

**Being with Babies: Vocal soothing for  
preterm infants during painful procedures  
in the Neonatal Intensive Care Unit**

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## **ABSTRACT**

Traditionally infant mental health needs have been attended to in the Neonatal Intensive Care Unit (NICU) by supporting parent-infant relationships. There has been little focus in either the Nursing or the Infant Mental Health literature on the role that non-parental caregivers have in supporting preterm infant social and emotional development. Infants in the NICU experience many painful and stressful procedures yet there is evidence that both pharmacological and non-pharmacological methods of pain relief are under-used in the preterm infant population. This PhD programme of research investigated the NICU nurse-infant relationship, with a focus on vocal soothing. Two observational studies investigated the use of voice by NICU nurses during painful and non-painful procedures. A model of vocal soothing was developed and tested for its ability to provide comfort to preterm infants undergoing painful procedures.

Two observational studies recorded the numbers of words spoken to 50 infants in NICU during two procedures; a painful one (heel prick) and a non-painful one (nappy change). Three feasibility studies tested the proposed methods and refined the planning for a study that assessed the effectiveness of the vocal soothing intervention in reducing manifestations of pain and stress in preterm infants during painful procedures. In the first feasibility study the research protocol was tested with twenty infants and their nurses. The remaining two feasibility studies further refined the methods for collecting enough saliva from preterm infants for salivary cortisol analysis. In the main study for this PhD research programme, fifty-one infants received both the intervention condition (vocal soothing) and the control condition (silence) during two routine heel prick blood tests in their first 10 days of life. Measures of stress included cortisol, heart rate and oxygen saturation. Pain was measured using the Premature Infant Pain Profile Revised (PIPP-R).

Nurses were found to speak infrequently to infants during both painful and non-painful procedures, but were less likely to speak to infants during painful procedures than during non-painful procedures. The feasibility studies led to changes in methods that included the researcher providing the intervention rather than the nurses, the use of a polygraphic system for recording the physiological data and the administration of a 5% aqueous solution of citric acid to increase saliva volume. The results of the main study found no statistically significant differences in cortisol response or physiological data between the vocal soothing

and control conditions, although there was some indication that the vocal soothing intervention is unlikely to have an adverse effect on preterm infant cortisol levels.

In bringing together the results of these studies, this thesis argues that vocal soothing is an important aspect of emotional care in the NICU. A case is made for 'companionship' as a concept that promotes attuned emotionally sensitive care by non-parental caregivers. The international problem of the under-use of pain management interventions is viewed through a psychoanalytic lens and it is proposed that the psychological defence of denial may be a contributing factor. Future directions for research are suggested, including the emotional experience of NICU nurses and the efficacy of a 'psyche-education' for improving pain management practices in the NICU.

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## LIST OF ABBREVIATIONS

ADBB	Alarme Détresse du Bébé (Alarm Distress Baby Scale)
ATVV	Auditory, tactile, Visual and Vestibular intervention
CA	Chronological age
CCDHB	Capital and Coast District Health Board
CI	Confidence interval
CV	Coefficient of variation
DAN	Douleur Aiguë du Nouveau-né (a behavioural pain scale)
ECG	Electrocardiogram
EIA	Enzyme immunoassay
Elect LUSCS	Elective lower uterine segment caesarean section
Em LUSCS	Emergency lower uterine segment caesarean section
ELISA	Enzyme-linked immunosorbent assay
FAOPS	Federation of Asian and Oceania Perinatal Societies
GA	Gestational age
GLO	Good learning opportunity
HCL	Hydrochloric acid
HPA	Hypothalamic Pituitary Adrenocortical
HR	Heart rate
ICU	Intensive Care Unit
mg	milligrams
ml	millilitre
MOH	Ministry of Health
NANN	National Association of Neonatal Nurses
NAPI	Neurobehavioural Assessment of the Preterm Infant (scale)
NICU	Neonatal Intensive Care Unit
NIDCAP	Newborn Individual Development Care and Assessment Program
nm	nanometer
nmol/l	nanomol/litre
NVD	Normal vaginal delivery
pH	Acidity or basicity of an aqueous solution
PIPP	Premature Infant Pain Profile
PIPP-R	Premature Infant Pain Profile Revised
PMA	Post menstrual age
PPN	Pre and perinatal psychology
PROM	Premature rupture of membranes

PSANZ	Perinatal Society of Australia and New Zealand
RAG-M	Research Advisory Group Maori (Wellington)
RIA	Radio immunoassay
SpO <sub>2</sub>	Oxygen saturation (as measured by pulse oximetry)
SPSS	Statistical Package for the Social Sciences
SS	Sensorial Saturation
μl	microlitre
WAIMH	World Association for Infant Mental Health

# 1 INTRODUCTION

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*Naku te rourou nau te rourou ka ora ai te iwi*

*With your basket and my basket the people will live*

---

Māori *Whakatauki* (proverb)

This Māori proverb refers to the importance of co-operation and the combination of resources in order to get ahead; to improve outcomes. In this PhD research programme I offer my basket of infant mental health knowledge to sit alongside the basket of neonatal care knowledge in order to forge a new way of thinking about how preterm infants are cared for in the Neonatal Intensive Care Unit (NICU). This research programme looks at the emotional care of infants in the NICU and proposes that vocal soothing may be one way in which infants may be able to receive emotional care from non-parental caregivers in the NICU.

The field of infant mental health has made many important discoveries about the social and emotional capacities of humans from birth and what they need in order to thrive. Most of the research in the infant mental health field thus far has focussed on term infants and older, but it is also important to consider what preterm infants need in the NICU in order to support their social and emotional development. The idea for this thesis came some years ago, during my training as a Parent Infant Psychotherapist in England.

I had the opportunity to spend three months undertaking research into the experiences of staff, families and their babies in a NICU. On one occasion, I was sitting next to the incubator of a little girl born at 32 weeks gestation and in her first week of life. After a short time observing her I noticed that I suddenly began to feel very nauseous. I was surprised, I had felt perfectly fine all day yet now I felt quite unwell. I started to get up to leave the room when the little girl turned her head towards me and a gush of milk came out of her mouth and hit the wall of the incubator. Her machine started beeping and I became very concerned for her health. After a moment I reminded myself that babies spill all the time and noticed that actually she looked perfectly fine now. I calmed myself, realising after a moment or two

that I did not feel nauseous anymore and I remained feeling well for the rest of the day. I continued observing this little girl for the next 45 minutes and she did not spill again.

This experience stayed with me because I was left wondering about the kind of social communication that might be able to take place between a preterm infant and an adult. If I could 'feel' her distress, then could she also sense my attuned calm state afterwards? What kind of emotional care might be able to be provided by non-parental caregivers of infants in the NICU?

Both Nursing and Mental Health consider infant mental health to be of importance in the NICU environment. Recommendations from both disciplines highlight the importance of attending to the parent-infant relationship in order to support the emotional needs of the infant. The focus on bonding and helping parents to feel connected to their infant is an important aspect of emotional care and there is no doubt that parents need to be supported during this often traumatic time of a hospital admission. Infants in the NICU have multiple caregivers, however, all of who need to have the emotional needs of the infant in mind if good enough emotional care is to be provided in this setting. The philosophy of developmental care supports this view, that infants are individuals with developmental needs as well as medical needs (Als & Gilkerson, 1997). Developmental care practices encourage NICU staff to consider how environmental changes and parental involvement in care can reduce pain and stress for preterm infants. It is acknowledged that this kind of care requires a particular 'state of mind' for the health care team (Goldstein, 2012), but developmental care does not focus on the individual psychological characteristics of the healthcare professional and how this may be impacting the care they provide the infant.

This research programme considers how infant mental health needs could be met by non-parental caregivers in the NICU, without overwhelming these caregivers with extra work in an already stressful working environment. The use of a soothing voice during painful procedures may be one way in which a caregiver can provide emotional care alongside medical and nursing care in the NICU.

The research began as an investigation into whether a soothing voice could reduce the physiological and behavioural manifestations of stress in preterm infants in the NICU. The first challenge however was to define a 'soothing' voice. While talking to infants in the NICU is a recommended practice in the nursing literature, there is no guidance as to how one



should actually do this. Knowledge from the field of infant mental health and parent infant psychotherapy led to the development of a model of vocal soothing that was designed to be an intentional way of emotionally 'being with' an infant, rather than relying on intuitive care. Intuitive care, as we discovered, may not necessarily be in the best interests of the infant.

With a model of vocal soothing developed, the next step was to ascertain whether non-parental caregivers of infants in the NICU were already providing this intervention. The decision to focus this research on the nurse-infant dyad was made because nurses are most often the primary caregivers for infants in the NICU where this study took place. Data on baseline levels of vocal soothing in the NICU studied were gathered through two observational audits, both painful procedures (heel prick) and non-painful procedures (nappy change). It was of most interest to discover that not only did nurses speak infrequently to infants in the NICU, but that they spoke more to infants during non-painful procedures than during painful procedures. It appeared that a vocal soothing intervention was worth investigating and if evidence could be found for its effectiveness then there would be a scientific reason for nurses to do it.

A feasibility study was carried out in order to test the planned methodology in which nurses were asked to speak soothingly to some infants during heel prick procedures and to remain silent with others. It became clear at this time however that the instruction to 'talk soothingly' to infants was not as simple as it may have seemed. Nurses were found to be an unreliable source of vocal soothing, speaking too little or too quietly or about things unrelated to the infant's current experience and so nurses were replaced with the researcher as the provider of vocal soothing for the main study. Three measures of infant stress, salivary cortisol, heart rate and oxygen saturation and one measure of infant pain, the Premature Infant Pain Profile (PIPP) were thought to be a robust way in which the effectiveness of the vocal soothing intervention could be assessed, but difficulties arose with data collection and the method had to be refined for the main study. This pilot study, involving twenty infants, found difficulties in collecting enough saliva from preterm infants for successful cortisol analysis and two further feasibility studies were carried out to investigate the use of a saliva stimulant to increase saliva volume. The decision was made to adjust the study to a within-subject design, with each infant acting as their own control, in order to reduce potential confounding variables found between infants.

By the time the main study was ready to begin, the methodology was well tested. Data were able to be collected successfully from the 51 infants who participated. A sophisticated mixed model statistical analysis was able to calculate differences in infant responses between conditions, while taking account for each infant's baseline starting point. There were a number of difficulties with recruitment, however, which meant that the planned sample size of 63 infants for this study was not achieved. While a strength of this study design was in the assessment of the vocal soothing intervention under ordinary NICU conditions, it may also have been a confounding factor. The results of this study highlighted how unreliable preterm infant physiological data can be.

It remains unclear whether a 'gold standard' study could be designed to assess the impact of vocal soothing on preterm infants during painful procedures, but there is a convincing argument for why nurses should do it anyway. The observational studies found that the preterm infants were experiencing painful and stressful procedures without any form of analgesia, neither pharmacological nor non-pharmacological. This result was consistent with international findings and researchers are perplexed as to why the evidence for interventions to reduce the impact of pain and stress on preterm infants does not appear to be translating into practice. When viewed through a psychoanalytic lens, the motivation for not talking and for not providing pain relief may be linked, both may be an unconscious way to avoid acknowledging infant pain. This raised the issue of the nurse's emotional experience of caring for infants in the NICU and how much more of an emotional cost to them there might be in connecting with the infant's experience through vocal soothing or in recognising the need for pain relief. This is an issue that needs further exploration and two ideas are proposed for further investigation. The first, a 'psyche education', would provide NICU staff with a theoretical understanding of the under-use of pain management interventions through an explanation of how the psychological defence of denial might be unconsciously contributing to the problem. The second idea, the concept of 'companionship', is proposed as a way of helping professionalise emotional care so that nurses may be able to provide it in a way that is beneficial to the infant but without the nurses having to become too emotionally involved.

The focus of this research was on a synthesis of physical and emotional care of infants in the NICU and it was thought that the intervention of 'vocal soothing' might be a way in which the emotional needs of infants could be attended to without adding to nurse workloads. As

it transpired, talking to babies may have required more emotional investment than was comfortable for the nurses in this study. This is an important aspect of neonatal care to continue to explore if the mental health needs of preterm infants are to be attended to adequately in the NICU setting.

I became known as the baby whisperer in the NICU; for some this was certainly a term of endearment, but for others there was still the question of what value I might add to their important work. Psychoanalytic thinking however, may be able to facilitate more effective emotional care of preterm infants and also shed some light on the problems of pain management in NICU. It would appear that the Māori proverb at the beginning of this chapter about the importance of sharing of resources in order to improve outcomes may be particularly apt for the NICU environment.

## **1.1 AIMS AND HYPOTHESIS**

The overall aim of this research programme was to develop and test an intervention that might enhance the emotional care of preterm infants in the NICU, by reducing their manifestations of pain and stress. The specific aims were:

1. To develop a model of vocal soothing that could be used by non-parental caregivers during a routine painful procedure
2. To investigate the current use of voice by neonatal nurses to soothe preterm infants during routine painful procedures
3. To investigate the current use of voice by neonatal nurses to soothe preterm infants during routine non-painful procedures
4. To test the feasibility of the proposed methodology for assessing the effectiveness of a model of vocal soothing in reducing manifestations of pain and stress in preterm infants during painful procedures
5. To assess the effectiveness of a vocal soothing intervention in reducing manifestations of pain and stress in preterm infants during painful procedures

The hypothesis for the main research question of whether talking soothingly to preterm infants has a beneficial effect on their pain and stress was that behavioural and physiological

pain and stress responses for the infant in the talking condition would be less pronounced and would return to baseline more quickly than for the infant in the silent condition.

## **1.2 PUBLICATIONS ARISING FROM THIS RESEARCH**

Three publications have arisen from this research programme so far:

1. Zwimpfer, L. & Elder, D. (2012). Talking to and being with babies: the nurse-infant relationship as a pain management tool. *Neonatal, Paediatric and Child Health Nursing*, 15(3), 10-14.
2. Zwimpfer, L. (2016). Talking to, and being with, babies: the importance of relationship in the neonatal intensive care unit. In S. Acquarone (Ed.), *Surviving The Early Years: The Importance of Early Intervention with Babies at Risk* (pp. 113-126). London: Karnac Books Ltd.
3. Zwimpfer, L., Wiltshire, E., & Elder, D. (2012). Talking to babies: a baseline study of vocal soothing by neonatal nurses during painful procedures. *Journal of Paediatrics and Child Health*, 48 (Suppl. 1): 76.

The first publication derived from the literature review in chapter two and is presented in appendix I. The second publication is a chapter in a book on the topic of infant mental health. This chapter explores ways in which the NICU nurse may be able to support the emotional care of preterm infants and is also presented in appendix I.

The third publication is an abstract for the oral presentation given at the combined 17<sup>th</sup> Congress of the Federation of Asian and Oceania Perinatal Societies (FAOPS) and the 16th Annual Congress of the Perinatal Society of Australia and New Zealand (PSANZ), held in Sydney, Australia in March 2012. It presents the results of the first baseline study, described in chapter four and is presented in appendix I.

Aspects of this research programme have also been presented at two conferences:

1. 'Emotional Care in the NICU' IMHAANZ Conference, Queenstown, NZ, April 2015.
2. 'Minding the baby: Infant mental health in Neonatal Care' IMHAANZ Conference, Wellington, NZ, Feb 2012.

## 2 BACKGROUND

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*There is no such thing as a baby... A baby cannot exist alone but is essentially part of a relationship*

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Winnicott, 1947/1957: 137

The words of Donald Woods Winnicott, who was both a Paediatrician and Psychoanalyst, are a good place to begin in a thesis that brings together ideas from psychoanalysis and medicine. Winnicott was referring to the importance of the primary caregiving relationship for healthy infant development. This programme of research looks at the primary caregivers of preterm infants in the Neonatal Intensive Care Unit (NICU) and considers whether a nurse–infant relationship, as communicated through vocal soothing, is of benefit to preterm infants.

This chapter begins with an introduction to the field of infant mental health, its definition and focus on infant research. Psychoanalytic theories of emotional development and the practice of parent infant psychotherapy are presented. Sections two and three focus on preterm infants, their capacities, their experiences of pain and stress and how these can be mitigated. Sections four and five consider the emotional experience of infants in the NICU and proposes vocal soothing as a pain management intervention.

### 2.1 INFANT MENTAL HEALTH

The term ‘infant mental health’ was first introduced in 1980 by Selma Fraiberg, a social worker who, at the time, was working with blind babies and their parents. It referred primarily to the importance of sensitive and attuned caregivers for the optimal emotional development of infants (Zeedyk, 2008). Since then the concept has expanded to a whole field of infant mental health that promotes the emotional, cognitive, social and physical development of the young child from 0-3 years of age (up to the fourth birthday) (ZeroThree, 2016). The field is interdisciplinary; it includes research, clinical practice and policy-making, it crosses health, education and welfare and has become the responsibility of families, professionals and societies.

Infant mental health now refers to the emotional health of an infant within the context of their family, community, culture and society. A definition of infant mental health used in the New Zealand Ministry of Health's guidance document 'Healthy Beginnings' (published in January 2012) was derived from an Infant Mental Health Taskforce within the American organisation 'Zero to Three' (MOH, 2012) (ZeroToThree, 2016). It describes infant mental health as the:

- *developing capacity of the child to experience, regulate and express emotion*
- *ability to form close, secure relationships*
- *capacity to explore the surrounding environment and learn*
- *ongoing social-emotional and behavioural wellbeing of the infant and young child and their family and whānau.*

Infants are completely dependent on their caregiving environment for survival and opportunities for healthy mental development. The field of infant mental health includes promotion, prevention, intervention and treatment (Weatherston, 2015). Promotion may be provided by the community through new baby support groups while prevention may be undertaken by healthcare professionals, education providers or home visitors who have identified an infant and family at risk of developing a relationship that is not supportive of the infant's social, emotional and cognitive development. Intervention and treatment can be provided by infant mental health services when, for whatever reason, the infant does not have a reliable and robust relationship in which to express and learn to manage their emotions. Infant mental health clinicians focus on supporting families to be able to connect with and manage the emotional experience of their infant so that they can provide the kind of caregiving required for healthy infant mental development. The elements of an infant mental health service may include concrete resources, emotional support, developmental guidance, parent infant psychotherapy and reflective supervision to support the clinicians in work that is complicated and emotionally challenging (Weatherston, 2015). District Health Boards in New Zealand were advised by the Ministry of Health to set up and provide infant mental health services in all areas of New Zealand and in 2016 this had been achieved to varying degrees across the country (MOH, 2012).

The 'Healthy Beginnings' document includes a second definition that additionally focuses on the development of policies promoting and supporting infant mental health in infants at risk (Knitzer, 2000). These policies should:

- *promote the emotional and behavioural wellbeing of all young children*
- *help strengthen the emotional and behavioural wellbeing of children whose development has been threatened by environmental or biological risk(s) in order to minimise the impact of further environmental risks and enhance the likelihood that they will enter school with appropriate skills*
- *help families of young children overcome whatever barriers they face to ensure their children's emotional development is not compromised*
- *ensure that young children experiencing clearly atypical emotional and behavioural development and their families have access to needed services and supports.*
- ***expand the competencies of non-familial caregivers, health professionals and allied social services to promote the wellbeing of young children and families, particularly those at risk due to biological insult or exposure to a less than optimal environment (emphasis added)***

This last point is of particular relevance for preterm infants in NICU who are 'at risk' and cared for by 'health professionals'. It is directly in line with the aim of this PhD thesis, to consider ways in which the competencies of health care professionals can be expanded to support infant mental health.

### **2.1.1 INFANT MENTAL HEALTH RESEARCH**

The past 45 years have seen an explosion of infant mental health research. There is now evidence for the social capacities of infants from birth and the importance of attuned caregiver-infant interactions for the development of healthy emotional regulatory capacities in infants. These particular areas of research have specific relevance for this thesis and some of the evidence is summarised below.

Up until the 1960s the popular view of infant emotional development was that the infant mind was not organised, that infants did not have intentions and that any expressions were just reflexes (Trevvarthen, 2001). In the 1970s there began a series of discoveries that would change the way infants were viewed. Traditionally infant behaviour had been viewed under strict experimental conditions, which meant that the behaviours of infants were seen in isolation and the discovery of infant capacities were therefore restricted by the design of these behavioural experiments. Researcher Mary Catherine Bateson presented evidence in

1971 indicating that infants were not just a mass of behaviours and reflexes but that they were able to communicate in a way that preceded verbal conversation and she termed this 'protoconversation' (Bateson, 1971). It was noted by prominent paediatrician Berry Brazelton and colleagues in 1974 that "Most mothers...are unwilling or unable to deal with neonatal behaviours as though they are meaningless or unintentional" (T Berry Brazelton, Koslowski, & Main, 1974). Parents were ahead of the researchers when it came to an awareness of the intentionality of infants. Through detailed observation of infants under three months of age engaging with others, it was made clear that infants have the ability to take turns and to be able to invite and respond to the expressions of emotions in others (Reddy & Trevarthen, 2004). Young infants were found to have the ability to understand and respond to communicative intention by adults (T. B. Brazelton, Tronick, Adamson, Als, & Wise, 1975; Stern, 1971).

Further research in the 1980s and 1990s confirmed that infants of 6-12 weeks of age were sensitive to the contingency of their mother's face-to-face communications. Infant researchers Lynne Murray and Colwyn Trevarthen conducted two experiments (L Murray & Trevarthen, 1985). In the first, mothers were asked to chat to their baby normally and there occurred two breaks in contact, a naturalistic one where the mother's attention was diverted to the experimenter and a second where she was asked to present a blank face (unresponsive and expressionless) for 45 seconds. In the second experiment, infants were played a video recording of the previous communication from their mother, meaning that her face and voice were equally as animated yet not contingent with the infant's communication and experience at this time. The researchers found that in the blank face condition the infants tried to elicit responsiveness but ultimately spent more time looking away from their mother. In the replay experiment the infants also turned away from their mother but this time showed increased signs of distress and diminished expressions of positive affect. These experiments clearly show the infants' expectation for and participation in attuned and contingent contact with their mothers. Infants only minutes old have been shown to mimic actions by others such as tongue protrusion and infants are able respond with synchronicity to human speech at 12-48 hours of age (Condon & Sander, 1974; L. A. Murray, Liz, 2007).

Emeritus Professor Colwyn Trevarthen, residing in Scotland although originally from New Zealand, has dedicated his career over the past 50 years to researching the communicative



abilities of infants and the importance of their relationships with others for their healthy emotional development (Zeedyk, 2008). Following detailed analysis of mother–infant pairs, Trevarthen proposed a theory of ‘innate intersubjectivity’, the idea that infants are born to expect to communicate meaningfully with others (Trevarthen, 1977). Trevarthen’s post doctoral student Steven Malloch analysed a mother-infant dialogue and found their sounds to be matched and coordinated in pulse, quality and narrative. His theory of ‘communicative musicality’ holds that infants are born with an innate ‘musicality’, an expectation for a response in time (S. N. Malloch, 2000). Since this discovery, more has been written about communicative musicality and its importance for human companionship and understanding of shared meanings (Stephen Malloch & Trevarthen, 2009).

### **2.1.2 INTERSUBJECTIVITY**

The concept of intersubjectivity has been expanded to include other aspects of infant mental health such as *affect attunement*, *the reflective function of the caregiver* and *affect regulation* (Balbernie, 2007). These three aspects are briefly described:

- *Affect attunement* was first described by psychologist Daniel Stern in 1985. He describes this as something more than the imitation or matching of the feeling in the infant by the caregiver and instead describes it as a modified response, one in which the caregiver responds to the infant with “...behaviours that express the quality of feeling of a shared affect state, but without imitating the exact behavioural expression of the inner state.” (Stern, 1985). Some aspects of the feeling are matched; the intensity, the timing and the shape, but the response is described as a ‘cross-modal response’, meaning that if an infant signals an emotion with their body for example, the caregiver may respond with their voice to communicate to the infant that they have understood their internal experience. Stern describes this as interpersonal communion rather than communication. Stern demonstrated that when an infant over 6 months is given an attuned response, the result is one of continuity, the infant ‘goes on being’ without interruption. However, if there is affect misattunement, the infant will stop their flow, and respond as if wondering what happened (Stern, 1985).
- The *reflective function of the caregiver* refers to the capacity of the caregiver to be able to ‘mentalise’, that is to simultaneously reflect upon their own psychological experience and corresponding behaviour and the psychological experience and

corresponding behaviour of the child. Research has shown that high reflective function in mothers prospectively predicts a secure attachment pattern for the infant (Peter Fonagy, Steele, & Steele, 1991; P. Fonagy et al., 1995; Kelly, Slade, & Grienenberger, 2005) and has both a mediating and preventative role in the development of psychopathology, specifically borderline personality disorder (P. Fonagy, Gergely, Jurist, & Target, 2002; P. Fonagy et al., 1995).

- Young infants have limited capacity to self-regulate their physical and emotional experience. In order to achieve *affect regulation*, infants require an attuned caregiver to help them gain homeostasis. This has been described in the literature as co-regulation (Fogel, 1993), or mutual regulation (Tronick, 1989). It is in moments of stress that the infant most needs the help of an adult caregiver to help them regulate their emotional state (Schore, 1996). When infants are attended to and soothed by an adult caregiver, their ability to do this for themselves is facilitated through development of the neural pathways for emotional regulation. When this does not happen, the infant is at risk of failing to develop adaptive affect regulation capacities, which can be the basis of psychopathology such as occurs in mood disorders and personality disorders (Schore, 1996) or conduct disorder (Frick, 2016). Affect regulation depends on having a responsive, emotionally available adult who can observe the infant and consider the mind of the infant. The availability of a caregiver who can tune in and communicate with an infant has important implications for brain development.

