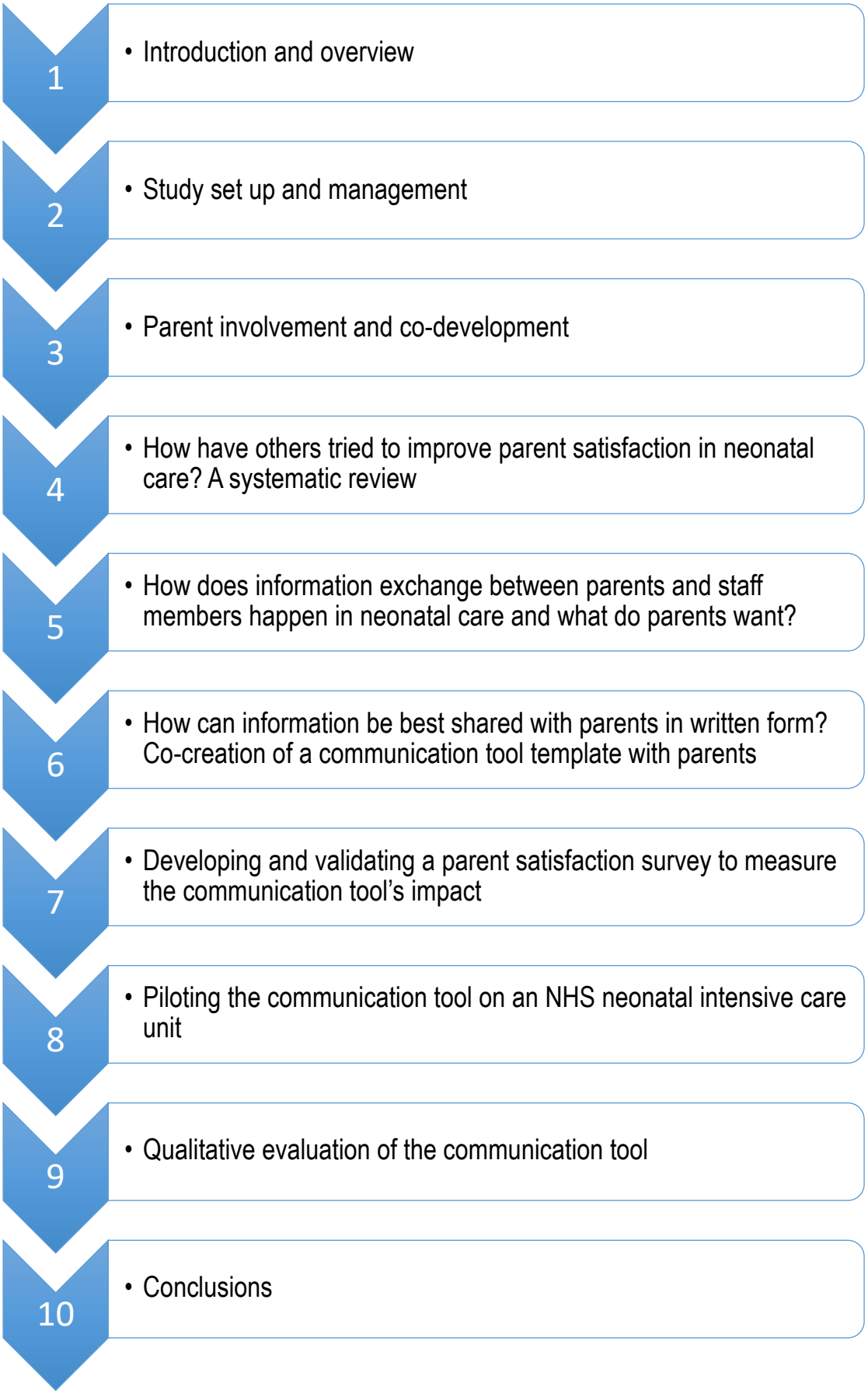
In Chapter 1, I provide an overview, background and rationale to the study, while in Chapter 2 I describe the initial steps of study set up, including developing a project steering group, engaging stakeholders, securing funding and raising study awareness. I involved parents throughout this study, from conception through to delivery and dissemination; in Chapter 3 I describe the parent involvement.

In Chapters 4 to 7 I describe the path to co-creating a communication tool with parents, starting with a systematic review (Chapter 4) to understand what parent interventions in neonatal care others had tried in the past and how they had evaluated them. In Chapter 5 I examine 'what happens now' in the neonatal unit and 'what parents want' by mapping out current information exchange between parents and staff and exploring parent information needs.

In Chapter 6 I describe the co-creation of a communication tool template with parents based on results from Chapter 5. There was no appropriate survey to evaluate a communication tool's impact on parent satisfaction; in Chapter 7 I describe the development and validity assessment of the first UK survey for real-time parent feedback in neonatal care.

In Chapter 8 I describe piloting the communication tool for 6 weeks on an NHS neonatal unit, including its detailed quantitative evaluation and subsequent translation into a mobile phone application. In Chapter 9 I describe the communication tool's qualitative evaluation separately, having interviewed parents and staff members pre and post intervention implementation. Finally, in Chapter 10 I discuss overall and final conclusions.

**Figure 1. Thesis overview (10 Chapters)**



## 1.2 INTRODUCTION

### 1.2.1 Parental stress and parent satisfaction in neonatal care

One in seven babies born in the UK will require hospital care on a neonatal unit (1). This is a very stressful and often traumatic time for parents, who frequently report it can be difficult to obtain clinical information from staff and feel excluded from their baby's care (2). More specifically, up to 35-40% of parents report symptoms of anxiety, depression and post-traumatic stress disorder following neonatal care (3-5). This stress has been shown to interfere with parent-child bonding (6), with a well-established link between maternal mental health and infant development (7).

In 2009, the Department of Health published the 'Toolkit for High-Quality Neonatal Services', as guidance to help the NHS improve neonatal care. The Toolkit emphasises the need to focus on family-centred care, which *'puts the physical, psychological and social needs of both the baby and their family at the heart of all care given'* (8). Furthermore, the national neonatal charity Bliss designed the 'Bliss Baby Charter' in 2011 to standardise high quality family-centred care across the UK. The Charter's fourth principle states that *'developing a culture of continuous improvement that involves and is informed by parents, maintains high quality care for babies and their families and encourages units to continually raise the bar in provision of family-centred care'* (9). It is therefore vital to assess parents' experiences of neonatal services to understand how quality of care can continually be improved.

Parent satisfaction, defined as '*the perception of parents' needs and expectations being met*' is inversely related to parental stress (10). As such, interventions aimed at improving parent satisfaction are increasingly being developed (11) as they have the potential to inversely reduce parent stress, which in turn has been shown to improve parent-infant bonding (12) and infant outcomes (13).

The 2014 *'Parents' experiences of neonatal care'* survey was developed by Picker Institute Europe (Picker) and is the most recent national neonatal

parent experience survey carried out in England, UK. 6000 parents from 88 participating neonatal units (from 72 NHS trusts) and across 13 neonatal networks responded to the survey, out of 157 total neonatal units in England. The results showed that *'parent satisfaction with receiving clinical information'* was among the lowest scoring of all areas evaluated (2). Improving the quality and quantity of communication between parents and neonatal staff benefits patient care, by promoting positive parent–child interaction and improving wider family well-being and satisfaction (14, 15). Improving verbal information provision can present challenges because of staff workload, the amount of medical jargon used and the difficulty in standardising the verbal information different staff members deliver to parents. Previous qualitative research on parent-staff interaction in neonatal care has highlighted a parental desire for readily available and consistent information provided by staff as well as more written information (see Chapter 5).

### 1.2.2 Improving parent satisfaction

There is indeed evidence that parent satisfaction can be improved through simple interventions, such as providing written information to parents. Examples include studies where parent satisfaction improved with parents receiving regular infant updates in a daily paper letter (16) or text message (17). There is also data suggesting that individualised information improves parent recall of information up to four months later and may reduce parental stress (18). Current technology is increasingly being used and requested by parents in neonatal care; a survey of 217 mothers of babies on neonatal units suggested that electronic messaging could improve communication with the medical team (19). In a 2021 systematic review examining parent/provider communication in neonatal care, parents' satisfaction with overall care was affected by communication and positively impacted by receiving comprehensible information (20).

A key limitation of previous interventions is that they require additional work from staff to collect, record, collate and provide information to parents. This raises concerns about their long-term sustainability and their generalisability to NHS neonatal care, where nurse staff shortages are common (21) and

recommended nurse-to-patient ratios are seldom achieved (22). A further limitation is that parents were rarely involved in developing previous interventions (11). Finally, parent outcomes were predominantly measured using unvalidated surveys and are therefore potentially unreliable, irreproducible or invalid. Further improvement in parent satisfaction may be achievable by implementing interventions co-designed by parents with lived experience of NHS neonatal care. The use of validated surveys for evaluation is critical to accurately evaluate the intervention in question.

In this PhD, I have built on the existing evidence for providing information to parents in written form by co-developing a communication tool with parents, giving them direct access to their babies' data. Sharing this information sensitively with parents has great potential to improve the parent neonatal unit experience and ameliorate its associated impacts. To make this sustainable and generalisable across NHS neonatal care I have used existing, routinely-recorded infant data from the neonatal electronic patient record system (EPR) to avoid additional burden on clinical staff. I have also developed and validated a parent satisfaction survey with parents for the communication tool's evaluation.

In the UK, a defined set of data items are extracted from neonatal EPR systems to form the National Neonatal Research Database (NNRD) (23). This holds information on all babies admitted for NHS neonatal care and is used for audit, benchmarking and research, but is not routinely shared with parents. Data completeness in the NNRD is high (23) for many data items (but not for all), and therefore has the potential to further improve. There is a lack of evidence for interventions to improve the completeness of routinely collected data in neonatal care and more widely. Involving parents in their babies' data could act as an incentive for clinical staff to record data in a more complete way. Optimising data completeness will further increase their clinical utility and lead to potential patient benefit.

More detailed literature reviews are presented in the following chapters accordingly.

## 1.3 STUDY AIM, OBJECTIVES AND HYPOTHESIS

The aim of this study is to use existing, routinely-recorded data, from the neonatal electronic patient record system (EPR) to work with parents experiencing neonatal care to co-develop, implement, further improve and evaluate a neonatal communication tool.

The objectives are to evaluate the impact of sharing routinely-recorded infant information with parents on:

- Parent satisfaction with 'communication of clinical information' using a validated survey
- Staff workload
- Completeness and accuracy of NNRD data extracted from the neonatal EPR

My hypothesis is that sharing individualised, daily, clinical EPR data with parents will lead to higher reported parent satisfaction with 'communication of clinical information' and higher data completeness of routinely recorded neonatal EPR data, without increasing staff workload.

# Chapter 2
# Study Set up and Management

In this chapter, I describe setting up my study, including developing a project steering group, engaging stakeholders, and raising study awareness.

## 2.1 SETTING

The study's setting was NHS neonatal care, with representative neonatal unit being the Chelsea and Westminster Hospital neonatal unit (CW NNU) in London, UK. The CW NNU provides tertiary level neonatal intensive care, including specialist surgical care, with 800 annual admissions and a 36-cot capacity. Over 100 staff members, including neonatal nurses and doctors work on the unit. The CW NNU is the neonatal surgical referral unit for North West London (and one of only two tertiary NNU in Nort West London). As such, it cares for patients from across North West London (and London more widely), including a very broad range of socioeconomic and ethnic backgrounds within patients.

## 2.2 PROJECT STEERING GROUP

At study inception, I created a multi-professional project steering group (PSG), including parents with experience of neonatal care and a representative from Bliss (the national neonatal charity), to ensure parents continuously guided my study.

I appointed a parent representative as a key PSG member, who co-led all aspects of study development and delivery with me, from designing and implementing parent engagement strategies to co-facilitating focus groups with parents and co-designing project materials. Sophia Kotzamanis (SK) took on this role as a parent with experience of preterm twins, having suffered the tragic loss of one of them, Monroe, who was cared for in the CW NNU. SK had already been supporting parents experiencing neonatal care on the CW NNU as a Bliss volunteer following her personal experience when she agreed to participate in my study.

My PSG consisted of (Appendix 1):

- Myself as Project Lead
- Parent representative
- Nursing representative (senior neonatal research and clinical nurse)
- PhD supervisor and neonatal consultant
- Bliss neonatal charity research engagement officer
- Improvement science manager and a statistician, based at National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care Northwest London (NIHR CLAHRC NWL)

Myself, the nursing representative (IA) and my PhD supervisor (CG) conducted project team management, under the guidance of the NIHR CLAHRC team. The NIHR CLAHRC team also supported me through training and advice on quality improvement methodology and public and parent involvement (PPI).

The PSG met regularly (once monthly) and additionally at key stages of the project when joint decisions on engagement, methodology and project delivery were required. As Project Lead, I regularly updated the wider PSG and worked very closely, daily, with the parent and nursing representatives, as well as the improvement science manager.

### 2.3 STAKEHOLDER ENGAGEMENT

In consultation with my PSG, I identified my project stakeholders:

- Parents with former neonatal experience (on any NHS neonatal unit in the United Kingdom)
- Parents of babies currently receiving care on the CW NNU
- Neonatal nurses and doctors on the CW NNU
- Bliss neonatal charity
- CW Hospital chief medical director, CW NNU matron (sponsors)
- NIHR CLAHRC NWL (quality improvement methodology, PPI and project management support)

- Picker Institute Head of Research (survey methodology and design support)
- Study funders

I devised an individualised communication plan for each stakeholder by considering their motivation for engaging with my work, what their influence was and who in turn influenced them.

My communication plans included a monthly email update to all stakeholders, and a bespoke combination of regular face-to-face meetings, phone calls, writing and sharing online blogs and posts via my study's social media pages (see Chapter 5, Online Engagement campaign), as required to individual stakeholders. I regularly mapped each stakeholder onto a stakeholder matrix grid (24), a quality improvement stakeholder engagement tool used by NIHR CLAHRC, based on each stakeholder's influence over my study's success and their level of interest in my study. I reviewed my stakeholder matrix and communication plans regularly, with all stakeholders gradually moving closer to the matrix's top right corner of '*high interest-high influence'* (Figure 2). I did this by ensuring stakeholders were directly involved in project activities and decisions and I maintained regular reciprocal communication with them.

**Figure 2. Stakeholder matrix**

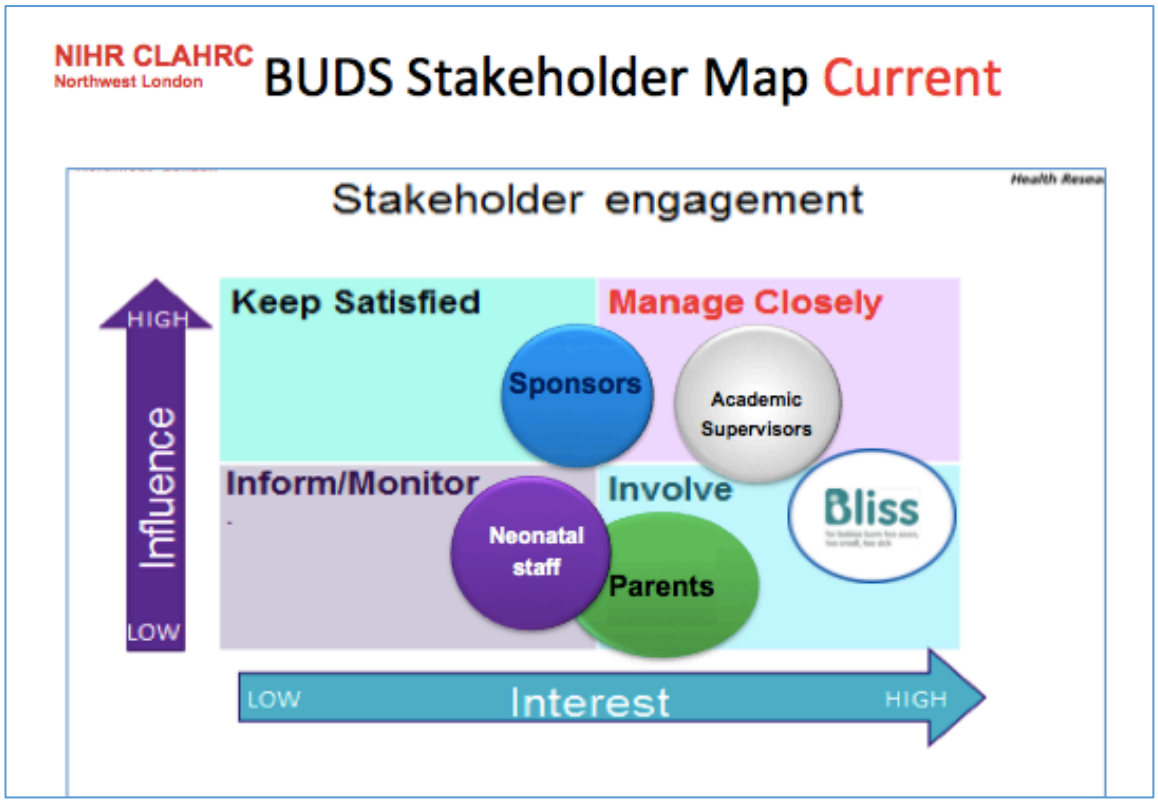



*Figure 2. Stakeholder matrix template from NIHR CLAHRC NWL QI4U online learning module (24). Example of stakeholder mapping during the study,*

## 2.4 GRANT FUNDING

I secured competitive grant funding from 4 sources:

- NIHR Doctoral Research Fellowship (DRF-2017-10-172) £407,681.00 (£119,208 for PPI).

- NIHR CLAHRC NWL Research Driven Improvement Project grant (IP006) £55,749.33: Funding nursing representative's work, PPI activities.

- Rosetrees Trust grant (A1653) £15,000: Funding PPI activities and development of mobile phone application prototype.

- CWPLUS charity "Small Change Big Impact " grant (SCBI) £2,000: Funding project materials.

## 2.5 RAISING STUDY AWARENESS

As part of raising awareness about my study during the initial project set up (and subsequently in maintaining regular stakeholder engagement), I delivered many presentations to:

- The CW Hospital Trust Board
- The CW Research and Development team meetings
- The CW Clinical Innovations forums
- The CW NNU team meetings
- The CW Neonatal nurse training days meetings
- Bliss charity national conference
- NIHR CLAHRC collaborative learning events
- NIHR CLAHRC Early Years steering group meetings
- Wellcome trust 'PPI involvement in research' meeting

## 2.6 DISCUSSION

To ensure parents continuously guided my study and the right people were involved, I created a multi-professional PSG including parents with neonatal care experience. My stakeholder engagement strategy was individualised, using the quality improvement stakeholder matrix tool, and including presentations in a variety of forums to raise study awareness. In response to my engagement activities, all stakeholders gradually moved to the matrix's top right corner of '*high interest-high influence',* which greatly contributed to the study's success.

My active stakeholder engagement strategy was key to ensuring regular study progress. The importance of involving stakeholders in implementation and improvement has been increasingly recognised over recent years (24). The formation of the NIHR Collaborations for Leadership in Applied Health Research and Care (NIHR CLAHRCs) in England are a prominent example: their aim is to implement research through closer interactions between academia and health services (24). In complex health services and systems, a wide range of stakeholders can sometimes have different or conflicting

interests; some wanting to see change while others aiming to preserve the status quo. With active stakeholder engagement, study teams can recognise different stakeholder needs and prioritise action accordingly. Aligning stakeholders' support in this way considerably increases the chance of success.

It would therefore be strongly recommended for future neonatal units adopting this study's intervention to similarly identify and proactively engage key stakeholders from study inception, for their particular study settings. The exact level of engagement required is unknown and settings-dependent; I have used empirical methodology and it is unknown if similar results would have still been obtained with less stakeholder engagement. However, as a minimum, it would be vital for key stakeholders to be identified and regularly consulted throughout any such study.

## 2.7 CONCLUSIONS

Working closely with a multi-professional PSG including parents with neonatal care experience, I employed an individualised active stakeholder engagement strategy using the quality improvement stakeholder matrix tool and regular study presentations, greatly contributing to the study's success.

# Chapter 3
# Parent involvement and co-development

In this chapter, I describe how I involved parents throughout my study, from conception and design through to delivery and dissemination.

## 3.1 4Pi NATIONAL INVOLVEMENT STANDARDS

Studies show that, in clinical trials, patient involvement can lead to improvements in design, selection of relevant outcome measures and recruitment of trial participants (25).

I actively involved parents in all my study's stages, in line with the 4Pi National Involvement Standards for effective co-development (26, 27). The 4Pi standards form a framework that was launched in 2013 following a UK government-funded National Involvement Partnership project to ensure effective co-production with service users aiming to improve experiences of services and support.

The 4Pi framework established some basic principles to encourage people to think of when involving service users in projects:

- **P**rinciples (sharing principles and valuing everyone equally)
- **P**urpose (ensuring the involvement purpose is clearly communicated to all)
- **P**resence (ensuring all relevant service users are involved)
- **P**rocess (ensuring the involvement's process is carefully planned)
- **I**mpact (ensuring the involvement' s impact is communicated back to participants).

## 3.2 STUDY CONCEPTION

I initially conceived my study in response to the clinical need identified by parents with neonatal care experience, as evidenced in parent feedback received in the most recent national Picker survey in England (see Chapter 1). Importantly, a partnership including families with experience of preterm birth

also identified as one of the top 10 research priorities the question *'what emotional and practical support improves attachment and bonding, and does the provision of such support improve outcomes for premature babies and their families?*' (28).

## 3.3 ACTION-EFFECT DIAGRAM MEETING

### 3.3.1 Background

When embarking on a new study, it is important that project teams confirm a shared project aim amongst them from the start, in line with quality improvement methodology (29). In the context of neonatal care, parents should be included as key players. To facilitate the execution and evaluation of quality improvement initiatives, the NIHR CLAHRC NWL team developed the Action-Effect Method. The Action-Effect Method is *'a systematic and structured process to identify and articulate an agreed aim, potential interventions to achieve this aim, anticipated cause/effect relationships between interventions/aim and measures to monitor improvement. It connects potential interventions and implementation activities with an overall improvement aim through a diagrammatic representation of hypothesised and evidenced cause/effect relationships'* (29).

### 3.3.2 Methods

I chaired an Action-Effect Method meeting early on in my project to jointly discuss what influences a parent's experience of neonatal care and to confirm shared agreement of the study's aim with parents.

The meeting included my PSG, parents with previous neonatal care experience from the CW NNU and BLISS volunteers, as well as other stakeholders (including nurses, doctors and NIHR CLAHRC researchers). In this meeting I facilitated a focus group discussion about what a good parental neonatal experience would look like to each individual, exploring any specific factors that might influence this. As a group, we discussed any factors influencing the parent experience at different times in babies' neonatal care journeys. Parents identified these chronological 'emotional touch points' from

admission through to discharge as being:

- Admission
- First update
- Ward round
- Daily care
- Clinical deterioration
- Clinical decision needed
- Transfer
- Preparing for discharge home

I utilised large flipchart sheets to capture ideas against each touch point along the timeline and used the Action-Effect Method to set the project's aim and proposed intervention to achieve the aim.

### 3.3.3 Results

Using the Action-Effect Method (29), we jointly identified poor communication and poor involvement in care as significant factors that negatively influence the neonatal parent experience and jointly confirmed the project's overarching shared aim to be *'to improve the experience of parents with a baby being cared for in the neonatal unit (by improving how we give information to parents)'.*

During this meeting, I produced an Action-Effect Diagram (Figure 3). This provided a diagrammatic representation of key factors that influence a parent's experience in neonatal care, the cause/effect relationships between them, and the links with potential interventions that can influence them, to achieve the *'shared aim'*.

Working backwards from the *'shared aim'* on the Action-Effect Diagram helped visually identify and formulate my study's planned intervention with parents: a communication tool to share daily, written, individualised infant information with parents, using existing, routinely recorded data from the neonatal EPR.

**Figure 3. The Action-Effect Diagram**

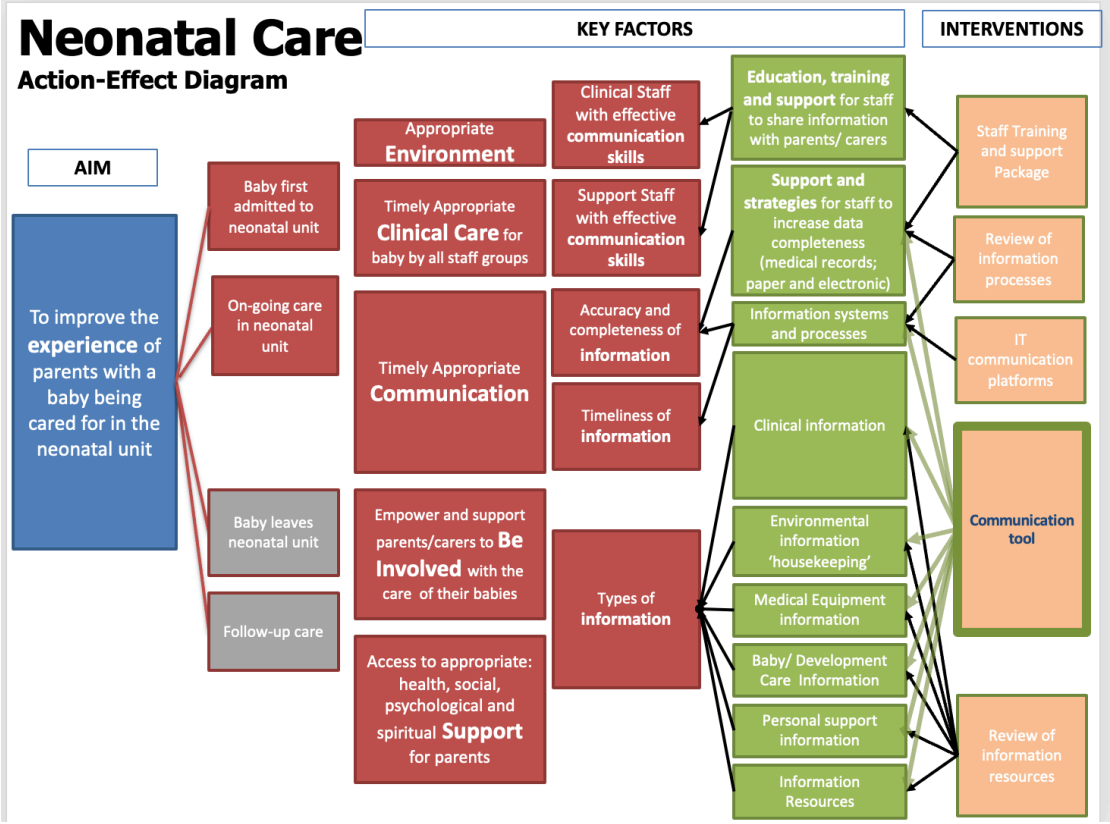



*Figure 3. Moving from left to right: AIM→ key factors→ potential interventions (LAST COLUMN). Each colour represents the next stage down the line.*
*Moving from right to left: ←Interventions feed back into key factors (arrows) and eventually lead onto the AIM. The communication tool as a potential intervention is seen to feed back into key factors, to meet the study's AIM. Grey boxes are outside the study's remit.*

### 3.4 STUDY DESIGN

I continually directly engaged parents of babies previously requiring NHS neonatal care in my study's design. Parents played a vital role in the preparatory phase through an Action-Effect Method meeting (see above) and continued to actively participate in all key stages of study design, including research ethics application drafting, co-presenting the project to stakeholders to gain buy-in (including hospital management), intervention design and outcomes' selection.

More specifically, my study's parent representative (SK), participated in all planning meetings as a key member, assisted me in study design with the parent view in mind and advised regarding all project activities, particularly organising focus groups and parent engagement activities. A group of parents

that had been recruited to my focus groups helped to further improve parent recruitment by co-designing an innovative study method: an online survey to enable more parents who could not attend face-to-face focus groups due to work/childcare constraints to take part in the study in 'virtual process mapping sessions' (see Chapter 5).

### 3.5 STUDY DELIVERY

I continued to involve parents with neonatal care experience throughout my study in a variety of ways, including co-developing the study's intervention. I co-designed the intervention with parents in focus groups (Chapters 5 and 6) and I supported the study's parent representative (SK) in co-facilitating these meetings with me. Furthermore, to measure the intervention's impact, I developed and validated a parent satisfaction survey working with parents currently experiencing neonatal care on the CW NNU (Chapter 7). Finally, during the intervention's piloting on the CW NNU, parents currently experiencing neonatal care again played a key role in continually improving and further iteratively developing the intervention, as per study protocol (see Chapter 8).

### 3.6 DISSEMINATION

My parent representative has participated in drafting all study interim output reports and publications and I have supported her in co-presenting study findings at research conferences. Together we recorded a video with other parents from my focus groups, discussing how the use of routinely recorded neonatal data can benefit parents. This video formed part of the Imperial College research team's joint presentation at the 2017 National Health Service Journal (HSJ) award competition, where I co-presented alongside prof Modi on using National Neonatal Research Database (NRRD) data for parents in research (won second place for the category *"Enhancing Care by Sharing Data and Information").*

Following study publication, parents will have direct input into study reports for dissemination through the Bliss charity (over 60,000 Facebook followers, 48,000 Twitter followers) and social media. Study participants will be informed

of the results through the study's website and via email in a study newsletter.

### 3.7 PARENT REPRESENTATIVE AWARD AND FORMAL TRAINING

In recognition of her role representing parents with neonatal care experience in my study and co-leading on parent co-design activities under my guidance, SK was awarded the NIHR CLAHRC 'Brian Turley prize', taking first place in the 'Influence category' on Patient and Public Involvement (PPI), when competing against other parent representatives of project teams that were also funded by NIHR CLAHRC NWL. I subsequently nominated her for a NIHR CLAHRC Improvement Leader fellowship, which she successfully completed, following the end of my study.

### 3.8 DISCUSSION

In this chapter I have described how I actively involved parents throughout all study stages, in line with the 4Pi National Involvement Standards for effective co-development (26, 27). I involved parents with neonatal experience from study conception by holding an Action-Effect Diagram meeting, which helped identify a communication tool to share information as a potential intervention to improve the experience of parents in neonatal care. In addition to providing a framework to guide a quality improvement initiative this was also a valuable tool in stakeholder engagement for involving parents from the start (29). It ensured parents were actively involved in agreeing the project's aim and planned intervention, in line with the 4Pi National Involvement Standards (and particularly: *'Purpose: ensuring the involvement purpose is clearly communicated to all'*). Studies show that, in clinical trials, patient involvement can lead to improvements throughout the research cycle, including participant recruitment (25); therefore, this approach could be beneficial for any future neonatal study.

For the reasons outlined above, ensuring high quality PPI work was a key priority in my study. It is however difficult to know the level to which this PPI work influenced the study's success. It is unknown if similar progress would have still been achieved with less PPI work, making it difficult to recommend an exact level of PPI work required by other NNUs in future similar work. In my

own subsequent systematic review of interventions aiming to improve parent satisfaction in neonatal care (described in Chapter 4) only 16% of included studies reported involving parents in intervention design, of which two studies reported improvement of parent satisfaction (11). Unfortunately, the number of included studies was too small to estimate any effect of parent involvement on the success of interventions at study level. Nevertheless, it remains widely recommended that parents are involved in all study stages (26, 27), with the exact level of involvement differing between individual study settings.

My study's parent representative's work in co-leading parent co-design activities with me was recognised by being awarded a PPI prize; she subsequently went on to complete a NIHR CLAHRC Improvement Leader fellowship; a further example of involving parents in research.

### 3.8 CONCLUSIONS

In this study, I have actively involved parents with neonatal experience through all study stages, in line with the 4Pi National Involvement Standards for effective co-development (26, 27). An Action-Effect Diagram meeting at study conception, ensured a shared study aim and planned study intervention could be agreed with parents. High quality PPI work in this study has been recognised by the study's parent representative being awarded a competitive NIHR CLAHRC PPI prize.

# Chapter 4
# How have others tried to improve parent satisfaction in neonatal care? Systematic Review

In this chapter I discuss my systematic review entitled *'Interventions to improve quantitative measures of parent satisfaction in neonatal care: a systematic review'*. This has been peer-reviewed and published in BMJ Paediatrics Open (11) and I have presented it at the international 2019 Pediatric Academic Societies conference (PAS) in Baltimore, USA and the 2019 Neonatal Society Conference in London.

## 4.1 BACKGROUND

A range of parent-centred interventions, such as including parents on ward rounds, have recently become widespread in neonatal practice. Many have been implemented on a small scale, and have not evaluated their impact on parent experience, making long-term integration into neonatal services challenging. Others have used parent surveys to measure their effect.

Evaluation of 'Parent satisfaction' as an outcome is gaining momentum, as hospital trusts attempt to match more 'business-like models', where effectiveness of interventions (and evidence for change) is measured quantitively. There are multiple experience measures available in addition to parent satisfaction, including parent stress, anxiety and depression scales; these can be measured both quantitatively and qualitatively. There have been no previous systematic evaluations focused on interventions measuring parent satisfaction with neonatal care as an outcome. Finally, it is not known the degree to which parents are involved in the design of such interventions.

The aim of this review was to identify and describe neonatal interventions relating to parents of infants of all gestations where an outcome was parent satisfaction. This was to gather information to help design the implementation and evaluation of my study's intervention. I aimed to report each intervention's effect on parent satisfaction, as well as parent input in intervention design.

## 4.2 METHODS

I prospectively registered this study on PROSPERO (30) (registration number CRD42017072388) and reported it using PRISMA (31) guidelines (PRISMA Checklist in Appendix 2). I searched MEDLINE (Medical Literature Analysis and Retrieval System Online), EMBASE (Excerpta Medica database), PsychINFO (Psychological Information), Cochrane Central Register of Controlled Trials, CINAHL (CUMULATIVE Index to NURSING and Allied HEALTH LITERATURE), HMIC (Health Management Information Consortium), Maternity and Infant Care for English papers published between 1946-October 2017, with update searches on 1st September 2018. See OVID MEDLINE search strategy in Appendix 3.

Inclusion criteria were:

- Randomised controlled trials (RCT) and non-randomised studies (non-RCT)
- Participants were parents of infants receiving neonatal care
- Interventions were implemented in neonatal units
- At least one quantitative outcome of parent satisfaction was measured.

I restricted this review to studies where at least one quantitative outcome of parent satisfaction was measured to enable comparison of interventions; this had previously not been possible in any published review. Including studies with all available measures of parent experience (in addition to parent satisfaction), as well as those only qualitatively evaluated, would have made any comparison very difficult.

Using these pre-registered search criteria I ensured I included studies measuring parent satisfaction both as a primary and secondary outcome. I included studies from all neonatal care level units and all healthcare settings, without excluding studies in low or middle-income settings. This was because definitions of neonatal care levels differ between different countries and healthcare settings, making them not easily comparable. Moreover, different levels of care are found within the same hospital settings. I excluded systematic reviews, entirely qualitative studies, grey literature (e.g. conference

abstracts), studies only reporting protocols or abstracts and full reports not in English.

Two authors, myself and my study's nursing representative (IA, Izabela Andrzejewska) independently double-screened titles and abstracts, reviewed full texts for eligibility and resolved any discrepancies with an experienced third reviewer, clinical research fellow (JW, James Webbe). I extracted data using a pilot-tested, standardised data extraction form including study characteristics, interventions, outcomes and parent input into interventions' design. I assessed methodological quality with the Cochrane Collaboration risk of bias tool (32) for RCT and the ROBINS-I tool (33) for non-RCT.

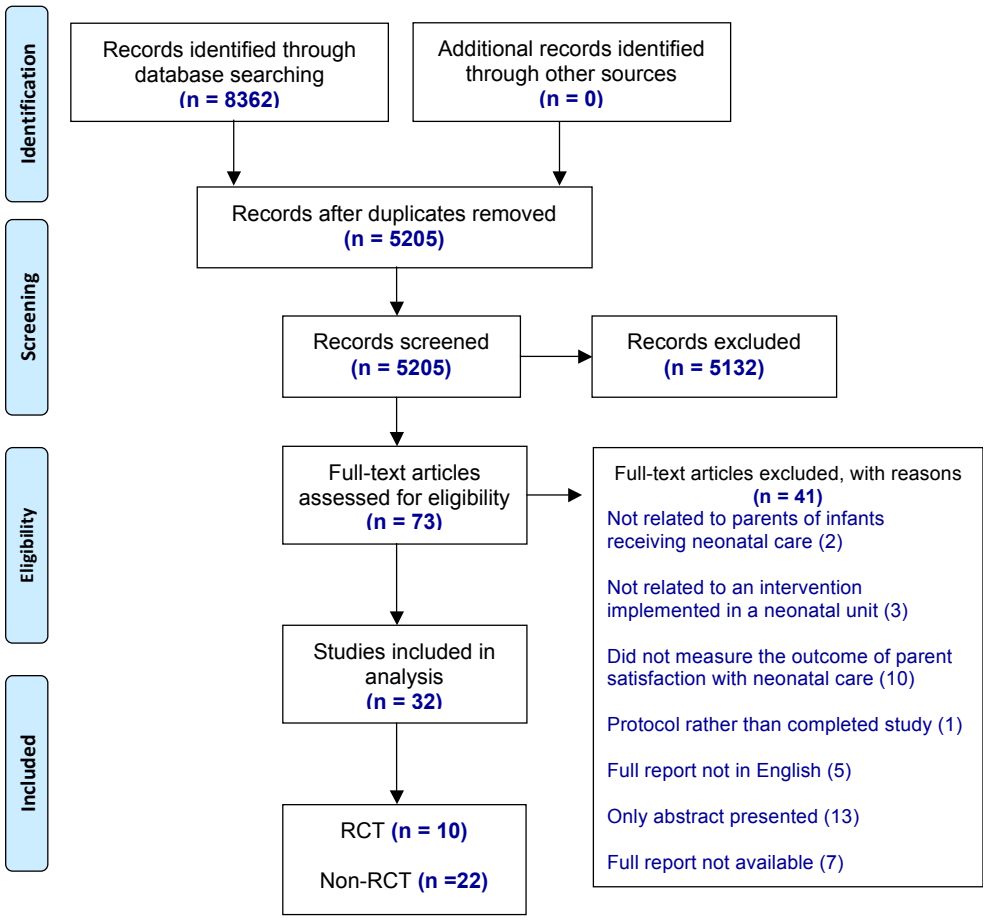
I presented individual study aggregate data in a narrative synthesis, and grouped studies into themes using a Grounded Theory Approach (34). I planned meta-analysis where data were appropriate for pooled quantitative synthesis.

## 4.3 RESULTS

### 4.3.1 Overall

I identified 8362 studies for screening and assessed 73 full text articles for eligibility (Figure 4). A total of 32 studies describing interventions that measured parent satisfaction in neonatal care as an outcome met the inclusion criteria, reporting data from over 2866 parents (1 study did not report number of parents).

**Figure 4. PRISMA Flow diagram of selected studies**




My analysis included 10 RCT and 22 non-RCT: 3 cohort trials, 18 unspecified designs and 1 implementation project (Tables 1-3). I further classified the unspecified non-RCTs into 2 types, depending on how they defined their control groups and how they evaluated parent satisfaction (Table 3):

1. *"Unit-level effect":* Studies that assessed parent satisfaction during a period of routine care (control group) and subsequently introduced the intervention in a different group of parents, during a different time period. In these studies, improvement in parent satisfaction was evaluated between different parent groups, at the level of the *unit.*
2. *"Group-level effect":* Studies that formed intervention and control groups using convenience sampling during the same time period. Both groups, or sometimes only the intervention group, had satisfaction measured after the intervention period (post-intervention testing). Baseline parent satisfaction was also measured in both groups (pre-intervention testing) in

some studies. Improvement in parent satisfaction was demonstrated either by comparing outcomes between intervention/control groups following the intervention, or in comparison with the pre-intervention data. Satisfaction was measured at the level of the *group* that received the intervention in these studies.

Parent participants (over 2866 in total) included mothers (14 studies), mothers and fathers (10 studies) or were not specified (7 studies). One study defined parent participants as a dyad of the mother with her designated support person. Median parent sample size was 63, ranging 7-482. This was higher for RCT (108 parents) compared to non-RCT (61 parents).

Study participants included parents of babies across the full range of gestations (23-42 weeks). Overall, 24/32 (75%) of studies involved preterm infants, 5/32 (16%) term infants and 7 studies did not state gestational age. Most studies (19, 59%) involved only preterm infants (up to 37 weeks); only 1 study (3%) involved only term infants and 5 studies (16%) involved both preterm and term infants. Preterm infants were included in 44% of RCT, versus 63% of non-RCT.

Definitions of neonatal levels of care are not standardised and vary across different countries; none of the included studies explicitly stated the definition of neonatal care in their setting. Levels of care were stated as 'level I, II or III', which as per the American Academy of Pediatrics would generally correspond to basic care (level I), specialty care (level II), and subspecialty intensive care (level III). Most studies were reported as having been conducted in (the highest intensity care) level III neonatal units (17 studies), followed by no level stated (9 studies), level II-III (3 studies), level II (2 studies) and level I (1 study).

Tables 1-3 show the key characteristics of included studies. They include a description of each study's parent and infant sample, study design and intervention, outcome measures (timing and methods), results, parent input into intervention design and study impact on parent satisfaction.

## Table 1. Included Randomised Controlled Trials (RCT)

| **Randomised controlled trials (RCT) by publication year** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Author (Date), Country | Parent Gender/ sample size | Infants Gestation age (weeks)/ NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 1. Northrup et al. (2016), USA | Mothers and fathers /116 | <28 / level III | RCT | Intervention: **Free Parking (FP).**<br><br>Parents received 7 parking vouchers at a time (value: $10/each) and continued to receive vouchers until infant discharge. Each voucher allowed free entry and exit for 24hr.<br><br>Control: Parents received the standard care and did not receive vouchers. | ***Parent satisfaction with NICU care*** | After babies were discharged (once)<br><br>- During the first high-risk-infant clinic visit after discharge<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>Validation: No content validity or reliability testing reported.<br><br>11 questions<br><br>- Seven items were summed (score 7-35) to measure "Support" (e.g., information sharing).<br><br>- Three items measured "Emotional Connection" to the infant (score 3-15)<br><br>- One item assessed "family involvement in infant care" (responses: not enough-just right-too much).<br><br>Greater scores indicated higher perceived support, connection and satisfaction. | **The groups did not differ significantly with respect to satisfaction.**<br><br>**Interv Mean (SD) Control p-value**<br><br>NICU support<br>30(2.7) 28.7(3.7) 0.07<br><br>Emotional connection<br>12.3(1.7) 12.3(1.7) 0.96<br><br>Family involvement "Just right"<br>81.4% 85% 0.07 | **No** | **2** |
| 2. Abdel-Latif et al. (2015), Australia | Mothers and fathers /63 | 25-42 / level III | Cross-over RCT | Intervention: **Parental Presence at Clinical Bedside Rounds (PPCBR).**<br><br>Parents attended bedside clinical rounds. Parents had opportunity to ask questions | ***Parent satisfaction assessed by questions of 3 domains:***<br>*1. Knowledge and understanding* | During babies' admission (once)<br><br>- At the end of each study arm, separated by a washout period | *Satisfaction questionnaire*<br><br>The authors stated "the research team designed the questionnaire". | **PPCBR had significantly higher adjusted mean (95% CI) scores for some questions from domains 1 and 2.** | **No** | **1** |

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| | | | | about their baby's condition and management.<br><br><u>Control:</u> Parents received the standard care with no parental presence at bedside clinical rounds. | *2. Communication and collaboration*<br>*3. Privacy and confidentiality* | - No pre-intervention parent satisfaction data available for comparison | <u>Validation:</u> No content validity or reliability testing reported.<br><br>Number and format of questions: not stated | Domain 3 was comparable between the two study groups.<br><br>**Interv Control p-value**<br>Domain 1 question:<br>*"I have received adequate information about my baby's condition and management"*<br>**Mean**<br>4.321 3.947 0.03<br><br>Domain 2 questions:<br>*"In the last week I have been able to communicate effectively with my baby's healthcare team"*<br>**Mean**<br>4.407 4.250 0.05<br><br>*"In the last week I have collaborated with my baby's healthcare team in the planning of care for my baby"*<br>**Mean**<br>3.843 3.426 0.02<br><br>*"In the last week I have been able to ask the healthcare team questions about my baby's care"*<br>**Mean**<br>4.642 4.259 0.004 | | |
| Author (Date), Country | Parent Gender/ sample size | Infants Gestation age (weeks)/ NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 3. Bastani et al, (2015), Iran | Mothers /100 | 30-37<br>Mean (SD)<br><br>Control: 33.90 (2.33) | RCT<br>block randomisa-tion | <u>Intervention:</u> **Family-centered Care (FCC).**<br><br>Mothers allowed access to their baby at any time, participated in the care process and were provided | ***Maternal satisfaction* relating to three themes:**<br>1. Parental presence | During babies' admission (twice)<br><br>- 24 hours after admission<br>- At the time of discharge | *Satisfaction questionnaire* (Validated)<br><br>A modified satisfaction questionnaire was used, based on a parental satisfaction instrument | **In the FCC group, pre and post intervention difference in maternal satisfaction was statistically significant p<0.001** | **Unclear**<br><br>Mothers determined the reliability of the satisfaction tool and approved the educational pamphlet. Authors | **1** |

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| | | Interv: 34 (1.9)<br><br>/ level not stated | | with information about neonatal care.<br><br>Control: Mothers received the standard care where they were only allowed to be present at the time of the infant's entry to the neonatal care unit, and were only routinely informed. | 2. Participation in neonatal care<br>3. Information about neonatal care | | developed for measuring satisfaction in Paediatric intensive care Units (PICU).<br><br>18 questions<br><br>Graded 0 (very dissatisfied) to 4 (very satisfied).<br><br>The overall satisfaction rate was classified based on the mean scores (score<50%, between 75-50% and > 75%). | **Interv Control p-value Mean (SD)**<br><br>**At 24 hr**<br>22.36(8.90) 22.06(9.77) 0.87<br><br>**At discharge**<br>59.28(6.86) 30.18(14.09)<0.01 | did not report if mothers had direct input in the intervention design. | | |
| 4. Clarke-Pounder et al. (2015), USA | Mothers and fathers /19 families | 23-39 / level III | RCT | Intervention: **Sharing information obtained from parent interviews with the primary NICU provider.**<br><br>Parents interviewed using the *NICU- adapted Decision Making Tool (N-DMT).* Information obtained was placed in the electronic medical record (EMR) and shared with the primary neonatal provider via email. Daily rounds on all infants were audio-recorded for 3 consecutive days after enrolment to see if information from the N-DMT was incorporated into daily care planning.<br><br>Control: The content of a recent social work note was communicated with the primary provider via e-mail, creating an attentional control group. | ***Parent satisfaction with care*** | During babies' admission (once)<br><br>- 2 weeks after study entry<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>A *NICU- adapted Decision Making Tool (N-DMT)* – specific questionnaire was used.<br><br>Validation: Partially reported. Authors stated reliability testing took place; no information on content validity provided.<br><br>8 questions: e.g."My baby's doctors considered my goals and hopes for my baby during decision-making".<br><br>Likert scale (1 strongly agree-4 strongly disagree). Total N-DMT score range 8–32. | **There was no significant difference in satisfaction with care as measured by the N-DMT scale between the control group and intervention groups in a univariable model or multiple variable model controlling for gestational age.**<br><br>**Interv Control Median** (range)<br>26(15–28) 28.8(19–32)<br><br>**No p-value reported**<br><br>There was, however, a pattern of decreased satisfaction with care among the intervention group compared to the control group across the N-DMT-specific survey questions, although the differences were not statistically significant. | **Yes**<br><br>Information obtained from parents using the N-DMT was placed in the electronic medical record (EMR) and shared with the primary NICU provider via email (forming the intervention) | **2** |

| Author (Date), Country | Parent Gender/ sample size | Infants Gestation age (weeks)/ NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
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| 5.Holditch-Davis et al. (2013), USA | Mothers /208 | Preterm infants<br><br>Mean (SD)<br><br>Overall group 27.2 (3.0)<br><br>/ 4 centres, levels II-III | RCT<br><br>3 groups (2 intervention and 1 control)<br><br>Post-intervention testing only. | Interventions: **1. Mothers were taught how to massage infants with auditory, tactile, visual, and vestibular stimulation (ATVV intervention)**<br>**2. Kangaroo care**<br><br>Control: Attention control group. Mothers spent a similar amount of time with the study nurse discussing the equipment needed for preterm infant care at home. Study nurses provided education and support for all three groups. Mothers were not prevented from engaging in interventions of the other groups but did not receive formal education from the study nurse on the other interventions. | **1. *Parent (mother) satisfaction with the intervention***<br><br>***2. Satisfaction with the helpfulness of the study nurse***<br><br>***3. Whether the mother would recommend the study to others and the degree of change in the mother as a person and as a mother as a result of being in the study.*** | During admission period and post discharge<br><br>- At the time of discharge<br><br>- At 2 months corrected age<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>The questionnaire was designed by the study team.<br><br>Validation: Partially reported. Authors stated reliability testing took place; no information on content validity provided.<br><br>26 questions: relating to three dimensions of satisfaction: efficacy, caring, and technical quality.<br><br>Likert (1 least satisfied-5, 5 most satisfied) | **No significant differences occurred between the groups.**<br><br>Mothers in all three groups were satisfied with the intervention (mean scores of 3.3 or higher on a 5-point scale) and the helpfulness of the nurse (mean scores of 4.6 or higher on a 5-point scale). | **No** | **2** |
| 6. Franck et al. (2011), UK | Mothers and fathers /169 | Mean (SD)<br><br>Control: 31.94 (5.17)<br><br>Interv: 29.40 (3.17) /4 centres, level III | Cluster RCT | Intervention: **Increasing parental involvement in infant pain management in the NICU.**<br><br>Parents received a booklet providing evidence-based information about pain and comforting infants in the NICU setting. Parents received 2 visits from a research nurse showing them how to apply the comforting techniques described in the booklet. | At baseline:<br><br>***1. Parent satisfaction with NICU care***<br><br>One week after the intervention:<br><br>***1. Satisfaction with information about pain control*** | During babies' admission (twice)<br><br>-At baseline (within 3 to 7 days of admission)<br><br>- 1 week after the intervention | *Individual questions*<br><br>Validation: No content validity or reliability testing reported.<br><br>1. At baseline:<br><br>Parent satisfaction was measured by 1 question: *"Satisfaction with NICU care"* (1 very satisfied-6 very unsatisfied) as part of the baseline parent characteristics questionnaire. | **At baseline: there was no significant difference in satisfaction between intervention and control group**<br><br>**Interv Control**<br>**Mean (SD)**<br>1.45(0.71) 1.51(0.76)<br><br>**p-value** missing<br><br>**1 week after the intervention: Intervention parents were more** | **Yes**<br><br>The booklet was reviewed by 12 parents of infants who had been cared for in NICUs in the United Kingdom. | **1** |

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| | | | | Control: As part of usual care, parents in both the intervention and control groups received a detailed booklet with generic information about NICU care. Parents in the control group also received 2 visits from a research nurse listening to what parents had to say about their NICU experience (attention placebo). | ***2. Satisfied nurses make infant comfortable***<br><br>***3. Satisfied pain medicines help infant*** | | 2. One week after the intervention:<br><br>Three questions using the word "satisfied' were selected from the validated *Parent Attitudes About Infant Nociception (PAIN)* survey (Likert scale 1 very satisfied-6 very unsatisfied) | **satisfied with the information about pain control received than control parents.**<br><br>**Interv Control**<br>**Mean (SD)**<br>2.10(0.97) 3.28(1.27)<br><br>**p-value** < 0.001 | | |
| 7.Livingston et al. (2009), USA | Mothers /12 | Mean (SD)<br><br>Control: 33.4 (6.4)<br><br>Interv: 38.5 (3.1)<br><br>/ level III | RCT | Intervention: **Touch and massage.**<br><br>Mothers attended a 1hr massage class taught by a nurse CIMI (certified infant massage instructor) and were asked to participate in at least 3 bedside massage instruction sessions taught within the next week. Infants received massage for 7 consecutive days, from the mother or a CIMI. The touch procedure lasted 20 minutes.<br><br>Control: Infants received all usual hospital services including medical care, physical and occupational therapy services and developmentally supportive nursing care. | ***1. Caregiver (mother) satisfaction with their infant's care***<br><br>***2. Caregiver satisfaction with the neonatal unit and the massage therapist*** | During babies' admission (three times)<br><br>- At baseline<br><br>- Upon completing the 7-day massage program<br><br>- 1 month following intervention | *Satisfaction questionnaire*<br><br>Two questionnaires were developed by the research team.<br><br>Validation: No content validity or reliability testing reported.<br><br>-1st questionnaire (at baseline): a brief self-report questionnaire about caregiver satisfaction with their infant's care until that moment. No further details reported.<br><br>-2nd questionnaire (upon completing the 7-day massage program and 1 month following intervention): a 10-minute satisfaction questionnaire relating to infant's response and caregiver satisfaction with the neonatal unit and the massage therapist.<br><br>Number of questions: not stated.<br><br>Likert scale (1 very dissatisfied-4 very satisfied).<br><br>Sample statements: | **It is unclear in the report if specific between-group comparisons and statistical analysis were conducted.**<br><br>At baseline and day 7:<br>All caregivers were highly satisfied with the medical treatment their infant received.<br><br>At day 7 and 1 month follow-up:<br>All caregivers participating in the massage group reported high levels of satisfaction regarding their relationship with their infant and the massage program's impact on that relationship.<br><br>Slight improvements in satisfaction regarding time the caregiver spent with the infant and involvement in the infant's care were observed between day 7 and the 1-month follow-up (no further information reported). | **No** | **3** |

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| | | | | | | | *'How satisfied do you feel giving massage to your infant?' 'I feel that massage improved my infant's hospital stay.'* | | | |
| Author (Date), Country | Parent Gender/ sample size | Infants Gestation age (weeks)/ NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 8. Koh et al. (2007), Australia | Mothers /200 | Not stated / not stated | RCT | Intervention: **Provision of taped conversations with neonatologists to mothers.**<br><br>The initial conversation and subsequent conversations of significance with a neonatologist were taped and analysed (for both groups). Mothers received a tape of each conversation and a tape recorder.<br><br>Control: Usual care. Mothers were not given the tape or recorder. | ***Satisfaction with conversations held with the neonatologist***<br><br>***Satisfaction with the tape*** | During admission period and post discharge<br><br>- At 10 days<br><br>- At 4 months<br><br>- At 12 months<br><br>No pre-intervention parent satisfaction data available for comparison. | *Individual questions and a satisfaction scale*<br><br>Validation: No content validity or reliability testing reported.<br><br>Number of questions: not stated.<br><br>Likert scale (1-5 most satisfied)<br><br>Questions related to:<br>Satisfaction with amount and quality of information presented, doctors' communication skills, patient's participation in the conversation.<br><br>A satisfaction scale was used to assess:<br>Satisfaction with the tape | No differences were found between the two groups in satisfaction with conversations.<br><br>**Mothers of babies with a poor outcome in the tape group were, however, significantly more satisfied with the conversations:**<br><br>**Interv Control Mean (95%CI)**<br>115(104-123.2) 100.5(94.1-109.4)<br><br>**p-value** 0.0051<br><br>Most (71-92%) of the mothers given the tapes stated that they helped their understanding, reminded them of what had been said, and helped their family to understand and recall information. | **No** | **1** |
| 9. Mitchell-DiCenso et al. (1996), Canada | Mothers and fathers/ 482 | Mean (SD)<br><br>Interv: 35.1 (4.5)<br><br>Control: 35 (4.3) | RCT | Intervention: **Clinical Nurse Specialist/ neonatal practitioner team (CNS/NP) care.**<br><br>Infants of intervention parents were assigned to be cared for by the Clinical nurse special/neonatal practitioner CNS/NP team during the day | ***Parent satisfaction with care*** | During admission period and post discharge (twice)<br><br>- On 5th day after admission (full survey)<br><br>- After discharge over the phone (only | *Satisfaction questionnaire (Validated)*<br><br>The study team developed and used the validated *Neonatal Index of Parent Satisfaction (NIPS)* questionnaire[17].<br><br>Number of questions: not stated. | **No statistically significant difference between groups.**<br><br>**Interv Control p-value**<br>**NIPS Mean** 140 139 0.67<br><br>**Difference in means**<br>1.0, CI (-3.6-5.6) | **No** | **2** |

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| | | / level III | | and by paediatric residents during the night.<br><br><u>Control:</u> Paediatric residents cared for infants of control parents around the clock. Neonatologists supervised both teams. | | questions related to satisfaction with discharge process)<br><br>No pre-intervention parent satisfaction data available for comparison. | NIPS score range (27-189); higher scores indicating greater satisfaction with care. | | | | |
| 10. Broyles et al. (1992), USA | Mothers /25 | Mean (SD)<br><br>Interv: 33.4 (4)<br><br>Flexible: 34 (4)<br><br>/ level III | RCT | <u>Intervention:</u> **Detailed consent.**<br><br>Mothers were given information about mechanical ventilation. Detailed risk/benefit disclosure was provided both verbally and in writing.<br><br><u>Control:</u><br>Mothers were given a brief verbal description about mechanical ventilation supplemented with detailed verbal and written disclosure if desired by them (flexible consent). | ***Maternal satisfaction with the information provided about mechanical ventilation*** | During babies' admission (once)<br><br>- 24-48 hours after the intervention<br><br>No pre-intervention parent satisfaction data available for comparison. | *An interview* evaluating maternal satisfaction with the information provided about mechanical ventilation.<br><br><u>Validation:</u> A psychiatrist with a special interest in interviewing techniques was consulted in designing and standardising this assessment.<br><br>A research nurse conducted the interview, "checking" each mother against one option regarding:<br>- Amount of information: Right amount-Too much-Too little<br><br>- Information made coping: More Difficult-Easier-No effect-Uncertain. | This study is measuring and comparing satisfaction with two different interventions (detailed vs flexible consent process), neither of which formally represent the usual routine care for all babies (no control).<br><br>**Small numbers. No data indicating statistical analysis conducted or evidence of statistically significant results.**<br><br>**Detailed** **Flexible**<br>**Right amount of information** 75% mothers 100%<br><br>**Too little information** 25% mothers<br><br>**Made coping easier** 67% mothers 69% | **No** | **3** |

## Table 2. Included Prospective Cohort Studies

**Prospective cohort studies by publication year**

| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
|---|---|---|---|---|---|---|---|---|---|---|
| 1. De Bernardo et al (2017), Italy | Mothers and Fathers /96 | Mean (SD)<br><br>Control: 34.2 (5.25)<br><br>Interv: 32.7 (5.25)<br><br>/ level III | Non-randomized, prospective cohort pilot study<br><br>*Unit level effect*: Two different time periods | Intervention: **FCC (Family-Centered Care).**<br><br>Parents had access to NICU for 8 hours/day. The NICU was widened and paediatric nurses taught parents procedures/practices for 10 days. Parents could observe clinical bedside rounds, hold meetings with the physicians, use the rooms and kitchen.<br><br>Control: Parents were permitted to visit their baby in NICU for 1 hour a day. | ***Parent satisfaction relating to 3 specific domains:***<br><br>1. Knowledge and Understanding<br><br>2. Communication and Collaboration<br><br>3. Privacy and confidentiality | During babies' admission (once)<br><br>- At discharge (pre-FCC cohort and post-FCC cohort)<br><br>No pre-intervention parent satisfaction data available for comparison (different parent groups pre and post intervention). | *Satisfaction questionnaire.*<br><br>Validation: The authors state the survey *"was designed and validated by Abdel-Latif et al"*. No content validity or reliability testing reported in the original paper.<br><br>9 questions<br><br>3 questions: Related to adequate and timely information about the baby's condition.<br><br>3 questions: Related to communication and collaboration with the healthcare team.<br><br>3 questions: Related ~~to respect~~ of patient privacy.<br><br>Likert (1 strongly disagree-5 strongly agree) | **7/9 individual statements in the parent satisfaction questionnaire scored higher in the FCC compared to the NFCC (statistically significant difference).**<br><br>Example statement:<br>*"I have received adequate information about my baby's condition and management."*<br><br>**Interv** **Control**<br>**Median** 5 (3.45-5) 4 (3-5)<br><br>**p-value** <0.05 | **No** | **1** |
| 2. Petteys et al. (2015), USA | Not stated/ 10 parents included in sample analysis | 24-36+ / level III | A prospective cohort design.<br><br>A feasibility study.<br><br>*Group level effect:* Intervention/ control groups<br><br>Post-intervention testing only | Intervention: **PC (Palliative care).**<br><br>PC nurses provided important continuity of care for NICU infants clinically requiring PC and at least weekly verbal support of parents. The PC service also coordinated family conferences, provided or requested orders to improve infant symptom management and comfort, and addressed parental coping and self-care. | ***Overall satisfaction with care received*** | During babies' admission (once)<br><br>- At discharge (or study closure for infants who remained hospitalised)<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>A researcher-created questionnaire based on extensive current literature review.<br><br>Validation: Partially reported. Authors stated content validity testing took place; no information on reliability testing provided.<br><br>1 question<br><br>Likert (1 extremely dissatisfied-4 to extremely satisfied). | **Parent satisfaction response numbers were small (n= 10), thus statistical comparison of parental satisfaction between cohorts was not possible.**<br><br>However, 100% of responding PC parents (n= 2) reported being "extremely satisfied" with care, whereas only 50% of responding usual care parents (n= 4) reported extreme satisfaction. | **No** | **3** |

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| | | | | Control: Usual clinical care for infants not requiring PC. | | | Optional free text (description of specific experiences impacting satisfaction with care) | | | |
| 3. Stevens et al. (2011), USA | Mothers /147. For the OPBY NICU, 58 surveys were returned. For the SFR NICU, 89 were returned | Mean (SD)<br><br>Control: 35 (4)<br><br>Interv: 34 (3)<br><br>/ level not stated | Cohort trial. This research was part of a large prospective evaluation.<br><br>*Unit level effect:*<br>Two different time periods | Intervention: **SFR (Single-family room) NICU for neonatal care.**<br><br>Parents could visit their baby, room-in, do kangaroo care and breastfeed at any time, in individual rooms (containing bed, desk, closet, telephone, chair, refrigerator for breast-milk storage).<br><br>Control: OPBY (Open-bay) NICU. The traditional open-bay NICU was typical of facilities built before 1980. All neonates, family members, staff, monitors, and equipment were visible for all neonates in each room. Portable partitions were placed around the incubator for breastfeeding and kangaroo care. | ***Parent satisfaction with different elements of NICU:***<br>*- Delivery*<br>*- Environment*<br>*- Nurses*<br>*- Physicians*<br>*- Discharge*<br>*- Personal*<br>*- Overall Assessment* | After babies were discharged (once)<br><br>- Mailed within 60 days of discharge of parents' infants from the NICU<br><br>No pre-intervention parent satisfaction data available for comparison (different parent groups pre and post intervention). | *Satisfaction questionnaire*<br><br>A questionnaire from Press Ganey Associates was used. Also included were three questions added by the investigators.<br><br>Validation: Partially reported. The original questionnaire was validated questionnaire but no content validity or reliability testing was reported regarding the 3 questions added by the study team.<br><br>42 questions in total (7 categories):<br>Delivery, Environment, Nurses, Physicians, Discharge, Personal,<br>Overall Assessment.<br><br>Likert (1 very poor-5 very good). | **Statistically significant improvement was found for the survey categories of Environment, Overall and the Total survey.**<br><br>Estimated numbers from report's figures as numbers not provided):<br><br>**Median SFR OPBY p-value**<br>Environment 4.7 3.7 <0.001<br>Overall 5 4.8 0.018<br>Total 4.7 4.5 0.045<br><br>16 items composite score for family-centered care:<br>4.4 4.0 0.017 | **Yes**<br><br>Former NICU parents were involved in all phases of planning for the new SFR NICU. | **1** |

## Table 3. Included "Other" non-Randomised Controlled Trials (non-RCT)

| "Other" Non-Randomised controlled trials (Non-RCT) by publication year | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 1. Kadivar et al. (2017), Iran | Mothers /68 | <=30 – 36<br><br>/ level not stated | Non-randomised, Convenience sampling.<br><br>*Group level effect:* Intervention/ control groups.<br><br>Pre and post-intervention testing. | Intervention: **Internet-based education.**<br><br>Mothers used an educational website set up by the research team (files and clips). Mothers could visit the website from 5:00-6:00 pm for 10 days. They were also allowed to use the website outside of the above hours and to report the duration of using the website to the researcher. Mothers had to use the website at least 3 times during 10 days, each time for at least 30 min.<br><br>Control: Mothers in the control group received the routine education provided in the NICU. | ***Maternal satisfaction*** | During babies' admission (twice)<br><br>- Day 1 of intervention<br><br>- Day 10 of intervention | *Satisfaction questionnaire (Validated)*<br><br>The *"What Being The Parent of a Baby is Like-Revised" Questionnaire (WBPL- Revised)* was used. The original English version by Pridham and Chang was translated to Persian.<br><br>11 questions<br><br>Total satisfaction score range (11–99) | There was a significant difference in the mean score of satisfaction between cases and controls while the mean score of satisfaction increased in both groups.<br><br>**Comparison of the mean score between the two groups showed that the level of satisfaction was significantly higher in the case group versus the control group.**<br><br>**Interv Control**<br>**before intervention**<br>**Mean (SD)** 81.62(13.50) 85.71(9.46)<br>**p-value** 0.993<br><br>**after intervention**<br>**Mean (SD)** 93.88 (5.38) 90.12 (7.78)<br><br>**p-value** 0.024 | **No** | **1** |

| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
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| 2. Kadivar et al. (2017), Iran | Mothers /70 | Mean (SD)<br><br>Control 31.6 (2.4)<br><br>Interv: 32.9 (3.1)<br><br>/ level not stated | Non-randomised, Convenience sampling.<br><br>*Unit level effect*: Two different time periods | Intervention: **Narrative writing.**<br><br>Mothers did narrative writing at least 3 times until the 10th day of admission.<br><br>Control: Mothers in the control group received the routine NICU treatment and care. | ***Mothers' satisfaction with medical care provided by physicians, medical students, and nurses during neonatal admission to the NICU*** | During babies' admission (twice)<br><br>- Day 3 of intervention<br><br>- Day 10 of intervention | *Satisfaction questionnaire (Validated)*<br><br>The *NIPS questionnaire* by Mitchell et al was used and translated to Persian.<br><br>24 questions (Likert scale)<br><br>Likert (1 always or not satisfied-7 never or completely satisfied). A higher score indicates more satisfaction. | **The satisfaction level of the mothers in the intervention group increased significantly during the study.**<br><br>The results of independent t test showed a significant difference in the satisfaction changes of the mothers on the 3rd and 10th day of NICU admission between intervention and control groups, indicating the effectiveness of narrative writing.<br><br>The results of paired t-test also showed a significant difference in the mean satisfaction level of the mothers between the 3rd and the 10th day in the intervention group.<br><br>**Interv Control**<br>**After intervention**<br><br>**Mean (SD)** 137 (15.2) 102.3 (25.6)<br><br>**p-value** 0.001 | **No** | **1** |
| 3. Garingo et al. (2016), USA | Not stated /9 | 23-39 / level III | Non-randomised, Convenience sampling.<br><br>*Group level effect:* Intervention/ control groups<br><br>Post-intervention group testing only | Intervention: **Tele-rounding.**<br><br>Infants of intervention parents were cared for by an OFFSN (off site neonatologist) present via a remote-controlled robot. The OFFSN assessed infants via the robot's integrated stethoscope, with nursing staff assistance. During routine hours the OFFSN was called to discuss any issues with the patient. Emergencies/out of hours were covered by an ONSN (on site neonatologist).<br><br>Control: Infants of control parents received ONSN care. The attending | ***Satisfaction with telemedicine*** | During babies' admission (once)<br><br>- At the time of discharge<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>Validation: No content validity or reliability testing reported.<br><br>Number of questions: not stated.<br><br>Likert (1 excellent-5 very poor). | **Only the intervention group was assessed and only post-intervention.**<br><br>The authors reported that the parents surveyed were *"satisfied with their experience. 100% responded that they felt comfortable talking to the OFFSN on the mobile robot and would allow their infant or themselves to be cared for by a physician via telemedicine in the future."* | **No** | **4** |

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| | | | | neonatologist made daily patient rounds with the NICU team. After patient rounds, the NICU staff, under the supervision of the attending neonatologist implemented the care plan. | | | | | | |
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 4. Globus et al. (2016), Israel | Mothers and fathers /Total surveys returned: 178 | ~40% in each group <32 / level III | Non-randomised, Convenience sampling.<br><br>*Unit level effect:*<br>Two different time periods | Intervention: **SMSi-Short Message Services Implementation.**<br><br>Parents were updated daily regarding the health status of their infant via SMS (short-message-services) from the Electronic Patient Record. All SMS messages were sent at 09:00am, including one-sentence sections with updated information (e.g. location of the infant's crib and current weight). Information regarding acute events/deterioration of the infant's medical condition was not included in the SMS, but was delivered personally to the parents in real time.<br><br>Control: Routine care pre-SMS implementation. | ***1. Parent satisfaction related to parent communication with the medical staff***<br><br>***2. Overall parent satisfaction with treatment and staff attitudes throughout hospitalisation.*** | During babies' admission (once)<br><br>- pre-SMS cohort and post-SMS cohort<br><br>No pre-intervention parent satisfaction data available for comparison (different parent groups pre and post intervention). | *Satisfaction questionnaire*<br><br>The *"Parents' attitudes regarding their experience during their infants' hospitalisation in the NICU"* questionnaire was used, as well as selected items from a literature review of similar questionnaires, including that by York Hospital and by Conner and Nelson.<br><br>Validation: No content validity or reliability testing reported.<br><br>Selected items related to four aspects of the NICU experience. 2 out of 4 directly assessed parent satisfaction:<br><br>1. Parental assessment of their communication with the medical staff.<br><br>Likert scale (1 do not agree at all-5 strongly agree)<br><br>2. Overall satisfaction with treatment and staff attitudes throughout hospitalisation.<br><br>Visual analog scale (scores range 0-10). Higher scores reflect greater satisfaction. | Overall, in both periods, parents expressed a high degree of satisfaction regarding the medical treatment, the information given and the communication with the medical staff. Overall satisfaction with treatment and with staff attitudes throughout hospitalisation was slightly greater in the post-SMS cohort but did not reach statistical significance.<br><br>**In the post-SMS cohort, a statistically significant improvement was noted regarding physician availability and patience, parental feelings of comfort in approaching the physicians and nurses, and regularly receiving information regarding the infants' medical status from the physicians.**<br><br>**Post SMS** **Pre SMS**<br>**Mean (SD)** 4.1 (1.0) 3.7 (1.3)<br>**p-value** 0.03<br>*Specific question: "I was pleased with the frequency with which I received information regarding my infant".*<br><br>Although improvement in all other categories was documented, it did not reach statistical significance. | **No** | **1** |

| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
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| 5.Kazemian et al. (2016), Iran | Mothers /220 newborns (assumed 220 mothers) | >37 / level not stated | Non-randomised, Convenience sampling.<br><br>*Group level effect:* Intervention/ control groups<br><br>Post-intervention testing only | Intervention: **Rooming-in care.**<br><br>Mothers and babies were admitted to a different atmosphere to the routine care. This facilitated the mothers and neonates with separate beds along with phototherapy devices and nursing clinical supervision.<br><br>Control: The routine care practiced in this neonatal unit supported partial stay of mothers beside their neonates, while sitting on chairs; however, most of the time the mother-infant dyad was separated. | ***Maternal satisfaction with the neonatal care services and hospital stay comfort*** | During babies' admission (once)<br><br>-Not stated exactly when<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>Validation: No content validity or reliability testing reported.<br><br>The authors state, *"a validated self-made questionnaire was employed, which was filled in by some trained midwives."* No further information on validation processes, number of questions or name of the questionnaire was provided.<br><br>Likert (5 very satisfied-1 dissatisfied). | **The level of satisfaction was significantly higher in the intervention group, compared to that in the control group.**<br><br>**Interv** **Control**<br>**Satisfaction %** 26.6 18.8<br><br>**p-value** 0.027 | **No** | **1** |
| 6. Van de Vijver and Evans (2015), UK | Not stated /105 | Not stated / not stated | Non-randomised, Convenience sampling.<br><br>*Unit level effect:* Three different time periods | Intervention: **Baby diary.**<br><br>Each parent received a communication diary on their infant's admission to the unit. Staff wrote-in infant status updates and kept an infant interaction log with parents. Parents wrote in memories and questions for staff to address during face-to-face communication.<br><br>Control: Routine care, before implementation of the diaries. | ***Satisfaction with communication from neonatal staff*** | During babies' admission (three times)<br><br>- On the day of babies' discharge at study baseline<br><br>- On the day of babies' discharge at 1 month<br><br>On the day of babies' discharge at 15 months | *Satisfaction questionnaire*<br><br>The study team designed a questionnaire, based on the Department of Health and the National Institute for Health and Care Excellence (NICE) quality standards for specialist neonatal care.<br><br>Validation: No content validity or reliability testing reported.<br><br>5 questions ("yes or no") | **Small numbers. No data indicating statistical analysis conducted or evidence of statistically significant results.**<br><br>*"I was receiving regular communication from staff"*<br>94% - 1 month post diary cohort<br>93% - 15 months post diary cohort<br>77% - pre diary cohort<br><br>*"My questions and concerns were being addressed"*<br>100% - 1 month post diary cohort<br>93% - 15 months post diary cohort<br>91% - pre diary cohort<br><br>"I feel more involved in my baby's care"<br>92% - 1 month post diary cohort<br>100% - 15 months post diary cohort<br>88% - pre diary cohort | **Yes.**<br><br>The intervention concept was created by the project leaders following analysis of baseline survey results and used after multi-disciplinary input and discussion with staff and parents. | **3** |
| 7. Voos and Park. (2014), | Not stated / 62 | Not stated / level III | Non-randomised, Convenience | Intervention: **OU (Open Unit) policy.** | ***Parent satisfaction with how much time*** | After babies were discharged (once) | *Single question (From a validated questionnaire)* | **Small numbers. No data indicating statistical analysis conducted or** | **Yes.**<br><br>The NICU has a | **3** |

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| USA | | | sampling.<br><br>*Unit level effect:* Two different time periods | Parents were allowed access to their baby 24 hours a day, 7 days a week.<br><br>Control: Parents pre-OU implementation received routine care. The unit was closed to parents during nurse change of shift in mornings and evenings. | ***parents get to spend with their baby*** | - After pre-OU parents were discharged<br><br>- After post-OU parents were discharged | The question *"Did you get to spend as much time as you wanted with your baby?"* was used from the NRC (National Research Corporation) Picker parent survey.<br><br>1 question ("yes or no") | **evidence of statistically significant results.**<br><br>*"Did you get to spend as much time as you wanted with your baby?" Yes.*<br><br>Pre OU 78% (18/23)<br>Post OU 92% (36/39) | Family-centered care committee including parents, which conducted this project. | |
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 8. Segre et al. (2013), USA | Mothers /23 | Mean (SD) 31.57 (5.30) / level III | For the outcome of parent satisfaction:<br><br>Non-Randomised, Convenience sampling.<br><br>*Group level effect:* Intervention/ control groups<br><br>Post-intervention group testing only | Intervention: **(LV) Listening visits.**<br><br>Mothers met with the LV provider for up to six 50-min LV sessions, conducted in a private hospital, every 2–3 days, within 1-month. Visits entailed greeting, debriefing, updating on current issues, working an agenda through listening and problem solving, and providing closure through summary.<br><br>Control: Women who did not meet the specific criteria (e.g. minimum score on depression scale) were not invited to join the treatment trial and received routine NICU care/support instead. | ***Satisfaction with the treatment and the outcome.*** | During babies' admission (once)<br><br>- Not stated exactly when<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>The *Client Satisfaction Questionnaire* was used.<br><br>Validation: Partially reported. Authors stated reliability testing took place; no information on content validity provided.<br><br>8 questions.<br><br>Format of questions: not stated | **Only the intervention group was assessed and only post-intervention.**<br><br>The authors reported:<br><br>*"The majority of women who received LVs were highly satisfied with the intervention".*<br><br>*"The average score for the Client Satisfaction Questionnaire was 29.91, comparable to levels of satisfaction reported by clients receiving depression treatment from a mental health professional."*<br><br>*"91.3% of our participants rated the quality of help they received as excellent."* | **No** | **4** |
| 9. Palma et al. (2012), USA | Not stated / 26 families returned the survey containing the satisf. measure) | Not stated / level II | Non-randomised, Convenience sampling.<br><br>*Unit level effect:* Two different time periods | Intervention: **YBDU (Your Baby's Daily Update). A daily parent update letter generated from the Electronic Medical Record (EMR).**<br><br>Parents were given daily YBDU reports, printed automatically from the EMR. The YBDU included information about an | ***Satisfaction with YBDU*** | During babies' admission (once)<br><br>- Not stated exactly when<br><br>No pre-intervention parent satisfaction data available for comparison (different parent groups pre and post | *Satisfaction questionnaire*<br><br>A questionnaire including items regarding adoption of and satisfaction with YBDU was used.<br><br>Validation: No content validity or reliability testing reported.<br><br>Number and format of | **Only the intervention group was assessed and only post-intervention.**<br><br>The authors reported:<br>*"When asked to rate the statement "I like receiving Your Baby's Daily Update", 96% of families who used YBDU as an information source responded with the highest rating, "always"."* | **No** | **4** |

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| | | | | infant's status during the past 24 hours and a hand-written update by the infant's care provider.<br><br>Control: Parents received routine care and usual verbal updates (6 months pre- adoption of YBDU). | | intervention). | questions: not stated. | | | |
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 10. Voos et al. (2011), USA | Not stated /28 | Not stated / level not stated | Non-randomised, Convenience sampling.<br><br>*Unit level effect:*<br>Two different time periods | Intervention: **Family-centered rounds (FCRs).**<br><br>Parents were invited to attend rounds and choose their level of involvement (attend every day/not at all/periodically). For confidentiality concerns, parents were asked to step outside while rounds of others' infants took place. The staff augmented FCRs by meeting with parents again after rounds if needed.<br><br>Control: Parents received routine care. Prior to FCR implementation parents were asked to leave the unit during rounds. | ***Global satisfaction with the NICU experience*** | During babies' admission (twice)<br><br>- Prior to FCR<br><br>- 6 months after starting FCR | *Satisfaction questionnaire (Validated)*<br><br>*The NIPS* questionnaire.<br><br>24 questions: looking at satisfaction in different areas of the NICU (medical caregivers, communication, tests, and procedures).<br><br>Likert scale (1-7 points). | **A subset of NIPS items related to communication (i.e. being kept informed as to changes in the infant's condition, meeting with physicians, and information about long-term expectations) yielded a significant increase from pre to post FCR scores.**<br><br>**post-FCR pre-FCR p-value**<br>**NIPS score** 5.5 4.4 <0.01<br><br>The average score on the NIPS did not change significantly. | **No** | **1** |
| 11. Weiss et al. (2010), USA | Mothers /84 | Mean (SD)<br><br>Pre-interv group: 32 (4.4)<br><br>Post-interv group: 32 (9)<br><br>/ level III | Non-randomised, Convenience sampling<br><br>*Unit level effect:*<br>Two different time periods | Intervention:<br>**An intervention to increase PMP (Principal Medical Providers) availability and communication frequency.**<br><br>(1) A brief education module for PMPs was introduced (2) parents received a contact card with PMP names, job descriptions and contact information (3) a poster of the faces, names and titles of the PMPs was | ***Parent satisfaction with physician and nurse practitioner communication*** | During babies' admission (twice)<br><br>- Pre-intervention<br><br>- Post-intervention | *Satisfaction Questionnaire (Validated)*<br><br>A pilot survey written by Press Ganey and the Picker Institute was used and revised based on parent responses.<br><br>6 open-ended questions (Quantity of communication)<br><br>6 Likert scale questions (range questions (Availability, understanding, reciprocity, empathy, overall satisfaction) | **Overall satisfaction, based on the ordinal analysis of the five-point Likert scale, was significantly higher after the intervention (P<0.01).**<br><br>**Overall satisfaction, dichotomised into a satisfied subgroup and a dissatisfied subgroup for each cohort, was also significantly increased after the intervention.**<br><br>**post –interv pre-interv**<br>**Very satisfied/** 97%(32/33)74%(37/50) | **No**<br><br>Authors stated that only after trialing the intervention many parents (both satisfied and unsatisfied) gave suggestions to improve it. | **1** |

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| | | | | placed at NICU entrance.<br><br><u>Control:</u> Parents received routine care in the pre-intervention cohort, without the above. | | | | **p-value** <0.01 | | |
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 12. Foster et al. (2008), Australia | Mothers and fathers /93<br><br>5 Special Care Nurseries | Mean (SD)<br><br>Headbox: 36.5 (2.6)<br><br>CPAP: 36 (3)<br><br>/level I | Non-randomised, Convenience sampling<br><br>*Group level effect:* Intervention 1/ intervention 2 groups<br><br>Post intervention testing only | <u>Intervention 1:</u> **Infants received headbox oxygen treatment for respiratory distress.**<br><br><u>Intervention 2:</u> **Infants received continuous oxygen positive airway pressure (CPAP) treatment for respiratory distress.** | ***Satisfaction with treatment (i.e/headbox oxygen or CPAP)*** | During babies' admission (once)<br><br>- Within 5 days of the babies' admission<br><br>No pre-intervention parent satisfaction data available for comparison. | *Single question*<br><br><u>Validation:</u> No content validity or reliability testing reported.<br><br>1 likert scale question (1 not at all satisfied-5 extremely satisfied). | **Parents with babies receiving CPAP rated their satisfaction with the baby's treatment statistically significantly higher than the headbox group mean rating.**<br>**Headbox** **CPAP**<br>**Mean (SD)** 3.71 (1.31) 4.51 (0.79)<br>**p-value** 0.001<br><br>The CPAP group averaged between *very and extremely satisfied* compared with parents of babies receiving headbox, who averaged between *satisfied and very satisfied ratings.* | **No** | **1** |
| 13. Byers et al. (2006), USA | Only mothers reported /35 | Preterm infants<br><br>Mean (SD)<br><br>Control: 28.9 (3.44)<br><br>Interv: 28.6 (3.37)<br><br>/ level II/III | For the outcome of parent satisfaction:<br><br>Non-randomised, Convenience sampling<br><br>*Group level effect:* Intervention/ control groups<br><br>Post-intervention testing only | <u>Intervention:</u> **Infants received individualised, developmentally supportive family-centered care.**<br><br>Infants received care within the framework and philosophy of individualised, developmentally supportive family-centered interventions.<br><br><u>Control:</u> Infants received the traditional NICU standard of care. | ***Parent satisfaction relating to:***<br>*- parental perceptions of staff caring*<br>*- education received*<br>*- preparation for the parental role*<br>*- overall satisfaction with the NICU experience* | During babies' admission (once)<br><br>- On the day before discharge<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>The *NICU's parental satisfaction tool* was used.<br><br><u>Validation:</u> Partially reported. Authors stated content validity testing took place, but "because of the disparate nature of the items, survey reliability was not assessed".<br><br>11 questions<br><br>Likert scale (1-5 strongly agree) | **Independent t-test analysis of parent satisfaction/perception scores showed no significant difference between groups.**<br><br>Example statement: "*I was satisfied with the car my baby and I received in the NICU*"<br>**Interv** **Control**<br>**Mean (SD)** 4.94(0.23) 4.71(0.47)<br>**p-value** 0.064<br><br>Both groups reported very high satisfaction with their NICU experience (4.4-5.0) | **No** | **2** |
| 14. Mills et al. (2006), USA | Not stated/ not stated<br><br>Parents of infants from 6 hospitals | Not stated / level not stated | Implementation project<br><br>Plan Do Study Act (PDSA) quality improvement testing | <u>Intervention:</u> **5 potentially better practices (PBPs) in the area of discharge planning.**<br><br>The project team iteratively implemented 5 PBPs:<br>1. Created an easy-to-use, | ***General satisfaction***<br>*- with care*<br>*- parents' feelings about preparedness for discharge*<br>*- ability and confidence in feeding* | During babies' admission (4 times)<br><br>- Not reported exactly when | *Satisfaction questionnaire*<br><br>The Internet-based parent satisfaction survey *"howsyourbaby.com"* that was developed especially for this NICU population was used.<br><br><u>Validation:</u> No content | Through multiple rapid-cycle projects, the project's collaborative group made changes within the 5 PBP plans.<br><br>**Parent satisfaction measures were used to longitudinally monitor the changes made, rather** | **No** | **3** |

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| | | | | easy-to-access discharge planning tool kit.<br>2. Restructured communication tools and processes to reflect a "plan for the day, the stay, and the way" to discharge.<br>3. Maximised the impact and use of caregiver educational tools, and updated materials and delivery systems for caregiver education.<br>4. Used various continuous quality improvement tools and processes to ensure parent/caregiver and staff satisfaction.<br>5. Analysed and enhanced interactions with and transfers into the community.<br><br>Control: N/A. No discrete control group. PDSA quality improvement methodology was applied to parent participants. | *- familiarity with their infant*<br>*- feeling like a parent*<br>*- participation in care*<br>*- adequacy of information from staff about medical and care issues* | | validity or reliability testing reported.<br><br>Number and format of questions: not stated. | **than make direct group comparison. No data indicating statistical analysis conducted or evidence of statistically significant results.**<br><br>Parent satisfaction survey results (all centers combined) were high across 4 measurement quartiles. No specific interquartile analysis was reported.<br><br>Parent readiness for discharge was high at the beginning and throughout the collaborative. Parents' receiving *"just the right amount of information"* regarding car seat trials and safe sleep demonstrated some variability throughout the collaborative. | | |
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 15. Wielenga et al. (2006), The Netherlands | Mothers and fathers / 46 | Mean (SD)<br><br>Control: 28.5 (26.0–29.9)<br><br>Interv: 28.3 (25.6-29.9)<br><br>/ level III | Non-randomised, Convenience sampling<br><br>*Unit level effect:*<br>Two different time periods | Intervention: **The Newborn Individualised Developmental Care and Assessment Program (NIDCAP).**<br><br>Infants received care according to NIDCAP principles and parents were taught how to provide it. Caregiving plans were designed based on the infant's current developmental stage, medical condition and family needs. Caregivers learnt to watch sensitively and note the infant's reactions to different types of handling and | ***Parent satisfaction relating to:***<br>*-Overall rating*<br>*-Care of the baby*<br>*-Communication with staff*<br>*-Involvement in care -Being prepared -Support*<br>*-Being a parent*<br>*-Being near your baby -Total score* | After babies were discharged (on day of discharge/ transfer)<br><br>- Pre NIDCAP cohort<br><br>- Post NIDCAP cohort | *Satisfaction questionnaire (Validated)*<br><br>The *NICU-PSF* was used and translated from English to Dutch.<br><br>62 questions<br><br>Closed and open-ended questions.<br><br>Different rating scales used (5-point rating scale from "extremely satisfied" to "not at all satisfied" or "excellent" to "poor").<br><br>Total score range (50-243 points) | **The intervention group's mean total score was significantly higher than the control.**<br><br>**Interv Control**<br>**Mean (SD)**<br>185.67(17.74) 174.04(20.98)<br><br>**p-value** 0.041<br><br>Almost all separate concepts showed an increase in their mean scores. The concept of *"being a parent"* had a slightly lower mean score (9.39, SD = 1.73) in the intervention group than in the control group (9.78, SD = 2.09).<br><br>**The concept of *"preparedness"* showed statistically significant difference:** | **No** | **1** |

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| | | | | care, making continuous adjustments.<br><br>Control: Infants received traditional neonatal care practiced at that time. | | | | **Interv Control**<br>**Mean** 16.38 13.83<br>**p-value** 0.038 | | |
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 16. Penticuff and Arheart. (2005), USA | Dyads (both parents or mother with her support person)/ 122 mothers<br><br>Results based only on mothers' data. | Not stated / Level III | A repeated measures design<br><br>- First 2 years (control group data collection)<br><br>- Year 3 (staff training)<br><br>- Year 4 (implementing the intervention)<br><br>- Year 5 (collecting data from the intervention group)<br><br>*Unit level effect:* Two different time periods | Intervention: **The Newborn Individualised IPC- CPM intervention (Infant Progress Chart) - (Care Planning Meetings).**<br><br>Both the mother and father (or the mother and her designated support person) were shown how to use the Infant Progress Chart and attended 3 Care Planning Meetings (with neonatologists/Neonatal Nurse Practitioners).<br><br>Control: During the control phase, professionals carried out usual communication and interaction with control group parents. | ***Satisfaction with participation in decision making* was measured by 5 collaboration indices:**<br><br>Satisfaction with<br>(1) Care<br>(2) Relationships with professionals<br>(3) Decision input<br>(4) The process of decision making<br>(5) Decisions made | During babies' admission (three times)<br><br>- Within 0–3 days<br><br>- 9– 12 days<br><br>- 25–28 days of an infant's admission to the NICU | *Three satisfaction questionnaires*<br><br>1. Two subscales of the investigator-designed *"Parents' Understanding of Infant Care and Outcomes Questionnaire"* were used to measure Satisfaction with Care (1).<br><br>Validation: Partially reported. Authors stated content validity testing took place; no information on reliability testing provided.<br><br>30 questions.<br><br>Five-point Likert scale.<br><br>2. A subscale of the investigator-designed *"Relationships with Professional and Decision Input Questionnaire"* was used to measure Satisfaction with relationships (2).<br><br>Validation: Partially reported. Authors stated content validity testing took place; no information on reliability testing provided.<br>12 questions.<br><br>Five-point Likert scale<br><br>3. Validated.<br>The *"Collaboration and Satisfaction About Care Questionnaire"* developed by Baggs, was used to measure Satisfaction with decision input (3), with | **The intervention group was more satisfied with the amount of decision input they had (3) and with the process by which medical decisions were made (4).**<br><br>**Interv Control p-value**<br>Decision input amount (3)<br>**Mean** 33.44 30.05 0.058<br><br>Process of decision making (4)<br>**Mean** 120.20 104.95 0.012<br><br>There were no statistically significant differences between control and intervention groups in satisfaction with their infants' care (1), with relationships with NICU professionals (2) and with the decisions made for infant treatment (5). | **No** | 1 |

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| | | | | | | | decision process (4) and with decisions made (5).<br><br>9 questions.<br><br>7-point scale, (1 strongly disagree -7 strongly agree) | | | |
| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
| 17. Byers et al. (2003), USA | Mothers/ 19 | Mean (SD)<br><br>Control: 29 (2.00)<br><br>Interv: 28.9 (2.42)<br><br>/ level II-III | For the outcome of parent satisfaction:<br><br>Non-randomised, Convenience sampling<br><br>*Group level effect:* Intervention/ control groups<br><br>Pre and post-intervention testing | Intervention: **Co-bedding premature multiple-gestation infants in incubators.**<br><br>Infants were nursed in the same incubator using a co-bedding protocol (e.g. recording all of the care provided to one infant before providing care to the second infant)<br><br>Control: Single-bedding premature multiple-gestation infants in incubators. | ***Parent satisfaction related to:***<br>*- staff concern*<br>*- support of family*<br>*- staff explanations*<br>*- infant environment,*<br>*- comfort with feeding*<br>*- kangaroo care encouragement*<br>*- staff explanation of signs of infant stress*<br>*- visiting schedule*<br>*- overall satisfaction with the NICU experience* | During babies' admission (twice)<br><br>- At baseline<br><br>- 5 days later | *Satisfaction questionnaire*<br><br>The NICU's standard parental satisfaction tool was used.<br><br>Validation: Partially reported. Authors stated content validity testing took place, but because of the disparate nature of the items, survey reliability could not be assessed.<br><br>11 questions.<br><br>5-point Likert-type scale. | **The only significant difference for a post-intervention item was a higher score for the item "Attempts were made to create a quiet environment for my baby."**<br><br>**Interv Control p-value**<br>**Mean** 4.80 3.89 0.033<br><br>Independent t-tests comparing the co-bedded and control group parental scores found no significant differences in their parental satisfaction scores, except for higher baseline parental satisfaction scores (p=0.029) in the co-bedded group. | **No** | **1** |
| 18. Polizzi et al. (2003), USA | Mothers and fathers/ 33 | Mean (SD)<br><br>Control: 32.97 (1.9)<br><br>Interv: 33.08 (1.31)<br><br>/ level III | A retrospective, comparative, descriptive design.<br><br>*Unit level effect* | Intervention: **Co-bedding multiple-gestation infants in the NICU.**<br><br>Multiple-gestation infants were nursed in the same incubator or crib. The intervention was evaluated retrospectively after implementation of a co-bedding practice protocol.<br><br>Control: Traditionally-bedded group (babies were routinely placed in separate incubators or cribs) | ***Parental satisfaction as measured by 9 questions relating to parent perceptions and their baby's care*** | After babies were discharged (once)<br><br>- All parents were mailed the survey. A second survey was sent to those who did not respond after 2 months<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>The *parental perception/ satisfaction tool* was used.<br><br>Validation: Partially reported. Authors stated content validity testing took place; no information on reliability testing provided. 6/9 questions were from a similar tool that was validated by the Vermont Oxford NICU Quality Improvement Initiative.<br><br>9 questions (such as *"I was satisfied with the care my babies received in the hospital").*<br><br>Likert (1 strongly disagree- 5 strongly agree) | Mothers reported overall satisfaction with the NICU care and staff, as well as adequacy of their ability to care for their infants after discharge, with scores ranging from 4.19 to 4.71.<br><br>**The only survey item score that was significantly different between groups was for the item *"I was encouraged by the hospital staff to bond with my babies."***<br><br>**Interv Control p-value**<br>**Mean** 4.71 4.36 0.049 | **No** | **1** |

| Author (Date), Country | Parents' gender/ sample Size | Infant Gestation age (weeks) /NICU level | Study design | Intervention | Outcome measures | Timing of measurement | Method of measurement | Results | Parent co-design? | Improved parent satisfaction? |
|---|---|---|---|---|---|---|---|---|---|---|
| 19. Legault and Goulet. (1995), Canada | Mothers/ 61 completed both tests | Mean (range)<br><br>30 (24-35)<br><br>/ level II | Time-series design<br><br>*Group level effect:* Same group exposed to both methods with post-method testing only. | Intervention: **Kangaroo method of removing an infant from an incubator.**<br><br>Mothers were taught the "kangaroo method" (skin-to-skin contact): infant wears a diaper/head cap and is placed in a vertical position on the parent's bared chest. A blanket covers the infant and the parent's clothing is fastened around the infant. The parent sits in a rocking chair, inclined so that the infant's head is at 60'.<br><br>Control: Traditional method. Newborns wearing a diaper and a head cap, are wrapped in a blanket and placed in their parent's arms. | ***Mothers' satisfaction with:***<br>*- Each method of removing an infant from incubator*<br>*- Her feelings after each method* | During babies' admission (twice)<br><br>- After the intervention<br><br>- After the control method<br><br>No pre-intervention parent satisfaction data available for comparison. | *Satisfaction questionnaire*<br><br>The *"Maternal Satisfaction Questionnaire"* was used. It was developed by integrating components described by Affonso et al and the clinical experience of the investigators.<br><br>Validation: Partially reported. Authors stated content validity testing took place; no information on reliability testing provided.<br><br>15 questions<br><br>Likert (1 very much-5 don't know)<br><br>An open-ended question invited the mother to list and explain anything else related to her experience. | **Regardless of the method tested, mothers expressed high levels of satisfaction (it was the first time since giving birth that they could hold their infants).**<br><br>Three statements proved more powerful in discriminating between the methods:<br><br>**Rated higher after the kangaroo method test:**<br>*- "I like the contact with my baby's skin"*<br>(p=0.0001)<br><br>**Rated higher after the traditional method test:**<br>*- "I like to talk to and whisper to my baby" (p = 0.015)*<br>*- "I looked into my baby's eyes and stared at his/her face" (p=0.0001)* | **No** | **1** |

*Tables 1-3: The number in the last column illustrates each intervention's reported effect on parent satisfaction:*

*1. Parent satisfaction was statistically significantly higher in the intervention group;*

*2. Parent satisfaction was not reported to be statistically significantly different in the intervention group;*

*3. Unclear if parent satisfaction improved (small study numbers and/or no statistical analysis performed);*

*4. Only the intervention group was assessed*

### 4.3.2 Parent satisfaction

#### 4.3.2.1 Outcome measures

All 32 studies reported they measured parent satisfaction as an *a priori* outcome. Only one study confirmed this through a protocol, that was however registered retrospectively. Overall 18/32 (56%) of studies (4/10, 40% RCT and 14/22, 64% non-RCT) reported a higher level of parent satisfaction with the intervention studied. Multiple different outcome measures within the domain of parent satisfaction were used; I grouped these into 4 categories: i) Parent satisfaction (no additional description); ii) Parent satisfaction with neonatal care; iii) Parent satisfaction related to specific components such as communication, staff or information; iv) Parent satisfaction with a specific intervention.

