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Development of outcome measurement tools for the integrated family delivered care project

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ABSTRACT

The Integrated Family Delivered Care Project (IFDC) aims to empower parents to become experts in their baby's care, and create an ethos, which truly reflects and responds to the families' unique needs. This quality improvement project was developed based on emerging evidence from research studies, which has demonstrated the effectiveness of Family Integrated Care (FIC) model. Although this programme was designed as a quality improvement (QI) project using QI tools to avoid the inflexibility and certain barriers that academic research and randomised studies are associated with it is imperative that we collect reliable data on the effect of this new care model. As part of the IFDC project, a set of pre-defined outcome measures will be collected for infants enrolled in the IFDC project; these measures will be compared with retrospective matched controls cared in traditional neonatal care settings.

1. Introduction

The aim of the Integrated Family Delivered Neonatal Care (IFDC) project at Imperial College Healthcare NHS Trust was to improve parent-experience, parent-infant bonding, parental mental health, and infant health outcomes by pioneering a new care model at Imperial College Healthcare NHS Trust (ICHNT) based on international evidence. The Plan-Do-Study-Act (PDSA) cycle (Fig. 1) (Langley et al., 1996) was created to demonstrate the model for improvement for this quality improvement (QI) project. The PDSA (Langley et al., 1996) cycle is an experimental learning approach, which allows for continuous reflection, evaluation and change at all stages of the project.

There is growing evidence that educating and engaging parents with the care of their baby can reduce their anxiety, improve parent experience and facilitate bonding. Current evidence (Levin, 1994; O'Brien et al., 2013; Bracht et al., 2013; Macdonell et al., 2013; Pineda et al., 2014; O'Brien et al., 2015) has established now not only the feasibility of Family Integrated Care (FIC) in neonatal settings but actually proved that clinical outcomes are better than traditional neonatal healthcare models. To decide what dataset to collect in our QI programme, outcome data used in different FIC studies were reviewed. The evidence for FIC dates back to 1979, when a shortage of trained neonatal intensive care nurses in Estonia prompted Levin to implement a "Humane Neonatal Care" model (Levin, 1994). This unexpectedly resulted in significant improvement in weight gain, a reduction in infections, length of stay in NICU, a reduction in nurse utilisation and overall improved satisfaction among parents and staff (Levin, 1994).

Professor Shoo Lee from Canada closely investigated the Estonian model and felt that this type of care is feasible and could be similarly effective in more developed countries. The pilot cohort analytical study carried out in 2011–2012 at Mount Sinai Hospital, in Canada, confirmed the feasibility of FIC in a multicultural western country (O'Brien et al., 2013). Infants born ≤35 weeks gestation with a parent willing and able to spend ≥8 h a day was included in the study (n = 42 families). For each infant, two matched controls were identified from the previous years' database. The primary outcome of the study was weight gain (over 21 days following enrollment). Secondary outcomes included other medical outcomes as breastfeeding at discharge, number of clinical incidents, mortality and major morbidities related to prematurity as nosocomial infection, intracranial haemorrhage, necrotizing enterocolitis, retinopathy and bronchopulmonary dysplasia. Parental Stressor Scale (PSS) was used to measure parental anxiety in the first week following admission and before discharge. Parental experience was assessed by using semi-structured one-to-one interviews prior to discharge. O'Brien and colleagues showed that in this care model weight gain improved; and there were some tentative improvements in secondary outcomes (O'Brien et al., 2013).