### **2.1.3 INFANT BRAIN DEVELOPMENT**

The development of the human brain begins in the first trimester of pregnancy with the development of neurons in the neural tube of the embryo. These neurons migrate out to form the other parts of the brain and by the end of the second trimester of pregnancy the foetus has completed its production and migration of neurons (Berk, 2006). The human brain is made up of 100-200 billion neurons that store and transmit information. Each neuron connects with other neurons by releasing chemical neurotransmitters that cross synapses, or spaces between the cells. The neurons are developed by the 20<sup>th</sup> week of pregnancy and for the remaining 20 weeks in utero and throughout life, brain growth and maturation is brought about by these neurons forming connections with each other, through synapses, with the help of glial cells (Berk, 2006).

There is enough evidence now to be absolutely certain that the experiences infants and young children have with caregiving adults influence their brain architecture (Harvard, 2004; Panksepp, 1998; Perry, Pollard, Blakley, Baker, & Vigilante, 1995; Schore, 1996). While genes provide the blueprint for the brain circuitry, the circuits are strengthened by the repeated use that comes from experience in their relationships (Harvard, 2004; Schore, 1996). Brain scans looking at the pattern of brain glucose metabolism in Romanian orphans who were neglected showed clearly how their brains failed to develop (smaller with a lack of neuronal connectivity) compared with infants exposed to normal relational opportunities (Chugani et al., 2001). Nurturing experiences in the early years are critical in the proliferation and consolidation of neural connections.

#### ***2.1.4 EARLY EXPERIENCES MATTER***

A key component in the development of the infant's brain architecture is the day-to-day experiences of care involving 'serve and return' interactions (Harvard, 2004). In serve and return experiences, the child 'serves' by babbling, facial expression, gestures and the adults 'return' with vocalisations, facial expressions and gestures back. Every time an adult returns a child's serve, whether it's in a positive or a negative way, a connection between neurons is being made. This is supported by evidence that neural circuits will only fully develop in the presence of adequate stimulation such as social interaction (Cummins, Livesey, & Evans, 1977; Jacobson, 2013). Serve and return does not just happen with parents, it happens with everyone, from grandparents, to crèche teachers to other adults to strangers on the street. Anyone is able to respond to the serves offered them by a young child.

The concepts described above in sections 2.1.3 and 2.1.4 marry well with a psychoanalytic viewpoint and altogether they form the basis of parent infant psychotherapy. The next sections will provide an overview of some of the key psychoanalytic theories that pertain to infant development and describe the process of parent infant psychotherapy.

#### ***2.1.5 PSYCHOANALYTIC THEORIES OF INFANT EMOTIONAL DEVELOPMENT***

Psychoanalytic theories are based on the idea that behaviour is driven by both conscious and unconscious processes. This approach was first postulated by Sigmund Freud in the 1890s and later developed by psychoanalysts including Melanie Klein, Wilfred Bion and Donald Winnicott. While all psychoanalysts are concerned with early development, these theorists each made significant contributions to thinking about the experience of the infant in the

early weeks and months. Bion and Winnicott (and contemporary theorists since) focussed on describing how relationships with primary caregivers (external environment) meet an infant's experience (internal environment) to co-create the infant's emerging sense of self. Melanie Klein's theories centred around the internal psychological experience and how it develops in relation to caregiving activities.

Klein suggested that in the first six months of life an infant does not relate to the mother or father as a whole person, but instead as part of a person, called a 'part object' (Klein, 1975). This might be something like the breast, their voice, or their smell. The infant's experience of these things will be coloured by the feelings they have experienced, for example if they are calm and satiated, then they will experience these things as good and safe, however if the infant is experiencing discomfort such as hunger they are likely to experience the same part objects as negative or threatening. A common example of this is when an infant takes a while to accept the breast or bottle after having to wait for so long, despite the comfort being available. Contemporary Psychoanalyst Gertraud Diem-Wille has considered Klein's contribution in a recent book on early emotional development and suggested that "only the mother's calming words can diminish this stress and make the baby receptive to receiving the mother's skin contact as positive and accepting the offered bottle or breast" (Diem-Wille, 2011, p.83). Melanie Klein made many important contributions to psychoanalytic theories of emotional development and she was the first to psychoanalyse children (Klein, 1997).

Wilfred Bion was one of the early psychoanalysts to stress the importance of primary caregivers for helping infants manage 'big feelings', both joyful and painful (W.R. Bion, 1962; Ogden, 1992). He described this process as *containment*. Bion suggested that in infancy we have many raw feelings and experiences, but they cannot be made sense of without a container, without someone else who can 'metabolise' them for us and give them back in a digested form. Bion said that in this way, through the receiving of thought about thoughts, we develop the capacity to think ourselves. The infant has the emotional experience, the parent recognises it, accepts it, and reassures the infant that it is a valid feeling to have and they are not alone. In order for a mother to be able to offer containment to her infant, Bion suggested that she needed to be in a state of reverie, a sort of daydream state, where she is emotionally open to receiving the infant's communications, both good and bad. He postulated that this state of attunement allows the mother to more accurately and intuitively understand the infant.

Donald Winnicott (introduced at the beginning of this chapter) broke away from the Kleinian tradition in that he saw the environment as having more of an importance for child development than Klein had articulated. Winnicott added to the growing literature on the importance of attuned caregiver relationships for children with his writings published between 1935 and 1988 (two publications were posthumous following his death in 1971). He described the role of the 'good enough mother' as being to respond soothingly to the feelings expressed by the infant and suggested that failure of this leads the infant to develop a 'False Self' or as sometimes called a 'Caretaker Self' created by the infant to protect the 'True Self' in the absence of another to do it for them (Abram, 2007). Winnicott wrote in 1960 that "It is an essential part of my theory that the True Self does not become a living reality except as a result of the mother's repeated success in meeting the infant's spontaneous gesture or sensory hallucination" (Winnicott, 1990). Winnicott wrote in an accessible way about the importance of 'ordinary mothering' for the development of the infant's trust in the world, with specific focus on the need for the mother to be emotionally available for the infant in order to understand and respond to the infant's needs (Winnicott, 1988).

There are many reasons why an adult caregiver may not be available to tune in and communicate with an infant. The caregiver may be preoccupied with their own experience of depression, anxiety or trauma. They may be preoccupied with problems in their adult relationships including family violence. They may find that being with the infant brings up the 'ghosts' of problematic past relationships so that they interpret the infant's behaviour in negative ways (Fraiberg, 1975). Parents might find it hard to feel that they love their infant and may feel unable to cope with the demands of parenting. Or there may be a situation in which the infant has had multiple caregivers, none of whom are emotionally invested in the infant. Infants who are not emotionally well regulated develop symptoms such as avoidance, sleeping issues, difficulty self-soothing, feeding concerns or failure to thrive. It is usually symptoms in the infant, or the parents, or both infants and parents together that bring an infant and their family to intervention services. Assessment of the difficulties typically leads to decisions about which intervention will most appropriately support improvement in the relationship care of this particular infant.

The aim of a relationship-based therapy is to ensure a caregiving environment that is responsive to the social and emotional needs of the infant. Approaches differ according to

theoretical orientation. Parent infant psychotherapy is one of the approaches found to be effective in improving infant mental health outcomes (Acquarone, 2004; Baradon, Broughton, Gibbs, Joyce, & Woodhead, 2005; Pozzi-Monzo, 2007).

### **2.1.6 PARENT-INFANT PSYCHOTHERAPY**

Parent - infant psychotherapies are generally aimed at recognising and soothing the emotional expressions of the infant. While some psychotherapists may do this by focusing on helping the parents to 'talk to' and 'be with' their infant (Baradon et al., 2005; N. J. Cohen, 1999; Fraiberg, 1975), others 'talk to' and 'be with' the infant directly (Acquarone, 2004; Norman, 2001; Thomson-Salo, 2007).

The approach of psychoanalyst Johan Norman was to focus on the help the therapist could offer directly to the infant (Norman, 2001). Three important features of his technique have been described: (Salomonsson, 2010)

1. The analyst seeks to establish a therapeutic relationship with the baby
2. The analyst assumes the infant will use his primary intersubjectivity (Trevarthen & Aitken, 2001) to obtain containment (W.R. Bion, 1962)
3. The analyst assumes that the baby processes the non-lexical aspect of interactions

In other words, the infant will try and communicate with the therapist and the therapist will respond verbally in a way that is attuned and soothing to the infant.

### **2.1.7 SUMMARY**

The field of infant mental health is focussed on the importance of the caregiving environment for infant social, emotional and cognitive development. Research has shown that infants are capable social partners from birth and that affect attunement, affect regulation and the reflective function of the caregiver are important aspects of infant mental health. Infant brains are immature at birth and caregiving experiences determine their brain architecture in the early years of life. Psychoanalytic theorists and infant research into the behavioural and physiological regulation of infants have also identified relationships with caregivers as being integral for an infant's emotional development. Parent infant psychotherapy is one of the treatments available to support caregivers and infants to attune and connect with each other and as such, support infant brain development.

The theories and research described thus far do not focus on preterm infants, who are experiencing the external world in a different way to term infants given their relative developmental immaturity. The next section will consider the capacities and challenges faced by infants born preterm.

## **2.2 PRETERM INFANTS**

Any infant born before 37 weeks completed gestational age (GA) is considered to be preterm. Preterm birth rates across 184 countries range between 5-18% of all births and more than 80% of these preterm births are infants 32-37 weeks GA (Howson, Kinney, & Lawn, 2012). Preterm infants are categorised as late preterm (34 to <37 weeks), moderate preterm (32 to <34) very preterm (28 to <32 weeks) and extremely preterm (<28 weeks). The first global report of preterm birth, 'Born too Soon: The Global Action Report on Preterm Birth' published in 2012, suggests that rates of prematurity are rising (Howson et al., 2012).

The latest available data from New Zealand reports that of the 59, 494 live births in 2014, 4421 (7.4%) were preterm (MOH, 2015). Of these preterm births 748 (1.3%) were born at less than 32 weeks gestation and 3673 (6.2%) between 32 and 36 completed weeks gestation. These rates are similar to those over the past ten years with infants born at less than 32 weeks gestation ranging from 1.2%-1.4% and infants born 32-36 weeks gestation ranging from 5.9% to 6.3%.

Preterm birth can occur under two main conditions, (1) the infant is born following spontaneous onset of labour or preterm rupture of membranes (PROM) or (2), labour induction or caesarean section for maternal or foetal indications (Goldenberg, Culhane, Iams, & Romero, 2008; Howson et al., 2012). While a number of risk factors for spontaneous preterm birth have been identified, more research is required in order to ascertain exactly how they lead to preterm birth (Goldenberg et al., 2008).

Postmenstrual age (PMA) refers to the GA at birth plus the chronological age (CA). For example an infant born at 31 weeks GA who is two weeks old, will have a PMA of 33 weeks.

### **2.2.1 CAPACITIES OF PRETERM INFANTS**

Preterm infants, like term infants, are able to adjust their behavioural states in order to try and maintain an optimum level of arousal (Als & Brazelton, 1981). Even very premature

infants are able to take in information and learn from it (Stone, 1973) and their responses to painful stimuli are deliberate attempts to control their sensory input (K. J. S. Anand & Hickey, 1987; K. D. Craig, Whitfield, Grunau, Linton, & Hadjistavropoulos, 1993).

Infants from 32 weeks GA/PMA have a fully developed auditory system and it is recommended that the infant be exposed to human voices, directed towards the infant using 'parentese', a manner of speaking typically associated with higher pitch and longer sounds (Goines, 2008; Lutes, Graves, & Jorgensen, 2004; Milford & Zapalo, 2010).

Recommendations in the latest guidelines from the National Association of Neonatal Nurses (NANN) for auditory sensory integration from 32 weeks PMA onwards is to keep Neonatal Intensive Care Unit (NICU) noise below 50 decibels, use quiet voices to interact with the infant in order to support the learning of speech patterns that the infant would ordinarily be exposed to in utero between 31 and 40 weeks gestation (Liu et al., 2007) and to play lullabies and/or read books to the infant from 33 weeks PMA (C. Kenner & McGrath, 2010). The focus in these nursing guidelines is on the importance of auditory stimulation for cognitive learning and no mention is made of it being a possibility for soothing emotional dysregulation or as a way of being relationally in contact with an infant.

It has been shown that even a premature infant at age 32 weeks PMA can interact with 'protoconversational' patterns. Saskia van Rees was undertaking research on kangaroo care with premature infants and their parents when she recorded an exchange between an infant at 32 weeks PMA and her father. There appeared to be clear turn taking between them and when the father was distracted by another person, his daughter cooed to him as if inviting him back into conversation with her (van Rees & de Leeuw, 1993).

### **2.2.2 COMPLICATIONS OF PRETERM BIRTH**

Preterm infants face a number of difficulties related to their prematurity. They are likely to have feeding difficulties, are at higher risk for infection, have lung immaturity that can lead to respiratory distress and are at risk of metabolic complications such as developing jaundice due to an immature liver. Preterm infants are also at risk of intraventricular haemorrhage, necrotising enterocolitis, retinopathy of prematurity and anaemia of prematurity. All these complications of prematurity can potentially compromise brain development (Howson et al., 2012).



Premature infants can spend up to three or four months in a neonatal intensive care unit and may not only have fewer opportunities for intimate interaction with their primary caregiving parents, but also are subject to painful and therefore stressful experiences.

### **2.2.3 PRETERM INFANT EXPERIENCES OF PAIN**

Traditionally infants were considered to be insensitive to pain, but this view has been proven incorrect (F. L. Porter, Grunau, & Anand, 1999; Bonnie J. Stevens et al., 2011) and infants have been shown instead to have an increased sensitivity to pain (K. J. S. Anand, Sippell, & Aynsley-Green, 1987; Fran Lang Porter, Miller, & Marshall, 1986).

Preterm infants in an NICU environment experience between 5-16 painful procedures per day, with a heel prick procedure to obtain blood samples occurring in 55-86% of those and it has been suggested that infants may find it difficult to return to a stable physiologic state in between these procedures (Carole Kenner & McGrath, 2004; B. Stevens et al., 2003). It is not always obvious behaviourally that an infant is in pain. It has been shown that infants in neonatal care for four weeks demonstrated a reduced behavioural response but increased physiologic response to heel prick procedures over time and that this was predicted by the number of painful procedures they had received previously (C. Celeste Johnston & Stevens, 1996).

Repeated painful experiences have been shown to alter infant responses to pain in the short term (K. J. S. Anand, 1998). Longer term effects on the developing brain, such as impaired cognitive functions, may be caused by neuronal death following painful experiences (Bouza, 2009). Preterm infant cortisol responses to painful stimuli may be initially inhibited and later increased in comparison to term controls (Ruth E. Grunau et al., 2007; Provenzi et al., 2016). For infants born at or less than 32 weeks gestation, poorer cognition and motor function at 8 and 18 months were both found to be independently associated with the number of exposures to skin-breaking procedures experienced during their time in the neonatal unit (Ruth E. Grunau et al., 2009). Paediatric pain researchers Anand and Scalzo have proposed that exposure to pain and stress in human infants may create changes in the developing brain that can be linked to “increased anxiety, altered pain sensitivity, stress disorders and hyperactivity/attention deficit disorder, which lead to impaired social skills and patterns of self-destructive behaviour” (K. J. S. Anand & Scalzo, 2000, p.60). They based this hypothesis on research that suggests that neonatal pain and stress in rat pups leads to changes in adult

rat behaviour (Fillion & Blass, 1986; F. S. Hall, 1998). It has also been suggested that the more pain they are exposed to as infants, the more sensitive to pain they may be when they are older children or adults (K. J. S. Anand & Scalzo, 2000; Ruth E Grunau, Whitfield, & Petrie, 1998). The assessment of pain in immature infants is difficult in both the research and the clinical setting. This is discussed in more detail in chapter three.

#### **2.2.4 SUMMARY**

Preterm infants accounted for 7.4% of all live births in New Zealand in 2014 and international evidence suggests this figure is increasing. Infants born premature have the capacity to adjust their behavioural states in order to try and self-regulate. From 32 weeks gestation their auditory system is fully developed and it is recommended that they be exposed to 'parentese'. There is evidence that infants can engage in protoconversation as early as 32 weeks gestation. Infants perceive and feel pain and can be exposed to many painful procedures per day while in NICU care. Researchers and clinicians have sought to develop effective pharmacological and non-pharmacological methods to manage pain for preterm infants and these will be discussed in the following section.

### **2.3 INTERVENTIONS FOR PAIN AND STRESS IN THE NICU**

International research has focussed on developing effective ways to manage preterm infant pain and stress. While pharmacological interventions are indicated for surgery and major procedures, both pharmacological and non-pharmacological interventions are available for the management of routine procedural pain (Keels et al., 2016).

#### **Pharmacological interventions**

Pharmacological interventions for procedural pain are available but their role is still being evaluated, both in terms of effectiveness and potential adverse consequences. Topical local anaesthesia (Lidocaine-Prilocaine (EMLA) cream) has been found to be ineffective for reducing heel prick and venepuncture pain, two of the most common painful procedures in the NICU (Bonnie Stevens et al., 1999).

There are concerns regarding preterm infant exposure to opioid and acetaminophen (paracetamol) analgesia during such a vulnerable stage of development (van den Anker & Allegaert, 2016). Opiates have been used for severe pain (e.g. post-operative), but their use in procedural pain is less well established. Side effects of opiate use include hypotension and

respiratory depression for some preterm infants (R. W. Hall, Kronsberg, Barton, Kaiser, & Anand, 2005; Rennie, 2012). A recent study found a link between opioid exposure and poorer cognitive outcomes at 20 months in extremely low birth weight infants (Kocek, Wilcox, Crank, & Patra, 2016). Another study found that morphine exposure led to smaller cerebellar growth and poorer neurodevelopmental outcomes (Zwicker et al., 2016). Opioids have been found to be sensitive to the developmental age of the infant but inter-individual variability has been observed and more research on optimal doses is required (Allegaert, Simons, Vanhole, & Tibboel, 2006; K. J. Anand, 2016; Nandi & Fitzgerald, 2005; Pacifici, 2016). There is also an indication that morphine is not effective for acute procedural pain (Carbajal et al., 2005). Intravenous acetaminophen has been found to decrease the need for morphine in very preterm infants (Härmä, Aikio, Hallman, & Saarela, 2016) In this study 108 infants were regularly given paracetamol during their stay in NICU and were given morphine whenever their pain (measured using the Neonatal Infant Acute Pain Assessment Scale) was unable to be first managed non-pharmacologically. The cumulative dose of morphine over their time in NICU was calculated for these infants and was found to be significantly lower than for control infants who did not receive the paracetamol. It is not clear what the long term effects of increased acetaminophen use in infancy are (van den Anker & Allegaert, 2016). There is some evidence that links exposure to acetaminophen in pregnancy with hyperkinetic disorders at age 7 and attention-deficit/hyperactivity disorder symptoms at age 7 and 11 (Liew, Ritz, Rebordosa, Lee, & Olsen, 2014; Thompson et al., 2014). Due to the possible iatrogenic effects of pharmacological pain management and the paucity of data around the short and long term outcomes of its use, there is a need for non-pharmacological methods of pain relief (Keels et al., 2016).

### **Non-pharmacological interventions**

Oral sucrose, considered to be a non-pharmacological intervention, has been found to be effective for reducing term and pre-term infant pain during heel prick procedures, venepuncture and intramuscular injections (B. Stevens, Yamada, Ohlsson, Haliburton, & Shorkey, 2016). In a recent Cochrane review, involving 74 randomised controlled trials, the reviewers concluded that sucrose is safe in the short term, with a low incidence of minor events such as choking or gagging, which also happened in control groups so were not attributable to the sucrose itself (B. Stevens et al., 2016). There were no reported major adverse events although more research is needed regarding the lowest effective dose and

the potential long-term impact of repeated use (C Celeste Johnston et al., 2007; B. Stevens et al., 2016).

Kangaroo Care, Non-nutritive sucking (Pacifier), Swaddling/Tucking and Environment Modification have been identified as evidence-based non-pharmacological interventions (Pillai Riddell, Racine, Turcotte, & Uman, 2011). Non pharmacological interventions do not appear to have any short or long term negative sequelae, however some studies provide evidence that suggests they are not frequently used by NICU staff during routine painful procedures (Carbajal et al., 2008; Jeong, Park, Lee, Choi, & Lee, 2014; C. Johnston, Barrington, Taddio, Carbajal, & Fillion, 2011; Roofthoof, Simons, Anand, Tibboel, & van Dijk, 2014). The focus in the literature is now on the development of strategies to encourage nursing and medical staff to use these interventions more often (Harrison, Bueno, & Reszel, 2015).

The NICU is increasingly being seen as a place not just for the physical care of the infant, but also their emotional and developmental care (Legendre, Burtner, Martinez, & Crowe, 2011). Psychological or relationship based interventions such as infant led singing, sensorial saturation and ATVV (Auditory, Tactile, Visual and Vestibular) Intervention have evidence supporting their use during painful procedures and each of these interventions are described in detail in chapter seven.

Some of these non-pharmacological interventions may be more suitable for some infants than others and may be more applicable in particular types of stressful situations than in others. The importance of individualising the care for each infant in NICU is increasingly being seen as necessary, especially given the understanding that procedures and routine and non-routine handling are both painful and stressful for infants in NICU. In a paper published in 2011, Robert White summarised the evidence for individualising the care for preterm infants. He proposed that since it is a time in which infant brain growth and development proceed at a pace unmatched at any other time in life, attention must be paid to the environment that is needed to facilitate the healthy development of these infants. It is no longer enough to just keep infants alive in the NICU, their brain development needs to be considered as a part of the equation (White, 2011). Developmental Care is an ideology and cluster of care practices with a specific focus on the infant's neurodevelopment.

### **2.3.1 DEVELOPMENTAL CARE**

Developmental Care began as a formalised assessment of individual infant needs, developed by a clinical psychologist, Heidelise Als and called the 'Newborn Individual Development Care and Assessment Program (NIDCAP). The NIDCAP approach focuses on planning individualised care based on observations of the infant's behaviour thereby recognising the infant as a person with goals and facilitating the development of a caregiver relationship with the infant (Als & Gilkerson, 1997). Studies have been published reporting favourable medical outcomes and enhanced brain function and structure for infants using this approach (Als, Duffy, & McAnulty, 1996; Als et al., 2004; Westrup, Sizun, & Lagercrantz, 2007). However, a meta-analysis involving eighteen studies with 627 preterm infants found there to be no evidence that the NIDCAP intervention improves long-term neurodevelopmental outcomes or short-term medical outcomes (Ohlsson & Jacobs, 2013). The outcomes measured in this meta-analysis were physical, for example the primary long term outcomes that were considered were whether the child was alive or not, whether they had a major sensorineural disability and/or cognitive delay and/or hearing loss and/or blindness. Similarly, the short-term outcomes measured were also physical and included clinical diagnoses such as chronic lung disease, retinopathy of prematurity and necrotising enterocolitis. Other short-term outcomes were length of hospitalisation, daily weight gain, infant behaviour and sleep. There were no assessments reported of an infant's psychological functioning either in the short term or the long term.

The Developmental Care approach is based on Als' Synactive Theory of Infant Development in which the infant is viewed as having five 'subsystems of functioning' - motor, autonomic, states, attention/interaction and self-regulatory - which all interact with each other and the environment (Als, 1982). If the environment is felt to be too overstimulating or stressful for the infant, the infant will react behaviourally and physiologically and these subsystems will become unbalanced. These subsystems in preterm infants are not yet fully developed, meaning that they become unbalanced easily and the infant will often show signs of stress. The theory outlines the behavioural manifestations of stress for each subsystem and lists strategies for helping the preterm infant maintain equilibrium.

Developmental Care has grown to become a caregiving philosophy that aims to minimise the potential adverse effects of the NICU environment on infants. It acknowledges the preterm infant as being at a critical stage of brain development and advocates for individualised

relationship based care. Family involvement is seen as a very important aspect of this philosophy. An interdisciplinary task force on developmental care developed the following philosophy statement: “Developmental Care is a philosophy that embraces the concepts of dynamic interaction between the infant, family and surrounding environment.

Developmentally supportive care provides a framework in which the environment of care and the process of delivering care are modified and structured to support the individualized needs of the developing newborn and family” preface p(ix) (C. Kenner & McGrath, 2010).

Developmental Care aims to help the infant keep a physiological and behavioural equilibrium. In practice it means that the caregiver needs to assess the infant’s state and readiness for interaction with the environment before intervening with them. It requires caregivers to be alert to the infant’s manifestations of stress and to offer appropriate comfort. Caregivers need to be in tune with the infant in order to offer this relationship based care and are encouraged to practice ‘mindfulness’ when interacting with the infant (Epstein, 2003; C. Kenner & McGrath, 2010). Mindfulness means being with the baby in the moment. Caregivers are encouraged to empathise with the baby’s experience (Ballweg & Nepstad, 2010) and to be mentally and emotionally engaged during interventions (R. C. White-Traut, Dols, J. & McGrath, J.M., 2010) in order to be able to offer truly supportive Developmental Care. A reflective stance is suggested whereby the caregiver both notices and adjusts their behaviour according to their own and the infant’s responses to an interaction.