#### 4.3.2.2 Timing of measurement

Parent satisfaction was most commonly measured *'during infant admission only'* (24 studies; between 1-4 times), followed by *'after infant discharge only'* (5 studies; 1 time) and '*both during admission and after discharge'* (3 studies; between 1-3 times). In the majority of studies (19/32, 59%) pre-intervention parent satisfaction measurements were not conducted in the same parent groups that had post-intervention measurements (i.e. they did not record paired parent data for satisfaction). Instead, impact of interventions was determined by comparing intervention/control group measurements in different time periods *('unit-level effect'*) (Tables 1-3).

#### 4.3.2.3 Method of measurement

Parent satisfaction was assessed using 32 different methods: 29 different surveys, 2 different single questions, and by structured interview in 1 study; in total 334 different questions were used to assess parent satisfaction. Only 6/29 (21%) of surveys were reported to be fully validated; 23/29 (79%) surveys were partially or completely unvalidated. The most commonly used survey was the validated 'Neonatal Index of Parent Satisfaction' (NIPS) (35) survey (3 studies).

### 4.3.3 Interventions and impact on parent satisfaction

I grouped included studies into 5 intervention themes: parent involvement (14 studies); information provision/communication (8 studies); clinical care (7 studies); parent emotional support (2 studies); other (1 study). Parent involvement interventions were more commonly assessed in non-RCTs (9 studies) compared to RCTs (5 studies).

I categorised interventions as *'effective*' or '*not effective'* based on whether a statistically significant difference between intervention and control groups was reported for parent satisfaction (Tables 4, 5). None of the studies reported significantly lower parent satisfaction in the intervention group compared to the control group. I classified studies as *'unclear if effective'* if they included small sample numbers or if statistical analysis was not performed (Table 6). Finally, I highlighted studies where '*only the intervention group was assessed and only post-intervention',* where comparison to a control group was not undertaken (Table 7).

Overall, 18/32 studies (56%) reported higher parent satisfaction in the intervention group; 4/10 RCT and 14/22 non-RCT. The intervention theme where higher satisfaction was most consistently reported was parent involvement (10/14 studies). Due to the heterogeneity of outcome measure scales quantitative synthesis and meta-analysis was not possible.

**Table 4. "*Effective"* interventions in themes**

| **Interventions by theme and publication year** | **Study type** |
|---|---|
| **Theme: Parent involvement** | |
| More NICU access, parents on ward rounds, education **(De Bernardo et al, Italy, 2017)** | Non-RCT |
| Rooming-in care **(Kazemian et al, Iran, 2016)** | Non-RCT |
| Parental Presence at Clinical Bedside Rounds **(Abdel-Latif et al, Australia, 2015)** | **RCT** |
| More NICU access, care involvement, education **(Bastani et al, Iran, 2015)** | **RCT** |
| Education re: pain management **(Franck et al, UK, 2011)** | **RCT** |
| Single-family NICU rooms **(Stevens et al, USA, 2011)** | Non-RCT |
| Family-centered rounds **(Voos et al, USA, 2011)** | Non-RCT |
| Newborn Individualised Developmental Care and Assessment Program (NIDCAP) **(Wielenga et al, Netherlands, 2006)** | Non-RCT |
| Infant Progress Charts filled by parents and 3 Care Planning Meetings **(Penticuff and Arheart. USA, 2005)** | Non-RCT |

| | |
|---|---|
| Kangaroo care **(Legault and Goulet, Canada, 1995)** | Non-RCT |
| **Theme: Information provision / communication** | |
| Internet-based education **(Kadivar et al, Iran, 2017)** | Non-RCT |
| Daily SMS from Electronic Patient Record **(Globus et al, Israel, 2016)** | Non-RCT |
| Staff education, staff contact card given to parents, staff poster at NICU reception **(Weiss et al, USA, 2010)** | Non-RCT |
| Provision of taped conversations with neonatologists to mothers **(Koh et al, Australia, 2007)** | **RCT** |
| **Theme: Clinical care** | |
| Provision of Headbox oxygen to infants for respiratory distress versus b. Provision of CPAP to infants for respiratory distress **(Foster et al, Australia, 2008)** | Non-RCT |
| Co-bedding infants in incubators (prospective) **(Byers et al, USA, 2003)** | Non-RCT |
| Co-bedding infants in incubators (retrospective) **(Polizzi et al, USA, 2003)** | Non-RCT |
| **Theme: Parent emotional support** | |
| Narrative writing **(Kadivar et al, Iran, 2017)** | Non-RCT |

*Table 4. Interventions where parent satisfaction was reported to be statistically significantly higher in the intervention group. RCT: Randomised Controlled Trial; Non-RCT: Non-Randomised Controlled Trial.*

## Table 5. "*Ineffective*" interventions in themes

| **Interventions by theme and publication year** | **Study type** |
|---|---|
| **Theme: Parent involvement** | |
| Provision of Massage to infants with auditory, tactile, visual, and vestibular stimulation versus b. Kangaroo care **(Holditch-Davis et al, USA, 2013)** | **RCT** |
| Individualised, developmentally supportive family-centered care interventions **(Byers et al, USA, 2006)** | Non-RCT |
| **Theme: Information provision / communication** | |
| Sharing information obtained from parent interviews with the primary NICU provider **(Clarke-Pounder et al, USA, 2015)** | **RCT** |
| **Theme: Clinical care** | |
| Clinical Nurse Specialist/ neonatal practitioner team care **(Mitchell-DiCenso et al, Canada, 1996)** | **RCT** |
| **Theme: Other** | |
| Free Parking **(Northrup et al, USA, 2016)** | **RCT** |

*Table 5. Interventions where parent satisfaction was not reported to be statistically significantly different in the intervention group; RCT: Randomised Controlled Trial; Non-RCT: Non-Randomised Controlled Trial.*

**Table 6. *"Unclear if effective"* interventions in themes**

| Interventions by theme and publication year | Study type |
|---|---|
| **Theme: Parent involvement** | |
| Open Unit policy: 24/7 NICU access **(Voos and Park, USA, 2014)** | Non-RCT |
| Touch and massage for 7 days **(Livingston et al, USA, 2009)** | **RCT** |
| **Theme: Information provision / communication** | |
| Clinical staff enter updates in baby diary **(Van de Vijver and Evans, UK, 2015)** | Non-RCT |
| Detailed information provided during consenting **(Broyles et al, USA, 1992) RCT** | **RCT** |
| **Theme: Clinical care** | |
| Palliative clinical care to infants and weekly verbal support to parents by palliative care team **(Petteys et al, USA, 2015)** | Non-RCT |
| Five potentially better practices in the area of discharge planning (Discharge Planning toolkit; New communication process; Updated parent education materials; Use of QI tools for parent satisfaction; Improved interactions with community team)**(Mills et al, USA, 2006)** | Non-RCT |

*Table 6. Interventions where small study numbers and/or no statistical analysis performed; RCT: Randomised Controlled Trial; Non-RCT: Non-Randomised Controlled Trial.*

**Table 7. Interventions in themes where "only the intervention group was assessed and only post-intervention"**

| Interventions by theme and publication year | Study type |
|---|---|
| **Theme: Information provision / communication** | |
| Daily parent update letter from Electronic Patient Record **(Palma et al, USA, 2012)** | Non-RCT |
| **Theme: Clinical care** | |
| Tele-rounding robot, off-site neonatologist **(Garingo et al, USA, 2016)** | Non-RCT |
| **Theme: Parent emotional support** | |
| Listening visits: 6 counselling-type sessions in 1 month (50 min each) **(Segre et al, USA, 2013)** | Non-RCT |

### 4.3.4 Parent input into design of interventions

Five studies (5/32, 16%) reported involving parents in intervention design, of which two reported improvement of parent satisfaction. The number of

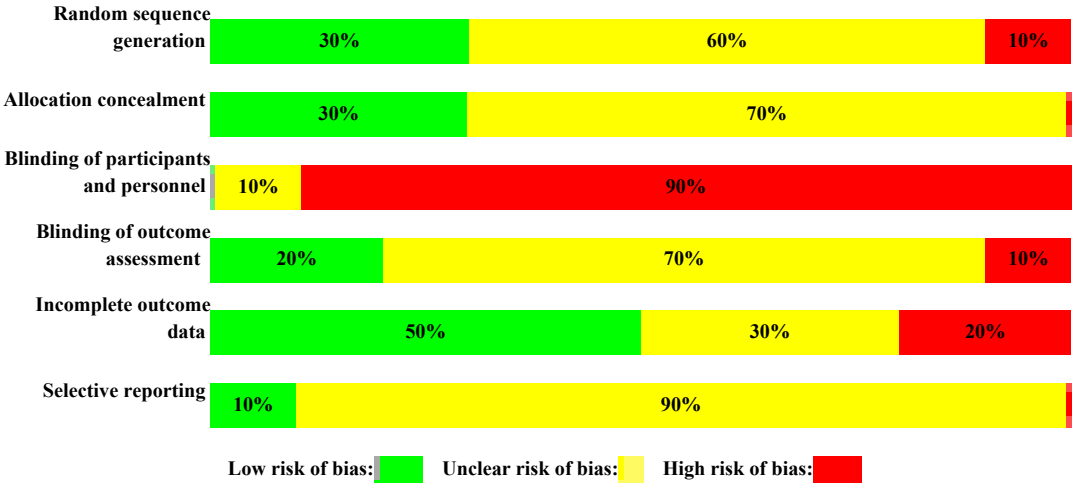
included studies was too small to estimate any effect of parent co-design on the success of interventions at study level.

### 4.3.5 Methodological quality

For the majority of RCTs key study characteristics, such as randomisation, allocation concealment and blinding of outcome assessment, were either not stated or unclear (Figure 5). Only one RCT had an available study protocol (retrospectively registered) and none described blinding of study participants and/or personnel. All RCT scored a high/unclear risk of bias in at least 4/6 Cochrane tool domains, except for one, which scored a high/unclear risk in 3/6 categories.

**Figure 5. Risk of Bias Cochrane tool assessment (RCT)**

| Author by publication year | Random sequence generation | Allocation concealment | Blinding of participants and personnel | Blinding of outcome assessment | Incomplete outcome data | Selective reporting |
|---|---|---|---|---|---|---|
| 1. Northrup (2016) | ? | + | - | ? | + | ? |
| 2. Abdel-Latif (2015) | + | + | - | - | - | ? |
| 3. Bastani (2015) | ? | ? | - | ? | + | ? |
| 4. Clarke-Pounder (2015) | ? | ? | - | ? | + | ? |
| 5. Holditch-Davis (2013) | + | + | - | + | ? | ? |
| 6. Franck (2011) | - | ? | - | ? | - | + |
| 7. Livingston (2009) | ? | ? | - | ? | + | ? |
| 8. Koh (2007) | ? | ? | - | ? | ? | ? |
| 9. Mitchell-DiCenso (1996) | + | ? | ? | ? | ? | ? |
| 10. Broyles (1992) | ? | ? | - | + | + | ? |



I assessed 21/22 non-RCT studies using the ROBINS-I tool (33), excluding the 'implementation project'; I was unable to use the *Standards for Reporting Implementation Studies (StaRI) Statement Tool* (36) for assessing the implementation project, as the reporting was incomplete. All 21 studies were assessed as having an overall *serious* risk of bias and 7/21 of studies (33%) were further categorised as having *critical* risk of bias (Figure 6). Blinding of participants, personnel and outcome assessment was poorly reported across all non-RCT and no study reported a published study protocol. None of the included non-RCT measured or corrected for important parent/infant confounding variables, or other relevant neonatal unit co-interventions taking place at the same time as the intervention.

**Figure 6. ROBINS-I risk of bias assessment (Non-RCT)**

| Author<br><br>by publication year | Bias due to confounding | Bias in selection of participants into the study | Bias in classification of interventions | Bias due to deviations from intended interventions | Bias due to missing data | Bias in measurement of outcomes | Bias in selection of the reported result | OVERALL risk of bias |
|---|---|---|---|---|---|---|---|---|
| 1. De Bernardo (2017) | SERIOUS | LOW | LOW | SERIOUS | LOW | SERIOUS | SERIOUS | SERIOUS |
| 2. Kadivar (2017) *Internet-based education* | SERIOUS | LOW | LOW | SERIOUS | LOW | SERIOUS | MODERATE | SERIOUS |
| 3. Kadivar (2017) *Narrative writing* | SERIOUS | SERIOUS | LOW | SERIOUS | LOW | SERIOUS | MODERATE | SERIOUS |
| 4. Garingo (2016) | CRITICAL | LOW | LOW | SERIOUS | SERIOUS | SERIOUS | SERIOUS | CRITICAL |
| 5. Globus (2016) | SERIOUS | LOW | LOW | NO INFO | SERIOUS | SERIOUS | SERIOUS | SERIOUS |
| 6. Kazemian (2016) | SERIOUS | NO INFO | LOW | SERIOUS | NO INFO | SERIOUS | SERIOUS | SERIOUS |
| 7. Petteys (2015) | SERIOUS | LOW | LOW | SERIOUS | MODERATE | SERIOUS | MODERATE | SERIOUS |
| 8. Van de Vijver (2015) | CRITICAL | LOW | LOW | SERIOUS | MODERATE | SERIOUS | MODERATE | CRITICAL |
| 9. Voos (2013) | CRITICAL | LOW | LOW | SERIOUS | NO INFO | SERIOUS | SERIOUS | CRITICAL |
| 10. Segre (2013) | CRITICAL | NO INFO | LOW | SERIOUS | SERIOUS | SERIOUS | MODERATE | CRITICAL |
| 11. Palma (2012) | CRITICAL | NO INFO | LOW | SERIOUS | SERIOUS | SERIOUS | CRITICAL | CRITICAL |
| 12. Stevens (2011) | SERIOUS | LOW | LOW | SERIOUS | SERIOUS | SERIOUS | MODERATE | SERIOUS |
| 13.Voos (2011) | SERIOUS | LOW | LOW | SERIOUS | SERIOUS | SERIOUS | MODERATE | SERIOUS |
| 14. Weiss (2010) | SERIOUS | LOW | LOW | SERIOUS | LOW | SERIOUS | MODERATE | SERIOUS |
| 15. Foster (2008) | SERIOUS | CRITICAL | LOW | SERIOUS | SERIOUS | SERIOUS | MODERATE | CRITICAL |
| 16. Byers (2006) | SERIOUS | LOW | LOW | SERIOUS | SERIOUS | SERIOUS | MODERATE | SERIOUS |
| 18. Wielenga (2006) | SERIOUS | LOW | LOW | SERIOUS | LOW | SERIOUS | MODERATE | SERIOUS |
| 19. Penticuff (2005) | SERIOUS | LOW | LOW | SERIOUS | LOW | SERIOUS | MODERATE | SERIOUS |
| 20. Byers (2003) | SERIOUS | LOW | LOW | SERIOUS | LOW | SERIOUS | SERIOUS | SERIOUS |
| 21. Polizzi (2003) | SERIOUS | MODERATE | LOW | SERIOUS | SERIOUS | SERIOUS | MODERATE | SERIOUS |
| 22. Legault (1995) | SERIOUS | CRITICAL | LOW | CRITICAL | LOW | SERIOUS | MODERATE | CRITICAL |

There was no association between methodological quality assessments and the studies' reported effect on parent satisfaction. All 4/10 RCT that reported a higher level of parent satisfaction associated with their intervention, scored a *'high/unclear risk of bias'* in at least 4/6 Cochrane tool categories, one of which scored *'high/unclear risk'* in all categories. Out of the 14/22 non-RCT reporting an improved parent satisfaction, two were deemed to be at *'critical*

*risk of bias'* on the ROBINS- I tool, whilst the rest were assessed to be at *'serious risk of bias'.*

## 4.4 DISCUSSION

Parent satisfaction with neonatal care is increasingly recognised as an important measure of parent experience and is being used to evaluate hospitals and healthcare providers; implementation of interventions to improve parent satisfaction in neonatal units is increasing. This is the largest review of interventions (32 studies) where an outcome was parent satisfaction with neonatal care. I found low quality evidence that interventions targeting 'parent involvement' may improve parent satisfaction with neonatal care, but this result must be interpreted cautiously in view of the high risk of bias in included studies.

A key result of this review is in highlighting the complexity inherent in evaluating parent satisfaction. As a multidimensional construct, parent satisfaction can be affected just as much by interventions directly relating to infant care (e.g. Kangaroo care) as well as interventions relating to neonatal care facilities (e.g. free parking). By grouping included interventions into themes (Tables 4-7) I have highlighted the variety of interventions available and find that the majority of interventions are unsurprisingly related to 'parent involvement'.

A key reason for only selecting parent satisfaction as the outcome of interest was to focus on a single component of parent experience, to reduce outcome heterogeneity and allow direct comparison. Despite this approach, the key methodological limitation identified in this review was inconsistency in how parent satisfaction is defined and measured. In keeping with neonatal studies more widely (38), this review therefore confirms inconsistent outcome selection as a major source of research waste in neonatal studies examining parent experience and resulting barrier to improving care. Another important methodological limitation is that the majority of surveys used (23/29) lacked validation, with therefore the potential to produce unreliable, irreproducible or invalid data, leading to the wrong conclusions. Finally, this review finds that

there is limited involvement of parents in study design, which does not comply with the 4Pi National Involvement Standards for effective co-development with service users, that aims to improve experiences of services (26, 27). There is evidence that patient involvement can lead to improvements in design, selection of relevant outcome measures and recruitment of trial participants (25).

Strengths of this review include identifying studies with both mother and father participants, inclusion of the full range of infant gestations and a wide range of interventions. I followed a pre-registered protocol and reported this review in line with PRISMA guidelines (31). To further aid direct comparison of interventions, I only included studies that evaluated parent experience using ≥1 quantitative outcome of parent satisfaction. One limitation of this approach is that by excluding studies which evaluated parent experience using other measures (e.g. stress, anxiety and depression scales) I was unable to comment on interventions that targeted those other components of parent experience.

Another limitation is that I have only included studies in the English language, due to resource and time constraints. By not including studies in other languages, it is possible my results are more focused on work conducted in specific countries. Furthermore, I acknowledge that much of the research in parent experience is qualitatively evaluated. By restricting my review to studies where ≥1 quantitative outcome of parent satisfaction is measured, I have not included any interventions with solely qualitative outcomes. This was in an attempt to enable direct comparison of interventions, which had previously not been possible in any published review and was similarly not possible in this review either. By not including studies evaluated by qualitative measures only, it is possible these results are more focused on a particular type of interventions where quantitative evaluation would be preferable and/or easier. It also means I may not have included all studies ever conducted on a particular intervention, where some were only evaluated qualitatively, making some interventions appear more ‘widespread’ than others.

Brett et al (39) systematically reviewed interventions aimed at improving the parent experience more widely, but only included parents of preterm infants. Their large number of outcome domains and heterogeneity of outcome measures (including studies that reported only qualitative outcomes) meant the authors were unable to draw firm conclusions about the efficacy of interventions and that comparison and meta-analysis was not possible. The majority of my review's studies have been published in the 7 years since the Brett review, highlighting the increasing interest in this area. However, despite including all gestations and focusing on a specific aspect of parent experience, heterogeneity in measurement of parent satisfaction meant I was also unable to conduct a quantitative synthesis. Inconsistency and lack of validation of instruments measuring parent satisfaction in neonatal care (specifically with family-centred care) has also previously been highlighted by Dall'Oglio et al (40).

Although 31% of included studies were RCT, all were assessed as having a high risk of bias. Well-designed RCTs are traditionally considered the highest-ranking form of evidence. However it is worth considering whether such a design is feasible or desirable to evaluate interventions targeting parent satisfaction, especially if (as indicated by the high risk of bias in included studies) such RCT are methodologically challenging to undertake robustly. Parents in neonatal care talk to each other, compare notes and anecdotally create parent-support communities – hence it is inherently difficult to avoid contamination between parents receiving an intervention and those who are not, and blinding of parents or health professionals is near impossible. Furthermore, parent satisfaction is likely to be particularly susceptible to the Hawthorne effect (41), whereby parents may modify their reported satisfaction levels in response to receiving a particular intervention or merely to their awareness of being observed.

These factors may explain the low number of RCTs identified in our review and the high risk of bias seen in those that were included. In non-RCT studies, the main methodological concern is the degree to which unmeasured and uncontrolled confounders may explain any differences seen between

groups. The non-RCT studies included in this review were classed as having either a serious or critical risk of bias. The overwhelming majority of studies did not adequately report baseline variables or report other interventions during the study period, making it impossible to assess studies for selection bias or treatment bias. Furthermore, limitations such as contamination bias and the Hawthorne effect affect non-RCT as well. Only two non-RCT studies evaluated the outcome of interest (parent satisfaction) both before and after the intervention, in the same group of parents *(group level effect),* with most studies evaluating different parent groups pre and post intervention *(unit level effect).* An inherent weakness of this latter approach is that it assumes parent satisfaction is a static measure at the unit level, which is unlikely to be true. As a result of these numerous important limitations identified across all included studies, I find only low-quality evidence in support of interventions to improve parent satisfaction with neonatal care, despite most studies reporting a beneficial effect of interventions. These limitations may explain the limited uptake of these interventions by the wider neonatal community.

Changing neonatal practices to incorporate any new intervention requires robust evidence. In this review, I have demonstrated that such evidence is not currently available for interventions to improve parent satisfaction. I have highlighted the use of non-randomised study designs, inconsistency in definition and measurement of parent satisfaction, the use of unvalidated surveys, methodological limitations and a lack of parent involvement as contributors to the limited evidence base. My review empirically documents the extent of these issues in studies that use quantitative parent satisfaction surveys, and their contribution to research waste in neonatology.

Given the importance of parent satisfaction for both parent and offspring wellbeing, methodologically robust studies that involve parents, use standardised definitions and validated parent satisfaction measures are needed. Given the nature and challenges of the neonatal care environment and the limitations I have identified in existing research, a cluster trial may be the most appropriate study design to rigorously evaluate interventions to improve parent satisfaction with neonatal care on a larger scale. In the first

instance, a single centre pilot trial, like the one described in Chapter 8, could inform such a cluster trial.

## 4.5 CONCLUSIONS

Many interventions, commonly relating to increasing parent involvement, are reported to improve parent satisfaction with neonatal care but inconsistency in definition and measurement of parent satisfaction and high risk of bias in all studies makes this low-quality evidence. Standardised definitions and validated parent satisfaction measures are needed, as well as methodologically robust studies of parent experience, involving parents in intervention design. In Chapter 7, I describe the development and validation of a parent satisfaction survey with parents in neonatal care and in Chapter 8 the trial with parents.

## Chapter 5

## How does information exchange between parents and staff members happen in neonatal care and what do parents want?

In this chapter, I explore how information flows between staff and parents in neonatal care (*'What happens now'*) and how parents would like this to happen (*'What do parents want'*). I presented this work at the 2019 3rd International Congress of Joint European Neonatal Societies (3rd jENS), Netherlands, entitled '*What happens now and what do parents want? A quality improvement approach to understand parent information needs in neonatal care'.*

### 5.1 BACKGROUND

The overarching aim of this study is to use existing, routinely recorded data, from the neonatal electronic patient record system (EPR) to co-develop, implement and further improve with parents, and subsequently evaluate, a parent communication tool in neonatal care. Before designing and implementing such an intervention directly involving service users it is important to explore what is currently happening and how service users feel about it. Exploring 'what happens now' with parents in neonatal care allowed me to visualise a starting point for the project and understand how parents felt about current information exchange in neonatal care; this facilitated co-development of the communication tool with parents in direct response to their feedback.

Previous qualitative research on parent-staff interaction in neonatal care has highlighted a parental desire for easier access to conversations with doctors, as well as more consistent updates in between shifts with less conflicting information (42). Moreover, parents in interview studies have discussed the importance of neonatal staff being attentive to their emotional needs as being crucial to their neonatal experience (43). Some studies have highlighted the differences in parental communication frequency with nurses versus doctors, rather than the different content of information shared by different staff members (44). In a recent qualitative interview study, parents in NNU identified a general lack of written information, indicating a strong preference

for shared, written information to complement conversations with staff (44). There is a lack of studies examining the entire 'process' of information exchange in neonatal care from admission through to discharge, from both parent and staff perspectives, and how this may be further improved.

### 5.1.1 Challenges of engaging parents with neonatal care experience and the role of social media

The engagement and recruitment of parents for studies in neonatal care poses several challenges. Engaging with parents requires different approaches depending on if the proposed study is to take place during an infant's neonatal stay or after discharge from a neonatal unit. In studies conducted during neonatal admission, parental anxiety and stress related to their infant's clinical condition can impact recruitment, as can difficulties with parents not being physically present on the neonatal unit (45). Similarly, following discharge from neonatal care, parent recruitment and follow up in the community can be challenging. Reasons include factors such as barriers to transportation to and from hospital (or any other meeting venue) and the infant's health status. Follow-up studies of infants born prematurely have showed attrition rates of up to 70% (45), with higher retention demonstrated when there was regular contact between researchers and parents in the follow-up period.

Following discharge from neonatal care many parents join local support groups, directly affiliated with their local neonatal unit, local hospital charity or wider national Bliss charity, or privately created amongst themselves. Given there are approximately 200 neonatal units across the United Kingdom, and with parents and infants continuously being discharged home at different time points, connecting face-to-face is logistically challenging for parents.

Online groups are useful options for parents and the key features of social media (public accessibility, interactivity, and social connectedness) make it a popular mode of modern communication. With 396 million active Twitter users sending half a billion tweets and 2.9 billion Facebook accounts uploading 350 million photos a day, social media platforms provide a very powerful, instant,

familiar environment, with no travelling, where parents can offer insights into their neonatal experience on a large scale (46).

Researchers have traditionally approached patients and members of the public by publishing adverts in newspapers and posters in busy public places. However, studies are increasingly being conducted by recruiting and collecting data from participants entirely online (46). In my study I engaged parents with previous neonatal experience primarily online, to target a high number of parents with a wide range of demographics in a short amount of time. Engaging services users from study inception enabled the exploration of existing processes with parents with lived experience of NHS neonatal care, using the method of process mapping (see next).

### 5.1.2 The concept of process mapping

Process mapping is a quality improvement method designed to provide insight into systems and processes in which interventions are introduced; it is regarded as particularly useful in healthcare projects, where the complex interplay of different factors in dynamic environments may not be immediately apparent (47). It is intended to lead to a holistic understanding of the process under review, by including five phases: Process map organisation and process identification, information gathering, map generation, process analysis and taking improvement forward (47).

A process mapping session can be facilitated in a variety of ways, including as part of workshops, focus groups and semi-structured interviews. One of the key aspects is the generation of a process map by the facilitator in response to the information elicited from participants (creating a visual representation of the process under analysis). Generating a visual map helps researchers gain a better understanding of current practice and embraces the social aspects involved in the process mapping process, such as interactions between participants. Studies have also highlighted that process mapping is particularly useful for mapping complex, variable and dynamic healthcare processes as it provides improvement teams with insight into *'work as it is'* rather than *'work as imagined'* (47). Studies in neonatal care are more

commonly using process mapping; an example is the *'Perinatal Excellence to Reduce Injury in Preterm* birth' (PERIPrem) perinatal care bundle. This 11-element bundle was designed to improve outcomes for preterm babies across the South West and West of England, it has significantly improved targets and was highly commended as *'Patient Safety Pilot of the Year'* at the 2021 HSJ Patient Safety Awards (48).

## 5.2 AIMS

To map and describe the current information exchange in neonatal care between parents and neonatal unit staff members, elicit the key information themes that are exchanged and explore parents' needs regarding the optimal content, format and delivery of information through a communication tool.

## 5.3 METHODS

### 5.3.1 Online engagement campaign

I engaged parents with neonatal experience online to identify parents for inclusion in my study's parent database and subsequently recruit them and conduct process mapping sessions face-to-face.

#### 5.3.1.1 Establishing a social media presence

I designed a study logo (Appendix 4) and created social media accounts for my study on:

- Facebook: 'BUDSProject' page (49)
- Twitter: 'BUDS_study' page (50)
- The 'Neoepoch' research website (51)

I designed an online study advert (Appendix 4) and shared it on the above social media study pages, including the Facebook and Twitter pages of the Bliss national neonatal charity (52, 53), in collaboration with the Bliss research engagement officer.

5.3.1.2 Online articles and videos

As part of my wider online parent engagement, I collaborated with an international neonatal entrepreneur who interviewed me about my study and showcased the video interview (54) on her website and on YouTube (278 views).

I wrote a series of articles that were published online through portals I specifically chose as being relevant to different stakeholder groups, to both raise study awareness and continuously engage my key stakeholders.

These were published by:

- The BabyLivingLab neonatal team in an international neonatal online innovation blog (55).
- CW hospital online sources, including in the divisional update for women and children (56) and the CW Hospital trust online magazine (57).
- The Imperial College London university, in the online division of medicine blog (58).
- NIHR CLAHRC NWL, in their online newsletters (59, 60).
- The national neonatal charity Bliss, in their online parent newsletter (61).

5.3.1.3 Creating a parent database

I registered parents of infants previously requiring neonatal care on my study's parent database, through a combination of social media engagement, and approaching parents face-to-face.

I asked parents with previous neonatal experience from throughout the UK to comment online on the study advert I posted on the Bliss Facebook page (an open, public forum). Parents reached out on Facebook for more information and emailed me directly responding to the advert. I emailed a study information pack to parents that expressed an interest, who subsequently confirmed they were interested in face-to-face participation.

Additionally, parents contacted me through the 'Neoepoch' research website by filling out and electronically submitting a contact form for more information

on how to get involved in my study. Finally, I had a project stand at the CW Hospital open day, where I engaged interested parents face-to-face.

5.3.1.4 Initial parent reactions to study

Parents commented on my study's Facebook advert, offering their thoughts on 'what it would be like to have a mobile phone app that would provide neonatal infant updates to parents'.

Receiving parent feedback in the early stages of project design gave me a useful overview of issues I needed to consider in the later stages of research ethics application and intervention design.

Using social media for parent engagement in research, although increasingly used to collect data in a small amount of time (46), raises the issues of patient consent and selection bias. In the public Facebook page, comments were freely posted in an open domain with implicit consent and I collated parent comments and anonymised them. In order to address possible selection bias, I included all comments that were posted on the Facebook page for analysis. It was not possible to collect descriptive information for the parents that posted comments as the majority of Facebook profiles had privacy settings about personal information.

For data analysis, I coded parent comment extracts about my study's intervention into subthemes, themes and categories, using a thematic analysis approach. Thematic analysis is *'a method for identifying, analysing and reporting patterns (themes) within data. It minimally organises and describes data in (rich) detail, identifying patterns of meaning across a dataset to provide an answer to the research question being addressed'*. Conducting thematic analysis in an inductive way means the development of 'theories' (in this case, parent opinions about an intervention in neonatal care) happens inductively after one has collected the data (62).

Following coding, I grouped parent comments into 'positive comments' and 'comments with concerns'.

### 5.3.2 Research ethics

The Imperial College and CW Hospital Research and Development departments confirmed this work was considered 'service evaluation' and as such no Research Ethics Committee review was required.

### 5.3.3 Neonatal staff process-mapping

I held a neonatal staff process-mapping session ahead of a parent process mapping session. This timeline was part of raising study awareness in the CW NNU and gaining buy-in from neonatal staff, whilst also waiting for more parents to register their interest to participate in process-mapping.

#### 5.3.3.1 Participants and recruitment

I facilitated an interactive process-mapping session with neonatal unit staff members in the CW NNU seminar room to temporally map how information flows between parents and staff on the neonatal unit. I invited all neonatal staff members, including both clinical (nurses, doctors, health care assistants) and non-clinical staff (receptionists) that were working on the NNU on the day of process mapping to participate during their lunch break (with lunch provided). Participant numbers were dependent on their workload and consent was implicit for staff members agreeing to participate.

#### 5.3.3.2 Design

I created a 'virtual' NNU in the seminar room by depicting each NNU area using large individual flipchart sheets that I attached along the wall in sequence. NNU areas included: Reception; Intensive care Unit area (ITU); High Dependency Unit area (HDU); Special Care Baby Unit area (SCBU); Expressing/ Breastfeeding room; Parent/ Family room; Quiet room (for parent discussions); Other. While these were specific to the CW NNU layout, most neonatal units have a very similar room structure. Each sheet on the wall included a vertical timeline of 'emotional touch points' in parent-staff interactions during a baby's neonatal journey, including:

- Admission
- First update
- Ward round

- Daily care
- Clinical deterioration
- Clinical decision needed
- Transfer
- Preparing for discharge home

These were the same ‘emotional touch points’ identified during the Action-Effect diagram meeting with parents and all other stakeholders (see Chapter 3).

I asked staff to describe what type of information they communicated to parents, in which NNU area they usually provided it and at which ‘emotional touch point’ in a baby’s journey. I invited staff members to walk around the room, examine the different sheets (‘NNU areas’) and sheet sections (‘emotional touch points’), write their thoughts on colour-coded post-it notes according to job role (nurse, doctor, other) and attach their post-it notes to the corresponding parts of each sheet.

The study’s parent representative (SK), three NIHR CLAHRC NWL team members and the Bliss charity research engagement officer participated as co-facilitators.

5.3.3.3 Data collection/ Analysis

I collected anonymous post-it notes and transferred all written comments verbatim onto a Microsoft Word document to assist with the organisation and management of data. Analysis was inductive and reflexive using a thematic analysis approach (62) to develop themes (types of information exchanged in neonatal care). For this I followed a process of different stages, with qualitative analysis support from NIHR CLAHRC NWL.

- Data familiarisation: I read the comments many times, in depth and recorded initial ideas.

- Data coding: I identified important features of the comments and generated concise labels (*'codes'*) for selected extracts. In this way I coded the entire dataset and iteratively organised all codes together for the development of themes. The NIHR CLAHRC Improvement Science manager (WC), nursing representative (IA) and parent representative (SK) reviewed the initial coding framework and advised on how to further refine it.

- Theme development and revision: I examined all codes to progressively identify broader patterns of information categories (*'themes'*). I continuously refined the themes by checking them against the data. This involved merging, splitting, deleting or adding further themes as I progressed. WC, IA and SK reviewed the theme development and advised on any suggested revisions.

- Producing a results 'virtual map': I combined the final themes into a 'virtual map' to provide a summary, as a visual representation of the data. In the 'virtual map' of information flow across the NNU, information themes emerge temporally in infant journeys moving from 'admission' and clockwise towards 'preparing for home'.

### 5.3.4 Parent process mapping and exploration of information needs

#### 5.3.4.1 Participants and recruitment

I invited all parents from my project's parent database via email to attend a focus group in a CW Hospital meeting room. Eligible parents had a baby previously requiring NHS neonatal care in the UK (now discharged) and could speak and read English. I aimed to recruit a convenience sample of 10-12 parents. Parents were reimbursed £60 for travel and £50 for childcare costs. I emailed parent participants study the information sheets and consent forms prior to the meeting and consented them on the day, face-to-face. Parents could withdraw at any time without having to give a reason.

#### 5.3.4.2 Design

- Face-to-face focus group

I facilitated a focus group starting with asking parents open questions about their past neonatal experiences and taking field notes. I subsequently asked

targeted questions about how they received information about their baby when in neonatal care. I also explored parent preferences regarding the optimal content, format and delivery of information in neonatal care.

For data collection I used the same flipchart sheet format as with the staff process mapping session to represent NNU areas and 'emotional touch points'. During the discussion I wrote down anonymised parent thoughts verbatim on corresponding sheets and time points. I audio-recorded the meeting with parent consent.

The study's parent representative (SK), two NIHR CLAHRC NWL project steering group members and the Bliss charity research engagement officer participated as co-facilitators.

- Online survey

In order to enable remote participation for parents that could not attend the face-to-face focus group, I developed and launched a parent online survey. I designed the survey with NIHR CLAHRC NWL support, using the 'Qualtrics research and experience' software (Qualtrics; London, England). I emailed the survey to all parents from my study's database that indicated they would like to participate remotely. Parents consented to participate by ticking the 'consent section' on the online survey's first screen and submitted their completed surveys anonymously.

The survey's outline and questions matched the format of the in-person focus group and the parents who attended the focus group reviewed its design. I included both open and targeted 'free text' questions and structured them around the concept of different NNU areas and 'emotional touch points'.

5.3.4.3 Data collection/ Analysis

From the face-to-face focus group session, I collected the completed flipchart sheets and copied all anonymous comments verbatim onto a Microsoft Word document. Reviewing the audio-recording and my field notes further helped

me develop the overarching information themes. From the online survey I exported all anonymised text entries onto the same Microsoft Word document.

Similarly to the staff process mapping, I used a thematic analysis approach (62) to create a 'virtual map' of information flow across the NNU, this time from the parent perspective. Additionally, I examined the themes most important to parents and their preferred way of receiving written information. SK, IA and WC reviewed and contributed to the analysis.

Finally, I created a combined 'virtual map' of information flow from the staff and parent perspective together, noting any areas of overlap and/or differences.

## 5.4 RESULTS

### 5.4.1 Online engagement campaign

#### 5.4.1.1 Establishing a social media presence

My study's online advert reached 23,989 people on the Bliss Facebook page in the first week, according to the official metrics provided by the Bliss social media moderator. The advert generated 981 'post clicks' and 399 reactions, comments and shares (Appendix 4).

#### 5.4.1.2 Creating a parent database

In total, 27 parents reached out on the Facebook platform for more study information and a further 26 emailed me directly responding to the online advert. Six parents contacted me through the 'Neoepoch' research website and 17 parents expressed interest in the study at the CW Hospital open day.

Overall, I registered 76 parents of infants that had previously required neonatal care on my study's database. Of those, 91% were mothers (69/76) and 9% fathers (7/76), 95% of parents had experienced neonatal care with a baby born prematurely at less than 37 weeks gestation (72/76) and 5% of parents had a sick baby born at term (4/76). Seven parents had had two consecutive pregnancies where their baby required neonatal care and 8

parents had twins born prematurely (3 of which had one of their twins pass away whilst in neonatal care). I did not collect additional demographic details from parents at the point of registration to my database, as this was my initial contact with them, ahead of consenting for specific project activities.

5.4.1.3 Initial parent reactions to study

In their comments posted online, parents offered feedback about their neonatal experience and opinions about my study's planned intervention, while also expressing their interest in attending project focus groups. One parent voluntarily collated and sent me additional parent comments about my study advert from a private neonatal Facebook group with parent consent.

In total, 27 parents commented on my study's Facebook advert, 25 mothers and 2 fathers (Appendix 4).

Examples of parents reflecting on their past experiences and commenting on my study included:

*'I had a premature baby last year and found communication between NICU and postnatal wards difficult'* Parent 4, Mother

*'I very much regretted not keeping a diary on neonatal and tried to retrospectively piece one together'* Parent 7, Mother

*'An app that I could follow results and updates on his care would have been extremely helpful'*
[POSITIVE for app: Parent benefit] Parent 19, Mother

*'It would save calls to the unit to check up etc so if the data is already recorded it's even more of a benefit as nurses will have more time to look out for the babies in care.'*
[POSITIVE for app: Infant benefit] Parent 3, Mother

*‘Something like an app would have been fantastic for us, being 3 hours away from home and having to travel meant both my partner and I couldn't go up all the time together.’*

[POSITIVE for app: Updates made easier for parents] Parent 9, Father

*‘Sometimes you feel like you're inconveniencing the nursing staff by calling for updates in the evenings so anything like an app that helps this would be fantastic’*

[POSITIVE for app: Updates made easier for parents] Parent 15, Mother

*‘The staff knew us and how to pass on information best to us quickly. You can ask face to face what something means. In writing it may be more of a worry and cause extra stress if not done right.’*

[CONCERN about app: Parents still want face-to-face communication] Parent 12, Mother

*‘Great idea although concerned about the sort of information that will be available. We focus too much on numbers as parents and to 'watch' heart rate etc at home could cause unnecessary stress.’*

[CONCERN about app: Emotional impact on parents]. Parent 22, Father

*‘We did get extremely frustrated at times with the lack of communication - mainly due to how busy the staff were. And so my biggest question is about how it would the app get updated, realistically the nurses just don't seem to have time?’*

[CONCERN about app: Impact on staff] Parent 25, Mother

Using a thematic analysis approach (62) I identified 6 categories of parent reactions to my study’s planned intervention, which I further categorised into 3 categories of ‘positive comments’ and 3 categories of ‘comments with concerns’ (Tables 8, 9).

## Table 8. Positive comments online (from 19 parents)

| **Parent involvement benefit** |
|---|
| - Parent empowerment<br>- Parents would feel more involved in care<br>- Parent emotional benefit (less stress)<br>- Would allow for parent family commitments at home/other children<br>- Would help parents with long distance and travel cost to get to unit every day<br>- Good to involve parents in routine daily care updates (not always able to be on unit)<br>- Improve sense of involvement in care when parents at home |
| **Infant and staff benefit** |
| - Could lead to less staff workload (less need to discuss with parents)<br>- Could maximise staff time with babies |
| **Updates made easier for parents** |
| - Parents feel neonatal apps in general are helpful for updates<br>- Would help parents with general understanding of baby's condition<br>- Better consistency of information communicated with an app<br>- Parents could obtain updates when staff are busy<br>- Staff verbal updates insufficient- could get more updates without relying on staff<br>- Parent could obtain updates when baby changes hospitals/transfer times<br>- Parents could obtain updates from home<br>- Parent could obtain updates when baby changes room/deteriorates<br>- Can access information without relying on clinical staff and without 'inconveniencing staff'<br>- With app could access information irrespective of staff workload |

## Table 9. Comments with concerns online (from 8 parents)

| **Parents still want face-to-face communication** |
|---|
| - App would not replace or lessen face-to-face communication with staff<br>- App wouldn't be as reassuring as speaking to someone |
| **Emotional impact on parents (anxiety, disappointment, panic)** |
| - The type of information could cause anxiety<br>- Watching real time numerical updates could cause anxiety<br>- Fear of losing staff face-to-face support causing anxiety<br>- Not being able to clarify written information with someone causing anxiety<br>- Not being able to discuss written information with someone causing anxiety<br>- Possible comparing of written notes between parents can cause anxiety<br>- Disappointment if positive update doesn't appear on app<br>- Possible failure of 'live feedback' causing panic |
| **Impact on staff** |
| - Concern about staff having to input data and increased workload |

### 5.4.2 Neonatal staff process mapping

5.4.2.1 Participants

In total, 43 staff members participated in a 1-hour session in the CW NNU seminar room, including: 14 doctors, 26 nurses, 1 healthcare assistant, 1 administrator/receptionist and 1 clinical observer.

5.4.2.2. Staff process mapping results

Thematic analysis results showed that staff members reported discussing 20 information themes with parents in neonatal care, further categorised under 'Communication' or 'Parent Involvement' (Table 10).

These themes are further illustrated in a 'virtual map', where the information themes exchanged with parents 'appear' at different time points along the neonatal journey, as reported by neonatal staff members. Moving clockwise along the map, information themes emerge from the time of babies' 'admission' towards 'preparing for home', according to when they are first discussed.

Analysis shows that 'verbal clinical updates' (a staff member updating a parent about their baby's clinical condition verbally) were shared with parents throughout the neonatal journey, at every different time point (Figure 7). Conversely, 'written information' was provided to parents only at the beginning, middle and end of the neonatal journey (Figure 8). 'Parent involvement information' (for example information on how to do a baby's cares and feeds) was not shared with parents during times of clinical deterioration, when infants were being transferred to different hospitals or when making clinical decisions about a new therapy or procedure (Figure 9).

**Table 10. Staff reported discussing 20 information themes with parents**

| Communication | Parent involvement |
|---|---|
| **- General updates offered**<br>**- Specific clinical update details**<br>**- Written information provided**<br>- NICU housekeeping<br>- NICU equipment and monitoring<br>- Questions encouraged<br>- Telephone conversations<br>- Invite parents to formal meeting in quiet room<br>- Staff role information<br>- Discharge medication | **- Parent involvement information provided**<br>**- Teaching and empowering parents**<br>- Parent support available<br>- Information about the transfer process<br>- End of life information<br>- Check for parent satisfaction<br>- Shared decision making<br>- Information about the discharge process<br>- Follow up arrangements information<br>- Briefing information about future new neonatal unit plans |

*Table 10. 20 information themes that staff members reported discussing with parents, categorised under 'Communication' or 'Parent involvement'. Themes in bold were reported by staff members as being exchanged more frequently with parents. NICU: Neonatal Intensive Care Unit.*

**Figure 7. Virtual map of information exchange between staff/parents at different time points (verbal updates offered)**

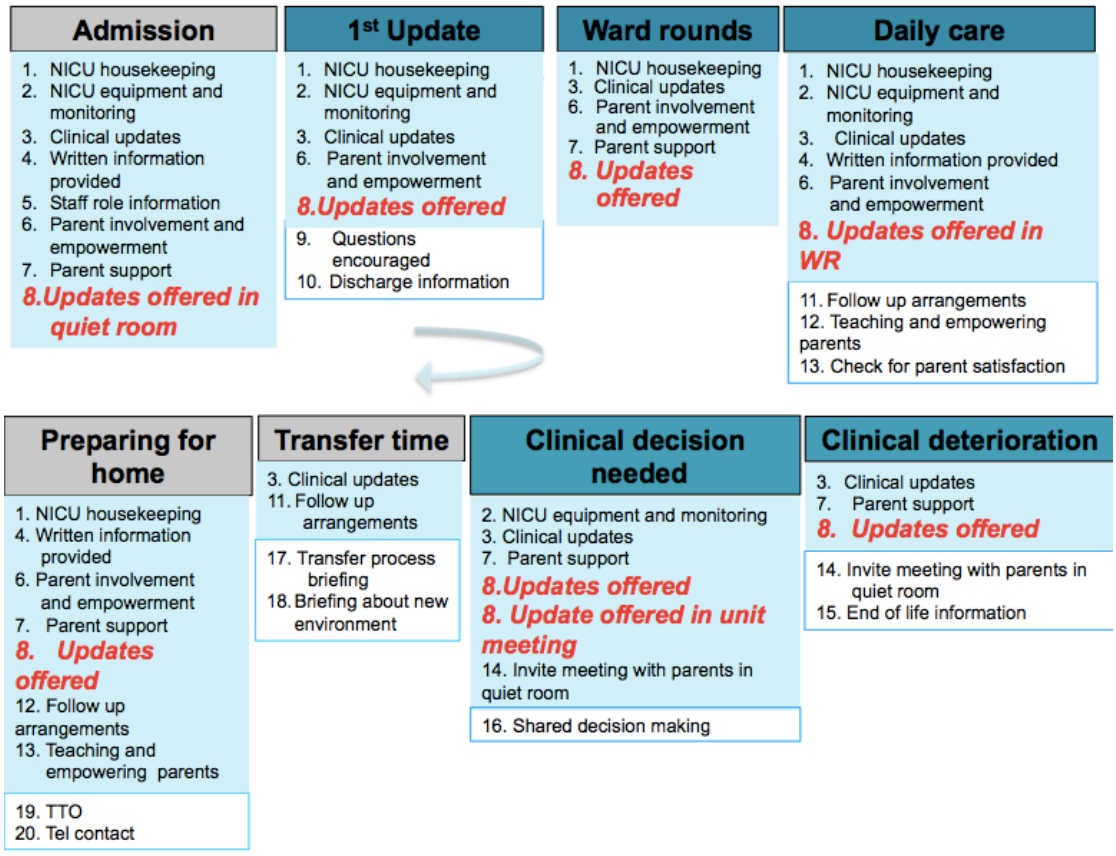



*Figure 7. Light blue boxes: Time points in neonatal journeys. Information themes that staff members discuss with parents at each time point, appear in corresponding light blue boxes. Following clockwise, as new information themes are first discussed at a certain time point, they first appear in a white box for that time point. Themes are continually added along the*

*neonatal journey until 20 themes 'appear'. Staff members reported the information theme of 'offering general verbal updates to parents' at every time point in the neonatal journey (RED). NICU: Neonatal Intensive Care Unit; TTO: (discharge medication) To Take Out.*

**Figure 8. Virtual map of information exchange between staff/parents at different time points (written information)**

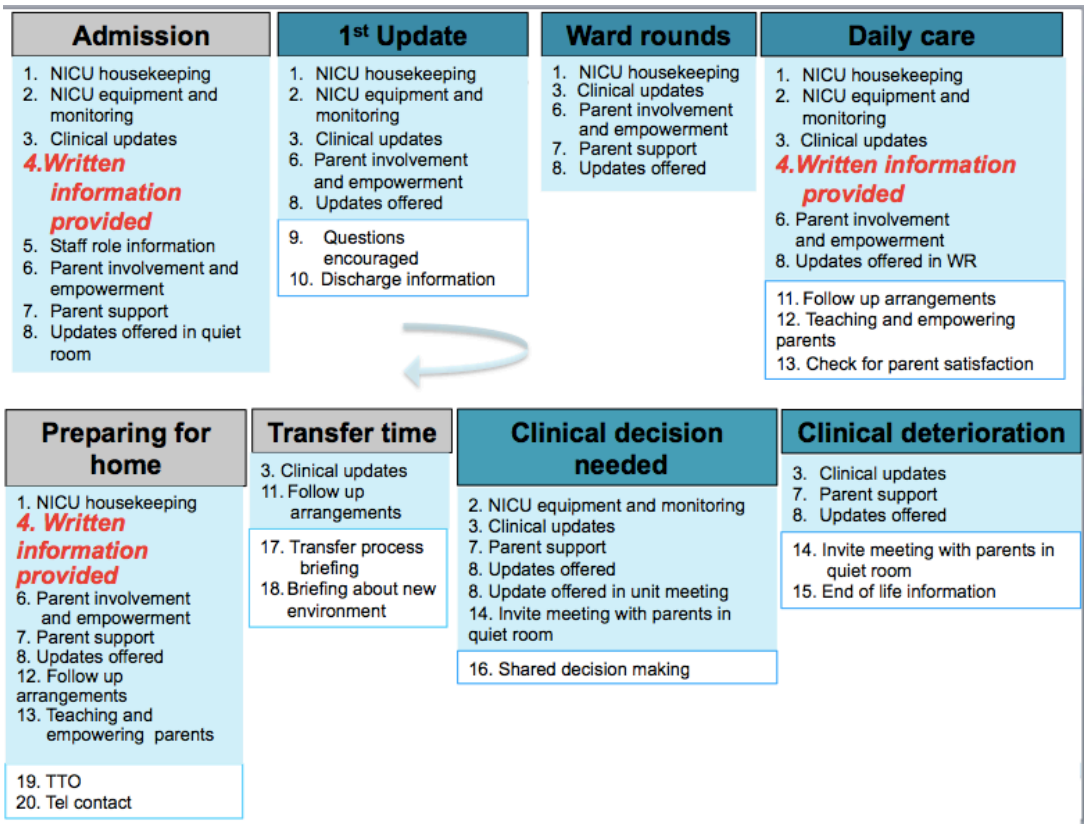



*Figure 8. Light blue boxes: Time points in neonatal journeys. Information themes that staff members discuss with parents at each timepoint, appear in corresponding light blue boxes. Following clockwise, as new information themes are first discussed at a certain time point, they appear in a white box for that time point. Themes are continually added along the neonatal journey until 20 themes 'appear'. Staff members reported the information theme of 'providing written information to parents' only at the beginning, middle and end of the neonatal journey (RED). NICU: Neonatal Intensive Care Unit; TTO: (discharge medication) To Take Out.*

**Figure 9. Virtual map of information exchange between staff/parents at different time points (parent involvement information)**

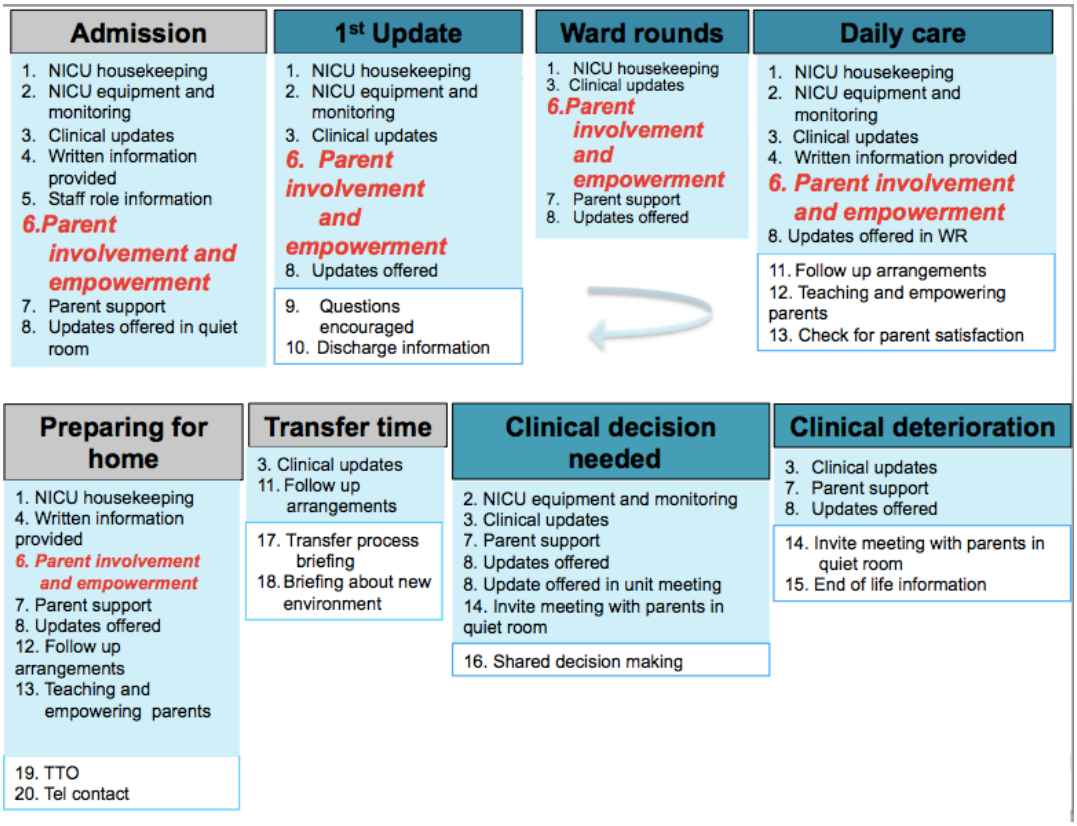



*Figure 9. Light blue boxes: Time points in neonatal journeys. Information themes that staff members discuss with parents at each time point, appear in corresponding light blue boxes. Following clockwise, as new information themes are first discussed at a certain time point, they appear in a white box for that time point. Themes are continually added along the neonatal journey until 20 themes 'appear'. Staff members reported the information theme of 'sharing information about parent involvement with parents' at all times apart from times of clinical deterioration, infants being transferred to different hospitals and when making clinical decisions (RED). NICU: Neonatal Intensive Care Unit; TTO: (discharge medication) To Take Out.*

### 5.4.3 Parent process mapping

5.4.3.1 Participants

- Face-to-face focus group

In total 9 parents confirmed attendance by email, but 6 parents cancelled prior to the meeting. More than 20 parents emailed to offer to help remotely as they were not able to attend the face-to-face meeting in view of work and childcare commitments.

4 parents (2 fathers and 2 mothers), including the study's parent representative (SK) participated in a 3-hour face-to-face focus group session in a CW Hospital meeting room (Table 11).

**Table 11. Parent demographics (Process mapping focus group)**

| Gender | Age (years) | Ethnicity | NICU location | Gestation (weeks) /gender | Length of stay in NICU (weeks) |
|---|---|---|---|---|---|
| Male | 49 | White British | London | 25 / Male | 3 |
| Male | 46 | White British | London | 35 / Female<br>24/ Male | 2<br>18 |
| Female | 24 | White other | London | 29 / Male | 7 |
| Female (parent rep) | 26 | White other | London | 32/ Male | 2 |

- Online survey

In total, 50 parents completed the online survey in one month. Only 56% of parents (28/50) completed the survey's anonymous demographic section online (Table 12). Of those parents who provided their demographic information, the majority were mothers (86%), aged between 25-29 years (39%), White (79%), their baby was between 24-28 weeks gestation (40%) at the time of requiring neonatal care and the neonatal unit's location was in England, outside London (54%). Most common length of stay in neonatal care was 1-6 months (71%).

**Table 12. Parent demographics, n=28 parents (Online survey)**

| Gender (%) | Age (years) (%) | Ethnicity (%) | NICU location (%) | Gestation (weeks) (%) | Length of stay on neonatal unit (weeks) (%) |
|---|---|---|---|---|---|
| **24 Female (86)**<br>4 Male (14) | Over 35 (18)<br>30-35 (32)<br>**25-29 (39)**<br>18-24 (11) | **22 White (79)**<br>2 Asian (7)<br>2 Mixed (7)<br>1 Black (4)<br>1 other (4) | **15 England (not London) (54)**<br>11 London (39)<br>1 Scotland (4)<br>1 Wales (4) | <24 (6)<br>**24-28 (40)**<br>28+1-32 (27)<br>32+1-36 (20)<br>36+1-40 (7) | 1-4 weeks (25)<br>**1-6 months (71)**<br>>6 months (4) |

*Table 12. Most prevalent demographic information in BOLD.*

5.4.3.2 Parent process mapping results (*'What happens now'*)

Like the staff session, I created a 'virtual map' of information flow in the neonatal unit from the parent perspective and subsequently identified the type of information important to parents. Parents reported discussing 10 information themes with staff; 8 matching the ones reported by staff and 2 new ones (Table 13).

**Table 13. Parents reported discussing 10 information themes with staff: 8 matched those reported by staff (blue) and 2 new ones (red)**

| Communication | Parent involvement |
|---|---|
| - General updates offered | - Parent involvement information provided |
| - Specific clinical update details | - Parent support available |
| - Written information provided | - Information about the transfer process |
| - NICU housekeeping | - End of life information |
| - NICU equipment and monitoring | - Teaching and empowering parents |
| - Questions encouraged | - Check for parent satisfaction |
| - Telephone conversations | - Shared decision making |
| - Invite parents to formal meeting in quiet room | - Information about the discharge process |
| - Staff role information | - Follow up arrangements information |
| - Discharge medication | - Briefing information about future new neonatal unit plans |
| - Staff introduction | |
| - Electronic resources offered (DVD, websites, baby photo) | |

*Table 13. Themes in BLUE and RED were reported by parents. All themes were reported by staff members (apart from those in RED). Highlighted in BLUE: 8 themes also reported by parents, matching those reported by staff. Highlighted in RED: 2 new information themes were ONLY reported by parents. NICU: Neonatal Intensive Care Unit.*

5.4.3.3 Parent information preferences *('What do parents want')*

In terms of preferred *content* of information, parents identified 7 specific themes as most important, prioritising clinical updates. I categorised these into '*infant-specific'* and '*unit-specific'* information (Table 14)

**Table 14. Information themes identified by parents as most important, categorised into infant-specific and unit-specific.**

| | Infant-specific information | Unit-specific information |
|---|---|---|
| **THEMES** | Clinical updates: Primarily weight, respiratory and feeding information, medication | 'Housekeeping': Explanation of commonly used neonatal terms and procedures/ unit policies |
| | Changes to infant's location on the unit | Equipment and monitoring explanations |
| | | Information on available parent support |
| | | Information on opportunities for parent involvement in care/ training |
| | | Information on infant transfer process |

In discussing preferred clinical updates, parents consistently identified some key information, including:

- Baby's up to date weight
- Details of respiratory support
- Details of feeding
- A list of current medication, all described in concise, plain English.

*'Weight gain updates, this could automatically link to the premature baby weight graph as the Red book doesn't start early enough. Ventilation.. my baby was on Vapotherm for a long time being weaned off slowly, I would like to have seen her oxygen settings'*

Parent 3 Focus group, Mother

*'List of current medicines - maybe with a short, easy to understand description of most common ones?'*

Parent 7, Online survey

In terms of preferred format of written information, parents reported information should be:

- Concise
- Illustrated with a basic, non-complicated design
- Easy to read

- Consistent
- Updated daily
- Saved chronologically like a prospective diary
- With enabled open access to it at any time

*'Quick and easy to read that lists all the key terms you`ll hear about when in a neonatal unit'*

Parent 1, Online survey

*'I don't think an app should be too complex as not everyone is techy so needs to be basic with simple straight forward information'*

Parent 13, Online survey

### 5.4.4 Combined parents and staff process mapping results

Overall, parents agreed with staff on the *type* of information shared during parent-staff interactions in neonatal care (Figure 10). Further analysis revealed that parents reported discussing the same information themes as staff members, but they wished those had been discussed in a *different way;* specifically, parents wanted information to be:

- More objective
- More consistent
- Readily available
- Jargon-free

*'I wanted doctors to be honest about not knowing what is going to happen'*

Parent 2 Focus group, Father

*'I wanted precise information about NICU without jargon'*

Parent 3 Focus group, Mother

*'I wanted to be called at all times- but they didn't call me during the night'*

Parent 3 Focus group, Mother

*‘I would have liked weekly updates by the same consultant, coming at the same time of day’*

Parent 1 Focus group, Father

Figure 10 shows an overall agreement between staff and parents on the key information themes discussed in neonatal care (highlighted in blue). These overlapping themes match the parent information preferences reported in section 5.4.3.3. It is also noted that staff and parents jointly reported the provision of written information (by staff to parents) only at the time of admission (Figure 10).

**Figure 10. Virtual map of information exchange between staff/parents at different time points (Combined parent and staff perspective)**

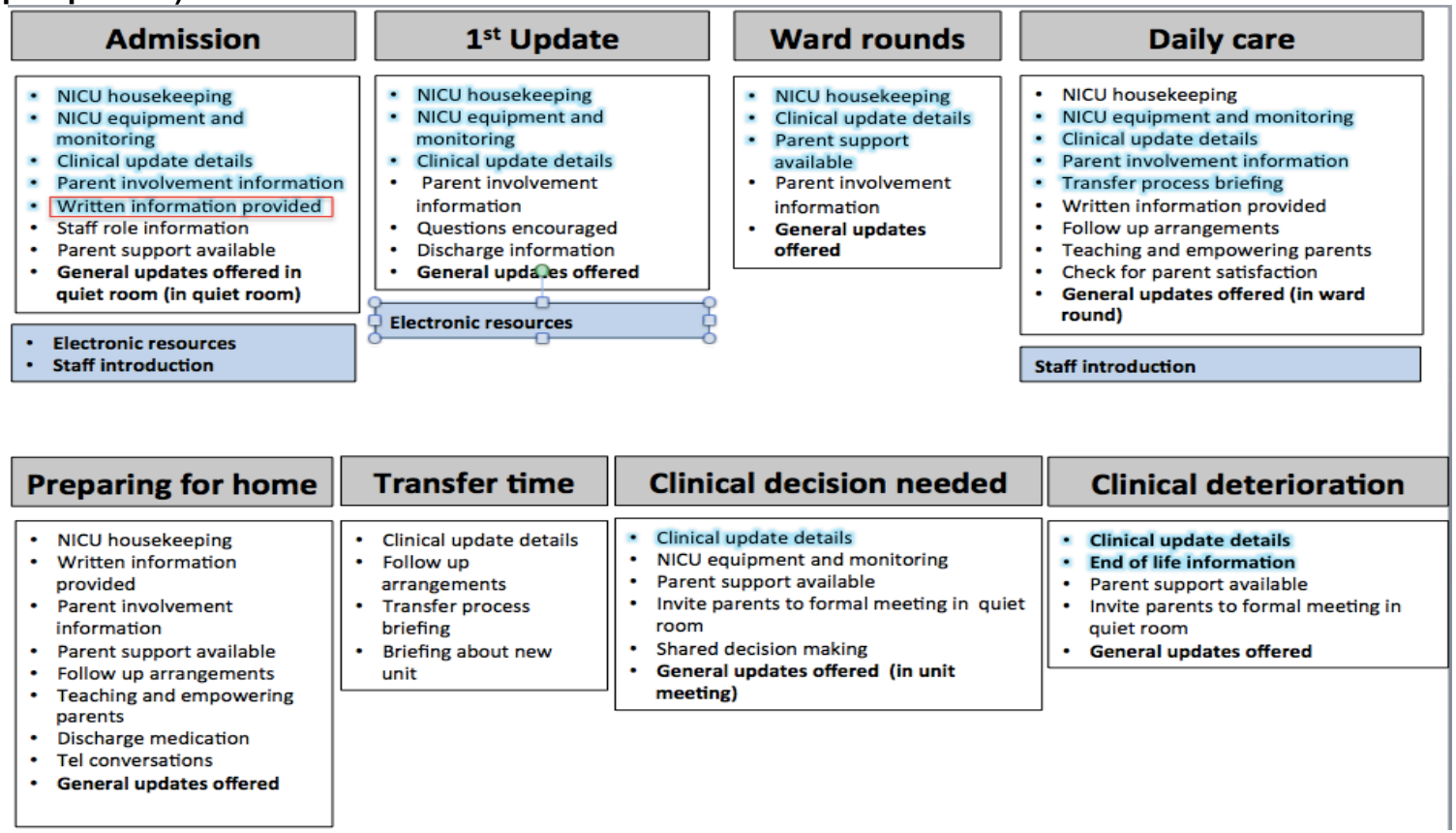



*Figure 10. Information themes discussed in neonatal care, as reported by parents and staff, following clockwise in infant journeys, from admission to discharge. In white boxes: all information themes reported as being discussed by staff, at each time point. Highlighted in blue: information themes reported by both parents and staff at each time point (8 themes). Blue boxes: Information themes only reported by parents. Highlighted in red: parents and staff both reported written information was provided only during the admission period. NICU: Neonatal Intensive Care Unit*

## 5.5 DISCUSSION

### 5.5.1 Key findings

- Parents

Parents participated in this work through a combination of social media, in-person focus group and online survey. Initial parent project reactions formed 3 categories of positive comments (Parent involvement benefit; Infant and Staff benefit; Updates made easier for parents) and 3 categories of comments with concerns (Parents still want face-to-face communication; Emotional impact on parents- anxiety, disappointment, panic; Impact on staff).

- Neonatal staff

Staff members reported discussing 20 themes with parents, categorised under 'Communication' or 'Parent Involvement'. Analysis of themes as they emerged temporally along the infant journey showed that verbal clinical updates were shared with parents throughout the neonatal journey; written information was provided only at the beginning, middle and end. Parent involvement information was not shared during clinical deteriorations, infant transfers and when making clinical decisions.

- Parent-Staff comparison

In process mapping, parents reported discussing 10 information themes with staff in neonatal care, 8 matching those reported by staff and 2 new, further categorised under 'Communication' or 'Parent Involvement'. The themes that both staff and parents reported appear to reflect the most common conversations in neonatal care, including clinical verbal updates, neonatal unit information and parent involvement, as well as support information. The themes reported by staff but not mentioned by parents likely reflected conversations that were either less of a priority to parents (e.g. staff briefing about future new neonatal unit) or that parents assumed would always take place and therefore failed to mention during the process mapping session (e.g. general updates offered). Parents identified 7 themes as most important to them, prioritising clinical updates. Categorisation of parent information preferences into '*infant-specific'* and '*unit-specific'* information (section 5.4.3.3) informed the subsequent development of the communication tool template with parents (Chapter 6).

Overall, parents agreed with staff on the type of information shared, but wanted it communicated in a different way: more objective, more consistent, readily available and jargon-free. It is noted that parents only reported receiving written information at the time of admission to the neonatal unit, while staff reported providing it to parents at the beginning (admission), middle (daily care) and end of neonatal journeys (preparing for discharge home). It is likely parents either did not remember receiving written information after admission or did not receive enough to mention it as having been useful.

Analysis of parent comments while discussing the overlapping information themes also reported by staff, revealed what parents thought of existing information delivery, the type of information parents wanted and how they wanted it delivered. These overlapping themes match the parent information preferences reported in section 5.4.3.3.

### 5.5.2 Strengths and limitations

A key strength was seeking direct feedback from parents with lived experience of NHS neonatal care and neonatal staff members. Parents were recruited both in-person and online, including both mothers and fathers of preterm and term infants. The parent sample included a range of ethnicities with neonatal experience from neonatal units in England, Scotland and Wales, whose infants of all gestations had a wide range of duration of stay in neonatal care (1 week->6 months). A key strength was therefore that parent recruitment was not limited to a single geographical location or neonatal unit.

A limitation was using a convenience sample rather than purposive sample. Recruiting parents with neonatal care experience following discharge from neonatal care can be challenging, with recorded attrition rates as high as 70% (45). Large geographical distances and parental work/childcare commitments can make recruitment difficult and time-consuming to achieve (45). A key and novel strength of this study in overcoming this was engaging and recruiting parents using social media, by convenience sampling. Social media platforms are increasingly being used for research participation and online data

collection (46), enabling participation on a larger scale, without need for travel. Receiving parent feedback in the early stages of project design gave me an important overview of issues I needed to consider in the later planning stages.

The three areas of concern raised by parents informed the need to reassure participating parents from the outset that:

- The planned intervention was not intended to replace face-to-face communication with neonatal staff members but rather supplement it.
- Communication of new important information would still be done by direct communication between parents-staff.
- The project did not involve any additional work for staff members as infant data is already routinely recorded.

Another limitation was the small sample size of the in-person parent process-mapping group. This group eventually included four parents, after many (previously confirmed) parents were not able to attend at short notice, because of work and/or childcare commitments. All 4 parents were white, with previous neonatal experience in a London NICU, 2 were mothers and 2 fathers. In response to over 20 parents offering to instead participate remotely I developed an online survey with direct input from the in-person parent group. A key strength was that through the online survey, 50 parents from across the United Kingdom were able to participate in process mapping remotely, within a very short period.

Other studies have primarily focused on exploring the parent experience in neonatal care through in-person interviews (63); there is a lack of studies conducting process mapping with parents to identify the information themes discussed with staff at specific chronological time points and parent information preferences. Previous qualitative research on parent-staff interaction in neonatal care has highlighted a parental desire for readily available and consistent information provided by staff (42), as well as more written information (44), which directly aligns with my study's process-mapping results.

Using ‘virtual process-mapping’ via an online survey was an additional novel methodology I used in response to parent feedback in this study; the number of parent respondents to the online survey was comparable to that of large studies using one-to-one interviews or paper-based surveys for parents in neonatal care.

Of the 56% of parents that completed the survey’s anonymous demographic section online, the majority were white mothers of premature infants (<28 weeks) that had received care in a NNU in England, outside London. Whilst this is clearly not representative of the wider neonatal parent population, it is not clear if the remaining 44% of parents who did not complete their demographic information would have reflected a more diverse population, or if the available results are indicative of a demographic profile of parents most likely to participate in such a study, with convenience sampling and online recruitment.

It is important to note that the information themes that were reported in the in-person parent group with parents from the CW Hospital NNU were very similar to the ones from the online parent survey, indicating that findings could be generalisable across different neonatal units.

Finally, another limitation was that whilst utilising social media for initial parent project reactions and the online survey for process mapping allowed me to collect more data from a wider geographical population of parents in a shorter amount of time, it also meant analysing occasional shorter parent messages, with the potential to lack context and detail. I was also not able to collect descriptive information for the parents that posted initial reactions on social media as their profiles had restrictive privacy settings.

### 5.6 CONCLUSIONS

Communication between parents and staff members in neonatal care predominantly involves verbal updates throughout the neonatal admission. Written information provision is inconsistent through an infant’s journey and primarily offered to parents at the time of admission to the neonatal unit.

Parents and staff reported the same types of information as being shared, but parents felt it was delivered inconsistently, using too much medical jargon. A communication tool providing daily written information in a parent-centred way could be a valuable adjunct to verbal communication in neonatal care.

# Chapter 6

# How can information be best shared with parents in written form? Co-creation of a communication tool template with parents

In this chapter, I describe the co-creation of a communication tool template with parents, based on results from Chapter 5, as well as the concurrent re-design of the information booklet provided to parents on admission to the CW NNU. I presented this work at the international 2018 European Academy of Paediatric Societies conference (EAPS), Paris, entitled '*Improving parent information in neonatal care: A ward-based co-design activity with parents to improve satisfaction'.*

## 6.1 BACKGROUND

In Chapter 5, I described parent information preferences *('what do parents want')* and categorised preferred information into '*infant-specific'* information (e.g. updated infant weight) and *'unit-specific'* information (e.g. explanation of neonatal terms and equipment).

This study's aim is to co-design and evaluate a communication tool template with parents *('My Baby's Summary Report', MBSR)* to share *'infant-specific'* information with parents in written form. '*Infant-specific'* information is available in the individualised, daily-updated data items routinely recorded in the neonatal Electronic Patient Record (EPR).

*'Unit-specific'* information does not need to be individualised or updated every day and is provided to all parents on admission to a neonatal unit, in the form of a written admission booklet. I therefore aimed to utilise parent feedback from Chapter 5 to re-design (with parents) the *'unit-specific'* information booklet provided to parents on admission to the CW NNU.

There is a lack of studies describing the co-design of neonatal care information resources together with parents who are currently receiving neonatal care. In general, my systematic review of interventions implemented

in neonatal care (Chapter 4) showed that only 16% of included studies reported involving parents in intervention design at all (11).

### 6.1.1 Neonatal Electronic Patient Records (EPR) and 'Clevermed Ltd' platform

In the UK, the use of Electronic Patient Records (EPR) being shared across neonatal units began in 2004, as a regional initiative with the commercial platform 'Clevermed Ltd' (Edinburgh, UK). This platform gradually expanded nationally and is currently used by most neonatal units in the UK to record National Health Service (NHS) neonatal EPR data, plan services and record activity for payment by NHS England (64).

Infants admitted for NHS neonatal care in England, Scotland, Wales and the Isle of Man have clinical data recorded as part of routine clinical care by neonatal staff (usually nurses) onto the 'Clevermed Ltd' platform at the point of care. To avoid any confusion, the terms EPR and 'Clevermed Ltd' will be used interchangeably in this thesis to refer to the location where neonatal staff members record daily infant data items (see section 6.1.3).

### 6.1.2 National Neonatal Research Database (NNRD)

In 2007, the Neonatal Data Analysis Unit (NDAU) was established at the Chelsea and Westminster Hospital campus of Imperial College London to improve the quality of EPR data and promote their use to support neonatal services and research (65). Data are extracted from the Clevermed Ltd platform as recorded by 181 participating neonatal units in England, Wales, Scotland and the Isle of Man to form the National Neonatal Research Database (NNRD) (65). Approximately 400 predefined data items of those entered onto the 'Clevermed Ltd' platform (the 'Neonatal Data Set': DAPB1595, an NHS Information Standard), are extracted quarterly, undergo quality assurance procedures, are anonymised and form the NNRD.

Due to the work of doctors and nurses entering routine clinical data every day, the NNRD *'has become established as a unique, award-winning, national resource containing quality-assured, 'real-world' clinical data'*. Currently the

NNRD contains information from approximately one million babies and 10 million days of care, with data from around 100,000 new patients being added each year (65).

### 6.1.3 Neonatal EPR infant data summaries

EPR data summaries contain a wide range of infant information and medical jargon. The CW NNU admits around 800 infants every year. Neonatal staff members (usually nurses) routinely update 14 EPR data sections daily. In addition to 13 daily-updated EPR sections, staff members record one 'general information' data section on admission, including 'once-only' entry data items such as age, gestation, weight etc.

Each daily data section represents a different physiological body system and includes several discrete data items. Daily data sections include:

- Respiratory
- Cardiovascular
- Gastrointestinal
- Neurology
- Opthalmology
- Lines in situ/ sepsis
- Metabolic/ jaundice
- Haematology/ transfusions
- Renal/ genitourinary
- Skin
- Fluids/feeding
- Other
- Diagnosis/ procedures/ medications

In total, the above data sections include 101 discrete data items (e.g. method of respiratory support, amount of oxygen, method of feeding).

### 6.1.4 Parent information booklet (clinician-designed)

All parents of infants admitted to the CW NNU, like in most other neonatal units, are given an information booklet as part of their 'admission pack'. This booklet had been designed exclusively by neonatal nurses and doctors, without parent input. It included a wide range of information topics relevant to neonatal care and the CW NNU, as well as medical jargon, and was printed and prepared by the neonatal receptionist using standard A4 paper sheets in black ink.

## 6.2 AIM

*'Infant-specific'* information is routinely recorded, updated daily on EPR and stored quarterly into the NNRD. To share this information with parents daily, I aimed to identify the specific EPR (and therefore also eventual NNRD) data sections and data items parents considered important to receive, 'translate' them into language parents can understand and incorporate them into a communication tool.

Neonatal staff exclusively designed *'unit-specific'* information for parents in the CW NNU, in the form of an information booklet. I aimed to re-design this information booklet with parents.

## 6.3 METHODS

To design a communication tool template and re-design the CW NNU parent information booklet, I utilised the parent information preferences results from Chapter 5, regarding '*infant-specific'* information and '*unit-specific'* information, respectively.

- Communication tool template - '*infant-specific'* information

To utilise parent feedback about preferred '*infant-specific'* information, I conducted work within my project steering group (PSG) and facilitated a parent co-design focus group with parents that had previous neonatal experience.

- Parent information booklet - '*unit-specific'* information

For preferred '*unit-specific'* information, I conducted work within my PSG and used quality improvement methodology to re-design and further improve the CW NNU information booklet based on feedback from parents on the neonatal unit.

### 6.3.1 Research ethics

The Imperial College and CW Hospital Research and Development departments confirmed this work was considered 'service evaluation' and as such no Research Ethics Committee review was required.

### 6.3.2 Plan-Do-Study-Act (PDSA) cycles

In line with quality improvement methodology, I have used the Plan-Do-Study-Act (PDSA) cycle method in this chapter and throughout the study, as a practical scientific way of rapidly testing small changes in supporting implementation of interventions (66-68).

The PDSA method is part of the 'Model for Improvement' framework, which helps teams to structure improvement efforts (Figure 11). The Model for Improvement is made up of a set of fundamental questions that drive all improvement and are used in conjunction with the PDSA cycle.

The PDSA method follows a defined four-stage cyclical learning approach to develop changes aimed at improvement. In the 'plan' stage a change is identified, in the 'do' stage this change is tested, the 'study' stage examines the success of the change and the 'act' stage identifies adaptations and next steps to inform a new cycle (66-68). The four stages reflect the scientific experimental method of forming a hypothesis, collecting data to test this hypothesis, analysing and interpreting the results and drawing conclusions to prove or disprove the hypothesis.