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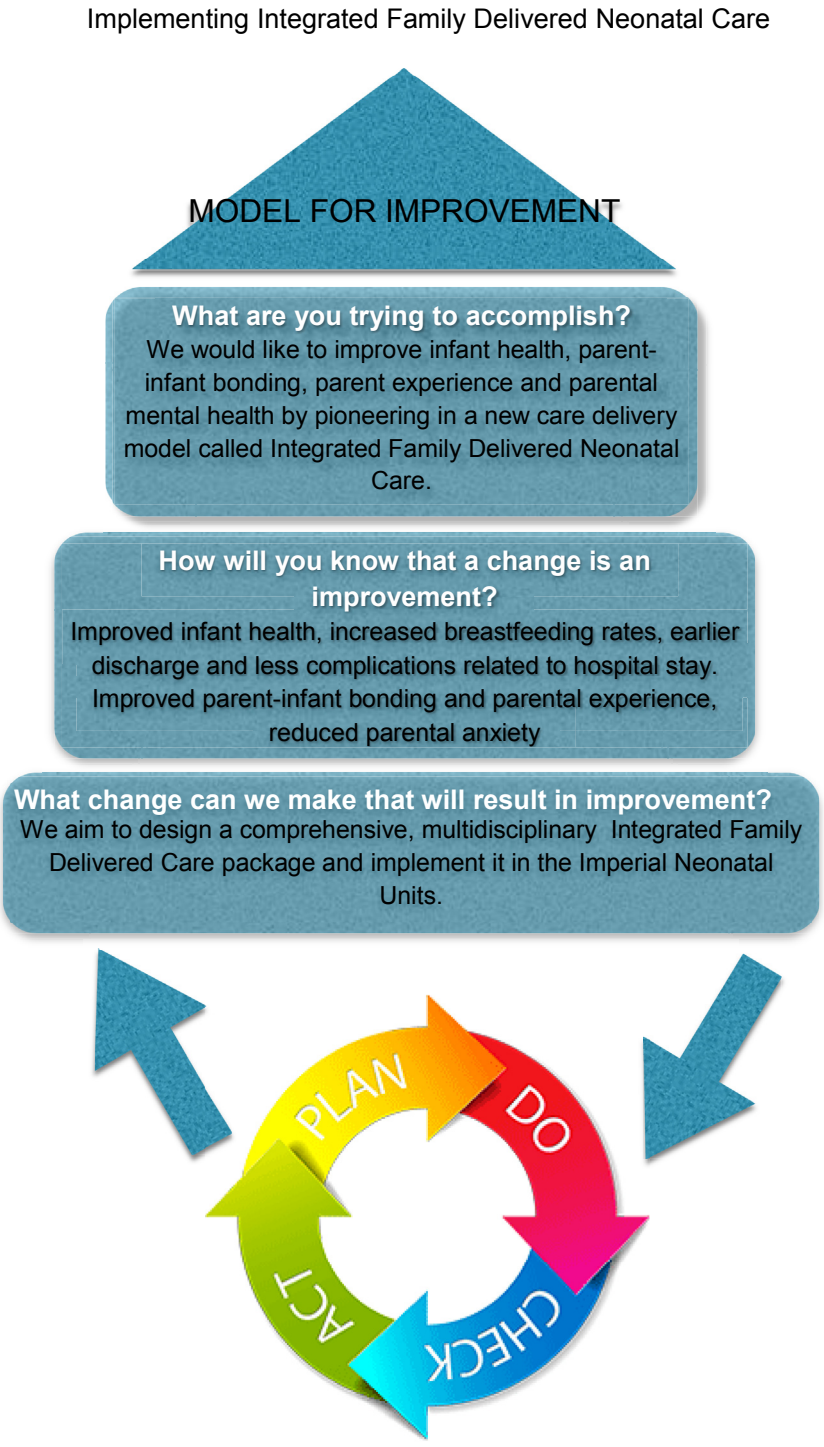

Fig. 1. PDSA cycle.

From the parents' responses, several themes were identified around FIC including gaining knowledge and confidence; better relationships with the medical team and other parents (O'Brien et al., 2013); and a reduction in the measurable degree of stress in parents (O'Brien et al., 2013; Bracht et al., 2013). This pilot study has several limitations. It was highlighted that as sample size was small, and statistical power was limited; therefore a larger randomised controlled trial was required to further evaluate the efficacy of FIC. Additionally as not all eligible parents were approached due to limited cot capacity; it was not possible to conclude that the results are generalisable to the entire patient population in the NICU.