One of the issues with Developmental Care has been a lack of specificity and uniformity in its definition and practice (S. Gibbins, Coughlin, M. & Hoath, S., 2010). In order to address this the ‘Universe of Developmental Care Model’ was developed (S. Gibbins, Coughlin, M. & Hoath, S., 2010). This theoretical and practical model builds on Als’ synactive theory and is conceptualised as a solar system. The infant is at the core and the surrounding planets form orbits that surround the core, affecting it and being affected by it more or less depending on how close they are. The planets refer to specific care interactions that caregivers may have with the infant and include feeding, positioning, infection control, safety, comfort, thermoregulation, skin care, respiratory and monitoring/assessment. Key to this model is that the infant’s self-regulating abilities are seen as being dependent on caregiver behaviour. This distinction highlights the importance of caregiver activity yet also provides a clear research guide; it is the behaviour of the caregiver that can be assessed for its impact on the

infant's regulation, rather than trying to assess the infant's ability to self-regulate. It is suggested that as the infant's central nervous system cannot be observed and assessed directly, the 'skin level surface' of the infant, for example how they look, their skin tone and their behaviour, is the place that directly interfaces with both their internal functioning and the external caregiving environment and the impact of the interplay between these can be observed visually by looking at the infant. Five core measures for Developmental Care have been identified in order to try and standardise the developmentally supportive care practices and they include protected sleep; pain and stress assessment, management of activities of daily living, family centred care, and the healing environment. It is proposed that these measures form the basis for research planning but that also an individual caregiver should keep them in mind during every single interaction with each infant in their care. The idea is that caregivers are continually asking themselves what they can do to ensure that this intervention they are about to undertake with the infant is in line with these core measures (S. Gibbins, Coughlin, M. & Hoath, S., 2010).

Developmental care continues to evolve as ways to involve the family in the care of their infants are developed. 'Family Centered Developmental Care' focuses on how NICU staff can support parents to provide developmentally supportive care to their infants. The philosophy now considers parents to be vital members of the NICU team and includes them in decision-making processes in order to support the 'lifelong' relationship they have with their child (J. Craig et al., 2015). The 'Neonatal Integrative Developmental Care Model' uses seven core measures for 'neuroprotective family-centered developmental care' (Altimier, 2011). These measures include strategies for supporting the healing environment, partnering with families, positioning and handling, safeguarding sleep, minimizing stress and pain, protecting skin and optimizing nutrition. Programs such as the Wee Care Neuroprotective NICU training program are proving effective in improving neonatal care and practices in each of the seven measures (Altimier, Kenner, & Damus, 2015).

### **2.3.2 SUMMARY**

There are a number of 'relationship-based' non-pharmacological interventions such as infant led singing, sensorial saturation and the ATVV intervention that have been developed. The Developmental Care literature focuses on how to adapt the environment and caregiving practices to help regulate the infant and include the family in their care. An attitude of relationship-based care is assumed in which the infant is acknowledged as a human being.

This involves connecting with infants in order to gauge what kind of interactions they can tolerate at this moment in time. It also aims to support the family to be able to feel competent and connected with their infant. The model does not further define nor discuss what 'connecting' with an infant might consist of.

## **2.4 INFANT MENTAL HEALTH IN THE NICU**

### **2.4.1 SUPPORTING PARENT INFANT RELATIONSHIPS**

Consideration of the parent-child relationship in hospital is not a new idea. 'Care by Parent Units' in the 1960's were considered to lessen the emotional trauma of hospital for children by allowing parents to stay with their children and provide the majority of their care (James & Wheeler, 1969). For infants in NICU, 'Family Integrated Care' is a model that encourages and supports parents to provide all the care to their infant in the NICU, with the support of medical and nursing staff as required. A Canadian pilot study assessing the effectiveness of this model found it led to increased weight gain for infants, better breastfeeding rates and lowered parental stress (O'Brien et al., 2013). Further studies of this model are underway in other NICUs in Canada, Australia, New Zealand and China (Hei et al., 2016; O'Brien et al., 2015) and if found effective this is a model that appears to support the physical health of infants and the emotional health of parents. It may also support the parent-infant relationship.

A Developmental Care 'Guide for health professionals', now in its second edition, includes a chapter on infant mental health with strategies for how the NICU caregiver can promote the parent-infant relationship (C. Kenner & McGrath, 2010). These strategies are aimed at helping the parent feel they are an effective parent to their baby and are designed to help parents recognise and respond to their infant's cues in order to support reciprocal communication (Gale & Heffron, 2010). In this way infant mental health is seen as the responsibility of the parents with the role for non-parental caregivers being to support parents in this role with their infants. Similarly, in a recent infant mental health textbook, the chapter concerning premature infants focuses on helping parents to be able to connect with and care for their infants in the NICU (Mares, Newman, & Warren, 2011). Neither of these books considered the ways in which the care offered (or not) by healthcare staff may impact upon infant mental health.



An article in 2016 in the *Infant Mental Health Journal* described a survey undertaken of NICU staff around their perceptions of 'attachment and socio-emotional development' of infants. It was found in this relatively small sample, involving 57 staff from one NICU in Ireland, that 95% of the respondents considered their role as important for supporting parent-infant relationships (Twohig et al., 2016). An argument is made for supporting the parent-infant relationship in order to facilitate attachment, however it is not acknowledged that the attachment strategy of the infant does not become organised until well into the second half of the first year of life (Bretherton, 1985). Twohig et al. state that the attachment relationship is important in the early months for emotional regulation of infants and it is implied that it is the role of parents to provide this kind of care to preterm infants in order to give them the best chance to develop. The term attachment can be misrepresented in the literature to mean 'relationship', for example Flacking wrote that "Parental attachment to the infant, also called psychological bonding, begins and is strengthened throughout pregnancy" (Flacking et al., 2012). In fact, attachment security refers to the set of strategies that an infant has developed by the end of their first year for use under stress. It is not synonymous with parental bonding to their infant (Bretherton, 1985).

The parents of an infant in the NICU studied are not usually the day-to-day caregivers of the infant until near to discharge. Parents do not sleep in the unit and if the mother is still an inpatient she is likely to be physically unwell. A model of Family Integrated Care does not operate there and even if it did, mothers and fathers may not be psychologically stable enough to provide attuned care, they may be recovering from a traumatic delivery or still coming to terms with the early arrival of their infant. Their stress levels are likely to be high (Holditch-Davis, Bartlett, Blickman, & Miles, 2003) and they may be managing other family members at home. Mothers have been found to visit their infant for a mean length of 3 hours per day (Franck & Spencer, 2003). The mother may spend much of her time expressing milk in a room away from her infant or she may spend time away from her infant because she is trying to manage her own experience of depression or other perinatal mental illness (Miles, Holditch-Davis, Schwartz, & Scher, 2007). There will also be infants for whom their mother has died or who have parents who are not visiting, perhaps due to neglect or adoption processes or because they have to care for other children at home in the regional centre where they live. A NICU stay is not in itself detrimental to the parent-infant relationship; a meta-analysis of the literature found that preterm infants were just as likely

to eventually form secure relationships with their mothers as term infants (Korja, Latva, & Lehtonen, 2012).

Infants undergoing traumatic experiences may have an added (or double) trauma that is the absence of an attuned loving relationship (through the physical absence of parents and/or emotional absence of parents and/or caregivers/healthcare staff) to help them manage these experiences. In describing her work as psychiatric consultant to the NICU, Goodfriend found that the lack of reciprocally positive contact from a consistent, caring adult contributed to irritability and failure to thrive in hospitalised premature infants who remained in the NICU for many months. She diagnosed these infants with reactive disorder of infancy and suggested that volunteers be assigned to provide the consistent positive human contact necessary for the development of normal mental health (Goodfriend, 1993).

The promotion and support of parent-infant relationships seem to be seen as the goal for emotional care in the NICU. 'PremieStart' is another programme that focuses on helping the parent to attune more to the specific care needs of their infant (Dibley, Rydin Orwin, Stedmon, & Dallos, 2016). However in a setting such as the NICU, where there is high exposure to pain and stress and potentially many caregivers, there is more to emotional care than an infant's relationship with their parents. Soothing and comfort are what is important for the infant's sense of psychological regulation and it is not essential for this care to come from parents (Bretherton, 1985). Perhaps it would be more accurate to say that parent-infant relationships should be supported alongside ensuring that every caregiver that comes into contact with the baby has their emotional needs at the forefront of their mind.

#### **2.4.2 A CASE FOR 'COMPANIONSHIP'**

Infants seek communication and comfort from caregivers: that is, anyone who offers them care. Colwyn Trevarthen promotes 'companionship' for infants and suggests that it does not necessarily have to be the biological mother who provides this. Infants are born ready to have their needs met by any sympathetic adult willing and able to enter their emotional world (Trevarthen, 2001). Volunteer Cuddler programs exist in many hospitals (e.g. Golisano Children's Hospital, New York; Saint Boniface General Hospital, Winnipeg, Canada) and these are designed to promote health by providing premature infants with touch and talk in the absence of their parents (Fritsch-deBruyn, Capalbo, Rea, & Siano, 1990).

The nurse on any given shift is responsible for the medical care of the infant and it may not be enough for the infant to have to wait for the parents to visit to receive their emotional care. In considering the brain development literature summarised above, it would be a logical assumption to make that, in order to meet an infant's mental health needs in the NICU, every caregiver of the infant would need to be attuned to his/her emotional as well as physical needs. This does not mean that each nurse (or other health professional) needs to be emotionally invested in each of their infant charges, but more that each interaction with the infant is considered to be a meeting of two human minds, an act of companionship. Is it a missed opportunity for infant development if there is not enough attention paid to the importance of their contact with medical and nursing staff? Preterm infants can spend up to three or four months in the NICU following birth and have many experiences of contact with adults other than their parents. Many of these experiences are painful and stressful, exactly the kinds of experiences through which infants need the most soothing.

### **2.4.3 SUMMARY**

There is a focus in both the nursing and infant mental health literature on supporting parent infant relationships in the NICU as a way of promoting good infant mental health. Parents are not often the day-to-day caregivers of their infants in the NICU until they are close to discharge. During the time infants are in the NICU, they are able to be physically and emotionally regulated by anybody who offers them care. The goals for infant mental health and nursing care are the same in the early months: for infants to be soothed and comforted, especially when stressed and distressed.

## **2.5 VOCAL SOOTHING: A PSYCHOLOGICAL PAIN MANAGEMENT INTERVENTION**

Although infants in the NICU often cannot be picked up and rocked to be soothed in the same ways that term or healthy infants are able to be, they can listen to a soothing voice and this may have a soothing effect. From birth, infants seem to be predisposed to listen and respond to the human voice (Eisenberg, 1976; L Murray & Trevarthen, 1985) and infants only one hour old can orient to the sound of gentle human speech (Alegria & Noirot, 1978). Is it possible that a soothing voice during painful interventions could reduce the experience of pain and stress for preterm infants?

Talking to children during painful procedures is not a new concept. Studies in the field of paediatric psychology have looked at the impact of adult vocalisations on children's distress during painful procedures and found that certain kinds of vocalisations were associated with more child distress than others. Specifically, vocalisations categorised as either reassuring, empathic or apologetic were found to be associated with higher child distress than vocalisations that were categorised as distracting (Blount et al., 1989). Blount and colleagues used the 'Child – Adult Medical Procedure Interaction Scale – Infant Version' to assess the impact of vocalisations and other soothing behaviours on infant distress during immunisations (Blount, Devine, Cheng, Simons, & Hayutin, 2008). The study included 49 infants, aged between 2 and 20 months of age with either their parent or a nurse. They found infant sucking and holding the infant 'belly to belly' to be the most helpful when an infant was most distressed and found distraction (either verbal or playing with an object) to be helpful when an infant is less distressed. Like the previous study with older children, they found verbal reassurance, empathy and apology to be unhelpful in relieving infant distress. In this study 'infant distress' was measured by intensity of cry and the use of a facial coding system. No physiological measures of infant distress were measured. The authors acknowledge in this study that no causal statements can be made as the measure does not take into account the fact that an infant in more distress may encourage more reassuring, empathic or apologetic responses from the adult. There do not appear to have been any studies such as this done with preterm infants.

Infants prefer infant-directed speech to adult-directed speech (Cooper & Aslin, 1990). The specific linguistic features of infant directed speech, as described in a review of the literature by Saint-Georges and colleagues, are that compared to adult directed speech there are fewer words, more repetitions, clearer articulation and simpler sentence structures. The prosodic features include a higher and wider pitch with more distinctive pitch contours, a slower tempo with longer pauses and more emphatic stress (Saint-Georges et al., 2013).

Descriptions of infant directed speech focused initially on the linguistic and prosodic features (e.g. (Ferguson, 1964; Anne Fernald, 1989)), but have since expanded to include the relational aspects, as the infant and caregiver respond to each other in an interactive loop (Saint-Georges et al., 2013). Infant directed speech is now considered to be as much about connecting and communicating emotional intent with the infant as it is a description of how the language sounds. The prosodic features of infant directed speech have been found to

vary according to the caregiver's intention for example, falling pitch contours if the infant is being comforted or rising pitch contours if their attention is being attracted (A Fernald, 1991). Because of these cadences in the speech, infants can sense the emotions being conveyed (Caron, Caron, & MacLean, 1988). Communicative intent and preference varies with age. Infants under the age of 3 months have been shown to both receive and prefer more 'comforting' infant directed speech than 'approving' or 'directive' infant directed speech (Kitamura & Lam, 2009).

Although the importance of infant directed speech has been identified for language production in young children, it is also considered to have importance for cognitive and emotional development as well (Saint-Georges et al., 2013). There may also be benefits for physical development as one study found that 3-4 month old infants had more rapid growth when they were exposed to infant directed speech (Monnot, 1999).

The focus on the relational aspects of the interaction (interactive loop) described in the infant directed speech literature also occurs in the theory and practice of parent infant psychotherapy. The assumption in parent infant psychotherapy is that although infants do not understand the actual words spoken to them, they do understand the emotional intention behind the words. If this is the case, then there may be therapeutic value in nurses offering vocal soothing to infants under stress. This vocal soothing would need to be truthful, that is recognise and name the infant experience, in order to be meaningful to the infant and help them feel understood, reassured and therefore contained.

It would not be practical for nurses to enter a state of reverie with every infant in their care, however tuning into the infant during a painful experience would be achievable. There is evidence that interventions can be more effective when the clinician focuses their attention on the infant (Ventegodt & Merrick, 2004). Anand and colleagues stress the importance of clinicians working in the NICU expressing empathy and love for their patients and suggest that this is crucial in order to 'maximise the benefits' of evidence-based medical interventions to reduce stress (K. J. S. Anand & Hall, 2008).

If nurses are to offer their voice and emotional presence to an infant during a procedure as a pain management tool, they need to be in an attuned state, thinking about the infant and 'being with' the infant emotionally. Nurses who speak to their colleagues while carrying out a painful procedure on an infant are physically present with the infant during the procedure

but not likely to be emotionally present. When nurses say to infants during painful procedures that 'it doesn't hurt' or 'nothing is happening' the infant's experience is in fact, being minimised or denied and the nurse is not providing an attuned response. Containment is only possible if the caregiver is open to receiving and accepting the infant's communications and in particular their level of stress. The psychotherapeutic viewpoint is that the human presence is about 'being with' and 'thinking about' the infant emotionally not just physically.

### **2.5.1 A MODEL OF 'NURSE VOCAL SOOTHING'**

A model of nurse vocal soothing is proposed. The model is based on both the infant directed speech literature and the theory and practice of parent infant psychotherapy. The vocal soothing would consist of the linguistic and prosodic features of infant directed speech, offered in a way that recognises and is emotionally responsive to the cues of the infant. Specifically the infant directed speech would consist of simple words with many repetitions provided with many falling pitch contours and a slower tempo. The intervention is further defined in chapter three, section 3.2.

If a nurse is emotionally available to the infant's communications and conveys this to the infant through an attuned, empathic voice, similar to 'parentese', it is hypothesised that the infant may achieve containment. In this way, the nurse is responsive to the infant's communications in the moment, leaving the infant feeling that they are accompanied in their pain and, therefore, soothed.

The words used by the nurse are a critical component of this communication. They must be truthful and used in context in order to help the infant feel that their experience has been well understood. One way to ensure this is to consider these steps suggested for procedural pain management (Halimaa, 2003):

- Creating an environment that is favourable to effective pain management
- Safe preparation of the infant for the procedure
- Pain alleviation during the procedure
- Restoring the infant's sense of security after the procedure.

These steps can be understood in terms of vocal soothing. Firstly offer a warning about what is about to happen, then talk the infant through the procedure and finally have a time of debriefing afterwards. The aim is to accompany an infant through their experience from the

start to the finish, to see it from their point of view, to offer warning or preparation about what is to come, to be aware of how the infant is feeling during the procedure and then to have a review of what has happened before moving on to the next task. Pain management as a process can enhance the emotional health of the infant through making the experience meaningful to them. Someone is thinking about them and how they are feeling and the infant is aware of this. Talking through a procedure has been found to be beneficial to children aged 2-7 years. Salmon and colleagues found that talking to children about what was happening to them reduced their distress compared with standard care or receiving a cartoon distraction only (Salmon, McGuigan, & Pereira, 2006).

During this process the nurse must be attuned to the experience of the infant. They need to feel both empathic and confident that the infant will tolerate the procedure well and recover well from any temporary stress that they experience. The essence of the theory of containment is that an infant is reassured and soothed when they feel that another person understands how they are feeling, without being overwhelmed by that feeling, and is able to remain calm and supportive.

### **2.5.2 SUMMARY**

This chapter has introduced the field of infant mental health and briefly discussed two definitions that acknowledge that infants are completely dependent on their caregiving environment for survival and opportunities for healthy mental development. There is evidence for the social capacities of infants from birth and the importance of attuned caregiver-infant interactions for the development of healthy emotional regulatory capacities in infants. Important aspects of the caregiver-infant relationship have been identified as the ability of the caregiver to recognise and respond to the feeling that an infant has (affect attunement), the ability of the caregiver to consider their own behaviour and emotional state as well as that of the infant (reflective capacity) and the help that the caregiver provides the infant in returning to physical and emotional equilibrium (affect regulation). The architecture of the infant brain is dependent upon the early experiences they have.

The psychoanalysts Melanie Klein, Wilfred Bion and Donald Winnicott all made significant contributions to theoretical thinking about the infant in the early weeks and months of life. Bion and Winnicott particularly considered the role that the caregivers have in connecting with and soothing the emotional experience of the infant. Relationship based therapies,

such as parent infant psychotherapy aim to ensure a caregiving environment that is responsive to the social and emotional needs of the infant.

Preterm infants are born before 37 completed weeks of gestation and comprised 7.4% of all live births in New Zealand in 2014. From 32 weeks PMA, preterm infants have a fully developed auditory system and exposure to human voices for cognitive learning is recommended. There are no explicit recommendations for the use of human voice in soothing emotional dysregulation in the National Association of Neonatal Nurses guidelines for practice. Preterm infants in a NICU environment experience between 5-16 painful procedures per day and exposure to pain and stress may lead to adverse outcomes.

There is evidence for psychological or relationship-based interventions in the NICU and Sensorial Saturation is aimed specifically at mitigating preterm infant pain and stress. Developmental Care is both a set of practices and an ideology that aims to help the infant keep a behavioural and physiological equilibrium by attuning to the infant's manifestations of stress and offering comfort.

Both the nursing field and the infant mental health field appear to consider infant mental health to be an important aspect to consider in the NICU. The focus is on how nursing and medical staff can support parents, to then enable them to attend to the mental health needs of their child. Parents are not usually the day-to-day caregiver of their infant in the NICU and as infants in their early weeks and months respond to care from anybody, all caregivers of preterm infants are responsible for the infant mental health.

Vocal soothing as a pain management intervention is proposed, using ideas from infant research and parent infant psychotherapy. In this intervention nurses would attune to infant emotional experiences during painful experiences and offer vocal comfort using infant-directed speech.

The research programme for this thesis aims to assess the effectiveness of a vocal soothing intervention in reducing manifestations of preterm infant pain and stress during a routine painful procedure. The methodology chapter will describe in detail the vocal soothing intervention, measures of preterm infant pain and stress and the method journey for this research programme.



## 3 METHODOLOGY

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*...the very first requirement in a Hospital (is) that it should do the sick no harm.*

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(Nightingale, 1863, p.iii)

Nurse Florence Nightingale was famous for her reforms of the unsanitary conditions in hospitals during the Crimean war and her words above encapsulate this. The same could be said of neonatal care and research. This is an important ethical issue to consider now that more is known about the experiences of preterm infants and how they are affected by painful procedures. Any study involving preterm infants should consider carefully whether ethical care is withheld for the sake of a control condition. The very first requirement of the methodology of this research with preterm infants was that it should do them no harm.

This chapter will describe the decision-making regarding the population chosen to be studied, provide more detail regarding the vocal soothing intervention and explain the rationale for choosing the heel prick procedure as the painful procedure to study. Four measures of infant stress will be discussed and reasons given for their inclusion in this research programme. A description of the cultural consultation that took place for this research is provided and finally an overview of the method journey will be presented.

### 3.1 POPULATION

#### 3.1.1 INFANTS

The participants for this research project came from a population of premature infants, born between 32 and 35 weeks completed GA, in their first 2-10 days of life and requiring two heel prick blood tests as part of their usual care. The parents of infants were approached for inclusion if the nurse caring for the infant thought they were healthy enough to participate. The infants born in this age range are less likely to have comorbidities and as such are expected to be a fairly homogenous population, usually admitted for straightforward reasons such as feeding issues, hypoglycaemia or jaundice. This meant that they would be more likely to require treatment that included at least two consecutive blood sampling procedures in the NICU. Trevarthen has demonstrated that an infant from 32 weeks GA has

the capacity for vocal expression and exchange (Trevarthen, 2000) and the part of the brain that is necessary for receiving and producing the sounds of words is present from 30 weeks GA (Delafield-Butt & Trevarthen, 2013). This age range is also similar to research populations that have been used to assess other non-pharmacological pain management interventions.

Infants who were sedated or post-surgical were excluded due to the potential influence of pharmacological analgesia on their pain response. Infants on respiratory support were excluded as they were considered to be under stress already and infants with major congenital anomalies, chromosomal disorders or hypoxic-ischaemic encephalopathy were also excluded. If the infant had parents who were considered by their nurse to be too emotionally upset to be approached for a research study, they were also excluded. In a similar study, Kawakami et al did not find an effect for gender difference so while gender was recorded for the infants in this study, they were not actively recruited by gender (Kawakami, Takai-Kawakami, Kurihara, Shimizu, & Yanaihara, 1996).

Infants were recruited through a three-step process. Firstly, the daily NICU admissions list was searched for infants in the designated age range. Then the nurses caring for the potential participants were approached for their opinion on whether the infant was healthy enough to manage the study. If so, the parents were provided with a written information sheet and in some cases, a brief verbal overview by either the researcher or the nurse. Parents were given time to consider whether to take part. Parents who indicated an interest but had not provided written consent were followed up by the researcher.

### **3.1.2 NURSING STAFF**

The nursing staff of the NICU were an integral aspect of this research project. It became important to establish good working relationships with the NICU nurses in order to ensure their participation in the observational and feasibility studies and their co-operation with the research protocol in the main study. Support was provided by the NICU Nurse Manager during consultation in the planning stages of the research. A series of meetings with senior nurses from NICU ensued, with plans for the research, sharing of results and consultation regarding next steps. The final level of relationship was with the shift nurses. These relationships were made at a group level, through emails explaining the study and with home baking for the staff room at the beginning of each study. On an individual level, an effort was made by the researcher to get to know each nurse on a one-to-one basis to

ensure that a positive working relationship was made. Presentations on infant mental health at the psychosocial study days helped promote positive relationships with the staff. Over time, the researcher became less like a visitor and more like a member of the unit staff.

This investigation focussed on non-parental caregivers of preterm infants. Parents were not asked to vocally soothe their infants for this study as the purpose was to find an intervention that could be used by non-parental caregivers that would contribute in a positive way to the infant's mental health. If parents were there they were asked to be silent and not be in their infant's line of sight. It was important not to exclude parents who wanted to be there, in case it was upsetting for them and sometimes they wanted to observe so that they would know how to talk to their infant.

The Central Regional Ethics Committee asked about male nurse soothing versus female nurse soothing and whether this was something that might be a potential confounder. There were three male nurses who could have potentially participated in the research and it was possible that different types of voice and tone may have made a difference to the results. This study however, was designed to focus primarily on whether there is a difference between any attuned voice and silence, in the first instance and to do so in a working NICU 'real world' environment, which includes male nurses.

The original plan for this research was to ask the nurses caring for the infants in the study to provide the vocal soothing. The nurses of participant infants in the study were offered a verbal introduction to the study as well as an information sheet. If in agreement, they provided written consent. In the feasibility study however it became apparent that there was considerable variation between nurses in their ability to provide vocal soothing. Some nurses spoke a lot to the babies, others spoke little and many of the nurses expressed discomfort at being asked to perform this task while being observed. The methodology was changed halfway through the feasibility study and vocal soothing was then provided by the researcher, a registered parent infant psychotherapist with training in how to connect emotionally with infants. There were benefits of using the researcher for vocal soothing in that it ensured consistency and also meant that nurses were not asked to perform additional duties. However, it does raise the question of how much of an effect the training of the vocal soother had and whether the intervention would be reproducible by others.