**Figure 11. The model for improvement**

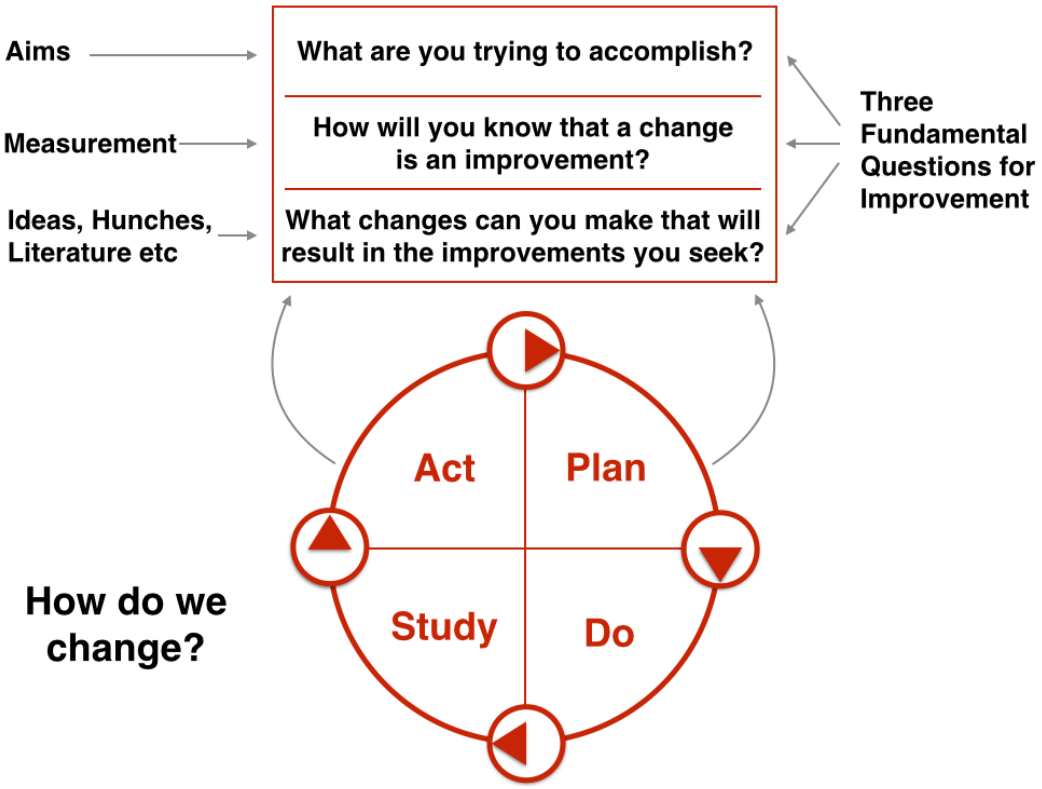



*Figure 11. Image from NIHR CLAHRC NWL QI4U online learning module, https://clahrcnwl.qi4u.org/scorm/6, accessed 23rd September 2019.*

### 6.3.3 '*Infant-specific*' information for parents

6.3.3.1 Participants and recruitment

Similar to recruitment for the *'parent process mapping and exploration of information needs'* focus group described in Chapter 5 (see section 5.3.4) I invited all 76 parents on my project's parent database via email to attend a face-to-face focus group in the Bliss charity's headquarters meeting room in central London, UK. Eligible parents had a baby previously requiring NHS neonatal care in the UK (now discharged) and could speak and read English. I aimed to recruit a convenience sample of 10-12 parents. Parents were reimbursed £60 for travel and £50 for childcare costs. I emailed parent participants study information sheets and consent forms prior to the meeting and consented them on the day face-to-face. Parents could withdraw at any time without having to give a reason.

I used PDSA improvement cycles (66-68) to identify ways of maximising face-

to-face parent attendance in view of previous challenges encountered when organising the parent process mapping focus group. Specifically, I offered a wider variety of dates/times as meeting options to parents (ensuring these did not include school holiday dates), suggested both in-hospital and external meeting venues and offered the option to accommodate babies in the focus group. I communicated the above to parents with a longer notice period compared to previously.

6.3.3.2 Parent co-design focus group

I facilitated a focus group with parents where I shared the process mapping results with them (see Chapter 5) and used parent co-design methodology in line with the 4Pi National Involvement Standards (Principles, Purpose, Presence, Process and Impact) (26, 27) to design the communication tool's template. Specifically, I presented parents with all the electronically available EPR data items and guided them through the process of selecting the specific items that matched parent-reported information needs. My study's parent representative (SK), one NIHR CLAHRC NWL steering group team member (WC) and the Bliss charity research engagement officer (MP) also participated as co-facilitators.

Parents identified '*infant-specific'* EPR data items for inclusion in the communication tool and designed an initial communication tool template to deliver daily clinical updates.

6.3.3.3 Project steering group work

Working within my PSG and co-led by the parent representative (SK) I developed parent-friendly explanations for the EPR items chosen by parents in the co-design focus group.

In consultation with parents, I named the communication tool *'My baby's summary report'* (MBSR).

6.3.3.4 Communication tool template design

My original plan when conceiving this study was to develop and pilot the communication tool as a mobile phone application, through which parents would directly access their baby's EPR data. There is evidence that parents in NICU strongly support the use of eHealth technology in neonatal care (including mobile phone applications and websites), as these can provide readily accessible information (69, 70).

In March 2018 the CW Hospital trust decided it would be changing neonatal EPR providers (from 'Clevermed Ltd' to 'Cerner') in September 2019, placing any other IT developments on hold. Due to this externally imposed timeline alteration, it was necessary for me to amend my protocol to develop a paper version of the communication tool for piloting and evaluation.

The communication tool is a printed sheet of paper, containing the daily-updated EPR data items for each infant as chosen by parents in the co-design focus group. I manually downloaded these items from EPR and incorporated them into an individualised *'My Baby's Summary Report'* template for each infant, matching a pre-prepared parent-friendly explanation to each data item.

### 6.3.4 '*Unit-specific'* information for parents

I co-led this workstream together with my study's parent representative (SK), in 3 stages. Parents had already described their information needs and preferences for '*unit-specific'* information in Chapter 5.

6.3.4.1 Stage 1: Steering group work (Co-design)

Working within my PSG, I used parent feedback from Chapter 5 to re-design the existing clinician-designed '*unit-specific'* information provided to parents on admission to the CW NNU (Booklet A) and created booklet B.

6.3.4.2 Stage 2: Parent participation in NICU (Evaluation and Iterative development)

In this stage, I used quality improvement methodology to further refine booklet B's information based on feedback from current parents in NICU (and created

Booklet C). Together with my study's parent representative (SK) and PSG neonatal nurse, I distributed satisfaction questionnaires to all parents with infants on the CW NNU over 2 weeks, in my clinical role on the unit as a neonatal registrar. Parents who were interested in completing the questionnaires did so anonymously.

I initially assessed parent satisfaction on the neonatal unit with information booklets A and B in sequence. By utilising NNU parent feedback in PDSA improvement cycles (66-68), I further iteratively improved the information in booklet B, to create Booklet C.

6.3.4.3 Stage 3: Parent satisfaction questionnaire (Re-evaluation)

I assessed parent satisfaction with information booklets A, B and C using a brief 7-question tailor-made questionnaire, over 2 weeks. Parents evaluated booklets A, B or C according to when during those 2 weeks they were approached and how long they remained on the unit for.

I developed the questionnaire (Appendix 5) within my PSG to cover 3 themes: parent satisfaction with information content, information format and overall satisfaction (5 point Likert scale, 1 least satisfied – 5 most satisfied). The questionnaire also included an open question for parents to suggest any improvements to the booklet. PSG members confirmed that the selected questions effectively captured the booklets' evaluation and collectively further refined them for clarity and precision.

6.3.4.4 Analysis of parent questionnaire data

I analysed parent responses using the statistics software SPSS version 25. For Likert scale questions I produced percentage graphs of responses relating to booklets A, B and C. For free-text questions 4 and 5, I utilised the free entry responses within my PDSA cycles to further improve the booklet.

For the Likert scale question on overall satisfaction, I conducted a comparison of overall parent satisfaction with (initial) Booklet A versus (final) Booklet C. Because parents evaluated booklets A, B or C according to when they were

approached and how long they remained on the unit for, a proportion of this parent data set was partially paired. As such, the parent data set consisted of two subsamples: one sample of parents who evaluated both Booklet A and Booklet C (the paired subsample), and another subsample of parents who evaluated only one of the booklets, either A or C (unpaired subsample). For this analysis I used the optimal pooled t-test (71), as this is optimal for paired data with missing values and small samples.

## 6.4 RESULTS

### 6.4.1 '*Infant-specific'* information for parents

6.4.1.1 Parent co-design focus group participants

In total, 12 parents confirmed attendance, 3 parents subsequently had to cancel and a further 5 parents unexpectedly did not attend on the day (there was a terrorism threat for the main train station near the venue); parents emailed to offer to help remotely.

Four parents (2 men and 2 women), as well as my study's parent representative (SK) participated in a 3-hour face-to-face focus group session (Table 15). All parents were different to the ones who had participated in the process mapping session (Chapter 5), apart from 1 mother who attended both meetings.

**Table 15. Parent demographics (Co-design focus group)**

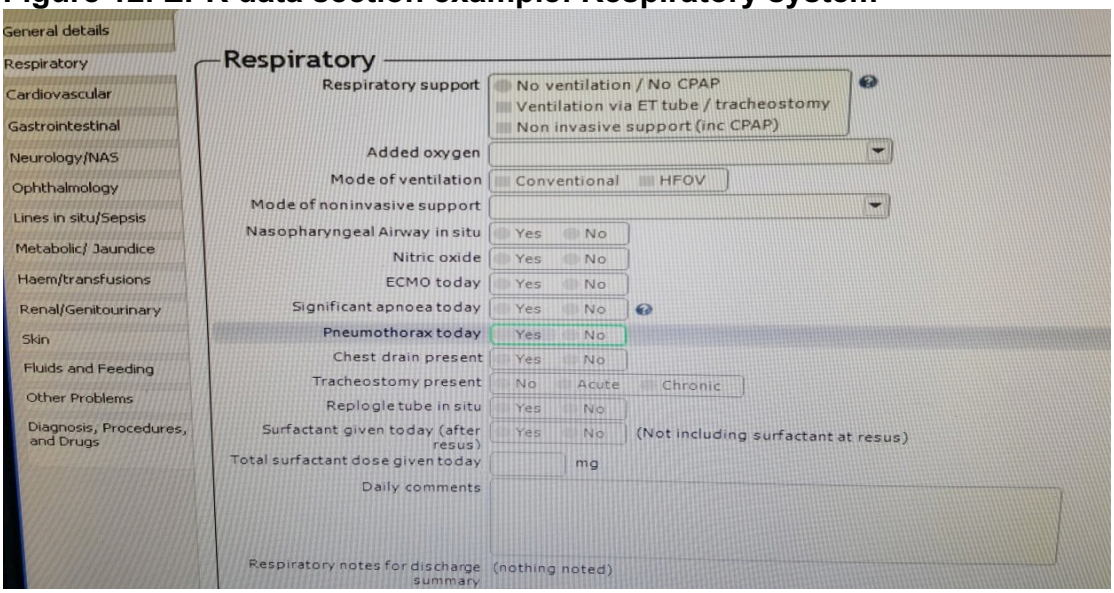
| Gender | Age (years) | Ethnicity | NICU location | Gestation (weeks) /gender | Length of stay in NICU |
|---|---|---|---|---|---|
| Male | 43 | White British | London | 25 / Female | 120 days |
| Male | 38 | White British | London | 25 / Male twins | 107 days |
| Female | 24 | White British | London | 25/ Female twins | 138 days |
| Female (also participated in process mapping) | 24 | White other | London | 29 / Male | 7 weeks |
| Female (Study's parent representative) | 26 | White other | London | 32/ Male | 2 weeks |

6.4.1.2 ‘ My Baby’s Summary Report’ (MBSR) template development

- **EPR DATA ITEMS SELECTED BY PARENTS (Focus group output)**

There are 14 available routinely-recorded EPR data sections on the Clevermed platform (e.g. respiratory system section) including a total of 101 available discrete EPR data items (example data section in Figure 12).

**Figure 12. EPR data section example: Respiratory system**




Parents identified 5 out of the 14 available EPR data sections as matching their information needs, including 12 out of the 101 available discrete data items (Table 16). These 12 data items were selected by parents for inclusion in the MBSR template.

Parents also strongly requested to include an up-to-date location of their infant on the neonatal unit (room and cot number). Unfortunately, as infant locations are liable to change at any time and at short notice, owing to availability of cots and/or high turnover, updated infant locations are not routinely recorded in the neonatal EPR and therefore could not be included in the MBSR.

**Table 16. EPR data sections and data items identified by parents as important**

| | 5 data sections | 12 EPR data items |
|---|---|---|
| **EPR data** | • General details | • Age (days)<br>• Corrected gestational age (weeks/days)<br>• Weight (g) |
| | • Respiratory | • Respiratory support method *(ETT: endotracheal tube/tracheostomy; No ETT/No CPAP; Non-invasive support)*<br>• Supplemental oxygen *(Y/N)* |
| | • Fluids and feeding | • Parenteral nutrition today *(Y/N)*<br>• Intravenous glucose and electrolyte solution *(Y/N)*<br>• Any enteral feeds today *(Y: Mum's milk; Formula; Donor milk/ N')*<br>• Method of feeding *(Bottle, breastfeeding, OG, NG, NJ)*<br>• Baby tube fed *(Y/N)* |
| | • Sepsis (infection) | • Blood culture done today / CSF culture done today *(Y/N)* |
| | • Drugs (medication) | • Medicines received today *(List)* |

*Table 16. In right hand column, discrete EPR data items chosen by parents. In brackets all potential dropdown menu options are included for each data item. CPAP: Continuous Positive Airway Pressure; CSF: CerebroSpinal Fluid.*

Parents designed an initial communication tool template to deliver both '*infant-specific'* data (daily-updated on EPR) and '*unit-specific'* information (information included in unit's written parent booklet) to parents in the neonatal unit (Figure 13). Parents gave specific feedback on the template's format, wanting a 'general details' section for their infant's key information (e.g. date of birth, weight), as well as a 'dashboard' of their preferred body systems, a tracking graph for weight and a dropdown menu for each daily infant summary by date.

**Figure 13. Initial communication tool template developed by parents**

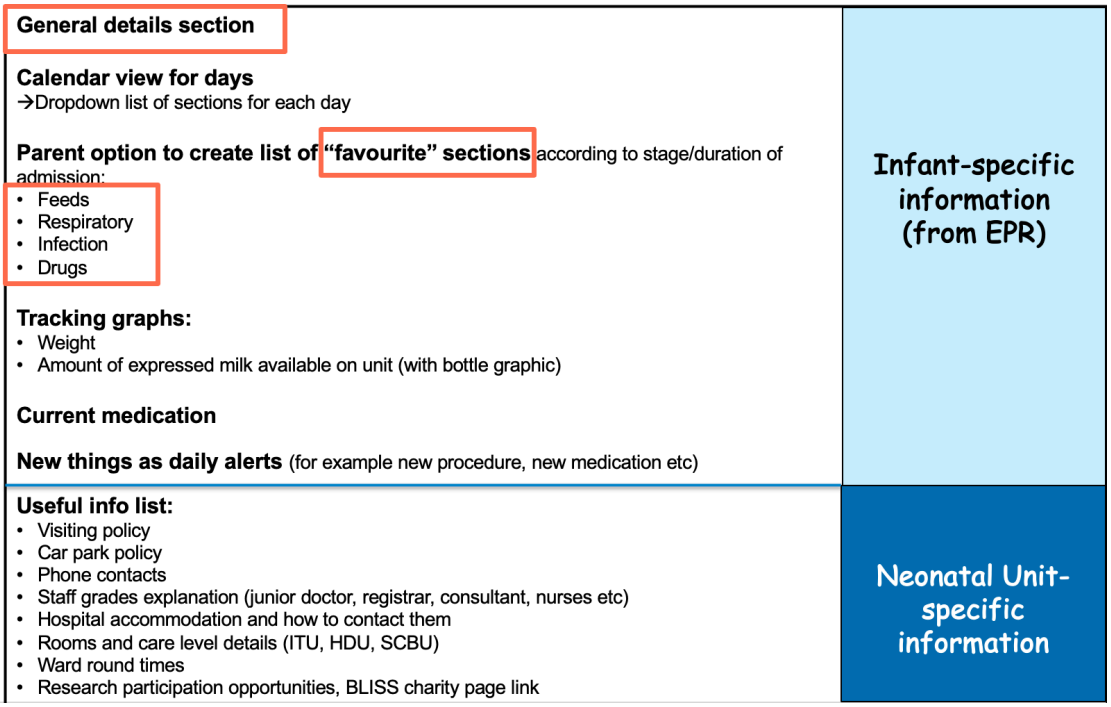



*Figure 13. Communication tool template includes 'infant-specific' daily-updated data (from EPR) [TOP SECTION] and 'once-only' 'unit-specific' information available in the unit's parent booklet [BOTTOM SECTION]. ITU: Intensive Therapy Unit; HDU: High Dependency Unit; SCBU: Special Care Baby Unit.*

- **PARENT FRIENDLY EXPLANATIONS DEVELOPED FOR SELECTED EPR ITEMS (Steering group output)**

I manually downloaded the parent-chosen items from EPR every day to incorporate them into an individualised *'My baby's summary report'* (MBSR) for each infant. On the EPR platform, each data item has a blank space for a value to be inserted, a choice of *'Yes/No'* or a list of dropdown menu options to select from. Together with my PSG members and the parent representative (SK) we developed parent-friendly explanations for each data item and its associated answer options. All explanations were further reviewed and approved by parents that attended the focus groups, over email (template with list of explanations in Appendix 6).

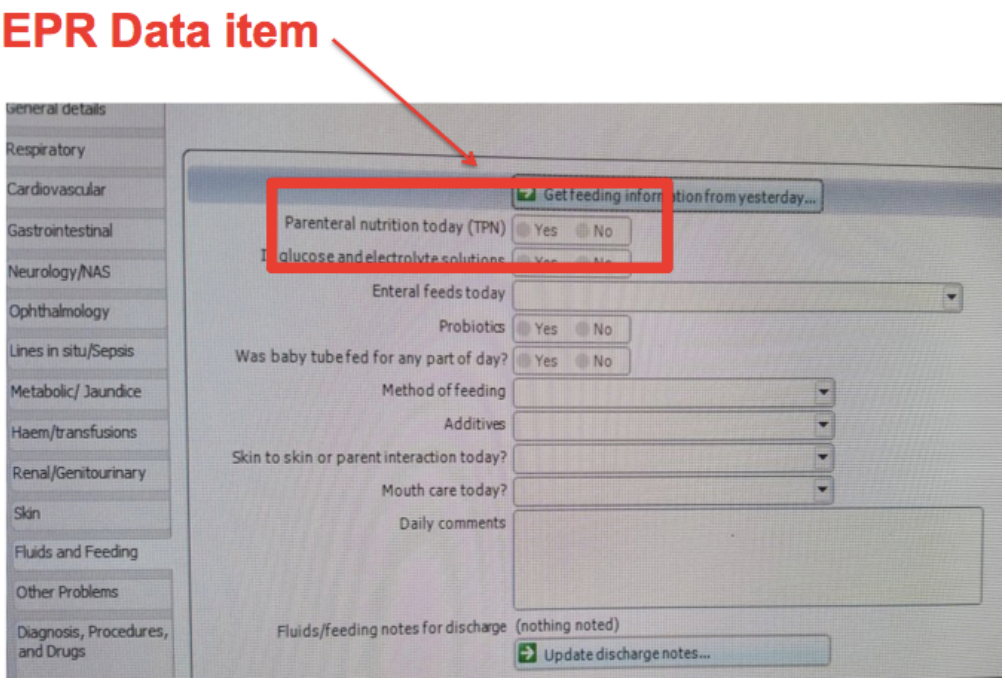
For example, for the EPR item *'method of feeding'* one drop-down menu option is *'Nasogastric tube feeding'*. The parent-friendly explanation for this was *'baby is feeding through a small tube that goes from the nose straight to the stomach (medical term "nasogastric tube").*

• **BUILDING A 'MY BABY'S SUMMARY REPORT (MBSR) FOR EACH INFANT**

The following is an example of building an individualised MBSR using the template co-designed with parents.

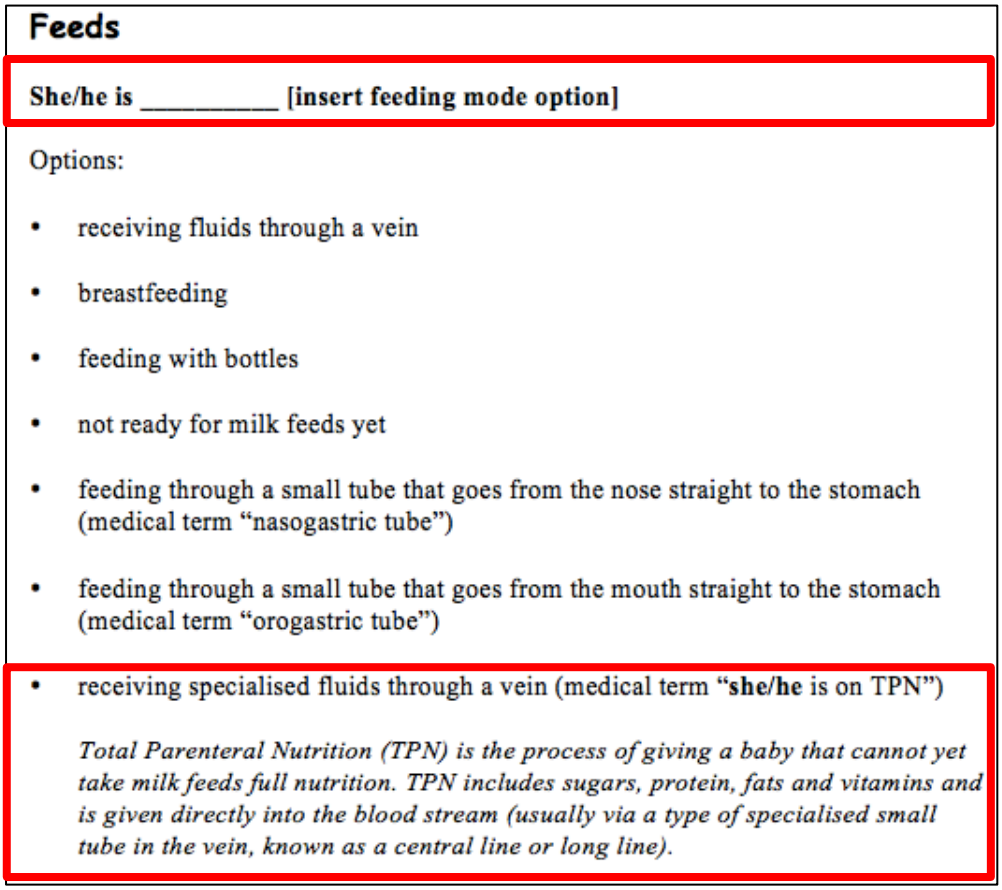
For a given baby, I downloaded the recorded information for each of the 12 EPR data items (as per Table 16). For example, in the EPR data section *'Fluids and Feeding'*, for the data item *'parenteral nutrition today (TPN)'* there is a choice of 'Yes/No' (Figure 14).

**Figure 14. EPR data section *'Fluids and Feeding'* → data item *'Parenteral nutrition today (TPN)'* → Yes/no.**




For a baby receiving TPN where *'Yes'* has been selected by neonatal staff, I included the parent-friendly explanation for TPN in the MBSR (Figure 15).

**Figure 15. Parent-friendly explanations for feeding options**



**Feeds**

**She/he is _____ [insert feeding mode option]**

Options:

- receiving fluids through a vein
- breastfeeding
- feeding with bottles
- not ready for milk feeds yet
- feeding through a small tube that goes from the nose straight to the stomach (medical term "nasogastric tube")
- feeding through a small tube that goes from the mouth straight to the stomach (medical term "orogastric tube")
- receiving specialised fluids through a vein (medical term "**she/he** is on TPN")

*Total Parenteral Nutrition (TPN) is the process of giving a baby that cannot yet take milk feeds full nutrition. TPN includes sugars, protein, fats and vitamins and is given directly into the blood stream (usually via a type of specialised small tube in the vein, known as a central line or long line).*

In a similar way, I matched the corresponding parent-friendly explanations to each of the baby's completed EPR data items. If any of the items had not been completed by neonatal staff, I left that section in the MBSR blank.

Figure 16 is an example of a completed MBSR, including recorded information from the 12 EPR data items selected by parents (Table 16) and presented in parent-friendly language.

**Figure 16. Example of completed MBSR**

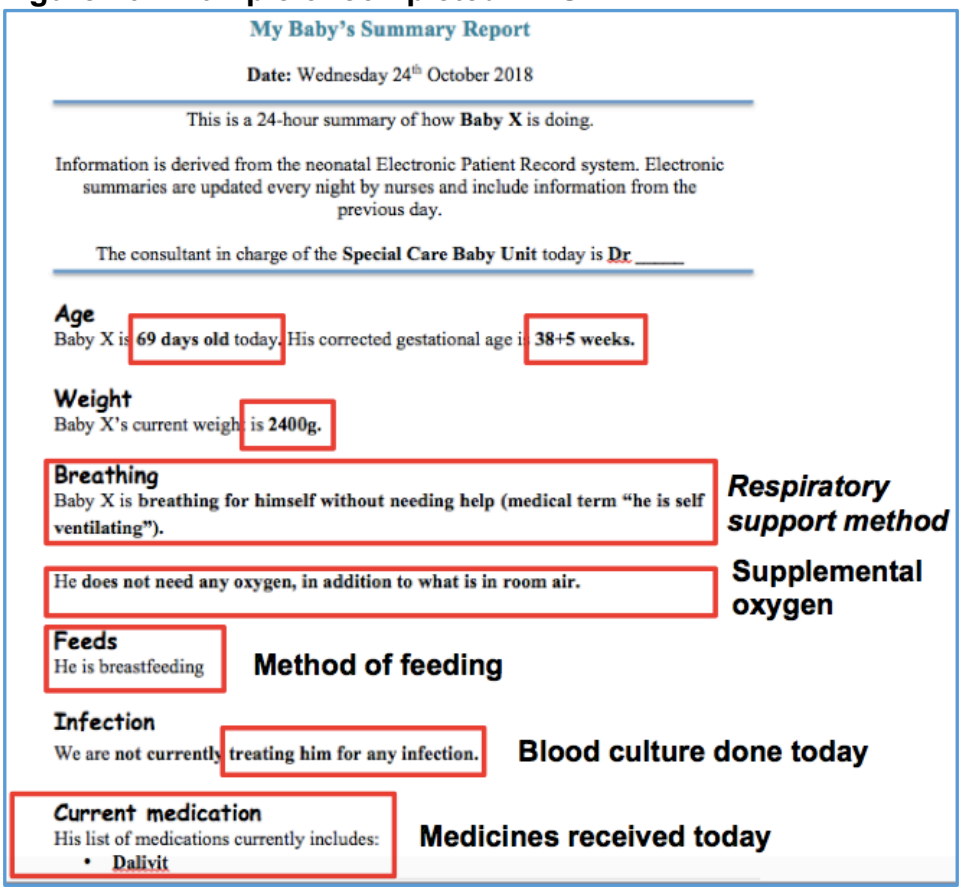



*Figure 16. EPR data items on right hand side in BOLD; parent-friendly explanations in RED BOXES.*

### 6.4.2 '*Unit-specific*' information for parents

6.4.2.1 NICU parent participants

In total, 26 parents completed satisfaction questionnaires on the neonatal unit over 2 weeks. 14 parents evaluated booklet A, 19 parents booklet B and 11 parents booklet C. Overall, the same 4/26 parents evaluated all booklets A, B and C. Most parent participants were mothers (70.5% versus 29.5% fathers), most parents had been on the neonatal unit for between 1 week-1 month (40.9%) and their babies were born at between 24-30 weeks gestation (34.1%).

6.4.2.2 Iterative development of Parent information booklet

Working with feedback from parents with previous neonatal experience in my PSG and then utilising further feedback from parents on the NNU in PDSA improvement cycles (66-68), I gradually improved parent Booklet A to create the final Booklet C (Appendix 7).

6.4.2.3 Parent satisfaction questionnaire results

Results showed a continual improvement from the clinician-designed booklet A through to the parent-designed booklet C, which was consistent for all questions, assessing both parent satisfaction with content (Figure 17) and format of information (Figure 18).

**Figure 17. Parent evaluation of booklets A to C (information content)**

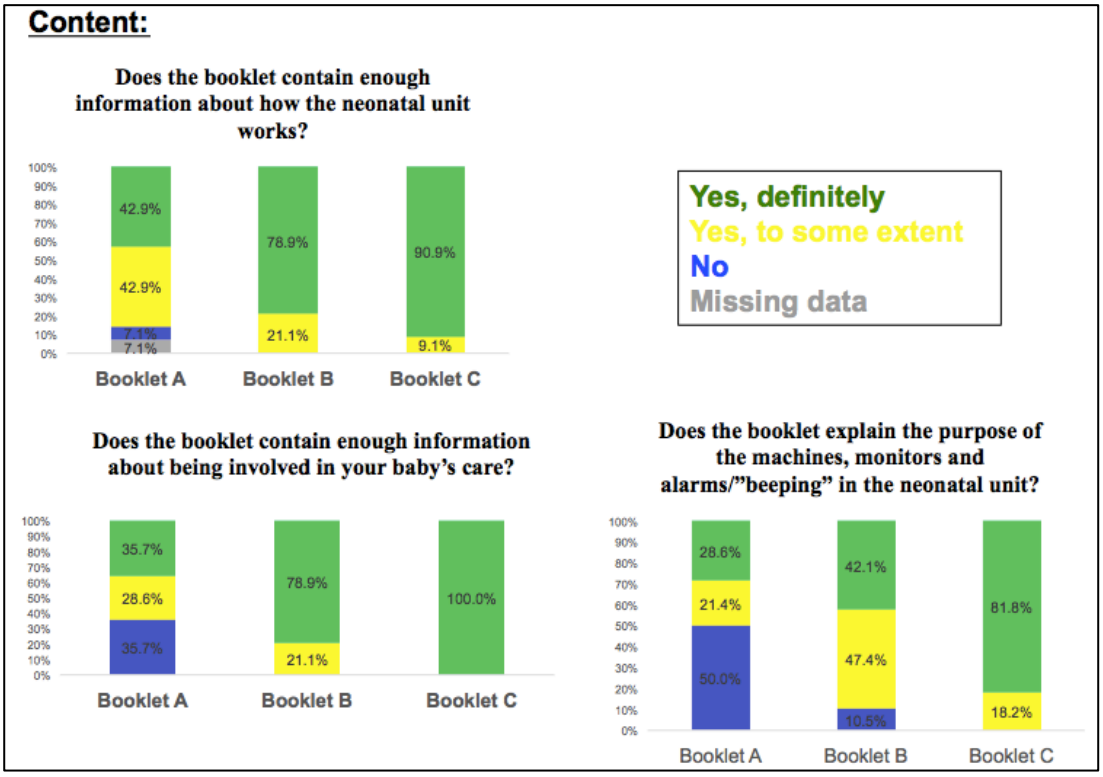



*Figure 17. Parent responses in percentages, colour coded as per box.*

**Figure 18. Parent evaluation of booklets A to C (information format)**

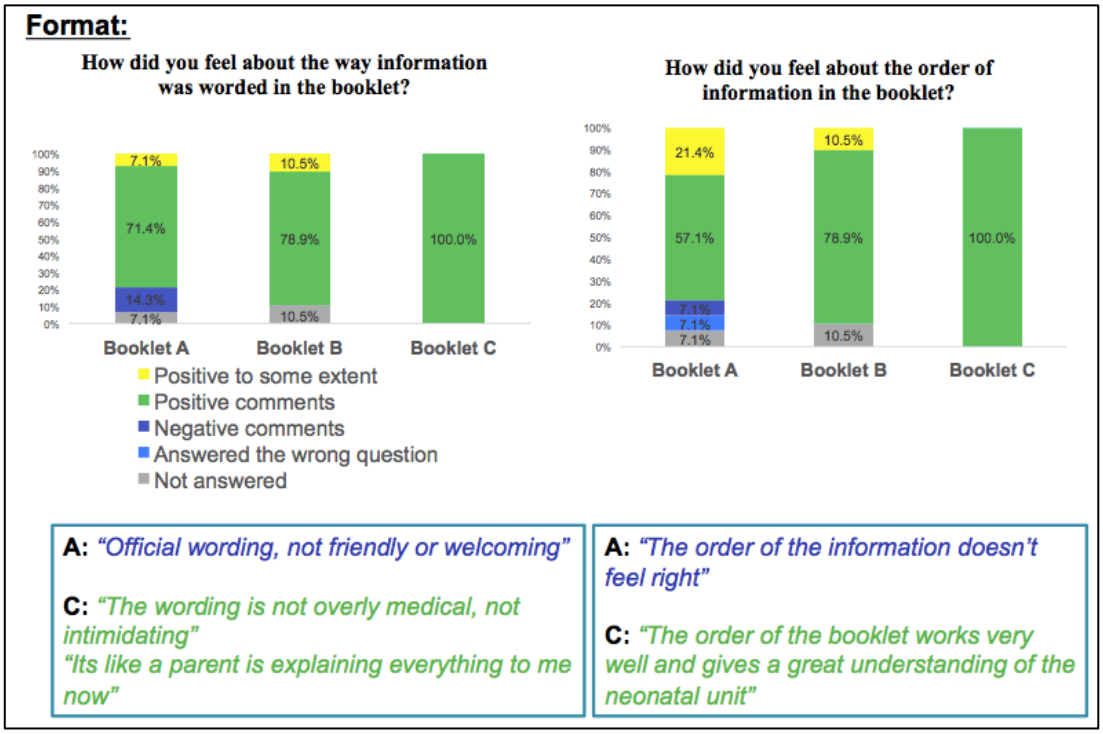



*Figure 18. Parent responses in percentages, colour coded as per colour guide. Verbatim parent comments relating to booklets A and C in boxes.*

Overall, mean parent satisfaction with the information provided in booklet A was 3.71 out of 5 and in booklet C 4.72 out of 5 (Figure 19). On conducting the optimal pooled t-test, this difference was statistically significant (p=0.003).

**Figure 19. Overall parent satisfaction with booklet A versus booklet C.**

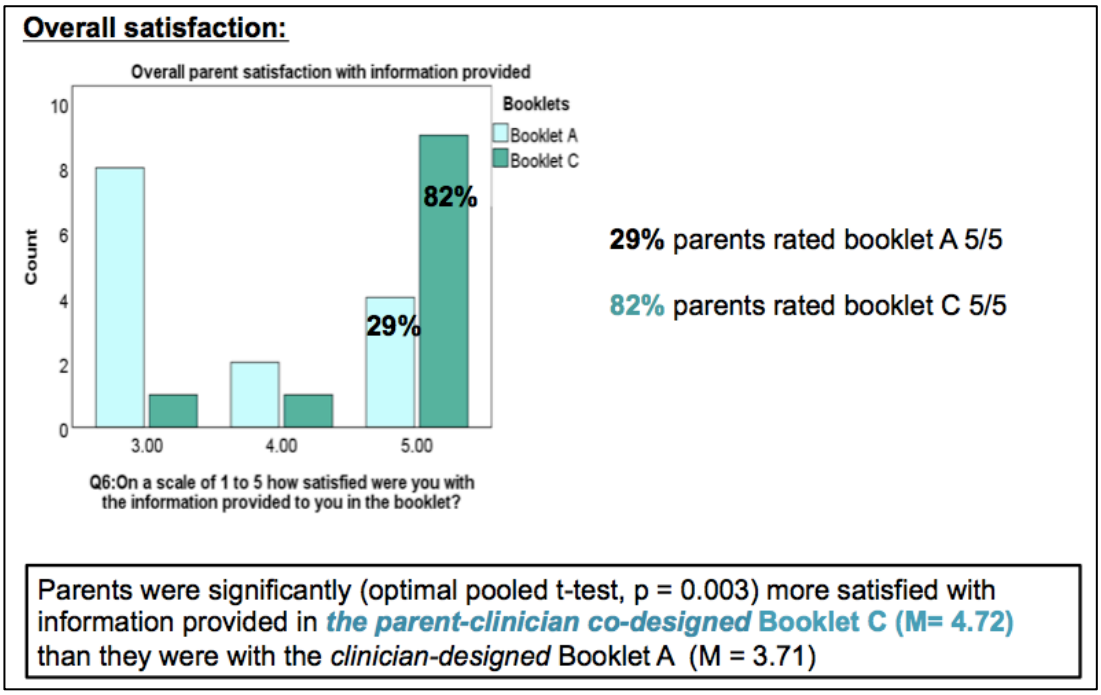



*Figure 19. Light blue bars= Booklet A; Green bars= Booklet C; M= Mean.*

## 6.5 DISCUSSION

### 6.5.1 Key findings

For '*infant-specific'* information, I have described the development of a communication tool template with parents, called 'My Baby's Summary Report' (MBSR). The MBSR has been designed to share parent-selected EPR data items in parent-friendly language, in a format designed by parents.

To date, only one 2012 study in the United States has evaluated the impact an EPR-based daily update letter in a neonatal intensive care unit, finding a trend towards improved parent communication, and improved perceived parental competence to manage information in the neonatal unit (16). However, parents were not involved in designing the daily letter or in any other study aspect. This PhD reports sharing EPR infant data summaries with parents in neonatal care, using a communication tool designed by parents with neonatal experience.

For '*unit-specific'* information, I have described the iterative improvement of the CW NNU parent information booklet with parents on the neonatal unit. Parents were more satisfied (statistically significant p = 0.003) with information provided in the final parent-designed booklet than they were with the initial clinician-designed booklet. Admission information booklets for parents in neonatal care are anecdotally either exclusively designed by the clinical teams or just approved by parents at the end. There is lack of studies reporting the development of these materials together with parents; this is the first study where parents have co-developed a neonatal unit information resource whilst their infants are still receiving neonatal care as inpatients.

### 6.5.2 Strengths and limitations

A key strength of this workstream was co-designing the communication tool template and parent information booklet with parents with experience of NHS neonatal care, both previous and current. The involvement of parents currently receiving neonatal care was a novel contribution to the field.

Parents designed the content and format of information to be shared in a communication tool, whilst also using the original parent feedback from over 50 parents obtained in the process mapping stage (Chapter 5). Additionally, a substantial number of parents with infants receiving neonatal care (26 parents) were involved in re-designing the CW NNU parent information booklet over a 2-week period. Continuous evaluation using a purpose-made questionnaire enabled rapid changes to the parent information booklet through PDSA improvement cycles, leading to a statistically significant improvement in parent satisfaction with the final parent-designed booklet, compared to the initial clinician-designed booklet.

In my systematic review of interventions in neonatal care (Chapter 4), only 16% of included studies (5/32) reported involving parents in intervention design, of which 2 reported improvement of parent satisfaction (11). However, the number of included studies was too small to estimate any effect of parent co-design on the success of interventions at study level. Within healthcare, the science of intervention development is still in its infancy (72). Few studies

report the development process, giving the impression that interventions 'just appear' and proceed straight to trial. Lack of clarity in this area was one of the factors that prompted the revision of the UK Medical Research Council's guidance on development and evaluation of complex interventions in 2008 and again in 2021 (73, 74). The new guidance highlights the importance of good preparation, including conducting interviews with service users targeted by the intervention, to develop a detailed understanding of the likely process of change and to ensure acceptability. This study has complied with this guidance by conducting process mapping with parents and involving them in all study stages, including intervention design.

Another key strength is that this work has the potential to be applied to other neonatal units. Using the MBSR communication tool to share *'infant-specific'* EPR data with parents could be easily adopted by other NNUs in NHS neonatal care (as well as outside the NHS, worldwide). Almost all NNUs currently routinely record daily infant data, primarily for reasons such as audit and benchmarking purposes. Regardless of the specific type of EPR system utilised by any NNU, as long as the specific EPR data items can be matched to corresponding parent-friendly explanations, a bespoke MBSR template for any NNU could be created.

Similarly, any NNU could adopt a similar process to the one described in this chapter to co-design a *'unit-specific'* information booklet with parents, for parents. Once an initial working group of NNU parents is established and the required *'unit-specific'* information content is identified, the booklet's format could be co-designed using PDSA improvement cycles together with current NNU parents. There would be a list of information categories commonly included in all neonatal units, such as infection control, explanation of neonatal terms, parent involvement and parent support, as well as Bliss neonatal charity resources.

A study limitation was the small sample size of the in-person parent co-design group. This group included 5 parents, after many parents were not able to attend because of work and/or childcare commitments and an un-anticipated

security alert that limited attendance at the meeting venue on the day. All 5 parents were white, with previous neonatal experience in a London NNUs, 3 were mothers and 2 fathers, with infants born at between 25-32 weeks. While this sample is likely an over-representation of a specific parent demographic from within London, one must bear in mind that this was the initial template design stage with a planned further iteration and improvement with parents for the piloting trial (Chapter 8). Therefore, this small (and specific) parent sample size was not restrictive to the process, since it served as 'the starting point' to continually further improve the MBSR with parents in Chapter 8.

### 6.5.3 Dissemination and further grant

To maintain active stakeholder support and project momentum, I published online articles on this chapter's work in the CW Hospital divisional update for women and children (56), CW Hospital trust online magazine (57) and NIHR CLAHRC NWL online newsletters (59, 60).

Additionally, following this work's completion, I worked with an illustrator to produce an infographic that told the 'story' of parent involvement in improving the CW NNU parent information booklet, highlighting the impact parent co-design methodology in neonatal interventions can have on improving parent satisfaction (Appendix 8). I distributed the infographic as a leaflet to parents with previous neonatal care experience and those currently experiencing neonatal care through both the 'CWPLUS' and Bliss charities.

My fourth project grant by the CW Hospital charity 'CWPLUS' (see Chapter 2) funded an NIHR CLAHRC NWL affiliated graphic designer to develop parent-friendly illustrations for the new parent-designed booklet (Appendix 7) and the printing of 800 copies for the CW NNU for 1 year. Together with parents, the new booklet was named *"Your neonatal unit guide- created by parents for parents".* The newly illustrated booklet was printed and distributed to all CW Hospital NNU parents after this work's completion as part of standard care, therefore the illustrations could not have impacted on the preceding booklet's evaluation by parents. I coordinated a launch event for the new parent booklet on social media (including on my project pages, the CW Hospital and Bliss

social media pages) and uploaded an electronic version of the booklet on the official CW NNU webpage, in collaboration with the CW trust communications team (75). I have subsequently successfully negotiated ongoing yearly funding of the booklet prints for the CW NNU by the CW NNU local fund, with 6-12 monthly reviews of the booklet's content in collaboration with parents experiencing neonatal care.

### 6.6 CONCLUSIONS

In this chapter I have described how I worked with parents to share their preferred '*infant-specific'* and neonatal *'unit-specific'* information with them in written form.

Using '*infant-specific'* information in neonatal care, I co-designed this study's MBSR intervention with parents to share parent-selected EPR data items in parent-friendly language, in a parent-chosen format. This communication tool template forms the baseline intervention implemented in the piloting trial (see Chapter 8).

Using '*unit-specific'* information, I described the iterative improvement of the CW NNU parent information booklet with parents on the neonatal unit, leading to a statistically significant increase in parent satisfaction with the final parent-designed booklet versus the initial clinician-designed booklet. This shows parent co-design methodology provides potential for improving communication and parent satisfaction in neonatal care.

Both the MBSR intervention and parent-designed booklet have potential to be widely generalisable to other NNUs, as long as *'unit-specific'* EPR considerations and *'unit-specific'* information details are applied, respectively.

In Chapter 8, I discuss using parent co-design methodology to further develop and improve the MBSR based on continuous parent feedback, during the piloting phase of the intervention. To obtain this feedback I used a purpose-made parent satisfaction survey, the development and validation of which I describe in the next Chapter 7.

# Chapter 7
# Developing and validating a parent satisfaction survey to measure the communication tool's impact

In this chapter I describe the development of the first parent satisfaction survey in the United Kingdom that is validated to obtain feedback from parents in 'real time', whilst their infants are still inpatients in neonatal care. I presented this work at the 2021 Neonatal Society Conference in London and it has been peer-reviewed and published in the Archives of Disease in Childhood Fetal and Neonatal edition (76).

## 7.1 BACKGROUND

To inform continuous evaluation and development of my communication tool and examine its impact I needed a validated measure of parent-reported satisfaction with neonatal care for use while infants are still inpatients. Inconsistent and unvalidated instruments measuring parent satisfaction in neonatal care internationally have recently been highlighted in systematic reviews (11, 40). Furthermore, most existing validated instruments in the English language worldwide have been largely designed for retrospective parent feedback, near to or after discharge from neonatal care (11, 40).

In UK neonatal care, only one validated survey for parents in neonatal care exists: the "Parents' Experiences of Neonatal Care". This survey was developed in 2010 by Picker Institute Europe (Picker) and revised in 2014, in collaboration with Bliss and UK neonatal network representatives to measure parent satisfaction after a baby had been discharged from neonatal care. Having formed the first national survey of parents' experiences of neonatal care in England, it has been successfully used to measure and understand experiences of neonatal care in England (2). This survey is validated for use by parents after their baby has been discharged from neonatal care and therefore provides a retrospective account of parent experience, aimed at helping neonatal units to make improvements to the care they can provide for future parents. The Picker survey examines parent experience with many

aspects of neonatal care, some of which were outside my project's remit (e.g. security on the neonatal unit and parking).

Central to conducting trials on parent experience is the ability to collect 'real time' parent feedback whilst babies are still receiving neonatal care. Real time feedback enables continuous evaluation of parent outcomes during the neonatal admission period, with parent co-design, further iterative development, and improvement of interventions. Interventions being developed to improve parent satisfaction (11) require a validated and robust prospective measure of parent satisfaction.

## 7.2 AIMS

1. To revise and validate the "Parents' Experiences of Neonatal Care" Picker survey to prospectively measure the satisfaction of current parents in neonatal care. This prospective instrument would provide 'real time' feedback and enable continuous 'measurement for change' in my study.

2. To focus the new survey on measuring parent satisfaction specifically with 'communication of clinical information', to facilitate more specific evaluation of the MBSR intervention developed in chapter 6.

3. To assess the validity of the revised survey.

## 7.3 METHODS

I conducted this work with the Picker Institute as a collaborator. My NIHR doctoral research fellowship grant (DRF-2017-10-72) funded an Imperial-Picker agreement, including licensing of the original questions from Picker, and advice from Picker's Head of Research (one of the original survey developers) regarding survey revisions and selection, cognitive testing and assessing validity.

### 7.3.1 Research ethics

I obtained research ethics approval on 26/06/2018 from the West Midlands-South Birmingham REC (18/WM/0175).

### 7.3.2 Survey development

I conducted this workstream together with the study's parent representative (SK) as co-lead in two stages:

#### 7.3.2.1 Stage 1: Survey design and revision

Picker licensed the "Parents' Experiences of Neonatal Care" survey (Appendix 11) to Imperial College London for adaptation. The survey included 61 questions in 10 sections, covering all aspects of parent experience, in the past tense. As approved by my PSG, Picker's Head of Research and group of methodology experts, I selected questions from the survey that focused on assessing parent satisfaction with communication, added new questions for further exploration (as primarily suggested by the parent representative, supported and advised by the neonatal charity representative) and modified all question wording to capture information prospectively.

#### 7.3.2.2 Stage 2: Survey validation

Survey validation was a continual process conducted over three phases:

1. Face validity
2. Cognitive interview testing with parents
3. Data validation

1. Face validity

Face validity is a subjective assessment of a survey. To establish face validity my PSG and I evaluated the survey to ensure the questions adequately captured the topic under investigation. In addition, Picker experts on survey construction checked the survey for common errors, such as double-barrelled, confusing, and leading questions. Final questions were approved by the parent representative as appropriately capturing the topic using parent-friendly language.

2. Cognitive interview testing with parents

Cognitive testing involves exploring the parents' question interpretation and response processes to ensure the questions accurately investigate what the researcher truly intends to (77). Picker had already cognitively tested the full original survey twice with a large number of parents (four focus groups across the UK including 27 parents and 15 cognitive interviews in 2010). In 2014, the performance and relevance of the 2010 survey responses were evaluated. This included examining missing response data from the 2010 survey and undertaking a consultation exercise with neonatal network leads to ensure that items were consistent with current service provision. The amended survey was again cognitively tested in a further 12 interviews with parents before being finalised for use (2). I conducted further cognitive testing on the adapted survey version to evaluate how the new questions performed, together with the original adapted questions. Adjustments to survey questions were expected to be minor due to previous cognitive testing and extensive validation. As such, in agreement with Picker validation methodologists, I estimated that six parents would be sufficient for testing the revised survey.

Figure 20 shows the flowchart detailing the qualitative cognitive testing process.

**Figure 20. Qualitative cognitive testing flowchart.**

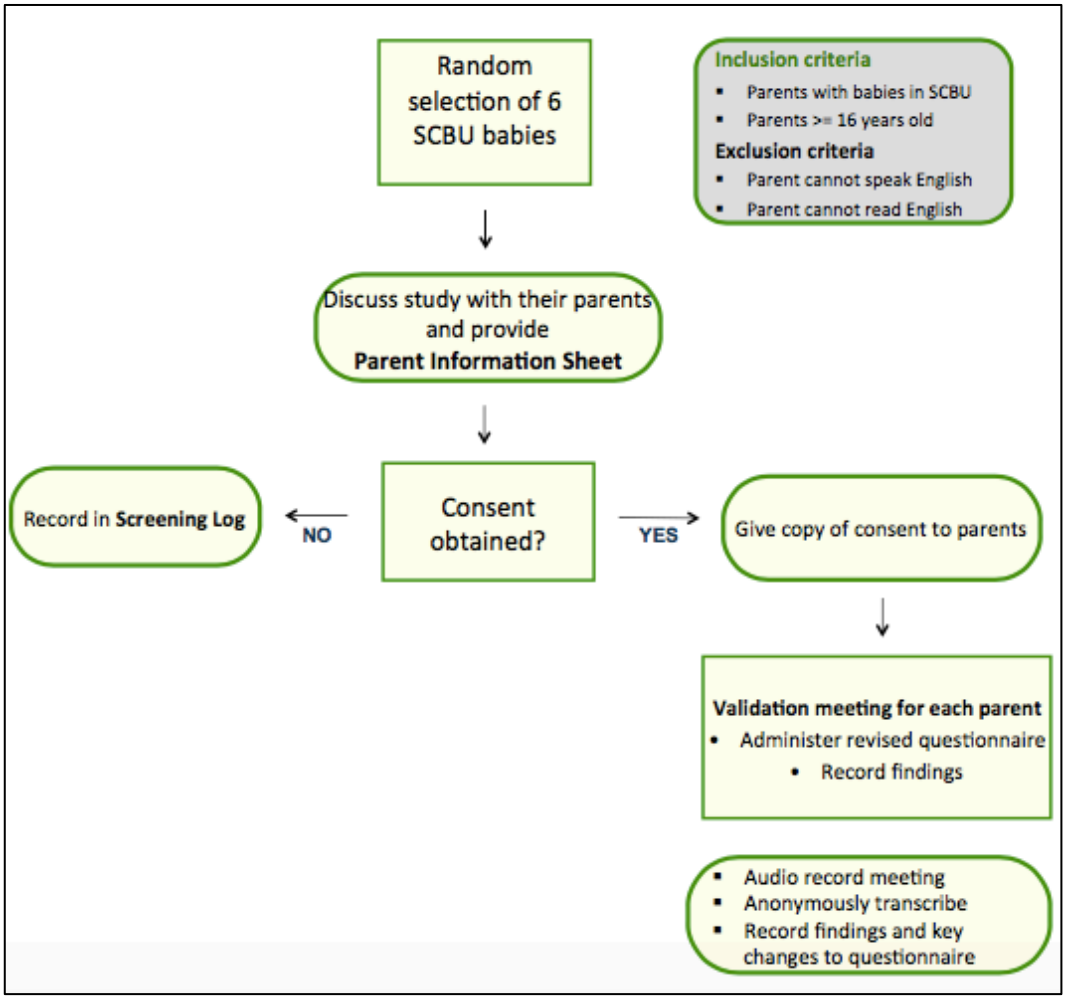



*Figure 20. SCBU= Special Care Baby Unit (lowest intensity unit area)*

a. Participants: I aimed to recruit six parents of infants that were inpatients on the neonatal unit at CW Hospital. I randomly selected babies receiving care in the Special Care Baby Unit area (SCBU, the lower intensity area where babies are medically more stable) to avoid causing anxiety to parents of more acutely unwell babies.

b. Inclusion criteria: Parents of babies in SCBU that were minimum 16 years of age.

c. Exclusion criteria: Parents that could not speak and/or read English and parents younger than 16 years of age were excluded. This was because my project's information documents and survey were only available in English. The option of accommodating additional languages would need to be

explored in a future project.

d. Consent: I directly approached their parents, provided them with an information sheet (Appendix 9) and sought written informed consent (Appendix 10). Parents were able to withdraw at any time, including during the interview (for example if something happened to their baby, and without having to give a reason).

e. Cognitive testing process: I conducted a 30-minute cognitive interview with each parent, in the private 'parent room' in the CW NNU. This is a quiet room within the neonatal unit, providing anonymity and confidentiality and at the same time ensuring that parents do not have to be away from their baby for long. Parents were given the option to nominate another member of the clinical team, friend, or family member to join them in the interview for support. The parent room is also in very close proximity to the clinical area and the rest of the team were available for additional support if required.

In the interviews, I explored the parents' question interpretation and response processes using the model described by Tourangeau (77). Specifically, I administered the revised survey asking parents to answer while thinking aloud and used techniques including probing, paraphrasing and observation. This allowed exploration of parents' thought processes to ensure consistency in how they understood the questions and how they drew on their experience to answer appropriately. I recorded key findings during the interviews, and audio recorded the interviews with parent consent. After each interview I recorded field notes with suggested survey changes and listened to the parent recordings again to further identify survey sections to revise. I adapted the survey according to parent feedback, through 3 revision cycles (one after every two parents), including wording and formatting changes.

3. Data validation

I conducted a data validation study following the completion of the intervention's piloting phase, by assessing data from all completed parent

surveys (Chapter 8). The purpose was to further improve the survey based on assessment of how it functioned. I evaluated the following domains:

a. Response completion rates: I used my completed surveys dataset to produce frequency tables and overall percentage rates of completion per question. If any question had more than 5-10% missing responses this was considered for removal from the survey. I accounted for question 'routing' by coding certain questions as appropriately 'routed past', rather than 'not completed (for example where a question was not intended to be asked or answered by a subset of respondents).

b. Drop out: I identified the last question answered in each survey by each parent and produced a table to enable an assessment of data for any significant drop off. If there were many parents dropping out at a particular question, that could indicate that there was a problem with the question, or the survey was too long.

c. Uninformative responses: Using frequency tables I assessed the percentage of uninformative responses for each question. If the percentage of *'I don't know or 'N/A'* responses for each question was more than 5% the question was considered for removal.

d. Differentiation: I assessed the completed survey dataset for hugely negative or positive (floor and ceiling) responses, defined as >95% negative or positive. In those cases, the question was considered for removal for not effectively distinguishing positive and negative experiences of care (i.e., everyone answering in a similar manner).

e. Inter-item correlation: I used Kendall's Tau non-parametric test to check for inter-item correlation of survey questions with numerical answers. I included only the survey questions that were ordinal and could be coded (e.g. Likert type) or measured (i.e. could take any number). A positive correlation co-efficient result would indicate that as one question response 'increases' the other does too. A negative value would indicate that as one increases, the other decreases. A correlation co-efficient of more than 0.7 or -0.7 was

defined as signifying a significant correlation. If questions met this threshold, I assessed them side-by-side to understand if both were necessary to retain.

I undertook analysis using SPSS version 25.

## 7.4 RESULTS

### 7.4.1 Stage 1: Survey design and revision

In consultation with my PSG and Picker's Head of Research, I selected 18/61 questions from the original Picker survey (Appendix 11), omitting questions not relevant to communication with parents. For example, I removed the question '*In your opinion, was there adequate security on the neonatal unit?'.*

Subsequently, I added 16 new questions to enable further exploration. These included:

- Three questions to help demonstrate a specific improvement in parent satisfaction following the introduction my intervention; for example, question *'On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit?'.*
- Six questions to help further improve my MBSR intervention; for example, question *'How do you feel about the type of information included in "My Baby's Summary Report"? For example: Is there anything else you would like to see included, is there anything unnecessary?'.*
- Seven questions to evaluate parent-staff interactions; for example, question *'On a scale of 1 to 10 how satisfied are you with the frequency of updates you receive from doctors about your baby on the neonatal unit?'*.

I modified all questions to enable prospective measurement; for example, *'If you ask(ed) questions about your baby's condition and treatment* (became *(ask)), d(id) you get answers you can understand* (became *(do))?*'. I also renamed the survey from *'Parents' experiences of Neonatal Care'* to *'The PEC questionnaire: Parents' Experiences of Communication in Neonatal Care'*.

### 7.4.2 Stage 2: Survey validation

#### 7.4.2.1 Face validity

My PSG discussed the question set over the course of a 2-hour meeting, and by mediating any disagreements, I determined a set of questions upon which the group agreed.

#### 7.4.2.2 Cognitive interview testing with parents

I randomly approached ten parents of infants that were inpatients on the CW Hospital neonatal unit between 01/08/2018 and 12/09/2018, of which I recruited six (5 mothers and 1 father). The infants of 2 of 10 parents were discharged before parents consented; 1 parent was excluded because their English understanding was not deemed sufficient (this occurred after initial screening and before recruitment) and 1 parent did not visit the unit again to be recruited.

Table 17 shows demographic details for parents that were interviewed. Four out of six parents were from a white ethnic background, and most were 30-35 years of age. Infant gestations at birth ranged 23-37 weeks (most under 30 weeks) and length of stay ranged 2 weeks- 5 months (most 2-4 weeks).

Following parent interviews and one revision cycle after every two interviews, I made changes to the administered PEC survey questions, including wording and formatting (for example questions presented in subsections, N/A options given) and added a further new question for further exploration and depth (Appendix 12).

**Table 17. Demographic information of parents in cognitive interviews (n=6)**

| Gender (n) | Age (years) (n) | Ethnicity (n) | Gestation (weeks) | Length of stay (n) |
|---|---|---|---|---|
| Female (5)<br>Male (1) | 30-35 (4)<br>25-29 (2) | White (4)<br>Black (1)<br>Indian (1) | < 24 (1 infant)<br>24-28 (2 infants)<br>28+1-32 (2 infants)<br>36+1-40 (1 infant) | 2-4 weeks (4)<br>1-2 months (1)<br>4-6 months (1) |

7.4.2.3 The PEC survey (*Parents' Experiences of Communication in Neonatal Care)*

The original Picker survey included 61 questions, covering all aspects of parent experience, in the past tense (Appendix 11). Following the above changes, the PEC survey contained 35 questions in the present tense (17 new), focusing on communication of clinical information with parents (Appendix 13). The PEC survey includes both Likert scale and free text questions, structured in five sections: Staff on the neonatal unit (9 questions); Information and support for parents (20 questions, 6 of which specific the MBSR); Your involvement in your baby's care (4 questions); Leaving the neonatal unit (1 question); Your comments (1 question). I used the PEC survey in Chapter 8 to evaluate the impact of piloting the MBSR (Appendix 13).

7.4.2.4 Data validation

During the intervention's piloting phase (Chapter 8), 67 parents of babies receiving neonatal care in the CW NNU completed 197 PEC surveys over a 3-month period. This included 107 surveys completed by 43 parents during the 6-week baseline measurement period and 90 surveys completed by 24 parents during the intervention period (Chapter 8). As per study protocol, some parents completed the survey more than once, each time with regards to their experience of neonatal care at the particular point in time in which they were given a survey. Survey completion times by parent ranged between 1-12

times (mean 2.42), with 28 parents being onetime responders. Most respondents were female, aged over 30, and from a white ethnic background (Table 18). Demographic details for 5 parents were missing.

**Table 18. Demographic information of survey responses (n=192)**

| Gender (%) | Age (years) (%) | Ethnicity (%) | Gestation (weeks) (%) | Length of stay (%) |
|---|---|---|---|---|
| **Female (77)** | **Over 35 (39)** | **White (53)** | < 24 (3) | <1 week (20) |
| Male (23) | 30-35 (36) | Mixed (5) | 24-28 (31) | 1-2 weeks (14) |
| | 25-29 (17) | Asian/Asian | **28+1-32 (38)** | **2-4 weeks (30)** |
| | 18-24 (8) | British (23) | 32+1-36 (15) | 1-2 months (26) |
| | | Black/Black | 36+1-40 (12) | 2-4 months (8) |
| | | British (10) | >40 (1) | 4-6 months (1) |
| | | Other (9) | | >6 months (1) |

*Table 18. Most prevalent demographic information in BOLD.*

a. Response completion rates: Nine questions had >5% non-response rates. I reformatted and retained 8/9 questions as they had performed well during cognitive testing and removed 1 question (Table 19).

## Table 19. Survey questions with high non-response rates

| Question | Non-response rate | Details of reformatting |
|---|---|---|
| **A7. '***What is the main reason you have not been able to speak to a doctor as much as you want?'* | 7.6% | Even though missing entries exceeded 5% of responses, parents were directed to this question after answering question A6:<br><br>***A6.*** *'Have you been able to speak to a doctor about your baby as much as you want?'*<br><br>45% of parents answered *'Yes, to some extent'* or *'No'* and were therefore redirected to answer question A7 to explain why. Parents specifically requested this additional question A7 during cognitive testing. This question was retained. |
| **B4. '***In the last 24 hours, how many times have you telephoned the neonatal unit? Please insert number of times'* | 12.4% | This question performed well during cognitive testing. I amended its open response format to a pre-defined list: *'One time; Two times; Three or more times; I have not telephoned the unit in the last 24 hours.'* |
| **B6***. 'In the last 24 hours, how many times have you asked your baby's nurse for an update about your baby, face-to-face?'* | 5.6% | This question performed well during cognitive testing. I have amended its open response format to a pre-defined list: *'One time; two times; Three or more times; I have not asked my baby's nurse for an update face-to-face in the last 24 hours'.* |
| **B9.** *'In the last 24 hours, how many times have you asked to speak with a doctor (outside ward round times)?'* | 6.1% | This question performed well during cognitive testing. I have amended its open response format to a pre-defined list: '*One time; two times; Three or more times; I have not asked to speak with a doctor in the last 24 hours'.* |
| **B12 (4 parts).**<br>*'On a scale of 1–10, how satisfied are you with how you receive information about your baby on the neonatal unit?'* | 43.7% | This question contains four subquestions (Verbal information, Telephone information, Written information and Overall).<br><br>There was a large proportion of non-respondents on analysis for Telephone (34%), Written (44%) and Overall (8.1%). As these performed well during cognitive testing, this was likely due to the questions' format. I have added a letter prefix to each subquestion (a, b, c and d) so it is more obvious all questions need to be answered. I have added the response option N/A to all subquestions. |
| **B14 Open .**<br><br>**(Removed)**<br><br>*'If there is anything else you would like to tell us about how you receive information about your baby on the neonatal unit then please do so here'* | 73.1% | In view of the high proportion of non-respondents and the fact that another open question at the end allows parents to give similar feedback, **I removed this question.** |
| **E1 Open.**<br>*'If there is anything else you would like to tell us about the way you are* | 61.4% | After removing question B14 this remains the survey's only generic open question. I reworded it to '*If there is anything else you would like to tell us* |

| | | |
|---|---|---|
| *given updates about your baby on the neonatal unit then please do so here'* | | *about your experience of care on the neonatal unit then please do so here.'* |

Table 20 shows missing entries for the MBSR-specific questions only (free text questions completed by parents only after they had received the intervention, in 59 surveys). Considering that most of these were open questions, completion rates (although low to moderate) were satisfactory enough for purpose. These questions will not be included in the PEC's generic future use as they were specific to my study's particular intervention.

**Table 20. Missing entries from intervention-specific questions only (completed by parents only after they had received the intervention, n=59 surveys).**

| Question | Missing entries in surveys from intervention period only, after parents had received the intervention. N=59 |
|---|---|
| **B15 (OPEN Q).** *'How do you feel about the type of information included in "My Baby's Summary Report"?'* | 10.2% |
| **B16 (OPEN Q).** *'How do you feel about the layout of information in the "My Baby's Summary Report"?'* | 8.5% |
| **B17 (OPEN Q).** *'How do you feel about the way information is worded in the "My Baby's Summary Report"?'* | 10.2% |
| **B18.** *'On a scale of 1 to 5 how satisfied are you with the frequency of receiving "My Baby's Summary Report"?'* | 8.5% |
| **B19.** *'On a scale of 1 to 5 how satisfied are you with "My Baby's Summary Report"?'* | 5.1% |
| **B20 (OPEN Q).** *'If there is anything else you would like to tell us about "My Baby' Summary Report" then please do so here'* | 64.4% |

*Table 20. Questions in red: missing entries exceeding 5% of completed surveys.*

b. Drop out: Table 21 shows how many parents answered each question as their last question of the survey. Overall, 2% of parents dropped out prior to the penultimate question and 58.4% of parents stopped completing the survey

after its penultimate question. As the last question (E1) was an open question, where non-responses are common, I did not make any changes to the PEC survey based on these results.

**Table 21. Frequencies per last question answered**

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|
| **A5.** *'Have you been able to talk to staff on the unit about your worries and concerns?'* | 1 | 0.5 | 0.5 | 0.5 |
| **B12Verb.** *'On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? (Verbal Updates)'* | 1 | 0.5 | 0.5 | 1.0 |
| **C4.** *'Are you involved as much as you want in the day-to-day care of your baby?'* | 4 | 2.0 | 2.0 | 3.0 |
| **D1.** *'How likely are you to recommend this neonatal unit to friends and family, if their baby needed similar care or treatment?'* | 115 | 58.4 | 58.4 | 61.4 |
| **E1.** *'If there is anything else you would like to tell us about your experience of care on the neonatal unit then please do so here.'* | 76 | 38.6 | 38.6 | 100 |
| Total | 197 | 100.0 | 100.0 | |

c. Uninformative responses: No questions exceeded uninformative responses of 5% or more, therefore no items were excluded on this basis. Overall, only one question (D1.*'How likely are you to recommend this neonatal unit to friends and family, if their baby needed similar care or treatment?'*) had any uninformative responses at all (1.5% of completed surveys).

d. Differentiation: In testing for floor and ceiling responses, no question had >95% negative responses. Question A4 ('*Have you been told which nurses are responsible for your baby's care each day she/he is in the neonatal unit?')* had a 97% positive response. As this is quite an important aspect of involving parents in their baby's care and is important to monitor, I have retained this question, in an effort to continue to aim for 100% *'Yes'* responses.

e. Inter-item correlation: We assessed the questions with numerical answers (23/35) for interitem correlation. A strong correlation was seen between 2 sets of questions:

- B2*.'Have you been given enough written information (in paper or electronic form) to help you understand your baby's condition and treatment? 1.I have not wanted or needed any written information; 2.Yes, definitely; 3.Yes, to some extent; 4.No, I have not been given enough; 5.No, I have not been given any'* and B12Written.*'On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit?- With written information'* (correlation coefficient: -0.775; p<0.001).

This indicated that parents who felt they were given enough written information were also likely to be more satisfied with the method of communication being 'written information'. As question B2 primarily assesses the amount of information provided and question B12Written assesses satisfaction with the written information as a method of communication, I have retained both questions in the PEC survey.

- B12Verbal.*'On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit?- With verbal updates'* and B12Overall*.'On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit overall?* (Correlation coefficient: 0.726; p<0.001).

This indicated that parents who were more satisfied with verbal updates were also likely to be more satisfied with overall communication. As question B12Verbal assesses parent satisfaction with a method of communication and question B12Overall assesses parents' overall impression of communication, I have retained both questions in the PEC survey.

7.4.2.5 Final post validation PEC survey

Based on the validation study results described above, I have made minor formatting changes to the PEC survey I used in the intervention piloting phase

in Chapter 8 and removed one question (Question *B43 Open*). I have therefore developed a final post validation PEC survey version for future wider use by the neonatal community (Appendix 14).

The original Picker survey contained 61-questions in 10 sections, worded in the past tense and capturing a broad parent experience of neonatal care. The final post validation PEC survey contains 28 questions in 5 sections in the present tense (13 new), focusing on communication of clinical information with parents. It includes both Likert scale and free text questions that are worded to enable prospective evaluation and focus on the principles of family-centred care. It does not include the 6 MBSR-specific questions (B15-B20), as it is intended for generic future use.

### 7.4.3 Intellectual property

Following in-depth discussions with the Imperial College London Innovations team and Picker, the licensing agreement states that all survey Intellectual Property (IP) rights will continue to belong to Picker, including rights to any amended Picker survey versions (PEC survey) made using their adaptation guidance. This is because all amended survey versions are considered derivatives from the original Picker survey, following minor changes. Imperial College London is acknowledged in the PEC survey's development by inclusion of the 'Imperial College London' logo on the survey's first page.

### 7.4.4 Dissemination

In its final revised form following validation analysis, the PEC survey is now available to be used by NHS neonatal services, subject to licensing agreements with the Picker Institute. Four neonatal units to date (2: London; 1: Wales; 1: United States) have requested and obtained access to it for use in evaluating parent-centred practices.

## 7.5 DISCUSSION

In this Chapter I have described the adaptation of the 2014 UK *'Parents' experience of neonatal care'* Picker survey (Appendix 11) and subsequent development and validity assessment of a new 28-question prospective parent experience survey, in collaboration with parents of babies in neonatal care, '*The PEC questionnaire: Parents' Experiences of Communication in Neonatal Care'* (Appendix 14).

I used the PEC survey to evaluate my study's MBSR intervention (Chapter 8). Following completion of the intervention's piloting I conducted a retrospective validation study based on completed survey pilot data. Based on the validation results, I made minor revisions accordingly and created a final post validation PEC survey version for future wider use by the neonatal community (Appendix 14).

This newly developed parent experience survey, which focuses on communication of clinical information with parents in neonatal care, performed well on validation assessment in the neonatal parent population and can be used to evaluate the parent experience in UK neonatal care. Inconsistency and lack of validation of instruments measuring parent satisfaction in neonatal care (and specifically with family centred care) have been highlighted worldwide (11, 40). My systematic review of interventions aiming to improve parent experience of neonatal care (Chapter 4) identified that less than 20% of studies used fully validated surveys (11). Most surveys are administered around the time of discharge from neonatal care and retrospectively assess parent experience (11, 40). Among validated surveys, no existing survey in the UK measures *'*real-time' parent feedback in neonatal care. Therefore, the PEC survey is the first parent experience survey in the UK validated for use whilst infants are still receiving neonatal care. Internationally, one real-time tool exists, developed since the PEC's inception; the nine-question *'digiFCC-P'* (78). This administers one question a day to parents in neonatal care via text message, evaluating the quality of family-centred care. Comparison between the two tools and evaluation within the UK neonatal parent population would be important future work.

### 7.5.1 Strengths and limitations

Strengths of this study include parent codesign with the parent representative throughout (maintaining the parent perspective) and the evaluation and feedback from parents of infants currently receiving NHS neonatal care. I have built upon an existing well validated tool and further extensively validated it for prospective use by parents in neonatal care. Containing 28 questions the PEC survey is substantially shorter than the original 61-question Picker survey. Overall, 98% of parent respondents completed all questions except for the last two questions and over 50% of respondents dropped off after the penultimate question. Non-responses to the last question were expected, as this was an open question.

A main limitation was recruiting only parents that could speak and understand written English, thereby potentially excluding parents from different cultures who may experience neonatal care differently. Because the self-administered survey was only available in English, revising and assessing the survey's validity in other languages would require one-to-one interpreters and a cultural survey revision, which was not within this study's remit. Another limitation is that this was undertaken at a single centre; however, the wide parent sample used for validation analysis included mothers and fathers, as well as a range of ethnicities and infants' gestational age, and partly mitigates this limitation (Table 18). I conducted cognitive interviews with parents as a sole researcher, however I reviewed feedback in revision cycles together with methodology experts from Picker.

Due to the nature of the study, I recruited parents for cognitive testing by convenience sampling. I conducted a small number of 6 individual parent cognitive interviews; however, this sample was deemed sufficient in view of extensive prior validation assessment of the original survey (27 cognitive interviews) and as anticipated, my analysis reached data saturation within the 6 interviews. My parent sample included 5 mothers and only 1 father, as more mothers were present on the neonatal unit during the day. While interviews predominantly explored maternal views, the original Picker survey's extensive

cognitive testing included both mothers and fathers, as did my own PEC survey analysis.

After being used to evaluate my study's intervention (Chapter 8), the PEC survey has been peer-reviewed and published and is now available under licence to NHS neonatal services, via Picker. To date, it has been licensed to 4 neonatal units in the UK and the United States. It can be used as part of service evaluation on neonatal units and as an instrument for continuous assessment of parent experience in research, audit, and quality improvement projects. Its use will support the iterative development, piloting, and improvement of family-centred interventions in neonatal care. As this is the first survey to be used for real-time feedback in neonatal care, it is intended that baseline per-question scores are established for each neonatal unit by initial survey administration, ahead of introducing any new intervention. Scores would be anticipated to differ between neonatal units, with the aim to achieve as close as possible to 100% for the parent satisfaction questions and to monitor the unit-specific scores for staff/parent interaction questions, as appropriate for each neonatal unit. Change in unit level scores would therefore be appropriate to use to monitor the impact of any intervention over time. Future research could further assess the final updated PEC survey to explore how it functions following minor refinements made, to evaluate the survey for use in other English-speaking countries, to investigate translation to other languages and to explore how parent responses vary in relation to changes in infants' clinical status/ outcomes alone.

### 7.5.2 Conclusion

Adapted from the 2014 UK "Parents' experience of neonatal care" Picker survey, the "Parents' Experiences of Communication in neonatal care" (PEC) survey is the first in the UK and one of two tools in English-speaking countries worldwide, where formal validation supports its use in collecting 'real time' parent feedback in neonatal care. The PEC survey focuses on communication of clinical information with parents in neonatal care, enabling continuous assessment and iterative improvement of family-centred interventions in neonatal care and is available under licence from Picker. I use it in the

following Chapter 8, to evaluate this study's parent-centred MBSR intervention.

# Chapter 8

# Piloting the communication tool on an NHS neonatal intensive care unit

## 8.1 BACKGROUND

In this chapter I describe the piloting of the communication tool, *'My Baby's Summary Report'* (MBSR), developed in Chapter 6. The protocol for this pilot has been peer-reviewed and published in BMJ Paediatrics Open (79).

Neonatal care includes a complex interplay of many different aspects of care which can change in unpredictable ways. It is therefore difficult to foresee how effective and sustainable a new intervention will be, making delivering improvement in such an environment challenging. Ideas need to be tried, tested and iteratively developed.

In more traditional research methodologies, such as Randomised Controlled Trials (RCT), interventions are pre-determined and efforts are made to control for or eliminate variation, resulting in a single, pre-set and well-defined intervention being tested. In my systematic review in Chapter 4, I discussed the methodological challenges of designing, conducting and evaluating interventions aiming to improve parent satisfaction in neonatal care. Only 31% of included studies were RCT and these were all assessed as having a high risk of bias. I subsequently discussed how appropriate or feasible it is to select RCT designs in this area of research in the first place, given contamination between parent groups, difficulties with blinding and the Hawthorne effect (41). The majority of included studies in the systematic review used a non-RCT design, and had similar serious or critical risk of bias. The lack of a traditional RCT-type 'control' group poses difficulties in evaluating an intervention's impact on parent satisfaction. There was further variation in the level of the evaluation in included studies: only two non-RCT studies evaluated parent satisfaction both before and after the intervention, in the same group of parents *(group level effect),* with most studies evaluating different parent groups in different time periods, pre and post intervention *(unit level effect).* An inherent weakness of this latter approach is that it assumes

parent satisfaction is a static measure over time at the unit level, which is unlikely to be true.

The PDSA cycle method (Chapter 6) is a practical scientific method for rapidly continually testing small-scale changes in complex systems, such as neonatal care. It is designed to support implementation of interventions into everyday practice, allowing teams to learn what is working, reflect on progress over time and iteratively modify an improvement intervention over time before it is formally rolled out.

In this chapter, I describe the implementation, continuous evaluation of outcomes (including parent satisfaction) and iterative development of the MBSR, using quality improvement methodology. PDSA cycles allowed me to test small changes along the way, and continuous measurement of data over time helped me understand natural variation on the neonatal unit, identify potential other factors influencing processes or outcomes and better understand the impact of my intervention. To evaluate the intervention in the most robust way, I have additionally used traditional ‘before’ and ‘after’ statistical testing, including both a quantitative component and interviews with parents and neonatal staff member (qualitative component). The qualitative component of evaluation is described separately in Chapter 9.

In quantitative evaluation I have included the assessment of data completeness and data accuracy, considering that involving parents in their babies’ data could potentially act as an incentive for clinical staff to record data in a more complete and/or accurate way. Data completeness in the NNRD is high (23) for many data items (but not for all), and therefore has the potential to further improve. Data accuracy is not routinely recorded in the NNRD. There is a lack of evidence for interventions to improve the completeness and/or accuracy of routinely collected data in neonatal care.

## 8.2 METHODS OVERVIEW

### 8.2.1 Research ethics

I obtained research ethics approval on 26/06/2018 from the West Midlands-South Birmingham REC (18/WM/0175).

### 8.2.2 Study design overview

I prospectively registered the protocol in the ISRCTN registry (80) (trial number ISRCTN62718241). I used a prospective before-and-after design employing mixed methods. I implemented the communication tool in stages across the three different intensity areas of the CW NNU (from low to high) over an 8-week period. A 2-week Stage 1 'Proof of concept' phase preceded a 6-week Stage 2 'Roll out' phase (Figure 21). Outcome evaluation included continuous evaluation of data over time using run charts, as well as a before-and-after quantitative evaluation (parent survey, staff survey, data completeness and accuracy) and qualitative evaluation (parent and staff interviews). The qualitative component is described separately in Chapter 9.

**Figure 21. Study design overview.**

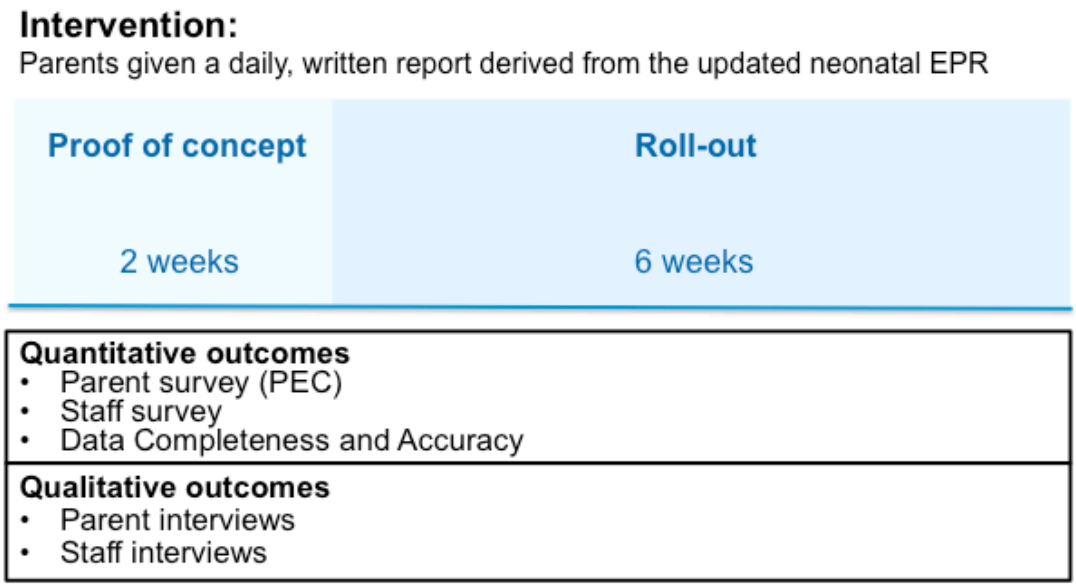



*Figure 21. EPR, electronic patient record; PEC, Parents' experiences of communication in neonatal care.*

### 8.2.3 The intervention

The intervention was a communication tool called '*My Baby's Summary Report'* (MBSR), a printed sheet of paper including individualised, daily infant-specific updates for parents derived from daily EPR data, in parent-centred language (Chapter 6).

I administered an individualised MBSR to recruited parents in a sealed folder every weekday. During the study period, there was no change in the CW NNU protocols for medical treatment, parent education, environmental factors or parent accommodation. Overall, there was no change in physician or nursing staff roles. Other parent-centred interventions already in place during the piloting process included parent-led ward rounds in the Special Care Baby Unit (SCBU) area once a week, noise-cancelling headphones provided to parents, enabling them to stay with their baby throughout the duration of ward rounds, and breastfeeding and resuscitation training by neonatal nurses.

### 8.2.4 Run charts

Every process, such as the process of communicating with parents in neonatal care, can include both common and special causes of variation. Causes inherent to the process are called natural or 'common causes of variation', whereas causes that are not part of the process and only come into play under certain circumstances are 'special causes of variation' (81-83). Identifying and distinguishing common and special cause variation is key in making good decisions about data observed over time.

If only common causes of variation are present, the process is stable over time, and is said to be *'in statistical control'.* If a process is in statistical control it is possible to predict its behaviour within certain limits. If one or more special causes of variation are present, the process is not stable over time, it is said to be *'out of statistical control'* and it is not possible to predict its behaviour within limits (81-83). The special causes behind this can be desirable or undesirable; in the case of improvement, the special cause is desirable. In the context of evaluating an intervention, the aim is for the special cause to be the intervention that drives improvement.

A simple and objective tool for distinguishing special from common cause variation is the run chart. A run chart is a graphical display of data plotted over time, a type of time series chart. It is used to display data to visualise performance, examine for effects of interventions and determine if these effects are sustained.

The main steps in creating and interpreting a run chart are (81-83):

1. Collect baseline data and add to the chart.
2. When at least 10 data points are collected for a baseline, add a median line to it, extending it to the right. Collect data until a stable baseline of 10 points is formed.
3. Continue adding data points from the intervention period. Using the baseline median line, check for any rule breaks indicating a special cause variation.

There are 3 rules to detect special cause variation; if one of the rules is broken this is a sign of special cause variation (81-83). These rules are based on a probability of less than 5% chance of occurring just by chance with no change in practice:

1. Rule 1 is broken if there are six or more consecutive points all on the same side of the median (all above or all below), this is a *'shift'.*
2. Rule 2 is broken if there are five or more points all going up or all going down, this is a *'trend'.*
3. Rule 3 is broken if there are too many or too few *'runs'*. A *'run'* is a set of consecutive points all on the same side of the median. The decision of too many or too few runs is based on the law of probability (83), the number of runs and total number of data points on the run chart (Appendix 15).

### 8.2.5 Setting and participants

I recruited parents of infants that were inpatients on the CW NNU and neonatal staff members on the CW NNU by directly approaching them on the unit, creating a convenience sample.

8.2.5.1 Parents

I approached any parent that was visiting their baby during daytime clinical shift hours (~08:00-20:00).

a. Inclusion criteria: I recruited parents with infants in the lowest intensity part of the unit (SCBU) for 4 weeks first, where infants were medically stable and not acutely unwell. Subsequently, I recruited parents in the High Dependency Unit (HDU) area for 2 weeks and parents from the Intensive Therapy Unit (ITU) area for the final 2 weeks.

b. Exclusion criteria: I excluded parents that could not speak and/or read English as my study's information documents and communication tool were in English. Parents younger than 16 years of age were also excluded, as well as parents of infants where neonatal care was being re-directed to palliative care.

c. Screening and consent: Once I confirmed eligibility, I discussed the study with parents and provided them with the relevant parent information sheet (Appendix 16). I sought written informed consent from parents face-to-face on the CW NNU (Appendix 17), where I discussed the nature and purpose of the study and included the opportunity for any questions. I read each part of the consent form out loud to parents, highlighting confidentiality, anonymity, secure transfer and storage of data, their right to withdraw at any time, without having to give a reason, as well as inviting and clarifying any questions. Following recruitment, I asked parents to complete a demographic form including their age, gender, ethnic group, infant's gestational age and infant's length of stay on the neonatal unit (Appendix 18).

8.2.5.2 Neonatal staff members

In my role as part of the clinical team, I recruited staff members (nurses and doctors) by approaching any staff member that was working a day shift (~08:00-20:00). Staff members completed anonymous staff surveys at specific time points according to study protocol, depending on their workload at the time. Additionally, I approached staff members of all grades/seniority and

working in any of the neonatal unit areas (SCBU, HDU, ITU), provided them with an information sheet (Appendix 19) and sought written informed consent (Appendix 20) for one-on-one interviews, pre and/or post intervention (see Chapter 9).

### 8.2.6 Outcome measures

In consultation with my project's steering group, I chose 15 questions from the 35-question *'Parents' Experiences of Communication in neonatal care'* (PEC) survey (Appendix 13) for outcome evaluation and analysis (12 continuous and 3 categorical questions). These 15 questions were deemed to be the most specific for evaluating the impact of the communication tool. Table 22 summarises the specific PEC questions assessing each outcome.

#### 8.2.6.1 Primary outcome

The primary outcome was parent satisfaction 'with communication of clinical information'. It was assessed using 7 continuous and 2 categorical questions (Table 22) from a self-administered PEC survey (Appendix 13).

Measurement time points: At recruitment, twice a week once the parent started receiving the MBSR (Tuesdays and Fridays) for six weeks or until their baby's discharge, whatever came first.

#### 8.2.6.2 Secondary outcomes

The secondary outcomes included an assessment of:

1. Parent–Staff interactions: Assessed using 3 continuous and 1 categorical question from the PEC survey.
Measurement time points: As per primary outcome.

2. Parent satisfaction with the MBSR: Assessed using 2 continuous questions from the PEC survey.
Measurement time points: After recruitment and first use of the MBSR, and subsequently as per primary outcome.

3. Staff workload: Staff members completed a three-question ‘Staff Survey’ (Appendix 21):
Measurement time points: Twice weekly (Tuesdays and Fridays) for six weeks.

4. Electronic Patient Record (EPR) data completeness and EPR data accuracy (expressed in %): I manually compared daily EPR-recorded data to handwritten clinical documentation, producing a daily measure of EPR data completeness and accuracy.

Measurement time points: Daily for 6 weeks. As data are extracted from the Clevermed platform and stored in the NNRD quarterly, measuring EPR data completeness and EPR data accuracy was a way to assess these outcomes daily during the trial (NNRD data not available daily). For analysis purposes, I also used historic completeness data from the National Neonatal Research Database (NNRD) to create a baseline measure and evaluated how NNRD data completeness changed over time, retrospectively using the NNRD data corresponding to my study’s intervention period.

## Table 22: PEC survey questions assessing each outcome

| Outcomes | Questions |
|---|---|
| **Primary outcome:**<br><br>***Parent satisfaction with communication of clinical information*** | <u>7 Continuous</u><br><br>B7: *On a scale of 1 to 10 how satisfied are you with the frequency of updates you receive from nurses about your baby on the neonatal unit?*<br><br>B11: *On a scale of 1 to 10 how satisfied are you with the frequency of updates you receive from doctors about your baby on the neonatal unit?*<br><br>B12 verbal: *On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? Verbal updates*<br><br>B12 telephone: *On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? Telephone calls*<br><br>B12 written: *On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? Written information*<br><br>B12 overall: *On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? Overall*<br><br>B14: *I get the information I need to understand my baby's health status (1 strongly agree-5 strongly disagree)* |
| | <u>2 Categorical</u><br><br>B2: *Have you been given enough written information (in paper or electronic form) to help you understand your baby's condition and treatment?*<br><br>D1: *How likely are you to recommend this neonatal unit to friends and family, if their baby needed similar care or treatment?* |
| **Secondary outcome:**<br><br>***Parent - staff interactions*** | <u>3 Continuous</u><br><br>B4: *In the last 24 hours, how many times have you telephoned the neonatal unit? Please insert number of times*<br><br>B6: *In the last 24 hours, how many times have you asked your baby's nurse for an update about your baby, face-to-face? Please insert number of times*<br><br>B9: *In the last 24 hours, how many times have you asked to speak with a doctor (outside ward round times)? Please insert number of times* |
| | <u>1 Categorical</u><br><br>A8: *Have staff given you conflicting information about your baby's condition or care?* |
| **Secondary outcome:**<br><br>***Parent satisfaction with the MBSR*** | <u>2 Continuous</u><br><br>B18: *On a scale of 1 to 5 how satisfied are you with the frequency of receiving "My Baby's Summary Report"?* |

| | |
|---|---|
| | B19: *On a scale of 1 to 5 how satisfied are you with "My Baby's Summary Report"?* |

### 8.2.7 Blinding of participants and researcher

Due to the nature of the intervention, it was not possible to blind parent participants to receiving the MBSR. Similarly, as I was the sole researcher recruiting and interviewing all participants, it was not possible for me to be blinded to allocation of intervention. I analysed parent PEC surveys and staff surveys using code identifiers.

## 8.3 IMPLEMENTATION OF THE INTERVENTION

### 8.3.1 Stage 1: 'Proof of concept' (2 weeks—SCBU, lowest intensity area)

8.3.1.1 Methods

I planned to recruit three parents of infants in SCBU and administer an individualised MBSR to them in a sealed envelope every weekday, over 2 weeks. I asked parents and staff members to complete PEC and staff surveys, respectively, at baseline, midweek and at week 2. I assessed EPR data completeness and accuracy daily.