Therefore a further clustered randomised controlled trial was undertaken in 16 NICU's across Canada and Australia to evaluate the efficacy of the FIC model. The primary outcome of the study again was weight gain (over 21 days following enrolment), and secondary outcomes included breastfeeding rates, clinical outcomes, safety, parental stress and anxiety. This study finished enrolment in September 2015, and results are due to be published soon. These results support the concept that medical outcomes and

survival are not the only neonatal outcomes that aid assessment of a service, but parental experience, parental anxiety and mental health are equally integral to the evaluation process.

After implementation of the IFDC project, it is now imperative that we continue to monitor and evaluate the progress of the IFDC project in our two neonatal units and highlight as to whether the project is meeting the individual needs of the parents, as well as whether the initial project aims and objectives are being met. Capturing and responding to parents' experiences of the project, as well as engaging in a process of active reflection, is therefore fundamental for the successful implementation of this new care model. The IFDC model is anticipated to improve medical outcomes and shorten length of stay which may improve the efficiency of our services. It is also equally important to receive staff feedback, and measure the staff training, engagement and experiences of the project. Lastly, evaluation of a project is not complete until the effectiveness is investigated through a health economic evaluation.

2. Defining outcome measures of the IFDC project

The impact of the project on the primary aim of improving parent experience and infant health would be demonstrated through parental assessments and patient outcome data, which are divided into four categories: infant health outcomes, parent experience, parental anxiety and mental health, process and balance measures including staff engagement and satisfaction (Fig. 2).

Pre-defined outcome measures including length of stay, corrected gestational age at discharge, weight velocity, discharge weight, breastfeeding rate, nosocomial infection rate and incidence of iatrogenic complications for infants enrolled in the IFDC project will be compared to matched retrospective controls managed in traditional neonatal care settings. The Project Coordinators and Assistant Psychologist collect data prospectively since the full implementation of the care model in April 2017. In addition to the patient outcome data, baseline patient demographics are also collected.

The project was registered as a QI project within our Trust and it was deemed not to need formal ethical approval; although it is still important to reflect on ethical considerations. All data collected for the purposes of evaluation are stored securely on the hospital's IT system and the files are password encrypted as to comply with the Data Protection Act (1998) (United Kingdom Acts of Parliament, 1998). Parents are provided with an information sheet and consent form explaining what data is collected and what will happen with the data. All data collected will remain confidential and anonymous, stored on a secure NHS computer network drive and will not be kept for any longer than is necessary.