### **3.1.3 SUMMARY**

The infant population for this research programme was relatively healthy infants born at 32-35 weeks completed GA, in their first two to ten days of life and undergoing treatment that required two heel prick procedures at Wellington Hospital's NICU. NICU staff were an integral aspect of the studies as they provided consultation to research plans, participation in the studies and infant recruitment support. Vocal soothing was intended to be provided by nurses but in the interests of uniformity and consistency, it was decided during the feasibility study that the researcher would provide the intervention.

## **3.2 INTERVENTION – VOCAL SOOTHING**

Vocal soothing in this research project refers to the use of words to calm a preterm infant in distress. The background chapter has provided the rationale and overall attitude required in the provision of vocal soothing and this section will describe the method of vocal soothing. For the purposes of this research, an assumption is made that although infants do not understand the actual words spoken to them, they do understand the emotional intent behind the words.

The purpose of the intervention was to communicate to the infant that an adult is there and is sympathetic towards them. The instruction to the nurses in the first part of the feasibility study was 'speak soothingly' to the infant while carrying out the heel prick procedure and during the caregiving activities that followed, such as face washing and nappy changing. This was deliberately left open to interpretation in order to allow the nurse to be as genuine in their interaction with the infant as possible without having to be concerned about whether they were following the method accurately.

When the researcher took over the vocal soothing in the second half of the feasibility study and in the main study, the method was as follows.

1. To use infant-directed speech, or 'parentese', which typically includes lots of repetition of words and sounds.
2. To match the vocal tone to the perceived infant emotional and physical experience, for example higher pitch, louder and with shorter sounds during the infant's high arousal and a lower pitch, quieter, longer sounds during low arousal.

3. To offer a warning about being touched, to acknowledge with words or sounds the point at which the infant experiences the heel prick and to try and bring the infant back to a state of equilibrium by using long sounds that reduce in pitch and intensity
4. To tell the truth to the infant in order to be as genuine as possible.

Psychoanalyst Gertraud Diem-Wille describes 'parentese' as 'baby talk' or 'wet-nurse language' and writes that in "this special manner of communicating, if it were between adults, would have an exaggerated and comical effect, as if it were a caricature or bad acting; it is however essential as the first, fundamental emotional understanding between the baby and the caregiving adults" (Diem-Wille, 2011, p.89). He suggests that this way of communicating does not have to be learnt, that it lives inside us as adults from the time when we were spoken to as babies and as such is 'intuitively' available. This may explain why in the feasibility studies some nurses found it easier to do than others.

There is much that can be communicated with tone, between adults also. For example, written communication such as emails can be problematic when tone cannot be heard and misunderstandings can happen. The purpose of adjusting the tone of voice to match the infant's experience is to encourage them to either remain in or move towards a more regulated state. The process of containment described in the background chapter can be understood in terms of words for example 'you are hurt, poor you' (acknowledgement) followed by 'you'll be ok' (reassurance), but it can also be understood by the infant in terms of tone for example a higher pitch 'oooooh' for acknowledging the hurt followed by a move towards reassurance 'its ok, its ok, its ooooooooook'. In this way emotional intent may be understood by preverbal infants.

Tone is also important for the hypothesis of 'intersensory redundancy'. This refers to the idea that the senses are all connected to reach other and intersensory redundancy occurs when "...the same information (is) simultaneously available and temporally synchronised across two or more senses..." (Lickliter, 2011). Lickliter suggests that sensory experience can be overwhelming for preterm infants in the NICU and receiving sensory stimulation across two senses concurrently may be better for their perceptual and cognitive development. With this in mind, the idea that an arousing experience such as a painful procedure could be coupled with a sound (caregiver voice) that is matched in intensity, could be considered to

be an opportunity for intersensory redundancy and be helpful for the infant in organising and processing their sensory experience.

Truth telling to infants is considered very important by Myriam Szejer, a child psychiatrist and psychoanalyst who works in maternity wards in France. Her work is focussed on understanding the communications offered by infants in hospital, particularly when there is cause for concern regarding the infant's health and no medical reason for it, for example with failure to thrive, food refusal or excessive crying. Szejer has written a book entitled 'Talking to Babies: Healing with words on a maternity ward' in which she details her clinical work with infants and how she uses language to help the truth be known by the infant and his/her family in order to treat the disturbance (Szejer, 2005). Truth telling to infants in this vocal soothing intervention is designed to keep the caregiver attuned to the emotional experience of the infant. Telling an infant 'it doesn't hurt' requires the use of a much different tone than 'it hurts' and it is the latter that could be considered attuned to the experience of an infant in pain.

### **3.2.1 AN EXAMPLE OF VOCAL SOOTHING**

Below is an example of vocal soothing from the main study. This transcript is taken from baby 9, test one (voice intervention). It took place at the 2am cares and was chosen by asking a colleague to randomly choose a number between 1 and 51 (representing the total number of babies in the main study). This extract is taken from a 3 minute 44 second segment of video. The length of the heel prick from the first touch of foot until the bandage is put on is 1 minute 28 seconds, during which time 102 words are spoken. If it is assumed that two words were able to be spoken per second, then 51 seconds of the 88 second procedure contained sound. The infant therefore received vocal soothing for 58% of the time taken for the procedure.

*Hello, you're wide awake now aren't you...(baby looks up at me)..you're wide awake now..all that fluffing around with you that I was doing...(baby looks away, pause, baby looks at nurse)..are you looking at (nurse's name) ...ohhh....ahhhh.. she's just taking off your booties...(baby continues looking at nurse and blinks and blows bubbles, then stretches whole body upwards)..theeere you go, theeere you go, you are making bubbles..those bubbles...just tying up your foot..you've had lots of these already (baby hiccups)...ohh have you got the hiccups, you've got the hiccups do you, do you, ok...just giving your heel a wee wipe..that's it, thaaat's it, thaaat's it, ok, ohhh-kay...(I pause. baby turns head to me) you're waiting very patiently, ok here comes the prick, it's coming in a moment, iit's coming (Baby makes a squeak sound)...heeeere it is, you'll be alright (heelprick – baby flinches,*

*eyes open wide, looking at me)..ohhh, ohhh, that was a shock...you weren't expecting that, aren't you a brave boy, aren't you brave, goodness me goodness me, what a clever wee man, huh, huh, you've still got those hiccups, those hiccups are taking over your whole body, that's it, that's it, nearly done, nearly done..wee bit more, wee bit more...aren't you being brave, so brave, just watching, just watching and blowing bubbles, it's alright, it's alright..it's done. It's all done. Just putting your bandage on, don't want to make a mess on your nice booties, huh, there we go, tucked in nice and tight, there you go. (end of heel prick) She'll be back in a minute, she'll be back in a minute, she'll be back, there she goes (baby turns head following nurse walking away)..ohhhh you're watching her, watching her go, aren't you, well done, aren't you a clever wee man..a clever wee man...well done...well done...well done...yes...well done..well done (baby hiccups)..oooh that was a big one!..a very big one. That was a very big hiccup. That. was. a. biiiig. hiccup.*

In this random sample of vocal soothing it is clear that there is repetition of words and lengthening of sounds at times. The content is truthful and attuned to the observed experience of the infant. When the infant looks away, the words pause too and gently start up again when the infant signals an interest in listening. The infant displays behaviours that suggests he is under stress such as stretching his body up and having the hiccups (Als, 1982).

There was no definition of 'vocal soothing' that could be found in the literature that identified the proportion of the procedure containing words that may be required to consider it a vocal intervention. For the purpose of the observational studies, vocal soothing was defined as being present if no less than 50% of the time taken for the procedure contained words, based on an assumption that two words could be spoken in a second of time. The proportion of sound in the example of vocal soothing provided above was 58% and therefore was considered to be a deliberate vocal intervention (see chapters four and five for further discussion of the definition of vocal soothing).

### **3.2.2 SUMMARY**

The method of vocal soothing used in this research study required the use of infant-directed speech, or 'parentese'. It meant matching the vocal tone to the perceived infant emotional and physical experience, offering a warning about being touched, acknowledgement of the pain experienced and being truthful and attuned to the infant. The following section will consider the choice of heel prick procedures as the painful intervention for this research.

### **3.3 HEEL PRICK PROCEDURE**

Heel prick procedures were chosen as the painful stimuli due to their frequency of occurrence with a relatively stable preterm infant population. Heel prick procedures are frequently carried out for preterm infants who are jaundiced or have low blood sugars, but are otherwise healthy. More than 50% of all procedures in the NICU are heel prick procedures (Barker & Rutter, 1995). When the method for the main study changed to a within-subject design, it was important to find a procedure that would be likely to be repeated within a day or so in order to ensure comparability between the two conditions (vocal soothing and silence).

After spending time in the NICU during the observational study, the researcher (who is not medically trained) obtained an understanding of the usual practice around heel prick procedures and observed that they were carried out in similar ways by different staff members. A research protocol was developed that matched the average clinical protocol as observed (see appendix II). The protocol was designed to ensure that each nurse carried out the heel prick in exactly the same way. The nurse was asked to first tie a bandage loosely around the ankle of the infant and then to wipe the heel with a wet wipe before collecting blood and fastening the bandage around the wound. The heel prick procedures took place in the infant's usual cot/incubator and the nurses were not asked to perform any tasks additional to their usual duties.

Blood sampling was facilitated using an automated incision device. These are recommended for use as they are less painful than manual devices (Burns, 1990; C. Kenner & McGrath, 2010; McIntosh, Van Veen, & Brameyer, 1994). A capillary tube was used to collect the blood. It is recommended that more noxious arousal stimuli such as heel pricks occur after the less noxious stimuli such as handling and nappy changes as these have been found to be more stressful than usual following painful stimuli (C. Kenner & McGrath, 2010). This sensory hypersensitivity or 'wind up phenomenon' was seen in research with immature rat pups who displayed a heightened sensitivity to touch following a painful experience (Fitzgerald, Shaw, & MacIntosh, 1988; Fitzgerald, Millard, & McIntosh, 1989). Despite the recommendation that infants should have rest periods immediately following painful clinical procedures, the usual practice in Wellington's NICU was to perform the blood test at the beginning of the care sequence. It was considered to be too disruptive to ask the staff to deviate from their established way of doing things for this research project.



### **3.3.1 SUMMARY**

Heel prick procedures were chosen for the painful procedure in this research programme because of their frequency of occurrence in a relatively healthy preterm population. An automated incision device and a capillary tube were used to extract the blood and the heel prick methodology did not differ from that usually undertaken in the NICU.

## **3.4 MEASURES OF INFANT PAIN AND STRESS**

Preterm infant pain and the associated stress are best measured using a range of assessment tools that are able to capture the endocrine, physiological and behavioural responses of infants to a painful stimulus. For this research, infant stress was measured metabolically using salivary cortisol, physiologically using heart rate and oxygen saturations and observationally with infant pain measured behaviourally using the Premature Infant Pain Profile (PIPP) and its revised version Premature Infant Pain Profile – Revised (PIPP-R). Each of these measures will be reviewed in turn, beginning with the primary outcome, salivary cortisol.

### **3.4.1 SALIVARY CORTISOL**

The hormone cortisol is produced by the hypothalamic-pituitary-adrenocortical (HPA) system in humans as a neuroendocrine response to stress (Gunnar, 1989). Cortisol plays an important part in our response to stressful situations, mobilising energy release necessary for survival, suppressing other systems not needed at this time and stimulating the body's behavioural response to stress (Johnson, Kamilaris, Chrousos, & Gold, 1992). Infants have mature cortisol responses from 31 weeks gestation (Castro et al., 2000). Painful experiences such as heel prick procedures are experienced as stressful and lead to changes in cortisol levels (Cong, Ludington-Hoe, & Walsh, 2011; Herrington, Olomu, & Geller, 2004).

Cortisol can be measured through plasma or saliva and in research studies, salivary cortisol has been the preferred alternative to the more invasive measure of serum cortisol (Calixto, Martinez, Jorge, Moreira, & Martinelli, 2002; Castro et al., 2000; Gunnar, Hertzgaard, Larson, & Rigatuso, 1991; Hanrahan, McCarthy, Kleiber, Lutgendorf, & Tsalikian, 2006; Mitchell, 2012; Nelson, 2001; Rosemary C. White-Traut, Schwertz, McFarlin, & Kogan, 2009). Many studies have been conducted on the assumption that salivary cortisol levels increase in response to a stressor 20 minutes after it has occurred (Cong et al., 2011; Gunnar et al.,

1991; Herrington et al., 2004; M. Lewis, Ramsay, & Kawakami, 1993; M. Lewis & Thomas, 1990).

As a measure of preterm infant stress, salivary cortisol has received mixed reviews in the literature and as yet no 'gold standard' for its use has been found for infants or children (Jessop & Turner-Cobb, 2008). As a biologic marker of stress it is a non-invasive, easy to collect and cost effective measure (Hanrahan et al., 2006), all of which make it appealing for use in research but there have been methodological and reliability issues reported by many authors. Some recommend not using it at all due to the difficulty in obtaining enough saliva for analysis from preterm infants and also the potential contamination by milk leading to inaccurately high cortisol results (Harrison, Johnston, Spence, Gillies, & Nagy, 2005). Others do support its use however, provided there is careful research design and strict reporting of methodological issues and variables impacting on reliability (Egliston, McMahon, & Austin, 2007; Gunnar, 1989). A number of studies have been able to use it effectively as a measure of preterm infant stress (Cignacco, Denhaerynck, Nelle, Bühler, & Engberg, 2009; Cong et al., 2011; Gitau et al., 2002; Herrington et al., 2004; Ivars, Nelson, Finnström, & Mörelius, 2012; Kleberg et al., 2008; Nelson, 2001; Rosemary C. White-Traut et al., 2009).

Cortisol levels peak at birth and then return to baseline on day 3-5 so it is not recommended to take cortisol measurements as a measure of stress in the first few days of life (Herrington et al., 2004). A within-subject design and the use of delta cortisol, that is the difference between cortisol levels at various time points, can go some way towards mitigating the effects of individual variation in cortisol levels (Gunnar, 1989; Hanrahan et al., 2006). For this research project, the decision was made to use salivary cortisol because it would allow changes in cortisol over time (i.e. baseline, peak and recovery values) to be recorded without having to draw blood on multiple occasions, which would increase infant stress levels and lead to less reliable results.

### **Methodological issues**

One of the main issues reported with salivary cortisol use is the difficulty in collecting enough saliva from preterm infants for cortisol analysis by radioimmunoassay (RIA). Various collection methods such as cotton dental rolls, cotton-tipped applicators, cotton dental gauze, Salivette swabs and syringes have been tried with mixed success. There is some concern expressed that the use of cotton-based materials may reduce the concentration of cortisol (Strazdins et al., 2005).

Some studies have used saliva stimulants such as citric acid, or lemon/sugar crystals to try and increase saliva volumes in the preterm infant population (Gitau et al., 2002). There have been concerns that the use of stimulants could contaminate the sample and affect the validity of the cortisol results (Nelson, 2001; Schwartz, Granger, Susman, Gunnar, & Laird, 1998). Concerns have also been raised regarding milk contamination, as formula and breast milk have been shown to elevate cortisol levels (Magnano, Diamond, & Gardner, 1989).

The timing of saliva samples also needs to be taken into account as diurnal patterns of cortisol release for preterm infants have been shown to emerge from around 8-12 postnatal weeks (Castro et al., 2000; Price, Close, & Fielding, 1983). Familiarity or repetition of events can reduce cortisol reactivity (Gunnar, 1989) but there has been shown to be no habituation of cortisol response to heel prick (Gunnar et al., 1991).

In a review of the use of salivary cortisol as an outcome measure, it was suggested by Eglinton and colleagues (Eglinton et al., 2007) that future studies using salivary cortisol should:

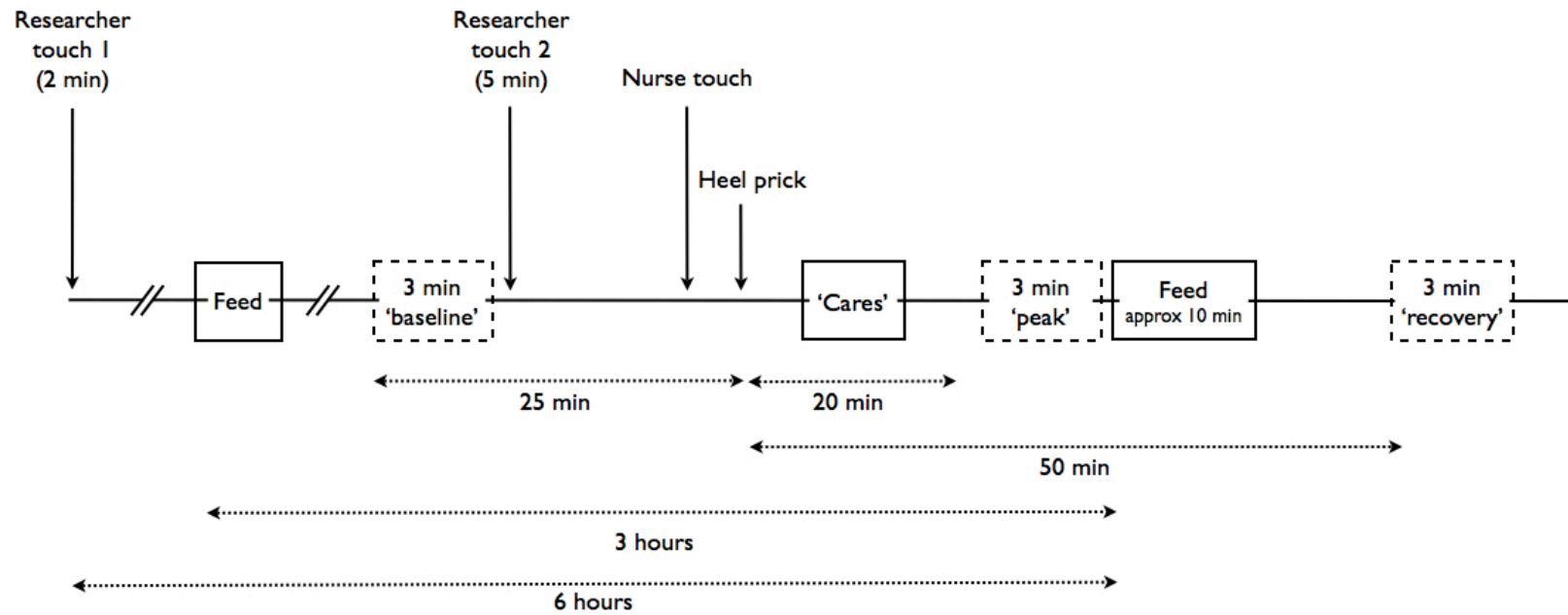
- a. provide clear descriptions of protocols and procedures including the frequency, timing and location of sampling
- b. describe the type of material/apparatus used for saliva collection and have consistency in the use of this method
- c. report the type and quantity of oral stimulant used
- d. describe the methods used to perform assays
- e. ensure standardisation of collection times
- f. conduct preliminary testing of collection methods to assess for acceptability and potential contamination

With the above guidelines in mind it was decided that this research programme would utilise salivary cortisol as a measure of stress. As suggested above (point f), a preliminary testing of collection methods was undertaken. The first feasibility study was designed to assess the collection method and the second feasibility study (the saliva study) was used to assess potential contamination of citric acid as a stimulant. Protocols, procedures, type of apparatus and methods for assay are described below.

### **Protocols, procedures and methods for assay**

Salivary samples were taken in order to assess levels of the stress hormone, cortisol. Three measures of salivary cortisol per infant were taken by placing a Salivette™ swab in the infant's mouth for approximately three minutes each time, twirling it around occasionally. Salivette swabs are recommended for use in populations with low saliva output, such as infants and children (Harmon, Hibel, Rummyantseva, & Granger, 2007). Three measures were required in order to assess the change in cortisol; baseline, 'peak stress' (twenty minutes after the start of the heel prick procedure) and 'recovery' (fifty minutes after the start of the procedure). These time frames have been shown to be optimal for assessing the impact of a stressor on cortisol levels (Gunnar, 1992; Herrington et al., 2004; Ramsay & Lewis, 1995). Each saliva sample was frozen at -20°C at Wellington hospital and then transported at room temperature to Canterbury Health Laboratories for analysis. The Salivette saliva collection tubes were centrifuged and the saliva was assayed by an "in house" enzyme-linked immunosorbent assay (ELISA) following extraction with dichloromethane. Briefly saliva (250µl) was extracted with 1.0ml of dichloromethane and 500µl of this solution was evaporated to dryness in a glass tube and reconstituted with 125µl of the ELISA assay buffer, with 50µl portions used in duplicate for the ELISA. Samples, along with standards (0 to 280 nmol/l), were added to the wells of a microtitre plate previously coated with a cortisol-thyroglobulin conjugate after which a monoclonal antibody cocktail containing a monoclonal antibody to cortisol and a peroxidase-labelled antimouse antibody was added for a 15 min incubation at room temperature (J. G. Lewis, Manley, Whitlow, & Elder, 1992). The plate was then washed and a tetramethylbenzidine chromogenic substrate added. Following colour development the reaction was stopped by the addition of 1M HCL and the absorbance of the wells read at 450 nm by an automated plate reader. The colour was inversely proportional to the cortisol concentration and the concentration of the unknown samples interpolated on the standard curve. The lower limit of analytical detection for saliva was 1-2 nmol/l. The coefficient of variation (CV) for intra-assay variability was 7.6% and that for inter-assay variability was 8.6%. All samples for each infant were analysed using the same assay and were near depleted during analysis. Unlike children and adults, neonates do not show diurnal variation in cortisol levels, until they are older than the infants in these studies, meaning that the time of day of the cortisol collection is unlikely to be a confounding variable (Price et al., 1983). Despite this, where clinically possible, every effort was made to

ensure that the blood tests were collected at a similar time of day. The timeline for study set up and cortisol data collection is presented in Figure 3.1.



Researcher touch 1: Attach ECG leads

Researcher touch 2: Attach ground leads to forehead and probe to hand

Figure 3.1: Timeline for set up and cortisol data collection. 'Three min' refers to period of data collection.

### **3.4.2 MEASURES OF HEART RATE AND OXYGEN SATURATION**

Infant stress was measured by continuous oxygen saturation and heart rate monitoring using the P series sleep system or P series Plus Sleep system (Compumedics P/L, Melbourne, Australia). The following were recorded simultaneously: SpO<sub>2</sub> (pulse oximetry measured at 1 sample/second – Nonin neonatal sensor attached to a built-in oximeter in the sleep system) and electrocardiogram (ECG).

Analysis was performed using Replay (V2.0, Compumedics P/L Australia). Heart rate and oxygen saturation data were analysed at three time points for each study. Mean baseline measurements for both heart rate and oxygen saturations were calculated from two adjacent 30-second epochs that were retrospectively chosen using the graphic monitoring. Criteria for choosing the baseline epochs were that they were the closest 60-second period, without movement artefact or lost signal, prior to the nurse touching the infant. 'Peak' measurements for heart rate were calculated using the maximum heart rate in the 30-second epoch immediately following the epoch containing the heel prick. When the heel prick occurred in the first half of an epoch, that epoch was used for analysis instead. These criteria meant that there was some variation between epochs, as some contained pre-heel prick data. However, as the maximum heart rate was visible on the graphic monitoring, it was ensured that the epochs chosen did contain the maximum figure for that period. 'Peak' measurements for oxygen saturations were calculated from the minimum figure recorded in a 30-second epoch beginning the moment of the heel prick. The mean recovery measurements for both heart rate and oxygen saturation data were calculated using the first 60 seconds clear of artefact and with a clear signal that occurred at least two minutes after the heel prick. This timing was chosen because the procedure was finished and the infant was not being handled at the time. Figure 3.2 displays the time line with data extraction points for heart rate, oxygen saturation and the Premature Infant Pain Profile – Revised (PIPP-R) (to be discussed in section 3.4.3). Although heart rate and oxygen saturation data were included in the PIPP-R measure, these data were also analysed separately in order to assess whether the vocal soothing intervention had any impact on these measures alone.

Data were extracted from the polygram recording and saved as separate excel documents. Means, standard deviations, median, minimum and maximum values were calculated using the function tool in Excel 2011.