8.3.1.2 Analysis

I conducted two PDSA cycles where I studied the implementation process for Stage 1 to improve the overall piloting process, in preparation for Stage 2 'Roll-out'. In Stage 1, I started administering the baseline MBSR template to parents (Appendix 6), the development of which I have described in Chapter 6. I utilised parent feedback from the MBSR-specific PEC survey questions (questions B15-B20) to develop the final MBSR template for use in Stage 2 'Roll-out'.

8.3.1.3 Results

**a. Recruitment and demographics**

- Parents and completed PEC surveys

I randomly approached and recruited 3 parents of infants cared for in SCBU.

I implemented the MBSR between 23.10.2018 - 31.10.2018; parents received the MBSR daily for 7 weekdays.

All three parents were female, aged between 25-40 years old and their infant's gestational age at birth ranged between 27-32 weeks. Their ethnicities were Asian, White, and Mixed. One infant's duration of stay on the CW NNU was under 1 month; the two other infants had spent between 1-6 months on the unit.

I asked parents to complete the PEC survey 3 times; at baseline, midweek and during the second week. One parent completed the PEC survey 3 times; the other two parents did not complete their third survey (one parent was discharged and one parent did not return the survey).

- Staff members and completed Staff surveys

Staff members working a clinical shift in the SCBU unit area completed staff surveys at the same time points as per PEC parent surveys (at baseline, midweek and during the second week). During this period, 12 staff surveys were completed. It was not possible to estimate the exact number of individual staff member participants, as the survey was conducted anonymously and some staff members could have completed the survey more than once during this period.

- EPR data completeness and accuracy

During this period, I evaluated data completeness and accuracy every weekday. For PEC surveys, staff surveys, EPR data accuracy and completeness, I focused on reviewing the piloting process rather than analysing quantitative results (very small sample numbers).

**b. MBSR template improvement**

I utilised parent feedback from the MBSR-specific PEC survey questions (questions B15-B20) to create the final MBSR template for use in Stage 2 'Roll-out'. This template contained information from 12 EPR data items.

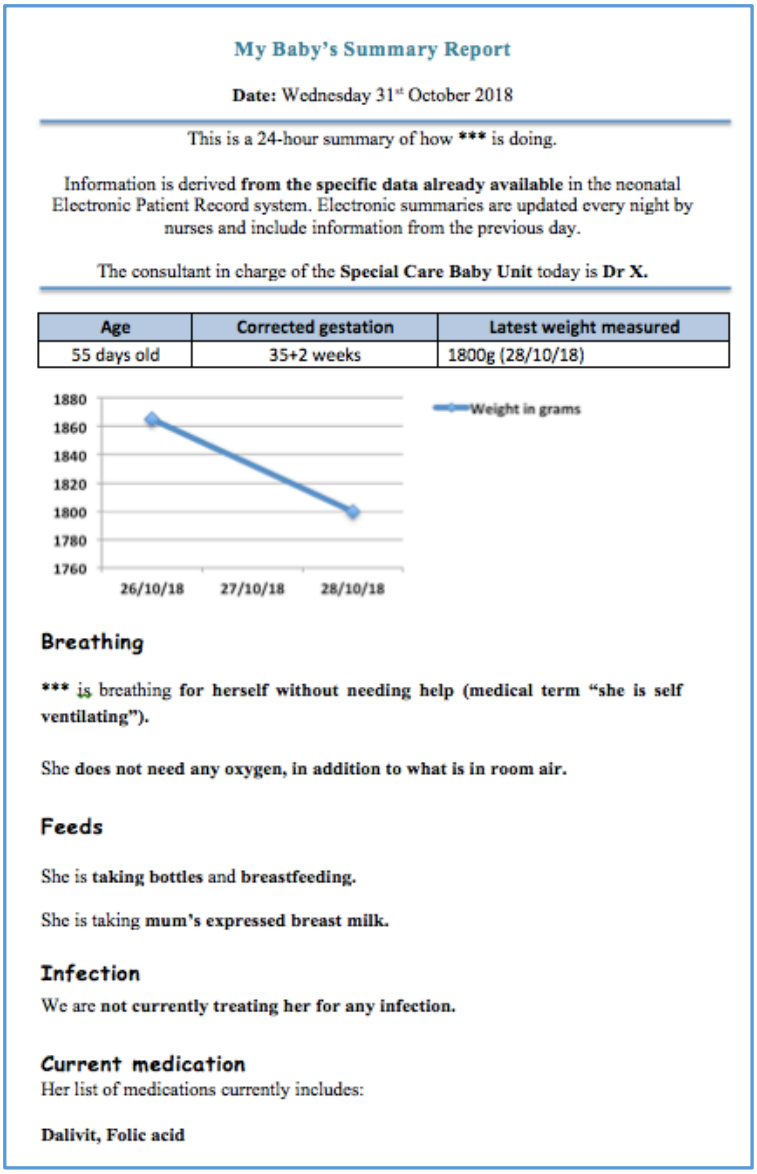
Main formatting changes to the MBSR from parent feedback included presenting baby's age (in days), corrected gestation (in weeks) and last measured weight (with dates) in a small table at the top of the MBSR, as well as adding a weight graph (Figure 22).

Furthermore, I made a minor amendment to the MBSR's data origin explanation, to clarify that MBSR information was being derived from the specific data already available in the neonatal EPR system, as recorded by nurses from the previous night shift. I made this change in response to participating parents reporting some missing MBSR data to their named nurse. In consultation with my PSG I considered it important to highlight to parents that if they received a MBSR with any missing data this was because information was not available in the neonatal EPR to transfer onto the MBSR, rather than a research team error in preparing the MBSR.

Data explanation in baseline MBSR:
*'Information is derived from the neonatal Electronic Patient Record system. Electronic summaries are updated every night by nurses and include information from the previous day.'*

Data explanation in revised MBSR at the end of Stage 1 'Proof of concept' (Figure 22):
*'Information is derived from the specific data already available in the neonatal Electronic Patient Record system. Electronic summaries are updated every night by nurses and include information from the previous day.'*

**Figure 22. MBSR example at the end of Stage 1 'Proof of concept'**



My Baby's Summary Report

**Date:** Wednesday 31st October 2018

This is a 24-hour summary of how *** is doing.

Information is derived **from the specific data already available** in the neonatal Electronic Patient Record system. Electronic summaries are updated every night by nurses and include information from the previous day.

The consultant in charge of the **Special Care Baby Unit** today is **Dr X.**

| Age | Corrected gestation | Latest weight measured |
|---|---|---|
| 55 days old | 35+2 weeks | 1800g (28/10/18) |



**Breathing**

*** is breathing **for herself without needing help (medical term "she is self ventilating").**

She **does not need any oxygen, in addition to what is in room air.**

**Feeds**

She is **taking bottles** and **breastfeeding.**

She is taking **mum's expressed breast milk.**

**Infection**

We are **not currently treating her for any infection.**

**Current medication**

Her list of medications currently includes:

**Dalivit, Folic acid**

### 8.3.2 Stage 2: 'Roll out' (6 weeks—SCBU 2 weeks—HDU 2 weeks—ITU 2 weeks)

#### 8.3.2.1 Methods

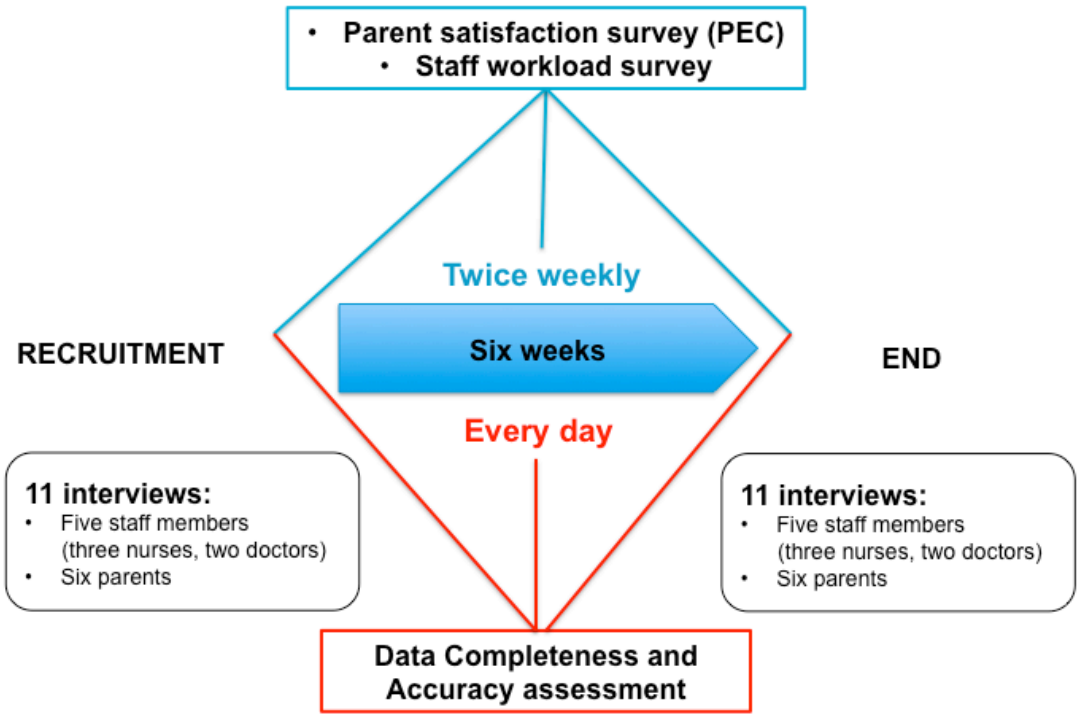
I planned to recruit a maximum of 90 parents, administer the MBSR every weekday and conduct a quantitative and qualitative evaluation over 6 weeks, while also using quality improvement methodology to further improve the MBSR (Figure 23). This 6-week period is defined as the 'intervention period'.

Parents completed their first PEC survey on recruitment (on any given weekday), began receiving the MBSR every weekday and subsequently continued to complete a PEC survey twice a week (Tuesdays and Fridays) for

six weeks or until their baby's discharge, whatever came first. I instructed parents not to answer the PEC survey questions related to the MBSR in their baseline recruitment survey, as they had not yet received the MBSR. Staff members completed the staff survey twice weekly, at the same time points as parents (Tuesdays and Fridays).

I interviewed parents and staff members one-on-one at recruitment and at the end of the intervention period (see Chapter 9). I assessed EPR data completeness and accuracy daily.

**Figure 23. Roll-out stage.**




8.3.2.2 Research ethics amendment

On 28/11/2018 I obtained a research ethics amendment approval from the West Midlands-South Birmingham REC (18/WM/0175). This amendment approved administration of the PEC survey to parents twice-weekly, instead of the originally planned once-weekly, to increase the number of PEC survey data points and optimise the use of run charts.

8.3.2.3 Analysis

- Baseline measurement and 'comparator' groups

To create 'comparator' groups for parents and staff members, I obtained baseline measures for parent satisfaction and staff workload from evaluations undertaken as part of clinical service evaluation on the CW NNU. For this, I used PEC survey and Staff survey data from a 6-week period preceding the start of the piloting process. During this 6-week period, surveys were distributed twice weekly to all parents and staff members, on Tuesdays and Fridays; this is defined as the 'baseline period' (Figure 24). With data from the 'baseline period' I generated baseline median values for PEC survey questions and staff survey questions using run charts (81-83), in Microsoft Excel.

- Quantitative outcome analysis: PEC survey, Staff survey, Data completeness/accuracy

For PEC surveys, I conducted three types of analysis to

(i) Demonstrate how the outcome changed over time (baseline versus intervention period).

(ii) Evaluate the MBSR's specific impact on the outcome (a 4-step analysis).

(iii) Evaluate how satisfied parents were with the MBSR.

For staff surveys, data completeness and data accuracy, I conducted two types of analysis to

(i) Demonstrate how the outcome changed over time (baseline versus intervention period).

(ii) Evaluate the MBSR's specific impact on the outcome.

I conducted the statistical analysis using the statistics software SPSS version 25 and R version 3.6.0, as well as Microsoft Excel.

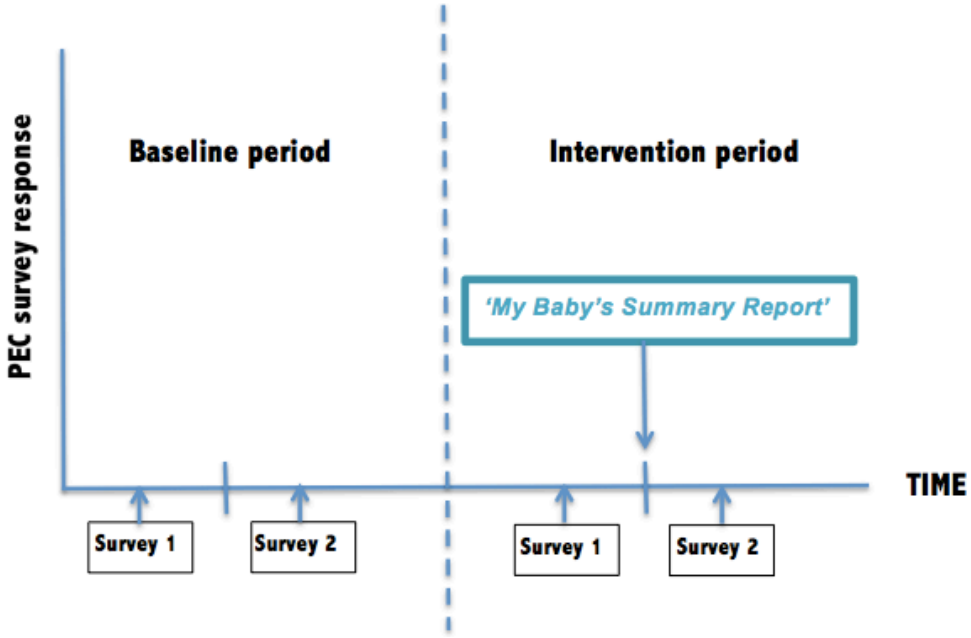
**a. PEC surveys**

(i) PEC surveys: Analysis to demonstrate how the outcome changed over time (baseline versus intervention period)

In both the baseline and intervention periods, it was anticipated that the same parents would complete the PEC survey more than once, whilst their baby was still receiving care in the NICU. In the baseline period there was no intervention introduced in between the first time any parent completed the PEC survey and any subsequent survey completions (Figure 24). In the intervention period, the MBSR was introduced after the first PEC completion and before the second PEC completion. Parents continued to receive the MBSR every weekday throughout the 6-week intervention period and completed the PEC survey twice a week.

To visualise how the means of PEC question responses changed over time from baseline to intervention period in the neonatal unit overall, I generated run charts in Microsoft Excel. Specifically, I combined PEC survey responses from every PEC survey administration time point and plotted the mean response from each time point pre and post MBSR implementation ("*baseline period"* versus *"intervention period"*). In the case of data not being enough for certain questions (such as the categorical ones), I have not generated a run chart (and there is no equivalent alternative method available). Specific considerations for the generation of run charts are included in Appendix 22.

**Figure 24. Timeline of baseline versus intervention period per parent**




(ii) PEC surveys: Analysis to evaluate the MBSR's specific impact on the outcome (a 4-step analysis)

This analysis was based around the completion of the first two consecutive PEC surveys by parents, in the baseline period versus the intervention period. In order to evaluate any specific effect the MBSR implementation had on PEC survey question responses, I conducted a 4-step analysis using *'first and second survey responses'* in the baseline period (no intervention implemented in-between) and *'first and second survey responses'* in the intervention period (MBSR implemented in-between).

Table 23 sequentially summarises the four analysis steps. The final analysis step (step 4) is the primary analysis for determining the MBSR's impact on PEC questions and answering my study's primary research question: *'Does sharing individualised, daily, clinical EPR data with parents lead to higher reported parent satisfaction with communication of clinical information?'*. Steps 1-3 serve as secondary analyses to provide additional context to each question.

In the primary analysis step 4, I compared 2nd surveys (*intervention period*) to 2nd surveys (*baseline period*) while adjusting for 1st survey responses.

In the secondary analysis I compared:

- Step 1: 1st surveys (*baseline period*) to 1st surveys (*intervention period*) (Appendix 23).
- Step 2: 2nd surveys (*baseline period*) to 2nd surveys (*intervention period*) (Appendix 23).
- Step 3: 1st to 2nd surveys (*baseline period*) and 1st to 2nd surveys (*intervention period*) (Appendix 24).

In the end I combined all analysis results together to interpret the MBSR's overall effect on each PEC question responses.

**Table 23: Analysis steps for evaluating the communication tool's overall effect on PEC survey questions (Step 4 primary analysis)**

| Analysis | Method | Reason for test |
|---|---|---|
| **STEP 1**<br><br>Compare<br><br>**1st surveys** (baseline)<br>to<br>**1st surveys** (intervention) | • Continuous questions<br>Independent t-test / Mann-Whitney<br><br>• Categorical questions<br>Chi-square | Were 1st surveys statistically significantly different between both time periods?<br><br>*NOTE: Parents in both periods had only received standard care before completing the 1st survey.* |
| **STEP 2**<br><br>Compare<br><br>**2nd surveys** (*baseline*)<br>to<br>**2nd surveys** (*intervention*) | • Continuous questions<br>Independent t-test / Mann-Whitney<br><br>• Categorical questions<br>Chi-square | Were 2nd surveys statistically significantly different between both time periods?<br><br>*NOTE: Parents in the intervention period received the communication tool before completing the 2nd survey. Parents in the baseline period continued only receiving standard care before completing the 2nd survey.* |
| **STEP 3**<br><br>Compare 1st to 2nd surveys (*baseline*)<br><br>AND<br><br>1st to 2nd surveys (*intervention*) | • Continuous questions<br>Optimal pooled t-test / Corrected z-test<br><br>• Categorical questions No appropriate method available | Were 1st and 2nd surveys statistically significantly different? (in both time periods) |
| Primary analysis step in evaluating study's primary outcome<br><br>**STEP 4** | • Continuous questions<br>ANCOVA test (analysis of covariance) | Were 2nd surveys statistically significantly different between both time periods, taking into account any impact from 1st survey responses? |

| | | |
|---|---|---|
| Compare<br><br>**2nd surveys** (*baseline*)<br>to<br>**2nd surveys** (*intervention*)<br><br>while adjusting for<br>**1st surveys** | • Categorical questions<br>Logistic regression | |

**STEP 4:** Evaluating the difference in means of *'second survey question responses'* in the baseline period versus the intervention period, while adjusting for *'first survey question responses'*.

Null hypothesis: There was no difference between *'second survey question responses'* in the baseline versus the intervention period, when adjusting for *'first survey question responses'*.

For the continuous PEC questions, I used the analysis of covariance (ANCOVA) test (84), a linear regression analysis for the 2nd survey score with the 1st survey score as a covariate (Appendix 25).

For the categorical PEC questions, I used a logistic regression analysis for the 2nd survey response distributions (baseline versus intervention period), correcting for the 1st survey response distributions, instead of the ANCOVA.

(iii) PEC surveys: Analysis to evaluate how satisfied parents were with the communication tool.

As per table 22, two continuous PEC questions (B18 and B19) specifically assessed parent satisfaction with the MBSR. I instructed parents to only answer these questions after they began receiving the MBSR. In line with my study's design, data for these questions was therefore anticipated only from parents during the intervention period and only from 2nd survey completions onwards.

To demonstrate how parent satisfaction with the communication tool evolved over the 6-week piloting period, I aimed to create run charts for questions B18

and B19, plotted both by the dates of PEC survey administration and by the number of PEC survey administration per parent.

Furthermore, I used the chi-square test to compare the percentage distributions of *'2nd survey responses'* (the first time parents answered these questions) to those of *'last survey responses'* (the last time parents answered these questions).

**b. Staff surveys**

(i) Staff surveys: Analysis to demonstrate how the outcome changed over time (baseline versus intervention period)

Due to the study's design, staff surveys were anticipated to be completed by doctors and nurses, who were working in any of the 3 neonatal unit intensity areas (SCBU, HDU, ITU). As a result, different proportions of completed staff surveys were expected by job role and unit area, across baseline and intervention periods. A priori, it was not known if baseline versus intervention survey proportions were statistically significantly related to job role and/or unit area.

To check if job role and unit area were confounding factors, I used the chi-square test to compare the proportions of completed staff surveys per job role and unit area in the baseline versus the intervention period.

I planned to generate staff survey run charts (baseline versus intervention period) if the samples were balanced.

(ii) Staff surveys: Analysis to evaluate the communication tool's specific impact on the outcome

The staff survey comprised of 3 questions: one categorical and two 'count' questions (Appendix 21). In the case of staff survey samples being unbalanced for job role and/or unit area, I planned to use a logistic regression

for the categorical staff survey question 1 and the Poisson regression for 'count' staff survey questions 2 and 3 (with study period, job role and unit area as covariates).

**c. Data completeness**

Healthcare professionals routinely record individual infants' neonatal EPR data as part of clinical care, data that is then extracted quarterly to form the National Neonatal Research Database (NNRD) (Chapter 6). In Chapter 6, I described the MBSR's template development, using 12 daily-updated EPR data items as selected by parents with neonatal experience.

The neonatal EPR (and subsequently the NNRD) contains a daily dataset of observations for every infant admitted for neonatal care, for as many observation days as their corresponding admission period. Therefore, by study design, daily data sets cannot be assumed to be independent.

I have defined incompleteness as an empty field. Of note is that in the neonatal EPR the true absence of a condition, for e.g. infection, is not always actively recorded.

(i) Data completeness: Analysis to demonstrate how the outcome changed over time

To evaluate how 'NNRD population level' data completeness changed over time I obtained historic de-identified 'cleaned' data from the NNRD (having removed corrupt or irrelevant values). To create the '*baseline period NNRD population dataset'* I used NNRD data corresponding to 1 year of all infant admissions to the CW NNU preceding the intervention's implementation. To create the *'intervention period NNRD population dataset'* I used NNRD data corresponding to my study's 6-week intervention period.

NNRD data are extracted from the Clevermed platform quarterly and each data field is recorded by month and year, but not by specific calendar day.

More specifically, NNRD data are time stamped as ‘minutes from birth’ for each baby (e.g. ‘data from day 2 of baby A’s life’) but cannot be linked to a specific calendar day (it is not recorded ‘what calendar day this day 2 of life is'). I therefore plotted the mean completeness per month of each data item included in the MBSR using run charts, in the baseline period followed by the intervention period. I also generated the baseline median completeness of each data item (before the communication tool’s implementation).

(ii) Data completeness: Analysis to evaluate the communication tool’s specific impact on the outcome

Null hypothesis: There was no difference between ‘*baseline period NNRD population dataset’* completeness and *‘intervention period EPR parent sample dataset’* completeness.

The NNRD population completeness data retrospectively includes all infants admitted to the CW NNU, without being restricted to my study’s intervention period. As already highlighted, it is not possible to identify completeness data corresponding to specific babies on specific calendar days within the NNRD. Therefore, for my study’s intervention period, I manually produced an additional *‘intervention period EPR parent sample dataset’,* derived from completeness data only for infants of recruited parents, which I manually collected as per my study’s protocol during the 6-week intervention period.

To evaluate the MBSR’s specific impact on data completeness, I compared the ‘*baseline period NNRD population dataset’* completeness to the *‘intervention period EPR parent sample dataset’* completeness for each data item included in the MBSR. For this, I used the binomial test; the binomial test compares a sample proportion (intervention parent sample proportion) to a presumed value (baseline NNRD population proportion).

For the presumed values, I generated an overall *‘baseline period NNRD completeness proportion’* for each data item, using all CW NNU infant data from 1 year preceding my study’s intervention period.

For the sample proportions, I generated an overall '*intervention period EPR parent sample completeness proportion'* for each data item using the CW NNU infant data I manually collected for recruited parents only, during the 6-week intervention period.

**d. Data accuracy**

The NNRD does not hold any data accuracy information, as this would require continuous manual comparison of recorded EPR data against handheld clinical documentation, which is not feasible considering existing neonatal care resources. As a result, I was not able to create a '*baseline period NNRD population dataset'* for data accuracy as a control group, for the 1 year preceding the intervention's implementation (like I did for data completeness).

During my study's 6-week intervention period, I manually collected data accuracy information on the daily-updated data items included in the MBSR, creating an *'intervention period EPR parent sample dataset'* for data accuracy. As with data completeness, I recorded several daily datasets for each infant and therefore daily data sets cannot be assumed to be independent.

I conducted two types of analysis to describe data accuracy information for each data item during the intervention period:

(i) I generated an overall '*intervention period EPR parent sample accuracy proportion'* for each data item. This is defined as the proportion of *'accurately completed data fields / total completed data fields',* for each data item.

(ii) I generated a proportion of infants for which observations were recorded accurately every day of the infants' admission, for each data item. This is defined as the proportion of *'infants with all daily datasets accurately recorded per item / all infants'.*

**e. Multiple statistical tests consideration**

When multiple statistical tests are being conducted using the same variables one should always consider if a correction for multiple testing in required, such as a *'Bonferroni correction'* (85). A Bonferroni correction serves to adjust probability values (p values) to avoid the risk of a *'type I error'.* In the case of a type I error, a true null hypothesis is rejected (resulting in a *'false positive'* finding or conclusion).

In the case of the above statistical tests applied to PEC survey questions and data items' completeness, each variable (survey question and data item, respectively) is different. As multiple tests are not being conducted for the same variable, I have not conducted any correction.

**f. MBSR template improvement**

During the 6-week *'intervention period'* in Stage 2 'Roll-out', I conducted further PDSA cycles to continually improve the MBSR, in response to parent feedback in the PEC surveys.

8.3.2.4 Results

**a. Recruitment and demographics**

- Parents and completed PEC surveys

*'Baseline period'*: 14.11.2018 – 21.12.2018

During the 6-week baseline period of clinical service evaluation on the CW NNU (preceding Stage 2 'Roll out'), 43 parents completed a total of 107 PEC surveys (Table 24). Survey completion times by parent ranged between 1-12 times, with a mean of 2.4 times. 43 parents completed the PEC survey at least once, of which 19 parents completed it twice. Figure 25 shows the number of parents that completed PEC surveys in the baseline versus the intervention period, specifically how many completed the PEC once versus

twice (for analysis purposes). All parents in the baseline period were different to the ones recruited in Stage 1 'Proof of concept' and Stage 2 'Roll out'.

'*Intervention period':* Implementation of the MBSR 12.02.2019 - 22.03.2019
I randomly approached 26 parents across the 3 neonatal unit areas (SCBU, HDU, ITU), of which I recruited 24 (Table 24). During the intervention period, 90 PEC surveys were completed in total; see consort flow diagram (Figure 26). Parents ended their participation according to when their infants were discharged, or at the end of 6 weeks, whichever came first.
All parents were different to the ones recruited in stage 1 'Proof of concept' or for pre-intervention interviews (Chapter 9).

**Table 24: Demographic details from parents that completed at least one PEC survey in baseline versus intervention period**

| | **Baseline period (n=43 parents)** | **Intervention period (n=24 parents)** |
|---|---|---|
| **Parent gender** | **Female, 28 (65%)**<br>Male, 15 (35%) | **Female, 18 (75%)**<br>Male, 6 (25%) |
| **Age in years** | **Over 35, 15 (35%)**<br>30-35, 13 (30%)<br>25-29, 12 (28%)<br>18-24, 3 (7%) | Over 35, 10 (42%)<br>**30-35, 11 (46%)**<br>25-29, 3 (12%)<br>18-24, 0 (0%) |
| **Ethnicity** | **White, 25 (58%)**<br>Mixed, 3 (7%)<br>Asian/Asian British, 9 (21%)<br>Black/Black British, 3 (7%)<br>Other, 3 (7%) (Asian; Arab/Middle Eastern) | **White, 10 (42%)**<br>Mixed, 1 (4%)<br>Asian/Asian British, 7 (29%)<br>Black/Black British, 2 (8%)<br>Other, 4 (17%) (Indian; African; White/Black Caribbean) |
| **Gestation in weeks** | < 24, 2 (5%)<br>**24-28, 10 (25%)**<br>28+1-32, 8 (20%)<br>32+1-36, 8 (20%)<br>**36+1-40, 10 (25%)**<br>>40, 2 (5%) | < 24, 1 (4%)<br>24-28, 6 (25%)<br>**28+1-32, 10 (42%)**<br>32+1-36, 3 (12%)<br>36+1-40, 4 (17%)<br>>40, 0 (0%) |

| | | |
|---|---|---|
| **Length of stay** | **<1 week, 22 (51%)** | **<1 week, 7 (29%)** |
| | 1-2 weeks, 4 (10%) | 1-2 weeks, 5 (21%) |
| | 2-4 weeks, 8 (17%) | **2-4 weeks, 7 (29%)** |
| | 1-2 months, 5 (12%) | 1-2 months, 4 (17%) |
| | 2-4 months, 3 (7%) | 2-4 months , 1 (4%) |
| | 4-6 months, 0 (0%) | 4-6 months, 0 (0%) |
| | >6 months , 1 (3%) | >6 months, 0 (0%) |

*Table 24: Demographic details for parents: the groups with highest percentages are in BOLD.*

**Figure 25. Parent participants in baseline versus intervention period**

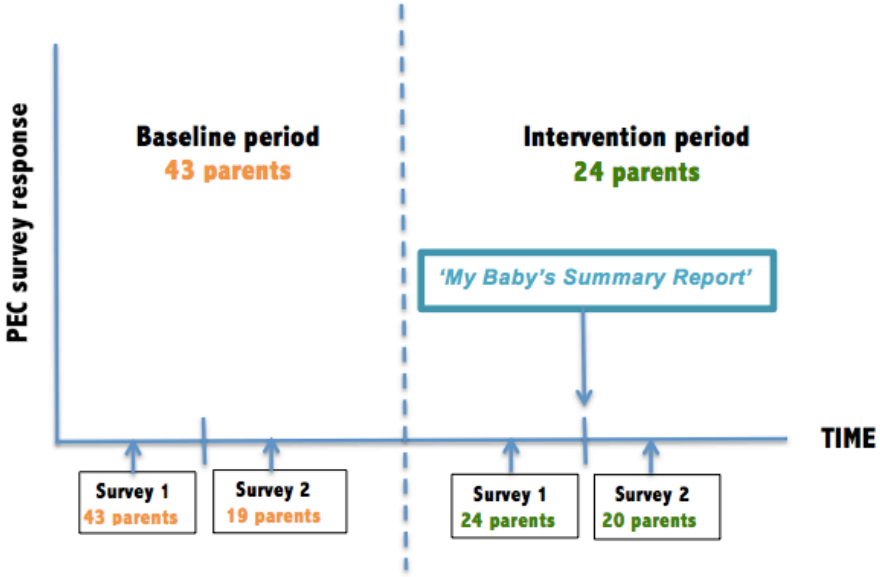
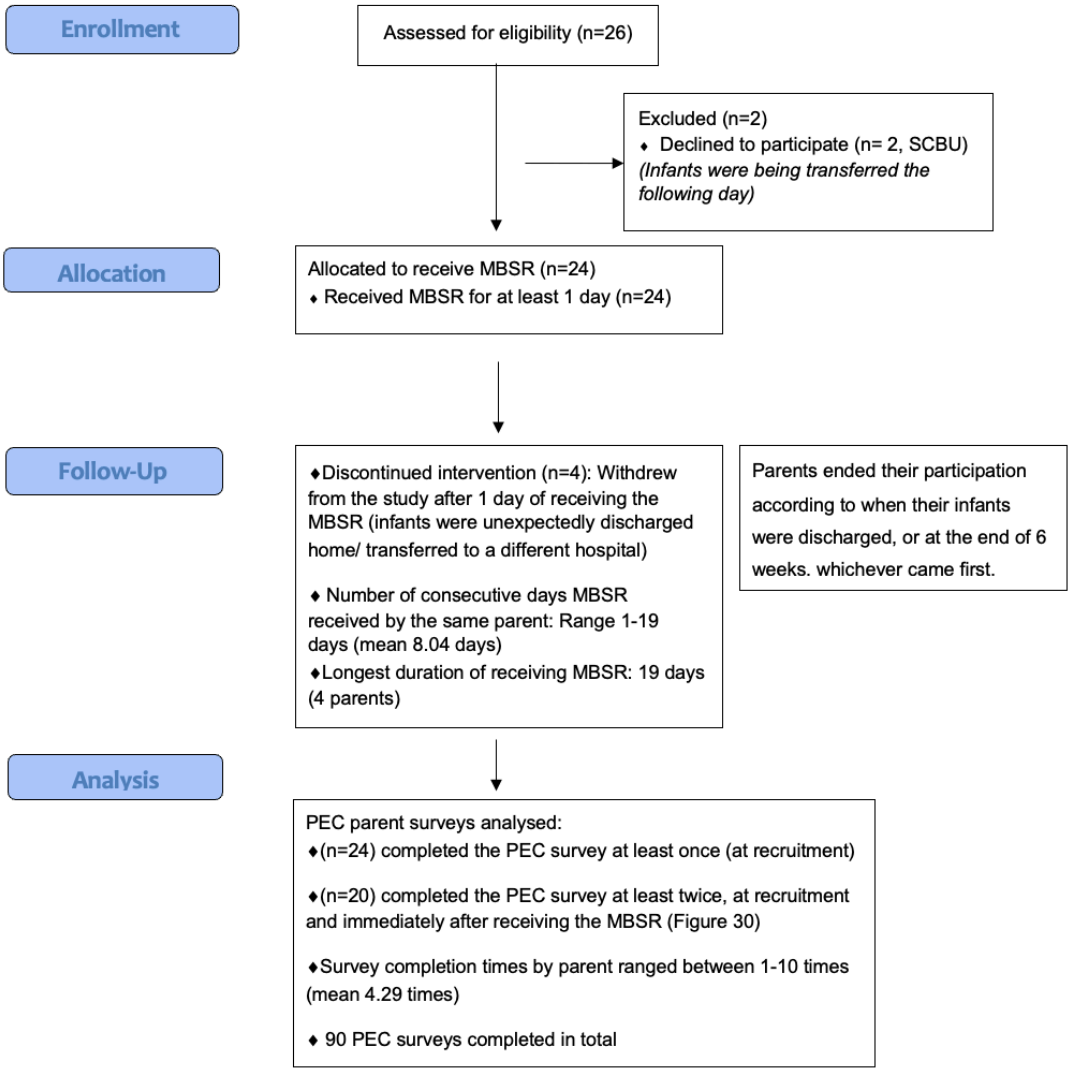


**Figure 26. CONSORT flow diagram: Implementation of MBSR (Parents)**




- Staff members and completed Staff surveys

*'Baseline period'*: 14.11.2018 – 21.12.2018

During the 6-week baseline period, 168 staff surveys were completed (Table 25). Most staff members that completed a staff survey during this period were nurses (79.8%), while the commonest unit area with completed staff surveys was ITU. In both the baseline and intervention periods, it was not possible to estimate the exact number of individual staff member participants, as the survey was conducted anonymously, and some staff members could have completed the survey more than once during the 6-week period.

'*Intervention period':* Implementation of the MBSR 12.02.2019 - 22.03.2019

During the intervention period, 70 staff surveys were completed (Table 25). Most staff members that completed a staff survey during this period were nurses (94.3%), while the commonest unit area with completed staff surveys was HDU (44.3%).

**Table 25: Staff surveys completed in baseline versus intervention period**

| | **Baseline period (n=168 surveys)** | **Intervention period (n=70 surveys)** |
|---|---|---|
| **Job role** | **Nurses 134 (80%)**<br>Doctors 34 (20%) | **Nurses 66 (94%)**<br>Doctors 4 (6%) |
| **Unit area** | SCBU 34 (20%)<br>HDU 47 (28%)<br>**ITU 87 (52%)** | SCBU 30 (43%)<br>**HDU 31 (44%)**<br>ITU 9 (13%) |

## b. MBSR template improvement

During the 6-week intervention period, I utilised parent feedback from the MBSR-specific PEC survey questions (questions B15-B20) and conducted four PDSA cycles to further improve the MBSR template containing 12 EPR data items (Appendix 26).

Figure 27 shows an example of a completed MBSR on the last day of the 6-week intervention period, including final PDSA changes. The final MBSR template contained 14 EPR data items.

**Figure 27. Final MBSR template at the end of 6-week intervention period**

## My Baby's Summary Report

**Date:** Friday 22nd March 2019

This is a 24-hour summary of how *** is doing.

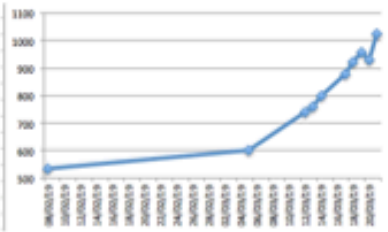
| | |
|---|---|
| **DOB** | 08/02/19 |
| **Gestation at birth** | 23+3 |
| **Birth weight** | 534g |

Information is **automatically extracted from the routine electronic database nurses manually update every night.**
This summary includes information from the previous day.

***** is receiving the highest level of care in the Intensive care Unit (ITU).**
**The next level down as babies improve is the High Dependency Unit (HDU).**

The consultant in charge of ITU today is **Dr X**
*****'s room number: 0203 315 7831**

| Age | Corrected gestation | Latest weight measured |
|---|---|---|
| 43 days old | 29+3 weeks | 1024g (21/03/19) |




### Breathing

***** is breathing through a breathing tube (medical term "she is intubated").**

*The breathing tube pushes air and in and out of her lungs, inflating and deflating them like a balloon. On the other end the tube is attached to a machine called a ventilator. By adjusting the ventilator's settings the doctors can control how much and how quickly air goes in and out of her lungs.* We **are giving her oxygen to help her breathing.**

### Feeds

She is **feeding through a small tube that goes from the nose straight to the stomach (medical term "nasogastric tube").** She is taking **formula.** She has taken **54.2 mls** of milk in the last 24 hours.

She is also receiving **specialised fluids through a vein (medical term "she is on TPN").**

### Infection

We are **not currently treating her for any confirmed infection.**

### Current medication

Her list of medications currently includes: **nil**

### Tests

Blood tests, head scans (medical term "cranial ultrasound") and other scans are done at different time points for each baby, according to gestation and clinical condition. Results are held in a few different electronic databases (not the one this summary comes from). Please ask us to discuss ***'s test results with you.

**c. PEC surveys: overview and 3 types of analysis**

Overall, 107 parent surveys were completed during the *'baseline period'* (by 43 parents) and 90 parent surveys during the *'intervention period'* (by 24 different parents).

Of the 15 pre-selected PEC questions for analysis, I examined 13 questions as continuous *[B4; B6; B7; B9; B11; B12 verbal updates; B12 telephone calls; B12 written information; B12 overall; B14; B18; B19 and D1 (re-classed from categorical and re-scaled for ease of analysis)]* and 2 questions as categorical *[A8; B2].*

(i) PEC surveys: Demonstrate how the outcome changed over time (baseline versus intervention period)

For the continuous variables derived from the PEC's Likert scale questions, I combined all completed PEC surveys and plotted the means on run charts in the pre versus post MBSR implementation periods (baseline versus intervention period). For the 2 categorical variable questions, it was not possible to use run charts. In the case of a larger sample size I could have produced percentages of categorical variable responses and applied those to a run chart. However, my sample size was too small for that and there is no alternative method to the run chart available.

The run charts in Figure 28 show the mean responses for all surveys in the baseline versus the intervention period, for those questions where at least one of the run chart rules was broken (81-83). Overall, Rule 1 of run charts was broken in the case of 7 questions, demonstrating a changing 'shift' in responses during the intervention period when compared to the baseline period. Rule 2 of run charts was also broken in the case of 3/7 of these questions, demonstrating a 'trend' in addition to a 'shift' in responses during the intervention period when compared to the baseline period.

Figure 28 indicates that during the period of introducing *'My Baby's Summary report'* (MBSR*)* on the CW NNU:

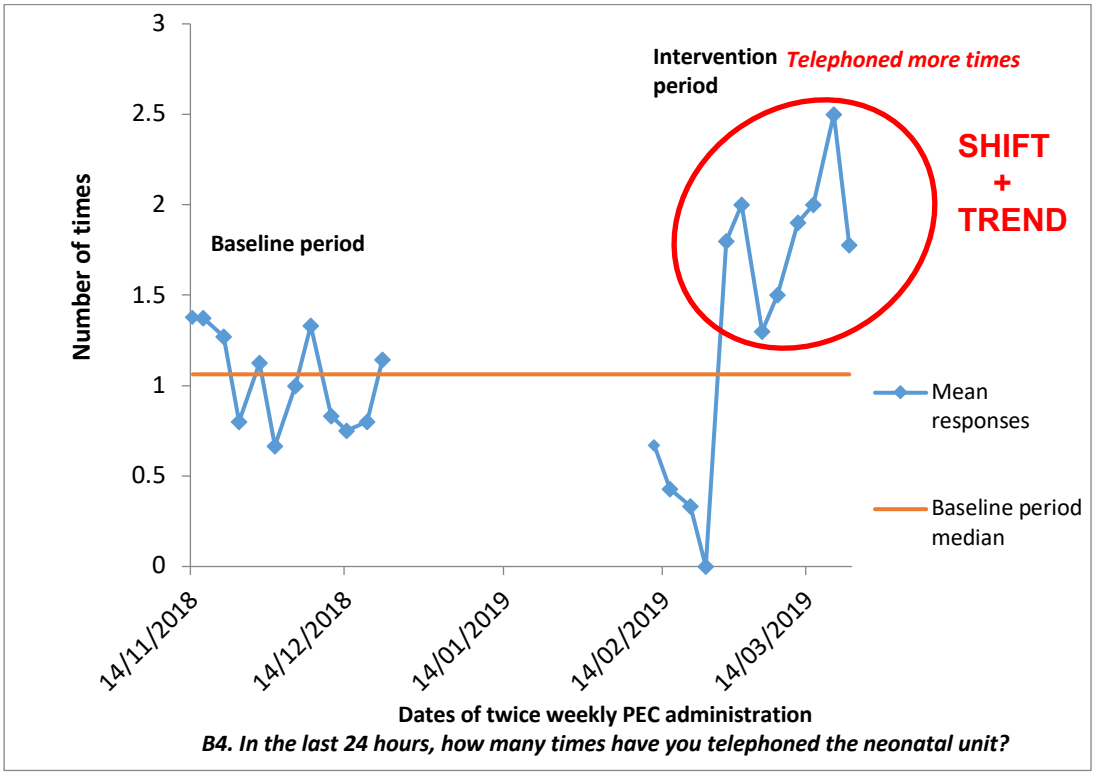
PRIMARY OUTCOME (Parent satisfaction with communication of clinical information):

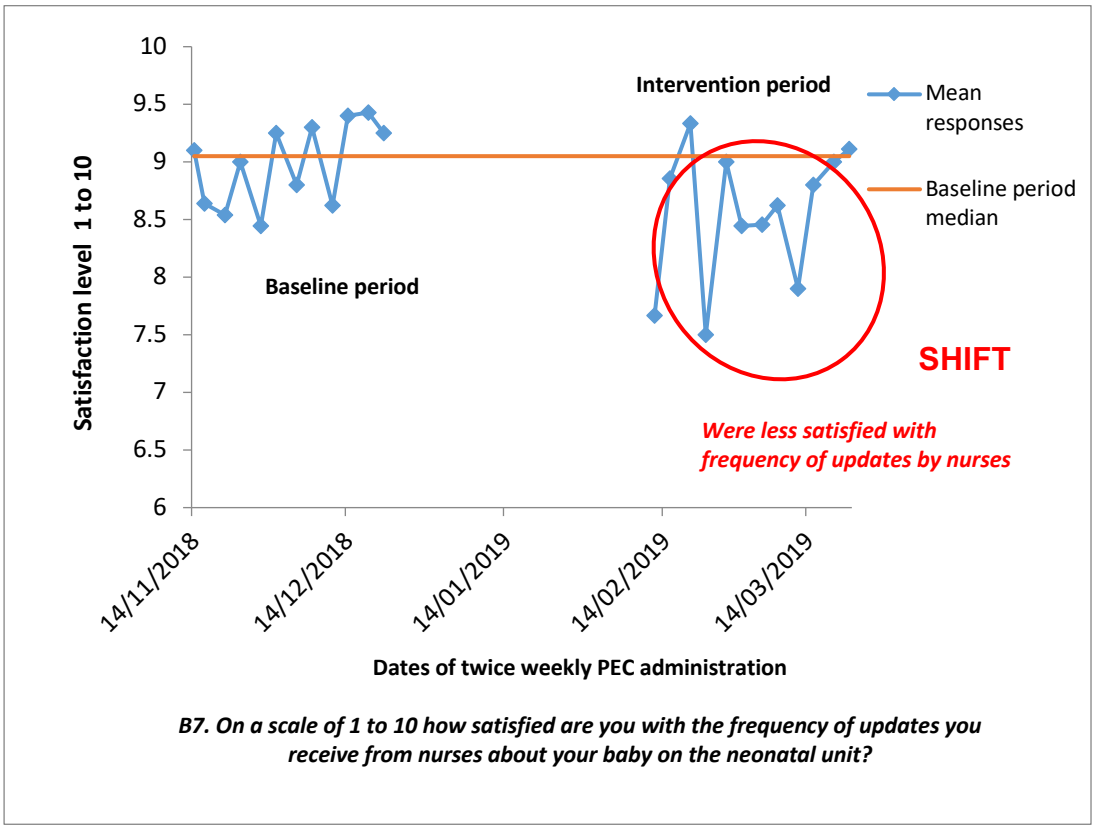
- Parents were less satisfied with the frequency of updates received by nurses *(question B7)* and doctors *(question B11),* and the method of communication being 'verbal updates' *(question B12 Verbal)* and 'telephone calls' *(question B12 Tel).*
- Were more satisfied with the method of communication being 'written information' *(question B12 Writ)* and were more likely to recommend the CW NNU to friends and family *(question D1).*

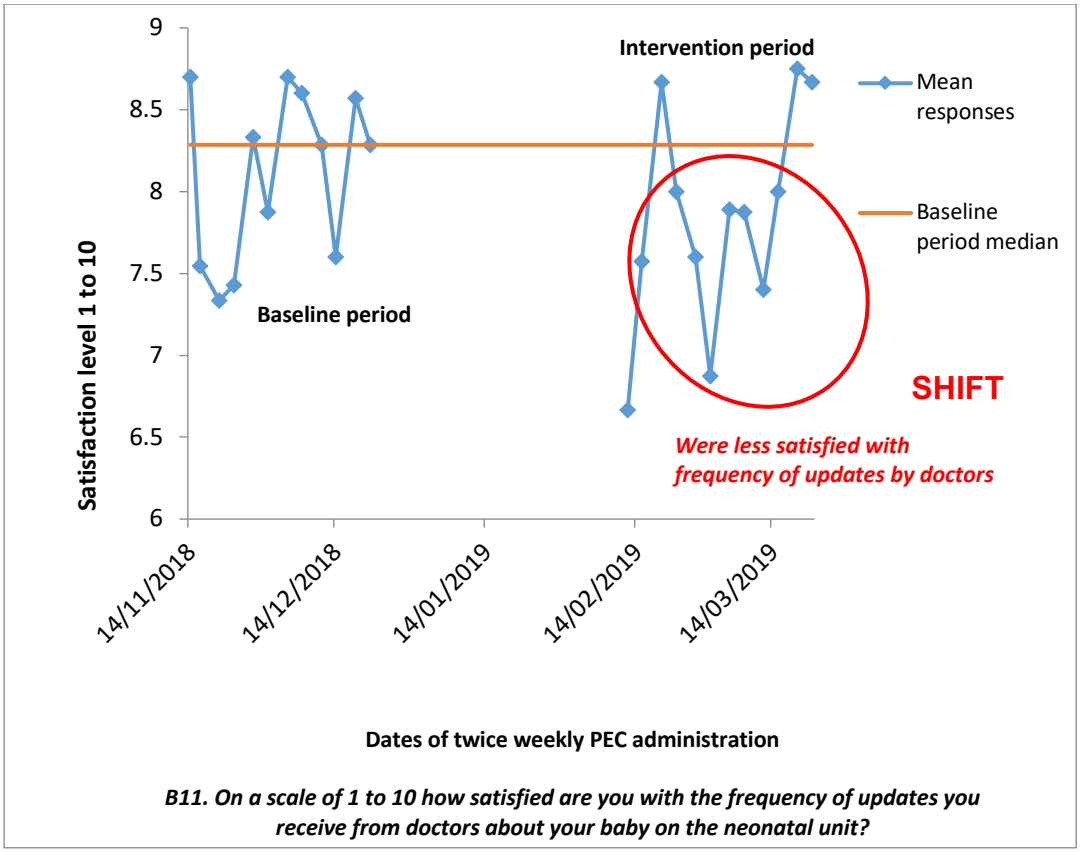
SECONDARY OUTCOME (Parent-staff interactions):

- Parents telephoned the unit more times in 24 hours *(question B4).*

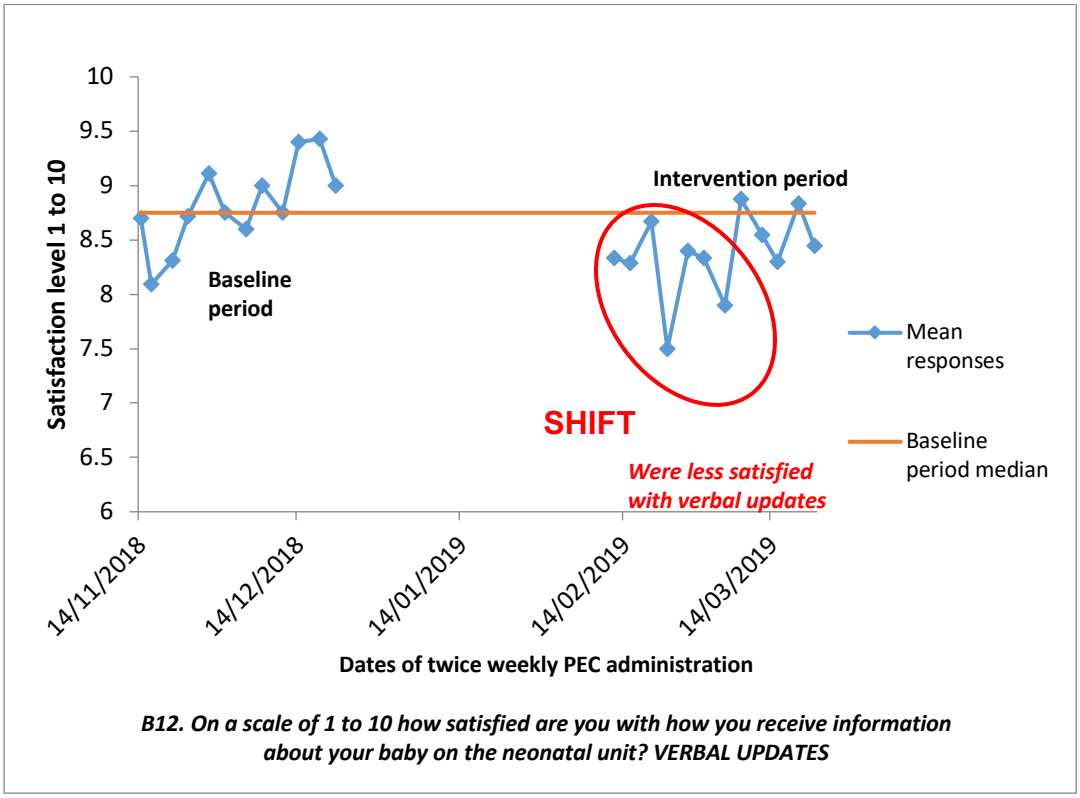
**Figure 28. Mean PEC responses in baseline versus intervention period (for questions breaking run chart rules)**



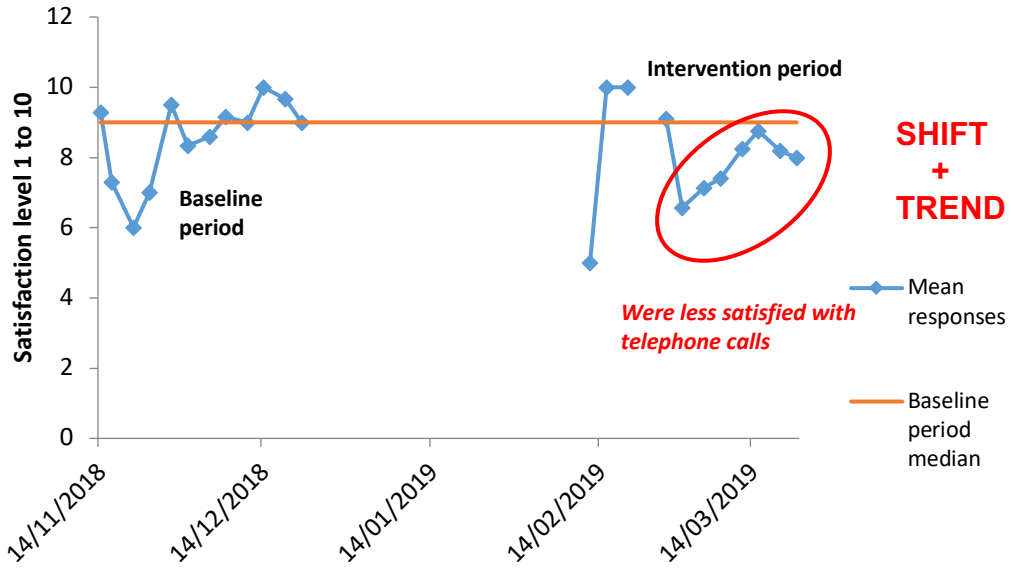





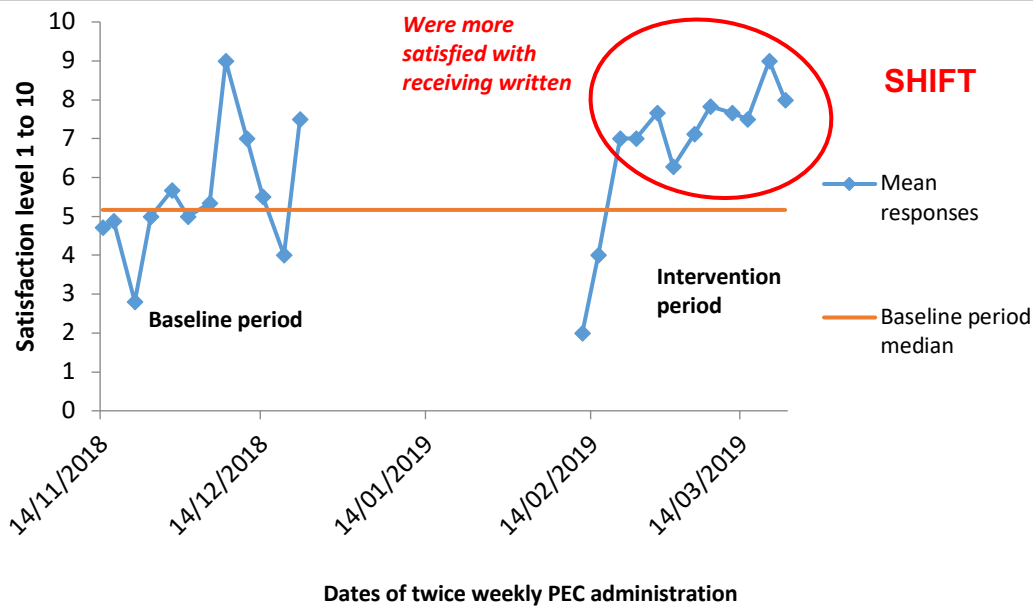

***B11. On a scale of 1 to 10 how satisfied are you with the frequency of updates you receive from doctors about your baby on the neonatal unit?***



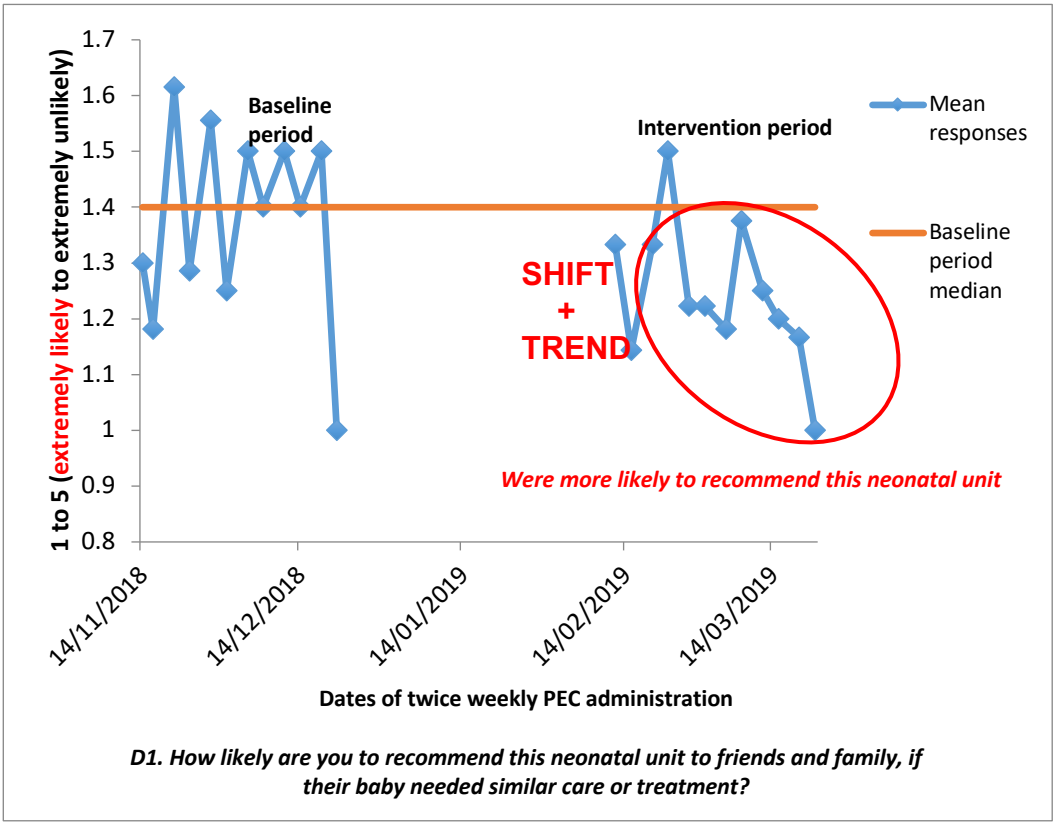

***B12. On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? VERBAL UPDATES***




***B12. On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? TELEPHONE CALLS***




***B12. On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? WRITTEN INFORMATION***




(ii) PEC surveys: Evaluate the communication tool's specific impact on the outcome

**STEP 4 [PRIMARY ANALYSIS]:** Evaluating the difference in means of *'second survey question responses'* in the baseline period versus the intervention period, while adjusting for *'first survey question responses'.*

<u>Continuous questions</u>

Table 26 shows the mean (paired data) responses to PEC questions in first and second surveys, in both the baseline and intervention period.

## Table 26: Mean values (paired data) of 1st and 2nd survey responses per PEC questions, in baseline and intervention period

| **Question** | **Baseline period**<br><br>Mean value (n=number of completed surveys)<br><br>*Total number of recruited paired survey respondents= 19 parents* | | **Intervention period**<br><br>Mean value (n=number of completed surveys)<br><br>*Total number of recruited paired survey respondents= 20 parents* | | *Were 1st surveys (the covariate) statistically significantly related to 2nd surveys?* (p<0.05) | *2nd surveys compared, while adjusting for 1st surveys* |
|---|---|---|---|---|---|---|
| **CONTINUOUS** | **1st survey** | **2nd survey** | **1st survey** | **2nd survey** | **ANCOVA** | **ANCOVA** |
| *B4: Number of times telephoned unit in last 24hrs* | 1.06 (n=16) | 1.25 (n=16) | 1.41 (n=17) | 1.71 (n=17) | F (1,30) =32.863, **p=0.000** | p=0.536 |
| *B6: Number of times asked nurse for update in last 24hrs* | 2.93 (n=14) | 1.64 (n=14) | 2.40 (n=20) | 2.45 (n=20) | F (1,31) =1.962, p=0.171. | **p=0.034** |
| *B7: Satisfaction (1-10) with frequency of updates from nurses* | 8.74 (n=19) | 9.00 (n=19) | 8.30 (n=20) | 8.90 (n=20) | F (1,36) =1.592, p=0.215. | p=0.907 |
| *B9: Number of times asked to speak to doctor in last 24hrs (outside ward round)* | 0.56 (n=18) | 0.28 (n=18) | 0.41 (n=17) | 0.35 (n=17) | F (1,32) =0.185, p=0.670. | p=0.711 |
| *B11: Satisfaction (1-10) with frequency of updates from doctors* | 8.44 (n=18) | 7.67 (n=18) | 7.37 (n=19) | 7.89 (n=19) | F (1,43) =0.813, p=0.374. | p=0.582 |
| *B12 verbal: Satisfaction (1-10) with way of receiving information (VERBAL UPDATES)* | 8.74 (n=19) | 8.89 (n=19) | 8.15 (n=20) | 8.60 (n=20) | F (1,36) =0.832, p=0.368. | p=0.521 |
| *B12 tel: Satisfaction (1-10) with way of receiving information (TELEPHONE CALLS)* | 8.90 (n=10) | 8.90 (n=10) | 7.64 (n=11) | 8.45 (n=11) | F (1,18) =6.736, **p=0.018** | p=0.888 |
| *B12 written: Satisfaction (1-10) with way of receiving information (WRITTEN)*<br><br>*NOTE: The number of parents respondents for this question in second survey completions was very small (7 in baseline and 4 in intervention period). In view of the small parent sample size this result should be interpreted with caution.* | 4.57 (n=7) | 5.00 (n=7) | 2.5 (n=4) | 5.00 *(n=4)* | F (1,8) =15.899, **p=0.004** | p=0.192 |
| *B12 Overall: Satisfaction (1-10) with way of receiving information (OVERALL)* | 8.27 (n=15) | 8.33 (n=15) | 7.65 (n=17) | 8.41 (n=17) | F (1,29) =6.252, **p=0.018** | p=0.582 |
| *B14: I get the information I need to understand my baby's health status (1 strongly agree-5 strongly disagree)* | 1.78 (n=18) | 1.78 (n=18) | 1.74 (n=19) | 1.63 (n=19) | F (1,34) = 15.547, **p=0.000** | p=0.579 |
| *D1: How likely to recommend this unit to friends and family (1 extremely likely-5 extremely unlikely* | 1.37 (n=19) | 1.32 (n=19) | 1.05 (n=19) | 1.11 (n=19) | F (1,35) = 34.695, **p=0.000** | p=0.828 |
| **CATEGORICAL** | **1st survey** | **2nd survey** | **1st survey** | **2nd survey** | **Binary logistic regression** | **Binary logistic regression** |
| *A8: Have staff given you conflicting information about your baby*<br>*1 Yes, often*<br>*2 Yes, sometimes*<br>*3 No, not at all* | Yes 10 (55%)<br><br>No 8 (45%)<br><br>(n=18) | Yes 10 (55%)<br><br>No 8 (45%)<br><br>(n=18) | Yes 5 (25%)<br><br>No 15 (75 %)<br><br>(n=20) | Yes 7 (35%)<br><br>No 13 (65 %)<br><br>(n=20) | The odds of *'2nd survey responses'* being option *'1.Yes'* were 13.7 times higher if *'1st* | Correcting for 1st surveys, the odds of parents replying *'1.Yes'* in 2nd |

| | | | | | | |
|---|---|---|---|---|---|---|
| Regrouped into<br>1.Yes<br>2.No<br><br>for binary logistic regression analysis | | | | | *survey question responses'* were option *'1.Yes'*<br><br>ExpB 13.652, CI 2.577-72.308).<br><br>**p=0.002** | surveys in the interv period were 16.5% lower than in the baseline period<br><br>ExpB 0.835, CI 0.165-4.220.<br><br>p=0.827 |
| *B2 part 1: Have you been given enough written information*<br>*1 I have not needed/wanted written info*<br>*2 I have needed /wanted written info* | I have needed 14 (74%)<br><br>I have not needed 5 (26%)<br><br>(n=19) | I have needed 12 (63%)<br><br>I have not needed 5 (37%)<br><br>(n=19) | I have needed 17 (85%)<br><br>I have not needed 3 (15%)<br><br>(n=20) | I have needed 18 (90%)<br><br>I have not needed 2 (10%)<br><br>(n=20) | The odds of *'2nd survey responses'* being option *'1. I have wanted or needed written information'* were 4.8 times higher if *'1st survey responses'* were option *'1. I have wanted or needed written information'*<br><br>ExpB 4.777, CI 0.797-28.638.<br><br>p=0.087. | Correcting for *'1st survey responses'*, the odds of parents replying *'I have wanted or needed written information'* in *2nd surveys* in the interv period were 4.9 times higher than in the baseline period<br><br>ExpB 4.900, CI 0.809-29.682.<br><br>p=0.084 |
| *Treated as continuous question for this step* | **1st survey** | **2nd survey** | **1st survey** | **2nd survey** | **ANCOVA** | **ANCOVA** |
| *B2 part 2: Have you been given enough written information*<br>*(1 Yes definitely – 4 No, not at all)* | 3.00 (n=10) | *3.00 (n=10)* | *3.25 (n=16)* | *2.06 (n=16)* | F (1,23) =9.716,<br>**p=0.005** | **p=0.012** |

*Table 26. Statistically significant different p<0.05 in red.*

As per the Appendix 25 considerations ahead of using the ANCOVA test, I first used Levene's test to test the assumption of homogeneity of variances of *'second survey question responses'* in the baseline period parent group versus the intervention period parent group (Appendix 27).

Table 26 includes all ANCOVA linear regression results per PEC question. The covariate, '*first survey question responses',* was statistically significantly

related to *'second survey question responses'* in six questions *(B4; B12 Tel; B12 Written; B12 Overall; B14; D1).* This means that the way parents answered these questions in their first survey completions, were statistically significantly related to the way they answered them in their second survey completions.

After controlling for the effect of *'first survey question responses'* (the covariate), there was a statistically significant difference between *'second survey question responses'* in the baseline versus the intervention period in one secondary outcome (Parent-staff interactions) question:

- B6*. 'In the last 24 hours, how many times have you asked your baby's nurse for an update about your baby, face-to-face?'*.

The second survey mean response in the baseline period was 1.64 (SD 0.842), versus 2.45 (SD 1.317) in the intervention period. This indicates that after correcting for first survey responses, during the intervention period and after having received the MBSR, parents on average asked their baby's nurse for a face-to-face update more frequently in a 24-hour period, compared to parents during the baseline period, who had not received the MBSR.

Categorical questions (A8, B2)

In the case of question *'B2. Have you been given enough written information (in paper or electronic form) to help you understand your baby's condition and treatment?',* I have further divided the responses into question B2 part 1 and part 2, for ease of analysis (Appendix 28).

For the categorical variable questions *(A8, B2 part 1)* I used a binary logistic regression analysis instead of ANCOVA. The covariate, '*first survey question responses',* was statistically significantly related to *'second survey question responses'* in question A8 (Table 26).

For categorical question *B2 part 2,* I have analysed it as a continuous question on this occasion, using the ANCOVA test. After controlling for the effect of *'first survey question responses'*, there was a statistically significant difference between *'second survey question responses'* in the baseline versus the intervention period for this primary outcome question:

- B2 part 2. *'Have you been given enough written information?' (1. Yes definitely – 4. No, not at all)*

The second survey mean response in the baseline period was 3.00 (SD 1.054), versus 2.06 (SD 1.181) in the intervention period. This indicates that after correcting for first survey responses, during the intervention period and after having received the MBSR, parents on average reported having received enough written information about their baby more frequently, compared to parents during the baseline period, who had not received the MBSR.

Detailed results from secondary analysis steps 1-3, are included in appendices 29-31, respectively. The statistically significant differences noted in each step's comparisons are summarised below:

**STEP 1:** Comparing the means of *'first survey question responses'* in the baseline period (43 parent surveys) to the means of *'first survey question responses'* in the intervention period (24 parent surveys)

- Primary outcome question B11: *'On a scale of 1 to 10 how satisfied are you with the frequency of updates you receive from doctors about your baby on the neonatal unit?'.*

The first survey mean parent response during the baseline period was 8.38/10 and during the intervention period 7.22/10, p=0.030. This indicates that during the intervention period, parents on average were less satisfied with the frequency of updates received from doctors, compared to parents during the baseline period, even before they received the communication tool.

- Primary outcome question B2 part 1: *'Have you been given enough written information to help you understand your baby's condition and treatment? '.*

The percentage of parents not wanting or needing any written information in first surveys in the baseline period (38.1%) was statistically significantly higher than in the intervention period (12.5%) ($x^2$=4.881, p=0.027).

**STEP 2:** Comparing the means of *'second survey question responses'* in the baseline period (19 parent surveys) to the means of *'second survey question responses'* in the intervention period (20 parent surveys)

- Secondary outcome (Parent-staff interactions) question B6: *'In the last 24 hours, how many times have you asked your baby's nurse for an update about your baby, face-to-face? Please insert number of times'*

The second survey mean parent response during the baseline period was '1.56 times' and during the intervention period '2.45 times', p=0.038. This indicates that during the intervention period and after having received the MBSR, parents on average asked their baby's nurse for a face-to-face update more frequently in a 24-hour period, compared to parents during the baseline period, who had not received the MBSR.

**STEP 3:** Evaluating the difference in means between *'first survey question responses'* and *'second survey question responses'*, both in the baseline and the intervention period.

Overall, there was no statistically significant difference between 'first survey question responses' and 'second survey question responses', neither in the baseline nor the intervention period.

**STEPS 1-4 OVERALL:** Appendix 32 includes the summary of all results from analysis steps 1-4. Appendix 33 includes example graphic representations combining all 4 analysis steps together, for the two PEC questions with statistically significant results from primary analysis STEP 4.

(iii) PEC surveys: Evaluate how satisfied parents were with the MBSR

The continuous PEC questions B18 and B19 specifically assessed parent satisfaction with the MBSR. Parents only answered these two questions after they began receiving the MBSR, during the 6-week intervention period (i.e. from the second time until the last time they completed the PEC survey).

Figure 29 shows run charts for questions B18 and B19, both by the dates of PEC survey completion (for all parents) and by the order of PEC surveys completed per parent (first survey – ninth survey completed). I am also presenting the data according to how many times parents evaluated the MBSR, to show the range of parent responses during the intervention period.

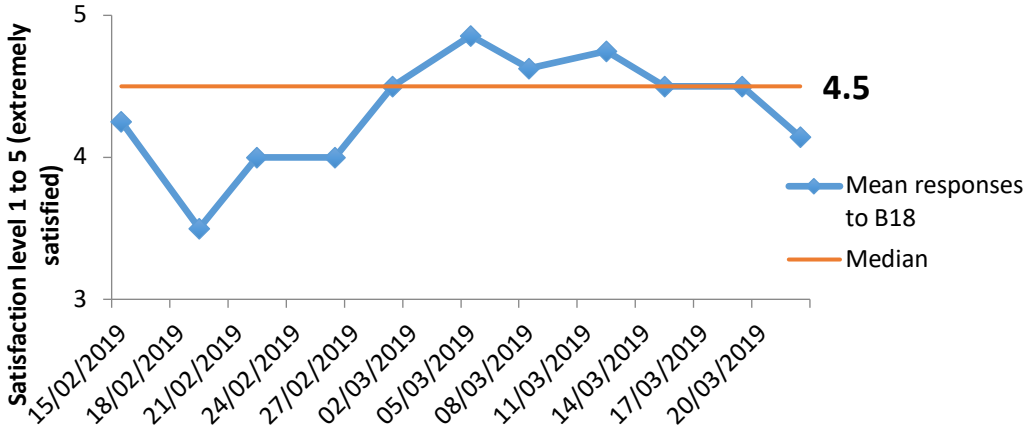
While there are not enough data points to conduct a formal analysis as per run chart rules, Figure 29 is useful for illustration purposes in that it does not reveal any obvious significant trend or shift by eye.

Parents appeared more satisfied with the communication tool following the first few weeks into the piloting process. Satisfaction levels appeared to drop towards the last 2 weeks of piloting, as well from the 8$^{th}$ time parents completed the PEC survey. These changes however do not satisfy run chart rules.

**Figure 29. Run charts: Mean responses to MBSR questions (B18, B19) by date of PEC completion and by order of completed PEC surveys per parent.**

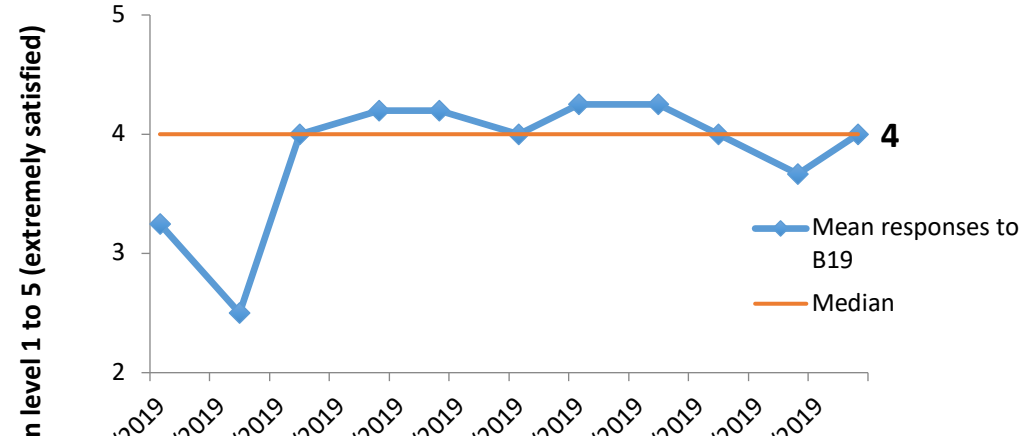
**By date of PEC completion (all parent surveys)**

*B18.On a scale of 1 to 5 how satisfied are you with the FREQUENCY of receiving "My Baby's Summary Report"*




*B18. On a scale of 1 to 5 how satisfied are you with the FREQUENCY of receiving "My Baby's Summary Report"?*

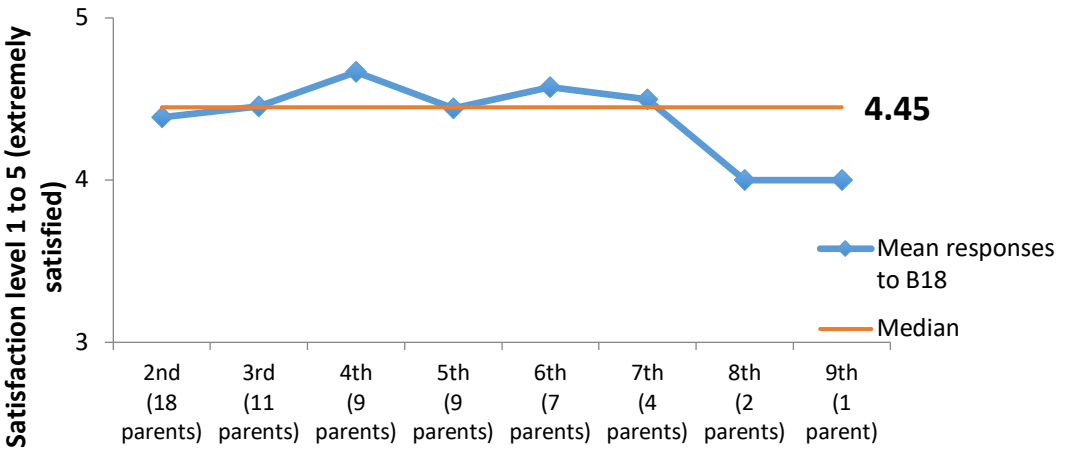
*'B19. On a scale of 1 to 5 how satisfied are you OVERALL with "My Baby's Summary Report"?'*




*B19. On a scale of 1 to 5 how satisfied are you OVERALL with "My Baby's Summary Report"?*

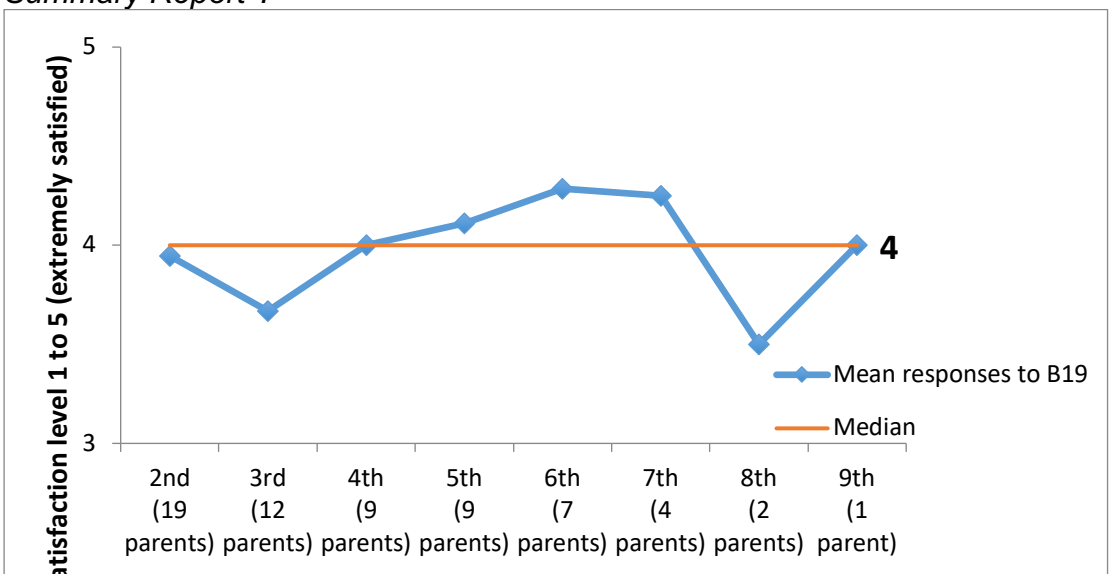
**By order of completed surveys**

*B18.On a scale of 1 to 5 how satisfied are you with the FREQUENCY of receiving "My Baby's Summary Report"?*




*B18. On a scale of 1 to 5 how satisfied are you with the FREQUENCY of receiving "My Baby's Summary Report"?…*

*B19. On a scale of 1 to 5 how satisfied are you OVERALL with "My Baby's Summary Report"?*




*B19. On a scale of 1 to 5 how satisfied are you OVERALL with "My Baby's Summary Report"?*

Appendix 34 includes the percentage distributions of responses to questions B18 and B19, comparing '*second survey responses*' (the first time parents

answered questions B18 and B19) to those of 'last survey responses' (the last time parents answered these questions). On applying the chi-square test, results were not statistically significantly different for either question.

**d. Staff surveys: 2 types of analysis**

(i) Staff surveys: Demonstrate how the outcome changed over time (baseline versus intervention period)

As already described, completed staff surveys were distributed differently by job role and unit area in the baseline versus the intervention period, with the differences being statistically significant (Table 25). As per study protocol, I had planned to generate staff survey run charts (baseline versus intervention period) if these samples were balanced; therefore, this was not possible.

(ii) Staff surveys: Evaluate the MBSR's specific impact on the outcome

For the 3 staff survey questions, I evaluated staff survey responses (baseline versus intervention period), correcting for job role and unit area (Appendix 35). After correcting for the covariates, results were statistically significant for one question:

- Question 1. '*In the last 24 hours, have you updated parents during a ward round?'*

The odds of staff members replying *"1.Yes"* in the intervention period were 2.15 times higher than in the baseline period (p=0.034). Full logistic regression and negative binomial distribution results are presented in Appendix 36.

**e. Data completeness: 2 types of analysis**

(i) Data completeness: Demonstrate how the outcome changed over time

In 2018 (calendar year 1 January 2018 to 31 December 2018), 104,577 infants were admitted to the 181 EPR participating neonatal units in England, Wales, Scotland, and the Isle of Man (1). Of these, 754 infants were admitted to the CW NNU.

My study's intervention period was between 12.02.2019 - 22.03.2019. Therefore, to create the '*baseline period NNRD population dataset'* I used NNRD data recorded for all infants that were on the CW NNU preceding the intervention period and between January 2018 - January 2019 (13 months, 801 infants, 12243 daily observations for each data item). To create the *'intervention period NNRD population dataset'* I used NNRD data recorded for all infants that were on the CW NNU during the 6-week intervention period only (February and March 2019, 98 infants, 1650 daily observations for each data item). It was not possible to match the intervention dates (12.02.2019 - 22.03.2019) to corresponding NNRD data precisely, as NNRD data are recorded by calendar month and not by calendar day.

The final MBSR template included 14 EPR data items:

1. *Age (days)*
2. *Corrected gestational age (weeks/days)*
3. Weight *(g)*
4. Respiratory support method *(ETT: endotracheal tube/tracheostomy; No ETT/No CPAP; Non-invasive support)*
5. Mode of non-invasive support *(CPAP: continuous positive airway pressure; high flow; nasal cannula)*
6. Supplemental oxygen *(Y/N)*
7. Parenteral nutrition today *(Y/N)*
8. Intravenous glucose and electrolyte solution *(Y/N)*
9. Any enteral feed today *(Y*: *Mum's milk; Formula; Donor milk/ N')*
10. Method of feeding *(Bottle; breastfeeding; Orogastric tube; Nasogastric tube; Nasojejunal tube)*
11. Baby tube fed *(Y/N)*
12. Volume of milk taken in 24 hours *(ml)*
13. Blood culture done today / CSF culture done today *(Y/N)*
14. Medicines received today *(List)*

The first 2 data items (age and corrected gestational age) are always fully recorded, as a counter automatically updates them daily.

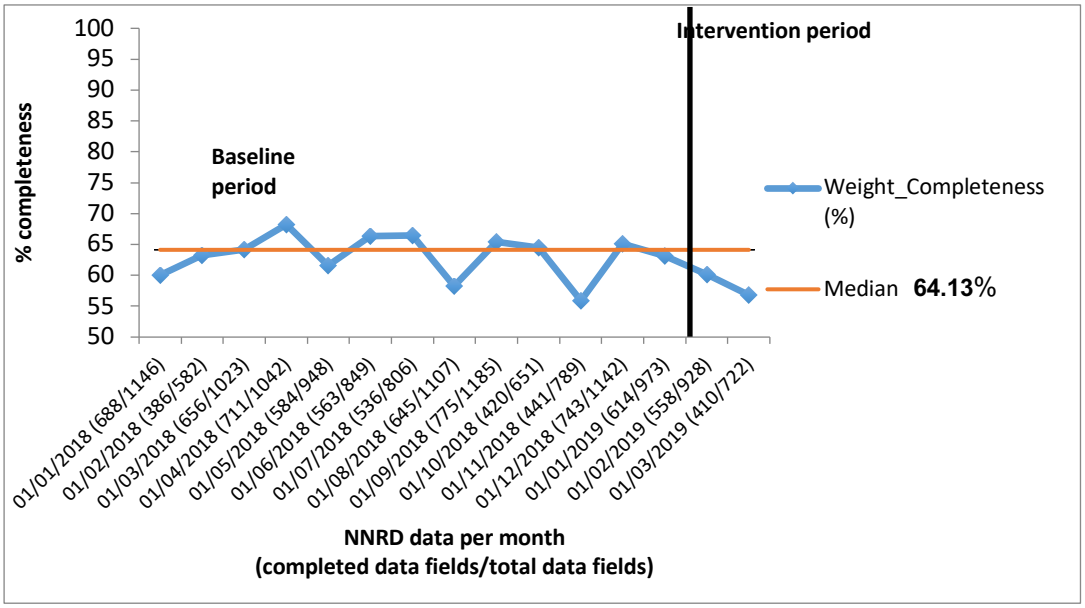
Of the remaining 12 items, the NNRD holds available completeness values

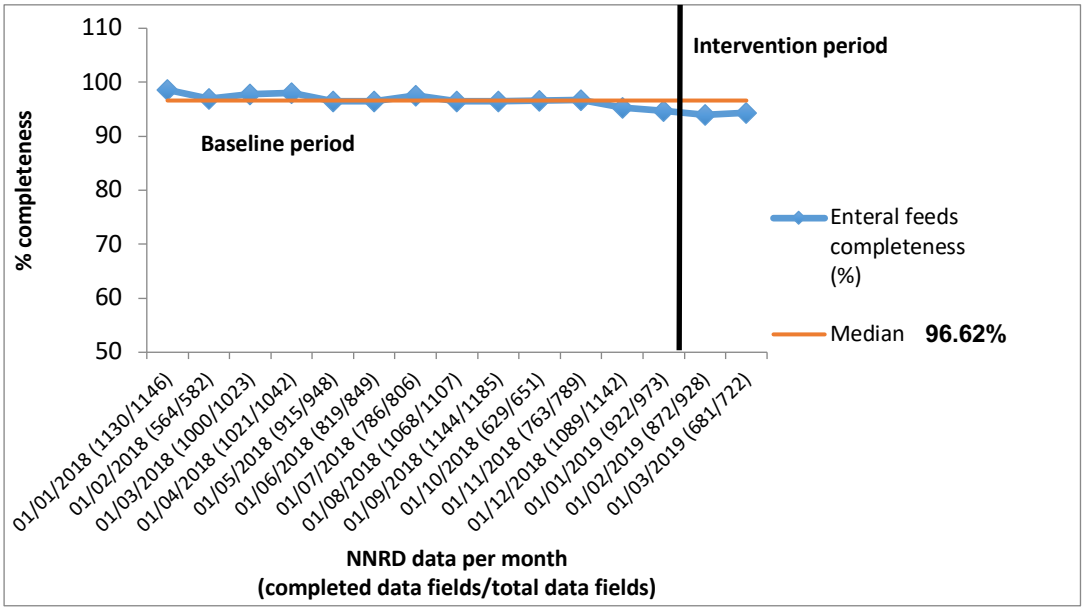
for the 11 items only. One item *('Baby tube fed Y/N')* is not included in designated NNRD items that are set to record completeness values.

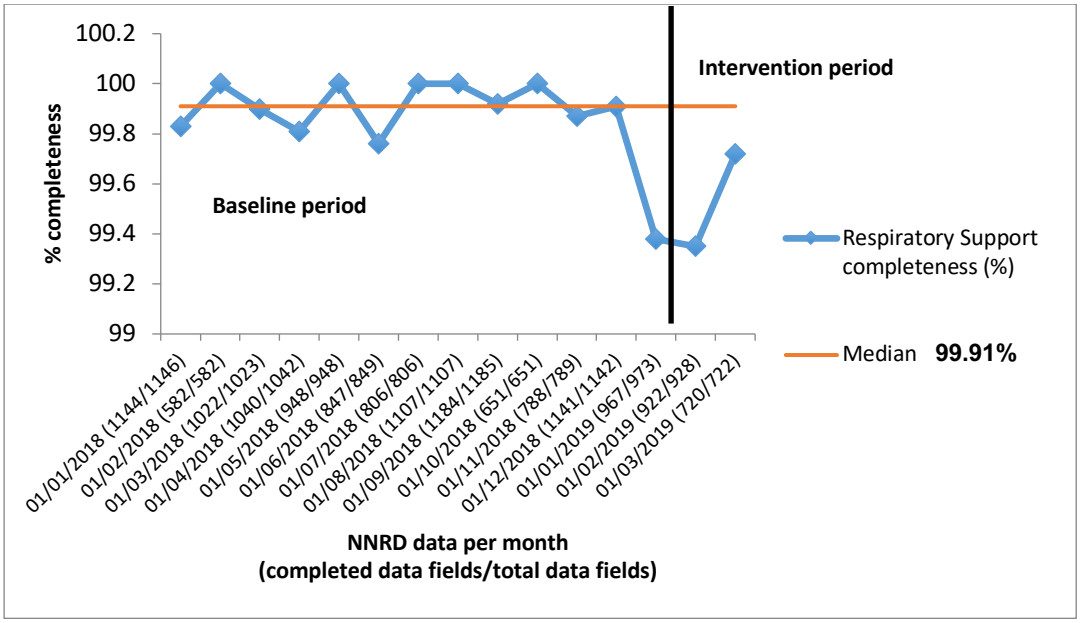
Of the 11 NNRD data items with available completeness data, 2 items *('Intravenous glucose and electrolyte solutions given today'* and *'Total Parenteral Nutrition (TPN) given today')* were 100% complete for all months throughout, from Jan18 - March19 and hence no run charts were generated.