3. Selected outcome measures

3.1. Infant health outcomes

The following data is collected for each infant participating in

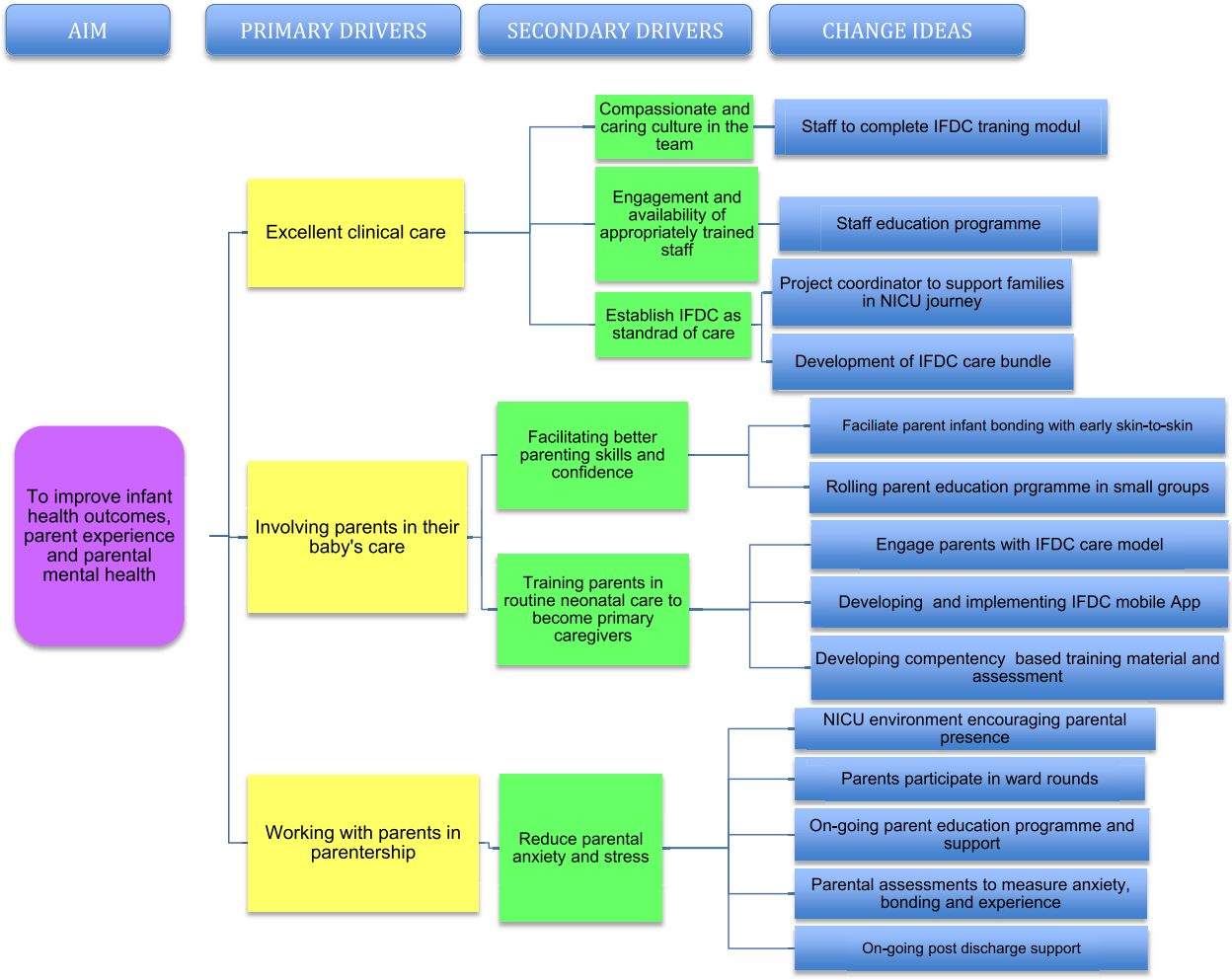

Fig. 2. Driver diagram of the IFDC project.

the IFDC care model from the medical notes additionally to baseline patient demographics:

- Corrected gestational age at discharge, Length of stay
- Weight, Head circumference, length at discharge
- Weight velocity
- Complications of prematurity. (It is not expected to see change in these complications, but data collection and comparison is needed to follow any unexpected change.)
  - Chronic lung disease (CLD)
  - Retinopathy of prematurity (ROP)
  - Necrotizing enterocolitis (NEC)
  - Intraventricular haemorrhage (IVH)
  - Culture positive hospital acquired sepsis episodes
- Feeding outcomes, length of establishing suck feeds
- Breastfeeding rate at discharge, Exclusive breastfeeding rate at discharge
- Breastfeeding rate post discharge up to 6 months of age
- Growth velocity during 1st year (weight and head circumference, length)
- Re-admission, hospital attendance, other contact with health professionals after discharge during 1st year of life
- 2 year developmental assessment for babies < 30 weeks gestation including neurodevelopmental assessment (Bayley III assessment tool)