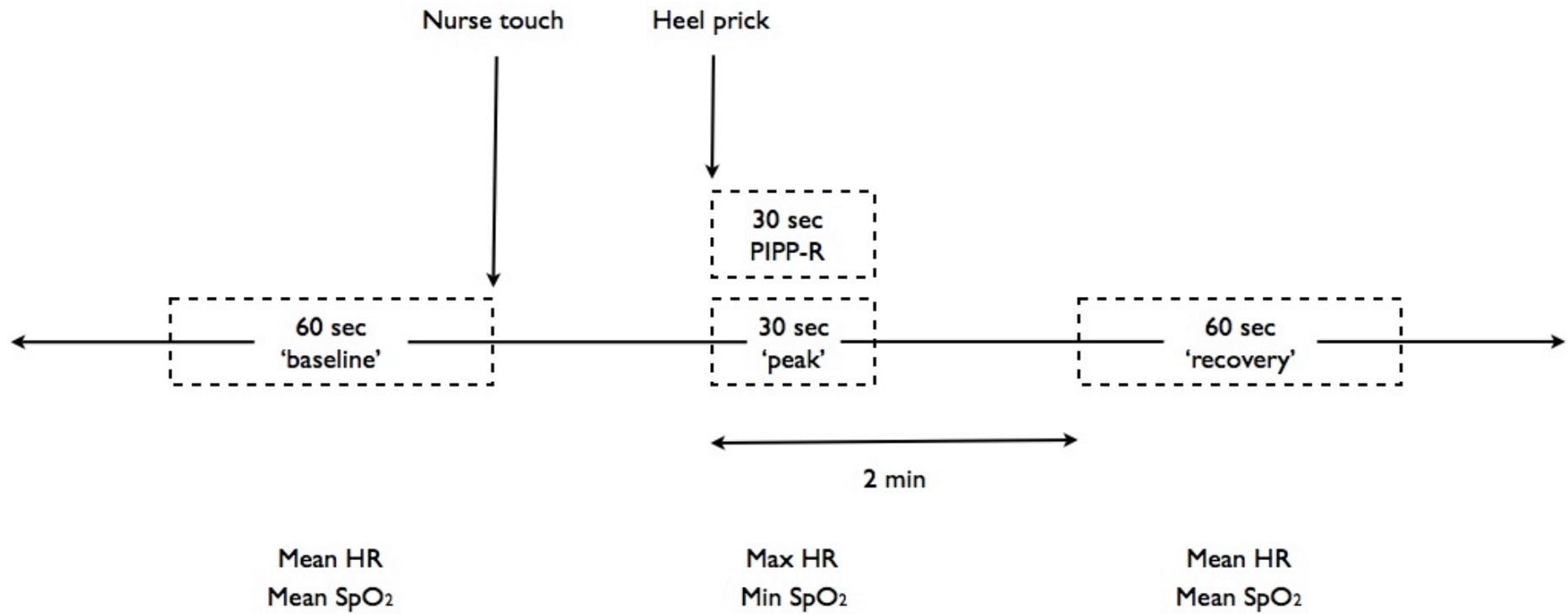


Figure 3.2: Time line with data extraction points for Heart rate, Oxygen saturation and PIPP-R data



### **3.4.3 PREMATURE INFANT PAIN PROFILE (PIPP)& PREMATURE INFANT PAIN PROFILE – REVISED (PIPP-R)**

Two versions of the PIPP were used in the course of this research programme, the Premature Infant Pain Profile (PIPP) and the Premature Infant Pain Profile – Revised (PIPP-R) (See appendix II). At the time of the feasibility study only the PIPP had been validated and as such was the best available option. By the time the data from the main study were analysed in 2015, the PIPP-R had been validated and was regarded to be a more accurate measure.

The PIPP-R is an acute pain measure designed to be used routinely with premature infants. The first version, the PIPP, was developed by Professor Bonnie Stevens and colleagues in 1996 (B. Stevens, Johnston, Petryshen, & Taddio, 1996). In 2010 a meta-analysis of its use found it to be a valid and reliable measure of term and preterm infant pain (B. Stevens, Johnston, Taddio, Gibbins, & Yamada, 2010). Reliability was assessed using Pearson  $r$ , Spearman  $\rho$  and intraclass correlation coefficients while validity was determined using extreme group comparisons and comparison with other validated pain measures (B. Stevens et al., 2010). In 2014 the PIPP was revised (PIPP-R) due to concern about inflated scores and to try to maximise feasibility (Bonnie J Stevens et al., 2014). Both the PIPP and the PIPP-R consider behavioural and physiological cues. The PIPP provides a pain score based on gestational age, the infant's behavioural state prior to the stimulus, changes in heart rate and oxygen saturation during the painful stimulus and facial features during the painful stimulus. While a number of pain measurement tools have been developed over the years, few of these have been found to be reliable, valid and appropriate for use with premature infants (Bonnie J Stevens et al., 2014). The revision of the PIPP was deemed necessary for two reasons: firstly, the scoring method of the PIPP took into account the fact that younger infants and infants who are asleep tend not to display pain behaviours as overtly as older infants or infant who are awake. Infants less than 28 weeks PMA receive an additional three points to their score, infants 28-31 weeks receive an additional two points, 32-35 weeks receive an additional point and infants over 36 weeks at the time of the procedure receive no extra points. The same scale applied to the behavioural state of the infant, quiet and asleep infants receive three points, active and asleep receive two points, quiet and awake receive one point and active and awake infants receive no additional points. The identified problem was that an infant who did not display any pain behaviours, could still receive a pain score of 6, if they were less than 28 weeks PMA and asleep during the procedure. It was

decided in the revision to only apply these extra points if the infant actually displayed pain behaviours (eg brow bulge, eye squeeze or naso-labial furrow) or physiological changes from baseline (change in heart rate or oxygen saturations). This meant that if an infant did not display any behavioural or physiological response to the painful stimulus, they received a score of zero and would avoid a potential score of six based on their age and state alone. The PIPP-R is scored using baseline data from a 60 second period prior to touch and peak data from a 30 second period following the heel prick.

For the main study in this project the PIPP-R was chosen for use given that it already had construct validation and inter-rater reliability. In a study involving 202 infants, 246 pairs of painful and non-painful experiences were independently assessed by an expert pain rater and a nurse (S. Gibbins et al., 2014). The PIPP-R scores were significantly higher during the painful procedures (mean 6.7 [SD 3.0]) than the scores during the non-painful procedures (mean 4.8 [SD 2.9]) and there was found to be a high degree of correlation between the nurses' and experts' scores. The fact that the PIPP-R is more feasible than the PIPP was less important for the present study as the data were all recorded by videotape and continuous physiological monitoring, so that exact calculations for heart rate, oxygen saturation and facial coding could be made.

#### **3.4.4 SUMMARY**

There was enough support in the literature to consider using salivary cortisol as a measure of stress. Three samples were taken, one each at baseline, peak (20 minutes after the heel prick) and recovery (50 minutes after the heel prick). Heart rate and oxygen saturations were continuously monitored throughout each study and data extracted at the three time points of baseline, peak and recovery. These time points varied for each infant due to movement and artefact. The PIPP was used to analyse the data in the feasibility study, while the PIPP-R was used in the main study.

### **3.5 CULTURAL CONSULTATION**

#### **3.5.1 MĀORI**

Up to 8% of infants born preterm in New Zealand in 2014 were of Māori ethnicity and in preparation for this research project cultural consultation was undertaken in order to ensure that the research was respectful of Tikanga Māori (MOH, 2015). This research was discussed

in its planning stages with key Māori professionals in NICU (social worker and lactation consultant) and the Tikanga Māori training for researchers was undertaken. This project sought formal consultation through the University of Otago's Ngai Tahu research consultation process as well as the CCDHB-based Research Advisory Group Māori (RAG-M) (appendix III). A special commendation from the Rag-M committee was made for the thoughtfulness around consideration of the participation of Māori and permission was requested to use the application as an example of 'best practice' for other researchers.

The fundamental premise of this research, that infants are important and that they should be respected is in line with the Māori worldview that holds children as 'taonga' or treasure.

This research involves using the English language with premature infants because it is the primary language used by the nursing staff and it is therefore an intervention that can be universally applied. With any infant research in New Zealand, it is necessary to acknowledge the importance of Te Reo, both in valuing Māori culture and out of respect for what may have been the infant's familiar language. This may be an important aspect to research in the future, whether it makes a difference to infants if they are spoken to in the language they are exposed to in utero or not.

Māori primarily have an oral tradition and have always used words to communicate with babies through *ori ori* (lullaby) or *karakia* (prayer). *Karakia* is seen as an essential element of maintaining and protecting *wairua* (spirituality), *hinengaro* (mental and emotional wellbeing), *tinana* (physical wellbeing) and *whānau* (social wellbeing), all of which are important aspects of Māori Health (Durie, 1998). While it is not specifically *karakia* that is used with the premature infants in this study, what is being communicated does go beyond the spoken words. The intonation is intended to communicate to the infants that they are not alone, that their emotional response is valued and that their body is being respected. There was face-to-face communication with the *whānau* of the infants approached for consent to participate in the study and every family that self-identified as Māori was offered a copy of the *Whānau Care* brochure. Where possible, the study was explained to more than one adult member of the *whānau*, so that a second person could hear the details of the study. Further to this, it was ensured that the parents of the infants knew who it was that would speak to their infant, information was shared with them about how the infant reacted and an effort made to support their emotional experience of having an infant in hospital. In these ways, the wellbeing of *whānau* was also addressed. This research brings together perspectives

from medicine and psychology and could be considered as being in line with the holistic Māori views on health.

Of particular relevance to Māori is the treatment of the infant's saliva. Saliva is a part of the human body and therefore tapu (or sacred) so there are strict Māori protocols surrounding it. The handling of the saliva from the infants in this study was in line with the Capital and Coast District Health Board (CCDHB) policy on the treatment of human tissue samples and was endorsed by the RAG-M committee. The saliva was frozen and then analysed, a process that depleted the sample of saliva, leaving no human tissue left to dispose of.

### **3.5.2 PACIFIC**

There are no formal consultation processes available through either Wellington Hospital or the University of Otago for research concerning people from the Pacific. For a study such as this, in which interactions with infants are directly affected, it was thought necessary to seek consultation. The CCDHB Pacific Health Unit was therefore approached to consider the study and its implications for Pacific people. The manager of the Pacific Health Unit supported the research plans and also drew attention to the importance of talking to babies for Pacific people.

### **3.5.3 SUMMARY**

This PhD research programme was developed in consultation with both Māori and Pacific health professionals and committees in order to ensure that the methods were appropriate and respectful of these cultural worldviews.

The research programme comprised six studies and is outlined in the next section.

## **3.6 METHOD JOURNEY**

The overall research programme included six studies: two observational audits, three feasibility studies and the main study. The statistical methods are included with each chapter.

### **3.6.1 OBSERVATIONAL STUDIES**

Two audits were undertaken in order to gather baseline data about how often nurses use their voice to soothe premature infants in their care and whether the type of intervention

(painful heel prick or non-painful nappy change) makes any difference to the amount of vocal soothing offered. The first audit (chapter four) looked at the numbers of words spoken to preterm infants during heel prick procedures and also recorded any other pain management interventions used during the procedure. The second audit (chapter five) looked at the numbers of words spoken to babies during a non-painful intervention (a nappy change).

### **3.6.2 FEASIBILITY STUDIES**

The rationale for the feasibility studies (chapter six) was to ensure a study such as this could be recruited to, to assess the feasibility of the research protocol and to ascertain whether successful salivary cortisol measurement could be achieved.

The first feasibility study was a randomised, controlled trial. Twenty participating infants were randomly assigned to one of two conditions, one in which a nurse spoke empathically to them during a heel prick procedure (intervention infants) or one in which the nurse remained silent (control infants). The aim of this feasibility study was to assess and refine the methodology for the main study. It led to some major revisions:

- a. To use the researcher's voice only for the intervention
- b. To use a crossover study design
- c. To standardize the blood tests used (i.e. capillary tube only)
- d. To ensure that the exact time of heel prick was recorded on the physiological data
- e. To ensure good recording of the infant's face during the heel prick.

The feasibility study also highlighted the need to find a more effective way to gather saliva for cortisol analysis, so two further feasibility studies for saliva collection were planned and executed. Both utilised a crossover design, the first testing the effectiveness of 5% citric acid solution in improving volumes of saliva collection in preterm infants and the second assessing the impact of this stimulant on salivary cortisol levels.

### **3.6.3 MAIN STUDY**

The main study for this PhD project was a randomised, crossover study with each infant acting as their own control. In one condition the researcher talked empathically to the infant during a heel prick procedure and in the other, remained silent. Fifty-one premature infants,

born at 32-35 weeks GA and having heel prick blood tests as part of their usual care were recruited for the study. Physiological, endocrine and behavioural indicators of infant stress were measured.

#### **3.6.4 SUMMARY**

The population for this programme of research consisted of infants born at 32-35 weeks GA and inclusion criteria included whether they were assessed to be healthy enough to take part and if they were likely to receive two or more heel prick procedures in their first two to ten days of life. This age range is in line with other research assessing non-pharmacological interventions in the NICU and reflects a level of maturity where preterm infants may be ready for social engagement. NICU nurse consultation and support was an integral aspect of this programme.

While there is no definition of the numbers of words per minute required to define an intervention as vocal, vocal soothing has been defined in this research project as infant-directed speech, with matched vocal tone to the infant's perceived emotional and physical experience while being truthful and attuned to the infant.

Heel prick procedures were chosen for the painful procedure in this research programme because of their frequency in a relatively healthy preterm population.

Four separate measures of infant stress were used throughout this research programme. Infant endocrine responses were measured using salivary cortisol, physiological responses were recorded using heart rate and oxygen saturation and behavioural responses were recorded using the PIPP and the PIPP-R.

Both Māori and Pacific health professionals and committees were consulted in order to ensure that the methods were appropriate and respectful of these cultural worldviews. This research is closely aligned with the Māori view of health.

This research programme comprised six studies in all. The two observational audits sought to gain a baseline understanding of the current levels of vocal soothing offered by NICU nurses in both painful and non-painful procedures. The feasibility studies were designed to assess and refine the methods for the main study and some major revisions were undertaken. The main study planned to recruit 63 infants for a within-subject randomised controlled trial.

Chapter four describes the first of the observational audits, in which nurses were observed for their use of words with infants during heel prick procedures.

## 4 BASELINE STUDY – USE OF VOCAL SOOTHING DURING HEEL PRICK PROCEDURES

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*Pain or sickness in one's body or mind can be endured more peacefully if there is sympathy from the other for the awareness of it*

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(Trevarthen, 2001, p.117)

Prominent infant researcher Colwyn Trevarthen has dedicated his career to investigating the importance of companionship for infants. He is referring to adults above, but preterm infants in the NICU may also benefit from hearing words that help them know that a sympathetic other is with them during their painful procedures.

Given that the overall aim of this PhD project was to investigate the effectiveness of vocal soothing for painful procedures, it was considered important to ascertain how often vocal soothing was already being used. The baseline study described in this chapter was designed as an audit. The aim of this study was to record the amount of vocal soothing offered to infants by NICU nurses. Data were also gathered on other non-pharmacological pain management techniques offered by nursing staff. In addition, this baseline audit provided the opportunity to observe usual practice around heel prick procedures so that later studies could be planned in the least disruptive way.

There is some variation in describing the specifics of the NIDCAP approach in the published literature. Some authors specify speaking soothingly to the infant during a painful procedure (e.g. (Kleberg et al., 2008)). Others do not specify this directly, (e.g. (Als & B McAnulty, 2011; Als et al., 2011)). Kleberg and colleagues in applying the NIDCAP approach described how, in addition to other developmental care practices, they spoke soothingly to the infant during a painful procedure. They described letting the baby know with their voice that something was about to happen, talking reassuringly throughout the procedure and then settling the child at the end with their soothing voice (Kleberg et al., 2008). Developmental Care standards prescribed by the National Association of Neonatal Nurses (NANN) also include talking to and being with the baby emotionally. Standard one “requires that nurses function ‘in the moment’ to have ‘mindful’ interaction with infants” (C. Kenner & McGrath, 2010, p.76). This includes nurses approaching infants with a soft whisper and calling them by name.



The general implementation of pain management techniques is thought to be insufficient internationally, despite considerable research demonstrating the effectiveness of various techniques (Sizun & Browne, 2005). A large multisite study in Paris found that infants were given either pharmacologic or non-pharmacologic interventions for pain in only 44% of heel prick procedures (Carbajal et al., 2008). Many infants do not receive sufficient treatment for procedural pain (Carbajal et al., 2008; Jeong et al., 2014; Roofthoof et al., 2014) and this is of concern (Keels et al., 2016). The NICU in which this study took place offers non-pharmacologic interventions. Four brochures available for parents/caregivers provide information on Developmental Care (protecting infants from light and noise, positioning), Sucrose for procedural pain management, Kangaroo Care and Non-nutritive sucking.

## **4.1 AIMS AND HYPOTHESIS**

It was important to undertake this audit in order to establish a baseline for frequency of words spoken by nurses to infants during a painful procedure in a neonatal unit setting.

The aims of the audit were threefold:

- a. To record the use of words by nurses to soothe infants during heel prick procedures
- b. To record the pain management techniques being used by nursing staff during heel prick procedures
- c. To observe the heel prick procedures generally in order to plan a 'least disruptive' protocol for the main study.

Given the literature around the general under-utilisation of pain management techniques internationally, it was hypothesised that *nurses would not regularly use vocal soothing as a pain management tool during heel prick procedures with infants on the Neonatal Intensive Care Unit.*

## **4.2 METHOD**

### **4.2.1 A CHALLENGE TO DEFINE 'VOCAL SOOTHING'**

There are two issues to consider in defining 'vocal soothing'. The first refers to how we can define something as soothing when we are measuring only one side of the interaction and

the second refers to how many words need to be spoken before it can be considered a 'vocal' intervention.

Something that may be intended to be soothing by the communicator is not necessarily experienced as soothing by the receiver of the communication. Vocal soothing in this context refers to the use of words to try to calm an infant in distress. Behavioural signs of stress can include skin colour changes, gagging, spitting up, hiccups, straining, coughing, sneezing, yawning and motoric flaccidity or hypertonicity (Als, 1982). Whether or not an infant is soothed is not always easy to observe. Crying may be an obvious measure of distress but there are physiological changes in the infant also that signal distress such as changes in heart rate and respiratory rate or oxygen saturation. Measures of the stress hormone cortisol are also a reliable method of assessing stress levels in infants.

Given that the main aim of this audit was to observe how often nurses use their voice to try to soothe infants during a painful procedure, it made sense to record the number of words spoken to each infant. To the author's knowledge, the number of words required to consider it a 'vocal' intervention has not previously been defined, thus for the purposes of this audit it was thought reasonable that if more than 50% of the time taken for the procedure contained vocalisations, then it could be considered a deliberate vocal intervention. Two assumptions were made in planning this study. The first was that two words could comfortably be spoken in one second of time and the second was that the heel prick procedure might take approximately 30 seconds to complete. Based on this, it was thought that in a 30 second procedure up to 60 words might be spoken and that the definition of vocal soothing in this study would be 31 words or more. See Table 4.1 for the calculations underpinning this definition of vocal soothing. The data were recorded in three categories prior to analysis; 0-30 words, 31-60 words and more than 60 words. The more than 60 words category was to account for any heel prick procedures that might take more than 30 seconds and thus contain more words.

**Table 4.1: Calculations of number of words spoken and corresponding time containing vocalisations for a 30 second procedure**

	<b>Not vocal soothing</b>	<b>Vocal soothing</b>
Words per procedure	0-30	31-60
Time containing vocalisations*	0-15 seconds	16-30 seconds
% of procedure containing vocalisations	0-50%	51-100%

\*Based on two words spoken per second

#### **4.2.2 THE LOGISTICS**

This audit was planned in consultation with the unit Nurse Manager who was supportive of the research and a special advisor to the overall PhD project. It was necessary that this audit be covert in order to gain a picture of routine practice in the unit. The nurses in the unit were unaware of the wider project plans. It was thought that if they knew later studies were to be looking at the impact of vocal soothing on infant stress, they could be inclined to talk more than they usually would. There were no identifying data of any kind gathered in the course of this audit. Ethical approval was granted from the Central Regional Ethics Committee (appendix IV).

The researcher was introduced to the staff on the unit as a PhD student there to observe heel prick procedures in order to help plan future research studies on this procedure. The staff were advised that the researcher was to become familiar with the procedures, how they were done and the ages of the infants receiving them. They were not told that the number of words they spoke during each procedure was to be recorded.

The issue of nurse and parental consent was considered. It would be usual practice for audits in the hospital to be advertised and staff made aware that they would happen within a specific time frame. These audits are aimed at measuring performance and outcomes and as such making an assessment of whether staff are performing well or less well against set performance objectives. This audit was different in that there was no formal directive in the unit for nurses to vocally soothe infants, meaning that no nurses were being assessed as whether they were meeting a standard or not. It was therefore decided that as this audit was primarily exploratory it could reasonably be undertaken in a covert way. Having said that, each nurse gave their consent for the heel prick they were administering to be observed and therefore gave consent to be observed in general.

Parental consent was not sought for the infants who participated in the audit because the focus was not on the infants and no data were collected in regard to them other than gestational age, gender and observed sleep state.

#### **Subjects**

Any baby having a scheduled heel prick blood test by a nurse during the time the researcher was on the unit was able to be included in the study.

## **Procedures**

At the beginning of each shift the researcher met with the charge nurse on duty and then visited each of the six nurseries asking each staff member if they would mind being observed during any heel prick procedures.

The nurse was asked to do the heel prick procedure as they usually would and were told that the researcher would be recording the age, gender and sleep state of the baby. Neonatal sleep-wake behavioural states were assessed by observation according to the Prechtl classification (Prechtl, 1974). The time taken for the procedure, any soothing techniques the nurse used and how many words they spoke to the baby and other people, including the researcher, were recorded covertly.

## **Analytic plan**

For this forty-bed Neonatal Intensive Care Unit it was thought that fifty heel prick observations would give a reasonable snapshot of usual practice. The observation period was planned to include roughly equal hours of night and dayshift. In this unit, the weekly routine blood tests were performed overnight on a Monday night, meaning that this became the most reliable observation period for blood tests. The observational period lasted six weeks and totalled 29.5 nighttime hours and 14 daytime hours.

As all of the heel prick procedures on the unit were of interest in this audit, the gestational ages of the babies were between 24 and 41 weeks. The time for each heel prick was measured using the large wall clocks in the unit and as such are accurate to the closest 15 seconds. The heel prick timing began at the nurse's first touch of the infant's foot and ended with the last touch of the infant's foot.

For results presented as proportions, 95% confidence intervals were calculated using Fisher's Exact Method (Armitage, Berry, & Matthews, 2008).

## **4.3 RESULTS**

### **4.3.1 PARTICIPANTS**

Fifty heel prick procedures were observed and descriptive statistics are presented in Table 4.2. No nurses refused to participate, although occasionally when the researcher returned at an agreed time, the heel prick had already been completed. This was either because the

infant had woken early or the nurse said that they had forgotten about the observation. One nurse participated more than once in the study (three times in total). Some infants participated more than once in the study, but as data that could identify them was not collected, details for how often this occurred is not known.

**Table 4.2: Participants in heel prick audit**

Infants	n(%)
Male	36 (72%)
24-29 weeks GA*	17 (34%)
30-35 weeks GA	23 (46%)
36-41 weeks GA	10 (20%)
24-29 weeks PMA	1 (2%)
30-35 weeks PMA	27 (54%)
36-48 weeks PMA	22 (44%)
Infants ≤ 7 days old	17 (34%)
Infants ≥ 8 days old	33 (66%)
Intubated infants	4 (8%)
Infants asleep during heel prick procedure	10 (20%)
Parent present during procedure	2 (4%)

\*GA = gestational age

\*PMA = postmenstrual age

Thirty-eight heel prick procedures were performed on night shift and 12 were performed on day shift. The following results are presented thematically, beginning with the average length of time for each heel prick and how many words were spoken to the infants and colleagues during this time. Other interventions used for soothing purposes are also reported.

### **4.3.2 TIME TAKEN FOR EACH HEEL PRICK PROCEDURE**

The assumption that each heel prick procedure would take approximately 30 seconds was found to be incorrect. The average length of time for the heel prick procedures observed in this audit was six minutes and thirty-one seconds ( $6.54 \pm 4.37$  minutes). Table 4.3 shows the

average length of time for the heel prick procedures depending on the type of blood test. This was important to know in order to plan the method for the main study.

**Table 4.3: Mean length of time for heel prick procedure**

<b>Age range of babies</b>	<b>Time for blood gas (capillary tube) Mean (Minutes) ± SD</b>	<b>Time for weekly bloods (capillary tube + 1 or 2 vials) Mean (Minutes) ± SD</b>
24-29 weeks PMA*	5 minutes (one infant only)	nil subjects
30-35 weeks PMA	4.63 ± 0.92	8.5 ± 2.59
36-48 weeks PMA	2.22 ± 1.64	7.89 ± 2.62

\*PMA = postmenstrual age

### ***4.3.3 Is VOCAL SOOTHING CURRENTLY USED AS A PAIN MANAGEMENT TOOL WITH PREMATURE BABIES IN THE NICU DURING HEEL PRICK PROCEDURES?***

The words spoken to each baby during their heel prick procedure are presented in Table 4.4. Ten of the infants remained asleep during the heel prick so data are also presented for the 40 infants who were awake during the procedure. Given that the mean time for the heel prick procedures was six minutes and thirty-one seconds, the category of 31-60 words per procedure ceased to be representative of 50% - 100% of the procedure containing vocalisations. Sixty words over the course of a 6 ½ minute procedure would result in only 30 seconds of vocalisations, which amounts to only 8% of the total procedure. The majority of the nurses spoke less than 60 words. Speaking was almost completely absent to the sleeping infants as all were in the no words (n=8) or 1-30 words (n=2) category. Infants who were awake received more than 61 words in 5% (CI 0.06%-17%) of procedures but information regarding how many words above 61 these infants actually received was not collected. This occurred because in this study the specific numbers of words offered were not recorded and data were gathered by ticking one of three boxes; 0-30 words, 31-60 words or ≥ 61 words. It is therefore not clear from this data whether either of the two infants in the ≥ 61 category were offered enough words to consider it a vocal soothing intervention.