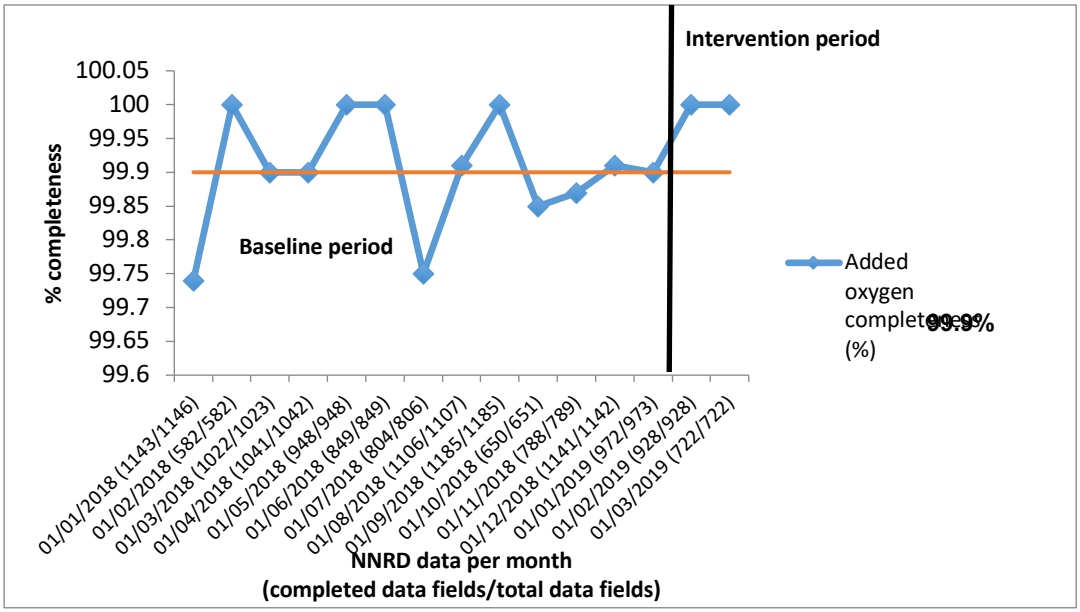
Figure 30 shows a run chart for each of the remaining 9/11 data items, including mean NNRD completeness per month, in the baseline (Jan18-Jan19) followed by the intervention period (Feb19-March19). While there are not enough data points to conduct a formal analysis as per run chart rules (2 intervention months available only), I have presented Figure 30 to illustrate how data completeness changed over time, on a unit level. The orange horizontal line indicates the median completeness percentage for each data item, generated from baseline period data.

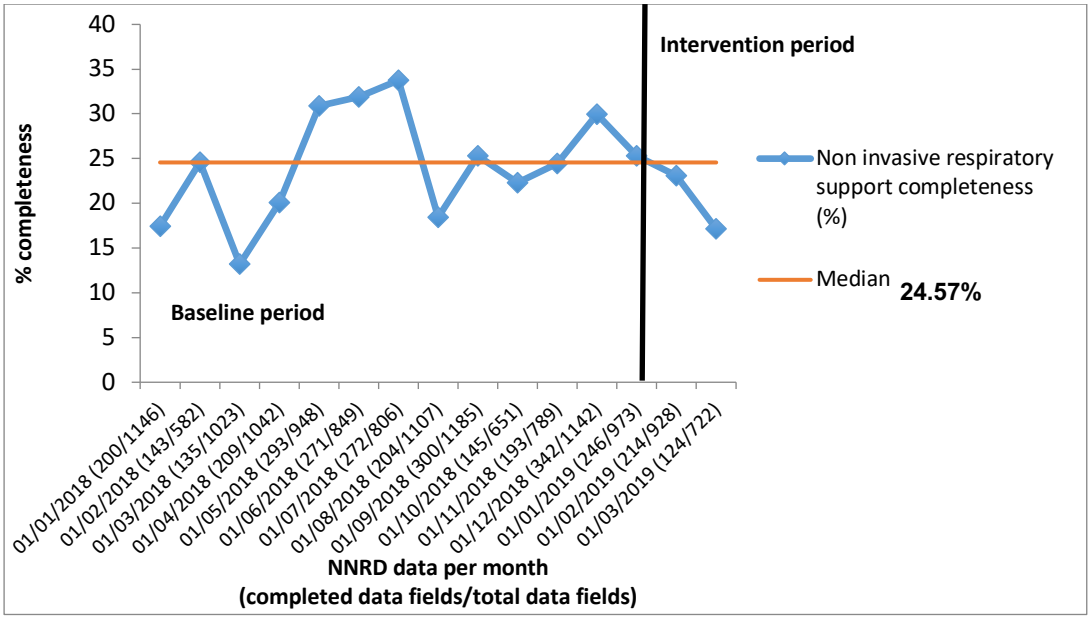
**Figure 30. Run charts with NNRD data mean completeness percentages per month in baseline period (13 months) and intervention period (2 months)**

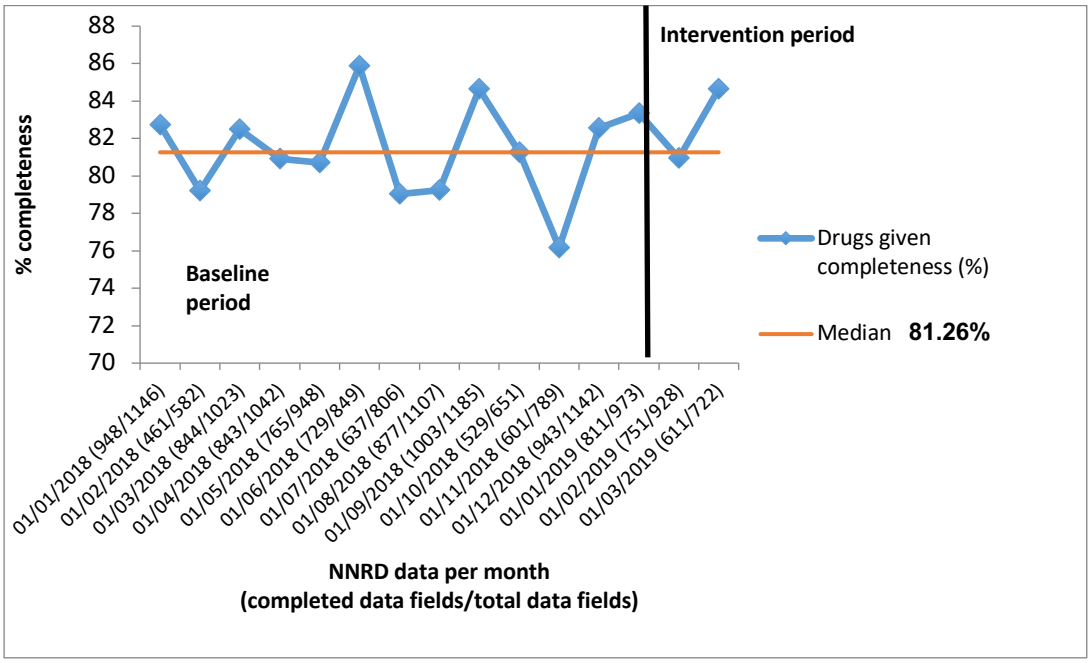


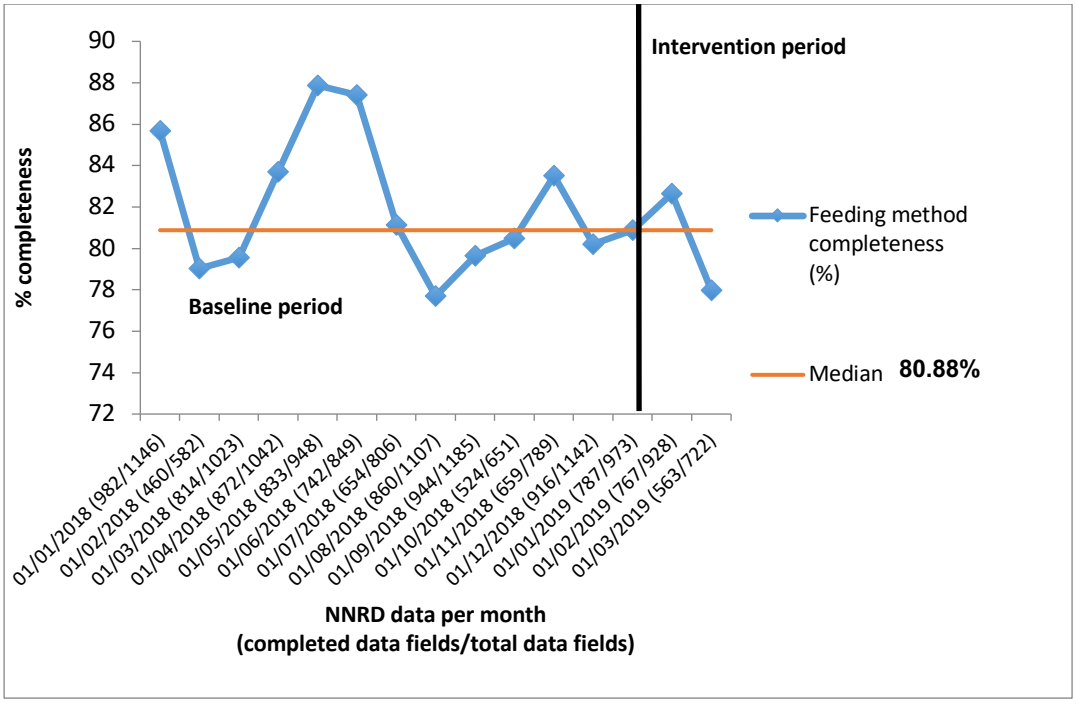



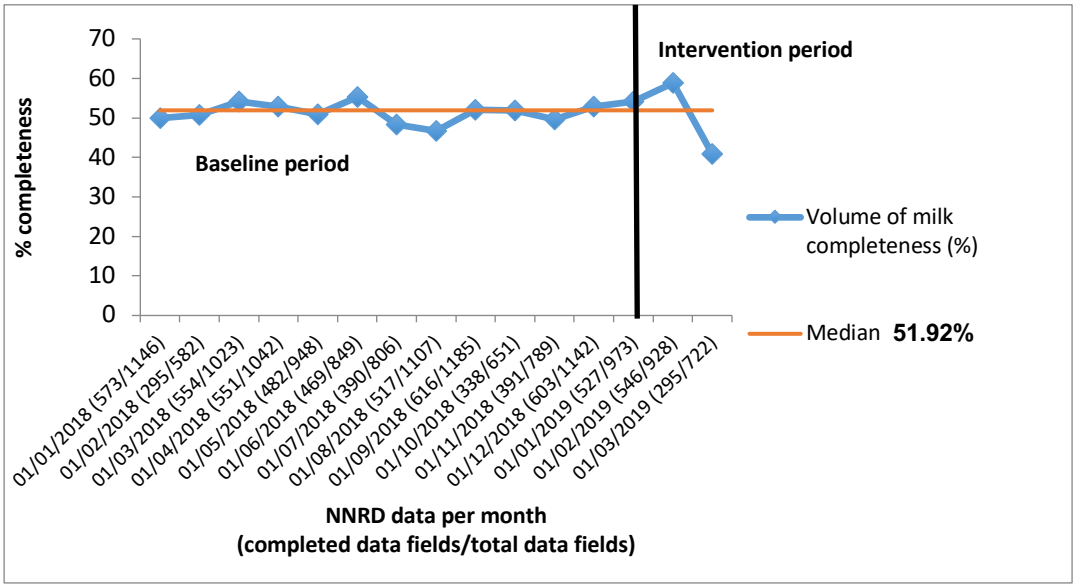

100.2
100
99.8
99.6
99.4
99.2
99
% completeness
Intervention period
Baseline period
Respiratory Support completeness (%)
Median 99.91%
01/01/2018 (1144/1146)
01/02/2018 (582/582)
01/03/2018 (1022/1023)
01/04/2018 (1040/1042)
01/05/2018 (948/948)
01/06/2018 (847/849)
01/07/2018 (806/806)
01/08/2018 (1107/1107)
01/09/2018 (1184/1185)
01/10/2018 (651/651)
01/11/2018 (788/789)
01/12/2018 (1141/1142)
01/01/2019 (967/973)
01/02/2019 (922/928)
01/03/2019 (720/722)
NNRD data per month
(completed data fields/total data fields)


100.05
100
99.95
99.9
99.85
99.8
99.75
99.7
99.65
99.6
% completeness
Intervention period
Baseline period
Added oxygen completeness (%)
99.9%
01/01/2018 (1143/1146)
01/02/2018 (582/582)
01/03/2018 (1022/1023)
01/04/2018 (1041/1042)
01/05/2018 (948/948)
01/06/2018 (849/849)
01/07/2018 (804/806)
01/08/2018 (1106/1107)
01/09/2018 (1185/1185)
01/10/2018 (650/651)
01/11/2018 (788/789)
01/12/2018 (1141/1142)
01/01/2019 (972/973)
01/02/2019 (928/928)
01/03/2019 (722/722)
NNRD data per month
(completed data fields/total data fields)


40
35
30
25
20
15
10
5
0
% completeness
Intervention period
Baseline period
Non invasive respiratory support completeness (%)
Median 24.57%
01/01/2018 (200/1146)
01/02/2018 (143/582)
01/03/2018 (135/1023)
01/04/2018 (209/1042)
01/05/2018 (293/948)
01/06/2018 (271/849)
01/07/2018 (272/806)
01/08/2018 (204/1107)
01/09/2018 (300/1185)
01/10/2018 (145/651)
01/11/2018 (193/789)
01/12/2018 (342/1142)
01/01/2019 (246/973)
01/02/2019 (214/928)
01/03/2019 (124/722)
NNRD data per month
(completed data fields/total data fields)


88
86
84
82
80
78
76
74
72
70
% completeness
Intervention period
Baseline period
Drugs given completeness (%)
Median 81.26%
01/01/2018 (948/1146)
01/02/2018 (461/582)
01/03/2018 (844/1023)
01/04/2018 (843/1042)
01/05/2018 (765/948)
01/06/2018 (729/849)
01/07/2018 (637/806)
01/08/2018 (877/1107)
01/09/2018 (1003/1185)
01/10/2018 (529/651)
01/11/2018 (601/789)
01/12/2018 (943/1142)
01/01/2019 (811/973)
01/02/2019 (751/928)
01/03/2019 (611/722)
NNRD data per month
(completed data fields/total data fields)


90
88
86
84
82
80
78
76
74
72
% completeness
Intervention period
Baseline period
Feeding method completeness (%)
Median 80.88%
01/01/2018 (982/1146)
01/02/2018 (460/582)
01/03/2018 (814/1023)
01/04/2018 (872/1042)
01/05/2018 (833/948)
01/06/2018 (742/849)
01/07/2018 (654/806)
01/08/2018 (860/1107)
01/09/2018 (944/1185)
01/10/2018 (524/651)
01/11/2018 (659/789)
01/12/2018 (916/1142)
01/01/2019 (787/973)
01/02/2019 (767/928)
01/03/2019 (563/722)
NNRD data per month
(completed data fields/total data fields)


70
60
50
40
30
20
10
0
% completeness
Intervention period
Baseline period
Volume of milk completeness (%)
Median 51.92%
01/01/2018 (573/1146)
01/02/2018 (295/582)
01/03/2018 (554/1023)
01/04/2018 (551/1042)
01/05/2018 (482/948)
01/06/2018 (469/849)
01/07/2018 (390/806)
01/08/2018 (517/1107)
01/09/2018 (616/1185)
01/10/2018 (338/651)
01/11/2018 (391/789)
01/12/2018 (603/1142)
01/01/2019 (527/973)
01/02/2019 (546/928)
01/03/2019 (295/722)
NNRD data per month
(completed data fields/total data fields)

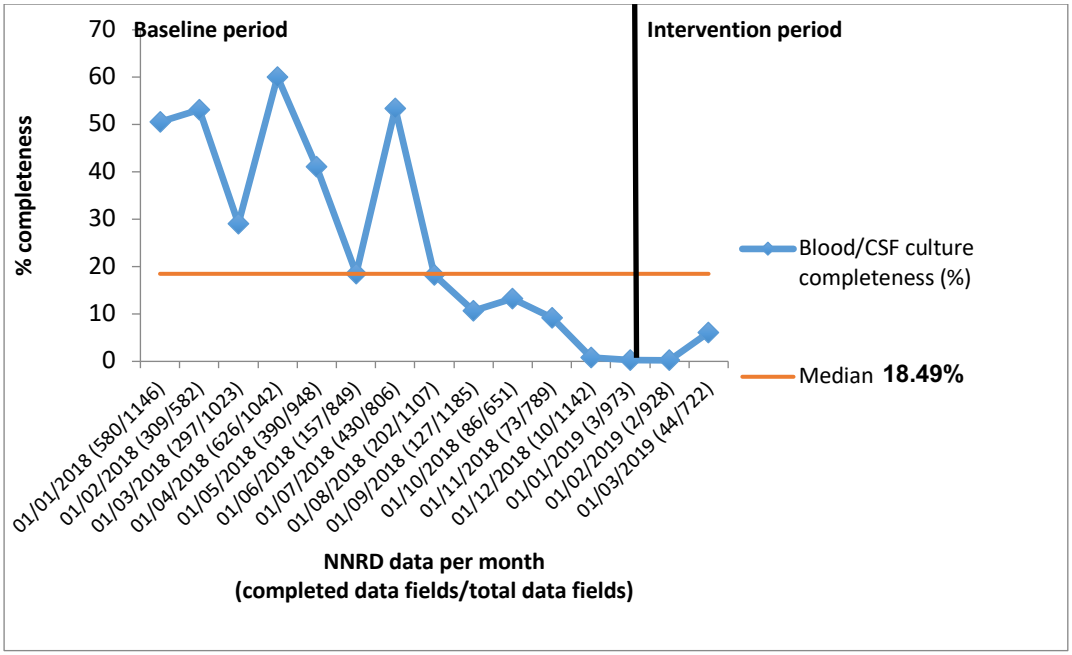



*Figure 30. For each run chart data point per month, per data item: "completed NNRD data fields/total NNRD data fields". Orange horizontal line: median completeness percentage for each NNRD data item for the baseline period.*

(ii) Data completeness: Evaluate the communication tool's specific impact on the outcome

- *'Baseline period NNRD population completeness proportion'* compared to '*intervention period EPR parent sample completeness proportion'* for each of the 11 data items

I generated a *'baseline period NNRD population completeness proportion'* for each data item, using NNRD data recorded for all infants that were on the CW NNU between January 2018 - January 2019 (13 months, 801 infants, 12243 daily observations for each data item) (Table 27).

**Table 27: Pre-intervention 'NNRD population completeness proportions' per data item from January 2018-January 2019**

| NNRD data item | Pre-intervention NNRD population completeness proportion *(completed data fields/total data fields)* | NNRD format considerations |
|---|---|---|
| Daily weight | 63.3% *(7744/12243)* | Some infants not weighed daily. The appropriate *'absence'* of a weight value is not actively recorded as *'non applicable'* (*'false negatives'*). |
| Enteral feeds given today | 96.8% *(11850/12243)* | A drop down menu to select from, includes the option *'no feeds today'*. Any missing values are recorded as *'incomplete'*. |
| Method of feeding today | 82.1% *(10047/12243)* | Drop down menu to select from. Any missing values are recorded as *'incomplete'*. |
| Volume of milk given in 24 hours | 51.5% *(6306/12243)* | Any missing values are recorded as *'incomplete'*. |
| Mode of non-invasive respiratory support | 24.1% *(2953/12243)* | The appropriate *'absence'* of a mode value for infants not requiring non-invasive support, is not actively recorded as *'non applicable'* (*'false negatives'*). |
| Medication given today | 81.6% *(9991/12243)* | The appropriate *'absence'* of medication entries for infants not requiring any medication is not actively recorded as *'non applicable'* (*'false negatives'*). |
| Blood or cerebrospinal fluid culture performed today | 26.9% *(3290/12243)* | Tick box to select yes or no. Any missing values are recorded as *'incomplete'*. |
| Intravenous glucose and electrolyte solutions given today | **100%** *(12243/12243)* | Tick box to select yes or no. Any missing values are recorded as *'incomplete'*. |
| Total Parenteral Nutrition (TPN) given today | **100%** *(12243/12243)* | Tick box to select yes or no. Any missing values are recorded as *'incomplete'*. |
| Respiratory support given today | **99.9%** *(12227/12243)* | Drop down menu to select from, including 'no support'. Any missing values are recorded as *'incomplete'*. |
| Added oxygen required today | **99.9%** *(12231/12243)* | Drop down menu to select from, including 'no added oxygen required'. Any missing values are recorded as *'incomplete'*. |

Considering the format by which data items are recorded in the NNRD, for 3/11 data items (*daily weight; mode of non-invasive respiratory support; medication*) any appropriate *'absence'* of a value in the database is not

actively recorded as *'non applicable'* (therefore generating *'false negatives')* (Table 27). For example, if a baby was not weighed on a particular day, the empty field value for 'weight' would still be recorded as an incomplete item on EPR. For the remaining 8/11 data items any missing values are appropriately recorded as truly *'incomplete'.*

Table 28 shows the comparison of these pre-intervention *'NNRD population completeness proportions'* to intervention period *'EPR sample completeness proportions'* using the binomial test. Highlighted are data items where data completeness increased during the intervention period (green) or reduced during the intervention period (red).

**Table 28: Data completeness binomial test results**

| NNRD data item | Pre-intervention NNRD population completeness *(binomial test proportion)* | Intervention period EPR sample completeness *(completed data fields/total data fields)* | P value |
|---|---|---|---|
| Enteral feeds given today | 97% | 94% *(181/193)* | **<0.001** |
| Daily weight | 63% | 98% *(189/193)* | **<0.001** |
| Method of feeding today | 82% | 93% *(180/193)* | **<0.001** |
| Volume of milk given in 24 hrs | 52% | 68% *(132/193)* | **<0.001** |
| Mode of non-invasive respiratory support | 24% | 91% *(175/193)* | **<0.001** |
| Blood or cerebrospinal fluid culture performed today | 27% | 96% *(186/193)* | **<0.001** |
| Medication given today | 82% | 87% *(167/193)* | 0.058 |
| Intravenous glucose and electrolyte solutions given today | **100%** | 95.9% *(185/193)* | Binomial test not possible |
| Total Parenteral Nutrition (TPN) given today | **100%** | 96.4% *(186/193)* | Binomial test not possible |
| Respiratory support given today | **99.9%** | 95.9% *(185/193)* | Binomial test not possible |
| Added oxygen required today | **99.9%** | 96.4% *(186/193)* | Binomial test not possible |
| Baby tube fed or not | **NNRD completeness data not available** | 95.9% *(185/193)* | Binomial test not possible |

*Table 28. In red: data completeness reduced during intervention period; In green: data completeness increased during intervention period. Statistical significance level p<0.05.*

## f. Data accuracy: 2 types of analysis

(i) Intervention period EPR parent sample accuracy proportion *("accurately completed data fields / total completed data fields"),* for each data item.

As previously discussed, there were no available pre-intervention NNRD data for accuracy to compare against. During the intervention period, 24 parents received the MBSR for at least one day. Overall, I recorded 193 daily datasets of observations for 24 infants, for each data item. Figure 31 shows overall accuracy proportions for each MBSR data item. I have arbitrarily defined low accuracy as <80%, intermediate accuracy as 80-89.9% and high accuracy as 90-100%.

**Figure 31. Overall accuracy proportions per data item**

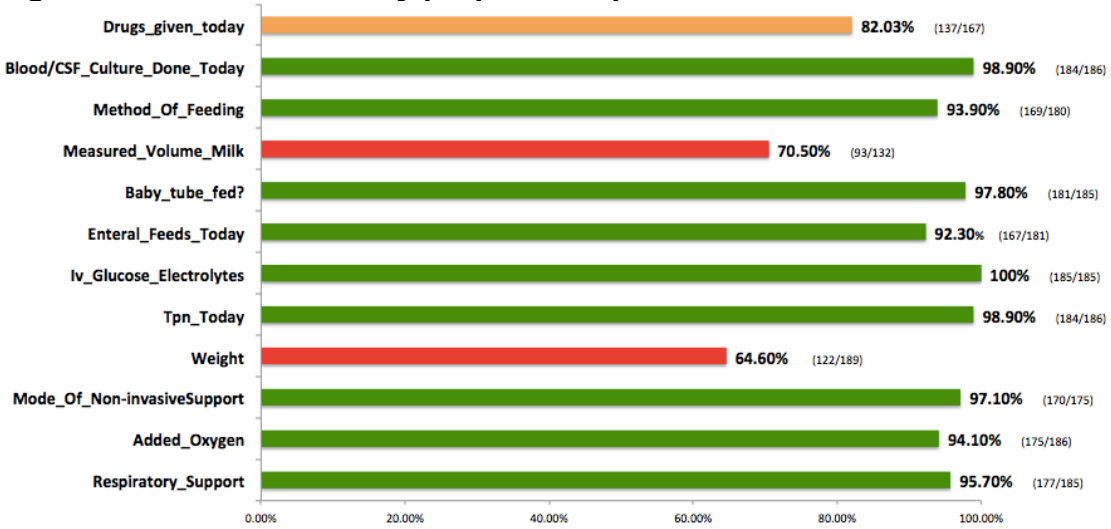



*Figure 31. For each data item: proportion of "accurately completed data fields / total completed data fields". Red: low accuracy <80%; Orange: intermediate accuracy 80-89.9%; Green: high accuracy 90-100%*

(ii) Proportion of *"infants with all daily datasets accurately recorded / all infants",* for each data item.

Figure 32 shows the proportions of infants with all daily datasets accurately recorded during the intervention period, per data item. Highlighted in Figure 32 are the 3 data items that were also seen to have intermediate/low overall accuracy proportions in Figure 34 *(Drugs; Volume of milk; Weight).*

**Figure 32. Proportions of infants with all daily datasets accurately recorded, per data item**

*Figure 32. For each data item: proportion of "infants with all daily datasets accurately recorded / all infants". Red: low infant proportions <80%; Orange: intermediate infant proportions 80-89.9%; Green: high infant proportions 90-100%.*

## 8.4 RESULTS OVERVIEW AND DISCUSSION

### 8.4.1 PEC parent surveys

In this chapter I have described the implementation, evaluation and continuous iterative improvement of the 'My Baby's Summary Report' (MBSR) communication tool, together with mothers and fathers of both premature and term infants on the CW NNU. Using the newly developed and validated PEC parent survey, allowed for regular real-time parent feedback, compared to previous interventions primarily evaluated by one-off retrospective parent surveys (11).

In conducting run chart analysis to examine how PEC survey responses changed over time (baseline versus intervention period), I have demonstrated that during the period of introducing the MBSR on the CW NNU parents overall:

- Were *more satisfied* with the method of communication being 'written information' and more likely to recommend the CW NNU to friends and family *(Primary outcome).*

- Were *less satisfied* with the frequency of updates received by nurses and doctors and the method of communication being 'verbal updates' and 'telephone calls' *(Primary outcome).*

- Reported telephoning the unit 'more times in 24 hours' *(Secondary outcome: Parent-staff interactions).*

Overall, parents reported being more likely to recommend this NNU to friends and family and more satisfied with receiving updates in written form. It is likely that receiving the MBSR also created increased expectations for parents in terms of communication frequency, resulting in parents feeling less satisfied with face-to-face and telephone updates and telephoning the unit more often. Despite establishing baseline median values for parent satisfaction prior to MBSR implementation and ensuring that no other interventions were being implemented during that time period, it is however still likely that (given the nature of neonatal care) factors other than the MBSR implementation (e.g. infant's clinical condition etc) could have also contributed to the above results.

In evaluating the communication tool's specific impact on PEC survey responses, statistically significant results indicated that:

- More parents in the intervention period reported they had 'received enough written information' compared to the baseline period *(Primary outcome).* This result is most likely a reflection of the MBSR's implementation.

- Parents reported asking their baby's nurse for a face-to-face update more frequently in a 24-hour period in the intervention period (mean 3 times) compared to the baseline period (mean 2 times) *(Secondary outcome: Parent-staff interactions).* This result could suggest that parents felt the need for more verbal information when they received additional written information

in the MBSR. This might reflect an increased need for information in line with piloting a communication intervention (and increased communication frequency expectations as already discussed) or a need to clarify or further discuss information received in the MBSR with staff.

Of note is that in the case of key PEC question B12 written *'On a scale of 1 to 10 how satisfied are you with how you receive information about your baby on the neonatal unit? – method being written information',* the paired parent samples were very small (7 parent pairs in baseline period, 4 parent pairs in intervention period), reporting 5/10 satisfaction in both the intervention and baseline period, a non-statistically significant result. Therefore, given the small sample numbers, this result should be interpreted with caution.

Secondary analysis was conducted which provided further context to the above results:

- During the intervention period and even before they received the communication tool, parents were less satisfied with the frequency of updates received from doctors, compared to parents during the baseline period. This could be related to a Hawthorne-type effect whereby parents had increased expectations of communication frequency, because they were expecting to receive additional written information in the MBSR.

- During the intervention period and even before they received the communication tool, the percentage of parents needing/wanting written information was higher than in the baseline period. Again, this could be related to parents feeling an increased need for written information, ahead of receiving the MBSR for the first time.

In evaluating how satisfied parents were with the MBSR over time, satisfaction levels during the intervention period were high for both '*frequency of receiving the MBSR' and the 'MBSR overall'.* There were not enough data points to conduct a formal analysis as per run chart rules; however, as a general pattern parents appeared more satisfied with the MBSR from the

second week onwards and slightly less satisfied during the last 2 weeks (and from the 8th time of PEC survey completion per parent). This would be expected, considering parents were able to provide feedback on the MBSR with each PEC survey completion (and see their feedback gradually being incorporated into the MBSR template from week to week). Towards the end of piloting it is likely parents experienced a degree of survey completion 'fatigue', with the MBSR having reached a ceiling effect of how much parent feedback was feasible to be incorporated (e.g. parents asking for further information to be included in the MBSR that was not routinely recorded in the neonatal EPR).

In comparing paired parent survey responses from the first and last time parents had received the MBSR, satisfaction levels were generally high and were not statistically significantly different.

### 8.4.2 Staff surveys

In evaluating staff survey responses (baseline versus intervention period), results were statistically significant for the question '*In the last 24 hours, have you updated parents during a ward round?'.* The odds of staff members replying *'1.Yes'* in the intervention period were 2.15 times higher than in the baseline period. This could indicate that during the period of receiving the MBSR parents attended ward rounds more frequently, where they had the opportunity to be updated by staff members. This explanation would be in line with findings from parent PEC surveys, indicating that parents had increased communication and information needs during the intervention period.

### 8.4.3 Data completeness

On comparing the *'baseline period NNRD population completeness proportion'* to the '*intervention period EPR parent sample completeness proportion'* for each of the 11 NNRD data items, completeness in the intervention period was generally high (10/12 items >90% completeness). Completeness in the baseline period was seen to be lower (>80% for 7/11 items).

For 6/11 data items completeness significantly increased in the intervention period (by at least 10% for each item); for 5 of these items this was statistically significant (*Daily weight; Method of feeding today; Volume of milk given in 24 hours, Mode of non-invasive respiratory support; Blood/cerebrospinal fluid culture performed today)* and for 1 item not statistically significant *(Medication given today*). This could indicate that staff members took more care to manually record these items in each baby's EPR, knowing that the data items were being presented to parents in the MBSR. Considering that the above items matched the information that parents primarily ask for in verbal conversations with staff (Chapter 9 Qualitative analysis), staff members could have had more of an incentive to complete these items in the EPR. Future research would be needed to understand any additional factors possibly unrelated to the MBSR.

One data item's completeness reduced during the intervention period (*Type of enteral feeds given today*) and this was statistically significant. As this was just a 3% reduction and completeness in the intervention period was still high (94%), this result could still be part of normal, common cause variation (median baseline completeness value in the NNRD 96.62%) or could be related to the small number of data items. For the 4/11 remaining items (*Intravenous glucose and electrolyte solutions; Total parenteral nutrition; Respiratory support today; Added oxygen today*) the comparison was not possible as completeness in the NNRD was 100% (and >95% in the intervention period).

In this study, I have defined incompleteness as an empty data field. The low completeness values for specific data items in both baseline and intervention periods could be explained by the appropriate *'absence'* of a value in some questions still being recorded as an incomplete data item (e.g. when an infant has not been weighted and the weight value is appropriately empty). Similarly, the absence of a condition, (e.g. infection) is not always actively recorded. Low completeness could also be explained by certain questions requiring manual entry of a value rather than ticking a box (e.g. volume of milk in ml), where human error could therefore be more likely.

Data completeness and accuracy are fundamental components of data quality, yet formal quality assurance of population health databases is rarely reported or even undertaken (86). A recent validation study by Battersby et al was the first to formally evaluate the population coverage and accuracy of NNRD data (23). By comparing NNRD data to a single large clinical trial between 2008 and 2015, that study showed that the completeness and accuracy of data held in the NNRD is high (23) but can also be further improved; however this focused only on data items entered once (e.g. baseline characteristics, diagnoses etc.) rather than daily recorded data. This PhD is the first study to report completeness and accuracy data for *'daily-recorded'* data items in the NNRD.

### 8.4.4 Data accuracy

As previously discussed, there was no available pre-intervention NNRD data accuracy comparator. Having arbitrarily defined low accuracy as <80%, intermediate accuracy as 80-89.9% and high accuracy as 90-100%, I have demonstrated that 9/12 items had a high accuracy proportion (defined as '*accurately completed data fields / total completed data fields*') over the whole intervention period, 1/12 had intermediate accuracy (*Medication today*) and 2/12 had low accuracy (*Milk volume; Weight*). Items with high accuracy (such as *Intravenous glucose and electrolyte solutions; Total parenteral nutrition; Added oxygen today),* are recorded by ticking 'yes' or 'no', meaning it is a lot more likely an observation is accurately completed once it is recorded. For the 2 items with low accuracy (*Milk volume; Weight*), a value needs to be manually entered by staff members, meaning human error is a lot more likely.

I additionally calculated the proportions of infants with all daily datasets accurately recorded during the intervention period, per data item; out of 12 data items, 7 had a low accuracy proportion *(*defined as *'infants with all daily datasets accurately recorded / all infants').* This was an assessment of accuracy considering that daily data sets for the same baby are not independent. However, the fact that most data items had a low accuracy proportion of *'infants with all daily datasets accurately recorded / all infants',* shows the variation of ways of completion within the same infant's record.

This could be explained by the fact different staff members record different daily data sets because of shift patterns.

Again, the 3/12 items that had high accuracy proportions (*Total parenteral nutrition; Intravenous glucose and electrolyte solutions; Blood culture today*) were items recorded by ticking 'yes' or 'no'; therefore, once accurately recorded for the first time these were more likely to be accurately recorded over subsequent days again, compared to questions that needed a value entered.

Data accuracy (how paper case records compare to NNRD records) is not routinely recorded in the NNRD as this would be very labour intensive, considering the amount of data item observations available. Therefore, baseline NNRD accuracy proportions were not available for use in this PhD. In the NNRD validation study (23), Battersby et al measured the accuracy of 44 'once-only' data items (16 patient characteristics, 17 processes, 11 clinical outcomes) for infants enrolled in the multi-centre randomised controlled trial, Probiotics in Preterm Study (PiPs). By comparing NNRD to PiPs data, they calculated discordancy rates using predefined criteria, and sensitivity, specificity and positive predictive values (PPV) of binary outcomes. Discordancy rates were seen to be <5% for the majority of data items, specificity of NNRD data was >85% for all outcomes and sensitivity ranged from 50-100% (23). The above accuracy rates are in line with the high accuracy proportions seen for most data items in this PhD.

### 8.4.5 Strengths

In this chapter I have discussed the piloting of a parent co-designed intervention, the MBSR, on an NHS NNU. The main overarching strength of this pilot was the active involvement of parent NNU service-users throughout. Parent participants included both mothers (primarily) and fathers of both preterm and term infants (between <24 and >40 weeks), of a range of ethnicities (predominantly white) and ages, with duration of stay on the NNU between <1 week and >6 months, providing a diverse sample. Over 70% of

parents were older than 30 years old, which could be reflective of this NNU's parental age population or be due to small sample size.
Parents of infants previously requiring neonatal care co-designed the MBSR's initial template and parents of infants currently receiving neonatal care further developed and improved it during the intervention period. This was done through parent satisfaction survey feedback obtained as part of PDSA improvement cycles conducted on the NNU, a well-established quality improvement methodology (66-68).

To evaluate the MBSR I measured a number of outcomes, including using a parent satisfaction survey, staff survey, data completeness/accuracy assessments and interviews with parents and staff (Chapter 9). This was in recognition of the complex nature of neonatal care, whereby any parent intervention can impact different elements of care. In contrast to previous neonatal care intervention studies where surveys have been mostly unvalidated (11, 40), I used a parent satisfaction survey that I validated with parents of infants receiving NHS neonatal care to provide real-time parent feedback of the MBSR (the PEC survey).

Parent satisfaction is not a static measure; it can change over time, even in the absence of any interventions, because of a number of (often unmeasured) factors (e.g. parent personal circumstances, infant clinical condition, neonatal unit environment etc). It is therefore important to establish what the baseline parent satisfaction is on a given NNU before introducing a new intervention (including its baseline upper and lower limits), allowing for 'common cause variation' over time. In Chapter 4, I highlighted how previous studies have mostly focused on solely comparing single pre-intervention to post-intervention parent-reported outcomes (11). In order to take into account the dynamic nature of parent satisfaction as an outcome, I also included run charts in my analysis. In this way I generated baseline median values for parent satisfaction for each PEC survey question, thereby defining the limits of 'common cause variation' over time in this particular neonatal unit, prior to implementing the MBSR. With run charts I was able to assess how my outcomes changed through the piloting process and by applying 'run chart

rules' I was able to offer interpretations of how the MBSR could have brought on significant changes outside of the baseline normal limits. During the study period, there was no change in CW NNU protocols for medical treatment, parent education, environmental or parent accommodations and there was no change in physician or nursing staff roles.

A further strength is that my intervention used routinely recorded NHS neonatal infant data, without incurring any extra work to neonatal staff. This PhD is the first study to report completeness and accuracy data for daily recorded items in the NNRD. There is a general lack of evidence for interventions to improve the completeness and/or accuracy of routinely collected data in neonatal care. This PhD is one of the first studies to measure the impact of a parent intervention on data completeness (and also be shown to improve it).

### 8.4.6 Limitations

One of the main study limitations was the study design, which was not randomised and therefore susceptible to bias. Randomisation of an intervention such as the one developed and evaluated in this study is inherently difficult to achieve in a single centre. Parents in neonatal care openly discuss their experiences between them, regularly converse and exchange ideas. In the case of randomising one group of parents to receive the MBSR over a control group, there would have been the risk of upsetting parents who were not receiving the MBSR while potentially magnifying the Hawthorne effect in the group receiving the MBSR (with parents being aware of being observed potentially affecting their survey responses). Furthermore, there would have been a high risk of contamination between groups owing to parents regularly discussing between them. Blinding parents to the allocation of the MBSR was not possible either, given the nature of the intervention.

In view of the non-randomised design, I took care to evaluate parent, staff and data outcomes using a combination of modalities (traditional statistical tests, interviews and quality improvement methodology), in order to make the analysis more robust. With this approach I also recognised the challenges

(and importance) of examining different aspects of the complex concept of parent satisfaction, which can also be affected by the wider parent experience of neonatal care and parent-staff communication. Indeed, as my results have also indicated, changes in one aspect of care can impact other areas, ultimately making it more difficult to draw overall conclusions.

Previous non-randomised intervention trials aimed at improving the parent experience have been primarily evaluated by using either only interviews or only quantitative surveys, with a lack of such studies utilising run chart analysis for parent-reported outcomes at all (11, 39). I also investigated PEC survey questions in different ways, considering the challenge of partially paired parent samples and the dynamic nature of parent satisfaction as a complex multi-layered outcome. In contrast, conducting only traditional 'static' before and after percentage comparisons of parent satisfaction (like in previous studies) would not have taken the above into account. However, having different types of analysis for each PEC survey question also meant it was challenging to identify overall patterns of results on a PEC survey level, to give overall conclusions. There were only a few statistically significant results seen in some of the statistical methods used for each PEC question; this could in part be related to the small parent sample size or the proportion of incomplete PEC questions in some surveys. A multiple testing correction was not required as the different types of analysis involved different parent samples (unpaired, paired or partially paired) and the PEC survey and data completeness tests were conducted for each variable separately (survey question and data item, respectively). It is important to note that most comparisons did not result in statistically significant differences anyway.

Given the above considerations, a cluster RCT could be the optimal methodological approach to further evaluate an intervention such as this in the future. This was not possible as this study aimed to locally develop, pilot and evaluate the MBSR with parents on a smaller scale first, in order to inform any future studies or a wider roll-out.

I created a convenience sample by approaching parents that were visiting their baby during daytime shift hours (~08:00-20:00). This unfortunately meant I was not able to recruit parents that were not regularly visiting their baby or could only visit during the night; this would have been a group of parents that could have greatly benefited from receiving the MBSR. In turn, parents who consented to the study could have been a self-selecting group with heightened information needs, who were always going to ask many questions, were present on the neonatal unit more and therefore available to consent and take part. This could in part explain the result of recruited parents having increased expectations of information-sharing and communication, even after receiving the MBSR. However, in terms of generalisability of results, having developed and further improved the MBSR with potentially 'high-information need parents' would still be expected to satisfy a wide range of parental information needs in NNUs.

I had initially planned to recruit 90 parents; however given the nature of convenience sampling and variable parent attendance on the unit I was able to approach 37 parents and recruit 30 in total for the intervention period (including 24 parents that received the MBSR and 6 additional parents for pre-intervention interviews). Parent recruitment and retention for studies in neonatal care is known to be challenging, considering parental anxiety and stress related to their infant's clinical condition, as well as transportation, work-related and other personal difficulties in being physically present on the neonatal unit (45). As per protocol there had been no formal power calculation for a particular treatment effect underpinning the sample size of 90 parents; instead, recruitment was planned depending on parent availability. Although the MBSR was still appropriately developed with parents as expected, the resulting small parent sample of 24 receiving the MBSR (although not formally considered underpowered) meant some of my statistical test choices were challenging, particularly in the case of paired and partially paired parent data; parents occasionally did not complete some PEC survey questions (see data validation in Chapter 7), which created unequal groups for analysis.

Furthermore, due to the nature of the intervention, it was not possible to blind parent participants to receiving the MBSR. As I recruited all participants in the same time period, it was not possible for me, as the researcher, to be blinded to allocation of intervention either. I analysed parent PEC surveys and staff surveys using code identifiers; any possible parent recognition during data extraction and analysis could not have affected results, as survey data was numeric, objective and self-administered by participants. I was the sole researcher who interviewed participants (chapter 9).

One of the other main limitations was recruiting only parents that could speak and understand written English, thereby potentially excluding parents from different cultures who may experience neonatal care differently. Because parents needed to be involved in the co-design and the self-administered PEC survey was only available in English, including different languages could not easily be facilitated (as one-to-one interpreters would need to be available throughout the study). Furthermore, I excluded parents where the clinical team had planned to redirect to palliative care for their baby, so as not to cause additional parent distress during an already difficult time. I was additionally only able to recruit parents who could visit the neonatal unit in person. The above exclusions could have limited how representative the parent sample was of the CW NNU parent cohort. Unpublished National Neonatal Research Database (NNRD) key demographic data for CW NNU parents are however still broadly comparable to national data (study period 2018-2019). My study's parent intervention sample primarily included parents over the age of 30 years (88%), with most prevalent age group being 30-35 years (46%) (NNRD CW NNU mean age: 33 years and 36 years for mothers and fathers, respectively). Parental study sample ethnicity was predominantly White (42%), followed by Asian/Asian British (29%), compared to NNRD CW NNU available data for mothers only of White British/Irish (36.1%), White Other (29.9%) and Asian (18.3%).]

Finally, due to this being a single centre study, all participants were from the CW NNU, in London, which could limit generalisability of results to other neonatal units. However, while the CW NNU may be located in an affluent

area, being the neonatal surgical referral unit for North West London it cares for patients from across North West London (and London more widely), including a very broad range of socioeconomic and ethnic backgrounds within patients. Indeed, unpublished NNRD available data from 2018-2019 (study period) are broadly comparable between CW and nationally: 12.2% of babies cared for at CW were from the top quintile (least deprived areas) and 10.7% from the bottom quintile (most deprived areas), compared to 13.4% and 29.1% nationally. Most mothers of babies cared for at CW were White British/Irish (36.1%), followed by White/Other (29.9%), compared to 65.5% White British/Irish and 10.7% White/Other nationally. Mean maternal age for CW was 33 years (30 years nationally) and paternal age 36 years (32 years nationally).

In terms of data completeness and accuracy, the neonatal EPR (and subsequently the NNRD) contains a daily dataset of observations for every infant's neonatal care admission, for as many observation days as their corresponding length of stay. Daily data sets cannot therefore be assumed to be independent. A way to overcome this could have been to only use the first or last daily datasets for each infant. However, this would mean discarding a large proportion of data within an already small sample size. I have therefore included all daily data sets in analysis with this limitation in mind.

Another limitation was that out of the 12 MBSR data items assessed for completeness, the 12$^{th}$ item ('Baby tube fed Y/N') is not included in the list of NNRD items that are set to record completeness values; therefore, baseline period completeness data for this item were not available.

## 8.5 DISSEMINATION: DEVELOPMENT OF BUDS MOBILE PHONE APPLICATION

### 8.5.1 BUDS app prototype

As previously described, I piloted the communication tool in paper form, in view of challenging logistics relating to a change in EPR provider for CW Hospital and the CW NNU during this study. Following completion of the piloting process, I worked with the mobile phone application developer

company ‘Cambridge Digital Health’, utilised the feedback from parents and translated the paper MBSR into a mobile phone application.

I combined parental feedback from results of the quantitative (Chapter 8) and qualitative evaluation of the MBSR (Chapter 9) to develop the BUDS (*Better Use of Data to improve parent Satisfaction*) app prototype (87), including parent-friendly bespoke NNU illustrations. Appendix 37 includes screenshots of the BUDS app, showcasing its initial ‘baby profile selector’ function, followed by 4 main sections (Quick view; Daily update; Notes; Information). Following parent feedback, the ‘Information section’ also includes the ‘unit-specific’ information developed by parents (link to the CW NNU parent information booklet) (Chapter 6) and Bliss charity resources.

Based on parent interviews (Chapter 9), the app prototype also delivers a daily individualised ward round plan for each baby, includes a function for parents to report incomplete and/or inaccurate data items and delivers information in language that matches the verbal information format provided by neonatal staff. It additionally includes explanations on how daily information compares to that of previous days, to describe each baby’s progress. These features are not currently built in to the neonatal EPR but were included in the app prototype as they were strongly requested by parents.

### 8.5.2 BUDS live app at CW NNU

Having received approval from the Health IT review board of CW Hospital trust and information governance approvals, I secured a contract between CW Hospital and ‘Cambridge Digital Health’ in October 2022 for the BUDS parent app to become live on CW NNU. Intellectual property rights will be jointly held by Imperial College London and CW Hospital. The app will deliver daily updated neonatal data items from the neonatal EPR to parents, is currently in production and is due to be released in the spring/summer of 2023.

## 8.6 CONCLUSIONS

During this study's intervention period, mothers and fathers of both premature and term infants on the CW NNU received the 'My Baby's Summary Report' (MBSR) communication tool, further improved it and developed its final template through providing regular feedback via the PEC real-time parent survey.

During the intervention period, the main analysis indicated that after receiving the MBSR, parents were statistically significantly more satisfied with the amount of written information received (*primary outcome: parent satisfaction with communication of clinical information)* but also asked their nurse for an update more frequently *(secondary outcome: parent-staff interactions).* Run chart analysis showed that while receiving the MBSR parents were more satisfied with the method of communication being 'written information' and were more likely to recommend the CW NNU to friends and family. Parents also telephoned the unit more often and were less satisfied with the frequency of updates received by nurses and doctors. Parent satisfaction with the MBSR (both overall and in relation to the frequency of receiving it) was high throughout the intervention period. During the intervention period, staff members reported updating parents more frequently on ward rounds *(secondary outcome: staff workload).* NNRD data completeness improved and data accuracy was high (>=90%) for the majority of data items. This PhD is the first study to report completeness and accuracy data for *'daily-recorded'* data items in the NNRD and one of the first to measure the impact of a parent intervention on data completeness (with evidence of improved completeness).

The above results suggest that the MBSR implementation increased parent satisfaction with the amount of written information received and parents were highly satisfied with the MBSR overall. Parental communication frequency needs on the CW NNU also unexpectedly increased, with staff members in response updating parents more frequently on ward rounds and manually recording infant EPR data items in a highly accurate and more complete way. This would support the use of the MBSR as a communication tool adjunct in neonatal care. Due to the dynamic nature of neonatal care and lack of

randomised design, future research would be needed to understand any additional unmeasured factors (possibly unrelated to the MBSR) that could have influenced the above results. The optimal study design for this type of intervention could be a cluster RCT, if time and resources allow.

Following the piloting process, I have developed a BUDS mobile application prototype and a contract to build a live app for use by parents on the CW NNU was signed in October 2022 (with the app due to be released in the spring/summer of 2023). This will allow for better efficiency and wider application of my study's findings.

# Chapter 9
# Qualitative evaluation of the communication tool

In this chapter I describe the qualitative evaluation of the MBSR communication tool. This is the qualitative element of the overall piloting process that I have otherwise described in Chapter 8. It includes one-to-one interviews with parents of infants receiving neonatal care on the CW NNU as well as interviews with neonatal nurses and doctors working on the CW NNU, during both the pre-intervention period and the post-intervention period.

## 9.1 OBJECTIVES

- To explore the views of parents of infants receiving neonatal care on:
  - Their experience receiving information about their baby in neonatal care.
  - Their experience receiving the daily MBSR communication tool (for post-intervention interviews)
  - How involved they feel in their baby's care.

- To explore the views of neonatal nurses and doctors on:
  - Their experience providing information to parents about their babies in neonatal care.
  - How updating parents on their baby's progress affects their workload.
  - Their experience being involved in the MBSR trial.

## 9.2 METHODS

### 9.2.1 Phenomenology theory

I have used Edmund Husserl's phenomenology theory as an overarching approach, focusing on the subjective, lived experiences and perspectives of participants (88-90). Phenomenology is the study of the Greek 'phenomena': appearances of things, or things as they appear in our experience, or the ways we experience things, thus the meanings things have in our experience. Phenomenology studies conscious experience as experienced from the subjective or first-person point of view. Therefore, Husserl aims to describe the meaning of people's life world as it manifests itself in their speech or

writing, with the focus being on the individual's narrative of the experienced phenomenon.

This theory is applicable to the in-depth exploration of parent and staff experience of communication in neonatal care, particularly in evaluating any impacts from the use of the MBSR. This qualitative study is one of the approaches in cumulatively evaluating the MBSR, in addition to the quantitative study described in Chapter 8. As this is a highly stressful environment for parents who are worried about their babies, in-depth individual interviews afforded privacy and sensitivity to participants and were therefore deemed more appropriate than conducting focus groups.

### 9.2.2 Setting and participants

The setting was NHS neonatal care, with representative unit the CW NNU in London, UK.

#### 9.2.2.1 Parents

Based on my work with parents conducting cognitive interviews for validating the PEC parent satisfaction survey (Chapter 7) it was anticipated that 6 parents would be recruited to reach data saturation point in interview analysis. This is when the major themes identified in new data are recurring from previous participants or transcripts and no new major themes are being discovered in analysis (91, 92).

I aimed to recruit 6 parents (two from each unit area, SCBU; HDU; ITU) for pre-intervention interviews and 6 parents for post-intervention interviews. These two parent cohorts were anticipated to include different parents, because of the duration of intervention piloting (8 weeks) and high turnover of neonatal admissions.

#### 9.2.2.2 Staff members

Similarly, I aimed to recruit 5 staff members (one nurse from each NICU area, SCBU; HDU; ITU and two doctors, consultant; registrar) for pre-intervention interviews and 5 staff members for post-intervention interviews. These two

staff cohorts were anticipated to include different staff members, because of the high number of employed staff and variable shift patterns. I attempted to recruit the same staff members for pre and post-intervention interviews subject to their availability.

### 9.2.3 Eligibility criteria

#### 9.2.3.1 Inclusion criteria

Parents of infants receiving care in the CW NNU, in any of the three intensity unit areas (SCBU; HDU; ITU). Neonatal nurses of all grades, working in any of the three intensity unit areas were included. Neonatal doctors at consultant and registrar level were included.

#### 9.2.3.2 Exclusion criteria

Parents that could not speak and/or read English as my study's information documents were only available in English. Parents younger than 16 years of age were also excluded, as well as parents of infants where active neonatal care was being redirected to palliative care. Neonatal doctors below registrar level were excluded as the more junior grades rotate through different hospitals more frequently (every 3-6 months), making them less likely to be able to participate in both pre and post-intervention stages. Their availability for interviews whilst on clinical shift was also anticipated to be more challenging due to the junior rota design and role responsibilities.

### 9.2.4 Recruitment procedure

I recruited parents of infants that were inpatients on the CW NNU and neonatal staff members by directly approaching them on the unit, creating a convenience sample. The pre-intervention recruitment period was 08.10.2018 - 22.10.2018, the communication tool's 6-week 'Roll out' pilot period was 12.02.2019 – 22.03.2019 and the post-intervention recruitment period was 27.03.2019 – 05.04.2019. I approached any parent that was visiting their baby during daytime clinical shift hours (~08:00-20:00) and any staff member that was working a day shift (~08:00-20:00). I approached parents and staff in two different time periods as per the piloting process outlined in Chapter 8, to create both pre-intervention and post-intervention interview participant

samples.

### 9.2.5 Screening and conduct of interviews

9.2.5.1 Parent interviews

- Screening

Once I confirmed eligibility, I discussed the study with parents, provided them with the relevant parent information sheet (Appendix 38) and scheduled an interview date and time.

- Informed consent

I sought written informed consent from parents face-to-face on the CW NNU *(*Appendix 39*).* I began with a discussion about the nature and purpose of the study and included the opportunity for any questions. I read each part of the consent form out loud to parents, highlighting confidentiality, anonymity, secure transfer and storage of data, their right to withdraw at any time, without having to give a reason, as well as inviting and clarifying any questions. This also included consent for audio-recording and receiving a copy of the findings when the study was complete. After signing the consent form, I asked parents to complete a demographic form including their age, gender, ethnic group, infant's gestational age and infant's length of stay on the neonatal unit (Appendix 18).

- Conduct of interviews

I conducted one-on-one in-depth interviews with parents in the NICU 'private parent room'. This was a quiet room within the neonatal unit, providing anonymity and confidentiality. It is in very close proximity to the clinical area, enabling parents to return to their baby at any time. Parents were given the option to nominate another member of the clinical team, friend or family member to join them in the interview for support.

I began interviews by reconfirming their consent and highlighting confidentiality, anonymity, secure transfer and storage of data, as well as their right to withdraw at any time, without having to give a reason. I used a parent interview question

guide (Appendix 40) to explore specific topics; within those topics the interviews were flexible and participant-led. Specifically, I explored:

- Their experience receiving information about their baby in neonatal care. In particular, the type of information conveyed, in what way, what form and by whom, their feelings about how this happens and what they would prefer.
- Their experience receiving the 'My Baby's Summary Report' (MBSR) communication tool, for parents interviewed in the post-intervention period.
- How involved they feel in their baby's care and how sufficient they feel the information provided about care involvement is.

After the interview, I gave parents a copy of the consent form. I was the sole researcher who conducted interviews.

9.2.5.2 Staff member interviews

- Screening

Once I confirmed eligibility, I discussed the study with nurses and doctors, provided them with the relevant information sheet (Appendix 19) and scheduled an interview date and time.

- Informed consent

I sought written informed consent from staff members face-to-face on the CW NNU *(*Appendix 20*),* which included consent for audio-recording. I began with a discussion about the nature and purpose of the study and included the opportunity for any questions. I read each part of the consent form out loud, inviting and clarifying any questions.

- Conduct of interviews

As with parents, I conducted one-on-one in-depth interviews with staff members in the NICU 'private parent room'. Being in very close proximity to the clinical area, this enabled staff members to return to the clinical area in the case of an emergency.

Like with parents, I began interviews by reconfirming their consent and highlighting confidentiality, anonymity, secure transfer and storage of data, as

well as their right to withdraw at any time, without having to give a reason. I used a staff interview question guide (Appendix 41) to explore the following topics, whilst also keeping the interviews flexible and participant-led:

- Their experience providing information to parents about their babies in neonatal care. In particular, if information is offered or requested by parents, in what way it is conveyed (verbal face-to-face, written, over the phone) and how frequently.
- How updating parents on their baby's progress affects their workload.

After the interview, I gave staff members a copy of the consent form. I was the sole researcher who conducted interviews.

### 9.2.6 Transcription

Digital audio-recordings were transcribed verbatim by an external professional transcription company (Way With Words Ltd, London, UK), with confidentiality agreements in place. Transcripts were anonymised and all patient identifiable information was removed.

### 9.2.7 Data analysis

In line with a phenomenological standpoint my analysis was focused on participant experience. I conducted line-by-line coding to analyse parent and staff interview transcripts, using the NVivo 12 plus software for Windows (QSR International, UK) to assist with the organisation and management of data. Analysis was inductive and reflexive using a thematic analysis approach, as previously described in Chapter 5 (62).

Conducting thematic analysis in an inductive way meant themes development was directed by the content of the data. For this I followed a rigorous process of different stages, in collaboration with researcher Dr Kerry Woolfall (KW) who provided supervisory qualitative analysis support:

- Data familiarisation: I read the interview transcripts many times, in depth, to become fully immersed in the data and wrote down initial ideas.

- Data coding: I identified important features of the data and generated concise labels (*'codes'*) for selected transcript extracts. In this way I coded the entire dataset and iteratively organised all codes together for the development of themes. KW reviewed the initial coding framework and advised on how to further refine it.

- Theme development and revision: I examined all codes to progressively identify broader patterns of meaning (*'themes'*). I continuously refined the themes by checking them against the data and research question (as per my interview question guides). This involved merging, splitting, deleting, or adding further themes as I progressed. I gradually uncovered the story each theme told by relating it back to my study objectives and named each theme accordingly. KW reviewed the theme development and advised on any suggested revisions.

- Finalising themes, pre and post-intervention: I analysed pre-intervention interviews first and used those themes as a coding framework for post-intervention interviews. I highlighted new codes and/or themes that emerged from post-intervention interviews as *'NEW post-intervention'* in the final combined summary report. I analysed parent and staff interviews separately. KW reviewed the pre and post-intervention coding frameworks and advised on how to present results.

- Producing a results report: I combined the final themes into a framework to provide a narrative summary, as a visual representation of the data. This narrative summarises how parents and staff interact on the neonatal unit, how information exchange takes place, how parents and staff feel about it and would like it to happen (pre and post communication tool usage). Importantly, it also includes a summary of parents' and staff impressions of the communication tool. KW advised on themes that related back to the study aims and objectives, to ensure the key findings presented were relevant and reviewed the manuscript and final report.

## 9.3 RESULTS

### 9.3.1 Participants: Parents

#### 9.3.1.1 Parent characteristics

- Pre-intervention

Of the 11 parents approached, 6 parents (two from each unit area, SCBU; HDU; ITU) took part in an interview. All parents were different to the ones recruited for the quantitative element of Stage 1 'Proof of concept', as described in Chapter 8. Of the five parents who were approached but did not participate, 1 SCBU parent's infant was discharged before consenting, 1 SCBU and 3 ITU parents declined to participate because of emotional distress and anxiety relating to their infants' clinical condition.

Parents included both mothers and fathers (50% males), with both preterm and term infants. Overall, the majority of parents were older than 35 years (5/6), of white ethnicity (4/6) and their infant's gestational age at birth ranged between 28-41 weeks. Except for one parent having spent longer than 1 month on the unit, the rest had spent between 1-4 weeks on the unit by the time of interview (Table 29).

- Post-intervention

I approached all parents who had received *'My Baby's Summary Report'* (MBSR) during Stage 2 'Roll out' and consented the first 6 parents who agreed to participate.

Parents were predominantly mothers (5/6), with only preterm infants (25-29 weeks gestational age). Overall, most parents were older than 35 years (4/6). Except for one parent having spent longer than 2 months on the unit, the rest had spent between 2-8 weeks on the unit by the time of interview (Table 29).

**Table 29: Demographic details for parents (pre-intervention and post-intervention interviews)**

| Parent | Unit area | Gender | Age (years) | Ethnicity | Gestational age at birth (weeks) | Duration on unit |
|---|---|---|---|---|---|---|
| **Pre-intervention interviews** | | | | | | |
| Parent 1 | SCBU | Female | >35 | Arab | 36 | 2-4 weeks |
| Parent 2 | SCBU | Male | >35 | Middle Eastern | 34 | 2-4 weeks |
| Parent 3 | HDU | Female | >35 | White | 28 | 1-2 weeks |
| Parent 4 | HDU | Female | >35 | White | 37 | 1-2 months |
| Parent 5 | ITU | Male | >35 | White | 37 | 1-2 weeks |
| Parent 6 | ITU | Male | 25-35 | White | 41 | 1-2 weeks |
| **Post-intervention interviews** | | | | | | |
| Parent 7 | SCBU | Female | >35 | White | 29 | 2-4 months |
| Parent 8 | SCBU | Female | 30-35 | Asian | 29 | 2-4 weeks |
| Parent 9 | HDU | Female | >35 | White | 29 | 1-2 months |
| Parent 10 | HDU | Female | 30-35 | Asian | 26 | 2-4 months |
| Parent 11 | ITU | Male | >35 | Indian | 25 | 1-2 months |
| Parent 12 | ITU | Female | >35 | Black | 25 | 1-2 months |

9.3.1.2 Parent interview lengths

Mean parent interview length was 25 minutes [12-38].

### 9.3.2 Participants: Neonatal staff members

9.3.2.1 Staff characteristics

- Pre-intervention

I randomly approached and recruited 5 neonatal staff members: one nurse from each NICU area (SCBU, HDU and ITU) and 2 doctors (one consultant and one registrar). All staff members had worked on the unit for at least 1.5

years by the time of interview, with time worked on unit ranging between 1.5-6 years (Table 30).

- Post-intervention

To minimise variation in analysis, I attempted to re-interview the same staff members I had already interviewed in the pre-intervention phase. I re-consented the consultant and 1 nurse (SCBU), however I had to consent 2 new nurses (HDU and ITU) and a new registrar, as the previously interviewed staff members were unavailable. Overall, 8 staff members were recruited in total for both pre and post-intervention interviews. All staff members had worked on the unit for at least 1 month by the time of interview, with time worked on unit ranging between 1 month-14 years (Table 30).

**Table 30: Demographic details for staff members (pre-intervention and post-intervention interviews)**

| Staff member | Grade | Unit area | Time worked on unit (years) |
|---|---|---|---|
| **Pre-intervention interviews** | | | |
| 1 (Nurse) | Band 5 | SCBU | 2 |
| 2 (Nurse) | Band 5 | HDU | 1.5 |
| 3 (Nurse) | Band 7 | ITU | 5 |
| 4 (Doctor) | Registrar | ALL 3 areas | 3.5 |
| 5 (Doctor) | Consultant | ALL 3 areas | 6 |
| **Post-intervention interviews** | | | |
| 1 (Nurse) *(also completed pre-intervention interview)* | Band 5 | SCBU | 2 |
| 6 (Nurse) | Band 5 | HDU | 4 |
| 7 (Nurse) | Band 6 | ITU | 14 |
| 8 (Doctor) | Registrar | ALL 3 | 1 month |
| 5 (Doctor) *(also completed pre-intervention interview)* | Consultant | ALL 3 | 6 |

9.3.2.2 Staff interview lengths

Mean staff interview length was 14 minutes [10-18].

### 9.3.3 Parent perspectives

Parents discussed their views on the following:

- Parental stress in neonatal care
- Parent personal style of communication
- Process of parent-staff information exchange
- Parent involvement in baby's care
- What parents want
- My Baby's Summary Report (MBSR) feedback

The pre-fix “pre” or “post” is included in parent quotes, to denote if each was captured during pre or post intervention interviews.

#### 9.3.3.1 Views on parental stress in neonatal care

Parents’ views on receiving information about their baby in neonatal care were affected by the stress they experienced in this environment. Specific themes identified include:

- NICU as a stressful and endless experience
- Loss of stability and control
- Parent-staff communication is stressful and overwhelming

These are presented below in more detail:

##### a. NICU as a stressful and endless experience

Parents described their distress at being *“stuck in hospital”* (P1 SCBU (pre), mother) after the birth of their child. In particular, the ‘endless’ and stressful nature of neonatal care was highlighted, with parents being separated from babies. As the following quotes illustrate, the overall NICU experience was stressful, relentless, and difficult to deal with on an emotional level.

> *“It is heart wrenching to leave the babies behind when you go home”*
>
> P9 SCBU (post), mother

*"Your baby's just been taken away from you, which is not how you would imagine anything happen"*

P10 HDU (post), mother

*"You spend a lot of time on this ward, and it can sometimes seem like time is endless and you're not advancing and baby's not progressing"*

P7 SCBU (post), mother

*"I chat to some of the mums in the pumping room. And there are some people going through really difficult, like, mental health issues with obviously having their baby's not well"*

P4 HDU (pre), mother

At the same time however, parents also understood babies' need for care and felt grateful for the care received:

*"But I understand this is the best place for her at the moment, um, because she needs extra care, extra attention, and she came early"*

P1 SCBU (pre), mother

*"I think we are lucky to be in this hospital"*

P2 SCBU (pre), father

<u>b. Loss of stability and control</u>

As part of responding to the fast turnover of babies in neonatal care with admissions and discharges, neonatal staff members have to frequently move babies around the neonatal unit. Parents discussed wanting some warning and preparation before any move; one parent described the negative impact the rapid unpredictable nature of this had on him at length, in terms of evoking feelings of loss of control and stability:

*"It just kind of happens quite suddenly... there's clearly a system at play here which is trying to manage capacity and demand, but the moves are quite rapid. And when you've just had a baby it is quite traumatic, you know? Yeah, yeah its almost like a control thing as well.. that you get a bit of control and then you have to readjust, isn't it? And I'd like to have some sort of say in this. It was very quick . It was like oh they're moving and then .. bang they're gone"*

P2 SCBU (pre), father

c. Parent-staff communication is stressful and overwhelming

The main method of communication on the neonatal unit was identified as being verbal updates, either face to face or by telephone. Communication with staff members was highlighted as being stressful for parents, no matter the type of information exchanged. One parent discussed the unsettling feeling of loss of control and having to rely on others for information about her child:

*"Having to get information from others about your own baby is stressful"*

*"We are waiting and relying on doctors to give us information"*

P1 SCBU (pre), mother

The impact of having an acutely unwell baby on the process of information exchange was highlighted quite early on during interviews. One parent described finding it particularly difficult to fully understand what was going on when staff were updating them whilst focused on treating their unwell baby:

*"My partner was relying on what was explained to her, uh, so in that time, probably, she could have had more information but as soon as the situation was a bit more under control, and we came back to have a chat with one of the doctors, we made our way around what was happening"*

P6 ITU (pre), father

Specific elements of information exchange with staff were particularly stressful for parents. Parents found the amount of new information relayed to them quite overwhelming and stressful, with some becoming hyper focused on details, feeling overloaded and having difficulty retaining information or remembering ever receiving it:

> *"We are all like burnt out and on overload.. my attention is hyper focused on all of this right now.. what is this saying like, people absorb like 10% of what we say to them, so it could've been that they told me, and I just forgot"*
>
> P3 HDU (pre), mother

> *"I'm just gonna soon be braindead. Um, I could definitely see it beneficial to have like a printout of what's going on"*
>
> P3 HDU (pre), mother

> *"I reckon I was quite out of it for the first couple of days.. it is possible my husband got an admission pack but I don't think so*.."
>
> P4 HDU (pre), mother

In trying to obtain information from doctors, in particular, one parent described conversations at the baby's cot side as intense and noisy, expressing preference towards having conversations privately in a room:

> *"Other people are coming around too, so it doesn't feel too, um, too kind of safe in asking all the questions maybe and obviously, it can be also an emotional time, so being in a quiet room like this does help"*
>
> P6 ITU (pre), father

Another key issue highlighted was the lack of continuity with doctors and nurses, given the changing shift patterns. Parents said these constant changes felt unsettling, leaving them to worry about important pieces of information not being handed over accurately:

> *"It would make sense to always have someone who's been there before and knows what's going on"*

> *" You just, sort of, get used to someone and they get used to her (their baby) and then there's a change, and it's.. that I appreciate it has to happen but that's.. I find that for me a bit unsettling"*

P5 ITU (pre), father

> *"There's sometimes tiny little details that don't get handed over and that's when I think it is good for a parent to be able to talk to the doctor, because you as the parent know the whole background, obviously we've been here through the whole process"*

P4 HDU (pre), mother

9.3.3.2 Views on parent's personal style of communication

Parents discussed how different people seek and interpret information in different ways, depending on their individual style of communication. Two fathers discussed wanting to know every single detail, being 'that annoying parent' and asking many questions:

> *"I'm one of those, I ask lots of questions and I want to try to understand myself what's going on. Um, some people, I appreciate, just let the doctors get on with it and have complete faith in them doing their thing. Just for me, I'm.. I just like to know what's happening. So throughout the day I'm wondering what's going on myself and asking the questions.. I'm learning and I now know what the different things are doing"*

P5 ITU (pre), father

*"I'm probably not your average parent.. there's a lot of information that I know because I just try and um, ask about everything. I'm a bit annoying like that"*

P6 ITU (pre), father

Conversely, two mothers discussed preferring just an overview if their baby's condition remained stable:

*"I feel like he (partner) wants to know more information whereas I'm kind of like, she seems well so I'm happy with that [laughs]. Um, so. For me I'm not, like, always seeking out the doctors. As long as she seems stable I don't need to know, like, every single little detail"*

P4 HDU (pre), mother

*"I don't normally retain information well, I think too much I'd be like oh, I don't even know what that means. You know, I'm not training to be a nurse or a doctor, I understand that there are other parents that do prefer to have everything. Um, but I think the bare minimum what you need to know really, yeah, as a parent"*

P12 ITU (post), mother

In particular, many fathers discussed being very focused on numbers, described by some as an *"unhealthy obsession, just staring at those numbers for the last two weeks"* (P2 SCBU (pre), father). This awareness is balanced against their need to understand what is going on with their baby:

*"I know I'm placing too much reliance on the sats numbers 'cos they're not, you know, the gospel, um, there are other things that go with it, but it gives me a quick steer on how she's doing and its, sort of, the thing unfortunately I dread as I come down the corridor and look in the door"*

P5 ITU (pre), father

*"Some nurses have the view that parents shouldn't worry about the numbers and that's for the doctors. Um that view frustrates me a little bit because I'm.. and I can understand for some parents that's the best approach, but I like to be involved with respect to exactly what's going on with the numbers. Because in some cases I understand what the numbers mean because of all the reading I've done to date. And I like to understand, I'd like to be kept informed and in the loop as much as possible. I'm a visual person anyway, having something written and some diagrams nicely presented in a friendly tone is very important"*

P11 ITU (post), father

9.3.3.3 Views on the process of parent-staff information exchange

a. Source of information (mainly nurses, doctors, parents between them, other parents, nursing folder, internet)

Parents described the most common source of information as being a combination of 'soft information' from nurses (more care-related information) and 'harder information' from doctors (more medical-related detailed information, mainly from consultants and primarily during the ward round):

*"It's those two things.. it's no one individual, right.. it's a combination of the consultant and the nurse, so, like I say, the soft and the harder information, and you take the combination of the two and that's how I do it"*

P2 SCBU (pre), father

*"The consultant this week doesn't talk very much, but, um, what I can't get from the consultant, I'll ask the nurse who is looking after her, and who is the person who spends most of the day with her. We usually stay there for the ward round and they give us a brief update and then when the ward round is over, we usually ask all the questions we have to the nurse"*

P6 ITU (pre), father

Parents generally described nurses as being the first point of contact for information, with nurses updating parents in the morning after their shift change having had handover from the night nurse, as parents arrive before the morning ward round. For parents present during the ward round, they tend to ask nurses about anything they might want to clarify after the ward round. Some parents rely on nurses for an update from the ward round if they have not attended:

> *"So the last couple of weeks I just came after 11, um, when I knew it would all be done. And then you, kind of, come in and then the nurse has basically the update"*
>
> P4 HDU (pre), mother

In the case of two parent families, they discussed how they relied on each other for sharing information between them from their individual visits to their baby:

> *"When my other half comes we alternate. So the days that I don't come in, he'll come in. So he's my report as well. You know, she looks well and yeah"*
>
> P12 ITU (post), mother

Another parent discussed obtaining information from other parents or just figuring it out when staff are too busy:

> *"I kind of figured no point asking someone, might as well figure out yourself, so… I'm not blaming anyone ...but another mum showed me how to pump. No one, the nurses were so busy to show me use the machines and all"*
>
> P8 SCBU (post), mother

In addition to being offered or actively seeking verbal updates from staff, parents discussed looking at the nursing folder and paper charts themselves, to gain information. Parents with medical backgrounds could understand the folder information and update their partner, whereas non-medical parents would ask their nurse to explain the folder information to them. Some parents also discussed doing their own research, particularly on the internet, to understand their child's condition:

> *"Yeah I asked her. I just wanted to see. Talk me through what's going on in this blood gas thing, um, and, I mean, I appreciate there are dangers to knowing too much 'cos you get... then worry about every single detail and you've just got to let things happen a bit"*
>
> P6 ITU (pre), father

> *"I don't think I was well informed as a result of information given to me by NICU in particular or the staff at NICU. I was probably informed very well because I did a lot of reading on the internet before we'd got here. I knew what the Dr was talking about because I'd already read all these points"*
>
> P11 ITU (post), father

> *"Just by asking questions and doing my own research, I've known about this for a while, so I've done my own reading about it. I myself had this condition when I was born, it was treated very differently back then, um, but I know what things are important and what they are trying to do"*
>
> P5 ITU (pre), father

<u>b. Type of information exchanged (general versus specific updates, equipment information, developmental care, emotional support)</u>

Many parents described certain type of information usually conveyed by doctors and nurses. Doctors focused on discussing planned neonatal care

before birth and/or admission to the neonatal unit. On the neonatal unit they focused on general updates and any changes to the plan (usually during the ward round) and plans around baby's discharge. They also focused on targeted updates relating to specific body system progress, physical examination and development prognosis, bloods/test results and medications. Nurses provided general updates, mainly around any changes between shifts or from the ward round. They also provided detailed body system updates (feeds, vomits, bowel, sleeping, temperature), as well as information on neonatal care equipment, which parents seemed to really value:

> *" There was a nurse who was looking after her that evening, er, who was fantastic. She explained the ventilator to me and everything"*
>
> P8 ITU (post), father

Parents also described receiving valuable information from nurses on developmental care and parent involvement as well emotional support, being very caring and putting their mind at ease:

> *"There were couple of other things that she went through, you know, several different parameters around all that with me, how to hold her. And I don't know, that was real neat. I really appreciate that. It's like tuning into the baby's emotional needs a little bit more than just the task at hand"*
>
> P3 HDU (pre), mother

> *"It's been quite interesting watching the system, because I think the system is set up to slowly wean us off the nurse care, right? I mean it's quite obvious to me, right, so we're encouraged to do nappies, we're encouraged to feed, we're encouraged, um, which we've done and I've loved doing it, so yeah that's just been something that's definitely happened, but I think it's also with an explicit intention to make sure that we can manage them when we go home, right, its quite clear"*

P1 SCBU (pre), father

c. Frequency and amount of information shared (most frequently by nurses and over telephone, more by doctors if baby is unwell)

Parents described on average obtaining one update a day from doctors, most often on the ward round. They were aware of doctors being busy and would use their time in the ward round to ask their most important questions:

*"I get once a day updates from doctors, on the ward round"*

P2 SCBU (pre), father

*"They have to see so many other babies and they don't have much time. And so, probably, that's not the, the best moment to ask too many questions. Uh, I'll ask only the most important ones and then if we think about other questions then we'll take our time later maybe. But nurses have been very good as well in answering all our questions so far"*

P6 ITU (pre), father

Parents seemed to specifically wait for the consultant update, but also took the opportunity to ask questions of the registrars during the day when available. In contrast, parents reported frequent discussions with nurses mainly around the daily ward round for updates; mostly in the morning after the night shift change and before the ward round. After the ward round parents described asking nurses any questions they might have forgotten to ask during the ward round or if they had missed the ward round all together:

*"We don't see the consultant that much because they will come in the ward round and then I don't know if they have to be anywhere else during the day but there's always a registrar or one or the other"*

P6 ITU (pre), father

*"Nurses are quite informative, um, as to when the doctors do their rounds and they pass on the information well"*

P1 SCBU (pre), mother

In general, parents described frequently telephoning the neonatal unit at least once per shift for an update:

*"I actually now use it more regularly to call in when I go home at night or sometimes when I can't make it first thing in the morning.. I inform whether I'll be there for the ward rounds and to check in on the kids as well and see how they're doing"*

P2 SCBU (pre), father

*"I think pretty much during the changeovers, so like when the new morning nurse comes on or in the evening.. if we've not been able to come back later in the evening because we tend to go home for dinner and then come.. either come back or call. But yeah.. so if we can't come back then we would probably call at like 9 o'clock or something"*

P4 HDU (pre), mother

Many parents discussed actively seeking more frequent doctor updates if their baby was clinically unwell. Otherwise they were happy with less frequent doctor updates:

*"As long as she seems stable I don't need to know every single little detail"*

P4 HDU (pre), mother

*"To be honest at this stage, they're at the end and about to be discharged, we're kind of at the final stages. All I really need to know is*

*did they take their feed and can they maintain their temperature, and I can get that from a nurse"*

P2 SCBU (pre), father

d. Parents more proactively seek information as neonatal stay progresses

One parent highlighted that the way of obtaining information on the neonatal unit changes over time; information is more proactively offered by staff members to parents at the beginning of their neonatal stay, with parents taking more initiative to ask for information as their stay progressed and they understood more. Conversely, one father discussed how the more he understood the less questions he needed to ask:

*"I think at the beginning, my experience has been that its more proactively given to us 'cos we don't know what we're doing probably, it's a guess, that therefore the nurses and doctors feel like they need to give us info"*

P2 SCBU (pre), father

*"Maybe the further I understand what's happening is kind of stopping me to ask more.. because I know we just have to wait and the baby will take her time to recover and get better"*

P6 ITU (pre), father

Parents also discussed originally relying on face-to-face updates offered to them at the beginning of their neonatal journey and later telephoning the unit themselves for updates when they felt more able to ask questions:

*"I'd originally get the information face to face, and then even though the phone number for special care was given to me at an early stage, I only started using it at a later stage"*

P2 SCBU (pre), father

e. Verbal updates (face-to-face and telephone) (parents prefer these being offered to them, depends on staff communication styles)

The main method of communication on the neonatal unit was identified as being verbal updates, either face to face (primarily) or by telephone. In general parents were in favour of updates being offered to them, both by doctors and nurses:

> *"It showed interest from the consultant to come and have a chat with us without us being the one going and looking for him. Um, so, you know, it felt really good"*
>
> P6 ITU (pre), father

> *"Like this morning, it was a perfect example, the nurse just went through like, all of the things that I just mentioned, without even being prompted.. she offered, which was really nice"*
>
> P3 HDU (pre), mother

Some parents discussed not always feeling comfortable to actively ask for updates:

> *"You know not all of us can go and ask, you know, You don't feel comfortable. So you have to make friends with the nurses, sometimes you do feel like you're bothering them"*
>
> P7 SCBU (post), mother

Many parents discussed how individual characters of doctors and nurses vary in how forthcoming they are with offering updates "a *little bit more chatty, so explaining a bit more or one that doesn't talk too much"* (P6 ITU (pre), father), highlighting an inconsistent approach dependent on individual communication styles:

> *"I think it depends on the individual doctor, like last week, there was a particular doctor who was on hand, and who was very informative, she*

*was very thorough, um, very forthcoming with the information and honest in a compassionate way"*

P1 SCBU (pre), mother

*"Some of the nurses are just not as chatty too.. probably because they're doing their job and their job is not to entertain me, but, um, I think with some of them they're just not as forthcoming with information. Some are more approachable than others"*

P12 ITU (post), mother

Some parents discussed certain challenges with obtaining verbal updates from staff members. One discussed language barriers in culturally diverse parent populations, while others described feeling anxious and stressed by medical jargon:

*"Yeah, and I think that just with having different learning styles and so many different ethnicities and cultures, and things like that too, when language is spoken. Having, um the ability to in a written document, translate into whomever's native language would probably be really useful to the management"*

P3 HDU (pre), mother

*"Um, I mean one of the terms that was used about my daughter was that my daughter's having heart failure, and when she said that to me, I had heart failure! And I was like, what do you mean, my daughter's having heart failure? Oh, no, it's a term that we use. Okay, don't say to a parent, your daughter's having heart failure"*

P8 SCBU (post), mother

f. Written information

Some parents discussed having received a large written admission pack containing information on neonatal care and the neonatal unit information (visiting times, the neonatal team etc), as well as how to register the birth. However, most parents did not remember receiving a pack, did not read it or could not remember what they had read in it, as they explained their emotional state *"I don't think I received one, I was quite out of it for the first couple of days"* (P4 HDU (pre), mother):

> *"Yeah I was looking as well at if there's a parents' hotel and stuff like that. That kind of thing.. um breastfeeding information I think was in there as well. God it seems like ages ago but its not [laughs]. Er, what else was in the pack? Um, there wasn't like what to expect.. I don't think that was in there. Like what to expect or anything. Um, I can't remember too much of what was in there"*
>
> P12 ITU (post), mother

> *"I was given a pack, um, which I probably haven't even gone through thoroughly now. I think at that point in time that you've got so much going on, it's very difficult to digest it all"*
>
> P10 HDU (post), mother

9.3.3.4 Views on parent involvement in baby's care

Overall, parents identified three ways in which they were involved in their baby's care:

- Participating in cares (e.g. nappy changes, administering tube feeds)
- Kept up to date with changes in management plans
- Involved in decision making

These are presented in more detail in Appendix 42.

9.3.3.5 What parents want

Parents discussed how they would ideally like things to be done, within different elements of neonatal care:

- Clinical care and information sharing (continuity of care; verbal updates; written information)
- Involvement in care and emotional support

a. Clinical care and information sharing

- Continuity of care: Parents would prefer their baby to be cared for by the same nurse and doctor if possible, with thorough handovers between shifts

> *"What's interesting is that there has been very little continuity, so I've seen that she was looking after her one day and then she was on the next-door bed another day. I don't know if that done on purpose to get experience with lots of different cases.. but um.. all you're worried about is your own child.. and so I think it would make sense to have someone who's been there before and knows what's going on"*
>
> P5 ITU (pre), father

- Verbal updates: Parents discussed wanting staff to avoid jargon or explain it more and doctors to proactively follow up regarding test results/meeting decisions:

> *"Terminology needs to be explained to parents, because some of the terminology can be.. shocking to the system"*
>
> P1 SCBU (pre), mother

> *"Like when they say to me that they're going to be meeting with a particular group of people or team they're going to discuss, I would like the conclusion of that to be relayed back to parents.. and tests.. if doctors have it on hand I would appreciate if they made the time to inform us as soon as possible"*

P3 HDU (pre), mother

Doctors to offer regular formal pragmatic updates not just when baby is unwell:

> *"I think that can be really helpful. Maybe 10, 15 minutes to sit down, here in the room where it's quiet and just give us an update and maybe we will feel that will be a good time to ask all the questions"*

P6 ITU (pre), father

> *"It was really stressful, it was like really giving us the worst case scenario and then us going away and feeling this like sense of despair to be honest. And then actually she got a lot better and then it was a totally different conversation. I felt like we could have had two conversations then. I think it's good to give people hope as well and it didn't feel like we had a lot to be hopeful for at that point"*

P4 HDU (pre), mother

Finally, some parents discussed the need for more consistency in how staff (particularly doctors) approach conversations with parents, in terms of offering formal meetings or ad-hoc updates as the communication style employed, as everyone has different levels of understanding:

> *"All the doctors have different approaches with updating parents. What would be good is if they all sat down and had a chat to work out an approach that suits all. They all have different qualities, maybe if they kind of amalgamated all the good qualities.."*

P11 ITU (post), father

> *"Some of the doctors and also the consultants need to learn how to speak to parents, cause I've had encounters where they're very*

*dismissive.. and actually sometimes you could be dealing with parents that don't have a great understanding of the medical world or actually have a large understanding of it"*

P10 HDU (post), mother

- Written information: Parents discussed how written communication can afford more transparency to doctors' communication, which can sometimes be conflicting.

*"You're being told one thing one day and another thing another day and the third day there's a completely different thing, written information will actually really help because instead of being called a liar, it's on paper. And I think that it helps everyone along the whole board, including the nursing staff"*

P10 HDU (post), mother

In terms of the type of information they would like to receive in written form, parents discussed wanting summarised bullet point concise information (including weight, infections, procedures, test results, plan for the day, psychologist contact details), general information (neonatal unit information, general baby update, graphs visual information, a list of things to bring for baby).