3.2. Parent experience, parent anxiety and mental health

It is anticipated that this new care model will improve parent experience, decrease parental stress, anxiety and depression; increase confidence in parenting skills; and improve parent-infant bonding. These outcome measures were defined, developed and obtained by the Neonatal Clinical Psychology team, and include a semi-structured interview, spot questionnaire and discharge questionnaire. The neonatal unit is an exceedingly complex and stressful environment whereby parents learn to navigate parenting in the midst of a highly medicalised and alienating environment whilst experiencing common emotions, such as guilt, joy, anger, worry and fear (Golish and Powell, 2003). Stress and anxiety are known to have negative implications for both parents, babies and their developing relationship, and parents with a premature baby have an elevated risk of experiencing post-traumatic stress disorder, anxiety and depression in the postpartum period (Davis et al., 2003; Singer et al., 2003; Carson et al., 2015; Veddovi et al., 2001). Beyond the impact upon both parents at an individual and relational level, having a premature baby also has a multi-layered influence on the wider family unit whereby siblings can be effected (Taylor et al., 2001; Saigal et al., 2000). Providing a supportive and family-centred environment by empowering parents in their baby's care is integral to sustaining positive parent-child relationships and promoting healthy parental and family coping and adjustment in these early few weeks. Ultimately, these principles underpin the aims and motives of the IFDC project.

Research on FIC has previously taken a quantitative outcome focused stance, but there is limited research which examines the parent's personal narratives and lived experiences of FIC (Kerr et al., 2016, 2017; Russell et al., 2014). This QI project therefore seeks to gather rich and detailed descriptions of parent's experiences of the IFDC project through qualitative evaluation, and examines how the IFDC project empowers and supports parents to learn to care for their baby. The designed semi-structured interviews will inform the qualitative evaluation aspects of this QI project. It will favour a subjective interpretive approach, which acknowledges the complexity and intricacy of being a parent within the neonatal environment (Creswell, 2007; Hennink et al., 2011). Concepts of mind-mindedness and attachment, parental self-efficacy, as well as coping and psychological adjustment have informed the formation of the interview schedule which aim to encourage parental confidence, attachment, empowerment and wellbeing (Meins, 2013; Lazarus and Folkman, 1984; Gross, 2002; Hess et al., 2004; Barnes and Adamson-Macedo, 2007).

The interviews will be conducted within one week of discharge from the unit, and if transferring to their local hospital then we will seek to interview within three days of this transfer. A degree of flexibility will be required to fit with parent's availability and whilst we will seek to offer face-to-face interviews, there may be instances where telephone or Skype interviews may be more appropriate. Interviews will be conducted in the parent's place of preference (home or hospital) to encourage the parent's comfort and authenticity. For the semi-structured interview, purposive sampling is used as parents must have been enrolled in the IFDC project, and convenience sampling will also be used as parents are able to decide if they wish to participate (Creswell, 2007; Hennink et al., 2011). Other than enrollment in the IFDC project, there are no other exclusion criteria for the spot questionnaire and discharge questionnaire.

Due to the subjectivity associated with qualitative evaluation, maintaining a constant degree of reflexivity is paramount in ensuring internal validity and thus avoiding potential researcher biases (Creswell, 2007; Hennink et al., 2011).

All parents involved in the IFDC project will also be given the opportunity to complete the spot questionnaire and discharge questionnaire, which gives parents a further opportunity to share their experiences of the project whilst their infant is an inpatient on the neonatal unit. The spot questionnaire will be distributed to parents throughout their baby's stay on the neonatal unit, whilst the discharge questionnaire will be distributed to parents on their baby's discharge date.

The Framework Method approach will be used to evaluate the semi-structured interviews (Gale et al., 2013). This method is widely used in applied health and medical research, and sits within the broader analysis network of thematic analysis (Ritchie et al., 1994). The Framework Method looks at establishing relationships within the data, and therefore identifying both descriptive and explanatory conclusions around these identified themes. It uses a matrix output to organise, compare and contrast the data *across* and *within* individual cases (Gale et al., 2013). In line with the PDSA model and nature of qualitative research, whether it takes an inductive or deductive approach depends on the course of the output though it is anticipated that it would follow an inductive approach (Creswell, 2007; Hennink et al., 2011; Smith and Firth, 2011). Peer examination via the IFDC core team will aid the process of ensuring that researcher biases are avoided.