**Table 4.4: The number of words spoken by nurses to infants during heel prick procedures**

	<b>≥ 61 words</b>	<b>31-60 words</b>	<b>1-30 words</b>	<b>No words</b>
	<b>n(%)</b>	<b>n(%)</b>	<b>n(%)</b>	<b>n(%)</b>
	<b>95% CI</b>	<b>95% CI</b>	<b>95% CI</b>	<b>95% CI</b>
<b>Number of procedures – all infants (n=50)</b>	2 (4%) 0.5-14%	9 (18%) 9-31%	25 (50%) 36-64%	14 (28%) 16-42%
<b>Number of procedures – awake infants (n=40)</b>	2 (5%) 0.6%-17%	9 (22.5%) 11%-38%	23 (57.5%) 41%-73%	6 (15%) 6%-30%
<b>Number of procedures – asleep infants (n=10)</b>	nil	nil	2 (20%) 3%-56%	8 (80%) 44%-97%

#### **4.3.4 IS IT TOO DIFFICULT TO CONCENTRATE ON A HEEL PRICK AND TALK AT THE SAME TIME?**

A reasonable question to ask is whether nurses were too busy concentrating on the task at hand to be able to simultaneously offer vocal soothing. Data in Table 4.5 suggest that in 34% (CI 21%-49%) of heel prick procedures, nurses speak more than 61 words to people other than the infant. Words spoken to others appear to be mostly in either of the two category extremes of more than 61 words category or no words at all (54% CI 39%-68%).

There were only nine heel prick procedures (18%, CI 9%-31%) in which the nurse remained silent, speaking to neither infant nor other people.

**Table 4.5: The number of words spoken by nurses to the infant and to people other than the infant during each heel prick procedure**

Number of words spoken	Procedures	Procedures
	Words to awake infants (n=40)	Words spoken to others (n=50)
	n(%) 95% CI	n(%) 95% CI
≥ 61 words	2 (5%) 0.6%-17%	17 (34%) 21%-49%
31-60 words	9 (22.5%) 11%-38%	3 (6%) 1%-17%
1-30 words	23 (57.5%) 41%-73%	3 (6%) 1%-17%
No words	6 (15%) 6%-30%	27 (54%) 39%-68%

#### **4.3.5 OTHER INTERVENTIONS USED WITH INFANTS DURING HEEL PRICK PROCEDURES**

Table 4.6 lists the other interventions offered by nurses during the 50 observed heel pricks. Only 4% (CI 0.05% - 14%) of awake infants received the heel prick procedure without any intervention (vocal or other). However, no single intervention was offered more than 50% of the time.

**Table 4.6 Other interventions offered**

Intervention	Number of times offered (n= 50) n (%) and 95% CI
Sucrose	11 (22%), 95% CI 12-36%
Warming the heel	17 (34%), 95% CI 21-49%
Dummy/Pacifier	10 (20%), 95% CI 10-34%
Touch	1 (2%), 95% CI 1-11%
Cuddle	2 (4%), 95% CI 0.5-14%
Parents present	2 (4%), 95% CI 0.5-14%
No intervention offered (vocal or other) - Baby asleep	7 (14%), 95% CI 6-27%
No intervention offered (vocal or other) - Baby awake	2 (4%), 95% CI 0.5-14%

#### **4.3.6 DISSEMINATION OF RESULTS TO STAFF**

The results were presented verbally to a senior team meeting in the Neonatal Unit. The wider study was explained and the staff given an opportunity for feedback. They were surprised by the results, thinking that nurses would talk to infants more than they appear to



do at present. Staff nurses were invited to attend one of two 'GLO' (good learning opportunity) sessions in order to hear the results of the baseline and have the main study explained to them. Three staff members attended the first session and no staff attended the second session. The information was then disseminated verbally and via email.

This observational audit was an important part of the wider research programme as it served as the beginning of the relationship building with the nursing staff. It was important that the results of this study were presented clearly and openly in order to gain nurse support and co-operation for the rest of the studies in this research programme.

#### **4.4 DISCUSSION**

The present study aimed to investigate how often nurses use words to soothe infants during heel prick procedures. The findings showed support for the hypothesis that nurses do not routinely use vocal soothing as a pain management tool during heel prick procedures in the NICU.

It is acknowledged that the idea that a vocal intervention would consist of vocalisations for at least 50% of the time was a somewhat arbitrary decision and perhaps if there had been many instances of 30%-40% of the time including vocalisations then this as a cut-off point may need to be questioned. As it happened however, in 48 out of 50 procedures (or 38 out of 40 procedures in which the infant was awake), there would have been vocalisations for no more than 8% of the procedures. It is difficult to imagine that a deliberate use of voice to vocally soothe could be effective for as little as 8% of the time taken for the procedure, lending further support for the hypothesis that vocal soothing is not a deliberate intervention used by nurses in the NICU.

The assumption that a heel prick procedure would last only 30 seconds was incorrect. The length of time taken for the heel prick procedure was also dependent on the amount of blood to be drawn. The least amount of blood was collected using the capillary tube and for infants closest to the age range for the overall research programme, 30-35 weeks, the procedure took a mean time of four minutes and thirty-eight seconds (or 278 seconds). This meant that a rate of two words per second suggested a maximum of 556 words per procedure (278 x2) and if 50% of this procedure was to contain vocalisations, then 278 words per procedure would be required. The major underestimation in length of heel prick

while planning this study is likely to have been a reflection of the researcher's unfamiliarity with heel prick procedures at the beginning of this research programme.

In this study there were only two instances out of 50 in which an infant was offered more than sixty words per procedure. Unfortunately, the actual numbers of words spoken in the more than 60 words category were not recorded, meaning that there is information missing around exactly how many words were used in these cases. It is unknown whether these numbers of words would have reached the threshold of 50% of the time including vocalisations but even if they did, the data suggest that it would only occur in 5% (CI 0.6%-17%) of heel prick procedures in this unit. These findings were a surprise to many of the nurses in this unit who assumed that words were used much more frequently than this.

While no analyses were made in this study regarding the influence of infant variables such as age, state or gender on numbers of words offered to them by nurses, it would be interesting to investigate this further. Is the age of the infant a factor considered by nurses when they decide to speak or not? Are there any gender differences? There were some instances of nurses wrongfully speaking of the baby's gender i.e. calling a female infant 'him' or a male infant 'her', so nurses may not have always known the gender of the child. Does the fact the infant cried make the nurse any more or less likely to offer vocal soothing? It may also be that the variables are associated with the nurse and are independent of the infant. In other words, what is it about nurses that leads to some speaking to infants and some not?

#### ***4.4.1 DO NURSES RECOGNISE THAT INFANTS ARE IN PAIN?***

The nurses in this unit did appear to acknowledge the pain and/or distress in the infants by the fact that in only 4% of the heel pricks (95% CI 0.5-14%) were the infants not offered an additional intervention for comfort. Although sucrose and non-nutritive sucking are advertised as being available for procedural pain in this NICU through the parent/caregiver information brochures, neither of these interventions were offered consistently. Sucrose was offered 22% of the time and non-nutritive sucking was offered 20% of the time. This fits with international data on the under-use of non-pharmacological interventions in the NICU environment and will be discussed further in chapter eight.

Without an exploration of nurse attitudes this study cannot come to any conclusions about why vocal soothing is not used in this NICU. Vocal soothing could be considered an integral aspect of, and also measure of, Developmental Care's 'standard one', in which nurses are

expected to be 'mindful' and 'in the moment' with the infant. Could it be possible that the lack of vocal soothing also represents a lack of mindfulness about the infant? Or in other words, a lack of focussing on or connecting to the infant in this NICU? Kenner and McGrath suggest that a fast paced society or the delegation of more responsibilities might have an adverse impact on a nurse's ability to be mindful, as they focus instead on the next task at hand rather than the one they are doing now (C. Kenner & McGrath, 2010). Perhaps, however, it is more complicated than that. Just as the Developmental Care literature encourages nurses to approach infants as individuals, so should nurses be considered in terms of their individual ability to be mindful, despite external stressors such as a fast paced society or increased responsibilities. The psychological capacity of any given nurse to be mindful of the baby may well be affected by the kind or quality of the interaction she is having with an infant. The recommendation to talk soothingly to the baby while performing a painful procedure is not as straightforward as it appears; it involves considerable psychological investment on the part of the nurse.

Acknowledging the pain verbally with the infant by offering the kind of vocal soothing described in chapter two, requires the nurse to maintain a level of empathic attunement during the actual moment of the painful procedure. Being empathic involves allowing oneself to feel some of the distress felt by the infant (Diem-Wille, 2011). The psychoanalytic theory of the mind holds that when the mind has something difficult to tolerate or process it will engage in defensive action such as denial (Spillius, Milton, Garvey, Couve, & Steiner, 2011). If the nurse feels some level of stress either consciously or unconsciously, they may find it very difficult to manage the negative impact of their interventions, which may lead to this unconscious denial of the infant's pain (Spillius et al., 2011). One nurse stated, 'I do it very quickly (the heel prick) because the sooner it is over the quicker I can pretend it didn't happen'. This attitude is an example of how the nurse manages her own emotional response to an infant in pain through the use of denial. Another nurse said to the infant who was squirming during the heel prick procedure 'you are ok, it doesn't hurt', while another said 'nothing is happening' to the baby during the blood test. Again these are perhaps examples of how the nurses are unconsciously aware of the pain the infant is in, yet in order to keep from feeling overwhelmed by this, soothe themselves by telling the baby that it does not hurt or even that the procedure is not happening at all. Some nurses may prefer to focus on the practical logistics of the task at hand or perhaps find it more comfortable to turn to a distraction, such as talking with someone else, in order not to focus on the infant in pain.

These decisions are on the whole made unconsciously; the nurse is unlikely to consciously choose to deny the infant's pain at these times. Considering this psychodynamic framework, talking to babies may be somewhat of a tall order for nurses performing painful procedures on infants.

To be consciously motivated to vocally soothe an infant requires an unconscious level of acceptance and tolerance of babies feeling pain. Everybody will have a different threshold for this, some are able to acknowledge pain easily and will readily offer comfort to another in distress. Others may find it harder, but are able to do it when they feel emotionally supported. Still others may find it hard to do at all. Staff in a NICU are in an emotionally difficult situation as it is, caring for fragile infants in a stressful environment is an emotionally demanding task. It is possible that acknowledging infant pain is harder emotionally under these circumstances and it may be easier not to acknowledge it in order to ensure a long career in a NICU.

#### **4.4.2 PARENTAL INVOLVEMENT**

The data in Table 4.6 suggest that parents were present for their infant's heel prick in 4% (CI 0.5% - 14%) of the procedures. On some occasions the nurse deliberately performed the heel prick test before the parents arrived, explaining that it was better to get the distressing procedure done before they arrived so that they could then be a part of the caregiving procedures such as the nappy changing and feeding. For these nurses, the procedure was considered to be distressing and a choice made to keep the parents away at this time. This may have been to 'protect' the parents from witnessing it or perhaps performing the procedure in front of the parent meant that the nurse could not disengage emotionally from it so easily. It may be more of an emotional burden to have two 'patients' to consider at once, the infant and their parent(s). Nurses may also have felt a performance anxiety in front of parents.

A focus group study involving 87 nurses in Finland, Sweden and the United States found nurses to vary considerably in their attitudes to parents being present for painful procedures. Some nurses preferred parents to be kept away in order to protect them from their infant's pain, some nurses allowed parent participation despite it being stated as causing nurse or parent anxiety and some nurses opted for a full collaborative approach with parents which was found to lead to an optimal pain management approach for infants (Axelin et al., 2015).

The optimal pain management approach was considered in this study to be one in which the parents and the nurse had joint roles in decision making about the optimal pain management for an infant. This decision was reached based on both the nurses knowledge of pain care and the parents knowledge of their infant (Axelin et al., 2015). While this study was focused on the attitudes of nurses to parent participation in pain management, it also provides information on the individual variation in nurse attitudes to infant pain. Clearly there is an acknowledgement of pain in all three groups of nurses and how they choose to manage it may depend on how comfortable they themselves are with recognising pain. In all of the options described by this study, the decision by each nurse appears to be a personal one, driven by their own psychological reasoning about what is best and therefore highlighting the subjective nature of these decisions. For example the assumption that parents would rather not see their child in pain can be challenged by the results of a study that looked at increasing parent involvement in pain management by providing a booklet on ways to comfort their infant. This study found that while encouraging parents to be more involved did not result in reducing the parent's NICU related stress, neither did it increase the parent's NICU related stress (Franck et al., 2011).

Further investigation is needed to ascertain ways in which parents might be supported to be present during painful procedures for their infants. The fact that some heel prick procedures are deliberately done without parents present, does however highlight the need for investigating how effective a nurse can be to psychologically soothe the infant. The finding that parental participation led to optimal pain management, may mean that this kind of collaboration helps the nurse keep the psychological experience of the infant in mind.

#### ***4.4.3 LIMITATIONS & LESSONS LEARNT FOR THE MAIN STUDY***

The total number of words beyond 61 spoken to each infant were not recorded, which was a lost opportunity towards understanding whether vocal soothing (as defined by this study) was ever used. This decision was made at the planning stage of the study, based on an incorrect assumption that the nurse would unrealistically be able to speak any more than 60 words during a 30-second procedure. The fact that the heel prick procedures took more time than anticipated was not a limitation in itself as most of the nurses spoke less than 60 words.

If the decision to offer vocal soothing is a subjective decision made by the nurse then it is not ideal that one nurse participated in the study three times as this may then be the equivalent

of a data set of 48 rather than 50. It would be important for any future studies to ensure that each nurse participates only once in order to ensure as representative a sample as possible.

While the nurses were not aware that the numbers of their words to infants were being counted, they were very aware that they were being observed. It could have been that they did not feel as free to be themselves and talk as they usually would with an observer present. Despite the instruction to just 'do what you would normally do', the nurse may have felt uncomfortable about being observed. Some nurses commented on their heel prick technique and said that they were worried they might not do a good enough job while the observer was watching. It is also possible that the nurses may have thought that their talking to the infant may have interrupted the observation. It would be hard to reassure nurses about these things without letting them know that it was their vocalisations that were being observed. The majority of the observed heel prick procedures occurred on night shift which may have had an impact on numbers of words spoken given that the nurses may have been tired or perhaps deliberately less engaging with the infant in order to let them rest.

With only fifty heel prick procedures observed, this study was of a small scale and therefore not necessarily representative of the total number of heel prick procedures in this particular neonatal unit. However, fifty procedures were sufficient in order to contribute to plans for the main study.

The time observing in the NICU provided valuable insight into how the main study could be planned in order to minimize disruption to the unit. Nightshift was thought to be the best time to gather data as it was quieter and the staff seemed less rushed. Blood tests were ordered weekly and were a reliable source of heel prick procedures. Given the variability in soothing interventions offered, it was decided to ask the nurses to conform to a specific protocol in order to ensure the results of the main study were not influenced by interventions other than vocal soothing. The study protocol was developed based on the actions of the majority of nurses during the observation period. It was common practice to perform the heel prick procedure before the caregiving procedures such as face washing and nappy changing. The feed was always the final activity. This sequence of 'cares' took place approximately every six hours, with three hourly feeding. This study also confirmed that there would be heel prick procedures performed regularly on infants in the targeted 32-35 week age group for the main study.

Most importantly, this observational study suggested that vocal soothing was not commonly used as a management strategy for painful procedures in this unit and therefore supported the idea that undertaking an intervention study incorporating vocal soothing would be potentially useful.

#### **4.4.4 CONCLUSION**

This heel prick baseline study was an important first step in this programme of research. The audit identified a low frequency of words spoken to infants during painful procedures and it is suggested that nurses may find ways to distance themselves from the infant's experience because painful procedures are distressing and nurses will have various levels of tolerance of this distress. The audit identified that the nurses in this unit did appear to be aware of the painful nature of heel prick procedures because comfort interventions such as sucrose, warming the heel, offering a dummy/pacifier or touch/cuddle were offered most of the time. There was however an under-use of the evidence based interventions, sucrose and non-nutritive sucking.

The theoretical framework applied here might suggest that nurses would feel more comfortable talking to infants during non-painful procedures, such as changing a nappy or feeding. It was decided to repeat this observational study, this time focusing on a nappy change in order to see whether a less painful procedure could be associated with more vocal soothing.

## 5 BASELINE STUDY – USE OF VOCAL SOOTHING DURING NAPPY CHANGE PROCEDURES

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*The staff have an important function, which is not merely medical, to bring the baby to life.*

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(Vanier, 2015, p.33)

The psychological sense of ‘bringing the baby to life’ refers to the idea that interacting with an infant as a communicating being may help the infant come to know that they are a person. Under ordinary circumstances, caregiving activities such as nappy changes would be an opportunity to connect psychologically with the infant. A chance to communicate verbally the message that the infant is in good, safe hands alongside recognition that they have conscious feelings and experiences. In the NICU, caregiving activities are often carried out by staff and these may be important times for an infant’s psychological development. Vocal soothing would be an important aspect of this care.

The study described in the previous chapter found that nurses did not often use their voices to soothe infants during heel prick procedures and it was suggested that a reason for this may be that nurses find it hard to connect emotionally with an infant when they are performing a painful procedure. This raises the question of whether nurses might use their voice to soothe infants more often during a non-painful procedure such as routine infant cares.

A second observational audit was executed to collect information about the numbers of words spoken to infants during a non-painful nappy change procedure. If the argument in the previous chapter about the need to avoid acknowledging infant pain in order to tolerate it is indeed plausible, then one might expect that nurses would talk more to infants during a nappy change than during a heel prick procedure. If this is the case, then there may be some resistance, albeit unconscious, to the use of a vocal intervention during painful procedures with premature infants in the NICU. A nappy change was chosen because it is more interactive than a feed and like the heel prick involves physical manipulation of the infant.

The study described in this chapter followed the same protocol as the heel prick study and was also designed as an audit. A limitation of the heel prick study was that the actual



numbers of words spoken to infants were not recorded beyond 61 words. This nappy change audit sought to gain information regarding current practice by counting all words spoken to infants during the audit.

## **5.1 AIM AND HYPOTHESIS**

The aim of this study was to record the numbers of words used by nurses during nappy change procedures.

It was hypothesised that *nurses would use more words with infants during nappy changes than during heel prick procedures with infants on the Neonatal Intensive Care Unit.*

## **5.2 METHOD**

### **The logistics**

Nurses were asked if the infant they were caring for could be observed by the researcher in order to get a sense of how infants react to nappy change procedures. In this way the nurses were unaware that data regarding their vocal soothing was being recorded. Ethical approval was granted from the Central Health and Disability Ethics Committee (appendix IV). As with the heel prick audit, the issue of nurse and parental consent was considered and the decision made to keep this audit covert in order to not influence practice and because no identifying data were being collected. It is acknowledged that the study was not completely covert as by the time this audit was undertaken, staff knew of the researcher as the 'talking to babies lady' and therefore may have adjusted their vocalisations to the infant.

### **Subjects**

Infants of any gestational age in the NICU who were having their nappy changed by a nurse during the time the researcher was on the unit were eligible to be included in the study.

### **Procedures**

At the beginning of each shift the researcher introduced herself to the charge nurse on duty and then visited each of the six nurseries asking each staff member if they would mind being observed during any nappy changes. The nurse was asked to do the nappy change procedure as they usually would and were told that the observer would be taking notes on the age of

the infant and how they reacted to their nappy being changed. The time it took to perform the procedure and how many words they spoke to the infant were recorded covertly.

### **Analytic plan**

This study was designed to be as similar to the heel prick audit as possible in order to ensure that results could be compared. As with the heel prick audit, there were 50 observed nappy change procedures. The observation period was primarily over the night shift as parents would usually carry out the nappy changes during the day. The observational period totalled twenty-two night-time hours and four day-time hours. Forty-four nappy changes were performed on nightshift and six were performed on dayshift. Some infants participated more than once in the study, but as data that could identify them were not collected, detail as to how often this occurred is unable to be reported. No nurse participated more than once in this study.

The gestational ages of the infants at birth were between 24 and 40 weeks. The time for each nappy change was measured using the large wall clocks in the unit and as such are accurate to the closest 15 seconds. The numbers of words were counted individually. As the nurse spoke, the researcher made small marks on a piece of paper and counted them at the end. Occasionally the content of the words was also recorded.

For results presented as proportions, 95% confidence intervals were calculated using Fisher's Exact Method (Armitage et al., 2008). The Mann-Whitney test, a non-parametric test that takes ordering of responses into account and calculated using SPSS, was used to compare distributions of words between heel prick procedures and nappy change procedures.

## **5.3 RESULTS**

### **5.3.1 PARTICIPANTS**

Fifty nappy change procedures were observed and the descriptive statistics are presented below in Table 5.1. For comparison, the descriptive statistics of the heel prick audit are presented alongside.

**Table 5.1: Participants in nappy change audit and heel prick audit**

Participants	Nappy change audit n(%)	Heel prick study n(%)
Male infants	31 (62%)	36 (72%)
24-29 weeks GA*	10 (20%)	17 (34%)
30-35 weeks GA	35 (70%)	23 (46%)
36-41 weeks GA	5 (10%)	10 (20%)
24-29 weeks PMA <sup>#</sup>	4 (8%)	1 (2%)
30-35 weeks PMA	25 (50%)	27 (54%)
36-48 weeks PMA	21 (42%)	22 (44%)
Infants ≤ 7 days old	16 (32%)	17 (34%)
Infants ≥ 8 days old	34 (68%)	33 (66%)
Intubated infants	0	4 (8%)
Infants asleep	5 (10%)	10 (20%)
Parent present	0	2 (4%)

\*GA = Gestational age

<sup>#</sup> PMA = Post menstrual age

The following results are presented thematically, beginning with the average length of time for each nappy change and how many words were spoken to the infants and colleagues during this time. The results of this study are then compared with the results of the baseline observational heel prick study.

### **5.3.2 TIME TAKEN FOR EACH NAPPY CHANGE PROCEDURE**

The average length of time for the nappy change procedures observed in this audit was three minutes and thirty-five seconds. This is important in terms of considering how many words per minute are offered to infants during these procedures. Table 5.2 shows the mean length of time for the nappy change procedures depending on the infants' PMA.

**Table 5.2: Mean length of time for nappy change procedure**

Infant post menstrual age (PMA)	Time for nappy change
24-29 weeks	1 min 53 sec
30-35 weeks	3 mins 50 sec
36-48 weeks	3 mins 36 sec

### **5.3.3 HOW MANY WORDS ARE USED BY NURSES WITH PREMATURE BABIES IN NICU DURING NAPPY CHANGES?**

The numbers of words spoken to each infant during their nappy change are presented in Table 5.3. More than 60 words were used in 22% (CI 12%-36%) of nappy changes. Five of the 50 infants remained asleep throughout the nappy change procedure, so data are presented for infants who were awake. Awake infants received more than 60 words in 24% (CI 13%-40%) of nappy change procedures. The percentage of the procedure that may have contained vocalisations is calculated using the mean time for the nappy change procedure. It can be seen that any less than 60 words is likely to have resulted in less than 13.9% of the procedure containing sound.

The proportions of each nappy change that may have contained words from the nurse are presented in Table 5.4. It can be seen from this data that in none of the procedures did the nurse speak to the infant for 50% or more of the time, although infant 47 was close in receiving vocalisations for 46% of the procedure. Infants 17 and 19 had the next highest rates of vocalisations, at 29% and 28% respectively. Overall 12 (24%) infants received words for 14% or more of their nappy change procedure.

**Table 5.3: Number of words spoken by nurses to infants during 50 nappy change procedures.**

	≥ 61 words n(%) 95% CI	31-60* words n(%) 95% CI	1-30 words n(%) 95% CI	No words n(%) 95% CI
<b>Number of procedures- all infants (n=50)</b>	11 (22%) 12%-36%	9 (18%) 9%-31%	25 (50%) 36%-64%	5 (10%) 3%-22%
<b>Number of procedures – awake infants (n=45)</b>	11 (24%) 13%-40%	8 (18%) 8%-32%	22 (49%) 34%-64%	4 (9%) 2%-21%

\*In a procedure lasting 3 minutes and 35 seconds (mean duration) a total of 60 words would only account for 13.9% of the procedure duration.

**Table 5.4: Proportion of each nappy change containing vocalisations**

Observed infant	Number of words spoken by nurse	Length of nappy change	Percentage of procedure with vocalisations*
Infant 1	15	3 min	4%
Infant 2	29	2 min 15 sec	11%
Infant 3	48	3 min 15 sec	12%
Infant 4	57	3 min 15 sec	15%
Infant 5	22	3 min 30 sec	5%
Infant 6	78	3 min 15 sec	20%
Infant 7	21	3 min 30 sec	5%
Infant 8	0	3 min 45 sec	0%
Infant 9	0	3 min	0%
Infant 10	75	7 min	9%
Infant 11	58	5 min 45 sec	8%
Infant 12	0	10 min	0%
Infant 13	7	5 min 15 sec	1%
Infant 14	23	2 min 15 sec	9%
Infant 15	4	2 min 15 sec	1%
Infant 16	46	2 min 30 sec	15%
Infant 17	96	2 min 45 sec	<b>29%</b>
Infant 18	92	5 min 15 sec	15%
Infant 19	99	3 min	<b>28%</b>
Infant 20	21	2 min	9%
Infant 21	35	4 min 15 sec	7%
Infant 22	16	3 min 30 sec	4%
Infant 23	0	4 min 30 sec	0%
Infant 24	67	4 min	14%
Infant 25	39	3 min 30 sec	9%
Infant 26	3	2 min 15 sec	1%
Infant 27	6	2 min 30 sec	2%
Infant 28	22	2 min 15 sec	8%
Infant 29	77	3 min	21%
Infant 30	4	2 min	2%
Infant 31	19	5 min	3%
Infant 32	20	2 min 45 sec	6%
Infant 33	0	4 min 15 sec	0%
Infant 34	33	3 min 15 sec	8%

Observed infant	Number of words spoken by nurse	Length of nappy change	Percentage of procedure with vocalisations*
Infant 35	15	2 min	6%
Infant 36	4	3 min	1%
Infant 37	76	3 min 30 sec	18%
Infant 38	145	5 min	24%
Infant 39	4	4 min 15 sec	1%
Infant 40	50	4 min	10%
Infant 41	29	4 min 30 sec	5%
Infant 42	114	5 min	19%
Infant 43	15	4 min 45 sec	3%
Infant 44	14	2 min 45 sec	4%
Infant 45	13	2 min	5%
Infant 46	30	2 min 15 sec	11%
Infant 47	316	5 min 45 sec	<b>46%</b>
Infant 48	2	3 min	1%
Infant 49	6	2 min	3%
Infant 50	1	1 min 30 sec	1%
Median (range)	21.5 (0 - 316)	3 min 15 sec (1 min 30 sec, 10 min)	6% (0% - 46%)

\*Based on time taken for nappy change procedure and words spoken at a rate of two words per second.