Parents particularly focused on wanting a written 'ward round plan':

*"Not every parent can get here for the morning round and the night round. So its nice to see what plan was made initially in the day and then what plan has been made in the night, if there is a night plan, or if we're gonna continue the same plan, it's nice to know that. Some people only come in between because they've got other children or very late at night. So I think a written plan would benefit greatly actually"*

P11 ITU (post), father

*"Yeah definitely the plan. And to be fair after a consultant or a doctor makes whatever decision that they do make they should be documenting it anyway. So that documentation that they've done should be something that is visible for the parents to be seeing"*

P10 HDU (post), mother

Many parents described how useful having written information would be so not to forget anything, while others would like to use it as a 'reference', so *"based on that, one can just ask the question during the ward round or to the doctors later or to the nurse looking after the baby" (*P6 ITU (pre), father):

*"If I could have their weights written down… because I do keep mixing it all up as well. I don't have it written anywhere, right, so I keep confusing it all, ah, 'cos there's lots of different datapoints"*

P2 SCBU (pre), father

Parents also discussed how they would like written information to provide a narrative of baby's progress, rather than just a static update:

*"At the end of the day to provide a single-side summary you might miss a lot of what's gone on before and after, so maybe you could give a but more , rather than just a number.. give a quick sentence as to how her day's been or her night, so through the day her heart rate was looking stable and good, her blood gas results were good"*

P5 ITU (pre), father

Finally, parents highlighted the potential to translate written information into many different languages, given the wide diversity of parent ethnicities and cultures:

*"With having so many different ethnicities and cultures, having the ability to, in a written document, translate into whomever's native language would probably be really useful to management"*

P3 HDU (pre), mother

Specifically thinking about a potential mobile phone application delivering written information to them, parents were very positive:

*"If the data is there and it's at my fingertips, it would be so wonderful"*

P2 SCBU (pre), father

*"An app would be a really good way of getting a little update, you wouldn't then need to call"*

P4 HDU (pre), mother

*"Being able to see the information on like my phone… I mean this is now going to an extreme case, right?*
*Researcher: That is the plan, actually, to make an app*
*Parent: That would be so amazing"*

P1 SCBU (pre), mother

<u>b. Involvement in care and emotional support</u>

- Care involvement: Parents expressed the desire to be as hands-on with cares as possible, as well as to receive more information and instruction on how to do cares:

*"To get some information like how to change even nappy, it sounds so silly now but it would be nice if someone had told me how to do it"*

P8 SCBU (post), mother

*"A little more information on doing cares wouldn't be bad because I'm still not exactly sure what my boundaries are with all of that"*

P3 HDU (pre), mother

- Emotional support: Some parents said they would have liked to have been introduced to the unit psychologist early on in their baby's admission, as well as to be told that neonatal care is unpredictable, so celebrate the good days when you can. Some also felt that involving parents in giving information to parents of new baby admissions would be good to provide the 'parent point of view':

*"At the same time, it was really helpful some nurses were like it is very up and down in here and you need to take the good days and really celebrate rather than focus on everything, yeah that was helpful"*

P4 HDU (pre), mother

*"It's a scary experience... and they need to have this information from a parent's point of view, what to expect, this that and the other. I actually volunteered myself to give a parent's point of view. I think it'd be nice if they know that that's happening. If they could.. the people in charge, perhaps could ask the parent if they'd be willing to talk to these new parents"*

*P9 HDU (post), mother*

9.3.3.6 Views on MBSR (My Baby's Summary Report)

During post-intervention interviews, parents discussed their experience receiving a daily MBSR about their baby, highlighting positive aspects as well as points for improvement.

a. Positives

Overall, parents were very happy with receiving the MBSR and reported feeling more informed:

> *"I thought it's excellent conceptually, it's really good... I'm surprised it wasn't already being done, in fact"*
>
> P11 ITU (post), father

> *"I like being part of the study. And I think it's a bonus. Anything extra, in my opinion anything extra you can get information wise is always helpful"*
>
> P8 SCBU (post), mother

Parents felt the information in the MBSR answered a lot of their questions that they didn't need to ask of the nurses anymore:

> *"I think in general it was very good. I think it perhaps, um, meant that certain pieces of information I didn't need to ask the nurses for.. because I did have that in the summary sheets"*
>
> P7 SCBU (post), mother

> *"I definitely felt more informed. I felt good like, oh, actually, I've got something to hold on to.. and it answered the majority of the general questions that I asked"*
>
> P10 HDU (post), mother

Parents specifically discussed the benefits of having a daily summary in written form compared to traditional verbal updates:

- Good to be able to track baby's progress when things otherwise feel static

*"It gave you a kind of sense of progress over the time that he'd been in there"*

P8 SCBU (post), mother

*"I think anything that can kind of track progress is quite helpful. Because I think you spend a lot of time on this ward and you spend, it can sometimes seem like time is endless and you're not advancing and baby's not progressing. And, and sometimes to kind of reflect back on where things started I think's really helpful"*

P7 SCBU (post), mother

In particular, parents found it very useful look at their baby's weight chart trajectory:

*"You know, I liked the fact that it had the weight chart, which was nice because as a visual to see the numbers go up or down or whatever, it gives you a better idea of how the.. the way in which the projectile is going.. I thought that was really great"*

P10 HDU (post), mother

*"So things like, um, the weight gain. Weight gain was quite hard to kind of locate from the nurses' notes at the beginning. So that was kind of much easier when it was coming through on the summaries. To see things like the weight gain plotted on a graph I thought was quite nice"*

P7 SCBU (post), mother

- Good to have something written to keep, as a record and reminder

*"As a visual it's nicer to see and it's easier to digest. And you don't need to remember it because it's written down"*

P10 HDU (post), mother

> *"I'm at the ward rounds pretty much every day. So for a parent who's not, it would be quite good to have it, actual specific detail written. Um, and even for us, actually, because we can't memorise everything. So written information would be useful. So conceptually, I think it's an excellent idea"*
>
> P11 ITU (post), father

One mother specifically discussed how she imagined the summaries would later serve as an important memento for her child and reminder of their neonatal journey as parents:

> *"I felt more informed. I felt good like, oh, actually, I've got something to hold on to. And I'm gonna put those into an area for my child as well. Like these are your pieces of information from when you were a baby, this is something for us to go through as well, like, wow, we.. we did this"*
>
> P10 HDU (post), mother

Another mother discussed how with the MBSR she could absorb information in her own time as opposed to processing verbal updates all at once:

> *"I thought it was a brilliant idea. Just to have that bit of written information in front of you that you could actually see and read through in your own time and not have to sit there thinking oh God, I've got to take in everything they're saying all at once. You could actually go away, digest what you're reading and then actually, if you want to look up extra things yourself, you could go from that and use that as your example"*
>
> P9 HDU (post), mother

In particular, parents expressed it was great to have information offered rather than having to ask staff or telephone the unit:

> *"For me, it's fantastic, I didn't have to ask. Um, I had the information in front of me"*
>
> P9 HDU (post), mother

> *"I know a few parents that don't call [the unit]... so for people like that it's brilliant because they can just look at the sheets and think, oh okay, cool"*
>
> P10 HDU (post), mother

Parents also discussed how taking a photo of the MBSR helped them share their baby's update with their partner and family that couldn't visit, which they found a lot easier than explaining to others verbally

> *"I had the information in front of me and dad's not here to come in very often because he's working still, he's not been very well. I was able to photograph the sheet, send it to him so he could actually see it as well. Um, rather than me trying to go through everything that they were doing and stuff like that. So yeah, I found it amazing"*
>
> P9 HDU (post), mother

> *"It was great because I could go home and show it to my partner as well"*
>
> P12 ITU (post), mother

> *"Oh really good. Really good. And plus, we've also, um, you know had relatives who want to know how she's getting on. Just scan it in and then just be like, here you go. Here's today's update and how she's getting on"*
>
> P12 ITU (post), mother

In terms of the MBSR's information content parents highlighted that:

- They liked receiving specific information (the weight graph, their baby's feed volume, breathing status information, 'consultant of the day' name, baby's medication and explanation of medication function):

> *"The list of the medications and the names and what they did. And I think that's very important for a parent that doesn't know the drug.. like they're on this medicine but what does it to? And it actually has what its for, like furosemide is a diuretic, you know, or vitamins or whatever it may be. And I think that's brilliant actually"*
>
> P10 HDU (post), mother

- Regarding understanding medical terminology, one parent with a nursing background discussed how the MBSR helped her non-medical partner understand medical terms:

> *"Oh he thought it was great. Especially as it was in a language that he understood. Because for me I've had the nursing background, so I know the terminology whereas dad doesn't. So for him to have that, put into a language that he understood, he thought it was great. He really did because he could actually understand it and know exactly what was going on. So, when he was up here and they say for example the NG tube.. he knew they were talking about feeding tube"*
>
> P9 HDU (post), mother

<u>b. Points for improvement</u>

- The information presented in the MBSR was not always accurate (e.g. feeds amount)

> *"The quantity of feeds, because those didn't seem to be in line with what was in the summary.. so I was having a hard time following that..*

*but yeah, the nurses confirmed that it was the figure that was reported [in the summary] that was inaccurate"*

P7 SCBU (post), mother

- The MBSR's information format should match what parents are told verbally by staff and information from nursing folder

*"I think it could have been put in terms of what he was having, the nurses seemed to have a target of his feeds per 24 hours in relation to his weight, things like that.. so I think that might have been interesting information to have as well"*

P7 SCBU (post), mother

*"I think normally I get told feed by hour how much she's having. And so the difference was I think it was written of her total feed. And I was like, oh, that's not the information I'm used to receiving. So I think that was the only thing where I thought, oh ok, there's you know, there's not continuity there. I prefer to have it by the hour to know what she's having. I think it's easier to break down rather than seeing like oh, 23 ml. Because I'm like what was that?"*

P12 ITU (post), mother

- They would prefer the MBSR to contain today's weight instead of yesterday's weight

*"The bit I found most useful was the weight, because I always forget the actual exact number of pounds she weighs. But with regards to weight it was always yesterday's weight, it wasn't today's. So it would be useful if it was updated more frequently"*

P11 ITU (post), father

- They would like even more information (MBSR too brief lacking detail, would like ward round plan, test results, scans and blood results)

*"I thought it's excellent conceptually. It's really good. And I think it's required. Um, what I think the information lacked was detail. So in some cases, it was relatively generic and it could have had more detail added to it, such as if that evening a blood test was done, the actual results of the blood test. If it's on the app, it would be very easy to do another section of what the results potentially mean.. or what they're testing for effectively*.. head scans too.. and things like that"

P11 ITU (post), father

"*I think it was really short and brief*"

*P8 SCBU (post), mother*

- Parents reported they still asked nurses questions as the MBSR's information was 12 hours old

*"In terms of other questions, I'm not sure that it always did mean that I didn't have to ask for extra things.. just because, like, things were being updated. As information was 12 hours old, there was already new information I guess"*

P7 SCBU (post), mother

- Parents wanted to make information more personalised to each baby, in particular:

Explaining reasons for changes, progress and prognosis:

*"What is the reason they're there for? I think it should be more personalised on those areas. Prognosis, like how is it going, what direction it is going. Example your baby was on 80% oxygen, today its on 60 because I think they passed a sleep study or whatever it is. Like you know the information of where have you been and which direction we are heading on"*

P8 SCBU (post), mother

*"That would have been really nice to know, so when they changed things I knew whether it was because he was improving or it was affecting him and he was going backwards a bit"*

P9 HDU (post), mother

Name of nurse/Drs looking after baby:

*"Definitely the names of everybody that's involved in your child's care should be visible on that said day, I believe that's a really crucial thing to have on that. Because at least you know who it was on that day, who was that nurse that was with my child on that day? You know? Not for a negative thing particularly, but it could be for a positive thing?"*

P10 HDU (post), mother

Nursing comments of baby's status:

*"Um, it didn't give detail with respect to also the nurse's comments with regards to whether the baby had a settled or unsettled night.. whether I don't know oxygen levels had to increase because of episodes or.. I don't know. Because the nurses make notes I assume and some of those notes would be nice to incorporate in the parenting information"*

P11 ITU (post), father

Finally, regarding the prospect of having the MBSR information presented in a mobile application form:

- Parents felt an app would provide instant access to their baby's information, instead of parents telephoning and 'interrupting staff' from their work, with telephone calls also often going unanswered. Nurses could focus on looking after the baby rather than running to answer the phone:

*"There's been a few times where I've phoned and I've called three times and there's been no answer. And when there was an answer, that's when the nurse was on a break. So you know, and then you feel a bit of a nuisance and that's why I think where having an app would really benefit from that. Because it would just eliminate all that then"*

P12 ITU (post), mother

*"It will save the nurses running to the phone when they're really, really busy. Cause naturally sometimes they have to deal with admissions at night.. so their last priority is actually getting to a telephone, but that person on the other end of the telephone wants to know how their child is."*

P10 HDU (post), mother

- Both parents could log on to the app for information at any time

*"If that was an app we could both log in, for ease. Because we're both up quite late and stuff, as well. So rather than having to phone up and having to ask someone, you feel like, bad, for interrupting them from doing their job. Logging in about 1:00 in the morning or something like that would be great to have the information right there.*

P11 ITU (post), father

- Parents would like an app to give them the option to choose what type of information they want, as well as to include videos (e.g. with information on neonatal unit orientation / expressing milk) and a web camera to see their baby from home when unwell:

*"You could possibly have a, b, c where they can choose, where they can itemise what information they want delivered to them on a daily basis and what they don't. And if they tick it, then they get that*

*information , when they don't then the information is not delivered to them through the app"*

P11 ITU (post), father

*"If you were to have in the app information about orientation as well as expressing milk.. a video. Put on a video like airlines have for flight emergency ones. Just put a video, because nothing's going to change, right. Pumping room is going to be there, toilet's going to be there. Just make a proper video and put it there. Then if you don't see the video then that's your fault"*

P8 SCBU (post), mother

*"I think especially in the last couple of days I felt I wish I could see my baby., its because definitely in the last few days we've had problems whereas my child needed a chest drain and then he had a pneumothorax. Maybe like a webcam or something of that nature would be brilliant, especially in this environment, I think it's one way to put the nervous parents at ease definitely. Because to be fair all you wanna do is see your child and see that they're at rest"*

P10 HDU (post), mother

9.3.3.7 Summary of thematic findings: Parent perspectives

a. Parental stress in neonatal care

From the outset, parents discussed first coming into the neonatal unit with underlying feelings of stress, relating to their baby being unwell after birth and requiring hospital care, which was often an unexpected event. They described the distress caused by their baby 'being taken away from them' and the 'loss of control' in what was an unfamiliar environment.

Their communication with staff members was described as stressful no matter the type of information exchanged as they experienced further parental loss of control with relying on others for information about their own baby. Parents

highlighted specific elements of information exchange that appeared to exacerbate stressful communication with staff members. This included an overwhelming amount of information provided by staff, opportunistic updates by staff members on the neonatal unit lacking privacy and feeling too intense, and lack of continuity in information exchange between nursing and medical teams.

b. Parent personal style of communication

Differences between parents on how they seek and interpret information were observed, highlighting individual parental styles of communication. In particular, fathers in this study seemed more focused on numbers and details, asking many questions, while mothers preferred an overview if the baby was otherwise stable.

c. The process of parent-staff information exchange

Parents described the process of information exchange on the neonatal unit, in terms of source, type, frequency and amount of information shared. They reported receiving information about their baby from a variety of sources; mostly a combination of neonatal nurses and doctors, as well as from their partner, other parents on the unit, looking through the nursing folders and conducting self-directed research on the internet.

Parents reported receiving a combination of general updates and detailed body system updates from nurses, including general updates regarding any changes between shifts or from the ward round as well as specific updates on feeds, vomits, sleeping etc. They also received and valued information about neonatal care equipment, developmental care and emotional support. Parents reported that in addition to this information, doctors focused on discussing planned neonatal care admissions before birth and plans around baby's discharge. They also focused on targeted progress updates relating to specific body systems, physical examination and development prognosis, bloods/test results and medications.

A difference in information sharing frequency between nurses and doctors was observed, with parents reporting mostly communicating with nurses face to face through the day and at least once per shift over the telephone, while doctor updates were once daily (and usually on the ward round), unless their baby was unwell and parents requested more frequent updates.

In terms of how information seeking behaviours may change during a neonatal admission, parents reported more proactively seeking information as their neonatal stay progressed, whilst also conversely asking fewer questions the more they understood. Parents discussed not always feeling comfortable to ask for updates and preferred these being offered to them, with some feeling stressed by medical jargon and experiencing language difficulties during the updates themselves. In general, parents highlighted an inconsistent approach in how staff members offered verbal updates, largely dependent on individual communication styles.

In terms of written information, some parents discussed having received an extensive written admission pack (about neonatal care information, visiting times, the neonatal team, registering a birth etc). However, most parents did not remember receiving or reading one, because of their state of mind during their baby's admission. Parents in the pre-intervention period discussed wanting summarised bullet point concise written information (including weight, infections, procedures, test results, ward round plan, psychologist contact details), as well as general information (such as neonatal unit information).

d. Parent involvement in baby's care

In terms of being involved in their baby's care, parents were mostly satisfied with participating in care procedures, although were reluctant to do so when their baby was unwell and would have liked more information on how to do this beforehand. Another way of being involved was identified as being updated about changes in management, which parents were mostly satisfied with (although once again dependent on individual doctor styles). Parents specifically wanted to be updated about their baby changing location on the unit ahead of time, which did not happen for most. In terms of being involved

in decision-making, parents reported mainly being informed of decisions retrospectively. Whilst this was largely appreciated and most parents were happy for doctors to make and act on the decisions, some parents did not feel able to prospectively challenge the doctors' judgement in participating in the actual process of decision-making themselves.

e. What parents want

Having described their overall experience of communication and information exchange in neonatal care, parents subsequently made suggestions on how to improve things for future parents. They would unanimously prefer their baby to be cared for by the same nurse and doctor for as long a period of time as possible, with thorough handovers between shifts. The certainty that vital information was not being lost with good continuity of care would greatly alleviate their stress.

In terms of verbal updates, parents would prefer staff to avoid jargon or explain it more and doctors to proactively follow up with them regarding test results / meeting decisions. Parents also discussed the need for more consistency in how staff (particularly doctors) approach conversations with parents, with a preference towards regular formal update 'sit-down' meetings (not just when their baby is unwell). They suggested that written communication could afford more transparency to doctors' communication, which could sometimes be conflicting between different staff members. In addition, parents highlighted the option to translate neonatal written information into many different languages.

Finally, parents expressed wanting to be as hands-on with cares as possible, as well as to receive more information and instruction. They would value an early introduction to the unit psychologist, as well as being told to celebrate good days when they come, given neonatal care's unpredictability. A specific suggestion was to involve parents in giving information to parents of new baby admissions, so as to provide the 'parent point of view'.

f. Views on MBSR

During post-intervention interviews, parents specifically discussed their experience receiving a daily MBSR about their baby, in the context of their wider experience of communication in neonatal care.

Overall, parents were very happy with receiving the MBSR and reported feeling more informed. Highlighting the benefits of having a daily summary in written form compared to traditional verbal updates, they liked the concept of being actively offered daily updates, as well as being afforded more time to absorb and process written information. They appreciated being able to track their baby's progress (particularly through the weight chart), felt the MBSR further facilitated their conversations with staff (e.g. on the ward round) and answered many questions they would have otherwise asked of the nurses. Parents particularly valued having a written record and reminder for information which can be otherwise difficult to remember, with some already treating the MBSR as a valued memento from their baby's neonatal experience.

Many parents discussed how the MBSR enabled them to share their baby's update with a non-visiting partner, family and friends, by taking a photo and sharing it; a process that can sometimes be difficult and stressful to do verbally. Parents especially valued the MBSR's weight graph, baby's feed volume, breathing status, 'consultant of the day' name, medication and explanation of medication function. They particularly commented on how the MBSR helped them understand medical terms that were regularly being used by staff on the neonatal unit, in plain language.

In terms of further improving the MBSR, parents wanted:

- Even more detailed information, including the ward round plan, test/ scans/ blood results to be reported through the MBSR
- Information more personalised to each baby, including reasons for changes, prognosis and progress between different days (providing a narrative), names of nurse/ doctor looking after baby and nursing comments from each shift

- The information to be more accurate and match the format of information relayed verbally
- Truly ‘live’ current information, rather than information that is 12 hours old (e.g. today’s weight)

Considering the next stage of presenting MBSR information in a mobile application form, parents reported they would indeed greatly value:

- Having instant digital access to their baby’s information, instead of telephoning and ‘interrupting staff’ from their work
- Being able to both log on to the app for information at any time
- Allowing nurses to focus on looking after the baby
- Having the option to choose what type of electronic information they would like to receive
- Including videos on the app (neonatal unit orientation and expressing milk tutorial) as well as a live web camera to be able to see their baby from home, especially when unwell

### 9.3.4 Neonatal staff member perspectives

Neonatal staff members discussed their views on the following:

- General thoughts on communication with parents
- Specific factors affecting perceived parent information needs
- Communicating with (both) parents in the day versus night shift
- Parent communication with nurses versus doctors
- Main update of the day: the ward round
- Written information in neonatal care
- My Baby's Summary Report (MBSR) feedback
- Staff role (Balancing parent communication with clinical care)

The pre-fix “pre” or “post” is included in staff quotes, to denote if each was captured during pre or post intervention interviews.

9.3.4.1 General thoughts on communication with parents

Early in the interviews, a consultant raised the issue of a recent 'changing culture of communication' in neonatal care, with neonatal staff putting more emphasis on how regular, earlier communication can improve the parental neonatal experience, more so than the quality of clinical care:

> *"I think there's out there in the world, there's a bigger emphasis and awareness of how we communicate with people and the fact that it makes so much of a difference the experience that the parents have with the unit. You can look after a child in a gold star way, but if you haven't communicated with the family their experience is awful. Which, which is really interesting. We're more conscious of updating them early. We're more conscious of the regular updates"*
>
> Staff 5 (pre), Consultant

- Staff members acknowledged the stress and anxiety parents experience in neonatal care, with a substantial part of their shift required to update and reassure anxious parents

> *"If you have a particularly anxious parent it takes an awful lot longer to go through things and to try and plicate their fears and worries"*
>
> Staff 3 (pre), Nurse ITU

- Staff members identified certain things they do that appear to have a positive impact on parents. These include:

Parents hearing something from a doctor (particularly a consultant, once they understand the hierarchy)

> *"It's a person they trust, sometimes they just need to see it and hear it. And sometimes they just need to see it and hear it from a consultant. Because I'll sit in here with the registrar and it does not make the same impact"*

Staff 5 (pre), Consultant

*"Just seeing a doctor. Like they'll always say can I see a doctor? Some of them that have been here a long time, they know exactly how it works, who the SHOs are, who the Regs are, who the consultants are, who's the day, who's the night, when the switch over is, they know everything. So sometimes they can be a bit more, I'd like to see a consultant. But then some would just any doctor. They like a doctor"*

Staff 6 (post), Nurse HDU

Parents being updated during the ward round, while staying near their baby:

*"And the more recent advent of parents being around on the ward round especially with the whole headphones thing, so that they don't feel that they might miss their child, they can be there in the morning has made a difference as well"*

Staff 5 (pre), Consultant

*"Ward round, yeah. A lot of parents will waist like, all day for ward round. As soon as that's happened, then they might feel like it's okay to go for lunch"*

Staff 6 (post), Nurse HDU

Staff being honest with parents and giving them all available information

*"Being open and honest.. when the parent feel like they know everything that you know, you're all on the same page. I think you get into trouble when they feel like we're not telling them things or we are privy to more information than we're letting on kind of thing. So I think just being open and honest.. I mean ultimately, it's their baby, they should know everything about them"*

*Staff 3 (pre), Nurse ITU*

Consultants giving parents ‘good update’ days, thereby showing belief in their baby, and removing ‘bad update’ stigma from consultation room

> *“ Where I found my relationship with families has improved on an average scale is the fact that I do good day updates. And that means you’re not always the bad person. They know that you believe in their child. And this room doesn’t have the stigma attached to it. And I think that’s really important. So, I think that’s good”*
>
> Staff 5 (pre), Consultant

- Staff members discussed parents having different personalities, in terms of some always asking more questions than others, some wanting to be present for everything and highly educated parents being very demanding

> *“I suppose in my last year I’ve recently felt more confident, I try and ask the how they think their baby’s doing. I think there are some parents who will just participate in the ward round and don’t need encouragement and will talk straight away, but there’s also lots of parents who would probably not say anything, maybe just ask one question. So I always say, how do you think your baby’s doing?”*
>
> Staff 8 (post), Registrar

> *“It all depends on the parent. It just varies with the personalities because some parents kind of stand back and want you to call them if something goes wrong, rather than them calling you. And then there’s those that call quite often because they just want regular updates every change day. There’s some that don’t leave the bedside because they want to be there for every change”*
>
> Staff 7 (post), Nurse ITU

> *“It’s so hard to know, you know. We have parents that are very highly educated and very demanding, you know. I’ve literally.. I’m covering*

*special care, a few hours I've now been covering for, two and a half hours and I have spoken to four sets of parents"*

Staff 5 (post), Consultant

9.3.4.2 Specific factors affecting perceived parent information needs

Staff members discussed 3 factors that appear to affect parent information needs, influencing primarily the frequency of parent questions and associated visiting routines:

- Having other children
- Length of stay on neonatal unit
- Level of neonatal unit area acuity / baby's clinical condition

In more detail:

- Having other children

Staff felt that first time parents ask more questions (many about general parenting) and stay on the unit all day

*"If it's their first baby, they're here all day and asking you everything all day. So, then you can't really put a time on it because you feel like you're talking to them all day"*

Staff 6 (post), Nurse HDU

Staff reported that parents with other children tend to focus on more medical questions, with a focus on any differences to their previous 'normal baby'. Having siblings can also impact parents' ability to visit, often limiting updates to one phone call a day

*"Whereas parent who've got other children, they're so much more relaxed and it's more the medical side of things, like will the baby be on*

*drugs at home like any changes that might be different to their first normal baby"*

Staff 1 (pre), Nurse SCBU

*"If you have a baby who's got loads of other siblings and the parents rarely come in, you might just get one phone call a day"*

Staff 6 (post), Nurse HDU

- Length of stay on neonatal unit

A senior nurse discussed how parents of newly admitted babies will constantly want updates but don't yet know what to ask; staff will usually offer them a broad overview

*"Just from experience I kind of know that some parents don't know to ask what they really want to know so I tend to give them a broad overview of what's happening and that tends to prompt more questions if they have it. But that's just purely from experience"*

Staff 3 (pre), Nurse ITU

Conversely, staff felt that long stay parents require less time from staff for updating and reassurance, are more confident to ask questions and seek information

*"Parents know their babies better when they're in special care because they've been with us longer so it's less like, oh, they're on more oxygen now.. and parents will be like oh, I know.. parents tend to still be a lot more on the ball"*

Staff 1 (pre), Nurse SCBU

*"Longer-term parents do go through nursing folder because they feel a bit more confident to kind of go through things and question things and scrutinize a little bit"*

Staff 7 (post), Nurse ITU

Regarding parents' visit routines, these appear to be different depending on their length of stay: parents of newly admitted babies arrive on the unit early, while or long-stay babies they tend to utilise telephone updates and visit later in the afternoon

*"So if they've only been recently admitted, you know that 08:20, nine o'clock they're going to be there wanting an update. Whereas if they've been fairly established in the NICU for a while, parents feel a bit more relaxed. They don't tend to come in for the ward rounds, and have a phone call update in the morning and then be there in the afternoon"*

Staff 3 (pre), Nurse ITU

Eventually, long stay parents start to build relationships with their nurse and struggle with regular changes of staff looking after their baby

*"There can be some discourse between the medical team and the patients. You know the babies have been here for some time and so especially difficult for parents when a new team of doctors come on and have to get to know their baby. Parents sometimes find that quite hard because they don't like people making mistakes.. not mistakes, but just getting to grips with their baby.*

Staff 8 (post), Registrar

- Level of neonatal unit area acuity / baby's clinical condition

Staff described that depending on how unwell a baby is and the level of care they require, being in each of the 3 acuity level areas (SCBU; HDU; ITU) can

influence parental expectations of updates and how they access information.

Parents in the highest intensity area (ITU) tend to be constantly present, getting their updates from their baby's nurse 'as they go'. While doctors in ITU are usually very busy parents are also more likely to directly approach them there

> *"When the baby's in intensive care, they seem to think because of the monitoring, the constant monitoring and the kind of high nursing ratio, they feel that that's all, they get all their information as they go"*
>
> Staff 8 (post), Registrar

> *"The intensive care parents will come directly at you, there are a few like that at the moment who will literally come seeking"*
>
> Staff 5 (post), Consultant

The consultant specifically discussed how if parents in ITU have not attended the morning ward round she asks to have a meeting with them to update them

> *"If they haven't been on the ward round and there are things that they need to be update about I may ask the nurses to give them a call or I give them a call to ask them to come in myself"*
>
> Staff 5 (post), Consultant

Staff discussed that when babies are very unwell (as would most commonly be the case whilst in the ITU area), parent tend to be present most of the time, meaning plenty discussions with staff. Conversely, staff can be very busy looking after the baby clinically in those times, thereby making the task of updating parents as well more challenging:

> *"Um, if the baby's sick then yes it does consume a lot of time. And, uh, I mean if parents are around, they are next to the baby they want to*

*know. Like today I've spoken to, uh, three or four parents, explaining them the basic things, but then it does take a lot of time"*

Staff 4 (pre), Registrar

*"The babies that are really unwell, parents, they're just around. But that time you spend more time looking after the babies.. its like in stages"*

Staff 7 (post), Nurse ITU

As babies move down to HDU, parents start to telephone for updates more and when they do visit require a longer face-to-face update. In HDU, nurses start involving parents that are present in practically doing their baby's cares

*"I find in those areas [HDU] it takes up much longer time because the parents might not be here as much because they, you know their babies are a bit more stable. So, they're not constantly sitting at the cot. You know, the dad will come in later and the mum will be here during the day. But they're not here every second, whereas in intensive care, they are. So, when they do come, they seem to want to have a long discussion"*

Staff 8 (post), Registrar

*"I think it's nice to start the normalisation in HDU for then going to special care where it's very much leaving them to doing the nappy and doing everything"*

Staff 1 (pre), Nurse SCBU

Once babies move to SCBU, staff felt that parents start being more present on the unit again, asking many questions about going home and less medical questions (as they by now know their baby better)

*"They all seem very engaged in SCBU... lots going on, lots of questions. Very present"*

Staff 8 (post), Registrar

*"So if you have four sets of parents, you are continuously with those parents. Most of them stay all day and only go out for like, lunch or you know? That is quite common for parents to be in special care for a long basis, um, of time. So, I'd say at least probably 70 to 80% of our time is with parents down there"*

Staff 6 (post), Nurse HDU

The consultant discussed how she finds it easier to update parents in SCBU as most of them are present on the ward round. In general, parents in SCBU interact throughout the day with nurses and doctors face-to-face, with telephone calls being kept brief and mostly about when they are coming in

*"There are some times if you're in special care [SCBU], you're quite a visible presence as a doctor, so parents think they can just come and, sort of, they can approach you any time. Um, and that is something that has to be managed, depending on what you're doing and the workload"*

Staff 8 (post), Registrar

*"In special care, it's more, I'm on my way, please wait for me to feed. So it's very brief, not an update sort of thing. It's an I'm on my way, do they need anything? Yes, nappies, please"*

Staff 1 (pre), Nurse SCBU

As babies in SCBU tend to be clinically stable and preparing to go home, updates are brief and broad:

*"If they're very stable you just update them of their general progress quickly, its clinically stable and um, yeah. Just briefly we just update parents"*

Staff 4 (pre), Registrar

9.3.4.3 Communicating with (both) parents in the day versus night shift

Staff members discussed how parents seek updates about their baby throughout the 24-hour period, however they are only able to have more frequent communication with parents during day shifts, due to high workload during the night. Night updates are usually done by short phone calls, while staff would not have much face-to-face contact with parents on a night shift, unless a new baby was being admitted to the unit overnight:

*"I mean, the beginning of a night shift to kind of midnight with all the fluid changes and bits like that when phone calls do happen.. it tends to be between 10 and midnight when they call.. so you're trying to juggle 14 things at the same times so phonecalls tend to be slightly more succinct"*

Staff 3 (pre), Nurse ITU

*"We wouldn't really have much contact with parents on a night, unless it's like an admission where it's mum and dad that don't know what day of the week it is, then that's still the same for them"*

Staff 1 (pre), Nurse SCBU

On the topic of updating both parents, a registrar described how having them together during a conversation saves a lot of time and potential misunderstandings:

*"If mum comes in and then maybe dad comes in later, and you have the conversation.. you have to update them both, but separately. Actually.. if we're going to have these repeated, you know, we need to be talking to you both together. Because I think often what happens is,*

*you tell mum one thing, and then a bit's lost in translation. And then she tells dad and then a bit more is lost in translation. So by the time dad comes back to ask you a question, or vice versa, the original question, they've clearly not understood you properly"*

Staff 8 (post), Registrar

9.3.4.4 Parent communication with nurses versus doctors

Nurses described they have on average 2 targeted conversations at least per day with the same parents (in the morning and after the ward round), with the rest of the time responding to ad hoc questions throughout the day, at any time:

*"Maybe two updates a day, I guess.. in the morning and then after ward round, there has been changes, I'll say, oh, no changes, we're going to stay the same or we've gone down on their flow, we've increased our feeds"*

Staff 1 (pre), Nurse SCBU

*"They intersperse their questions.. so it's not like that allocating half an hour now to talk to you about your baby's condition. They ask you things all day"*

Staff 2 (pre), Nurse HDU

Conversely, discussions with doctors are difficult to happen if unplanned, as doctors cannot immediately be available; nevertheless, parents often demand doctor meetings at short notice:

"The nurse will come and find you and say oh, so and so has a few questions. Can you come and speak to them? Sometimes you can't go and speak to them straight away"

Staff 8 (post), Registrar

*"At seven o'clock in the evening it is not appropriate time for an update. Um, and explaining that to family is really difficult. But sort of saying you know its fine to make appointment with the consultant to speak to them.. if it's something urgent you know critical matter then of course we'll make time. It is the demand aspect that's the problem"*

Staff 5 (pre), Consultant

In terms of the type of conversations with parents, nurses offer a variety of information, including providing general reassurance, managing parental anxiety, explaining monitoring equipment. They discuss all general updates and changes since parents last saw their baby. In comparing this to doctor conversations, the consultant discussed how she felt the nursing focus tends to be on 'what happened', rather than why and what it means. She subsequently described that doctors provide detailed formal updates (mostly on admission or if their baby is sick) as well as providing information about prognosis and where things are going:

*"Those things are nursing aspects. How much did baby get, how many mls an hour is this? Did baby put on any weight? Have we come down in the oxygen? Are we feeding them? It's a nursing update. My relationship with parents isn't about the daily updates it is about we're going in the right direction. Thing is, it's absolutely right. Now let's train for big camp we're doing really well. You'll get there. That's my job"*

Staff 5 (pre), Consultant

In addition to providing updates, nurses also described how they are constantly encouraging parents to care for their baby, teaching them and showing them how:

*"There's a lot of teaching that goes on. So we teach continuously throughout, so how's your baby doing, what to expect, how to change nappies, how to do the cares, helping them learn how to get babies in*

*and out, what's going on. And actually you spend a chunk of your every hour talking to them about what you're doing, how you're doing it and why, it's impact. Positively or negatively impacting the baby, so they know"*

Staff 2 (pre), Nurse HDU

In terms of mode of communication, doctors and nurses agreed that no matter how much information parents are given over the phone, they will always want a face-to-face update:

*"They are updated on the phone and then when they come in, they want another update. So that's two or three updates a day. Yeah, I think they do want a face-to-face"*

Staff 1 (post), Nurse SCBU

*"It doesn't seem to matter what information they have; they, they need that one-to-one contact"*

Staff 5 (post), Consultant

9.3.4.5 Main update of the day: the ward round

Staff members described parents waiting all day to be present on the ward round to be directly updated by doctors and know the plan for the rest of the day:

*"A lot of parents will wait like, all day for ward round. As soon as that's happened, then they might feel like it's ok to go for lunch"*

Staff 6 (post), Nurse HDU

*"If they're present for the ward round, then perfect because they get the update for the rest of the day"*

Staff 1 (post), Nurse SCBU

However, nurses discussed how the ward round can contain a large volume of complex information delivered by doctors, with many parents asking nurses to afterwards explain any jargon and/or unclear information from the ward round again:

> *"Parents will take in a little bit on ward round and then they'll come back and then ask you what it really meant.. So a lot of big words you use sometimes and then also, they're going, what does that actually mean? So then you go through it"*
>
> Staff 2 (pre), Nurse HDU

> *"I think sometimes it isn't explained to parents in a parent friendly way on the ward round so we try and adjust the conversation to the kind of level of understanding after to make sure they understand everything. Depending on how in-depth and clear it is to them on the ward round determines whether they revisit that later in the unit. Sometimes its good to say at a later time, did you understand all of that, so when do you want me to go through because ward rounds can be chaotic [laughter], really"*
>
> Staff 3 (pre), Nurse ITU

In discussing what could be done better with parent communication, standardising updates for parents was suggested, highlighting that anyone should be able to deliver update on a stable baby:

> *Probably standardisation because what I'm saying and what another nurse is saying could be very, very different with the time that you allow parents to be updated"*
>
> Staff 3 (pre), Nurse ITU

*"I think you know, the day to day for a lot of the babies who are very stable, there's nothing that changes. And actually then, the kind of regular update can be delivered by anybody, whether that is, you know, a nurse, the matron, a registrar. Actually, you know, the content doesn't change"*

Staff 8 (post), Registrar

9.3.4.6 Written information in neonatal care

Staff members discussed how they use written information in their communication with parents. From the outset they described an 'admission pack' containing a large volume of information, including information about the neonatal unit and neonatal care, as well as a discharge pack with information about going home. Staff acknowledged this was not a priority to give parents on admission and they weren't sure if parents "actually read it":

*"Personally, we're always focused on the admission and if parents are there. I'll talk to them. But if the admission pack isn't there, we're not going to immediately think, oh, let me go get one; it's more like setting up the CPAP and blood sugars. Do you know what I mean?"*

Staff 1 (pre), Nurse SCBU

*"Do they read the admission pack? I don't know. Some do, some don't. Because I see it lying there for weeks [laughs]. I don't know what they do with it"*

Staff 3 (pre), Nurse ITU

Apart from the admission and discharge packs, staff reported using written information to consolidate specific face-to-face updates, with available leaflets being limited to certain conditions only:

*"Mmm I just gave a cardiac leaflet to parents to go through.. uh what to look for, what you can expect. What's the management plan. But*

*they're only available for only few conditions. They're not available for most of the neonatal conditions.*

Staff 4 (pre), Registrar

In discussing challenges with parents accessing written information, staff highlighted the risk of data read out of context causing parental stress (such as information in nursing folders) and information only being available in English

*"I don't mind.. I rather they would ask me kind of what everything they read means because definitely in my experience parents are fixated on blood gases in the intensive care but they don't quite understand the relevance of what the blood gas means in relation to everything else, so they fixate on things that potentially causing the, more stress than it needs to"*

Staff 3 (pre), Nurse ITU

In general, parents reportedly do look at the nursing folders and ask for nurses' help to understand the information. When jargon is involved, this means longer conversations with staff to explain:

*"They ask, they want to know the trend, how's my weight going, is it going up, the weight is a nice graph.*

Staff 2 (pre), Nurse HDU

*"A lot of parents I think know the green form is weight. So a lot of them will look for that, which is fine. That's a nice one for the, to look at"*

Staff 6 (post), Nurse HDU

*"Sometimes you can accidentaly let jargon slip out and you'll say oh, don't worry, their sugar's stabilized, or their SBR's fine. Then they sort of go into like a mode, oh, what's that? What's this? And you sort of*

*think right, okay. Now I need to explain everything [laughs]"*

Staff 6 (post), Nurse HDU

Finally, the consultant discussed giving parents copies of the 'Small wonders' DVD (if available) which includes videos on supporting families through neonatal care.

9.3.4.7 Views on MBSR (My Baby's Summary Report)

During post-intervention interviews, staff members commented on seeing parents reading the MBSR, with some parents informing them that they were receiving them and others specifically telling them that they liked them.

In terms of general impressions of the MBSR, staff members were very positive. Neonatal nurses are the main staff members who enter daily infant data into the neonatal electronic patient record system (EPR) as part of their routine work, which subsequently populates the MBSR. Nurses discussed feeling more motivated to enter the data in EPR in the first place, knowing it was now going to parents. They also reported that the MBSR raised awareness about the importance and potential uses of neonatal EPR data among them, overall:

*"It felt like it's got more of a reason, rather than just staffing or facts and figures. It's actually quite nice to know that the parents are going to be like, seeing these, like 0.1ml is going to be such a big difference to them. And 2g is going to make such a big difference to them. So I think a lot of people are quite chuffed with how that's being used to benefit"*

Staff 6 (post), Nurse HDU

*"I don't think people really knew what use Badger had because it's only really the coordinators that deal with it, not necessarily the band five nurses. We just put the information in but not everyone knew where it went. I think that [the summary report] just makes people more inclined*

*to know the importance of it"*

Staff 6 (post), Nurse HDU

As a result, nurses were being more careful to enter data in the neonatal EPR more accurately, knowing it was going to parents, with many nurses reminding each other to complete their data entries:

*"It made me remember to do every night, to make sure I had everything correct because I knew that parents would be able to see it. So, it does make a difference"*

Staff 1 (post), Nurse SCBU

*"I think it's also improved people doing the Badger each night"*

Staff 6 (post), Nurse HDU

*"So if I did hear anything, I'd always repeat it back and just say look, make sure you all do your Badger because parents are actually more aware now of what's going on because they have the summaries"*

Staff 1 (post), Nurse SCBU

In terms of their training and knowledge of the neonatal EPR system (Badgernet), nurses discussed having had limited or no formal training on how to use it, as well as limited understanding on what the recorded data is used for, other than for monitoring the unit budget and recording discharge summaries (audit, research etc.):

*"So, when I was a new starter, I was told I have to do it. And I didn't know what it was. So, the coordinator just showed me and then you just sort of get on with it [laughs]"*

*"I think people know it's for a general consensus of allocating babies to*

*their level of care. So, I think we all just sort of assumed okay, like how many ITU nurses we'll need, how many HDU nurses we'll need. So I know they knew that. And I think that's about it really. I think it's also to help with discharge summaries, for a baby's family to know exactly what they've had throughout the stay"*

Staff 6 (post), Nurse HDU

*"I think yeah, because they need to know which baby's going to be special unit care sort of thing. And I guess how that affects their budget and treatments they've had. But I think it's mostly, from my understanding, budget related"*

Staff 7 (post), Nurse ITU

Generally, nurses described it taking only a few minutes to complete all daily data entries for a baby and the process of completing them during the MBSR's pilot trial did not make any difference to the time required. Nurses discussed how data was sometimes missing from EPR, and subsequently the MBSR (feeds, weight), mostly due to high workload. As recording data onto the EPR is usually their last action before their shift ends, sometimes some information is missed:

*"If you're busy or you have like, a big workload, badger's like, the last thing that we do really before we go home. So, sometimes you miss the odd, you know, daily amount of feeds that they've had or the weight. So, it is easy to do, yeah"*

Staff 1 (post), Nurse SCBU

When some data was missing from the MBSR, parents would assume the night nurse did not enter it onto the system but specifically wanted to be reassured that their baby's data would be entered onto the system. As parents would want to know why the data was missing, nurses would divert their attention away from the missing MBSR data and reassure them it is now on the EPR, explaining that perhaps the night nurse recorded it too late, after

the MBSR had been generated:

> *"Sometimes I think if something's missing, they would look at who had the baby the night before. Whereas sometimes we are genuinely really busy, aren't we? Some of them, if stuff was missing they'd ask me if I could have a look and why it was missing. So a few parents did comment on that. So just try and clear them away from the fact that the nurse forgot or just made them know that the information is there. We just have to have a look for it for them"*
>
> Staff 1 (post), Nurse SCBU

> *"I'll just say I can double check on Badger. Maybe it was done late and you know, it was a late, you know, data thing. I just tell them that and I have a look for them"*
>
> Staff 1 (post), Nurse SCBU

In discussing the concept of MBSR data being extracted from the EPR, a registrar highlighted the importance of that process being automatic, like via an app, so as to minimise any potential data entry duplication:

> *"Mum was in adult intensive care and baby was on the neonatal unit. Updating her was fine for just one case but I think if you had to do that for every baby every day, a couple of separate updates a day, that's quite a lot of extra work. So you really need a system that can extract it and send it to parents"*
>
> Staff 8 (pre), Registrar

The doctors in post-intervention interviews discussed how parents appeared to value the MBSR, were more engaged, empowered to ask questions and seemingly more involved in their baby's care:

> *"They seemed a bit more actively involved compared to other parents who weren't receiving the summaries, I think. Bit more engaged and a bit more, I don't know, empowered to ask a question. They just seemed*

*a bit more like, I think they just felt a bit more involved in their baby's care"*

Staff 8 (pre), Registrar

In terms of the MBSR's impact on parents asking questions, staff generally felt that the volume of questions and type of information parents asked for face-to-face and over the telephone did not change, rather parents appeared more empowered to ask questions. Staff also highlighted that some parents are always going to ask questions, no matter what:

*"I don't think it's necessarily any higher than it was before, but I certainly don't think it's any lower than it was before. So there are the parents that are always going to ask questions, but it hasn't stopped those parents from asking questions. I don't feel like my workload has lightened"*

Staff 5 (post), Consultant

*"The ones that I've been having are always quite vocal and involved, are generally quite verbal anyway [laughs]. So I haven't really seen a change with that. But then, if I had another parent group that was like a little bit more introverted, more quiet you know.."*

Staff 7 (post), Nurse ITU

*"If I'm honest, no dramatic change with parents. I think that's stayed pretty much the same. Um, they'll still always phone and want an update and come in and want an update as well"*

Staff 6 (post), Nurse HDU

*"Well it didn't feel like more questions. They just seemed a bit more engaged and a bit more, I don't know, empowered to ask*

Staff 8 (post), Registrar

In general, staff described it as challenging to assess the frequency of questions from parents following the introduction of the MBSR, as different parents visited every day and many didn't visit often:

*"No difference, not massively. No. To be honest, the parents I've had recently aren't in as much. So, I don't know if that's maybe different to if I'd have had the same patient continuously. Then I would have been able to see a difference. But because I've had a different patient, and then the ones that I have had the parents haven't been in very much"*

Staff 6 (post), Nurse HDU

Finally, staff commented on the possibility that the parents always wanting more information in general were the ones participating in the study:

*"The parents that had the summary seemed quite engaged, just more generally in terms of being on the ward round and asking questions and things like that"*

Staff 8 (post), Registrar

*"I they're a self-selecting group of people. They're parents that want lots of information, so they're participating in the study and they've been around for you to ask for their consent for the study. Do you see what I mean?"*

Staff 5 (post), Consultant

In terms of the MBSR's information content, the consultant felt this was matching the type of information nurses provide but wasn't offering the additional interpretation of information that doctors provide:

> *"There are parents that are aware and value the sheet. But it feels like it's replacing what the nurses told them. It's not replacing what the medics tell them. Instead of being, your baby had 180 ml of breast milk today, it should be, your baby tolerated feeds and weight went up today, or we haven't been able to increase the baby's feeds today, but they've stayed the same and not gone down"*
>
> Staff 5 (post), Consultant

9.3.4.8 Staff role (Balancing parent communication with clinical care)

From the outset, in discussing their job role, staff members expressed how challenging it is to keep the right balance between caring for babies clinically and supporting/updating their parents at the same time. It was widely accepted by staff that clinical care takes priority and the clinical workload dictates how long they can spend with parents, particularly during new admissions:

> *"If there's an admission, the ideal situation would be to talk to the parents and let them know this is what's going on and this is what we're doing for your baby and as it's happening. But it doesn't happen that way because everything just like, happens straight away. You're trying to stabilise a baby, the parents have just left. So occasionally there's a few nurses that are really good at taking the parents away and talking to them, because they're not involved in the resuscitation and stabilisaiton of the baby. But they're not always on"*
>
> Staff 7 (post), Nurse ITU

> *"I mean like the weekends when maybe there's just one of you and you're trying to go around, I don't know, 20, 25 babies potentially. So,*

*you cannot, if you spend 20 minutes updating every parent, that's your day gone and you haven't actually done anything, any essential duties, like cannulating, like reviewing gases, reviewing xrays, um, so I think it definitely detracts from your clinical duties"*

Staff 8 (post), Registrar

Staff discussed the need to balance clinical care and parent communication being stressful at times but also accepted this is part of their job:

*"I think its more stressful sometimes because you could be with one baby and then you have another set of parents who need you. And if you have four sets of parents who all need the same thing, or you know you've got one anxious set of parents and then you have to kind of prioritise your care. Who needs the most time? Who needs the most support?*

Staff 1 (post), Nurse SCBU

*"It's perfectly acceptable for them to be completely on their baby. That's their job. It's my job to split my time but it's not their job to split their time, so I just need to get.. do things the best we can"*

Staff 6 (post), Nurse HDU

Having acknowledged the need to balance clinical work with supporting parents, staff discussed how big a part of their shift involves talking to parents and teaching them to care for their baby:

*"I would say at least 60% of my time I am talking to parents"*

Staff 7 (post), Nurse ITU

*“Um so yes it takes a lot of time, updating parents, quite a lot [laughs]. But its part of my job”*

Staff 5 (post), Consultant

*“As the baby gets better, they need a little bit more support because you’re teaching them to do nappies, cuddles. If they’re there all the time, it just goes on. It depends on, on their involvement like, physically there. Do you know what I mean?*

Staff 7 (post), Nurse ITU

In terms of speculating how their workload might have changed since the introduction of MBSR (in terms of time needed to update parents), staff had already discussed how the frequency of parent questions was largely unchanged. In addition, the consultant highlighted that workload always changes ‘in waves’ but this was still probably overall unchanged:

*“I think it goes in waves anyway over time, I really do. Those things are nursing aspects. Are we feeding them? It’s a nursing update. So does it reduce my workload? No”*

Staff 5 (post), Consultant

Specifically referring to recording data on EPR for the MBSR to be populated, nurses highlighted this is something they already do in their role and therefore did not impact their workload:

“*“It doesn’t have an impact on our workload because its something we already do.. unlike other studies where samples etc are required”*

Staff 6 (post), Nurse HDU

9.3.4.9 Summary of thematic findings: Staff perspectives

a. General thoughts on communication with parents

Early in the interviews the issue of a recent changing staff culture towards better communication in neonatal care was raised, whereby staff members place more of a focus on updating parents regularly and early on. Whilst acknowledging that parental anxiety means more time required to update and reassure parents, certain things staff members do to alleviate parent anxiety were identified as: providing updates by a doctor, encouraging parents to be present on ward rounds, being honest with parents and providing all available information. Aiming for regular 'good day updates' was highlighted, to remove the stigma of being updated only when a baby is not well. Staff members acknowledged some parents with different personalities will ask more questions than others, while highly educated parents can be quite demanding.

b. Specific factors affecting perceived parent information needs

Staff members discussed 3 factors that can affect perceived parent information need, question frequency and visiting routines; having other children, length of stay on the neonatal unit and level of neonatal unit area acuity. Staff felt first time parents tend to ask more questions (including general parenting questions) and visit more, while parents with other children ask more focused medical questions and utilise telephone updates more. Parents of newly admitted babies require more time from staff to offer broad updates and reassurance in person, while long-stay parents are more concisely updated and more confident to seek information themselves, more often over the telephone. Over time, long stay parents build a relationship with nurses and struggle with shift changes in their baby's care. Parents in the highest intensity area (ITU) tend to be constantly present, getting their updates from their baby's nurse 'as they go' and directly approaching doctors; staff are particularly busy looking after babies clinically in this area, making parent communication challenging and time consuming. In HDU, with babies being slightly less acutely unwell, nurses start involving parents in babies' cares, parents telephone for updates more and when they do visit require a longer face-to-face update. In SCBU, staff felt that parents appear more

present on the unit again, asking many questions about going home and interacting throughout the day with nurses and doctors face-to-face. Telephone calls are brief and mainly serve to inform staff about when parents are coming in.

c. Communicating with (both) parents in the day versus night shift

Staff members reported being able to have frequent communication with parents mainly during day shifts, due to high workload during the night (when they are usually limited to short phone calls). Being able to update both parents together was highlighted as saving a lot of time and misunderstandings.

d. Parent communication with nurses versus doctors

All staff agreed that no matter how much information parents are given over the phone, they will always want a face-to-face update. Nurses described needing to respond to ad hoc parent questions throughout the day, while also managing to have around 2 more targeted conversations (at least) per day with the same parents. Whilst parents also often demand doctor meetings at short notice, these are difficult to happen if unplanned. Nurses deliver a wide range of information, as well as providing general reassurance, managing parental anxiety, discussing updates and changes since parents last saw their baby and teaching them how to care for their baby. Doctors focus more on providing information about progress and prognosis, in addition to formal general updates on admission and/or when a baby is unwell.

e. Main update of the day: the ward round

Staff members described parents waiting all day to be updated by doctors on the ward round, with subsequently requiring nurses to explain any jargon/unclear information from the ward round to parents. Standardising updates was suggested, highlighting that anyone should be able to deliver updates on stable babies, not just doctors (and specifically consultants).

f. Written information in neonatal care

Staff members discussed how they use written information in their

communication with parents. Staff mainly share an ‘admission and discharge pack’ with parents, containing information about the neonatal unit and about going home. This does not take priority over clinical care and staff are not sure if parents read it. In addition, staff consolidate specific face-to-face updates, with leaflets (that are only available for certain conditions) and the ‘Small wonders’ DVD (if available) on supporting families through neonatal care. Staff discussed the risk of parental stress if information is read out of context or when not available in their own language other than English, while acknowledging parents do look at the nursing folders and ask for nurses’ help to understand the information. When explaining jargon, longer time is needed with parents.

g. Views on MBSR (My Baby's Summary Report)

Staff members in post-intervention interviews discussed being aware of parents receiving the MBSR, with some parents directly telling them how much they enjoyed receiving them. Being the main staff members who enter daily data into the neonatal electronic patient record system (EPR) that populated the MBSR, nurses discussed this process considering the MBSR trial. Nurses felt more motivated to enter the data in EPR in the first place, were more careful to record data accurately and reminded each other to complete their data entries, knowing it was now going to parents. Nurses reported having had limited or no formal training on how to use the EPR, as well as limited understanding on what the recorded data is used for; trialing the MBSR raised their awareness about the importance and potential uses of neonatal EPR data. Nurses described it takes only a few minutes to complete data entries for a baby (usually last action during their shift) with no additional time needed during the MBSR trial period. Nurses discussed how data is sometimes missing from the MBSR (feeds, weight), mostly due to high workload, preventing them from entering it into the EPR. In general, staff discussed the importance of the EPR-MBSR data flow being automatic, like via an app, to minimise any potential data entry duplication.

The doctors in post-intervention interviews discussed how parents appeared to value the MBSR, were more engaged, empowered to ask questions and

seemingly more involved in their baby's care. In terms of the MBSR's impact on the frequency of parents asking questions, staff described it as challenging to assess as different parents visited every day and many didn't visit often. In general, staff felt that the volume of questions and type of information parents asked for (face-to-face, telephone) did not change, some parents would always ask questions anyway and the ones wanting more information overall were most likely to be the ones participating in the study. The MBSR was felt to match the type of information nurses provide but did not offer the additional interpretation of information that doctors tend to provide.

h. Staff role (Balancing parent communication with clinical care)

Staff discussed the challenge of balancing caring for babies clinically and supporting/updating their parents, with clinical care always taking priority. Staff reported a large part of their shift involves talking to parents and teaching them to care for their baby and that following the introduction of the MBSR the frequency of parent questions was largely unchanged. Specifically regarding data entries on EPR for the MBSR to be populated, nurses highlighted this is something they already do anyway and therefore did not impact their workload during the trial.

## 9.4 DISCUSSION

### 9.4.1 Key findings

Interviews with 12 parents and 10 neonatal staff members in neonatal care provided insight into their experience of the daily MBSR trial. They also provided the important context of their experience of communication, information sharing and parental involvement in care on the neonatal unit.

From the outset, parents discussed the stressful and 'endless' nature of neonatal care, describing the distress caused by their baby 'being taken away from them' and the 'loss of control' in what was an unfamiliar environment. One in seven babies born in the UK will require hospital care on a neonatal unit (1) and up to 35% of parents report symptoms of anxiety, depression and post-traumatic stress disorder following neonatal care (3-5).

Parents described their communication with staff members as stressful no matter the type of information exchanged as they experienced further loss of control with relying on others for information about their own baby. In the latest parent experiences in neonatal care England survey (2) parents reported finding it difficult to obtain clinical information from staff and feeling excluded from their baby's care. Parents highlighted certain things that exacerbated their stress (such as an overwhelming amount of information provided by staff) and suggested ways to improve communication; these focused around ensuring continuity of care, consistent and regular pragmatic baby updates offered by staff (not just when the baby is unwell), avoidance of medical jargon and/or better explanation of it. Previous cognitive interview studies have highlighted that jargon in neonatal care is often not understood by parents (93).

Staff members also discussed trying to improve communication with parents and identified things that appeared to alleviate parent anxiety, including being updated by a doctor, attending ward rounds, providing parents with all available information and regular 'good day updates'.

It is well known from other studies about provider-patient communication that different patients have different information needs (94). In this study, fathers were more focused on numbers and details, asking many questions, while mothers preferred an overview if the baby was stable. Staff members reported some parents ask more questions than others, while highly educated parents can be quite demanding. Previous studies have also focused on parent gender differences in neonatal care, but mainly around the fathers' desire to balance cultural and social expectations of being 'breadwinners' with their wishes to be equal co-parents and be fully updated about their baby by staff (95, 96).

Whilst in neonatal care, parents reported receiving information about their baby from a variety of sources; mainly a combination of neonatal nurses and doctors. Both parents and staff described some keys differences in their communication with nurses versus doctors, namely in terms of information

content and communication frequency. Previous studies have focused more on the differences in communication frequency with nurses versus doctors, rather than the different content of information shared (44). In this study, in terms of information content, both parents and staff described nurses as presenting a general overview and any changes to parents while doctors provide more of the clinical context to this information, with a focus on progress and prognosis. In terms of communication frequency and in line with previous studies, parents reported more ad hoc face-to-face communication with their baby's main nurse through the day (with at least a telephone call a day) and only once daily doctor updates, unless their baby was unwell.

All staff agreed that no matter how much information parents were given over the phone, parents always want a face-to-face update and nurses communicate with parents the most throughout the day. The main 'information sharing event' of the day was highlighted by parents as being the 'doctors' ward round', after which parents would again ask nurses to explain any jargon discussed. In a survey of 270 parents in neonatal care, parents wanted easier access to conversations with doctors, medical information to be given directly by doctors rather than by nurses and to be present during doctors' rounds (42). In my study, staff suggested standardising updates, highlighting that anyone should be able to deliver updates on stable babies, not just doctors (and specifically consultants). Nurses reflected on the challenge of balancing caring for babies clinically and supporting/updating their parents, with clinical care always taking priority. They reported a large part of their shift involves talking to parents (particularly when explaining jargon) and teaching them to care for their baby.

As their neonatal admission progressed, parents reported more proactively seeking information, whilst also conversely asking fewer questions the more they understood. Overall, parents discussed preferring updates being offered to them, as they found jargon and complex information very stressful to navigate.

In terms of being involved in their baby's care, parents were mostly satisfied with being updated about changes in management and participating in care procedures, although were reluctant to do so when their baby was unwell. Parents did not feel able to challenge doctors to actively participate in decision-making and were retrospectively informed of decisions instead, something most were happy with. Previous evidence reports parents being happy with staff to make urgent decisions but would prefer to be involved in decision making for non-urgent issues (44).

In addition to verbal face-to-face and telephone conversations, staff members discussed how they use written information in their communication with parents, including 'admission and discharge packs', individual information leaflets and neonatal care DVDs if available. Written information is often only available in English; staff discussed the risk of parental stress if information is misread or read out of context, while parents would like neonatal written information to be translated into many different languages. Staff reported that parents look for written information in nursing folders and ask for nurses' help to understand the clinical information recorded there.

Parents in the pre-intervention period discussed wanting a written overview of their baby in summarised bullet point form, as well as general neonatal unit information. In a recent qualitative interview study, parents in NICU identified a lack of written information, indicating a strong preference for shared, written information to complement conversations with staff (44).

Pre-intervention parents discussed how written information could provide more transparency in communication with staff, as well as serving as a useful reminder for them and 'reference' to help them ask questions on the ward round. Post-intervention parents were overall very happy with receiving the MBSR and reported feeling more informed. Staff members in post-intervention interviews discussed being aware of parents receiving the MBSR, with some parents directly telling them how much they enjoyed receiving them.

The doctors in post-intervention interviews reported parents appeared to value the MBSR, were more engaged, empowered to ask questions and seemingly more involved in their baby's care. Indeed, key MBSR benefits highlighted by parents included being actively offered daily updates, having more time to absorb and process information, being able to track their baby's progress as a narrative and feeling better prepared to have conversations with staff. Parents used the MBSR as a written record, reminder, memento and way of sharing their baby's progress with their loved ones (by sending a photo of it).

In terms of the MBSR's impact on the frequency of parents asking questions and type of information asked, staff felt it was challenging to assess as different parents visited at different times, but this was generally unchanged. Parents felt the MBSR answered a lot of their questions but equally they still needed to ask new questions (as the MBSR contained information from the preceding 24 hours). Staff suggested the MBSR was felt to match the type of information nurses provide but did not offer the additional interpretation of information that doctors tend to provide. Parents also highlighted they would like the MBSR to provide more information on progress and prognosis. This feedback has been considered in the prototype mobile phone application, including explanations on how daily information compares to that of previous days (Chapter 8).

Nurses discussed feeling more motivated to enter the data in EPR in the first place. They reported being more careful to record data accurately and reminded each other to complete their data entries, knowing it was now going to parents. Nurses described it takes only a few minutes to complete data entries for a baby, with no additional time needed during the MBSR trial period. To date, there is a lack of trials evaluating the impact of neonatal interventions on completeness and/or accuracy of data in EPR systems.

Parental feedback on the MBSR highlighted some issues resulting from how the information is entered and stored in the neonatal EPR (see Chapter 6). Parents reported feeling disappointed the feeding information in the MBSR

was not always accurate; the accuracy of MBSR information was directly dependent on the data entered into the EPR system overnight. Considering staff workload during busy night shifts, nurses discussed how omissions and/or errors in EPR data entry were common, resulting often in missing data from the MBSR (feeds, weight). In general, staff discussed the importance of the EPR-MBSR data flow being automatic, like via an app, to minimise any potential data entry duplication.

Parents also discussed the information format not matching that of information verbally provided on the unit. For example, staff members informally discuss feeds in a total 'ml/kg/day' format which parents grow accustomed to. The EPR system only has the option of recording feeds in 'total ml per 24 hours', which is the figure reported in the MBSR. This feedback was incorporated into the development of the prototype app, where information format was matched to what is delivered verbally on the unit (see Chapter 8).

Furthermore, parents gave feedback on wanting more detailed from the MBSR, including blood test, scans and other investigation results, as well more personalised prognostic information on their baby's clinical progress and the daily ward round plan. Currently the neonatal EPR holds a certain number of discrete daily-updated data items, with no daily 'free-text' entries, whilst investigation results are stored and reported through different electronic systems. This feedback was again incorporated in the prototype app, by including a daily 'plan from ward round' tab.

Parents expressed the preference to receive 'live', immediate data updates (specifically the updated daily weight), which is currently not possible. Neonatal EPR entries are manually updated daily by staff during each night shift to reflect the preceding 24 hours update. In the case of EPR fields being automatically updated by neonatal monitoring equipment, it may be possible to provide parents with near real-time data in the future.

Finally, in considering the MBSR in mobile application form, parents discussed the benefits of having instant access to information at any time,

having the option to customise the type of information they receive and allowing clinical staff to focus on providing clinical care to their baby. Parents also suggested including videos and a web camera function in a mobile phone application. While secure video messaging technology is currently being trialled on neonatal units (97), incorporating this element in the MBSR was beyond the scope of this project.

### 9.4.2 Strengths and limitations

In conducting a qualitative evaluation of a neonatal communication tool, such as the MBSR, one of the key strengths was seeking direct feedback from parents with lived experience of NHS neonatal care. Recruited parents included mothers and fathers of both preterm and term infants (25-41 weeks). The parent sample included a range of ethnicities (with predominant white ethnicity) and infants had a wide range of stay (1 week-4 months). Overall, 75% of parents (9/12) were older than 35 years, which may either reflect this neonatal unit's parental age population or be due to the small sample size.

Limitations were very similar to the ones already discussed in the overall MBSR piloting Chapter 8, particularly relating to using a non-randomised design (convenience sampling due to the nature of the study) and the consideration of the Hawthorne effect in parents agreeing to participate. One key limitation was participants being different in the pre and post-intervention period interviews. Ideally parents and staff members in both periods would have all been the same. However, for parents, this was impossible given the high neonatal unit infant turnover with families frequently being discharged. I therefore interviewed parents who visited often and were available for recruitment. As a result, the parent sample may also represent a self-selecting group that were naturally more engaged than other parents, wanted more information and therefore chose to be recruited to receive the MBSR.

It was not possible to recruit parents who were not able to visit, as receiving the daily MBSR required them to be physically present on the neonatal unit. Piloting the MBSR in a mobile phone application form rather than paper form would have enabled me to reach the parents that could not visit their baby. As

a result, I was unable to evaluate the potential impact of this intervention on parents that were absent for long periods of time from the unit, which were potentially the ones it could have benefitted the most. Results would therefore need to be validated with parents that are more absent from the unit. For staff, all effort was made to interview the same people pre and post intervention. However, due to high staff workload and day/night shift work only 2/10 staff members were available for interview in both time periods.

Another limitation, due to this being a single centre study, was that the entire parent and staff sample was based in the CW NNU, in London and this was a small sample of 22 participants. Furthermore, I was the sole researcher who interviewed parents and staff member participants. It was not possible to blind participants to the intervention received, neither was blinding possible during the interview process. I conducted the transcript analysis where transcripts were anonymised with code identifiers and a second independent reviewer (KW) examined and advised on coding frameworks.

Finally, the MBSR piloting period lasted 6 weeks, which is a limited amount of time to expect a sustained change in the culture of communication in neonatal care.

### 9.5 CONCLUSIONS

Interviews with parents and neonatal staff members in neonatal care highlighted that parents are always going to be stressed in these circumstances and the way neonatal staff members approach communication with them can further negatively or positively influence this. Parents and staff agreed that regular sharing of concise, jargon-free information can help alleviate this stress. The MBSR is a way to provide this daily information to parents.

Parents communicate with their baby's nurse throughout the day for any updates and particularly rely on doctors' updates during the ward round, to give more context to any information received. They also prefer updates being offered to them as it can be overwhelming to seek information in this

environment. Updating parents whilst providing clinical care is very challenging for nurses, who also often explain jargon from the ward round to parents after it has finished. The MBSR is a way to regularly offer parents information that nurses usually provide, in preparation for more detailed discussions with doctors.

Parents always need the face-to-face update; the MBSR serves as an adjunct to parent communication, rather than replacing in person discussions.

The MBSR appeared to empower parents, serving as a reference to ask questions during the ward round, with parents feeling more informed and involved. Key MBSR benefits identified by parents included: being actively offered daily updates, having more time to absorb and process information, being able to track their baby's progress and feeling better prepared to have conversations with staff. Parents used the MBSR as a written record, reminder, memento and way of sharing their baby's progress with their loved ones (by sending a photo of it). In terms of the MBSR's impact on the frequency of parents asking questions and type of information asked, staff felt it was challenging to assess as different parents visited at different times, but this was generally unchanged. Parents agreed, considering that the MBSR provided information from the day before and new questions would regularly arise. In terms of data flow processes, the MBSR created an increased motivation and accountability for nurses to record data on EPR correctly, since parents would question the accuracy/completeness of information in the MBSR. Parents had many requests for expanding the MBSR, namely in terms of including more types of information and making the information 'real time'. Suggestions have been incorporated as much as possible in the development of the app prototype, within the current constraints of the Hospital trust's information systems.

# Chapter 10
# Conclusions

This thesis examines one of the most stressful and traumatic times in a parent's life; experiencing neonatal care outside the family home and navigating a different path to the one imagined after a baby is born. With one in seven babies born in the UK requiring hospital care on a neonatal unit (1), up to 35-40% of parents reporting symptoms of anxiety, depression and post-traumatic stress disorder following neonatal care (3-5) and well-defined links between maternal mental health and infant development (7), developing interventions to improve the experience of parents in neonatal care becomes crucial. The latest national neonatal parent experience survey in England, the 2014 *'Parents' experiences of neonatal care'* survey developed by Picker, highlighted *'parent satisfaction with receiving clinical information'* as one of the lowest scoring areas (2). Parent satisfaction is inversely related to parental stress (10); therefore, improving parent satisfaction has the potential to reduce parent stress, improve parent-infant bonding (12) and infant outcomes (13).

In this thesis, I have built on previous evidence that parent satisfaction can be improved by providing written information to parents, whilst also addressing previous limitations such as interventions requiring additional work from staff to collect, record, and provide information to parents, not involving parents in intervention development and using unvalidated surveys to measure parent outcomes. I have used existing, routinely recorded data, from the neonatal electronic patient record system (EPR) and worked with parents to co-develop, implement, further improve and evaluate a neonatal communication tool.

From study inception, I actively involved parents throughout my study, in line with the 4Pi National Involvement Standards for effective co-development (26, 27). My multi-professional Project Steering Group (PSG), which included parents with neonatal care experience, and the study's main parent representative, who co-led project activities with me, helped ensure parents continuously guided this study. Whilst the 2014 Picker survey results informed

the idea for a parent communication tool at initial study inception, this was further confirmed at an Action-Effect Diagram project planning meeting with parents.

To understand what parent interventions in neonatal care others had tried in the past and how they had evaluated them, I conducted the largest systematic review of interventions (32 studies) where an outcome was parent satisfaction with neonatal care (11). In this review, I highlighted the use of non-randomised study designs, inconsistency in definition and measurement of parent satisfaction, the use of unvalidated surveys as also previously highlighted by Dall'Oglio et al (40), methodological challenges in designing, conducting and evaluating interventions and a lack of parent involvement in study design. In keeping with neonatal studies more widely (38), my review confirmed inconsistent outcome selection as a major source of research waste in neonatal studies examining parent experience.

Another key result of my review was highlighting the complexity in evaluating parent satisfaction as a multidimensional construct, that can be affected just as much by interventions directly related to infant care as well as by interventions relating to hospital facilities (e.g. free parking). By grouping included interventions into themes, I highlighted the various interventions available and found that most were related to ‘parent involvement’.

The latest systematic review of interventions aimed at improving the parent experience was conducted by Brett et al in 2011 (39), but only included parents of preterm infants, whereas I included the full range of infant gestations. Their large number of outcome domains and heterogeneity of outcome measures meant the authors were unable to draw firm conclusions about the efficacy of interventions and that comparison and meta-analysis was not possible. Similarly, heterogeneity in measurement of parent satisfaction meant I was also unable to conduct a quantitative synthesis. I found low quality evidence that interventions targeting ‘parent involvement’ may improve parent satisfaction with neonatal care, but this result must be interpreted cautiously in view of the high risk of bias in included studies.

This review was crucial in informing my study design, considering that only 31% of included studies were RCT, and all RCT and non-RCT studies were assessed as having a high risk of bias. It highlighted the methodological challenges in robustly undertaking both RCT and non-RCT to evaluate interventions targeting parent satisfaction in neonatal care, raising the question of how appropriate or feasible it is to select RCT designs in this area of research in the first place, given issues such as contamination between parent groups, difficulties with blinding and the Hawthorne effect (41). Given the above limitations, I concluded that a cluster trial may be the most appropriate study design to robustly evaluate interventions to improve parent satisfaction with neonatal care on a larger scale, whilst first conducting a well-evaluated single centre pilot trial, like the one described in this thesis.

The lack of a traditional RCT-type 'control' group raises the issue of how to best evaluate the intervention's impact on parent satisfaction. Most studies in my review evaluated different parent groups in different time periods, pre and post intervention, an approach which does not consider the continuously changing dynamic nature of parent satisfaction over time. I have therefore evaluated my intervention (My Baby's Summary Report- MBSR) using mixed methods to achieve the most robust assessment; quality improvement methodology to enable continuous evaluation of outcomes (including parent satisfaction) and iterative development of the MBSR with parents, as well as traditional 'before' and 'after' statistical testing, including both a quantitative component and interviews with parents and neonatal staff members (qualitative component).

During initial intervention design work, I engaged and recruited parents using social media; a key and novel strength of this study. Social media platforms are increasingly being used for research participation and online data collection (46). As such, I was able to overcome recruitment challenges relating to large geographical distances and parental work/childcare commitments. Obtaining parent feedback during the project early design phase gave me an important overview of issues I needed to consider in the later planning stages. I conducted process mapping with parents and neonatal

staff members to understand ‘what happens now’ and ‘what parents want’, mapping out the current information exchange and exploring parent information needs. Recruiting parents following discharge from neonatal care is known to be challenging, with recorded attrition rates as high as 70% (45). Using a convenience sample, my in-person parent group size was small, however I additionally developed an online survey with direct design input from the in-person parent group. ‘Virtual process-mapping’ via an online survey was an additional novel methodology I used; the number of parent respondents to the online survey was comparable to that of large studies who primarily explore the parent experience in neonatal care through in-person interviews (63).

In process mapping, it was reported that communication between parents and staff members in neonatal care predominantly involves verbal updates throughout the neonatal admission. Written information provision is inconsistent through an infant’s journey and mainly offered to parents at the time of admission to the neonatal unit. There was agreement between parents and neonatal staff members on the type of information shared, but parents wanted it communicated in a different way: more objective, more consistent, readily available, and jargon-free. Parents identified the information themes that were most important to them, prioritising clinical updates. Categorisation of parent information preferences into ‘*infant-specific’* and ‘*unit-specific’* information informed the subsequent development of the MBSR template with parents. Process mapping ascertained that a communication tool providing daily written information in a parent-centred way could be a valuable adjunct to verbal communication in neonatal care.

During an in-person parent co-design focus group, I matched ‘*infant-specific’* information in neonatal care to parent-selected EPR data items, co-designing the MBSR template with parents to share the EPR data items in parent-friendly language, in a parent-chosen format. For ‘*unit-specific’* information, I conducted an iterative improvement of the CW NNU parent information booklet with parents on the neonatal unit, showing a statistically significant increase in parent satisfaction with the final parent-designed booklet versus

the initial clinician-designed booklet. This showed the potential for parent co-design methodology to improve communication and parent satisfaction in neonatal care.

There is evidence that parents strongly support the use of eHealth technology in neonatal care (including mobile phone applications and websites) (69, 70); whilst my intervention pilot trial was initially planned as a mobile phone application, through which parents would directly access their baby's EPR data, an unanticipated change of EPR providers in the CW Hospital meant I piloted and evaluated the MBSR in a paper version. The MBSR was a printed sheet of paper, containing the daily-updated parent-chosen EPR data items for each infant. I manually downloaded these items from EPR and incorporated them into an individualised MBSR template for each infant, matching a pre-prepared parent-friendly explanation to each data item.

To robustly evaluate the MBSR, I developed with parents a new instrument to evaluate parent satisfaction, '*The PEC questionnaire: Parents' Experiences of Communication in Neonatal Care'* (Appendix 14). In line with my systematic review highlighting the widespread use of unvalidated surveys worldwide (11, 40), I performed a validation assessment of the PEC which supports its use in evaluating the parent experience in UK neonatal care.

All previous parent experience instruments collect parent feedback retrospectively, at or around the time of a baby's discharge from the neonatal unit. Adapted from the 2014 UK "Parents' experience of neonatal care" 61-question Picker survey (which has been extensively cognitively tested), the shorter 28-question PEC survey is the first in the UK and one of two tools in English-speaking countries worldwide, where formal validation supports its use in collecting 'real time' parent feedback in neonatal care. The PEC survey focuses on communication of clinical information with parents in neonatal care, to enable continuous assessment and iterative improvement of family-centred interventions in neonatal care and provide standardised evaluation of neonatal parent experience that is supported by validation analysis. It is available under licence from Picker and has already been formally requested

for use by four neonatal units across the United Kingdom and the United States.

Once the MBSR template and PEC survey were complete, I conducted the implementation of the MBSR in stages across the three different intensity areas of the CW NNU (from low to high) over 8 weeks. During this pilot's intervention period, mothers and fathers of both premature and term infants on the CW NNU received the MBSR, further improved it and developed its final template through providing regular feedback via the PEC parent survey. It is important to note that in examining a multidimensional topic such as parent experience in neonatal care, changes in certain areas lead to changes in other areas. Whilst I employed mixed methods and measured different outcomes to evaluate the MBSR in the most robust way, incorporating several different analysis approaches and results meant it was challenging to give overall study conclusions.

Results for the individual measured outcomes were, however, clear. During the intervention period, the main analysis indicated that after receiving the MBSR, parents were statistically significantly more satisfied with the amount of written information received (*primary outcome: parent satisfaction with communication of clinical information)* but also asked their nurse for an update more frequently *(secondary outcome: parent-staff interactions).* Run chart analysis showed that while receiving the MBSR parents were more satisfied with the method of communication being 'written information', telephoned the unit more often and were more likely to recommend the CW NNU to friends and family. Parent satisfaction with the MBSR (both overall and in relation to the frequency of receiving it) was high throughout the intervention period. During the intervention period, staff members reported updating parents more frequently on ward rounds *(secondary outcome: staff workload).* NNRD data completeness during the intervention period improved and data accuracy was high (>=90%) for the majority of data items.

The above results suggest that the MBSR implementation increased parent satisfaction with the amount of written information received and parents were

highly satisfied with the MBSR overall, results which align with other studies that have shared written information with parents (16, 17). Parental communication frequency needs on the CW NNU also increased (an unanticipated result), with staff members in response updating parents more frequently on ward rounds and manually recording infant EPR data items in a highly accurate and more complete way.

Interviews with parents and neonatal staff members gave a very useful insight into current information exchange in neonatal care, as well as their specific views on the MBSR. Issues highlighted included parental views on stress (and its inevitable nature under these circumstances) and how the way neonatal staff members approach communication with parents can further negatively or positively influence this. Parents and staff agreed that regular sharing of concise, jargon-free information can help alleviate this stress. The MBSR is a way to provide this daily information to parents. Parents reported always needing the face-to-face update; the MBSR could therefore serve as an adjunct to parent communication, rather than replacing in person discussions.

Parents reported communicating with their baby's nurse throughout the day and relying on doctors (usually during the ward round), to give more context to any information received. They also preferred updates being offered to them and described it can be overwhelming to seek information in this environment. Updating parents whilst providing clinical care is a challenging balance for nurses; the MBSR is a way to regularly offer parents information that nurses usually provide, in preparation for more detailed discussions with doctors.

The MBSR appeared to empower parents, serving as a reference to ask questions during the ward round, with parents overall feeling very happy with receiving the MBSR and reporting feeling more informed. Key MBSR benefits highlighted by parents included being actively offered daily updates, having more time to absorb and process information, being able to track their baby's progress and feeling better prepared to have conversations with staff. Parents used the MBSR as a written record, reminder, memento and way of sharing their baby's progress with their loved ones (by sending a photo of it). Staff

members also discussed receiving positive feedback from parents receiving the MBSR and reported that parents appeared to value the MBSR, were more engaged, empowered to ask questions and seemingly more involved in their baby's care.

Quantitative evaluation of the MBSR had shown that during the intervention period parents asked their nurse for an update more frequently and telephoned the unit more, while staff members also reported updating parents more frequently on ward rounds. Parents during interviews interestingly did not discuss an increase in their communication frequency needs; similarly, when asked about the MBSR's impact on the frequency of parents asking questions and type of information asked, staff members felt it was challenging to assess as different parents visited at different times, but that this was generally unchanged. This discrepancy between quantitative and qualitative results could be explained by parents perhaps not wanting to volunteer to the interviewer that they had asked for verbal information more frequently whilst receiving the MBSR, or those individual parents had simply not experienced a heightened communication frequency need. Pre-intervention parents had discussed how written information could serve as a useful reminder for them and 'reference' to help them ask questions on the ward round. As quantitative results were not yet available at the time of interview (and interviews were largely parent-led), this question was also not directly asked of parents. It is certainly plausible that in response to receiving additional written information about their baby, parental expectations for communication frequency were inadvertently increased in general. Another explanation could include parents asking for verbal clarifications about the MBSR's content, although this was not mentioned during interviews. Since the MBSR is being proposed as an adjunct to parent communication, it is anticipated that the MBSR can help better focus the verbal discussions, rather than replace or reduce them.

In terms of data flow processes, parents reported feeling disappointed the feeding information in the MBSR was not accurate 100% of time, since the accuracy of MBSR information was directly dependent on the data entered into the EPR system overnight by staff (often during busy night shifts). Nurses

discussed an increased motivation and accountability to record data on EPR correctly, since parents would question the accuracy/completeness of information in the MBSR (perhaps another potential reason for increased frequency of conversations between parents and staff). This PhD is the first study to report completeness and accuracy data at all for *'daily-recorded'* data items in the NNRD, as previous research has focused on *'once-only recorded'* NNRD data (23). Data completeness and accuracy of 'once-only recorded' data is known to be high (23), but can be further improved, particularly for 'daily-recorded' data items that can be further utilised in research. The MBSR pilot trial is an example of an intervention that can increase data completeness, with high data accuracy, by providing an incentive for staff members to record items on the database in a better way.

Finally, in considering the MBSR in mobile application form, parents discussed wanting to have instant access to information at any time, having the option to customise the information received and allowing clinical staff to focus on providing clinical care for their baby. Parents specifically requested to include more types of information in the MBSR, make the information 'real time', include videos and a web camera in an app.

Following the piloting process, I have developed a BUDS mobile application prototype (87) and signed a contract for a live app for use by parents on the CW NNU (due to be released in the spring/summer of 2023). A live app would have the potential to be applied to any other NNU, as long as EPR data can be appropriately extracted for use by the app.

Parent suggestions for information content have been incorporated as much as possible in the development of the app prototype, and are considered for the live app within the current constraints of the neonatal EPR and the CW Hospital's information systems. In the case of EPR fields being automatically updated by neonatal monitoring equipment, it may be possible to provide parents with near real-time data in the future, but this is currently not possible. While secure video messaging technology is currently being trialled on

neonatal units (97), incorporating a web camera in the parent app was beyond the scope of this study.

This thesis supports the use of the MBSR as a communication tool adjunct in neonatal care; its use in a mobile phone application format, the BUDS app, would allow for better efficiency and wider application of my study's findings. Due to the dynamic nature of neonatal care and lack of randomised design, future research would provide insight into any additional unmeasured factors (possibly unrelated to the MBSR) that could have influenced the above results. The optimal study design for this type of intervention could be a cluster RCT, to evaluate the implementation of the live BUDS app on the CW NNU and other neonatal units in the future.

Publications, online articles (including videos and app prototype) and presentations arising from this thesis are included in Appendix 43.

> *"If that was an app we could both log in, for ease. Because we're both up quite late and stuff as well. So rather than having to phone up and having to ask someone, you feel like, bad, for interrupting them from doing their job. Logging in about 1:00 in the morning or something like that would be great to have the information right there."*
>
> P11 ITU (post-intervention), father

> *"I felt more informed. I felt good like, oh, actually, I've got something to hold on to. And I'm gonna put those into an area for my child as well. Like these are your pieces of information from when you were a baby, this is something for us to go through as well, like, wow, we.. we did this"*
>
> P10 HDU (post-intervention), mother

**Appendix 1**
**Project Steering Group (PSG)**

Project team management

- **Project Lead**

Susanna Sakonidou (SS)

*Clinical Research Fellow, Imperial College London*

- **Nursing representative**

Izabela Andrzejewska (IA)

*Senior neonatal research and clinical nurse, CW NNU, London*

- **PhD supervisor and Neonatal Consultant**

Chris Gale (CG)

*Professor of Neonatal Medicine, Imperial College London*

PSG

- **Parent representative**

Sophia Kotzamanis (SK)

*Parent of preterm twins, London*

- **Nursing representative**

Izabela Andrzejewska (IA)

*Senior neonatal research and clinical nurse, CW NNU, London*

- **PhD supervisor and Neonatal Consultant**

Chris Gale (CG)

*Professor of Neonatal Medicine, Imperial College London*

- **Bliss Charity representative**

Mehali Patel (MP)

*Bliss Research Engagement Officer, London*

- **NIHR CLAHRC NWL team members**

Wendy Carnegie (WC)

*Improvement Science Manager, London*

Alan J Poots (AJP)

*Statistician and Health services researcher, London*

## Appendix 2
## PRISMA Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | 39 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | In published BMJ Open paper |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 39 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 39 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | 40 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | 40 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | 40 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | 40-41 |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | 40-41 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | 40-41 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 40-41 |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 41 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | N/A |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$) for each meta-analysis. | 41 |

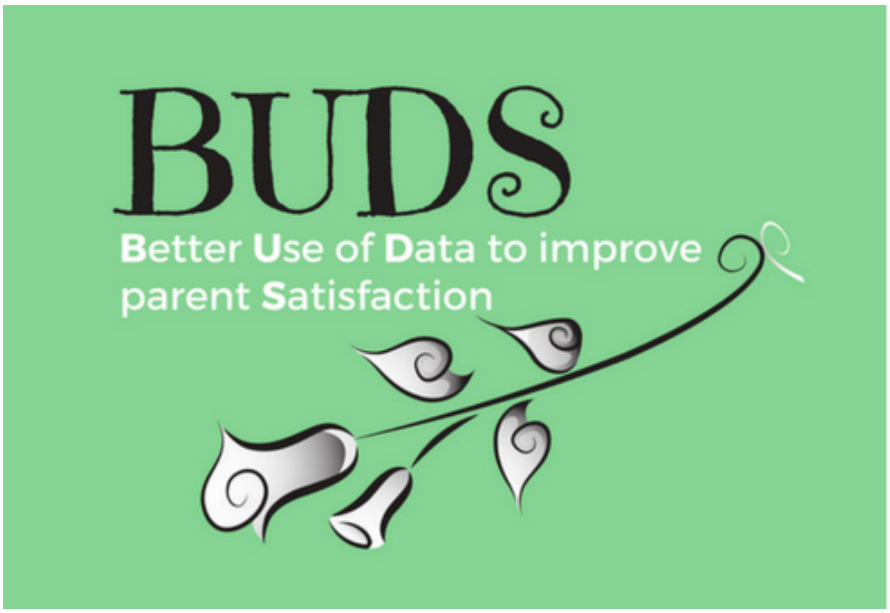
| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | 41 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | N/A |
| **RESULTS** | | | |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | Figure 4 |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | Tables 1-3 |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | Figures 5 and 6 |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | Tables 1-3 |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | N/A |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | Figures 5 and 6 |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | N/A |
| **DISCUSSION** | | | |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 70-71 |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 70-73 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 74 |
| **FUNDING** | | | |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | Chapter 2 |

## Appendix 3
## OVID MEDLINE search strategy

1. intervention$.ti,ab.
2. tool$.ti,ab.
3. way$.ti,ab.
4. updat$.ti,ab.
5. method$.ti,ab.
6. information.ti,ab.
7. sms.ti,ab.
8. implement$.ti,ab.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. bab$3.mp.
11. preterm$.ti,ab.
12. pre term.ti,ab.
13. premature.ti,ab.
14. postterm.ti,ab.
15. post term.ti,ab.
16. infant$.ti,ab.
17. newborn$.ti,ab.
18. exp Infant, Newborn/
19. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20. neonatal intensive care.ti,ab.
21. neonatal unit$.ti,ab.
22. NICU.ti,ab.
23. SCBU.ti,ab.
24. neonatal itu.ti,ab.
25. special care baby unit$.ti,ab.
26. neonat$.ti,ab.
27. Intensive Care Units, Neonatal/
28. Intensive Care Units/
29. Critical Care/
30. Neonatal Nursing/
31. 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32. parent$.ti,ab.
33. mother$.ti,ab.
34. father$.ti,ab.
35. exp Parents/
36. 32 or 33 or 34 or 35
37. satisfaction.ti,ab.
38. experience$.ti,ab.
39. Patient Satisfaction/
40. personal satisfaction/
41. communicat$.ti,ab.
42. exp Communication/
43. Health Communication/
44. Information Dissemination/
45. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44
46. 9 and 19 and 31 and 36 and 45

## Appendix 4
## Visual resources

BUDS study logo




Online study advert

Parents commenting on the Facebook study advert

SOCIAL MEDIA PRESENCE
BUDS
BUDS Neonatal Research Project
twitter
babylivinglab
FB post reached 23,989 people

# Appendix 5
# Parent questionnaire for Information Booklet feedback

Chelsea and Westminster Hospital NHS
NHS Foundation Trust

BUDS

**Parent Information Booklet Feedback A**

I am a mother / father / carer (please circle)

At how many weeks was your baby born? (please circle)
- Less than 24 weeks
- 24-30 weeks
- 30 weeks+1 day - 36 weeks
- More than 36 weeks

When did your baby first arrive on the unit? (please circle)
- Today
- Less than 1 week ago
- 1 week - 1 month ago
- More than 1 month ago

Please read **parent information booklet A** and answer the following questions by circling ONE answer:

1. **Does booklet A contain enough information about how the neonatal unit works?** ***(for example: ward contact telephone numbers, staff members and their different roles, types of care provided in the different rooms, ward round times, when is a good time to visit)***
- Yes, definitely
- Yes, to some extent
- No

2. **Does booklet A explain the purpose of the machines, monitors and alarms/*"beeping"* in the neonatal unit?**
- Yes, definitely
- Yes, to some extent
- No

3. **Does booklet A contain enough information about being involved in your baby's care?** ***(for example: being able to touch your baby, hold your baby/kangaroo care, feed your baby, change nappies)***
- Yes, definitely
- Yes, to some extent
- No

Please describe in your own words:

4. **How did you feel about the order of information in booklet A?**

5. **How did you feel about the way information was worded in booklet A?**

6. **On a scale of 1 to 5 how satisfied were you with the information provided to you in booklet A?**

(least satisfied) 1 2 3 4 5 (most satisfied)

7. **How would you improve booklet A?**

## Appendix 6
## 'My Baby's Summary Report' template with parent-friendly explanations of terms

**My Baby's Summary Report**

**Date: [insert today's date]**

This is a 24-hour summary of how _____ **[insert baby's first name]** is doing. Summaries are updated every night and include information from the previous day.

The consultant in charge of _____ **[insert unit area]** today is _____**[insert name]**

**Age**

_____ **[insert baby's first name] is** ____ **[insert age] old. His/her corrected gestational age is [insert CGA].**

**Weight**

_____ **[insert baby's first name] current weight is** ____ **g [insert weight]**

**Feeds**

**She/he is** _____ **[insert feeding mode option]**

Options:

- receiving fluids through a vein
- breastfeeding
- feeding with bottles
- not ready for milk feeds yet
- feeding through a small tube that goes from the nose straight to the stomach (medical term "nasogastric tube")
- feeding through a small tube that goes from the mouth straight to the stomach (medical term "orogastric tube")
- receiving specialised fluids through a vein (medical term "**she/he** is on TPN")

*Total Parenteral Nutrition (TPN) is the process of giving a baby that cannot yet take milk feeds full nutrition. TPN includes sugars, protein, fats and vitamins and is given directly into the blood stream (usually via a type of specialised small tube in the vein, known as a central line or long line).*

**Breathing**

**_____ [insert baby's first name] is breathing _____ [insert breathing mode option]**

Options:

- through a breathing tube (medical term "she/he is intubated").