3.3. Process and balance measures

We aim to use the following process and balance measures to assess if the new care model delivery by our team is effective, and also to monitor parent and staff engagement, satisfaction and feedback.

- Parental uptake of the project: Number of families approached; Number of families enrolled in the care model;
- Mobile App usage: Number of Mobile App user episodes; Time spent during each log-in; Time spent on each activity log.
- Parent education and training: Number of families participating in each group parent education session; Parent satisfaction of group parent education sessions; Completion of parental competency based training (the parental competency based training is a timeline and competency based curriculum which is

individualised to allow staff to monitor the progress of the parents and identify what extra support they may need to support them in this care model.)

- Staff training and engagement: Number of staff (nurses, junior doctors and allied health professionals) trained to deliver this care model; Staff expectations of the project ("hopes and fears"); Staff satisfaction of the project.
- Discharge: Number of babies discharged home from the unit; Number of babies discharged from this care model.

3.4. Additional measures

We aim to collect staff feedback by a specifically designed questionnaire. Additionally in the future we aim to collect sufficient data to carry out a health economic evaluation for the sustainability and future transferability of this model.

4. Summary

Our aim was to define and develop a dataset used for outcome measures of the IFDC project to make further observations and assess potential other benefits and challenges associated with the IFDC model. Since the full implementation of this new care model in April 2017, 30 families have participated in this project. We aim to publish details about our outcome data and initial findings shortly.

Unlike most neonatal units, Imperial neonatal units are in a unique position whereby staff cross-cover both level-2 and level-3 neonatal units and the parents may experience the benefit of seamless FIC in either or both settings. This will improve credibility that FIC is feasible in either tiered setting and that this can be rolled out in networks across the country. Continuous effective monitoring, data collection and evaluation remains paramount in ensuring that we can deliver a project in the most cost-effective way, that continues to remain beneficial to families and their infants and is tailored to their unique needs. This will ultimately ensure generalisability of the FIC model across all neonatal units.

References

Barnes, C.R., Adamson-Macedo, E.N., 2007. Perceived Maternal Parenting Self-Efficacy (PMP S-E) tool: development and validation with mothers of hospitalized preterm neonates. J. Adv. Nurs. 60, 550–560.

Bracht, M., O'Leary, L., Lee, S.K., O'Brien, K., 2013. Implementing Family Integrated Care in the NICU: a parent education and support program. Adv. Neonatal Care 13 (2), 115–126.

Carson, C., Redshaw, M., Gray, R., Quigley, M.A., 2015. Risk of psychological distress in parents of preterm children in the first year: evidence from the UK Millennium Cohort Study. BMJ Open 5.

Creswell, J.W., 2007. Qualitative Inquiry and Research Design: Choosing Among Five Approaches. SAGE Publications, London.

Davis, L., Edwards, H., Mohay, H., Wollin, J., 2003. The impact of very premature birth on the psychological health of mothers. Early Hum. Dev. 73 (1–2), 61–70.

Gale, N.K., Heath, G., Cameron, E., Rashid, S., Redwood, S., 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med. Res. Methodol. 117 (13).

Golish, T.D., Powell, K.A., 2003. Ambiguous loss': managing the dialectics of grief associated with premature birth. J. Soc. Personal Relat. 20 (3), 309–334.

Gross, J.J., 2002. Emotion regulation: affective, cognitive and social consequences. Psychophysiology 39 (3), 281–291.

Hennink, M., Hutter, I., Bailey, A., 2011. Qualitative Research Methods. SAGE Publications, London.

Hess, C.R., Teti, D.M., Hussey-Gardner, B., 2004. Self-efficacy and parenting of high-risk infants: the moderating role of parent knowledge of infant development. Appl. Dev. Psychol. 25, 423–437.