#### **5.3.4 DO NURSES SPEAK MORE TO OTHERS DURING NAPPY CHANGES?**

Table 5.5 presents the data by nurse. It can be seen that the most common occurrence (15 instances) was for a nurse to speak 1-30 words to the infants and no words to another adult. This is an identical finding to that in the heel prick study. In this data there may be a tendency for the nurse to speak more words to the infant when there are fewer words to another adult as there were nine instances of more than 61 words to the infant and no words to another adult.

**Table 5.5: The number of words spoken by each nurse to the infant and to another adult during each heel prick procedure**

		Words spoken to other adult			
		≥ 61 words	31-60 words	1-30 words	No words
Words spoken to infant	≥ 61 words	1	nil	1	9
	31-60 words	nil	1	4	4
	1-30 words	nil	2	8	15
	No words	nil	nil	1	4

### **5.3.5 ARE MORE WORDS OFFERED TO INFANTS DURING NAPPY CHANGES THAN HEEL PRICK PROCEDURES?**

The data in Table 5.6 compares the numbers of words spoken to infants during nappy changes and heel prick procedures. Nurses spoke more words to infants during nappy changes than during heel prick procedures for both the total group and when analysis was restricted to awake infants. This difference in distributions of words was found to be statistically significant for awake infants (Mann-Whitney  $U = 872$ ,  $P=0.005$ , two-tailed).

**Table 5.6: The number of words spoken by nurses to infants during nappy change and heel prick procedures**

All Infants	Nappy change n= 50 n (% , 95% CI)	Heel prick n=50 n (% , 95% CI)
≥61 words	11 ( 22%, CI 12-36%)	2 (4%, CI 0.5-14%)
31-60 words	9 (18%, CI 9-31%)	9 (18%, CI 9-31%)
1-30 words	25 (50%, CI 36-64%)	25 (50%, CI 36-64%)
No words	5 (10%, CI 3-22%)	14 (28%, CI 16-42%)
Awake Infants	Nappy change n=45 n (% , 95% CI)	Heel prick n=40 n (% , 95% CI)
≥61 words	11 (24%, CI 13-40%)	2 (5%, CI 0.6-17%)
31-60 words	8 (18%, CI 8-32%)	9 (22.5%, CI 11-38)
1-30 words	22 (49%, CI 34-64%)	23 (57.5%, CI 41-73)
No words	4 (9%, CI 2-21%)	6 (15%, CI 6-30)

### **5.3.6 DO NURSES TALK MORE TO OTHER PEOPLE DURING A NAPPY CHANGE COMPARED WITH A HEEL PRICK PROCEDURE?**

Table 5.7 compares the numbers of words spoken to people other than the infant during both nappy change and heel prick procedures. While a greater percentage of the nurses

spoke to their colleagues during heel prick procedures than during nappy change procedures, any conclusions about this are difficult to make given the potential confounders (see discussion below). These data are presented for descriptive reasons only.

**Table 5.7: The number of words spoken by nurses to people other than the infant during nappy change and heel prick procedures**

All Infants	Nappy change n= 50 N (% , 95% CI)	Heel prick n=50 N (% , 95% CI)
≥ 61 words	1 (2%, CI 1-11%)	17 (34%, CI 21-49%)
31-60 words	3 (6%, CI 1-17%)	3 (6%, CI 1-17%)
1-30 words	14 (28%, CI 16-42%)	3 (6%, CI 1-17%)
No words	32 (64%, CI 49-77%)	27 (54%, CI 39-68%)

## 5.4 DISCUSSION

The data in this nappy change observational audit support the hypothesis that nurses *would use more words with infants during a nappy change procedure than during a heel prick procedure*. Awake infants were offered more than 61 words in up to 24% (CI 13-40%) of nappy change procedures, compared with 5% (CI 0.6-17%) of heel prick procedures. A statistically significant difference in numbers of words offered was found between the two procedures, with infants receiving more words during a nappy change than during a heel prick procedure. The confidence intervals for the data in this study do all overlap however, so it would be worth repeating this experiment to be sure of the result. The sample populations had a similar spread in terms of age and gender (Table 5.1) and although there is not enough evidence to know whether these variables affect the outcome, it does make comparisons between the two studies more robust.

While nurses appear to speak more to infants during nappy changes than heel prick procedures, they still do not appear to offer vocal soothing as a deliberate intervention. Ninety-eight percent of the infants in the nappy change audit received less than 30% of the procedure with sound. This is unlikely to be enough words to consider it a deliberate vocal intervention. The example of vocal soothing that is provided in chapter three was taken from one of the heel prick procedures in the main study in which the researcher offered vocal soothing and the proportion of sound was 58%. While this figure is above 50% it is close enough to question the accuracy of the 50% cut off point. If vocal soothing provided by a



trained parent infant psychotherapist who is comfortable talking with infants about their experiences was only 58% of the procedure, then perhaps the cut-off point could be less than 50% and still be experienced by the infants as a deliberate vocal intervention. Further, as it can be seen in the example provided in chapter three, it also depends on how the infant responds. If the infant looks away then the words will be lower in pitch and pace. There are times where one word would take longer than half a second to speak, meaning that the calculation based on two words spoken per second leads to an underestimation of proportion of time the infant is exposed to sound.

As was described in chapters two and three, the theory and method of vocal soothing requires attention to be paid to other aspects of voice such as tone and content and also how attuned to the infant's experience they are. During many of the nappy changes the tone was soft and the content positive, for example "oh, oh, is that true?" "Well done", "It's alright", "I know", but there were other occasions where the tone was harder and the content negative, for example "You stink. You really stink", "Stop crying." Studies such as these, that count only words spoken, do not take these differences into consideration.

Regardless of whether the 50% cut-off point is an appropriate definition, these audits were able to generate some data around the current use of nurse voice during painful and non-painful procedures. The results of these two studies suggest that nurses speak more words to infants during nappy changes than during heel prick procedures, which lends support to the ideas raised in chapter four that it may be easier to connect emotionally with an infant during a non-painful procedure. If this is true it would have implications for introducing a vocal soothing intervention into a NICU as vocal soothing may be a psychologically challenging intervention to administer. There may be other reasons for nurses speaking less to infants during painful procedures such as the need to focus more during painful procedures or not being aware of the recommendations to expose infants from 32 weeks GA/PMA to human voices (Goines, 2008; Lutes et al., 2004; Milford & Zapalo, 2010). The finding that almost all nurses spent less than 30% of the time taken for the nappy change procedure speaking to the infant suggests that vocal soothing is not a common intervention currently provided in this NICU for any procedure.

The descriptive data in Table 5.7 may suggest that a greater percentage of the nurses spoke to their colleagues during heel prick procedures than during nappy change procedures but there are potential confounders to consider. For example, given there were only two heel

prick procedures in which the parents were present it may have been that heel prick procedures were scheduled at times where there were more opportunities to talk to colleagues because the parents were not around. The decision to talk to a colleague would have been influenced by whether or not there was someone available to talk to and as such, unrelated to the type of procedure. For these reasons a statistical analysis was not performed on these data. There was no way of controlling for whether the nurses had a colleague to speak to so the finding that nurses may have a tendency to speak no words to another when offering more than 61 words to an infant must also be interpreted with caution. Further investigation would be required in order to understand the reasons behind nurse choice to speak to others while in physical contact with an infant.

#### **5.4.1 LIMITATIONS**

By the time this study was underway the nursing staff knew the researcher as the 'talking to babies lady'. This may have influenced them to speak more to the baby than they usually would, which may also have been a factor in the finding that they spoke more words to the infants during nappy change procedures. If the data for both studies had been gathered at the same time then this is unlikely to have been an issue. It is also possible that, as in the heel prick study, nurses were influenced by the fact they were being observed and may have deliberately spoken less in order to not interfere with the observation or perhaps felt uncomfortable speaking to the baby while being observed. The majority of the observed nappy change procedures occurred on night shift, like the heel prick procedures, which may have had an impact on numbers of words spoken during to nurse tiredness or out of concern for the infant's need to rest.

The small sample size in these studies does affect generalizability. While the Fishers Exact method goes some way to providing a confidence interval, these intervals were often wide. The point of these baseline audits, however, was to answer questions for the feasibility of the main study.

#### **5.4.2 LESSONS LEARNT FOR THE MAIN STUDY**

These studies have provided important information in planning for the main study. Three key issues are listed here and elaboration on each is provided below.

1. The conclusion that vocal soothing is feasible yet not frequently used in this NICU

2. Consideration given to the impact of a painful procedure on the nurse's ability to provide vocal soothing
3. The development of a 'minimally disruptive' method for the main study

*Vocal soothing is feasible yet not frequently used in this NICU:*

The two baseline studies have highlighted how vocal soothing did not appear to be an intervention used very often (if at all) with preterm infants in the NICU. If evidence is found for its effectiveness then there is scope for improvement in practice in this NICU. Both audits have demonstrated that it is feasible for a nurse to talk while administering a procedure, for example nurses were only completely silent in 8% (CI 2-19%) of the nappy change procedures. Vocal soothing is therefore a feasible intervention to assess in the main study.

*The impact of a painful procedure on the nurse's ability to provide vocal soothing needs to be considered:*

The finding that nurses may find it easier to talk to infants during non-painful rather than painful procedures has important ramifications. If the main study does indeed find that vocal soothing is effective in reducing pain and associated stress during painful procedures, then any barriers to implementing this intervention will also need to be investigated. Barriers may include, but are not limited to, the need to focus more during a painful procedure, the impact of staff stress on their ability to provide vocal soothing and whether 'tuning into' infant pain carries an emotional 'cost'.

*The development of a 'minimally disruptive' method for the main study:*

The two studies provided information for the main study protocol as the protocol involved both heel pricks and nappy changes. The protocols around these were based on the nurse behaviours observed in order to minimise disruption during the feasibility and main studies.

### **5.4.3 CONCLUSION**

The aim of this study was to record the numbers of words used by nurses during nappy changes in order to test the hypothesis of whether more words are used with infants during non-painful versus painful procedures. These data suggest that nurses do use more words during nappy change procedures, however the overall use of words with infants is still low. Even if a definition of vocal soothing meant words offered for a minimum of 30% of the procedure, then still 98% of the infants in this nappy change observation would not have received a vocal soothing intervention. Vocal soothing does appear to be a feasible

intervention for use in the NICU, although consideration must also be given to the potential 'cost' to nurses in attuning more closely to the infants in their care.

The next step was to consider the feasibility of testing the effectiveness of vocal soothing as an intervention that reduces pain and stress in premature infants. The feasibility studies described in the next chapter were designed to test the feasibility of both the intervention and also of the measures of pain and stress in the infant.

## 6 THE FEASIBILITY STUDIES

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*The study of human emotion and social behaviour, perhaps even more so than any other problem confronted by science, highlights the absolute necessity of integrating the perspectives of various disciplines.*

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(Schore, 1996, p.532)

Dr Allan Schore, an American psychologist and researcher, wrote an influential book in which he synthesised the fields of psychology and neurology, showing how early emotional experiences are imprinted in the developing brain and comprise the basis of the origin of the self (Schore, 1996). In this text he particularly stresses how the matrix of human development is multi-faceted and cannot be understood by one discipline alone. This PhD research project brings together the disciplines of psychoanalysis and medicine by assessing the effectiveness of an intervention, based on psychodynamic theories of emotional development, on preterm infant pain and stress during a medical procedure. These feasibility studies were important in order to ascertain whether this cross-fertilisation of disciplines was able to be achieved.

The initial feasibility study was designed to assess three aspects of the main study: whether it would be possible to recruit infants and nurses to such a study, to test the research protocol and to ascertain whether the methods for measuring infant pain and stress were feasible. It became clear that two further feasibility studies were needed to assess the use of a stimulant to improve saliva volume collection and the possible impact of a stimulant on salivary cortisol measurement. In this chapter the initial feasibility study ('the feasibility study') is presented first, followed by the 'saliva volume study' and the 'saliva stimulant study'. Lessons learned that informed the design of the main study are presented at the conclusion of this chapter.

### 6.1 THE FEASIBILITY STUDY

This study was designed to test the feasibility of the methods chosen to assess the impact of vocal soothing on infant pain and stress during heel prick procedures. A research protocol

was tested with twenty infants and their nurses and involved measurement of endocrine, physiological and behavioural manifestations of preterm infant pain and stress.

### **6.1.1 QUESTIONS TO BE ANSWERED**

There were six questions to be answered in this feasibility study:

1. How easy is it to recruit infants and nurses to the study?
2. Is it feasible to standardise a research protocol around heel prick procedures?
3. Can reliable physiological measures be captured with the recording equipment available?
4. How feasible is it to use the Premature Infant Pain Profile (PIPP) as a measure of pain?
5. Is it possible to measure salivary cortisol accurately in the 32-35 weeks GA group?
6. Is it possible to document sufficient data in the relevant population to use for sample size calculations for the main study?

### **6.1.2 METHODS**

A convenience sample of twenty preterm infants, considered healthy enough by their nurse to participate in this study were recruited for this randomised, controlled trial. These infants were born at 32-35 weeks GA, in their first ten days of life at time of recruitment and were on no respiratory support. Participating infants were randomly assigned to one of two conditions, one in which a nurse spoke empathically to them during a heel prick procedure (intervention) and one in which the nurse remained silent (control). Each infant was having the heel-prick blood test as part of their usual cares. Infants who were sedated, on respiratory support or had had a surgical procedure were excluded because these factors or the potential influence of pharmacological analgesia may have had an impact on the physiological or behavioural responses of the infants. Infants with major congenital anomalies, chromosomal disorders and hypoxic-ischaemic encephalopathy were also excluded. It was planned to recruit up to 20 nurses, one for each infant heel prick procedure, although some nurses could participate in the study more than once. Ethical approval for this study was granted by the Central Regional Ethics Committee (Appendix IV).

## **Study protocol**

Notices about the study were put up in the NICU and parents were able to volunteer involvement with their infants. The initial approach to the parent was made by the nurse caring for the infant. Interested caregivers were then provided with further information about the study. The information sheet and consent form are provided in appendix V.

Once written consent was obtained from a parent, the nurse caring for the infant at the time of the next scheduled heel prick blood test was approached for their written consent to participate (see appendix V for a copy of the nurse information sheet and consent form). No nurses were excluded from participating in the study. Nurses were given a standardised protocol to follow describing how to do the heel prick procedure (see appendix II). In the intervention condition, nurses were asked to 'speak soothingly' to the infant while carrying out the heel prick procedure and during the caregiving activities that followed, such as face washing and nappy changing. The instruction was deliberately broad to allow the nurse to speak freely in a way that felt comfortable to them. It was thought that if the nurse had to follow too many instructions about how to speak to the baby, this could get in the way of their connection with the infant in front of them. In the control condition, the nurse was asked to remain silent throughout.

Throughout the study period infants were cared for by medical and nursing staff as per the usual unit routines. Should the participating infant have required urgent medical attention during the study period, their participation in the study would have been terminated. The study protocol and data collection methods were able to be modified during the feasibility study if it became obvious they were inappropriate for the population and data to be collected during the main study.

## **Data collection**

Demographic data (ethnicity, weight, GA, age in days) were collected from the infants as well as method of delivery, need for resuscitation, history of birth trauma and number of previous heel prick procedures.

Salivary samples were taken in order to assess levels of the stress hormone, cortisol, using the methodology outlined in chapter three. Infant stress was also assessed by measurement of continuous oxygen saturation and heart rate monitoring during the study period. Initially, heart rate was measured by impedance (electrocardiogram) and respiratory rate by

measurement of nasal pressure; however from infant five onwards a Masimo pulse oximeter (Rad-7, Masimo, Irvine Ca, USA) was used to collect both heart rate and oxygen saturation data (see 'methodological changes' below).

Data for the Premature Infant Pain Profile (PIPP) were collected using a video recording of the infant's face for 30 seconds post heel prick, together with physiological data from the pulse oximeter. This is standard protocol for this assessment tool, the 30 seconds post heel prick refers to the 30 seconds immediately following the moment of the prick and as such includes the blood collection time.

### **6.1.3 RESULTS**

#### **Methodological changes**

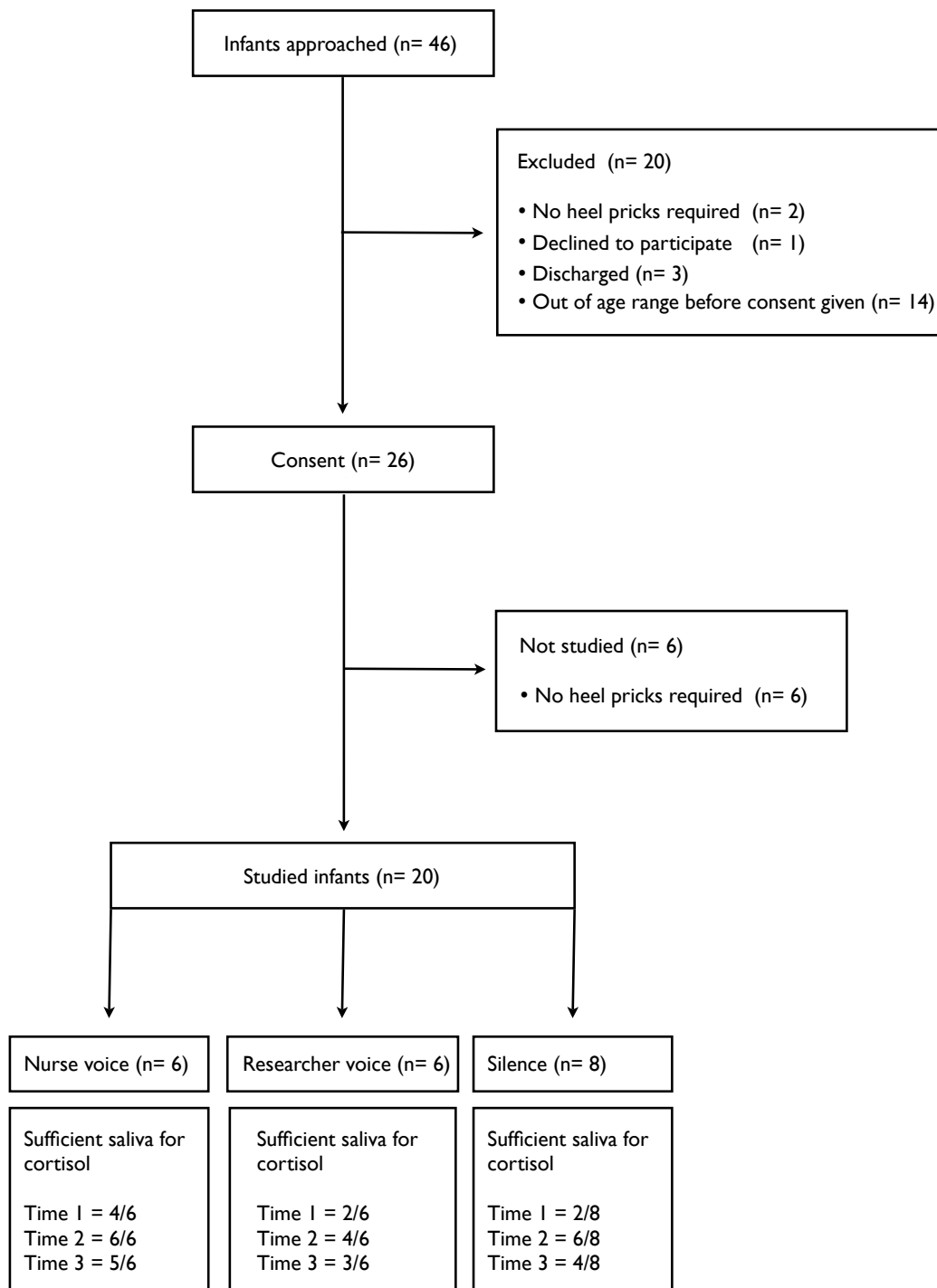
Methodological changes occurred during the study in response to clear difficulties with the originally planned methods. In particular, the method for assessing respiratory activity (measurement of nasal pressure) was not feasible for this study as some infants were distressed during the insertion of the nasal prongs and the extra stress associated with this was likely to be a confounding variable. Pulse oximetry was therefore used with infant five onwards; this measured both heart rate and oxygen saturation and required only a sensor probe around the infant's wrist. Respiratory rate was not measured.

It also became apparent that the nurses' vocal soothing attempts were too inconsistent for a research protocol. There were differences in volume, pitch, tone and numbers of words that meant comparing infants between each other would have been problematic. Further to this, some nurses expressed discomfort in being asked to speak to the infant under these conditions. It was therefore decided to use the voice of the researcher in order to provide more consistency in terms of soothing voice intervention (intervention two). At the time of this change in method, six of the infants had been exposed to the nurse voice condition (intervention one).

#### **Data quality**

Limited saliva volumes meant that only 36 of a total of 60 (60%) saliva samples could be analysed for cortisol. Figure 6.1 provides detail regarding recruitment and cortisol data quality. Only two infants had a full data set of three cortisol samples (baseline, peak and recovery).





**Figure 6.1: Flow diagram of recruitment for feasibility study indicating cortisol samples available for analysis**

Time 1 = Baseline (25 min prior to heel prick)  
 Time 2 = Peak (20 min post heel prick)  
 Time 3 = Recovery (50 min post heel prick)

A total of twenty infants and eighteen nurses participated in the study, with two of the nurses participating twice. The descriptive statistics are presented in Table 6.1.

**Table 6.1: Demographic details of participants in the initial feasibility study**

	<b>Nurse voice condition (Intervention1) n=6</b>	<b>Silent condition (Control) n=8</b>	<b>Investigator voice condition (Intervention2) n=6</b>
Male infants (%)	2 (33%)	5 (63%)	3 (50%)
GA at birth (weeks)	33 (32-35)	33.5 (32-35)	34 (32-35)
PMA (weeks)	34 (32-36)	34.5 (33-37)	35 (33-40)
Age (days)*	6.5 ±2.7	9 ±4.9	14.5 ±12.2
Weight (gms) at study time *	1880 ±308	1793 ±314	1892 ±309
No. previous heel pricks	12 (5-19)	12 (5-19)	14 (6-21)
Ethnicity n(%)			
- NZ European	3 (50%)	5 (62.5%)	3 (50%)
- Maori	1 (17%)	-	-
- NZ Euro/Other	-	1 (12.5%)	1 (16.6%)
- Maori/Other	-	2 (25%)	1 (16.6%)
- Not stated	2 (33%)	-	1 (16.6%)
Delivery method n(%)			
- NVD	2 (33%)	3 (37.5%)	2 (33.3%)
- Elect LUSCS	-	2 (25%)	2 (33.3%)
- Em LUSCS	3 (50%)	2 (25%)	2 (33.3%)
- Forceps	1 (17%)	1 (12.5%)	-

Median (range) unless otherwise stated. \* Mean ± SD.

NVD = Normal vaginal delivery. Elect LUSCS = Elective caesarian section. Em LUSCS = Emergency caesarean section. GA = Gestational age. PMA = Post menstrual age.

Table 6.2 presents the cortisol results for infants for whom there were both peak and recovery results. PIPP scores could be calculated for only seven of the 20 infants as thirteen of the infant faces were not visible to the camera at the time of the heel prick. Table 6.3 presents the PIPP results for those that could be analysed and also the amount of blood collected during each heel prick procedure. There was significant variation between the heel prick procedures in terms of amount of blood collected.

Heart rate and oxygen saturation data were successfully collected for all 16 infants using the pulse oximeter. These data were not analysed for this feasibility study as the aim was to ascertain whether the data could be collected easily from preterm infants during heel prick

procedures. As with any continuous physiological measurement, the data were subject to artefact due to infant movement, which needed to be manually edited.

**Table 6.2: Salivary cortisol (nmol/l) results of infants in the standardised voice and silent conditions**

Infant	Condition	Baseline	Peak	Recovery	Peak minus recovery
2	Silent	29.6	17.2	13.5	3.7
4	Silent	insufficient	104.5	57.9	46.6
7	Silent	insufficient	36.3	35.8	0.5
12	Silent	insufficient	22	26	-4
10	Voice	22	26	10	16
20	Voice	insufficient	29	27	2

The statistical results from the cortisol data were to be compared with existing results from other studies in order to calculate an estimate of sample size for the main study. However, this was unable to be achieved with such a small number of samples able to be analysed.