*The breathing tube pushes air and oxygen in and out of her/his lungs, inflating and deflating them like a balloon. On the other end the tube is attached to a machine called a ventilator. By adjusting the ventilator's settings the doctors can control how much and how quickly air and oxygen go in and out of her/his lungs.*

- for herself/himself, with a little help from a small mask (medical term "she/he is on CPAP")

*The tubes provide pressure into her/his lungs and help her/him open them up during breathing.*

- for herself, with a little help from small plastic tubes placed in her nostrils (medical term "she is on vapotherm")

*The tubes provide airflow into her lungs and help her open them up during breathing.*

- for herself/himself, with a little help from small plastic tubes placed in her/his nostrils (medical term "she is on optiflow")

*The tubes provide airflow into her/his lungs and help her/him open them up during breathing.*

- for herself/himself without needing help (medical term "she/he is self ventilating")

**We are giving her/him oxygen to help her/his breathing.**

**She/he is not needing any oxygen, in addition to what is in room air.**

- Through small plastic tubes placed in her/his nostrils (medical term "nasal cannula")

**Infection**

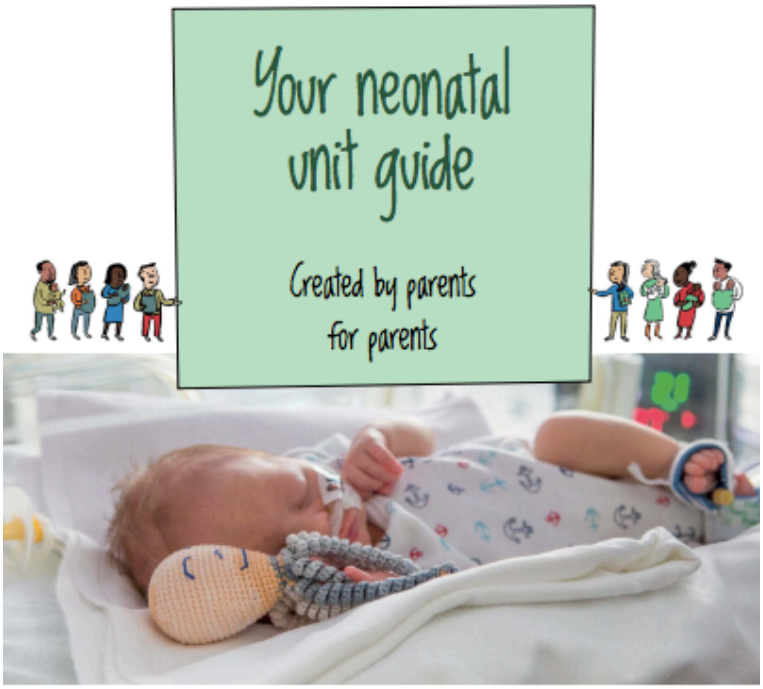
**We are giving her/him antibiotics for a suspected infection**

**We are not currently treating her/him for any infection**

**Current medication**

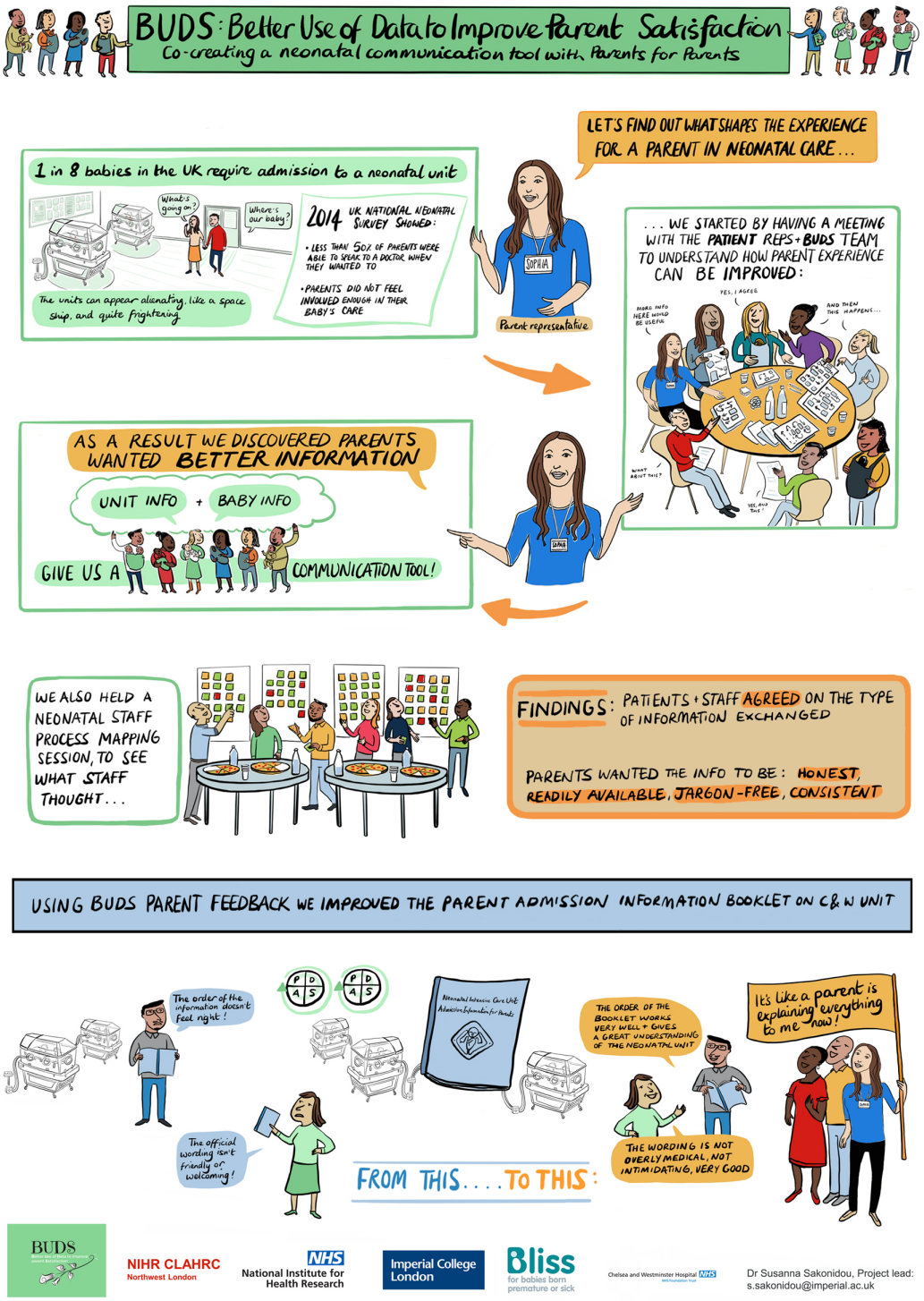
**Her/his list of medications currently includes:**

**Appendix 7**
**Final Parent-designed information Booklet (version C)**




This booklet has been funded by CW+, the charity of Chelsea and Westminster Hospital NHS Foundation Trust. CWPLUS registered charity n°1169897.

# Appendix 8
# Infographic showcasing improved satisfaction with new NICU information booklet




BUDS | NIHR CLAHRC Northwest London | NHS National Institute for Health Research | Imperial College London | Bliss for babies born premature or sick | Chelsea and Westminster Hospital NHS

Dr Susanna Sakonidou, Project lead:
s.sakonidou@imperial.ac.uk

# Appendix 9
# Parent Information Sheet 1: Questionnaire Development

**BUDS Parent Information Sheet 1: Questionnaire Development**
PIS1 v1.5/220618/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

**1 We would like to invite you to participate in the BUDS research project.**
Thank you for allowing us to discuss this with you. Please read this information and ask us about anything that is not clear.

**2 What is the purpose of this project?** 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. We 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. We want to give every parent a daily printed summary of their baby's information, taken from the electronic system. We have designed this with parents of babies that needed neonatal care and we now want to test it on our neonatal unit.

To see whether these summaries work we need a questionnaire that asks parents about how they feel about their involvement in their baby's neonatal care and the information they have been given. In this first part of the project we want to test whether this questionnaire works, by asking parents who have a baby on the neonatal unit to try the questionnaire.

**3 Why have I and my baby been invited?** We are approaching parents of babies who are currently receiving care within the Special Care Baby Unit (SCBU) area in our neonatal unit.

**4 Do I have to take part?** Not at all, this is entirely your choice and it will not affect the care you or your baby receives. If you agree you will be asked to sign a consent form and a copy will be given to you. If you decide to participate you may withdraw at any time without giving any reason. If you withdraw or lose capacity to consent, we will keep the information about you that we have already obtained and continue to use it confidentially in connection with the purposes for which consent is being sought.

**5 What does the project involve?** If you choose to take part you will be asked to talk for about 15-30 minutes with the lead researcher, Dr Susanna Sakonidou. You can ask a staff member, friend or family member to join you if you wish. You will be asked to read and think about each of the questionnaire questions, and then describe what you think each question means and how you would answer it.

**6 How long will the project last?** Your involvement in this part of the project will end after this interview. If your baby is still an inpatient during the next few months we may approach you again to be involved in other parts of the project. If this happens we will explain the other parts of the project at that time so you can decide whether or not you want to take part.

**7 What are the possible risks and disadvantages of taking part?** We don't think there are any risks or disadvantages of taking part in this project.

**8 What are the possible benefits of taking part?** There are no direct benefits to you or your baby. Your involvement will help us test these summaries for future parents, which we hope will lead to better communication with parents, and parents who feel more involved in their baby's care.

**9 What happens if something goes wrong?** It is extremely unlikely that anything will go wrong. However, if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the lead researcher, Dr Susanna Sakonidou. The normal National Health Service complaints mechanisms are also available to you. The Chelsea and Westminster hospital Patient Advice and Liaison Services (PALS) team can assist you with the NHS complaint process and provide independent advice (hospital ground floor, main atrium, opposite escalators and lift bank B, 0203 315 6727). If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office (JRCO) Sponsor Office.

**10 Will my taking part in this project be kept confidential?** It is likely the neonatal staff will know you are participating as the interview room is on the neonatal unit. However the interview itself will be conducted privately, away from the clinical team. Your decision to participate, as well as withdraw at any time will not affect the care your baby receives. We will audiorecord the interviews so we can transcribe and analyse them, but the transcripts will be anonymised and only read by members of our research team. Recordings will be destroyed at the end of the project.

Imperial College London will be using information from you in order to undertake this project and will act as the data controller and sponsor for this project. This means Imperial College London is responsible for looking after your information and using it properly. The Imperial College Neonatal Research Team will keep your name and contact details to contact you about the project, and make sure that relevant information about the project is recorded to oversee the quality of the project. The Imperial College Neonatal Research Team will keep identifiable information about you for 10 years after the project has finished at Imperial College London premises. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible. Individuals from the JRCO Sponsor, NHS and regulatory organisations may look at your research records to check the accuracy of the research project. The only people at Imperial College London who will have access to information that identifies you will be people who need to contact you to send you a summary of findings or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. You can find out more about how we use your information by contacting the lead researcher (see details below).

When you agree to take part in a research study, the information you give to the project about your experience of neonatal care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.** This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

**11 What will happen to the results of the project?** Project conclusions will be published in scientific journals and presented at scientific meetings, including anonymised direct quotes from interviews, but you will not be identified in any way. If you agree, we will send you a summary of the findings.



**12 Who is sponsoring this project?** Imperial College London is the sponsor, based in the United Kingdom.

**13 Who has reviewed and approved this project?** This project has been reviewed and approved by the West Midlands - South Birmingham REC (18/WM/0175) and is being conducted as part of the lead researcher's PhD.

**Thank you for reading this.**

**Lead researcher**
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# Appendix 10
# Parent Consent Form 1: Questionnaire Development

**BUDS Consent Form 1: Questionnaire Development**
v1.5/220618/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)
**Parent's Name:**

**Please initial each box to indicate agreement. You will be given a copy of this form.**

1. I confirm that the purpose of the project and what it involves has been explained to me. ☐

2. I have read the *Parent Information Sheet 1 : Questionnaire development v1.5/220618* and have been given the opportunity to ask questions and discuss this project with the BUDS team. ☐

3. I understand that my participation is voluntary, and that I am free to withdraw at any time without giving any reason and without affecting my medical care or legal rights or those of my baby. ☐

4. I understand that anonymised quotes may be included in research and consequent publications, but not in any way that might allow for identification of individual participants. ☐

5. 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. ☐

6. I give my permission for an audio recording of my interviews and for the audio recording to be used for anonymous transcription and analysis of results. ☐

7. I agree that all anonymised project data will be stored on secure NHS and Imperial College London computer systems/premises for 10 years (Imperial Policy). ☐

8. I agree that my details, including personally identifiable details and a copy of this consent form will be stored for 10 years (Imperial Policy) in a secure, locked, Imperial College neonatal research office with restricted access to members of the research team. ☐

9. I agree to take part in this study. ☐

10. I would like to be sent a summary of the study results. ☐

| _____ | _____ | _____ |
|---|---|---|
| Name of parent | Date | Signature |
| _____ | _____ | _____ |
| Name of researcher taking consent | Date | Signature |

# Appendix 11
# Original 'Parents' experiences of Neonatal Care' survey

picker Institute Europe
Making patients' views count

Bliss
for babies born too soon, too small, too sick

NHS England

## Parents' experiences of Neonatal Care

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**What is the survey about?**

This survey is about your baby's care **in the neonatal unit named in the letter sent with this questionnaire**. This may have been a Special Care Baby Unit (SCBU), a High Dependency Unit (HDU) or a Neonatal Intensive Care Unit (NICU).

Unless otherwise stated, please answer all questions **about the neonatal unit named in the letter** that came with this questionnaire. If you have had more than one experience of a baby who was cared for on this neonatal unit, please only think about your **most recent experience** when answering these questions.

Your views are very important in helping us find out what parents think of neonatal services and how they can be improved.

**Who should complete the questionnaire?**

The questions should be answered by the parent(s) or guardian(s) named on the front of the envelope.

**Completing the questionnaire**

The word 'baby' is used throughout to refer to either a single baby or more than one baby.

The questionnaire should take around 20 minutes to complete. For most questions, please tick clearly inside one box ☑ using a black or blue pen. For some questions you may be asked to tick more than one box.

Not all sections will apply to you, and sometimes you will find the box you have ticked has an instruction to go to another question. By following the instructions carefully, you will only answer the questions that apply to you.

Please **do not** write your name or address anywhere on the questionnaire.

**Taking part in this survey is voluntary. Your answers will be treated in confidence.**

**Questions or help?**

If you have any questions, or if you would like to complete the questionnaire over the phone or with the help of an interpreter, please call **Freephone 0800 783 2896** and we will do our best to help. The line is open Monday to Friday 8am-8pm and on Saturdays from 9am-12pm.

**NEO14**

## SECTION A. BEFORE YOUR BABY WAS BORN

**A1.** **Before** your baby was born (i.e. during pregnancy or labour), did you know that they might need care in a neonatal unit?

1 ☐ Yes ➔ **Go to A2**

2 ☐ No ➔ **Go to B1**

**A2.** Before your baby was born (i.e. during pregnancy or labour), did a member of staff from the **neonatal unit** talk to you about what to expect after the birth?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No

4 ☐ Don't know / can't remember

## SECTION B. YOUR BABY'S ADMISSION TO NEONATAL CARE

**B1.** Was your baby **first admitted** to the neonatal unit named in the letter sent with this questionnaire?

1 ☐ Yes ➔ **Go to B2**

2 ☐ No, my baby was first admitted to a neonatal unit at a different hospital ➔ **Go to C1**

**B2.** After you gave birth, were you offered a photograph of your baby?

1 ☐ Yes

2 ☐ No, but I would have liked this

3 ☐ No, but I took a photograph myself

4 ☐ I did not want a photograph taken

5 ☐ Don't know/ can't remember

**B3.** After you gave birth, were you ever cared for in the same ward as mothers who had their baby with them?

1 ☐ Yes, and this bothered me

2 ☐ Yes, but I did not mind

3 ☐ No, I stayed in a separate room/area

4 ☐ I was discharged from hospital

**B4.** After your baby was admitted to the neonatal unit, were you able to see your baby as soon as you wanted?

1 ☐ Yes

2 ☐ No

3 ☐ No, but this was not possible for medical reasons (baby and/or mother)

4 ☐ No, because we were in different hospitals

## SECTION C. STAFF ON THE NEONATAL UNIT

**Please answer the following questions about the unit named in the letter that came with this questionnaire.**

**C1.** When you visited the unit, did the staff caring for your baby introduce themselves to you?

1 ☐ All of the staff introduced themselves

2 ☐ Some of the staff introduced themselves

3 ☐ Very few or none of the staff introduced themselves

4 ☐ Don't know / can't remember

**C2.** Were you given enough information about the neonatal unit (such as rules, procedures and facilities for parents)?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No

4 ☐ Can't remember

**C3.** Was the purpose of the machines, monitors and alarms used in the neonatal unit clearly explained to you?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No

4 ☐ Don't know / can't remember

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**C4.** Were infection control practices explained to you, such as hand washing and procedures for visitors?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ Don't know / can't remember

**C5.** Were you told which nurses were responsible for your baby's care each day s/he was in the neonatal unit?

1 ☐ Yes
2 ☐ No

**C6.** Were you able to talk to staff on the unit about your worries and concerns?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ I had no worries or concerns

**C7.** Were you able to speak to a doctor about your baby as much as you wanted?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ I did not want or need to speak to a doctor

**C8.** Were the **nurses** on the unit sensitive to your emotions and feelings?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ This was not necessary

**C9.** Were the **doctors** on the unit sensitive to your emotions and feelings?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ I had no contact with doctors on the unit
5 ☐ This was not necessary

**C10.** In your opinion, was important information about your baby passed on from one member of staff to another?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No, information was not passed on
4 ☐ Don't know/ can't remember

**C11.** Did staff give you conflicting information about your baby's condition or care?

1 ☐ Yes, often
2 ☐ Yes, sometimes
3 ☐ No, not at all

**C12.** Did staff refer to your baby by his/her first name?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ My baby did not have a name

**C13.** Overall, did you have confidence and trust in the staff caring for your baby?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No

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## SECTION D. YOUR INVOLVEMENT IN YOUR BABY'S CARE

***Still thinking about when you were in the neonatal unit named in the letter that came with this questionnaire…***

**D1.** Were you involved as much as you wanted in the day-to-day care of your baby, such as nappy changing and feeding?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No, I was not involved as much as I wanted
4 ☐ No, my baby was too ill

**D2.** Did you have as much skin-to-skin contact with your baby as you wanted?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No, not as much skin-to-skin contact as I wanted
4 ☐ No, but this was not possible for medical reasons
5 ☐ I did not know about skin-to-skin contact

**D3.** Did the neonatal unit staff **include you in discussions** about your baby's care and treatment?

1 ☐ Yes, always
2 ☐ Yes, sometimes
3 ☐ No

**D4.** Were you told about any **changes** in your baby's condition or care?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No, I was not told about changes
4 ☐ Not sure/can't remember

**D5.** When a ward round was taking place, were you **allowed** to be present when your baby was being discussed?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No, I was not allowed to be there
4 ☐ Not sure / I did not know about ward rounds

**D6.** Where possible, did staff arrange your baby's care (such as weighing, bathing) to fit in with your usual visiting times?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No, but I would have liked this
4 ☐ No, but this was not necessary

**D7.** Overall, did staff help you feel confident in caring for your baby?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No

### Feeding your baby

**D8.** If you wanted to **express** breast milk for your baby, were you given the **support** you needed from neonatal staff?

1 ☐ Yes, definitely → **Go to D9**
2 ☐ Yes, to some extent → **Go to D9**
3 ☐ No → **Go to D9**
4 ☐ I did not want to express milk → **Go to D10**
5 ☐ I could not express milk → **Go to D10**

**D9.** When you were in the neonatal unit, were you given the **feeding equipment** you needed for expressing, such as a breast pump and sterilisation equipment?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No

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**D10.** Were you given enough privacy in the neonatal unit for expressing milk and/or breastfeeding your baby?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No and it bothered me
4 ☐ No, but I did not mind
5 ☐ This was not needed

**D11.** If you wanted to **breastfeed** your baby, were you given enough support to do this from neonatal staff?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ I did not want to breastfeed my baby
5 ☐ My baby was unable to breastfeed for medical reasons

**D12.** If you fed your baby **formula milk**, were you given enough support to do this from neonatal staff?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ I did not want to feed my baby formula milk

## SECTION E. ENVIRONMENT AND FACILITIES

***Still thinking about the neonatal unit in the hospital named in the letter…***

**E1.** Were you given enough privacy when discussing your baby's care on the neonatal unit with staff?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ No, but I did not mind

**E2.** Was there enough space for you to sit alongside your baby's cot in the unit?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No

**E3.** In your opinion, was there adequate security on the neonatal unit?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No

**E4.** If you wanted to stay overnight to be close to your baby, did the hospital offer you accommodation?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ I did not want/need to stay overnight

**E5.** Were you able to visit your baby on the unit as much as you wanted to? *(please only think about unit-related reasons and not personal reasons such as needing to care for other children)*

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ I did not visit my baby

## SECTION F. INFORMATION AND SUPPORT FOR PARENTS

***Still thinking about the neonatal unit in the hospital named in the letter…***

**F1.** If you asked questions about your baby's condition and treatment, did you get answers you could understand?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ I did not ask any questions

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**F2.** Were you given enough **written information** to help you understand your baby's condition and treatment?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No, I was not given enough written information

4 ☐ I did not get any written information

5 ☐ I did not want or need any written information

**F3.** Did you have an opportunity to go through your baby's **medical notes** (not just the nursing notes) with staff while they were in the neonatal unit?

*Please note – medical notes are <u>not</u> the notes left with the baby on the cot, but are stored securely with staff*

1 ☐ Yes

2 ☐ No, but I wanted to

3 ☐ No, but I did not want to

4 ☐ I did not know about the medical notes

**F4.** Were you offered emotional support or counselling services from neonatal unit staff?

1 ☐ Yes

2 ☐ No, but I would have liked to have been offered this

3 ☐ I did not need any emotional support or counselling

**F5.** Were you given **enough information** about help you could get with expenses related to your baby's stay in the neonatal unit (such as travelling/parking expenses, hardship funds or food vouchers)?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No

4 ☐ I did not need/want this information

**F6.** Did **staff give** you any information about parent support groups, such as Bliss or other local groups? (TICK ONE ONLY)

1 ☐ Yes, **staff gave** me this information

2 ☐ No, but this information was available in **the unit** (e.g. a leaflet in the parents' room)

3 ☐ No, I did not get this information

4 ☐ Don't know / Can't remember

## SECTION G. LEAVING THE NEONATAL UNIT

**G1.** In total, how long did your baby stay in **neonatal care** (include all the hospitals they stayed in)?

1 ☐ Up to 1 week

2 ☐ More than 1 week but less than 4 weeks

3 ☐ Between 4 and 8 weeks

4 ☐ More than 8 weeks, but less than 12 weeks

5 ☐ 12 weeks or more

**G2.** When your baby was discharged from the neonatal unit, where did they go next?

1 ☐ A hospital maternity ward ➔ **Go to G4**

2 ☐ Another ward in the hospital ➔ **Go to G4**

3 ☐ Home ➔ **Go to G3**

4 ☐ Somewhere else ➔ **Go to G4**

**G3.** Were you offered overnight accommodation with your baby at the hospital before they left the neonatal unit?

1 ☐ Yes

2 ☐ No, but I would have liked it

3 ☐ No, but I did not want or need it

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**G4.** Did you feel prepared for your baby's discharge from neonatal care?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No

**G5.** Were you given enough information on what to expect in terms of your baby's **progress** and **recovery**?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No

**G6.** How likely are you to recommend this neonatal unit to friends and family, if their baby needed similar care or treatment?

1 ☐ Extremely likely

2 ☐ Likely

3 ☐ Neither likely nor unlikely

4 ☐ Unlikely

5 ☐ Extremely unlikely

6 ☐ Don't know

## SECTION H. YOU AND YOUR BABY

**H1.** Did your baby stay in a neonatal unit in more than one hospital?

1 ☐ Yes ➔ **Go to H2**

2 ☐ No ➔ **Go to H3**

**H2.** Did your baby spend **most** of its time in the neonatal named in the letter that came with this questionnaire?

1 ☐ Yes, my baby spent most time in the unit named in the letter that came with this questionnaire

2 ☐ No, my baby spent most of its time in another unit

3 ☐ My baby stayed a similar amount of time in two or more different units

**H3.** Did you give birth to a single baby, twins or more in your most recent pregnancy?

1 ☐ A single baby

2 ☐ Twins

3 ☐ Triplets, quads or more

**H4.** Roughly how many weeks pregnant were you when your baby was born?

1 ☐ Before I was 25 weeks pregnant

2 ☐ When I was 25 to 29 weeks pregnant

3 ☐ When I was 30 to 32 weeks pregnant

4 ☐ When I was 33 to 37 weeks pregnant

5 ☐ When I was 38 weeks pregnant or more

**H5.** How much did your **baby weigh at birth**? (*If you had twins or more than two babies, please fill in this question about the baby who was born first*)

1 ☐ Less than 1000g (1kg / 2lb 3oz)

2 ☐ 1000g to 1500g (1kg to 1.5.kg / 2lb 3oz to 3lb 5oz)

3 ☐ 1500g to 2500g (1.5kg to 2.5kg / 3lb 5oz to 5lb 8oz)

4 ☐ More than 2500g (2.5kg / 5lb 8oz)

**H6.** How many babies have you given birth to before this pregnancy?

1 ☐ None ➔ **Go to H8**

2 ☐ 1-2 ➔ **Go to H7**

3 ☐ 3 or more ➔ **Go to H7**

**H7.** Have you previously had a baby admitted to a neonatal unit?

1 ☐ Yes

2 ☐ No

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**H8.** Who filled in this questionnaire?

1 ☐ The baby's mother

2 ☐ The baby's father

3 ☐ Parents together

4 ☐ The baby's guardian(s)

**H9.** To which of these ethnic groups would you say the mother of the baby belongs? (Tick ONE only)

1 ☐ White British

2 ☐ Any other white background

3 ☐ Mixed

4 ☐ Asian or Asian British

5 ☐ Black or Black British

6 ☐ Any other ethnic group

**H10.** Do you have a long-standing physical or mental health problem or disability?

1 ☐ Yes ➔ **Go to H11**

2 ☐ No ➔ **Go to H12**

3 ☐ I'd rather not say ➔ **Go to H12**

**H11.** Does this problem or disability affect your day-to-day activities?

1 ☐ Yes, definitely

2 ☐ Yes, to some extent

3 ☐ No

**H12.** In what **year** was the mother of the baby born?

***(Please write in)*** e.g. | 1 | 9 | 7 | 4 |

| Y | Y | Y | Y |
|---|---|---|---|

## SECTION J. YOUR COMMENTS

If there is anything else you would like to tell us about the neonatal care received in the **hospital named in the letter** sent with the questionnaire, then please do so here:

**THANK YOU VERY MUCH FOR YOUR HELP**

**Please post this questionnaire back in the FREEPOST envelope provided. No stamp is needed**

This survey is supported by Bliss, the special care baby charity. If this survey has raised any issues for you please contact Bliss on their free family support helpline number: 0500 618140 or visit: www.bliss.org.uk [Charity number: 1002973]

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## Appendix 12
## New question added for more depth following parent interviews

Question*: 'Have you been able to speak to a doctor about your baby as much as you want?'*
*1. Yes, definitely;*
*2. Yes, to some extent*
*3. I have not wanted or needed to speak to a doctor*
*4. No*

Most parents answered *'2. Yes, to some extent'* during cognitive testing. Parents raised issues such as staff shortages on weekends and wanted the opportunity to say that.

Added a routing option to answers 2 and 4, redirecting parents to an additional question:
*'What is the main reason you have not been able to speak to a doctor as much as you want?*
*1. Doctors don't appear approachable*

*2. Doctors appear too busy*

*3. Doctors are not present on the neonatal unit when I am there*

*4. I do not understand the doctors' explanations*

*5. Other (please specify)*

**Appendix 13**
**PEC questionnaire: 'Parents' Experiences of Communication in Neonatal Care'**

Picker

Imperial College London

## The PEC questionnaire:

### Parents' Experiences of Communication in Neonatal care

**What is the survey about?**

This survey is about your **parent experience** in the neonatal unit currently providing care to your baby.

**Completing the questionnaire**

The word 'baby' is used throughout to refer to either a single baby or more than one baby.

The word 'staff' is used throughout to refer to both neonatal doctors and nurses.

The questionnaire should take around 10 minutes to complete. For most questions, please tick clearly inside one box ☑ using a black or blue pen. For some questions you may be asked to tick more than one box. For questions with a range of answers (1-10) please circle your chosen answer.

Not all sections will apply to you, and sometimes you will find the box you have ticked has an instruction to go to another question. By following the instructions carefully, you will only answer the questions that apply to you.

Please **do not** write your name or address anywhere on the questionnaire.

**Taking part in this survey is voluntary. Your answers will be treated in confidence.**

**Thank you for completing this survey.**

## YOU AND YOUR BABY

**This information will help us ensure we include the experiences of a diverse group of parents. All answers will be anonymised and kept confidential for use within our research team.**

**Please circle what applies:**

**What is your age?**

- Under 18
- 18-24
- 25-29
- 30-34
- Over 35

**What is your gender?**

- Female
- Male
- Other (please specify) _____

**What is your ethnic group?**

- White
- Mixed
- Asian or Asian British
- Black or Black British
- Chinese
- Other (please specify) _____

**At how many weeks gestation was your baby born?**

_____

**How long has your baby been on this neonatal unit for?**

- Under 1 week
- 1-2 weeks
- 2-4 weeks
- 1-2 months
- 2-4 months
- 4-6 months
- Over 6 months

## SECTION A. STAFF ON THE NEONATAL UNIT

**A1.** Have the neonatal unit's **rules, procedures and facilities for parents** been clearly explained to you?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ Can't remember

**A2.** Has the purpose of the **machines, monitors and alarms** used in the neonatal unit been clearly explained to you?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ Don't know / can't remember

**A3. Have infection control practices** been explained to you, such as **hand washing and procedures for visitors?**

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ Don't know / can't remember

**A4.** Have you been told which nurses are responsible for your baby's care **each day** she/he is in the neonatal unit?

1 ☐ Yes
2 ☐ No

**A5.** Have you been able to talk to staff on the unit about your worries and concerns?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ I have had no worries or concerns

**A6.** Have you been able to speak to a doctor about your baby **as much as you want?**

1 ☐ Yes, definitely → **go to A8**
2 ☐ Yes, to some extent → **go to A7**
3 ☐ I have not wanted or needed to speak to a doctor → **go to A8**
4 ☐ No → **go to A7**

**A7.** What is **the main reason** you have **not** been able to speak to a doctor as much as you want?

1 ☐ Doctors don't appear approachable
2 ☐ Doctors appear too busy
3 ☐ Doctors are not present on the neonatal unit when I am there
4 ☐ I do not understand the doctors' explanations
5 ☐ Other (please specify): _____

_____

_____

**A8.** Have staff given you conflicting information about your baby's condition or care?

1 ☐ Yes, often
2 ☐ Yes, sometimes
3 ☐ No, not at all

**A9.** Overall, do you have confidence and trust in the staff members that have been caring for your baby?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No

## SECTION B. INFORMATION AND SUPPORT FOR PARENTS

**B1.** If you ask questions about your baby's condition and treatment, do you get answers you can understand?

1. ☐ Yes, always or nearly always
2. ☐ Yes, sometimes
3. ☐ No
4. ☐ I have not asked any questions

**B2.** Have you been given enough written information **(in paper or electronic form)** to help you understand your baby's condition and treatment?

1. ☐ I have not wanted or needed any written information
2. ☐ Yes, definitely
3. ☐ Yes, to some extent
4. ☐ No, I have not been given enough written information
5. ☐ No, I have not been given any written information

**B3.** Have you had an opportunity to go through ***your baby's medical notes** with staff in the neonatal unit? *(See box below)*

> **Your baby's medical notes:*
> *are **NOT the nursing notes** left with the baby on the cot.*
> *They are notes SECURELY STORED WITH STAFF and contain medical information about your baby (plans from ward rounds etc)*

1. ☐ I did not know about the medical notes, but had I known I would have wanted to
2. ☐ I did not know about the medical notes, but had I known I still wouldn't have wanted to
3. ☐ Yes
4. ☐ No, but I want to
5. ☐ No, but I do not want to

**B4. In the last 24 hours**, how many times have you telephoned the neonatal unit?

Please insert number of times: _____
*Please put N/A if you have not left the unit in the last 24 hours.*

**B5. If you telephoned the unit**, what was the reason for your call?

***PLEASE SELECT ALL THAT APPLY***

1. ☐ **I have not telephoned** the neonatal unit
2. ☐ I wanted information about ward round times
3. ☐ I wanted information about visiting times
4. ☐ I wanted information about parking
5. ☐ I wanted a general update about my baby
6. ☐ I wanted to discuss a change in my baby's care
7. ☐ I wanted information about breastfeeding and/or expressing
8. ☐ I wanted to discuss the information I received in "My Baby's Summary Report"
9. ☐ I wanted to ask for test results (please specify what type of tests): _____
10. ☐ I wanted to discuss a specific part of my baby's care (please specify which part): _____ _____
11. ☐ Other (please specify): _____ _____

**B6. In the last 24 hours**, how many times have you asked your baby's **nurse** for an update about your baby, face-to-face?

Please insert number of times: _____

**B7.** On a scale of 1 to 10 how satisfied are you with the **frequency of updates** you receive from **nurses** about your baby on the neonatal unit?

| Extremely dissatisfied | | | | | | | | | Extremely satisfied |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**B8.** When **ward rounds** take place, are you present when your baby is being discussed?

1. ☐ Yes, always or nearly always
2. ☐ Yes, sometimes
3. ☐ No, I have not been allowed to be there
4. ☐ No, the ward round times are not convenient for me
5. ☐ Other (Please specify)_____

_____

**B9. In the last 24 hours**, how many times have you asked to speak with a **doctor (outside ward round times)**?

Please insert number of times: _____

**B10. If you asked to speak with a doctor**, what did you want to discuss?

***PLEASE SELECT ALL THAT APPLY***

1. ☐ **I have not asked** to speak with a doctor
2. ☐ I wanted a general update about my baby
3. ☐ I wanted to discuss a change in my baby's care
4. ☐ I wanted to discuss the information I received in "My Baby's Summary Report"
5. ☐ I wanted to ask for test results (please specify which test): _____
6. ☐ I wanted to discuss a specific part of my baby's care (please specify which part): _____
7. ☐ Other (please specify): _____

_____

**B11.** On a scale of 1 to 10 how satisfied are you with the **frequency of updates** you receive from **doctors** about your baby on the neonatal unit?

| Extremely dissatisfied | | | | | | | | | Extremely satisfied |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**B12.** On a scale of 1 to 10 how satisfied are you with **how** you receive information about your baby on the neonatal unit?

| | Extremely dissatisfied | | | | | | | | | Extremely satisfied | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Verbal updates** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| **Telephone calls** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | **N/A** |
| **Written information** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | **N/A** |
| **Overall** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

**B13.** If there is anything else you would like to tell us about **how** you receive information about your baby on the neonatal unit then please do so here:

**B14.** "I get the information I need to understand my baby's health status".

1. ☐ Strongly agree
2. ☐ Agree
3. ☐ Neither agree nor disagree
4. ☐ Disagree
5. ☐ Strongly disagree

## MY BABY'S SUMMARY REPORT

### QUESTIONS B15- B20

Please answer only if you have received "My Baby's Summary Report"

**B15.** How do you feel about **the type of information** included in "My Baby's Summary Report"?

*For example: Is there anything else you would like to see included, is there anything unnecessary?*

**B16.** How do you feel about **the layout of information** in the "My Baby's Summary Report?

*For example: Does the order of information appear reasonable; how would you improve it?*

**B17.** How do you feel about **the way information is worded** in "My Baby's Summary Report"?

*For example: Is it too medical, is it easy to understand?*

**B18.** On a scale of 1 to 5 how satisfied are you with the **frequency of receiving** "My Baby's Summary Report"?

1. ☐ Extremely dissatisfied
2. ☐ Dissatisfied
3. ☐ Neither dissatisfied nor satisfied
4. ☐ Satisfied
5. ☐ Extremely satisfied

**B19.** On a scale of 1 to 5 how satisfied are you with "My Baby's Summary Report"?

1. ☐ Extremely dissatisfied
2. ☐ Dissatisfied
3. ☐ Neither dissatisfied nor satisfied
4. ☐ Satisfied
5. ☐ Extremely satisfied

**B20.** If there is anything else you would like to tell us about **"My Baby's Summary Report"** then please do so here:

## SECTION C. YOUR INVOLVEMENT IN YOUR BABY'S CARE

**C1.** Do the neonatal unit staff members include you in discussions about your baby's care and treatment?

1. ☐ Yes, always
2. ☐ Yes, sometimes
3. ☐ No

**C2.** Have you been told about any **changes** in your baby's condition or care?

1. ☐ Yes, always or nearly always
2. ☐ Yes, sometimes
3. ☐ No, I was not told about changes
4. ☐ Not sure/can't remember

**C3.** Overall, do staff help you feel confident in **caring** for your baby? **(nappy changes, feeds etc.)**

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No

**C4.** Are you involved as much as you want in the day-to-day care of your baby?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No, I am not involved as much as I want
4 ☐ No, my baby is too ill

## SECTION D. LEAVING THE NEONATAL UNIT

**D1.** How likely are you to recommend this neonatal unit to friends and family, if their baby needed similar care or treatment?

1 ☐ Extremely likely
2 ☐ Likely
3 ☐ Neither likely nor unlikely
4 ☐ Unlikely
5 ☐ Extremely unlikely
6 ☐ Don't know

## SECTION E. YOUR COMMENTS

**E1.** If there is anything else you would like to tell us about the **way you are given updates** about your baby on the neonatal unit then please do so here

THANK YOU VERY MUCH FOR YOUR HELP

## Appendix 14

## Post validation PEC questionnaire: 'Parents' Experiences of Communication in Neonatal Care'

Picker

Imperial College London

### The PEC questionnaire:

Parents' Experiences of Communication in Neonatal care

**What is the survey about?**

This survey is about your **parent experience** in the neonatal unit currently providing care to your baby.

**Completing the questionnaire**

The word 'baby' is used throughout to refer to either a single baby or more than one baby.

The word 'staff' is used throughout to refer to both neonatal doctors and nurses.

The questionnaire should take around 10 minutes to complete. For most questions, please tick clearly inside one box ☑ using a black or blue pen. For some questions you may be asked to tick more than one box. For questions with a range of answers (1-10) please circle your chosen answer.

Not all sections will apply to you, and sometimes you will find the box you have ticked has an instruction to go to another question. By following the instructions carefully, you will only answer the questions that apply to you.

Please **do not** write your name or address anywhere on the questionnaire.

**Taking part in this survey is voluntary. Your answers will be treated in confidence.**

**Thank you for completing this survey.**

## YOU AND YOUR BABY

**This information will help us ensure we include the experiences of a diverse group of parents. All answers will be anonymised and kept confidential for use within our research team.**

**Please circle what applies:**

**What is your age?**

- Under 18
- 18-24
- 25-29
- 30-34
- Over 35

**What is your gender?**

- Female
- Male
- Other (please specify) _____

**What is your ethnic group?**

- White
- Mixed
- Asian or Asian British
- Black or Black British
- Chinese
- Other (please specify) _____

**At how many weeks gestation was your baby born?**

_____

**How long has your baby been on this neonatal unit for?**

- Under 1 week
- 1-2 weeks
- 2-4 weeks
- 1-2 months
- 2-4 months
- 4-6 months
- Over 6 months

## SECTION A. STAFF ON THE NEONATAL UNIT

**A1.** Have the neonatal unit's **rules, procedures and facilities for parents** been clearly explained to you?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ Can't remember

**A2.** Has the purpose of the **machines, monitors and alarms** used in the neonatal unit been clearly explained to you?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ Don't know / can't remember

**A3. Have infection control practices** been explained to you, such as **hand washing and procedures for visitors?**

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No
4 ☐ Don't know / can't remember

**A4.** Have you been told which nurses are responsible for your baby's care **each day** she/he is in the neonatal unit?

1 ☐ Yes
2 ☐ No

**A5.** Have you been able to talk to staff on the unit about your worries and concerns?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No
4 ☐ I have had no worries or concerns

**A6.** Have you been able to speak to a doctor about your baby **as much as you want?**

1 ☐ Yes, definitely → **go to A8**
2 ☐ Yes, to some extent → **go to A7**
3 ☐ I have not wanted or needed to speak to a doctor → **go to A8**
4 ☐ No → **go to A7**

**A7.** What is **the main reason** you have **not** been able to speak to a doctor as much as you want?

1 ☐ Doctors don't appear approachable
2 ☐ Doctors appear too busy
3 ☐ Doctors are not present on the neonatal unit when I am there
4 ☐ I do not understand the doctors' explanations
5 ☐ Other (please specify): _____

_____

_____

**A8.** Have staff given you conflicting information about your baby's condition or care?

1 ☐ Yes, often
2 ☐ Yes, sometimes
3 ☐ No, not at all

**A9.** Overall, do you have confidence and trust in the staff members that have been caring for your baby?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No

## SECTION B. INFORMATION AND SUPPORT FOR PARENTS

**B1.** If you ask questions about your baby's condition and treatment, do you get answers you can understand?

1. ☐ Yes, always or nearly always
2. ☐ Yes, sometimes
3. ☐ No
4. ☐ I have not asked any questions

**B2.** Have you been given enough written information **(in paper or electronic form)** to help you understand your baby's condition and treatment?

1. ☐ I have not wanted or needed any written information
2. ☐ Yes, definitely
3. ☐ Yes, to some extent
4. ☐ No, I have not been given enough written information
5. ☐ No, I have not been given any written information

**B3.** Have you had an opportunity to go through *your baby's medical notes with staff in the neonatal unit?
*(See box below)*

> **Your baby's medical notes:*
> *are **NOT the nursing notes** left with the baby on the cot.*
> *They are notes SECURELY STORED WITH STAFF and contain medical information about your baby (plans from ward rounds etc)*

1. ☐ I did not know about the medical notes, but had I known I would have wanted to
2. ☐ I did not know about the medical notes, but had I known I still wouldn't have wanted to
3. ☐ Yes
4. ☐ No, but I want to
5. ☐ No, but I do not want to

**B4. In the last 24 hours**, how many times have you telephoned the neonatal unit?

1. ☐ One time
2. ☐ Two times
3. ☐ Three or more times
4. ☐ I have not telephoned the unit in the last 24 hours → **go to B6**

**B5. If you telephoned the unit,** what was the reason for your call?

***PLEASE SELECT ALL THAT APPLY***

1. ☐ I wanted information about ward round times
2. ☐ I wanted information about visiting times
3. ☐ I wanted information about parking
4. ☐ I wanted a general update about my baby
5. ☐ I wanted to discuss a change in my baby's care
6. ☐ I wanted information about breastfeeding and/or expressing
7. ☐ I wanted to ask for test results (please specify what type of tests): _____
8. ☐ I wanted to discuss a specific part of my baby's care (please specify which part): _____ _____
9. ☐ Other (please specify): _____ _____

**B6. In the last 24 hours**, how many times have you asked your baby's **nurse** for an update about your baby, face-to-face?

1. ☐ One time
2. ☐ Two times
3. ☐ Three or more times
4. ☐ I have not asked my baby's nurse for an update face-to-face in the last 24 hours

**B7.** On a scale of 1 to 10 how satisfied are you with the **frequency of updates** you receive from **nurses** about your baby on the neonatal unit?

| Extremely dissatisfied | | | | | | | | | Extremely satisfied |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**B8.** When **ward rounds** take place, are you present when your baby is being discussed?

1. ☐ Yes, always or nearly always
2. ☐ Yes, sometimes
3. ☐ No, I have not been allowed to be there
4. ☐ No, the ward round times are not convenient for me
5. ☐ Other (Please specify)_____

_____

**B9. In the last 24 hours**, how many times have you asked to speak with a **doctor (outside ward round times)**?

1. ☐ One time
2. ☐ Two times
3. ☐ Three or more times
4. ☐ I have not asked to speak with a doctor in the last 24 hours → **go to B11**

**B10. If you asked to speak with a doctor,** what did you want to discuss?

***PLEASE SELECT ALL THAT APPLY***

1. ☐ I wanted a general update about my baby
2. ☐ I wanted to discuss a change in my baby's care
3. ☐ I wanted to ask for test results (please specify which test): _____
4. ☐ I wanted to discuss a specific part of my baby's care (please specify which part): _____
5. ☐ Other (please specify): _____

_____

**B11.** On a scale of 1 to 10 how satisfied are you with the **frequency of updates** you receive from **doctors** about your baby on the neonatal unit?

| Extremely dissatisfied | | | | | | | | | Extremely satisfied |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**B12.** On a scale of 1 to 10 how satisfied are you with **how** you receive information about your baby on the neonatal unit?

| | Extremely dissatisfied | | | | | | | | | Extremely satisfied | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **a. Verbal updates** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | **N/A** |
| **b. Telephone calls** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | **N/A** |
| **c. Written information** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | **N/A** |
| **d. Overall** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | **N/A** |

**B13.** "I get the information I need to understand my baby's health status".

1. ☐ Strongly agree
2. ☐ Agree
3. ☐ Neither agree nor disagree
4. ☐ Disagree
5. ☐ Strongly disagree

## SECTION C. YOUR INVOLVEMENT IN YOUR BABY'S CARE

**C1.** Do the neonatal unit staff members include you in discussions about your baby's care and treatment?

1 ☐ Yes, always
2 ☐ Yes, sometimes
3 ☐ No

**C2.** Have you been told about any **changes** in your baby's condition or care?

1 ☐ Yes, always or nearly always
2 ☐ Yes, sometimes
3 ☐ No, I was not told about changes
4 ☐ Not sure/can't remember

**C3.** Overall, do staff help you feel confident in **caring** for your baby? **(nappy changes, feeds etc.)**

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No

**C4.** Are you involved as much as you want in the day-to-day care of your baby?

1 ☐ Yes, definitely
2 ☐ Yes, to some extent
3 ☐ No, I am not involved as much as I want
4 ☐ No, my baby is too ill

## SECTION D. LEAVING THE NEONATAL UNIT

**D1.** How likely are you to recommend this neonatal unit to friends and family, if their baby needed similar care or treatment?

1 ☐ Extremely likely
2 ☐ Likely
3 ☐ Neither likely nor unlikely
4 ☐ Unlikely
5 ☐ Extremely unlikely
6 ☐ Don't know

## SECTION E. YOUR COMMENTS

**E1.** If there is anything else you would like to tell us about your experience of care on the neonatal unit then please do so here.

**THANK YOU VERY MUCH FOR YOUR HELP**

## Appendix 15

## Run charts: Upper and lower limit of runs

| Total number of data points on run chart (not falling on the median) | Lower limit of runs for "too few" | Upper limit of runs for "too many" |
|---|---|---|
| 10 | 3 | 9 |
| 11 | 3 | 10 |
| 12 | 3 | 11 |
| 13 | 4 | 11 |
| 15 | 5 | 12 |
| --- | --- | --- |
| 22 | 7 | 17 |
| 24 | 8 | 18 |
| 36 | 13 | 24 |

*Table from NIHR CLAHRC NWL QI4U online learning module https://clahrcnwl.qi4u.org/scorm/6, accessed 23rd September 2019.*

# Appendix 16
# Parent Information Sheet 2: Piloting baby summaries

**BUDS Parent Information Sheet 2: Piloting baby summaries**
PIS2 v1.6/141118/IRAS ID:232205

**Title of Project: Better Use of Data to improve parent Satisfaction (BUDS)**

**1 We would like to invite you to participate in the BUDS research project.** Thank you for allowing us to discuss this with you. Please read this information and ask us about anything that is not clear.

**2 What is the purpose of this project?** 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. We 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. We want to give every parent a daily printed summary of their baby's information, taken from the electronic system. We have designed this with parents of babies that needed neonatal care and we now want to test it on our neonatal unit.

We want to give the summary sheet to parents every week day (not Saturdays or Sundays), and then ask them how they feel about this using a simple questionnaire. We would like to do this every week while a baby is on the neonatal unit. We will use this parent feedback to improve the way the summary sheet is designed. This project will go on for 2 months. It will only involve babies during their stay on the unit and not after discharge. In the future we hope to incorporate these summary sheets into a mobile phone application so that parents can access them even more easily.

**3 Why have I and my baby been invited?** We are approaching all parents of babies who are receiving care in our neonatal unit.

**4 Do I have to take part?** Not at all, this is entirely your choice and it will not affect the care you or your baby receives. If you agree you will be asked to sign a consent form and a copy will be given to you. If you decide to participate you may withdraw at any time without giving any reason. If you withdraw or lose capacity to consent, we will keep the information about you that we have already obtained and continue to use it confidentially in connection with the purposes for which consent is being sought.

**5 What does the project involve?** If you choose to take part you will be asked some basic details about yourself and your baby. You will then be given a printed summary sheet containing updates about your baby every morning on the unit on weekdays (Monday to Friday). We will ask you to complete an anonymous questionnaire before you start receiving the summaries and then twice a week until your baby is discharged. This will include questions on how you feel about receiving your baby's information and how involved you feel in your baby's neonatal care.

**6 How long will the project last?** We will test the summary sheets over 2 months. The number of times we will ask you to complete our questionnaire will depend on how long your baby is likely to stay on the unit and which unit area your baby is in at the time of recruitment. Your involvement in this project will end when your baby is discharged from our unit.

**7 What are the possible risks and disadvantages of taking part?** We don't think there are any risks or disadvantages of taking part in this project.

**8 What are the possible benefits of taking part?** You will be provided with written information specific to your baby during weekdays, which we hope will improve your understanding of your baby's condition and your neonatal experience in general. Your involvement will also help us evaluate and improve the summaries for use by future parents.

**9 What happens if something goes wrong?** It is extremely unlikely that anything will go wrong. However, if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the lead researcher, Dr Susanna Sakonidou. The normal National Health Service complaints mechanisms are also available to you. The Chelsea and Westminster hospital Patient Advice and Liaison Services (PALS) team can assist you with the NHS complaint process and provide independent advice (hospital ground floor, main atrium, opposite escalators and lift bank B, 0203 315 6727). If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office (JRCO) Sponsor Office.

**10 Will my taking part in this project be kept confidential?** It is likely the neonatal staff will know you are participating as the summaries will be administered on the neonatal unit. Your decision to participate, as well as withdraw at any time, will not affect the care your baby receives. Your questionnaire responses will be anonymised and only read by members of our research team.

Imperial College London will be using information from you in order to undertake this project and will act as the data controller and sponsor for this project. This means Imperial College London is responsible for looking after your information and using it properly. The Imperial College Neonatal Research Team will keep your name and contact details to contact you about the project, and make sure that relevant information about the project is recorded to oversee the quality of the project. The Imperial College Neonatal Research Team will keep identifiable information about you at Imperial College London premises and Chelsea and Westminster NHS Foundation Trust will keep identifiable information about your baby for 10 years after the project has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible. The only people at Imperial College London who will have access to information that identifies you will be people who need to contact you to send you a summary of findings or audit the data collection process. The JRCO sponsor office will not be sent any identifiable information about your baby from Chelsea and Westminster NHS Foundation Trust or any identifiable information about you from the Imperial College Neonatal Research Team. However, individuals from the JRCO Sponsor, NHS and regulatory organisations may look at yours and your baby's research records to check the accuracy of the research project. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. You can find out more about how we use your information by contacting the lead researcher (see details below).

When you agree to take part in a research study, the information you give to the project about your experience of neonatal care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

**11 What will happen to the results of the project?** Project conclusions will be published in scientific journals and presented at scientific meetings, including anonymised direct quotes from interviews, but you will not be identified in any way. If you agree, we will send you a summary of the findings.

**12 Who is sponsoring this project?** Imperial College London is the sponsor, based in the United Kingdom.

**13 Who has reviewed and approved this project?** This project has been reviewed and approved by the West Midlands - South Birmingham REC (18/WM/0175) and is being conducted as part of the lead researcher's PhD.

**Thank you for reading this.**


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## Appendix 17

## Parent Consent Form 2: Piloting baby summaries

**BUDS Consent Form 2: Piloting baby summaries**
v1.6/141118/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

**Parent's Name:**

**Please initial each box to indicate agreement. You will be given a copy of this form.**

1. I confirm that the purpose of the project and what it involves has been explained to me. ☐

2. I have read the *Parent Information Sheet 2 : Piloting Baby Summaries v1.6/141118* and have been given the opportunity to ask questions and discuss this project with the BUDS team. ☐

3. I understand that my participation is voluntary, and that I am free to withdraw at any time without giving any reason and without affecting my medical care or legal rights or those of my baby. ☐

4. I understand that anonymised quotes may be included in research and consequent publications, but not in any way that might allow for identification of individual participants. ☐

5. 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. ☐

6. I agree that all anonymised project data will be stored on secure NHS and Imperial College London computer systems/premises for 10 years (Imperial Policy). ☐

7. I agree that my details, including personally identifiable details and a copy of this consent form will be stored for 10 years (Imperial Policy) in a secure, locked, neonatal research office with restricted access to members of the research team. ☐

8. I agree to take part in this study. ☐

9. I would like to be sent a summary of the study results. ☐

| _____ | _____ | _____ |
|---|---|---|
| Name of parent | Date | Signature |
| _____ | _____ | _____ |
| Name of researcher taking consent | Date | Signature |

## Appendix 18

## Parent Demographic Form

**BUDS Parent Demographics Form**
v1.1/141118

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

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**We would like to know a bit more about you and your baby.**

**This information will help us ensure we include the experiences of a diverse group of parents. All answers will be anonymised and kept confidential for use within our research team.**

**Please circle what applies:**

**What is your age?**

- Under 18
- 18-24
- 25-29
- 30-35
- Over 35

**What is your gender?**

- Female
- Male
- Other (please specify) _____

**What is your ethnic group?**

- White
- Mixed
- Asian or Asian British
- Black or Black British
- Chinese
- Other (please specify) _____

**At how many weeks gestation was your baby born?**

_____

**How long has your baby been on this neonatal unit for?**

- Under 1 week
- 1-2 weeks
- 2-4 weeks
- 1-2 months
- 2-4 months
- 4-6 months
- Over 6 months

# Appendix 19

# Staff Information Sheet

**BUDS Staff Information Sheet**
SIS v1.4/170518/IRAS ID:232205

**Title of Project: Better Use of Data to improve parent Satisfaction (BUDS)**

**We would like to invite you to participate in the BUDS research project.**

**1 What is the purpose of this project?** One in eight babies born in the UK require neonatal care. This is stressful for parents, who rely on neonatal staff for verbal updates about their baby, and often feel they aren't involved in their baby's care. We want to improve how parents receive information and how involved they feel in their baby's care, by regularly sharing some of the electronic patient record information with parents in a printed 24-hour summary sheet that is easy to understand. We have designed a draft summary sheet with parents and we now want to test it on our neonatal unit. We will give the summary sheet to parents every day and ask them to complete a written satisfaction questionnaire every week, until their baby is discharged. We will use this parent feedback to continually adjust the summary design until we achieve overall parent agreement. We will do this for 2 months. The next step will be to incorporate these summaries into a mobile phone application for parents to automatically access themselves. In addition to assessing this tool's impact on parent satisfaction levels, we would like to find out how it affects parent-staff interactions and staff workload. We would like to speak with 1 neonatal nurse from each of the 3 intensity unit areas and 2 doctors from the unit at the beginning and end of the 2 month period.

**2 What does the project involve?** If you choose to take part you will be asked to speak with the lead researcher, Dr Susanna Sakonidou, for 10 minutes. You will be asked how you feel about the way parents approach you for updates about their babies and how updating parents affects your workload. We will audiorecord the interviews so we can transcribe and analyse them. Transcripts will be anonymised and recordings will be destroyed at the end of the project.

Imperial College London will be using information from you in order to undertake this project and will act as the data controller and sponsor for this project. This means Imperial College London is responsible for looking after your information and using it properly. The Imperial College Neonatal Research Team will keep your name and contact details to contact you about the project, and make sure that relevant information about the project is recorded to oversee the quality of the project. The Imperial College Neonatal Research Team will keep identifiable information about you for 10 years after the project has finished at Imperial College London premises . Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible. Individuals from the JRCO Sponsor, NHS and regulatory organisations may look at your research records to check the accuracy of the research project. The only people at Imperial College London who will have access to information that identifies you will be people who need to contact you to send you a summary of findings or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. You can find out more about how we use your information by contacting the lead researcher (see details below). Conclusions will be published in scientific journals and presented at scientific meetings, including anonymised direct quotes, but you will not be identified in any way.

When you agree to take part in a research study, the information you give to the project about your experience of neonatal care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of

health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

3. **Do I have to take part?** Not at all, this is entirely your choice and there will be no negative consequences if you decide not to participate If you withdraw or lose capacity to consent, we will keep the information about you that we have already obtained and continue to use it confidentially in connection with the purposes for which consent is being sought.

4 **Who is sponsoring this project?** Imperial College London is the sponsor, based in the United Kingdom.

5 **Who has reviewed and approved this project?** This project has been reviewed and approved by the West Midlands - South Birmingham REC (18/WM/0175) and is being conducted as part of the lead researcher's PhD.

**Thank you for reading this.**


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# Appendix 20

# Staff Consent Form

**BUDS Staff Consent Form**
v1.4/170518/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

**Staff member's name:**

**Please initial each box to indicate agreement. You will be given a copy of this form.**

1. I confirm that the purpose of the project and what it involves has been explained to me. ☐

2. I have read the *Staff Information Sheet v1.4/170518* and have been given the opportunity to ask questions and discuss this project with the BUDS team. ☐

3. I understand that my participation is voluntary, and that I am free to withdraw at any time without giving any reason. ☐

4. I understand that anonymised quotes may be included in research and consequent publications, but not in any way that might allow for identification of individual participants. ☐

5. 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. ☐

6. I give my permission for an audio recording of my interviews and for the audio recording to be used for anonymous transcription and analysis of results. ☐

7. I agree that all anonymised project data will be stored on secure NHS and Imperial College London computer systems/premises for 10 years (Imperial Policy). ☐

8. I agree that my details, including personally identifiable details and a copy of this consent form will be stored for 10 years (Imperial Policy) in a secure, locked, neonatal research office with restricted access to members of the research team. ☐

9. I agree to take part in this study. ☐

| _____ | _____ | _____ |
|---|---|---|
| Name of staff member | Date | Signature |
| _____ | _____ | _____ |
| Name of researcher taking consent | Date | Signature |

## Appendix 21

## Staff Survey

### Neonatal staff survey

The BUDS research team is conducting a brief unit survey on how updating parents affects staff workload. Thank you for answering this anonymous survey.

**I am a:**

- Nurse
- Doctor

**Q1. In the last 24 hours**, have you updated parents during a ward round?

- Yes
- No

**Q2. In the last 24 hours,** how many times have you spoken to parents face-to-face about their baby? **(outside ward round times)**

Please insert number of times: _____

**Q3. In the last 24 hours**, how many times have you spoken to parents over the phone?

Please insert number of times: _____

## Appendix 22
## Considerations for generation of PEC survey run charts

- In order to generate run charts for the '*baseline period'* versus *'intervention period'*, the frequency of data points had to be consistent in both periods

- During the '*baseline period'* PEC surveys were distributed on the CW NNU every Tuesday and Friday for 6 weeks. Due to the nature of neonatal care and parents' variable visiting patterns, it was not possible to only recruit parents specifically on Tuesdays or Fridays, during the *'intervention period'.*

- I recruited parents during the *'intervention period'* on any weekday (when they also completed a *'first survey response'*) after which they completed subsequent surveys on Tuesdays and Fridays.

- In order to match the twice-weekly pattern of data points from the '*baseline period',* I combined all *'intervention period'* survey responses from Mondays-Tuesdays into a *'Tuesday data point'* and all survey responses from Wednesdays-Thursdays-Fridays into a *'Friday data point'.*

## Appendix 23
## Methodological considerations for STEPS 1-2 of PEC survey analysis

**STEP 1:** Comparing the means of *'first survey question responses'* in the baseline period to the means of *'first survey question responses'* in the intervention period

Null hypothesis: *'First survey responses'* during the 6-week baseline period were not different to *'first survey responses'* during the intervention period.

For the continuous PEC questions, I planned to use either the parametric independent t-test or the non-parametric Mann-Whitney, depending on the final number of parents participants in both baseline and intervention periods.

For the categorical PEC questions, I used the chi-square test to compare the percentage distributions of *'first survey responses'* in the baseline versus the intervention period.

**STEP 2:** Comparing the means of *'second survey question responses'* in the baseline period to the means of *'second survey question responses'* in the intervention period.

Null hypothesis: *'Second survey responses'* during the 6-week baseline period were not different to *'second survey responses'* during the intervention period.

I used the same statistical tests as per Step 1.

## Appendix 24

## Methodological considerations for STEP 3 of PEC survey analysis

**STEP 3:** Evaluating the difference in means between *'first survey question responses'* and *'second survey question responses'*, both in the baseline and the intervention period.

Null hypothesis: *'Second survey responses'* were not different to *'first survey parent responses' (*separately in the baseline and the intervention period).

Due to the high turnover of infants in neonatal care, coupled with unpredictable transfers to other hospital or discharges, it was anticipated that minimum and maximum number of times of survey completion per parent would vary, both in the baseline and the intervention period. Some parents would likely complete the PEC survey only once if their infant was transferred or discharged before the second survey administration. Similarly, it was expected that some parents might omit answering certain survey questions (during any of the times they completed the survey).

Therefore, due to the nature of neonatal care and the study design, the inherent structure of the data was anticipated to be that of a partially paired data set, representing a combination of paired and unpaired observations. This would mean one sample of parents who have completed both first and second surveys (the paired subsample), and another subsample of parents who have completed only one of the surveys, either first or second (unpaired subsample).

As most parents were expected to complete the PEC survey more than once, a paired t-test would seem appropriate for this *'first versus second survey comparison'*, as it would test the within-subject first-to-second survey difference. However, I would have to discard part of the data (discard the unpaired surveys and use the paired t-test for the remaining paired surveys), meaning the paired t-test would not be efficient.

Guo and Yuan (71) conducted a review of different paired statistical tests to use when comparing paired to unpaired samples. On conducting extensive simulation studies including a wide range of scenarios with different sample sizes and effect sizes, they demonstrated that *'when the sample size is small, the optimal pooled t-test is to be recommended when both variables have missing data'* (71).

In line with Guo and Yuan's recommendations and to maximise my chosen test's power, I have used the optimal pooled t-test for those questions where both first and second survey responses had at least 2 fields of missing data on either side (unpaired data in both first and second survey responses).

For the questions with less than 2 fields of missing data from either survey, I have used the corrected z-test instead; another method discussed by Guo and Yuan (71) which performs best with unpaired data only from one of the surveys (first or second).

The above applies to the continuous PEC questions only. For the categorical PEC questions there is no available alternative partially paired data test to the optimal pooled t-test or corrected z-test.

Statistical tests:

- Optimal pooled t-test: A full description of the optimal pooled t-test is beyond the scope of this thesis. In summary, the optimal pooled t-test ($Tpool0$) pools the first and second survey mean differences between paired surveys and unpaired surveys to construct a t-test statistic. The standard 'pooled t-test' assigns equal weights to the two estimates of the mean difference, which may not be optimal in terms of the statistical power. Instead, the optimal pooled t-test (an extension of the pooled t-test) assigns optimal weights of the two estimates to achieve higher power (71). I conducted the corrected z-test using the statistical software SPSS 25.

- Corrected z-test: In summary, the corrected z-test compares the means of all *'first survey responses'* versus all *'second survey responses'* (i.e.

including all unpaired data), while accounting for the variance of the paired data samples only. I conducted the corrected z-test using the statistical software R 3.6.0.

## Appendix 25
## Considerations for use of ANCOVA test in STEP 4 PEC analysis

Using the ANCOVA test assumes homogeneity of samples, meaning that the comparison groups (in this case the *'second survey question responses'* in the baseline period versus the intervention period) have the same variance.

To test for homogeneity of variance I have used the most commonly used Levene's test. This uses an F-test to test the null hypothesis that variance is equal across both groups. A p value less than 0.05 signifies a violation of this assumption. However, the ANCOVA test is robust to the violation of assumption of homogeneity as long as the group sizes are similar enough (the ratio of the largest to smallest group being less than 1.5).

## Appendix 26

## Stage 2 'Roll-out': Four PDSA cycle changes during 6-week intervention period to improve MBSR template

**PDSA cycle 1 changes (from week 1 to week 2)**
I applied a box outline to each of the body systems, to visually categorise information for better ease of reading.

- I included a telephone number for the NICU area each infant was in at the time of MBSR administration.

- I included a 13th EPR data item in the template (Volume of milk taken, in ml), in response to parents wanting more detailed information about feeding.

**PDSA cycle 2 changes (from week 2 to week 3)**
I made a minor amendment to the data origin explanation on the top of MBSR, in order to highlight that MBSR information is not manually retrieved from clinical notes but rather directly originates from what is recorded on EPR overnight. This was in response to further parent feedback in PEC surveys about missing data from the MBSR.

Data explanation in week 2 MBSR template:
*'Information is derived from the specific data already available in the neonatal Electronic Patient Record system. Electronic summaries are updated every night by nurses and include information from the previous day.'*

Data explanation in revised week 3 MBSR template:
*'Information is automatically extracted from the electronic database that nurses manually update every night. This summary includes information from the previous day.'*

- I included a 14th EPR data item in the template (Mode of non-invasive support), for if an infant was receiving non-invasive respiratory support.

- I added a further explanation to the EPR data item *'Supplemental oxygen'* about what the amount of oxygen received means:

<=1 litre per minute (added the phrase *'a small amount'*)
>1 litre per minute (added the phrase *'a small/moderate amount'*)

- I added a section on *'Brain'*, in response to parents asking for the MBSR to include information about head scans. As head scan information is not consistently recorded on EPR (and head scans are not performed daily) this was explained in this section:

*'BRAIN: Head scans (medical term "cranial ultrasound") are done for every baby on the unit and are repeated at different time points for each baby,*

*according to gestation and clinical condition. Please ask us to discuss with you what applies to [baby's name].'*

**PDSA cycle 3 changes (from week 4 to week 5)**

- I added an explanation on how infants progress through the different levels of care in NICU:

*'[Baby's name] is receiving the highest level of care in the Intensive care Unit (ITU). The next level down as [baby's name] improves is the High Dependency Unit (HDU).*

*[Baby's name] is receiving intermediate level care in the High Dependency Unit (HDU). The next level down as [baby's name] improves is the Special Care Baby Unit (SCBU).*

*[Baby's name] is receiving the lowest level of care in the Special Care Baby Unit (SCBU). The next step as [baby's name] further improves will be to go home'.*

- I removed the *'Brain'* section from PDSA cycle 2 and instead added information about head scans in a generic section about *'Tests'*:
*'TESTS: Blood tests, head scans (medical term "cranial ultrasound") and other scans are done at different time points for each baby, according to gestation and clinical condition. Please ask us to discuss with you what applies to [baby's name]'.*

- I added basic explanations about different medication functions in the *'Current medication'* section. For example: '*Caffeine (to help stimulate his/her breathing)'.*

**PDSA cycle 4 changes (from week 5 to week 6)**

- I made a minor amendment to the '*Tests'* section, in order to highlight that information about tests in not available on the neonatal EPR and therefore cannot be shared on the MBSR.

*'Blood tests, head scans (medical term "cranial ultrasound") and other scans are done at different time points for each baby, according to gestation and clinical condition. Results are held in a few different electronic databases (not the one this summary comes from). Please ask us to discuss [baby's name] test results with you.'*

## Appendix 27

## Levene's test results for ANCOVA test in STEP 4 PEC analysis

Levene's assumption of homogeneity was violated only for one question: B6.' *In the last 24 hours, how many times have you asked your baby's nurse for an update about your baby, face-to-face? Please insert number of times'.*

F(1,32)=4.507, p=0.042. This means that the variance *of 'second survey question responses'* in the baseline period differed from the variance of *'second survey question responses'* in the intervention period. However, since the number of parents that gave *'second survey question responses'* in the baseline period (14 parents) and the intervention period (20 parents) are considered similar enough (the ratio of the largest to smallest group is 1.43 and less than 1.5), in this case the ANCOVA test was robust to the violation of assumption of homogeneity and could still be used.

## Appendix 28

## Dividing question B2 into 2 parts, for ease of analysis

Question B2: *'Have you been given enough written information (in paper or electronic form) to help you understand your baby's condition and treatment?'.*

Response options included:

*1. I have not wanted or needed any written information*
*2.Yes, definitely*
*3. Yes, to some extent*
*4. No, I have not been given enough written information*
*5. No, I have not been given any written information*

All response options *(1-5)* did not originally fall into the same Likert scale. I have therefore analysed responses by parents *'not wanting written information' (response option 1)* versus *'wanting written information' (response options 2-5).*

New question B2 part 1: *'Have you been given enough written information (in paper or electronic form) to help you understand your baby's condition and treatment?'.* New responses:

*1. I have not wanted or needed any written information*
*2. I have wanted or needed written information*

Subsequently I have analysed the parent responses of *'wanting written information' (response options 2-5)* separately, renumbered as 1-4; this is re-defined as:

New question B2 part 2: 'Have you been given enough written information (in paper or electronic form) to help you understand your baby's condition and treatment?'. New responses:

*1. Yes definitely*
*2. Yes, to some extent*
*3. No, I have not been given enough written information*
*4. No, I have not been given any written information*

## Appendix 29
## STEP 1 of PEC survey analysis results

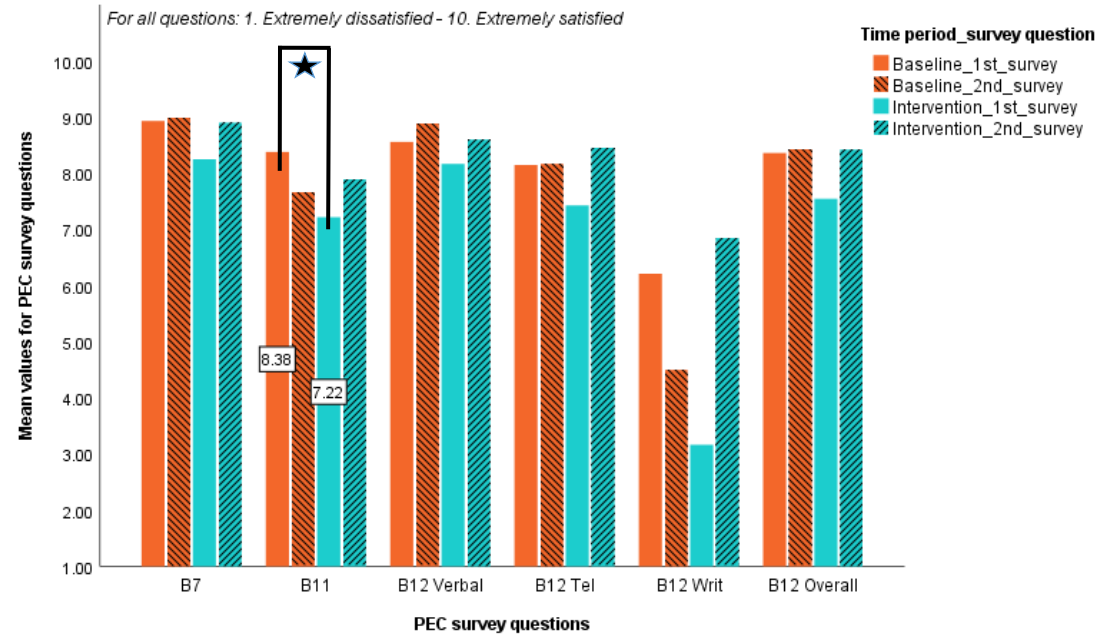
**STEP 1:** Comparing the means of *'first survey question responses'* in the baseline period (43 parent surveys) to the means of *'first survey question responses'* in the intervention period (24 parent surveys).

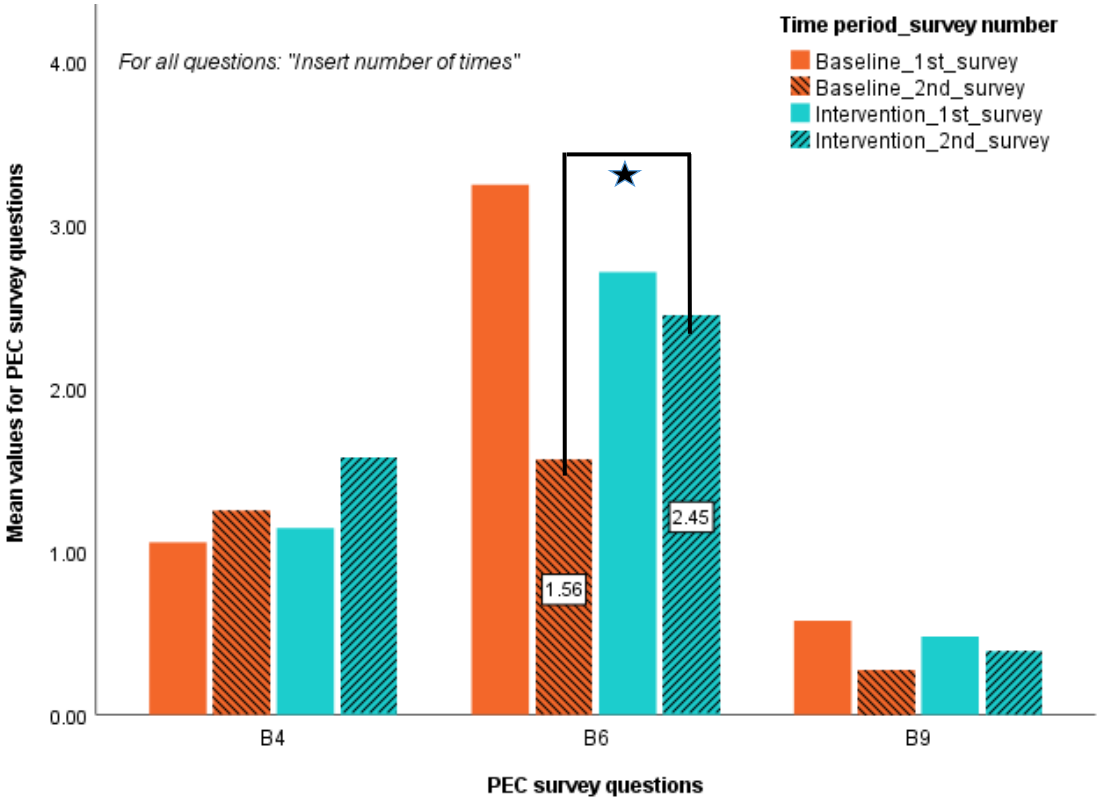
Continuous questions

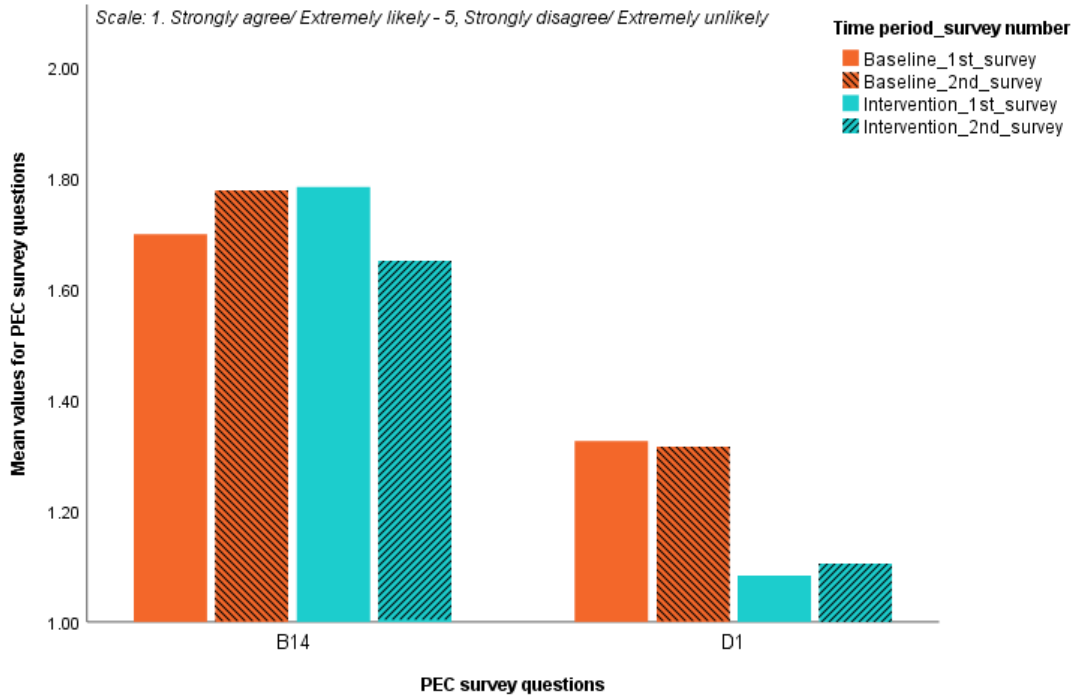
In view of the small number of parents completing a first survey in the intervention period (24 parents) and as per the Analysis section, I used the Mann-Whitney test for continuous questions in STEP 1. There was a statistically significant difference between *'first survey mean responses'* in the baseline versus the intervention period, only for primary outcome question B11: *'On a scale of 1 to 10 how satisfied are you with the frequency of updates you receive from doctors about your baby on the neonatal unit?'.* The first survey mean parent response during the baseline period was 8.38/10 and during the intervention period 7.22/10, p=0.030. This indicates that during the intervention period, parents on average were less satisfied with the frequency of updates received from doctors, compared to parents during the baseline period, even before they received the communication tool.

Below is a graphical representation of all mean responses for continuous questions in first and second completed surveys, in both baseline and intervention periods. It includes 3 separate graphs, to group questions with similar response scales together. Statistically significant difference is highlighted by an asterisk.

**Means of PEC survey questions, per time period (baseline/intervention) and per survey number (1st/2nd)**





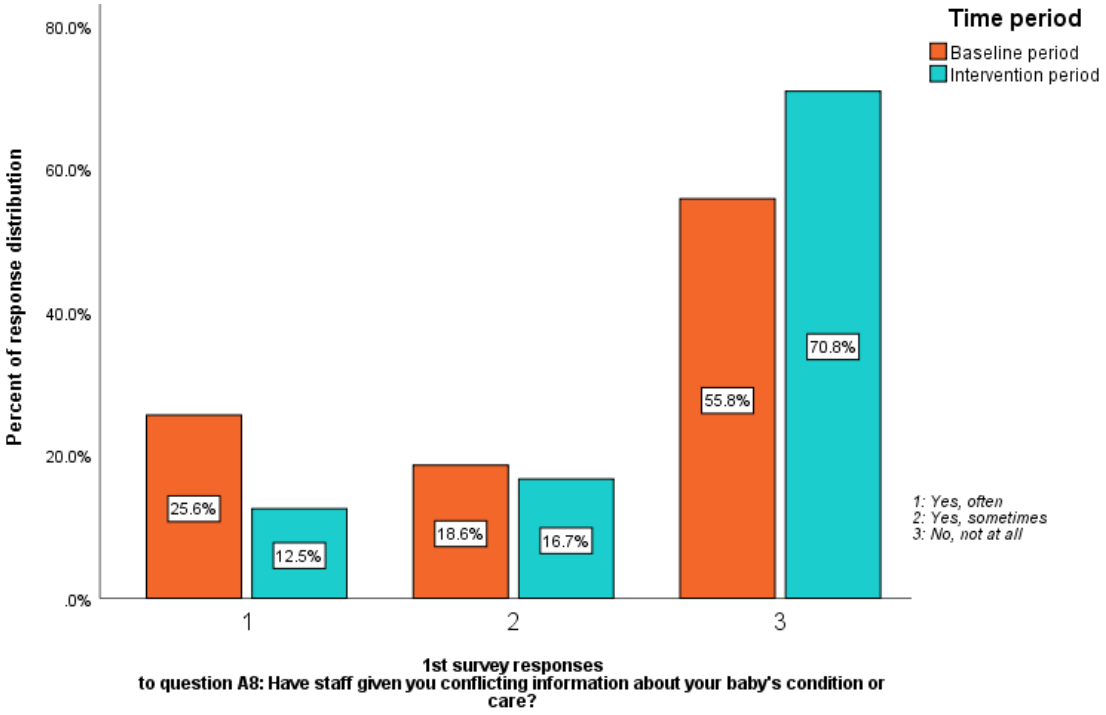

*Means of survey questions (order of bars: baseline 1st survey; baseline 2nd survey; intervention 1st survey; intervention 2nd survey). *Statistically significant difference between 2 marked bars on using the Mann Whitney test.*

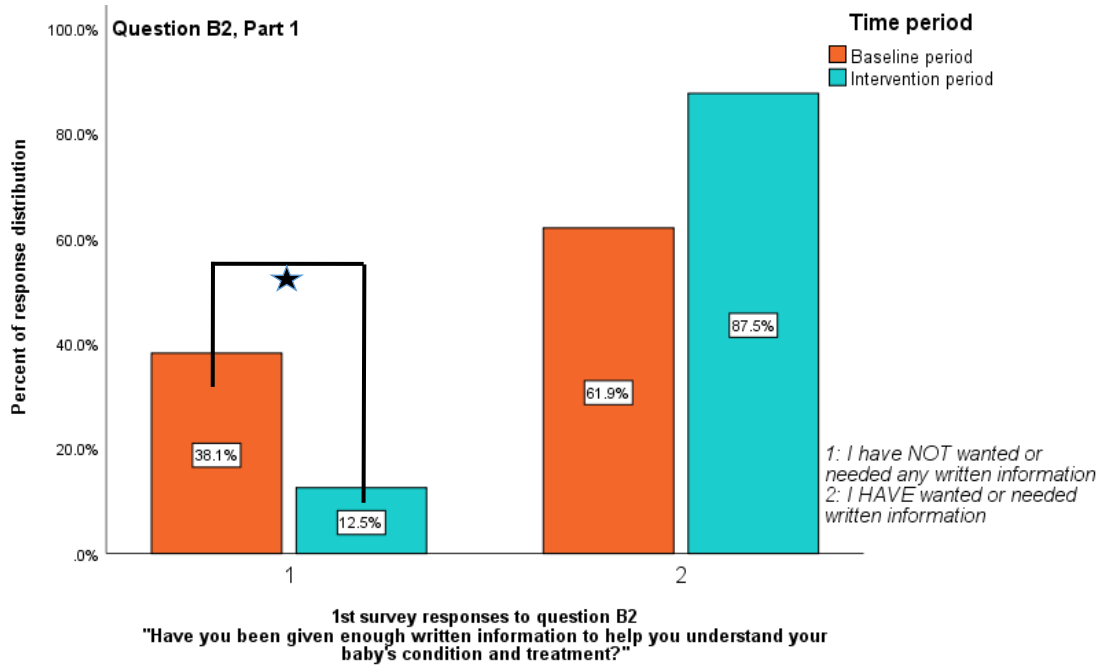
Categorical questions

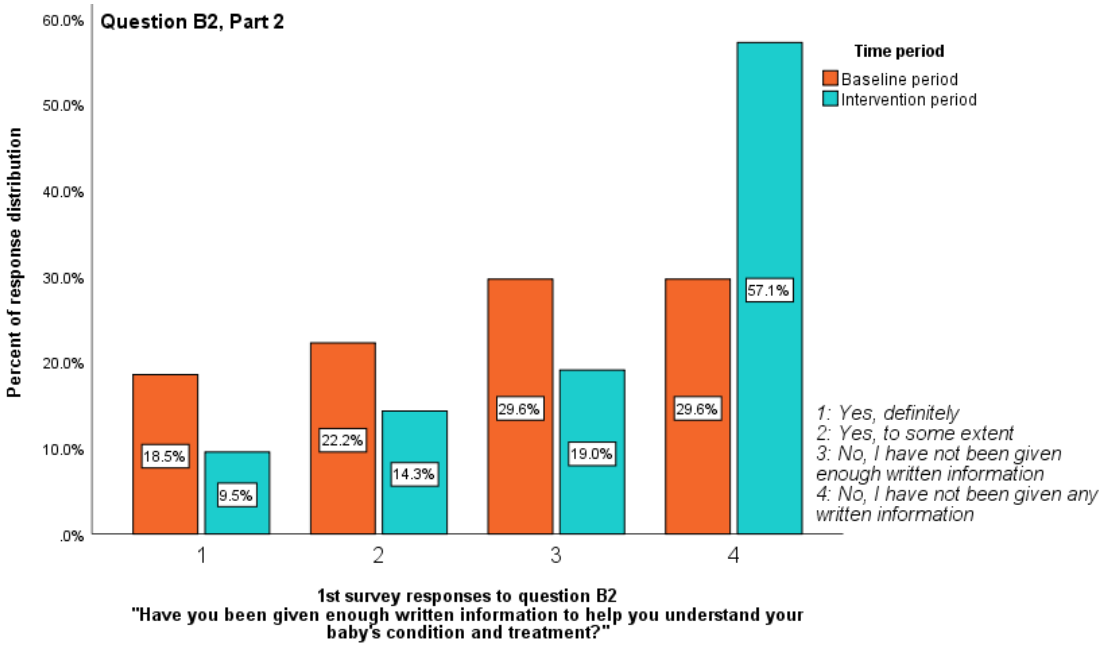
For the categorical variable questions (A8, B2 part 1, B2 part 2), the graphs below shows a comparison of *'first survey response'* distributions in the baseline versus the intervention period. Each graph displays the percentages of response distributions for each question.

There was a statistically significant difference between 'first survey response' distributions in the baseline versus the intervention period, only for primary outcome question B2 part 1: *'Have you been given enough written information to help you understand your baby's condition and treatment? '.* The percentage of parents not wanting or needing any written information in first surveys in the baseline period (38.1%) was statistically significantly higher than in the intervention period (12.5%) ($x^2$=4.881, p=0.027).

**1st survey response distributions in the baseline versus the intervention period (categorical questions A8, B2 part 1 and B2 part 2)**






*Percentages of first survey responses to survey questions, in baseline versus intervention period. *Statistically significant difference between 2 marked bars on using the chi-square test or Fisher's exact test.*

The following table includes the revised statistical tests and results for the categorical questions' analysis.