Kerr, S., King, C., McPherson, K., 2016. Helping Parents 'keep in Touch' with Their Babies in the Neonatal Unit: Evaluation of the Mylittleone Digital Solution. Glasgow Caledonian University, Glasgow.

Kerr, S., King, C., Hogg, R., McPherson, K., Hanley, J., Brierton, M., Ainsworth, S., 2017. Transition to parenthood in the neonatal care unit: a qualitative study and conceptual model designed to illuminate parent and professional views of the impact of webcam technology. BMC Pediatr. 17 (1), 158.

Langley, G., Moen, R.D., Nolan, K.M., Nolan, T.W., Norman, C.L., Provost, L.P., 1996. The Improvement Guide: a Practical Approach to Enhancing Organisational Performance. Jossey Bass Publishers, San Francisco.

Lazarus, R.S., Folkman, S., 1984. Stress, Appraisal and Coping. Springer, New York.

Levin, A., 1994. The Mother-Infant unit at Tallin Children's Hospital, Estonia: a truly baby friendly unit. Birth 21, 39–44.

Macdonell, K., Christie, K., Robson, K., Pytlik, K., Lee, S.K., O'Brien, K., 2013. Implementing family-integrated care in the NICU: engaging veteran parents in program design and delivery. Adv. Neonatal Care 13 (4), 262–269.

Meins, E., 2013. Sensitive attunement to infants' internal states: operationalizing the construct of mind-mindedness. Attachment Hum. Dev. 15 (5–6), 524–544.

O'Brien, K., Bracht, M., Macdonell, K., McBride, T., Robson, K., O'Leary, L., Lee, S.K., 2013. A pilot cohort analytic study of Family Integrated Care in a Canadian neonatal intensive care unit. BMC Pregnancy Childbirth 13 (1), 12.

O'Brien, K., Bracht, M., Robson, K., Ye, X.Y., Mirea, L., Cruz, M., Lee, S., 2015. Evaluation of the Family Integrated Care model of neonatal intensive care: a cluster randomized controlled trial in Canada and Australia. BMC Pediatr. 15 (1), 210.

Pineda, R.G., Neil, J., Dierker, D., Smyser, C., Wallendorf, M., Kidokoro, H., Inder, T., 2014. Alterations in brain structure and neurodevelopmental outcome in preterm infants hospitalized in different neonatal intensive care unit environments. J. Pediatr. 164 (1), 52–60.

Ritchie, J., Spencer, L., 1994. Qualitative data analysis for applied policy research. In: Bryman, A., Burgess, R.G. (Eds.), (1994) Analyzing Qualitative Data, pp. 173–194.

Russell, G., Sawyer, A., Rabe, H., Abbott, J., Gyte, G., Duley, L., Ayers, S., 2014. Parents' views on care of their very premature babies in neonatal intensive care units: a qualitative study. BMC Pediatr. 14, 230.

Saigal, S., Burrows, E., Stoskopf, B.L., Rosenbaum, P.L., Streiner, D., 2000. Impact of extreme prematurity on families of adolescent children. J. Pediatr. 137 (5), 701–706.

Singer, L.T., Fulton, S., Davillier, M., Koshy, D., Salvator, A., Baley, J.E., 2003. Effects of infant risk status and maternal psychological distress on maternal–infant interactions during the first year of life. J. Dev. Behav. Pediatr. 24, 233–241.

Smith, J., Firth, J., 2011. Qualitative data analysis: application of the framework approach. Nurse Res. 18 (2), 52–62.

Taylor, H.G., Klein, N., Minich, N.M., Hack, M., 2001. Long-term family outcomes for children with very low birth weights. Archives Pediatr. Adolesc. Med. 155 (2), 155–161.

United Kingdom Acts of Parliament, 1998. Data Protection Act. HMSO, Norwich.

Veddovi, M., Kenny, D.T., Gibson, F., Bowen, J., Starte, D., 2001. The relationship between depressive symptoms following premature birth, mothers' coping style, and knowledge of infant development. J. Reproductive Infant Psychol. 19 (4), 313–323.