### 1st survey response distributions in the baseline versus the intervention period: categorical questions

| Question | Test used | Result |
|---|---|---|
| ***A8:*** *Have staff given you conflicting information about your baby's condition or care?* | Fisher's exact test<br><br>This was used because 1 field had a count less than 5 and the originally planned chi-square test would not perform well | Percentage distributions of first survey responses for question A8 were not statistically significantly different in the baseline versus the intervention period (p=0.425). |
| ***B2 part 1:*** *'Have you been given enough written information to help you understand your baby's condition and treatment?'*<br><br>*1. I have not wanted or needed any written information*<br>*2. I have wanted or needed written information* | Chi-square test | The percentage of parents not wanting or needing any written information in first surveys in the baseline period (38.1%) was statistically significantly higher than in the intervention period (12.5%) ($x^2$=4.881, p=0.027). |
| ***B2 part 2:*** *'Have you been given enough written information to help you understand your baby's condition and treatment?'* | Fisher's exact test<br><br>This was used because 3 fields had a count less than 5 and the originally | Percentage distributions of first survey responses were not statistically significantly different in the baseline versus the intervention period (p=0.382). |

| | | |
|---|---|---|
| *1. Yes definitely*<br>*2. Yes, to some extent*<br>*3. No, I have not been given enough written information*<br>*4. No, I have not been given any written information* | planned chi-square test would not perform well | |

## Mean values of all 1st survey responses per question, in baseline and intervention period.

**Group Statistics**

| Intervention | | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| B4 (N of times) | Baseline_period | 36 | 1.0556 | 1.16972 | 0.19495 |
| | Intervention_period | 21 | 1.1429 | 1.35225 | 0.29508 |
| B6 (N of times) | Baseline_period | 37 | 3.2432 | 2.26575 | 0.37249 |
| | Intervention_period | 24 | 2.7083 | 1.82921 | 0.37339 |
| B7 (1-10) | Baseline_period | 43 | 8.9302 | 1.20308 | 0.18347 |
| | Intervention_period | 24 | 8.2500 | 1.96159 | 0.40041 |
| B9 (N of times) | Baseline_period | 40 | 0.5750 | 0.74722 | 0.11815 |
| | Intervention_period | 23 | 0.4783 | 0.99405 | 0.20727 |
| B11 (1-10) | Baseline_period | 42 | 8.3810 | 1.78000 | 0.27466 |
| | Intervention_period | 23 | 7.2174 | 2.33465 | 0.48681 |
| B12 (1-10: Verbal updates) | Baseline_period | 43 | 8.5581 | 1.68045 | 0.25627 |
| | Intervention_period | 24 | 8.1667 | 1.90347 | 0.38854 |
| B12 (1-10: Telephone calls) | Baseline_period | 27 | 8.1481 | 2.44483 | 0.47051 |
| | Intervention_period | 14 | 7.4286 | 3.32159 | 0.88773 |
| B12 (1-10: Written information) | Baseline_period | 19 | 6.2105 | 3.32631 | 0.76311 |
| | Intervention_period | 6 | 3.1667 | 2.31661 | 0.94575 |
| B12 (1-10: Overall) | Baseline_period | 39 | 8.3590 | 1.63010 | 0.26102 |
| | Intervention_period | 22 | 7.5455 | 2.01724 | 0.43008 |
| B14 (1-5) | Baseline_period | 43 | 1.6977 | 0.67383 | 0.10276 |
| | Intervention_period | 23 | 1.7826 | 0.73587 | 0.15344 |
| D1 (1-6) | Baseline_period | 43 | 1.3256 | 0.64442 | 0.09827 |
| | Intervention_period | 24 | 1.0833 | 0.28233 | 0.05763 |

## Comparing mean values of 1st survey responses per question, in baseline and intervention period, using the Mann-Whitney test

**Test Statistics[a]**

| | B4 (N of times) | B6 (N of times) | B7 (1-10) | B9 (N of times) | B11 (1-10) | B12 (1-10: Verbal updates) | B12 (1-10: Telephone calls) | B12 (1-10: Written information) | B12 (1-10: Overall) | B14 (1-5) | D1 (1-6) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Mann-Whitney U | 374.500 | 391.500 | 406.500 | 389.000 | 328.000 | 437.000 | 168.500 | 28.000 | 323.000 | 466.000 | 435.000 |
| Wilcoxon W | 1040.500 | 691.500 | 706.500 | 665.000 | 604.000 | 737.000 | 273.500 | 49.000 | 576.000 | 1412.000 | 735.000 |
| Z | -0.062 | -0.791 | -1.493 | -1.176 | -2.172 | -1.066 | -0.588 | -1.870 | -1.625 | -0.420 | -1.588 |
| Asymp. Sig. (2-tailed) | 0.951 | 0.429 | 0.135 | 0.240 | 0.030 | 0.287 | 0.557 | 0.062 | 0.104 | 0.675 | 0.112 |
| Exact Sig. [2*(1-tailed Sig.)] | | | | | | | .577[b] | .069[b] | | | |

a. Grouping Variable: Intervention

b. Not corrected for ties.

**Appendix 30**

**STEP 2 of PEC survey analysis results**

**STEP 2:** Comparing the means of *'second survey question responses'* in the baseline period (19 parent surveys) to the means of *'second survey question responses'* in the intervention period (20 parent surveys)

Continuous questions

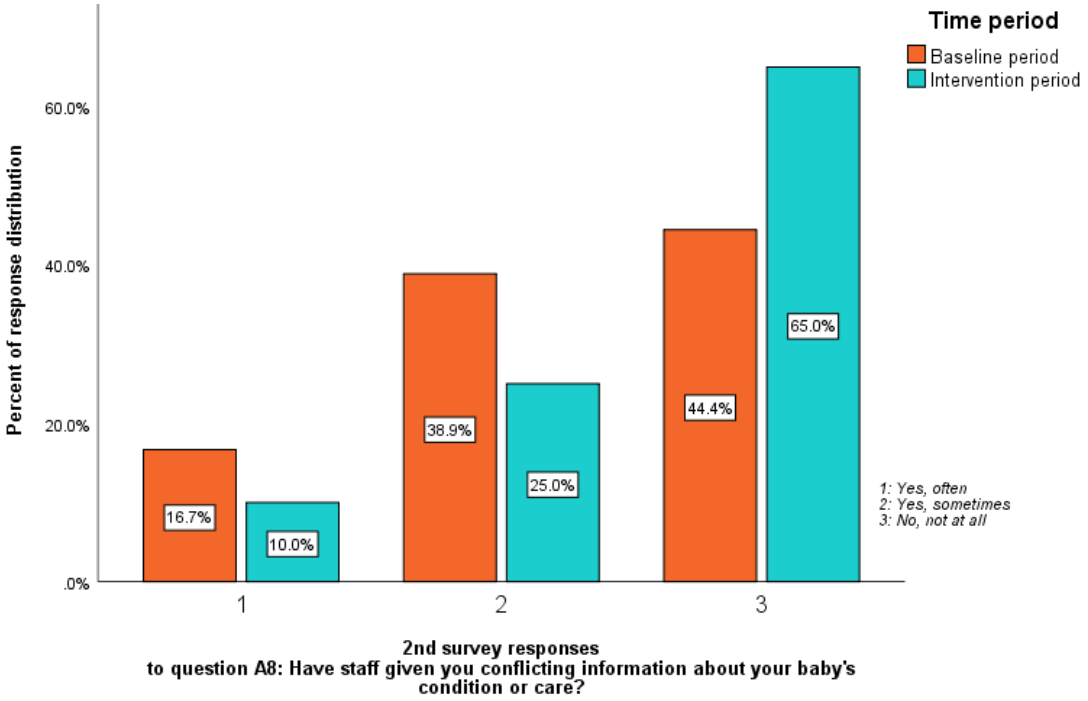
In view of the small number of parents completing a second survey in both time periods (19 and 20 parents, respectively), I used the non-parametric version of the independent t-test, the Mann-Whitney test, for continuous questions in STEP 2.

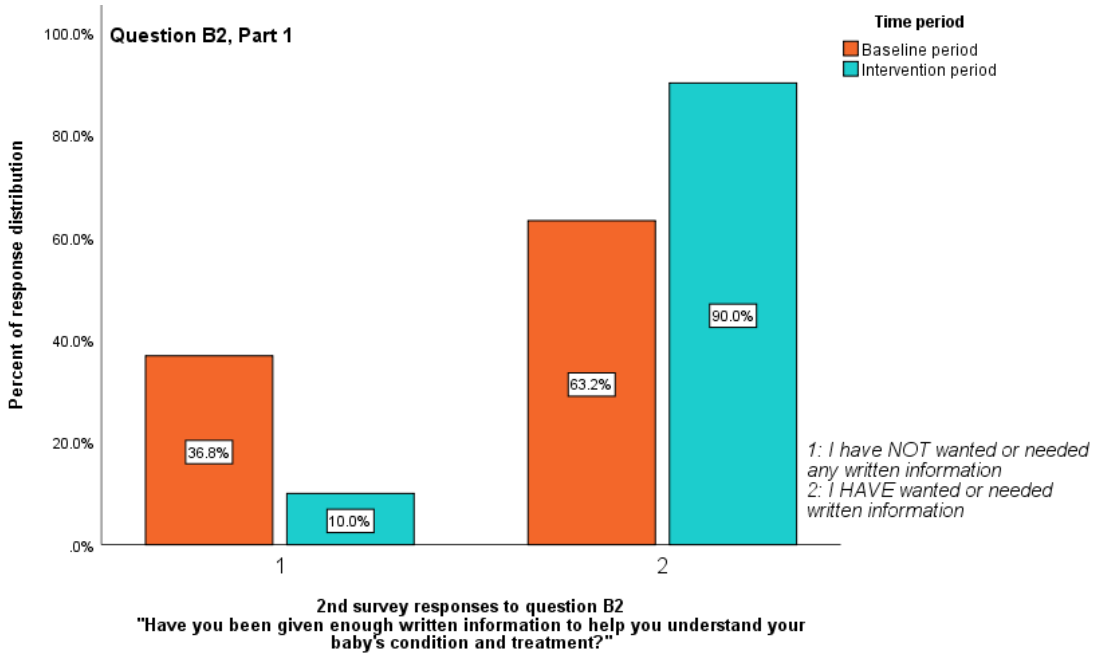
There was a statistically significant difference between 'second survey mean responses' in the baseline versus the intervention period, only for the secondary outcome (Parent-staff interactions) question B6: *'In the last 24 hours, how many times have you asked your baby's nurse for an update about your baby, face-to-face? Please insert number of times'.* The second survey mean parent response during the baseline period was '1.56 times' and during the intervention period '2.45 times', p=0.038. This indicates that during the intervention period and after having received the MBSR, parents on average asked their baby's nurse for a face-to-face update more frequently in a 24-hour period, compared to parents during the baseline period, who had not received the MBSR.

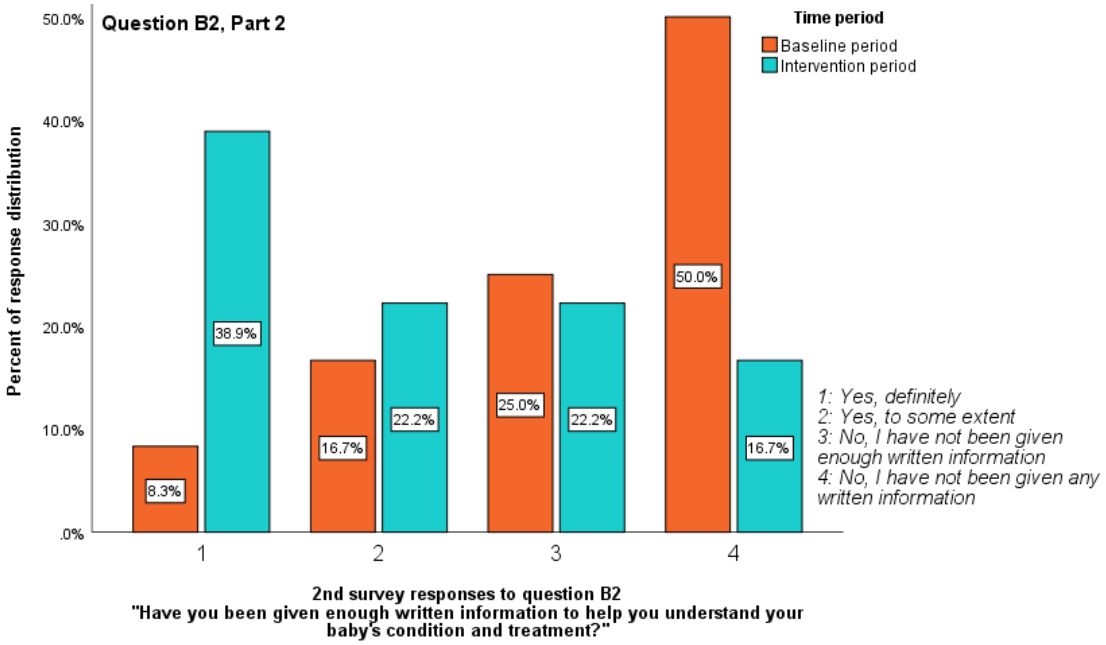
Categorical questions

For the categorical variable questions, the graph below shows a comparison of *'second survey response'* distributions in the baseline versus the intervention period; none were statistically significantly different.

## 2nd survey response distributions in the baseline versus the intervention period (categorical questions A8, B2 part 1 and B2 part 2)






*Percentages of 2nd survey responses to survey questions, in baseline versus intervention period.*

The following table includes the revised statistical tests and results for the categorical questions' analysis.

### 2nd survey response distributions in the baseline versus the intervention period: categorical questions

| Question | Test used | Result |
|---|---|---|
| ***A8:*** *Have staff given you conflicting information about your baby's condition or care?* | Fisher's exact test<br><br>This was used because 2 fields had a count less than 5 and the originally planned chi-square test would not perform well | Percentage distributions of second survey responses for question A8 were not statistically significantly different in the baseline versus the intervention period (p=0.486). |
| ***B2 part 1:*** *'Have you been given enough written information to help you understand your baby's condition and treatment?'*<br><br>*1. I have not wanted or needed any written information*<br>*2. I have wanted or needed written information* | Fisher's exact test<br><br>This was used because 2 fields had a count less than 5 and the originally planned chi-square test would not perform well | The percentages of parents not wanting or needing any written information in second surveys were not statistically significantly different in the baseline versus the intervention period (p=0.065). |
| ***B2 part 2:*** *'Have you been given enough written information to help you understand your baby's condition and treatment?'* | Fisher's exact test<br><br>This was used because 7 fields had a count less than 5 and the originally | Percentage distributions of second survey responses were not statistically significantly different in the baseline versus the intervention period (p=0.180). |

| | | |
|---|---|---|
| *1. Yes definitely*<br>*2. Yes, to some extent*<br>*3. No, I have not been given enough written information*<br>*4. No, I have not been given any written information* | planned chi-square test would not perform well | |

## Mean values of all 2nd survey responses per question, in baseline and intervention period

**Group Statistics**

| Intervention | | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| B4 (N of times) | Baseline_period | 16 | 1.2500 | 1.06458 | 0.26615 |
| | Intervention_period | 19 | 1.5789 | 1.38707 | 0.31822 |
| B6 (N of times) | Baseline_period | 16 | 1.5625 | 0.81394 | 0.20349 |
| | Intervention_period | 20 | 2.4500 | 1.31689 | 0.29447 |
| B7 (1-10) | Baseline_period | 19 | 9.0000 | 1.10554 | 0.25363 |
| | Intervention_period | 20 | 8.9000 | 1.11921 | 0.25026 |
| B9 (N of times) | Baseline_period | 18 | 0.2778 | 0.46089 | 0.10863 |
| | Intervention_period | 18 | 0.3889 | 0.60768 | 0.14323 |
| B11 (1-10) | Baseline_period | 18 | 7.6667 | 2.19625 | 0.51766 |
| | Intervention_period | 20 | 7.9000 | 2.04939 | 0.45826 |
| B12 (1-10: Verbal updates) | Baseline_period | 19 | 8.8947 | 1.19697 | 0.27460 |
| | Intervention_period | 20 | 8.6000 | 1.04630 | 0.23396 |
| B12 (1-10: Telephone calls) | Baseline_period | 12 | 8.1667 | 2.72475 | 0.78657 |
| | Intervention_period | 13 | 8.4615 | 2.50384 | 0.69444 |
| B12 (1-10: Written information) | Baseline_period | 8 | 4.5000 | 3.92792 | 1.38873 |
| | Intervention_period | 14 | 6.8571 | 3.25475 | 0.86987 |
| B12 (1-10: Overall) | Baseline_period | 16 | 8.4375 | 1.63172 | 0.40793 |
| | Intervention_period | 19 | 8.4211 | 1.26121 | 0.28934 |
| B14 (1-5) | Baseline_period | 18 | 1.7778 | 0.73208 | 0.17255 |
| | Intervention_period | 20 | 1.6500 | 0.81273 | 0.18173 |
| D1 (1-6) | Baseline_period | 19 | 1.3158 | 0.58239 | 0.13361 |
| | Intervention_period | 19 | 1.1053 | 0.31530 | 0.07234 |

# Comparing mean values of 2nd survey responses per question, in baseline and intervention period, using the Mann-Whitney test

**Test Statistics[a]**

| | B4 (N of times) | B6 (N of times) | B7 (1-10) | B9 (N of times) | B11 (1-10) | B12 (1-10: Verbal updates) | B12 (1-10: Telephone calls) | B12 (1-10: Written information) | B12 (1-10: Overall) | B14 (1-5) | D1 (1-6) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Mann-Whitney U | 132.500 | 97.500 | 178.500 | 150.500 | 164.500 | 158.500 | 75.000 | 38.000 | 142.000 | 157.500 | 151.000 |
| Wilcoxon W | 268.500 | 233.500 | 388.500 | 321.500 | 335.500 | 368.500 | 153.000 | 74.000 | 332.000 | 367.500 | 341.000 |
| Z | -0.667 | -2.078 | -0.340 | -0.453 | -0.466 | -0.918 | -0.172 | -1.247 | -0.341 | -0.720 | -1.279 |
| Asymp. Sig. (2-tailed) | 0.504 | 0.038 | 0.734 | 0.650 | 0.641 | 0.358 | 0.864 | 0.212 | 0.733 | 0.472 | 0.201 |
| Exact Sig. [2*(1-tailed Sig.)] | .523[b] | .046[b] | .749[b] | .719[b] | .654[b] | .380[b] | .894[b] | .238[b] | .756[b] | .515[b] | .402[b] |

a. Grouping Variable: Intervention

b. Not corrected for ties.

## Appendix 31

## STEP 3 of PEC survey analysis results

**STEP 3:** Evaluating the difference in means between *'first survey question responses'* and *'second survey question responses'*, both in the baseline and the intervention period.

Continuous questions

Using the optimal pooled t-test I compared the means of *'first survey question responses' to* the means of *'second survey question responses'* for each of the continuous PEC questions where both first and second survey responses had at least 2 fields of missing data on either side (6 'first /second survey' question pairs). I did this separately for the baseline and the intervention period. Overall, the optimal pooled t-test result was not statistically significant for any of the 6 question pairs (see table below).

### Optimal pooled t-test results for 6 'first/second survey' PEC question pairs

| **PEC Question 1st vs 2nd response (period)** | **mu-h** | **p-value** | **Stat. significance** |
|---|---|---|---|
| B4 (intervention) | -0.332 | 0.886 | FALSE |
| B6 (baseline) | 2 | 0.817 | FALSE |
| B12 tel (baseline) | 0.028 | 0.993 | FALSE |
| B12 tel (intervention) | -0.996 | 0.891 | FALSE |
| B12 written (intervention) | -2.568 | 0.924 | FALSE |
| B12 overall (intervention) | -0.919 | 0.843 | FALSE |

For the questions with less than 2 fields of missing data from either survey, I used the corrected z-test instead (16 'first / second survey' question pairs).

The corrected z-test result was not statistically significant for any of the 16 question pairs (see table below).

**Corrected z-test results for 16 'first/second survey' PEC question pairs**

| PEC question /period | 1st survey mean | 2nd survey mean | Mean difference | z_corr | p-value | Stat. significance |
|---|---|---|---|---|---|---|
| B4 baseline | 1.000 | 1.250 | -0.250 | -0.954 | 0.340 | FALSE |
| B7 baseline | 8.930 | 9.000 | -0.070 | -0.247 | 0.805 | FALSE |
| B9 baseline | 0.575 | 0.278 | 0.297 | 1.876 | 0.061 | FALSE |
| B11 baseline | 8.381 | 7.667 | 0.714 | 1.222 | 0.222 | FALSE |
| B12 verbal baseline | 8.558 | 8.895 | -0.337 | -1.072 | 0.284 | FALSE |
| B12 writ baseline | 6.211 | 4.500 | 1.711 | 1.377 | 0.169 | FALSE |
| B12 overall baseline | 8.359 | 8.438 | -0.079 | -0.216 | 0.829 | FALSE |
| B14 baseline | 1.698 | 1.778 | -0.080 | -0.449 | 0.653 | FALSE |
| D1 baseline | 1.326 | 1.316 | 0.010 | 0.087 | 0.930 | FALSE |
| B6 intervention | 2.708 | 2.450 | 0.258 | 0.601 | 0.548 | FALSE |
| B7 intervention | 8.25 | 8.900 | -0.650 | -1.493 | 0.136 | FALSE |
| B9 intervention | 0.478 | 0.389 | 0.089 | 0.335 | 0.737 | FALSE |
| B11 intervention | 7.217 | 7.900 | -0.683 | -1.158 | 0.247 | FALSE |
| B12 verbal intervention | 8.167 | 8.600 | -0.433 | -0.901 | 0.367 | FALSE |
| B14 intervention | 1.783 | 1.650 | 0.133 | 0.959 | 0.338 | FALSE |
| D1 intervention | 1.083 | 1.105 | -0.022 | -0.330 | 0.741 | FALSE |

Categorical questions

For the 2 categorical questions (A8, B2) there is no available alternative partially paired data test to the optimal pooled t-test or corrected z-test.

## Appendix 32

## Summary of STEPS 1-4 PEC survey analysis results

The table below summarises analysis steps 1-4 in evaluating the communication tool's impact on PEC questions, with the direction of effect highlighted. In count type questions (e.g. number of times telephoned the unit or level of satisfaction) I have highlighted the highest numerical mean in green (if the highest value was in the intervention period) or red (if in the baseline period). Similarly, in categorical type likert questions (e.g. likelihood of recommending this unit 1. Extremely likely – 5. Extremely unlikely) I have highlighted the most favourable mean in green (if this was in the intervention period) or red (if in the baseline period).

### STEPS 1 - 4 in summary: evaluating the communication tool's impact on PEC questions

| **Question**<br><br>**Paired / unpaired parent sample** | **STEP 1**<br>***1st** survey means*<br>*(baseline versus intervention period)*<br>**All data (unpaired)** | **STEP 2**<br>***2nd** survey means*<br>*(baseline versus intervention period)*<br>**All data (unpaired)** | **STEP 3**<br>***1st** survey means versus **2nd** survey means*<br>*(both in baseline and intervention period)*<br>**Partially paired data** | **STEP 4**<br>***2nd** survey means*<br>*(baseline versus intervention period, adjusting for 1st survey means)*<br>**Paired data only** |
|---|---|---|---|---|
| **Continuous questions** | | | | |
| *B4: Number of times telephoned unit in last 24hrs* | **BASE < INTERV**<br>(1.06) (1.14)<br>p=0.951 | **BASE < INTERV**<br>(1.25) (1.58)<br>p=0.504 | Not statistically significantly different in either period | **BASE < INTERV**<br>(1.25) (1.71)<br>p=0.536 |
| *B6: Number of times asked nurse for update in last 24hrs* | **BASE > INTERV**<br>(3.24) (2.71)<br>p=0.429 | **BASE < INTERV**<br>(1.56) (2.45)<br>***p=0.038***<br>**SECONDARY OUTCOME** | Not statistically significantly different in either period | **BASE < INTERV**<br>(1.64) (2.45)<br>***p=0.034***<br>**SECONDARY OUTCOME** |
| *B7: Satisfaction (1-10) with frequency of updates from nurses* | **BASE > INTERV**<br>(8.93) (8.25)<br>p=0.135 | **BASE > INTERV**<br>(9.00) (8.90)<br>p=0.734 | Not statistically significantly different in either period | **BASE > INTERV**<br>(9.00) (8.90)<br>p=0.907 |
| *B9: Number of times asked to speak to doctor in last 24hrs (outside ward round)* | **BASE > INTERV**<br>(0.58) (0.48)<br>p=0.240 | **BASE < INTERV**<br>(0.28) (0.39)<br>p=0.650 | *CLOSE to statistical significance in baseline period (1st survey 0.58 / 2nd survey 0.28)* | **BASE < INTERV**<br>(0.28) (0.35)<br>p=0.711 |

| | | | | |
|---|---|---|---|---|
| | | | ***p=0.061*** | |
| *B11: Satisfaction (1-10) with frequency of updates from doctors* | **BASE > INTERV**<br>*(8.38) (7.22)*<br>***p=0.030***<br>**PRIMARY OUTCOME** | **BASE < INTERV**<br>(7.67) (7.90)<br>p=0.641 | Not statistically significantly different in either period | **BASE < INTERV**<br>(7.67) (7.89)<br>p=0.582 |
| *B12 verbal: Satisfaction (1-10) with way of receiving information (VERBAL UPDATES)* | **BASE > INTERV**<br>(8.56) (8.17)<br>p=0.287 | **BASE > INTERV**<br>(8.90) (8.60)<br>p=0.358 | Not statistically significantly different in either period | **BASE > INTERV**<br>(8.89) (8.60)<br>p=0.521 |
| *B12 tel: Satisfaction (1-10) with way of receiving information (TELEPHONE CALLS)* | **BASE > INTERV**<br>(8.15) (7.43)<br>p=0.557 | **BASE > INTERV**<br>(8.17) (7.46)<br>p=0.864 | Not statistically significantly different in either period | **BASE > INTERV**<br>(8.90) (8.45)<br>p=0.888 |
| *B12 written: Satisfaction (1-10) with way of receiving information (WRITTEN)* | **BASE > INTERV**<br>(6.21) (3.17)<br>p=0.062 | **BASE < INTERV**<br>(4.5) (6.86)<br>p=0.212 | Not statistically significantly different in either period | **BASE = INTERV**<br>(5.0) (5.0)<br>p=0.192<br>*In view of the small paired parent sample size for this question, this result should be interpreted with caution* |
| *B12 Overall: Satisfaction (1-10) with way of receiving information (OVERALL)* | **BASE > INTERV**<br>(8.36) (7.55)<br>p=0.104 | **BASE > INTERV**<br>(8.44) (8.42)<br>p=0.733 | Not statistically significantly different in either period | **BASE < INTERV**<br>(8.33) (8.41)<br>p=0.582 |
| *B14: I get the information I need to understand my baby's health status (1 strongly agree-5 strongly disagree)* | **BASE < INTERV**<br>(1.70) (1.78)<br>p=0.675 | **BASE > INTERV**<br>(1.78) (1.65)<br>p=0.472 | Not statistically significantly different in either period | **BASE > INTERV**<br>(1.78) (1.63)<br>p=0.579 |
| *D1: How likely to recommend this unit to friends and family (1 extremely likely-5 extremely unlikely* | **BASE > INTERV**<br>(1.33) (1.08)<br>p=0.112 | **BASE > INTERV**<br>(1.32) (1.1)<br>p=0.201 | Not statistically significantly different in either period | **BASE > INTERV**<br>(1.32) (1.11)<br>p=0.828 |
| | | *Categorical questions* | | |
| *A8: Have staff given you conflicting information about your baby (1 Yes, often; 2 Yes, sometimes; 3 No, not at all)*<br><br>Regrouped into 1.Yes 2.No<br><br>for binary logistic regression analysis | **BASE > INTERV**<br>*'No, not at all'*: 55.8% (baseline)<br>*'No, not at all'*: 70.8% (intervention)<br>p=0.425 | **BASE > INTERV**<br>*'No, not at all'*: 44.4% (baseline)<br>*'No, not at all'*: 65% (intervention)<br>p=0.486 | No available partially paired data test | **BASE > INTERV**<br>Regrouped into '1.Yes; 2.No'.<br>The odds of parents replying *'1.Yes'* in the intervention period were 16.5% lower than in the baseline period<br>p=0.827 |

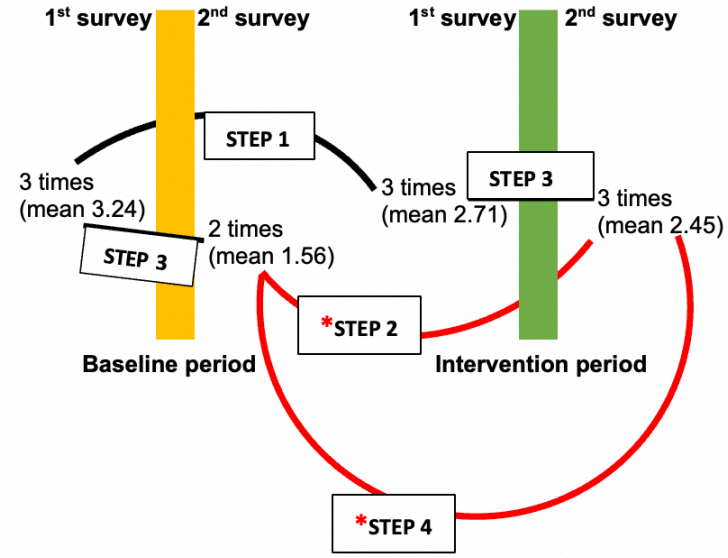
| | | | | |
|---|---|---|---|---|
| *B2 part 1: Have you been given enough written information (1 I have not needed/wanted written info; 2 I have needed /wanted written info)* | **BASE > INTERV**<br><br>*'I have needed /wanted written info'*: 61.9% (baseline)<br><br>*'I have needed /wanted written info'*: 87.5% (intervention)<br><br>**p=0.027**<br><br>**PRIMARY OUTCOME** | **BASE > INTERV**<br><br>*'I have needed /wanted written info'*: 63.2% (baseline)<br><br>*'I have needed /wanted written info'*: 90% (intervention)<br><br>p=0.065 | No available partially paired data test | **BASE > INTERV**<br><br>The odds of parents replying *'I have wanted/needed written information" in the* intervention period were 4.9 times higher than in the baseline period<br><br>p=0.084 |
| *B2 part 2: Have you been given enough written information (1 Yes definitely – 4 No, not at all)*<br><br>*Treated as continuous question for this step* | **BASE < INTERV**<br><br>*'No, not at all'*: 29.6% (baseline)<br><br>*'No, not at all'*: 57.1% (intervention)<br><br>*'Yes, definitely'*: 18.5% (baseline)<br><br>*'Yes, definitely'*: 9.5% (intervention)<br><br>p=0.382 | **BASE > INTERV**<br><br>*'No, not at all'*: 50% (baseline)<br><br>*'No, not at all'*: 16.7% (intervention)<br><br>*'Yes, definitely'*: 8.3% (baseline)<br><br>*'Yes, definitely'*: 38.9% (intervention)<br><br>p=0.180 | No available partially paired data test | **BASE > INTERV**<br>*(3.00) (2.06)*<br><br>The proportion of parents reporting they had been given enough written information was higher in the intervention period.<br><br>***p=0.012***<br>**PRIMARY OUTCOME** |

*Highest numerical mean (in count questions) or most favourable mean (in categorical type likert questions) highlighted in green (if in intervention period) or red (if in baseline period). Statistically significant different results (p<0.05) highlighted in red.*

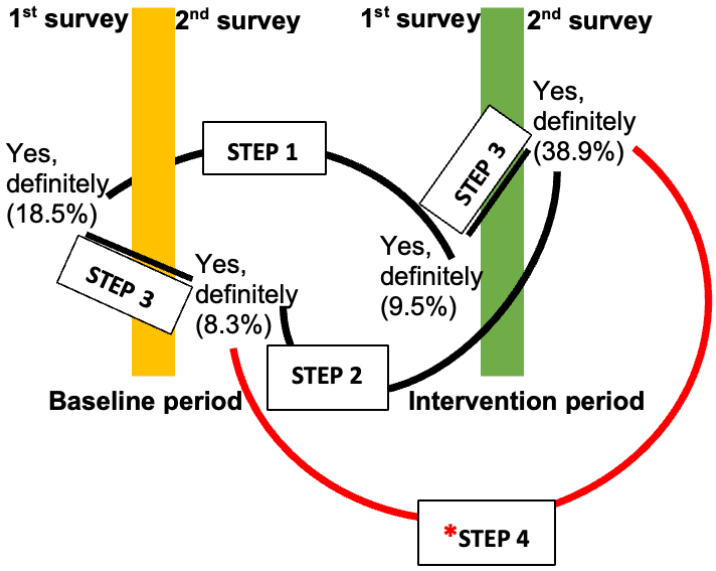
## Appendix 33

## Example graphic representation of combined STEPS 1-4 of PEC survey analysis results

Question B6: '*In the last 24 hours, how many times have you asked your baby's nurse for an update about your baby, face-to-face? Please insert number of times*'




Question B2 part 2: '*Have you been given enough written information?*'
*1.Yes definitely; 2.Yes, to some extent; 3.No, not enough; 4.No, not at all*




*Baseline line (orange) and intervention line (green) represent satisfaction level responses to questions. Lines for STEP 1, STEP 2, STEP 3, STEP 4 denote analysis steps comparisons. Red star * signifies a statistically significant result (p<0.05).*

## Appendix 34

## Comparison of parent satisfaction with MBSR question responses (2nd survey responses vs last survey responses)

On applying the chi-square test, results were not statistically significantly different for either question.

### Percentage distributions of MBSR question responses (B18, B19) from the first time parents responded *('2nd survey responses')* and the last time parents responded *('last survey responses')*

| **PEC question** | **Intervention period**<br>% distribution of question responses<br>n=number completed paired surveys<br>*Total number of recruited paired survey respondents= 19 parents* | | |
|---|---|---|---|
| | **2nd survey** | **Last survey** | **Chi-square** |
| *B18: On a scale of 1 to 5 how satisfied are you with the FREQUENCY of receiving "My Baby's Summary Report"?*<br>*1. Extremely dissatisfied*<br>*2. Dissatisfied*<br>*3. Neither dissatisfied nor satisfied*<br>*4. Satisfied*<br>*5. Extremely satisfied* | Responses<br><br>'1'= 0%<br>'2'= 0%<br>'3'= 5.6%<br>'4'= 50%<br>'5'= 44.4%<br><br>(n=18) | Responses<br><br>'1'= 0%<br>'2'= 0%<br>'3': 11.1%<br>'4': 44.4%<br>'5': 44.4%<br><br>(n=18) | $x^2$=0.392<br><br>p=0.822 |
| *B19. On a scale of 1 to 5 how satisfied are you OVERALL with "My Baby's Summary Report"?*<br>*1. Extremely dissatisfied*<br>*2. Dissatisfied*<br>*3. Neither dissatisfied nor satisfied*<br>*4. Satisfied*<br>*5. Extremely satisfied* | Responses<br><br>'1'= 5.3%<br>'2'= 5.3%<br>'3'= 5.3%<br>'4'= 57.9%<br>'5'= 26.3%<br><br>(n=19) | Responses<br><br>'1'= 5.3%<br>'2'= 10.5%<br>'3'= 5.3%<br>'4'= 57.9%<br>'5'= 21.1%<br><br>(n=19) | $x^2$=0.444<br><br>p=0.979 |

# Appendix 35

## Staff survey question results in baseline versus intervention period, correcting for job role and unit area

| **Staff survey question** | **Baseline period**<br><br>n= number of surveys | **Intervention period**<br><br>n= number of surveys | *Were the covariates (Job role and Unit area) statistically significantly related to survey responses?* (p<0.05) | *Surveys in baseline vs intervention period compared, while adjusting for covariates* |
|---|---|---|---|---|
| | % response distribution | | **Logistic regression** | |
| *Question 1. In the last 24 hours, have you updated parents during a ward round?*<br><br>1.Yes<br>2.No | Yes 103 (61%)<br><br>No 65 (39%)<br><br>(n=168) | Yes 55 (79%)<br><br>No 15 (21%)<br><br>(n=70) | • Job role: The odds of doctors replying *"1.Yes"* were 3.37 times higher than nurses<br><br>ExpB 3.371, CI 1.366-8.316, **p=0.008**<br><br>• Unit area: The odds of staff members replying *"1.Yes"* were 61.2% lower when working in HDU (intermediate intensity area) compared to SCBU (lowest intensity area)<br><br>ExpB 0.388, CI 0.172-0.874, **p=0.022**<br><br>and 68.2% lower when working in ITU (highest intensity area) compared to SCBU (lowest intensity area)<br><br>ExpB 0.318, CI 0.142-0.711, **p=0.005** | The odds of staff members replying ***"1.Yes"*** **in the intervention period were 2.15 times higher** than in the baseline period<br><br>ExpB 2.150, CI 1.058-4.370,<br><br>**p=0.034** |
| | Mean [range] SD | | **Negative binomial distribution** | |
| *Question 2. In the last 24 hours, how many times have you spoken to parents face-to-face about their baby (outside ward round times)?* | 5 times [0-40] SD 5.72 | 8 times [0-30] SD 6.279 | • Job role: Doctors spoke to parents face-to-face 26% less often than nurses<br><br>ExpB 0.741, CI 0.489-1.121, p=0.156<br><br>• Unit area: Staff members spoke to parents face-to-face 59.1% less often when working in ITU (highest intensity area), compared to SCBU (lowest intensity area)<br><br>ExpB 0.409, CI 0.285-0.586, **p=0.000**<br><br>Staff members spoke to parents face-to-face 13.4% less often when working in HDU (intermediate intensity area), compared to SCBU<br><br>ExpB 0.866, CI 0.608-1.232, p=0.422 | Staff members spoke to parents face-to-face 29.6% more often in the intervention period compared to the baseline period<br><br>ExpB 1.296, CI 0.944-1.780<br><br>p=0.109 |
| *Question 3. In the last 24 hours, how many times have you spoken to parents over the phone?* | 1 time [0-10] SD 1.445 | 1 time [0-6] SD 1.559 | • Job role: Doctors spoke to parents over the phone 87.4% less often than nurses<br><br>ExpB 0.126, CI 0.048-0.331, **p=0.000** | Staff members spoke to parents over the phone 0.2% more often in the intervention |

| | | | | |
|---|---|---|---|---|
| | | | • <u>Unit area:</u> Staff members spoke to parents over the phone 48.4% less often when working in ITU, compared to SCBU<br><br>ExpB 0.516, CI 0.302-0.881, **p=0.015**<br><br>Staff members spoke to parents over the phone 50.4% more often when working in HDU, compared to SCBU<br><br>ExpB 1.504, CI 0.950-2.380, p=0.082 | period compared to the baseline period<br><br>ExpB 1.002, CI 0.654-1.535<br><br>p=0.992 |
| *<u>NOTE:</u> For questions 2 and 3, I planned to use a Poisson regression to assess how many times in 24 hours staff members spoke to parents face-to-face (Q2) and on the telephone (Q3), in the intervention period versus the baseline period, correcting for job role and unit area. However, as data was over-dispersed for both questions, I used the negative binomial distribution instead.* | | | | |

*Statistically significant different p<0.05 in red.*

# Appendix 36

## Logistic regression results for staff survey question 1 and negative binomial distribution results for staff survey questions 2-3

### Logistic regression results for staff survey question 1 (baseline versus intervention period), correcting for job role and unit area.

**Staff survey Question 1:** *"In the last 24 hours, have you updated parents during a ward round?" Y/N*

**Variables in the Equation**

| | | B | S.E. | Wald | df | Sig. | Exp(B) | 95% C.I.for EXP(B) Lower | Upper |
|---|---|---|---|---|---|---|---|---|---|
| Step 1[a] | **Period: 0=baseline, 1=intervention. RESULT for 1=intervention. REFERENCE is 0=baseline** | 0.766 | 0.362 | 4.476 | 1 | **0.034** | 2.150 | 1.058 | 4.370 |
| | Job role: 0=Nurse, 1=Doctor. RESULT for 1=Doctor .REFERENCE is 0=Nurse | 1.215 | 0.461 | 6.955 | 1 | **0.008** | 3.371 | 1.366 | 8.316 |
| | Unit area: 0=SCBU, 1=HDU, 2=ITU REFERENCE is 0=SCBU | | | 8.108 | 2 | **0.017** | | | |
| | Unit area: 0=SCBU, 1=HDU, 2=ITU. RESULT for 1=HDU | -0.946 | 0.414 | 5.219 | 1 | **0.022** | 0.388 | 0.172 | 0.874 |
| | Unit area: 0=SCBU, 1=HDU, 2=ITU. RESULT for 2=ITU | -1.147 | 0.411 | 7.782 | 1 | **0.005** | 0.318 | 0.142 | 0.711 |
| | Constant | 1.132 | 0.364 | 9.678 | 1 | 0.002 | 3.101 | | |

**a. Variable(s) entered on step 1: Period: 0=baseline, 1=intervention, Job role: 0=Nurse, 1=Doctor, Unit area: 0=SCBU, 1=HDU, 2=ITU. STAFF SURVEY QUESTION 1 "In the last 24 hours, have you updated parents during a ward round? Y/N"**

## Negative binomial distribution results for staff survey questions 2 and 3 (baseline versus intervention period), correcting for job role and unit area.

### Staff survey Question 2: *'In the last 24 hours, how many times have you spoken to parents face-to-face about their baby (outside ward round times)?'"*

**Parameter Estimates**

| Parameter | B | Std. Error | 95% Wald Confidence Interval Lower | 95% Wald Confidence Interval Upper | Hypothesis Test Wald Chi-Square | df | Sig. | Exp(B) | 95% Wald Confidence Interval for Exp(B) Lower | 95% Wald Confidence Interval for Exp(B) Upper |
|---|---|---|---|---|---|---|---|---|---|---|
| (Intercept) | 2.014 | 0.1530 | 1.715 | 2.314 | 173.434 | 1 | 0.000 | 7.497 | 5.555 | 10.118 |
| [RESULT for Period: 1=intervention] | 0.260 | 0.1619 | -0.058 | 0.577 | 2.569 | 1 | 0.109 | 1.296 | 0.944 | 1.780 |
| **[Period: 0=baseline, 1=intervention, REFERENCE is 0=baseline]** | 0[a] | | | | | | | 1 | | |
| [RESULT for Job role: 1=Doctor] | -0.300 | 0.2116 | -0.715 | 0.115 | 2.012 | 1 | 0.156 | 0.741 | 0.489 | 1.121 |
| **[Job role: 0=Nurse, 1=Doctor, REFERENCE is 0=Nurse]** | 0[a] | | | | | | | 1 | | |
| **[RESULT for Unit area: 2=ITU]** | -0.895 | 0.1842 | -1.256 | -0.534 | 23.592 | 1 | **0.000** | 0.409 | 0.285 | 0.586 |
| [RESULT for Unit area: 1=HDU] | -0.144 | 0.1799 | -0.497 | 0.208 | 0.644 | 1 | 0.422 | 0.866 | 0.608 | 1.232 |
| **[Unit area: 0=SCBU, 1=HDU, 2=ITU, REFERENCE is 0=SCBU]** | 0[a] | | | | | | | 1 | | |
| (Scale) | 1[b] | | | | | | | | | |
| (Negative binomial) | 1[b] | | | | | | | | | |

**Dependent Variable: STAFF SURVEY QUESTION 2 "In the last 24 hours how many times have you spoken to parents face-to-face about their baby (outside ward round times)?"**
**Model: (Intercept), Period: 0=baseline, 1=intervention, Job role: 0=Nurse, 1=Doctor, Unit area: 0=SCBU, 1=HDU, 2=ITU**

a. Set to zero because this parameter is redundant.

b. Fixed at the displayed value.

### Staff survey Question 3: *"In the last 24 hours, how many times have you spoken to parents over the phone?"*

**Parameter Estimates**

| Parameter | B | Std. Error | 95% Wald Confidence Interval Lower | 95% Wald Confidence Interval Upper | Hypothesis Test Wald Chi-Square | df | Sig. | Exp(B) | 95% Wald Confidence Interval for Exp(B) Lower | 95% Wald Confidence Interval for Exp(B) Upper |
|---|---|---|---|---|---|---|---|---|---|---|
| (Intercept) | 0.184 | 0.2175 | -0.242 | 0.611 | 0.719 | 1 | 0.396 | 1.203 | 0.785 | 1.842 |
| [RESULT for Period: 1=intervention] | 0.002 | 0.2175 | -0.424 | 0.429 | 0.000 | 1 | 0.992 | 1.002 | 0.654 | 1.535 |
| **[Period: 0=baseline, 1=intervention, REFERENCE is 0=baseline]** | 0[a] | | | | | | | 1 | | |
| **[RESULT for Job role: 1=Doctor]** | -2.074 | 0.4938 | -3.042 | -1.107 | 17.649 | 1 | **0.000** | 0.126 | 0.048 | 0.331 |
| **[Job role: 0=Nurse, 1=Doctor, REFERENCE is 0=Nurse]** | 0[a] | | | | | | | 1 | | |
| **[RESULT for Unit area: 2=ITU]** | -0.662 | 0.2730 | -1.197 | -0.127 | 5.876 | 1 | **0.015** | 0.516 | 0.302 | 0.881 |
| [RESULT for Unit area: 1=HDU] | 0.408 | 0.2343 | -0.051 | 0.867 | 3.032 | 1 | 0.082 | 1.504 | 0.950 | 2.380 |
| **[Unit area: 0=SCBU, 1=HDU, 2=ITU, REFERENCE is 0=SCBU]** | 0[a] | | | | | | | 1 | | |
| (Scale) | 1[b] | | | | | | | | | |
| (Negative binomial) | 1[b] | | | | | | | | | |

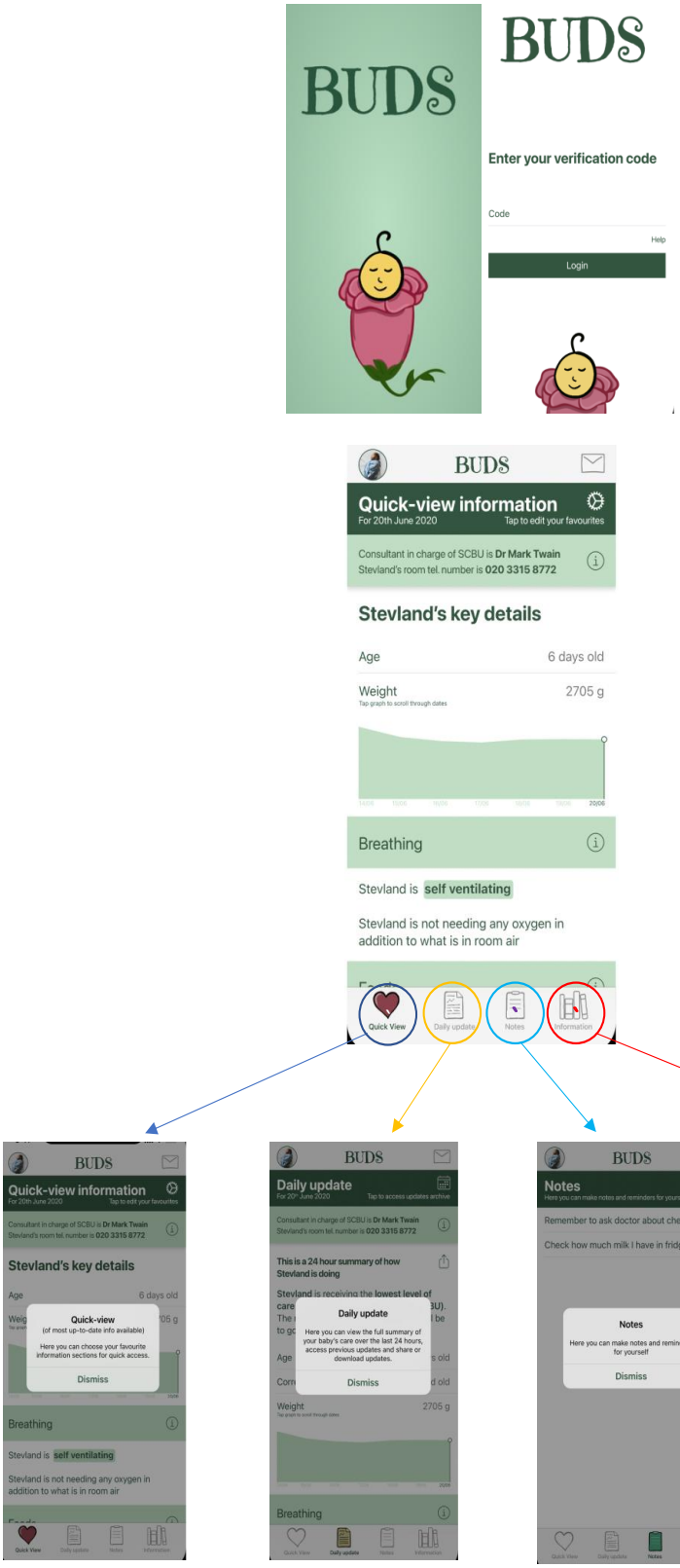
**Dependent Variable: STAFF SURVEY QUESTION 3 "In the last 24 hours, how many times have you spoken to parents over the phone?"**
**Model: (Intercept), Period: 0=baseline, 1=intervention, Job role: 0=Nurse, 1=Doctor, Unit area: 0=SCBU, 1=HDU, 2=ITU**

a. Set to zero because this parameter is redundant.

b. Fixed at the displayed value.

# Appendix 37

## BUDS mobile phone application prototype



# Appendix 38

## Parent information sheet 3: Initial and follow up discussions

**BUDS Parent Information Sheet 3: Initial and follow up discussions**
PIS3 v1.5/220618/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

---

**1 We would like to invite you to participate in the BUDS research project.** Thank you for allowing us to discuss this with you. Please read this information and ask us about anything that is not clear. This might be the first time we are approaching you to discuss this project or you might have already participated in its first stages.

**2 What is the purpose of this project?** 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. We 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. We want to give every parent a daily printed summary of their baby's information, taken from the electronic system. We have designed this with parents of babies that needed neonatal care and we now want to test it on our neonatal unit.

We want to give the summary sheet to parents every week day (not Saturdays or Sundays), and ask them how they feel about this using a simple questionnaire. We would like to do this every week while a baby is on the neonatal unit. We will use this parent feedback to improve the way the summary sheet is designed. This project will go on for 2 months. It will only involve babies during their stay on the unit and not after discharge. In the future we hope to incorporate these summary sheets into a mobile phone application so that parents can access them even more easily.

**3 Why have I and my baby been invited?** As part of assessing how the summaries impact on parents, we would like to speak with parents both at the beginning (initial discussions) and end (follow up discussions) of our project. We are approaching all parents of babies who are currently receiving care in our neonatal unit.

**4 Do I have to take part?** Not at all, this is entirely your choice and it will not affect the care you or your baby receives. If you agree you will be asked to sign a consent form and a copy will be given to you. If you decide to participate you may withdraw at any time without giving any reason. If you withdraw or lose capacity to consent, we will keep the information about you that we have already obtained and continue to use it confidentially in connection with the purposes for which consent is being sought.

**5 What does the project involve?** If you choose to take part you will be asked to talk for about 15-30 minutes with the lead researcher, Dr Susanna Sakonidou. You can ask a staff member, friend or family member to join you if you wish. You will be asked how you feel about the way information is communicated to you on the unit by neonatal staff.

**6 How long will the project last?** We will be working with parents on the unit for 2 months. If we are approaching you at the end of the 2 month period your active involvement in this project will end after this interview. If we are approaching you at the beginning of the 2 month period, we may approach you again to be involved in the baby summaries piloting stage and/or a follow up interview. If this happens we will explain the other parts of the project at that time so you can decide whether or not you want to take part.

**7 What are the possible risks and disadvantages of taking part?** We don't think there are any risks or disadvantages of taking part in this project.

**8 What are the possible benefits of taking part?** There are no direct benefits to you or your baby. We hope your involvement will lead to better communication with parents, who feel more involved in their baby's care.

**9 What happens if something goes wrong?** It is extremely unlikely that anything will go wrong. However, if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the lead researcher, Dr Susanna Sakonidou. The normal National Health Service complaints mechanisms are also available to you. The Chelsea and Westminster hospital Patient Advice and Liaison Services (PALS) team can assist you with the NHS complaint process and provide independent advice (hospital ground floor, main atrium, opposite escalators and lift bank B, 0203 315 6727). If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office (JRCO) Sponsor Office.

**10 Will my taking part in this project be kept confidential?** It is likely the neonatal staff will know you are participating as the interview room is on the neonatal unit. However the interview itself will be conducted privately, away from the clinical team. Your decision to participate, as well as withdraw at any time will not affect the care your baby receives. We will audiorecord the interviews so we can transcribe and analyse them, but the transcripts will be anonymised and only read by members of our research team. Recordings will be destroyed at the end of the project.

Imperial College London will be using information from you in order to undertake this project and will act as the data controller and sponsor for this project. This means Imperial College London is responsible for looking after your information and using it properly. The Imperial College Neonatal Research Team will keep your name and contact details to contact you about the project, and make sure that relevant information about the project is recorded to oversee the quality of the project. The Imperial College Neonatal Research Team will keep identifiable information about you for 10 years after the project has finished at Imperial College London premises. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible. Individuals from the JRCO Sponsor, NHS and regulatory organisations may look at your research records to check the accuracy of the research project. The only people at Imperial College London who will have access to information that identifies you will be people who need to contact you to send you a summary of findings or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. You can find out more about how we use your information by contacting the lead researcher (see details below).

When you agree to take part in a research study, the information you give to the project about your experience of neonatal care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

**11 What will happen to the results of the project?** Project conclusions will be published in scientific journals and presented at scientific meetings, including anonymised direct quotes from interviews, but you will not be identified in any way. If you agree, we will send you a summary of the findings.

**12 Who is sponsoring this project?** Imperial College London is the sponsor, based in the United Kingdom.

**13 Who has reviewed and approved this project?** This project has been reviewed and approved by the West Midlands - South Birmingham REC (18/WM/0175) and is being conducted as part of the lead researcher's PhD.

**Thank you for reading this.**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## Appendix 39

## Parent Consent Form 3: initial and follow up discussions

**BUDS Consent Form 3: Initial and follow up discussions**
v1.5/220618/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

**Parent's Name:**

**Please initial each box to indicate agreement. You will be given a copy of this form.**

1. I confirm that the purpose of the project and what it involves has been explained to me. ☐

2. I have read the *Parent Information Sheet 3 : Initial and follow up discussions v1.5/220618* and have been given the opportunity to ask questions and discuss this project with the BUDS team. ☐

3. I understand that my participation is voluntary, and that I am free to withdraw at any time without giving any reason and without affecting my medical care or legal rights or those of my baby. ☐

4. I understand that anonymised quotes may be included in research and consequent publications, but not in any way that might allow for identification of individual participants. ☐

5. 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. ☐

6. I give my permission for an audio recording of my interviews and for the audio recording to be used for anonymous transcription and analysis of results. ☐

7. I agree that all anonymised project data will be stored on secure NHS and Imperial College London computer systems/premises for 10 years (Imperial Policy). ☐

8. I agree that my details, including personally identifiable details and a copy of this consent form will be stored for 10 years (Imperial Policy) in a secure, locked, neonatal research office with restricted access to members of the research team. ☐

9. I agree to take part in this study. ☐

10. I would like to be sent a summary of the study results. ☐

| | | |
|---|---|---|
| _____ | _____ | _____ |
| Name of parent | Date | Signature |
| _____ | _____ | _____ |
| Name of researcher taking consent | Date | Signature |

# Appendix 40

## Parent Interview Question Guide

**BUDS Parent Interview Question Guide**
v1.1/230418/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

**Project aims to explore:**

- Parent experience of receiving information updates about their baby in neonatal care
- Parent experience of feeling involved in their baby's care

---

1. **Introduction (~5 min)**
   - Introduce self
     - Explain nature and purpose of project
     - Who research is for
   - Talk through key points:
     - Interview length 15-30 minutes
     - Interview like a discussion, although specific topics to cover
     - No right or wrong answers
     - Participation is voluntary and right to withdraw
   - Introduce audio recorder (so can actively listen to parent and for accuracy)
   - Stress confidentiality and anonymity, secure transfer and storage of data , how Findings will be reported
   - Check for parent understanding of information sheet and check consent form signed
   - Any questions they may have

2. **Background (~5 min)**
   - Check Parent Demographic Form completed
   - Their baby's sex, gestation at birth, current age, length of stay on unit, other children (ages), marital status, occupation

3. **Experience of receiving information updates in neonatal care (~10-15min)**
   *Aim to obtain an overview of how parents are given information about their baby in neonatal care*
   - How informed do they feel about their baby every day
   - What type of information are they given about their baby, where in the unit and when during their baby's admission
   - In what way are they given information (eg verbal, written, phone), what do they prefer
   - Who gives them information (eg doctors, nurses)
   - How do they feel about the way information is communicated to them
   - How often do they request face-to- face updates from staff / how satisfied are they with them / why
   - How often do they phone the unit for updates / how satisfied are they with telephone updates/ why

4. **Experience of feeling involved in their baby's care (~5-10min)**
    - How involved do they feel in their baby's care /why / why not
    - How sufficient do they feel the information provided about care involvement is

5. **Close**
    - Reassure them about confidentiality and anonymity
    - Ask if they would like to be informed of the outcomes of the research (take email address if that is their preferred way of being informed)

# Appendix 41

## Staff Interview Question Guide

**BUDS Staff Interview Question Guide**
v1.1/230418/IRAS ID:232205

**Title of Project:** Better Use of Data to improve parent Satisfaction (BUDS)

**Project aims to explore:**

- Neonatal staff experience of giving parents information updates about their baby in neonatal care
- Neonatal staff perceptions of how updating parents affects their workload

---

1. **Introduction (2 min)**
   - Introduce self
     - Explain nature and purpose of project
     - Who research is for
   - Talk through key points:
     - Interview length 10 minutes
     - Interview like a discussion, although specific topics to cover
     - No right or wrong answers
     - Participation is voluntary and right to withdraw
   - Introduce audio recorder (so can actively listen to staff member and for accuracy)
   - Stress confidentiality and anonymity, secure transfer and storage of data , how findings will be reported
   - Check for understanding of information sheet and check consent form signed
   - Any questions they may have

2. **Background (1 min)**
   - Job role, grade, length of time worked on the unit

3. **Experience of giving parents information updates about their baby in neonatal care (5 min)**
   - How do they give parents information about their baby on the neonatal unit (eg verbal, written, phone)
   - Do they volunteer information to parents or do parents ask for it
   - How often do they offer face-to-face updates to parents / how often do parents ask for them
   - How often do they update parents over the phone

4. **Neonatal staff perceptions of how updating parents affects their workload (5 min)**
   - How much of their job role / regular shift pattern involves updating parents
   - How does updating parents impact on their other clinical duties

5. **Close**
   - Reassure them about confidentiality and anonymity

## Appendix 42

## Parent views on parent involvement in baby's care

Overall, parents identified three ways in which they were involved in their baby's care:

1. Participating in cares (e.g. nappy changes, administering tube feeds)
2. Kept up to date with changes in management plans
3. Involved in decision making

1. Participating in cares (mostly satisfied with involvement, reluctant to do when baby is unwell, would like more information beforehand)

Many parents described feeling very involved in cares, including nappy changes, bathing, cleaning, moisturising, expressing milk and feeding their baby (by breastfeeding, bottle or tube), skin-to-skin holding and general developmental care to help sensory transitioning from the womb. Most reported feeling very happy with their level of involvement:

> *"100% I feel involved in his care. Um, they encourage me.. I'm stepping in to do what I can. I will set up the nasogastric tube please, if I could. But I will come in and I will take over. He's my baby and I want to do what I can to feel like his mum"*
>
> P9 HDU (post), mother

Some parents expressed some concerns regarding their involvement in cares; primarily in terms of their reluctance to do cares when their baby was quite unwell, being worried about any infection risk and feeling intimidated by all the equipment on their baby:

*"if she is a bit too sick or unstable, we wouldn't go for that. We'll just leave the nurses to do everything because we don't want to touch or move her too much"*

P6 ITU (pre), father

*"I wonder when I can be a little more hands on and more involved and also I'm so like terrified about the whole infection thing too"*

P3 HDU (pre), mother

*"And just the infection thing as well, if we just don't have to open up the doors then lets not do so, I suppose. We're here and stuff which is lovely but I think we understand that the most important thing is needing to do what needs to be done for her"*

P5 ITU (pre), father

*"We were encouraged to change them and, to be perfectly honest with you, at that time, I really didn't want to. I thought the time was a bit unnecessary for us but maybe necessary for, I don't know, the capacity of the nurses or something, when they were in high dependency and they just had wires everywhere and they were in the um, what's it called, the incubator"*

P2 SCBU (pre), father

*"I want to be as hands-on as I can. Um, but, at the same time, I'm also a little intimidated by all of the stuff on him"*

P3 HDU (pre), mother

Furthermore, some parents said they would have liked more information on how to do cares, rather than just be expected to do them and some felt there was too much pressure from nurses:

*"It is really frightening because no one has told us, oh, let me show you how to do a nappy, but they are like, oh, do you wanna do nappy today? Like, it's very overwhelming. I know its just a nappy, but like, you know, it's a small baby.. and it is just like the process was not explained. Okay let me show you, the next one you do it, It was never told. I would like to have a little bit more information"*

P8 SCBU (post), mother

*"I had to be quite forceful to say I didn't feel comfortable doing the cares"*

P2 SCBU (pre), father

2. Kept up to date with changes in management plans (mostly satisfied, depends on specific doctors, would like to be updated about baby changing location on unit)

Generally, parents reported feeling informed, mostly around any changes made to the management plan or during times when their baby might have deteriorated. Once again many were not happy about their baby being moved to another part of the unit suddenly, with no warning:

*"I was very actively communicated with, so if we're taking the heat down on the mat, if we're increasing the feed, or if we're taking them off the CPAP, I'm pretty confident I pretty much knew all of it"*

P2 SCBU (pre), father

*"Some doctors definitely involve you and some dismiss you, I've gauged from a lot of other parents that parents aren't involved in the treatment of their child"*

P10 HDU (post), mother

*"I had to try and find my babies, I didn't know where they were, but it wasn't a major thing I figured it out and I knew they were fine but it's a bit stressful"*

P2 SCBU (pre), father

3. Involved in decision making (mainly being informed of decisions retrospectively)

In terms of being involved in decision making, most parents appreciated being retrospectively informed about any clinical decisions and quite happy for doctors to make and act on the decisions; some had their reservations about this process but felt they couldn't prospectively challenge the doctors' judgement:

*"They always inform me that they're going to be doing this or they're going to be doing that, so I appreciate that, um, so far I've been quite happy for them to go ahead and do things, yeah"*

P3 HDU (pre) mother

*"I haven't studied the medical field, so if a doctor's coming to tell you something or a consultant is advising or telling you something for your baby, obviously, they're more in the know and they have better knowledge as to what's best. Do I have my reservations at the time? Yes, but then its like do I really want to be questioning their judgement? They're doctors at the end of the day, so.."*

P1 SCBU (pre), mother

*“The doctors are the ones that make the decisions and the nursing staff just almost have to do what the doctors say unfortunately, because that is generally how it is”*

P10 HDU (post), mother

## Appendix 43

## Publications, Online articles and Presentations arising

### Publications

- Sakonidou S, Kotzamanis S, Tallett A, Poots AJ, Modi N, Bell D, et al. **Parents' Experiences of Communication in Neonatal Care (PEC): A neonatal survey refined for real-time parent feedback.** *Archives of Disease in Childhood – Fetal and Neonatal Edition.* Published Online First: 30 January 2023. doi: 10.1136/archdischild-2022-324548

- Sakonidou S, Andrzejewska I, Webbe J, Modi N, Bell D, Gale C. **Interventions to improve quantitative measures of parent satisfaction in neonatal care: a systematic review.** *BMJ Paediatrics Open* 2020:4**:**e000613.

- Sakonidou S, Andrzejewska I, Kotzamanis S, Carnegie W, Nakubulwa M, Woodcock T, et al. **Better Use of Data to improve parent Satisfaction (BUDS): protocol for a prospective before-and-after pilot study employing mixed methods to improve parent experience of neonatal care.** *BMJ Paediatrics Open 2019;*3:e000515.

### Online articles / videos/ app prototype

- Sakonidou S, BUDS research team. **BUDS app prototype.** Developed by Cambridge Digital Health, September 2020. Available: *https://xd.adobe.com/view/05c8aecb-4705-4fcb-aa49-70f5a5947c8e-509b/?fullscreen*
  Accessed October 2022

- Sakonidou S and BUDS research team. **Your Neonatal Unit Guide, Chelsea and Westminster Hospital Neonatal Unit guide for parents,**

CW Hospital neonatal unit webpage. First published 2019, updated 3 times with parent input, 4th edition published July 2022. Available: *https://www.chelwest.nhs.uk/services/childrens-services/neonatal-services/a-guide-for-parents*
Accessed October 2022

- Sakonidou S. **Improved parent satisfaction levels on NICU**. CW trust online divisional update for women and children. 2018. Available: *http://chelseaandwestminsterhospitalnhsft.newsweaver.com/womenschildrenssexualhealthanddermnewsletter/1wacxwo0aop*
Accessed December 2019

- Sakonidou S, Kotzamanis S, CW trust magazine editors. **Mum's tragedy changes lives of families in NICU**. CW trust magazine "Going Beyond". Autumn/Winter 2018. Available: *http://www.chelwest.nhs.uk/about-us/news/trustnews/2018/Going-Beyond-Autumn-Winter-2018.pdf*
Accessed October 2022

- Sakonidou S. **Updating parents on neonatal units: You can also log in to the app.** Imperial College London Medicine online blog. March 2018. Available: *http://wwwf.imperial.ac.uk/blog/imperial-medicine/?s=log+app*
Accessed October 2022

- Sakonidou S. **Empowering parents with babies requiring use of neonatal intensive care units (NICU).** NIHR CLAHRC NWL Online Newsletter. 2018. Available: *https://www.clahrcprojects.co.uk/news/clahrc-nwl-empowering-parents-babies-requiring-use-neonatal-intensive-care-units-nicu*
Accessed November 2019

- Sakonidou S. **App gives parents daily updates on their baby**. Little BLISS national neonatal charity parent newsletter. Autumn/Winter 2017, Issue 39, Available: *http://www.bliss.org.uk/little bliss*
  Accessed November 2019

- Sakonidou S, Webbe J, Feitoza S. **Interview: Parents in the mix: co-creating care and research.** BabyLivingLab Neonatal Innovations Team Online video interview. April 2017. Available: *http://www.babylivinglab.com/new-blog/2017/4/24/neoniche-innovation-chats*
  YouTube: *https://www.youtube.com/watch?v=wc2XGByhfWQ&feature=youtu.be*
  Accessed October 2022

- Sakonidou S. **Updating parents on neonatal units: You can also log on to the app!** BabyLivingLab Neonatal blog. March 2017. Available: *http://www.babylivinglab.com/new-blog/2017/2/28/imperial-college-london*
  Accessed October 2022

- Sakonidou S. **Supporting vulnerable children**. NIHR CLAHRC NWL Online Newsletter. 2016. Available: *https://clahrcnwlblog.wordpress.com/2016/11/30/november-newsletter-supporting-vulnerable-children/*
  Accessed November 2019

**Presentations**

- Sakonidou S, Kotzamanis S, Tallett A, Poots AJ, Modi N, Bell D, Gale C. **The PEC survey (Parents' Experiences of Communication in neonatal care): The first UK survey validated for real-time parent feedback in neonatal care***.* Summer Neonatal Society Conference, London, June 2021

- Sakonidou S, Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **What happens now and what do parents want? A quality improvement approach to understand parent information needs in neonatal care.** 3rd Congress of Joint European Neonatal Societies (3rd JENS), Maastricht, Netherlands, September 2019

- Sakonidou S, Andrzejewska I, Webbe J, Modi N, Bell D, Gale C. **Interventions to improve parent satisfaction with care in neonatal intensive care units: a systematic review.** Pediatric Academic Societies (PAS), Baltimore, USA, April 2019

- Sakonidou S, Modi N, Bell D, Gale C. **Sharing Routinely Recorded Neonatal Data with parents.** Joint Research Seminar of Neonatal Medicine and Department of Epidemiology and Biostatistics**,** Chelsea and Westminster Hospital, Imperial College London, April 2019

- Sakonidou S, Andrzejewska I, Webbe J, Modi N, Bell D, Gale C. **Interventions to improve parent satisfaction with care in neonatal intensive care units: a systematic review.** Spring Neonatal Society Conference, London, March 2019

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Patel M, Poots AJ, Woodcock T, Modi N, Bell D, Gale C. **Improving parent information in neonatal care: A ward-based co-design activity with parents to improve satisfaction.** Rising Scientistic PhD meeting, Imperial College London, February 2019

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Patel M, Poots AJ, Woodcock T, Modi N, Bell D, Gale C. **Improving parent information in neonatal care: A ward-based co-design activity with parents to improve satisfaction.** EAPS conference (European Academy of Paediatric Societies), Paris, October 2018

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **Co-creating a neonatal communication tool with parents, for parents.** Homerton Hospital Neonatal Unit Postgraduate Meeting, London, May 2018

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **Co-creating a neonatal communication tool with parents-presentation and workshop delivery.** Bliss Baby Charter National Conference, Manchester, March 2018

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **Better Use of routine Data to improve parent Satisfaction.** NIHR CLAHRC NWL Spring Collaborative Learning Event, London, Spring 2018

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **Better Use of routine Data to improve parent Satisfaction.** Rising Scientistic PhD meeting, Imperial College London, February 2018

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W. **Better Use of routine Data to improve parent Satisfaction.** NIHR CLAHRC NWL-funded project update, Early Years Steering Group NIHR CLAHRC NWL, London, December 2017

- Sakonidou S. Kotzamanis S, Patel M, Gale C. **Making a difference together: public involvement in health informatics research, "Understanding Patient Data" theme.** Wellcome Trust, London, December 2017
  Available:
  *https://www.youtube.com/watch?v=rWHD13miiWM&feature=youtu.be*
  Accessed October 2022

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Patel M, Modi N, Bell D, Gale C. **Better Use of routine Data to improve parent Satisfaction.** NIHR CLAHRC NWL national conference, London, November 2017

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **Better Use of routine Data to improve parent Satisfaction.** NIHR CLAHRC NWL Winter Collaborative Learning Event, London, Winter 2017
- Modi N, Chivers Z, Sakonidou S. **Big data for Newborn Health: Creating sustainable healthcare infrastructure.** National Health Service Journal (HSJ) awards competition presentation, London, October 2017
  - Won 2nd place for the category "Enhancing care by Sharing Data and Information", *https://awards.hsj.co.uk/winners-2017*

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **Better Use of routine Data to improve parent Satisfaction.** NIHR CLAHRC NWL Autumn Collaborative Learning Event, London, Autumn 2017

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W, Modi N, Bell D, Gale C. **Better Use of routine Data to improve parent Satisfaction.** Research audit and Service Improvement (RASI) event, Chelsea and Westminster Hospital, London, September 2017

- Sakonidou S. Kotzamanis S, Andrzejewska I, Carnegie W. **Better Use of routine Data to improve parent Satisfaction.** Research & Development North West London meeting, Queen Charlotte Hospital, London, February 2017

- Sakonidou S, Andrzejewska I, Modi N, Bell D, Gale C. **Better Use of routine Data to improve parent Satisfaction.** Sowerby e-health conference, London, September 2016

## References

1. National Neonatal Audit programme report on 2019 data, 2020 Available: https://www.rcpch.ac.uk/sites/default/files/2020-11/nnap_report_2020_final_pdf2.pdf

2. Burger S, King J, Tallett, A. Parents' experiences of neonatal care in England. Patient Experience Journal. 2015;2(2):45-52.

3. Malouf R, Harrison S, Burton HAL, Gale C, Stein A, Franck LS, et al. Prevalence of anxiety and post-traumatic stress (PTS) among the parents of babies admitted to neonatal units: A systematic review and meta-analysis. EClinicalMedicine. 2021 Dec 21;43:101233.

4. Lefkowitz DS, Baxt C, Evans JR. Prevalence and correlates of posttraumatic stress and postpartum depression in parents of infants in the neonatal intensive care unit (NICU). J Clin Psychol Med Settings. 2010;17:230–7.

5. Beck CT, Woynar J. Posttraumatic stress in mothers while their preterm infants are in the newborn intensive care unit. Advances in Nursing Science. 2017;40:337–55.

6. Lee SK, O'Brien K. Parents as primary caregivers in the neonatal intensive care unit. Can Med Assoc J. 2014;186:845–7.

7. Grace SL, Evindar A, Stewart DE. The effect of postpartum depression on child cognitive development and behavior: a review and critical analysis of the literature. Arch Womens Ment Health. 2003;6:263–74.

8. London Neonatal Network, Toolkit for High Quality Neonatal Services Available: http://www.londonneonatalnetwork.org.uk/wp-content/uploads/2015/09/Toolkit-2009.pdf

9. The Bliss Baby Charter Standards 2011. Available: https://s3.eu-west-2.amazonaws.com/files.bliss.org.uk/images/Baby-Charter-booklet-2020.pdf?mtime=20210104142806&focal=none

10. Rocha G, Candeias L, Ramos M, Maia T, Guimarães H, Viana V. Stress and satisfaction of mothers in neonatal intensive care. Acta Med Port. 2011;24:157–66.

11. Sakonidou S, Andrzejewska I, Webbe J, Modi N, Bell D, Gale C. Interventions to improve quantitative measures of parent satisfaction in neonatal care: a systematic review, BMJ Paediatrics Open. 2020;4:e000613.

12. López-Maestro M, Sierra-Garcia P, Diaz-Gonzalez C, Torres-Valdivieso MJ, Lora-Pablos D, Ares-Segura S, et al. Quality of attachment in infants less than 1500g or less than 32weeks. related factors. Early Hum Dev. 2017;104:1–6.

13. Charpak N, Tessier R, Ruiz JG, Hernandez JT, Uriza F, Villegas J, et al. Twenty-Year follow-up of kangaroo mother care versus traditional care. Pediatrics. 2017;139:e20162063.

14. McCormick MC, Escobar GJ, Zheng Z, Richardson DK. Factors influencing parental satisfaction with neonatal intensive care among the families of moderately premature infants. Pediatrics. 2008;121:1111–8.

15. Weiss S, Goldlust E, Vaucher YE. Improving parent satisfaction: an intervention to increase neonatal parent–provider communication. J Perinatol. 2010;30:425–30.

16. Palma JP, Keller H, Godin M, Wayman K, Cohen RS, Rhine WD, et al. Impact of an EMR-Based daily patient update letter on communication and parent engagement in a neonatal intensive care unit. J Particip Med. 2012;4:e33.

17. Globus O, Leibovitch L, Maayan-Metzger A, Schushan-Eisen I, Morag I, Mazkereth R, et al. The use of short message services (SMS) to provide medical updating to parents in the NICU. J Perinatol. 2016;36:739–43.

18. Koh TH, Butow PN, Coory M, Budge D, Collie LA, Whitehall J, et al. Provision of taped conversations with neonatologists to mothers of babies in intensive care: randomised controlled trial. BMJ. 2007;334(7583):28.

19. Weems MF, Graetz I, Lan R, DeBaer LR, Beeman G. Electronic communication preferences among mothers in the neonatal intensive care unit. J Perinatol. 2016;36(11):997-1000.

20. Labrie NHM, van Veenendaal NR, Ludolph RA, Ket JCF, van der Schoor SRD, van Kempen AAMW. Effects of parent-provider communication during infant hospitalization in the NICU on parents: A systematic review with meta-synthesis and narrative synthesis. Patient Education and Counseling. 2021:104(7):1526-1552.

21. Buchan J, Aiken L. Solving nursing shortages: a common priority. J Clin Nurs. 2008;17(24):3262–3268.

22. Pillay T, Nightingale P, Owen S, Kirby D, Spencer A. Neonatal nursing efficacy: practical standards of nursing care provision in a newborn network. Arch Dis Child. 2011;96:A36.

23. Battersby C, Statnikov Y, Santhakumaran S, Gray D, Modi N, Costeloe K; UK Neonatal Collaborative and Medicines for Neonates Investigator Group.

The United Kingdom National Neonatal Research database: a validation study. Plos One. 2018;13(8):e0201815.

24. QI4U website, NIHR CLAHRC Stakeholder Engagement Module. Available: https://clahrcnwl.qi4u.org/scorm/6

25. Crocker JC, Ricci-Cabello I, Parker A, Hirst JA, Chant A, Petit-Zeman S, et al. Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. BMJ (Clinical research ed). 2018;363:k4738.

26. Faulkner A, Yiannoullou S, Kalathil J, Crepaz-Keay D, Singer F, James N, et al; NSUN National Involvement Partnership Team. Involvement for influence: 4Pi National Involvement Standards. London: National Survivor User Network; 2015. Available: https://www.nsun.org.uk

27. Involve website. Available: www.invo.org.uk

28. Duley L, Uhm S, Oliver S; Preterm Birth Priority Setting Partnership Steering Group. Top 15 UK research priorities for preterm birth. The Lancet. 2014;383:2041–2.

29. Reed JE, McNicholas C, Woodcock T, Issen L, Bell D. Designing quality improvement initiatives: the action effect method, a structured approach to identifying and articulating programme theory. BMJ Quality & Safety. 2014;23(12):1040-8.

30. PROSPERO database. Available: http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42016042110

31. Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epidemiol. 2009;62(10):1006-12.

32. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al; Cochrane Bias Methods Group; Cochrane Statistical Methods Group. The Cochrane collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011;343:d5928.

33. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016;355:i4919.

34. Green JTN. Qualitative Methods for Health Research. 3rd ed. London:SAGE;2014.

35. Mitchell-Dicenso A, Guyatt G, Paes B, Blatz S, Kirpalani H, Fryers M, et al. A new measure of parent satisfaction with medical care provided in the neonatal intensive care unit. J Clin Epidemiol. 1996;49(3):313-318.

36. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI) statement. BMJ. 2017;356:i6795.

38. Webbe JWH, Ali S, Sakonidou S, Webbe T, Duffy JMN, Brunton G, et al; COIN Project Steering Committee. Inconsistent outcome reporting in large neonatal trials: a systematic review. Arch Dis Child Fetal Neonatal Ed. 2020 Jan;105(1):69-75.

39. Brett J, Staniszewska S, Newburn M, Jones N, Taylor L. A systematic mapping review of effective interventions for communicating with, supporting

and providing information to parents of preterm infants. BMJ Open. 2011;1(1):e000023.

40. Dall'Oglio I, Mascolo R, Gawronski O, Tiozzo E, Portanova A, Ragni A, et al. A systematic review of instruments for assessing parent satisfaction with family-centred care in neonatal intensive care units. Acta Paediatr. 2018;107:391-402.

41. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. J Clin Epidemiol. 2014;67(3):267–277.

42. Wigert H, Dellenmark MB, Bry K. Strengths and weaknesses of parent-staff communication in the NICU: a survey assessment. BMC Pediatr. 2013 May 7;13:71.

43. Wigert H, Dellenmark Blom M, Bry K. Parents' experiences of communication with neonatal intensive-care unit staff: an interview study. BMC Pediatr. 2014 Dec 10;14:304.

44. Lorié ES, Wreesmann WW, van Veenendaal NR, van Kempen AAMW, Labrie NHM. Parents' needs and perceived gaps in communication with healthcare professionals in the neonatal (intensive) care unit: A qualitative interview study. Patient Education and Counseling, 2021;104(7):1518-1525.

45. MacBean V, Drysdale SB, Zivanovic S, Peacock JL, Greenough A. Participant retention in follow-up studies of prematurely born children. BMC Public Health. 2019;19(1):1233.

46. Rozenblum R, Greaves F, Bates DW. The role of social media around patient experience and engagement. BMJ Quality & Safety. 2017;26:845-848.

47. Antonacci G, Reed JE, Lennox L, Barlow J. The use of process mapping in healthcare quality improvement projects. Health Serv Manage Res. 2018;31(2):74-84

48. Glover Williams A, Tuvey S, McBain H, Menzies N, Hedge S, Bates S, et al; PERIPrem Steering Group. Perinatal excellence to reduce injury in preterm birth (PERIPrem) through quality improvement. BMJ Open Qual. 2022;11(3):e001904.

49. Facebook 'BUDSProject' page. Available: https://www.facebook.com/BUDSProject/.

50. Twitter 'BUDS_study' page. Available: https://twitter.com/BUDS_study.

51. Neoepoch research website. Available: http://neoepoch.com/parent-involvement/.

52. Bliss charity Facebook page. Available: https://www.facebook.com/Blisscharity/.

53. Bliss charity Twitter page. Available: https://twitter.com/Blisscharity.

54. Sakonidou S, Webbe J, Feitoza S. Interview: Parents in the mix: co-creating care and research. BabyLivingLab Neonatal Innovations Team Online video interview. 2017. Available: http://www.babylivinglab.com/new-blog/2017/4/24/neoniche-innovation-chats YouTube: https://www.youtube.com/watch?v=wc2XGByhfWQ&feature=youtu.be

55. Sakonidou S. Updating parents on neonatal units: You can also log on to the app! *BabyLivingLab Neonatal blog.* 2017. Available: http://www.babylivinglab.com/new-blog/2017/2/28/imperial-college-london

56. Sakonidou S. Improved parent satisfaction levels on NICU. CW trust online divisional update for women and children. 2018. Available: *http://chelseaandwestminsterhospitalnhsft.newsweaver.com/womenschildrenssexualhealthanddermnewsletter/1wacxwo0aop*

57. Sakonidou S, Kotzamanis S, CW trust magazine editors. Mum's tragedy changes lives of families in NICU. CW trust magazine *Going Beyond.* 2018. Available: http://www.chelwest.nhs.uk/about-us/news/trustnews/2018/Going-Beyond-Autumn-Winter-2018.pdf

58. Sakonidou S. Updating parents on neonatal units: You can also log in to the app. Imperial College London Medicine online blog. 2018. Available: http://wwwf.imperial.ac.uk/blog/imperial-medicine/?s=log+app

59. Sakonidou S. Supporting vulnerable children. NIHR CLAHRC NWL Online Newsletter*.* 2016. Available: https://clahrcnwlblog.wordpress.com/2016/11/30/november-newsletter-supporting-vulnerable-children/

60. Sakonidou S. Empowering parents with babies requiring use of neonatal intensive care units (NICU). NIHR CLAHRC NWL Online Newsletter. 2018. Available: https://www.clahrcprojects.co.uk/news/clahrc-nwl-empowering-parents-babies-requiring-use-neonatal-intensive-care-units-nicu

61. Sakonidou S. App gives parents daily updates on their baby. Little BLISS national neonatal charity parent newsletter. Autumn/Winter 2017, Issue 39, Available: http://www.bliss.org.uk/little bliss Accessed October 2019

62. Braun V, Clark V. 2006. Using Thematic Analysis in Psychology, Qualitative Research in Psychology 3(2):77-101.

63. Åberg Petersson M, Persson C, Massoudi P, Benzein E, Wåhlin I. Parents' experiences of family health conversations after having a child in need of neonatal intensive care. Scand J Caring Sci. 2021;35(4):1269-1277.

64. Gale C, Morris I, Neonatal Data Analysis Unit (NDAU) Steering Board. The UK National Neonatal Research Database: using neonatal data for research, quality improvement and more. Arch Dis Child Educ Pract Ed. 2016;101(4):216-8.

65. Digital N. National Neonatal Data Set NHS Data Dictionary. Available: https://datadictionary.nhs.uk/data_sets/clinical_data_sets/national_neonatal_data_set/national_neonatal_data_set_-_episodic_and_daily_care.html

66. Leis JA, Shojania KG. A primer on PDSA: executing plan–do– study–act cycles in practice, not just in name. BMJ Qual Saf. 2017;26:572–7.

67. Reed JE, Davey N, Woodcock T. The foundations of quality improvement science. Future Hospital Journal. 2016;3:199–202.

68. Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan–do–study–act method to improve quality in healthcare. BMJ Qual Saf. 2014;23:290–8.

69. Monaghan J, Kim T, Dol J, Orovec A, Campbell-Yeo M. Parents' learning needs and preferences in a neonatal intensive care unit: A desire for enhanced communication and eHealth technology. Journal of Neonatal Nursing. 2020;26(2):101-105.

70. Williams L, I'Anson J, Malarkey M, Purcell A, de Vries N, McKinlay C. Information sharing in neonatal intensive care: Parental perceptions and preferences. J Paediatr Child Health. 2020;56(7):1121-1125.

71. Guo B, Yuan Y. A comparative review of methods for comparing means using partially paired data. Stat Methods Med Res. 2017;26(3):1323-1340.

72. Hardeman W, Sutton S, Griffin S, Johnston M, White A, Wareham NJ. A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. Health Education Research. 2005;20:676–687.

73. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:979–983.

74. Skivington K, Matthews L, Simpson SA. Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update. Health Technol Assess. 2021;25(57):1-132.

75. Sakonidou S and BUDS research team. Your Neonatal Unit Guide, Chelsea and Westminster Hospital Neonatal Unit guide for parents. CW Hospital neonatal unit webpage. 4th ed July 2022. Available: https://www.chelwest.nhs.uk/services/childrens-services/neonatal-services/a-guide-for-parents

76. Sakonidou S, Kotzamanis S, Tallett A, Poots AJ, Modi N, Bell D et al. Parents' Experiences of Communication in Neonatal Care (PEC): a neonatal survey refined for real-time parent feedback. *Archives of Disease in Childhood - Fetal and Neonatal Edition.* Published Online First: 30 January 2023. doi: 10.1136/archdischild-2022-324548

77. Tourangeau R. Cognitive sciences and survey methods. In Jabine TB, Straf ML, Tanur JM, Tourangeau R. Cognitive Aspects of Survey

Methodology: Building a Bridge Between Disciplines. Washington, DC:National Academy Press;1984:73-100.

78. Axelin A, Raiskila S, Lehtonen L. The Development of Data Collection Tools to Measure Parent-Infant Closeness and Family-Centered Care in NICUs. Worldviews Evid Based Nurs. 2020 Dec;17(6):448-456.

79. Sakonidou S, Andrzejewska I, Kotzamanis S, Carnegie W, Nakubulwa M, Woodcock T, et al; BUDS Project Steering Group. Better Use of Data to improve parent Satisfaction (BUDS): protocol for a prospective before-and-after pilot study employing mixed methods to improve parent experience of neonatal care. *BMJ Paediatrics Open 2019;*3:e000515.

80. ISRCTN register record (International Standard Randomised Controlled Trials Number) Available: https://doi.org/10.1186/ISRCTN62718241

81. Fretheim A, Tomic O. Statistical process control and interrupted time series: a golden opportunity for impact evaluation in quality improvement. BMJ Qual Saf. 2015;24:748–52.

82. Provost LP, Murray SK. The Health Care Data Guide: Learning from Data for Improvement. 1st ed. San Francisco:Jossey-Bass;2011.

83. Perla RJ, Provost LP, Murray SK. The run chart: a simple analytical tool for learning from variation in healthcare processes. BMJ Qual Saf. 2011;20:46-51.

84. Field A. Discovering Statistics Using IBM SPSS Statistics. 5th ed. London, England:SAGE Publications;2017.

85. Armstrong RA. When to use the Bonferroni correction. Ophthalmic Physiol Opt. 2014;34:502–508.

86. Herrett E, Thomas SL, Schoonen WM, Smeeth L, Hall AJ. Validation and validity of diagnoses in the General Practice Research Database: a systematic review. Br J Clin Pharmacol. 2010;69(1):4–14.

87. Sakonidou S, BUDS research team. BUDS app prototype. Developed by Cambridge Digital Health, September 2020. Available: https://xd.adobe.com/view/05c8aecb-4705-4fcb-aa49-70f5a5947c8e-509b/?fullscreen

88. Goulding C. Grounded theory, ethnography and phenomenology :A comparative analysis of three qualitative strategies for marketing research. European Journal of Marketing. 2005;39:3/4:294-308.

89. Giorgi A. The Theory, Practice, and Evaluation of the Phenomenological Method as a Qualtitative Research Procedure. J Phenomnol Psychol. 1997;28:235-60.

90. Giorgi A. The status of Husserlian phenomenology in caring research. Scand J Caring Sci. 2000;14:3-10.

91. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. Qual Quant. 2018;52:1893–907.

92. Baker SE, Edwards R. How Many Qualitative Interviews is Enough? Southampton: National Centre for Research Methods, University of Southampton;2012. Available: https://eprints.ncrm.ac.uk/id/eprint/2273/4/how_many_interviews.pdf

93. Rau NM, Basir MA, Flynn KE. Parental understanding of crucial medical jargon used in prenatal prematurity counselling. BMC Med Inform Decis Mak. 2020; 20(1):169.

94. De Rouck S, Leys M. Information needs of parents of children admitted to a neonatal intensive care unit. A review of the literature (1990–2008). Patient Educ Couns. 2009;76(2):159-173.

95. Noergaard B, Ammentorp J, Fenger-Gron J, Kofoed PE, Johannessen H, Thibeau S. Fathers' Needs and Masculinity Dilemmas in a Neonatal Intensive Care Unit in Denmark. Adv Neonatal Care. 2017;17(4): E13–E22.

96. Deeney K, Lohan M, Spence D, Parkes J. Experiences of fathering a baby admitted to neonatal intensive care: a critical gender analysis. Social Science & Medicine. 2012;75(6):1106-1113.

97. Secure Video Messaging Technology for parents of children in neonatal and paediatric units. Available: https://www.vcreate.tv/diaries