**Table 6.3: Premature Infant Pain Profile (PIPP) results and amount of blood collected for the seven infants that could be analysed**

Infant	Heel prick type	Voice condition PIPP score*	Silent condition PIPP score*
Baby 15	2 vials 1 capillary tube	14	Not studied
Baby 16	1 capillary tube	9	Not studied
Baby 18	1 capillary tube	9	Not studied
Baby 20	1 capillary tube	15	Not studied
Baby 11	2 vials	Not studied	11
Baby 17	2 vials 1 capillary tube	Not studied	5
Baby 19	1 capillary tube	Not studied	15
Mean		11.75	10.33
Mean of capillary tube only		11 (n=3)	15 (n=1)

\*PIPP scores fall between 0-21, with 0 as lowest pain score and 21 as maximum pain score  
Not studied = because each infant was studied only once

#### **6.1.4 DISCUSSION**

The proposed research protocol was significantly modified throughout the study, because it quickly became apparent that elements were unfeasible, such as consistency in using nurse-

delivered vocal soothing and the measurement of some of the physiological data. Each of the methodology questions examined in this feasibility study is considered separately.

*1 How easy is it to recruit infants and nurses to the study?*

There were no difficulties with nurse or infant participant recruitment to the study.

Some families of eligible infants were not approached because the nurse thought that the parent/s were too upset about their infant's general condition to be asked. All participant nurses and families of infants in the study were offered and sent a summary of the study results at the conclusion of the study (see appendix VI).

*2 Is it feasible to standardise a research protocol around heel prick procedures?*

This study provided an opportunity to test and refine the research protocol. It was found that the instruction to nurses to interpret 'vocal soothing' as they wished was problematic under research conditions. The nurse's voices varied in terms of volume, tone and number of words. The nurses did not appear comfortable with the vocal soothing function and their words were spoken so quietly that the infant may not have been able to hear them.

It is possible that the pressure to perform may have got in the way of the nurse feeling free to speak as they usually would to an infant in their care, for example one nurse said, in a flat tone, "This is a lancet. We use these to assess the levels of bilirubin in the blood". It is likely that this nurse did not usually speak in this way to infants in her care, but it is also possible that she was not comfortable speaking to the infant while being observed during a heel prick procedure and the request to do so may have led her to feel quite uncomfortable and offer 'mechanical' words that were not in tune with the infant. It was important to find a more standardised vocal soothing intervention, so the decision was made to cease using nurse voices from infant ten onwards and instead for the remaining infants to trial the use of the researcher's voice as the intervention.

The researcher is a registered, practising parent-infant psychotherapist who felt comfortable speaking to infants about what was happening to them and how that might make them feel. The vocal soothing took account of how the infant was responding and in this way was like a conversation with the infant. As described in chapter three, the vocal soothing consisted of infant-directed speech. When the infant became agitated or upset, the researcher's voice would take a higher pitch and sound and as the infant

would recover, the researcher's voice would become lower and slower. In this way the infants were offered vocalisations that were aimed at helping them know that the adult acknowledged their experience and communicated that they will get through it and be ok.

It was difficult for the researcher to offer the vocal intervention while simultaneously taking the research notes. These notes involved recording the infant's state and the environmental sound at regular intervals and also noting down the times of activities such as the heel prick and the saliva swabs. It was therefore decided to engage an assistant for the talking condition in the main study.

The protocol for this study included any heel prick procedure, however, in practice these varied in length of time depending on the amount of blood to be collected. It was necessary to change the protocol for the main study to include heel prick procedures using capillary tubes only, in order to standardise the experience for the infant and time for blood collection as far as was possible.

The 'between subject' design of this study meant that the individual differences between infants in their reactions to painful stimuli could potentially be confounding variables. It was determined that a 'within subject' design would go some way to addressing these issues.

### 3 *Can reliable physiological measures be captured with the recording equipment available?*

Putting infants under additional stress through the use of nasal prongs was not appropriate for a research study measuring stress. It was decided not to proceed with the measurement of nasal pressure and respiratory variability and instead to focus on heart rate and oxygen saturations. The Masimo pulse oximeter was a much less invasive measure and data were able to be collected easily, without additional infant stress. It did not, however, have the capacity to record other events such as the moment of the heel prick, which would ensure a more accurate assessment of infant reactivity to the heel prick. There had been a manual recording of the time of the heel prick and this was matched against the data in order to ascertain the stress levels around this time. However, when the researcher was doing the vocal intervention, there were some instances when these times were not recorded. It was time consuming to match the time of the heel prick on the video with the physiological data and this method also

carried a risk of human error. It was thought that the use of a polygraphic system to record the physiological data for the main study would be preferable for the main study as this would enable electronic recording of actions and easier analysis of the data. This is discussed in more detail in chapter three, section 3.4.2.

4 *How feasible is it to use the Premature Infant Pain Profile (PIPP) as a measure of pain?*

There were two main difficulties in using the PIPP. Firstly it can only be used when the infant face is visible to the camera and secondly, there was no way of capturing the moment of the heel prick so that accurate heart rate and oxygen saturation data could be extracted. At the beginning of all of the studies, the camera was set up to be able to view both the infant face and the heel prick procedure. However, in many of the cases the infant moved their head and their face was unable to be seen for the 30 seconds post prick that is required for the PIPP. The heart rate and oxygen saturation data for this study could be out by up to 60 seconds because the video was not linked to the Masimo oximeter and the timing was dependent on manual recording of the time (in minutes) of the heel prick which was then correlated with the time on the video.

The PIPP takes into account the gestational age of the infant meaning that the score can vary by up to one point (out of 15) depending on the age of the infant. This was another reason to compare the results within subject so that this did not become a confounding variable. Although by the time the main study data were ready to be analysed, the decision had been made to use the PIPP-R (as described in chapter three), which reduced the variation in scores due to age.

5 *Is it possible to measure salivary cortisol accurately in the 32-35 weeks GA group?*

Saliva volume for cortisol analysis was problematic in this study, as it has been for other studies described in chapter three. Infants younger than three months of age have been found to secrete low levels of saliva (Herrington et al., 2004). In order to continue using salivary cortisol as a measure of stress for the main study, the problem of saliva volume needed to be addressed.

6 *Is it possible to document sufficient data in the relevant population to use for sample size calculations for the main study?*

It was planned to use data from the cortisol analysis and the PIPP to help calculate sample size for the main study, however this was unable to be achieved with such a small number of samples able to be analysed.

### **6.1.5 CONCLUSION**

This study was designed to test the feasibility of the methods chosen to assess the impact of vocal soothing on infant stress during heel prick procedures. The research protocol was tested with twenty infants and their nurses. It was found that although infants were able to be recruited for such a study, the involvement of nurses in regard to the use of vocal soothing was too variable to be able to reliably test the intervention. The researcher was able to carry out the intervention but would need help during the talking studies to collect data. The research protocol was further refined to include heel prick blood tests using capillary tubes only and the decision made to change the design of the study to a within subject methodology. The use of a polygraphic system for recording the physiological data would mean that the time of the heel prick procedure could be more accurately recorded thus allowing for more accurate analysis of heart rate and oxygen saturations and also for the assessment of the PIPP. Sample size calculations were unable to be made for the data in this feasibility study due to the failure to collect enough saliva to be analysed. Cortisol analysis was problematic in this study, so two further small feasibility studies were designed to assess the impact of a stimulant on saliva volume and whether this might impact negatively upon cortisol measurement. These studies are reported in the following sections.

## **6.2 SALIVA VOLUME STUDY**

Reports in the literature document mixed success regarding the effectiveness of various saliva collection methods for ensuring adequate saliva volume for cortisol analysis. Table 6.4 presents some of the studies that have used saliva stimulants and reported on their effectiveness.

**Table 6.4: Studies using saliva stimulants**

Author(s)	GA of subjects	Type of assay	Stimulant used	Effectiveness
(Rosemary C. White-Traut et al., 2009)	36-41 wks	EIA	Lemon and sugar crystals	40/60 (66%)
(Gunnar, 1992)	38-41 wks	RIA	Kool-Aid crystals	29/40 (72.5%)
(Francis et al., 1987)	Term	RIA	Citric acid powder	94%
(Calixto et al., 2002)	25-34 wks	RIA	3 drops of 5% citric acid solution	100%

EIA – enzyme immunoassay

RIA – radio immunoassay

Schwartz and colleagues carried out a set of studies aimed at assessing the impact of drink mix oral stimulants on cortisol concentrations and concluded that some stimulant types and concentrations and some assay protocols were more likely to lead to elevated cortisol levels in saliva samples (Schwartz et al., 1998). They recommended that wherever possible oral stimulants should be avoided, however if this is not possible, then pilot studies should be carried out to determine the impact of the particular oral stimulant on the saliva to be analysed. Further, they recommended that an oral stimulant should not be used if it resulted in an increase in the sample acidity to a pH of four or below. These recommendations were based on their results following analysis by RIA, a technique used for plasma cortisol analysis.

Some authors have suggested that citric acid as a stimulant also interferes with cortisol readings following RIA (Gitau et al., 2002; Nelson, 2001). Nelson et al suggest that false high readings of cortisol can be seen with concentrations greater than or equal to 60 mg/ml (6%) of citric acid, due to it interfering with the binding of radioligand to antibodies in the RIA, but do not report an effect for concentrations below this (Nelson, 2001). Given that the saliva samples for this project were to be analysed by an enzyme immunoassay (EIA - a technique designed specifically for salivary cortisol analysis) and given that citric acid was readily available from the hospital pharmacy and the relative ease of its administration, it was decided to undertake a trial using 0.1ml of 5% citric acid solution (50 mg/ml) to assess its effectiveness in obtaining sufficient volumes of saliva for cortisol analysis. A minimum volume of 50µl of saliva was required for the EIA used (Salimetrics ELISA). While this



concentration was considered likely to lower the pH of the saliva sample, it was thought that if stimulation was used for all samples then they would still be comparable.

### **6.2.1 METHODS**

#### **Study protocol**

All infants born between 32-35 weeks GA and who were thought to be well enough were able to take part in this study. Infants who were post-surgical or on respiratory support were excluded. Ethical approval for this study was granted by the Central Regional Ethics Committee (appendix IV).

Five infants were recruited for this study and as each acted as their own control. Following consultation with a biostatistician, this relatively small number of participants was thought to be sufficient for the purpose of this feasibility study. The information sheet and consent form are provided in appendix V. Each infant had two randomly assigned saliva collection periods, 24 hours apart, one “intervention” and one “control”. In the intervention saliva collection period a drop of 5% citric acid solution (the equivalent of the concentration found in lemon juice) was placed inside the infant’s mouth prior to collection of the first Salivette™ swab sample but was not repeated prior to collection of samples two and three. In the control condition no citric acid was administered at any point. Three samples of saliva were collected on both occasions. The saliva collection took place at the time of the infant’s routine cares (wash, nappy change, feed) and occurred in the same time frame as planned for the main study. A sample was taken before the nurse began the cares (baseline), 20 minutes after the cares began (peak) and then a further 30 minutes later (recovery). As there would be three measurement points in the intervention study, three samples were taken to test whether the effect of the citric acid, if there was one, lasted beyond the first saliva collection. All families of participating infants were offered and sent a summary of the results of this study (appendix VI).

#### **Data analysis**

Saliva samples were collected and analysed as described in the methodology chapter three. The samples for this study were analysed for saliva volumes only.

#### **Statistical Methods**

The data for the studies were non-parametric, so a Wilcoxon Signed Rank test was used to assess any difference in saliva volumes between groups. This test was applied using SPSS

(IBM SPSS Statistics. Armonk, NY, USA) and was appropriate due to the paired nature of the data.

## 6.2.2 RESULTS

The descriptive statistics are presented in Table 6.5.

**Table 6.5: Participants in the saliva volume study**

	Participants n=5
Male infants (%)	2 (40%)
GA at birth (weeks)	34 (33-35)
PMA (weeks)	35 (34-36)
Age (days) *	7 ±1.5
Weight (gms) at study time *	2310 ±284
No. previous heelpricks	9 (4-13)

Median (range) unless otherwise stated.

\* Mean ± SD. GA = Gestational age.

PMA = Post menstrual age.

Six saliva samples for each infant were gathered and were all suitable for analysis. Table 6.6 presents the saliva volumes for the ‘with stimulant’ (intervention) and ‘without stimulant’ (control) conditions at each of the three time points.

**Table 6.6: Means and (Standard Deviations) for saliva volumes ( $\mu$ l) for intervention and control conditions at three time points.**

Time point	With stimulant Mean ±SD	Without stimulant Mean ±SD	Wilcoxon Signed Rank Test
Baseline (0 mins)	150±99.5	76±31.4	p=0.043
Peak (20 mins)	20±12.9	56±40.2	p=0.104
Recovery (50 mins)	72±49.6	72±79.6	p=0.786

The differences in saliva volumes were significant for the baseline swab only, suggesting that the effect does not sustain over time. The data for this baseline group are presented in Table 6.7.

**Table 6.7: Differences in baseline saliva volumes (in  $\mu\text{l}$ )**

Participant	Intervention (Citric acid)	Control	Difference (intervention – control)
One	70	53	17
Two	140	98	42
Three	310	50	260
Four	167	120	47
Five	65	58	7

### **6.2.3 DISCUSSION**

This study demonstrates that the administration of 0.1ml of 5% citric acid solution is effective in increasing saliva volumes that can be collected from preterm infants using a Salivette™ swab. The volumes in the ‘peak’ condition were considerably lower than the baseline volumes, so it would be necessary to administer the citric acid prior to each individual saliva sample, as opposed to just once at the beginning of the saliva collection period, for this effect to be maintained throughout a complete study.

It was beyond the scope of this study to look at the minimum amount of citric acid required in order to increase saliva volumes to a level suitable for salivary cortisol analysis. Further research is needed to determine the lowest levels of stimulant required.

### **6.2.4 CONCLUSION**

While the sample size for this study was small, it was possible to determine whether the citric acid concentration was able to affect and increase saliva volumes. This study indicated that with the use of this stimulant there would be a higher chance of obtaining sufficient saliva from preterm infants to enable cortisol analysis. Before a decision was made to use the saliva stimulant in the main study it was important to consider any potential impact of the stimulant on cortisol measurements using enzyme immunoassay. The ‘saliva stimulant study’ sought to explore this issue and is described in the following section.

## **6.3 SALIVA STIMULANT STUDY**

The saliva stimulant study was designed to assess the impact of the saliva stimulant on cortisol levels in adults using the assay to be used in the main study. It is acknowledged that adults produce lower cortisol values than infants. For example a study assessing the impact

of skin to skin care on cortisol levels of mothers and infants found that the mother's salivary cortisol values ranged from 1-13 nmol/l, while the infant salivary cortisol values ranged from 5-145 nmol/l (Mörelus, Theodorsson, & Nelson, 2005). Another study found that infants less than one year of age produced higher salivary cortisol values than children, adolescents or adults (Kiess et al., 1995). However, adult participants were chosen for this study because of their increased likelihood of producing enough saliva for cortisol analysis in the control condition compared with infant participants. Given the wide range of results for infants compared with less variation for adults in the study by Mörelus and colleagues described above, it was also thought that any effect of saliva stimulant may be more obvious in a small adult sample. Using the 'Trier Social Stress Test' in adults Kirschbaum and colleagues found that an increase of 2.5 nmol/l above baseline was a minimum intervention effect (Kirschbaum, Pirke, & Hellhammer, 1993). Based on this, it was reasonable to expect that any increase of salivary cortisol value of more than 2.5 nmol/l could be considered to reflect an effect of the saliva stimulant.

### **6.3.1 METHODS**

#### **Study protocol**

A convenience sample of eight female adults (staff of the Paediatric Department) participated on the day of the study. All of the participants were aware of the wider research project and provided consent by their participation. The saliva collection took place at 10.30am on a weekday morning for all participants. Each participant provided two saliva samples in one saliva collection period. The first sample, using a Salivette™ swab, was taken for three minutes duration. A measure of 0.1ml of 5% citric acid solution was administered by syringe into the buccal pouch, followed by a two minute wait before taking the second saliva swab, also for three minutes duration. The syringe and swabs were all self-administered.

#### **Data analysis**

Saliva samples were analysed for cortisol values as described in chapter three.

#### **Statistical methods**

The cortisol data appeared to be skewed, so on the basis of this and previous studies, the data was log transformed and was found to have a log normal distribution. The ratio of

values were calculated using the difference between the log intervention and the log control values.

### **6.3.2 RESULTS**

Eight female adults with a median age of 34 years (range 21-53 years) participated in the study. All of the saliva samples were suitable for analysis for cortisol levels. Table 6.8 presents the cortisol levels for each of the samples.

**Table 6.8: Cortisol levels (nmol/l) and log transformed data with and without the use of 5% citric acid solution**

<b>Participant</b>	<b>Control (no citric acid)</b>	<b>Intervention (citric acid)</b>	<b>Log Control</b>	<b>Log Intervention (citric acid)</b>	<b>Difference (intervention – control)</b>	<b>Ratio of values</b>
One	8	8	0.9	0.9	0	1.00
Two	24	23	1.38	1.36	-0.02	0.98
Three	7	6	0.85	0.78	-0.07	0.94
Four	10	8	1	0.9	-0.1	0.91
Five	69	66	1.84	1.82	-0.02	0.98
Six	7	6	0.85	0.78	-0.07	0.94
Seven	5	5	0.7	0.7	0	1.00
Eight	8	7	0.9	0.85	-0.05	0.94

As can be seen from the above table, differences in cortisol values in individuals with or without citric acid were minimal. Two of the participants retained the same cortisol levels across the two conditions. The remaining six participants all produced a slightly lower cortisol response in the intervention condition than they did in the control condition, ranging from 1-3 nmol/l.

### **6.3.3 DISCUSSION**

The results of this study answered the feasibility question of whether a saliva stimulant of 5% citric acid is likely to confound the salivary cortisol results for the main study. The differences with and without citric acid were well within the CV for the assay (chapter three, page 44), suggesting citrate had no effect on cortisol values with the assay used in this study. Previous concerns in the literature with the use of citric acid have been with falsely elevated concentrations of cortisol (Nelson, 2001; Schwartz et al., 1998) and these results confirm that citric acid did not cause this problem with the assay used in this research.

While it would have been ideal to be able to test the effect of this saliva stimulant on the preterm infant population that were used for the main study, the cortisol results of the initial feasibility study highlighted the difficulty in obtaining enough saliva from preterm infants for the control condition. It was possible that in order to retrieve enough saliva for the matched controls, a much bigger sample size would have been required and would have taken up more of the allocated PhD project time. In the interest of gaining results in a timely manner, the decision was made to sample the adult population due to the likelihood of producing enough saliva for a matched control.

Gordon and colleagues looked at the impact of flavoured beverage crystals on cortisol values using enzyme immunoassay and found there to be a regular effect (Gordon, Peloso, Auker, & Dozier, 2005). They suggested that cortisol results would not be distorted by flavoured beverage crystals as long as there is consistency in their use or non-use. On balance, it was decided to use citric acid as a saliva stimulant for the main study in this research project given the plan to use it consistently across both conditions and the absence of any significant effect on cortisol values in this feasibility study.

### **6.3.4 CONCLUSION**

The saliva stimulant study was designed to assess the impact of 0.1ml of 5% citric acid solution on cortisol levels in adults using the assay to be used in the main study. Results

using a convenience sample of eight female adults suggested that the saliva stimulant was unlikely to confound the salivary cortisol results for the main study. Given that it was to be used consistently across both conditions and the indication that any effect is likely to be regular, the decision was made to use the stimulant in the main study.

## **6.4 CONCLUSIONS & LESSONS LEARNT FOR THE MAIN STUDY**

There were a number of methodological changes that were made for the main study based on the results of these three feasibility studies:

1. A within-subject design would reduce confounding variables.
2. The use of the researcher's voice would standardise the intervention and would be feasible so long as an assistant was recruited to take the study notes.
3. The Masimo pulse oximeter is an effective measure of heart rate and oxygen saturation without inducing additional stress, however it did not provide a way of recording the moment of the heel prick directly onto the recording. It was decided to use polygraphic recording system for recording the physiological data in the main study. A description of this methodology can be found in the methodology, chapter three.
4. The PIPP is useful as a measure of stress provided care is taken to ensure the infant's face is visible to the video camera. The within-subject design would reduce possible age related variation in PIPP scores.
5. A 5% aqueous solution of citric acid is useful in increasing the saliva volumes for preterm infants and any effect of this stimulant on cortisol values is minimal with the enzyme immunoassay to be used and should be reduced by consistent use prior to collection of each sample.

After two observational studies and three feasibility studies, it was thought that enough information had been gathered to confidently embark on the main study for this project, designed to test the hypothesis of whether vocal soothing could reduce manifestations of stress in preterm infants during painful procedures.



## 7 DOES A 'SOOTHING' VOICE ACTUALLY SOOTHE? THE TALKING TO BABIES STUDY

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*We do such dreadful things to them. I just hope that they forget.*

---

NICU Doctor (M. Cohen, 2003, p.10)

No doubt this is a sentiment expressed by many staff in a NICU. It may well be reassuring for staff to hope that these infants forget the negative experiences they have had, but what about their positive experiences? What about the times in which the infant felt safe and soothed? Would we wish them to forget these moments also? This study aims to lessen the impact of the 'dreadful things' by offering psychological company, by way of a 'soothing' voice, to a preterm infant during a painful procedure.

### 7.1 INTRODUCTION

Over the past 40 years researchers have been assessing the effectiveness of various non-pharmacological interventions for preterm infant pain and stress. Many of these interventions have largely been 'physical' in their nature due to the fact that they are actions performed on the body of the infant. Kangaroo Care, for example, is when the infant is held skin to skin with a parent, non-nutritive sucking is when preterm infants are offered a dummy or pacifier to suck on and swaddling/tucking is when the infant's limbs are held firmly to the body using a sheet. Physical interventions are designed to address the internal physiological experience of the infant by offering an intervention to the body of the infant. Kangaroo care (which includes breastfeeding), non-nutritive sucking and swaddling/tucking have all been found to reduce the pain reactivity and improve the pain regulation response of preterm infants during skin breaking procedures (Nimbalkar, Chaudhary, Gadhavi, & Phatak, 2013; Pillai Riddell et al., 2011).

These physical interventions, while important for ameliorating the physical manifestations of stress and pain in the infant, are not directly attuned to the moment-to-moment psychological experience of the infant. The field of infant mental health is concerned with the emotional experience of the infant and how to communicate with the infant in a way that helps them feel secure. The aim is to accompany the infant psychologically in their

experience in such a way that facilitates optimal infant brain development. An intervention that considers the emotional experience of the infant needs to be addressed to the mind of the infant not just the body. An aural intervention is a good option for conveying soothing meaning to an infant in the context of a NICU. A visual intervention would be dependent on the infant having a clear line of sight and their eyes open, a tactile intervention may be overwhelming or unfeasible during a painful procedure.

The relationship-based interventions such as sensorial saturation, infant led singing and the ATVV (Auditory, Tactile, Visual and Vestibular) intervention that were introduced in chapter two all offer the human voice as a main component and are designed to be carried out by both parents and professionals. Sensorial saturation has been found to be effective in reducing pain and stress for preterm infants during painful procedures, while infant directed singing and the ATVV intervention have been associated with general improvements in premature infant health. These interventions will be discussed in more detail here before the case is made for the investigation of an attuned soothing voice for premature infant pain and stress.

### **7.1.1 THE ATVV (AUDITORY, TACTILE, VISUAL AND VESTIBULAR) INTERVENTION**

The auditory, tactile, visual and vestibular intervention (ATVV) was developed by a group of researchers in Chicago, USA who were interested in taking aspects of typical mother-infant interaction and applying it as an intervention with preterm infants in the NICU. While not specifically for pain, the ATVV intervention is designed to help infants manage the general stress of being in a NICU environment. It was found that a tactile only intervention, that is massage alone without any human interaction, was over-stimulating for term infants leading the researchers to discourage the use of massage only interventions without human contact (Rosemary C. White-Traut, Nelson, Silvestri, Cunningham, & Patel, 1997). The ATVV intervention includes talking to, looking at and rocking the infant as well as massage. It has been found to have a positive effect on preterm infant alertness (without overstimulation), feeding behaviours and an earlier hospital discharge (Rosemary C White-Traut et al., 2002). The intervention is administered for 15 minutes, twice a day, to infants from 33 weeks PMA until discharge and is designed as a low-tech intervention that can be adjusted if and when the infant shows signs of stress during the intervention (White - Traut, 2004). The ATVV intervention has also been shown to have a positive impact on the above infant outcomes when administered by parents prior to discharge (R. C. White-Traut et al., 2015).

### **7.1.2 SENSORIAL SATURATION**

The aim of sensorial saturation is to distract the infant's senses so that pain has less chance of being perceived centrally (C. V. Bellieni et al., 2001). Bellieni and colleagues have studied the effectiveness of sensorial saturation extensively and have refined the technique in the 'Triple T intervention' using touch, taste and talk as the distractors (Carlo Valerio Bellieni, Tei, Coccina, & Buonocore, 2012).

In reviewing this approach, Bellieni found that the 'taste' intervention, oral glucose, was the critical component of the distraction intervention and without this component found touch and talk alone were ineffective (C Bellieni, 2002). A caveat to this finding is that the measures they used were purely behavioural. It would have been interesting to examine whether effects on physiological measures such as heart rate variability, respiratory rate and variability or salivary cortisol were demonstrated in the absence of a behavioural effect but these effects have not been studied in this context. Also the particular kind of talk offered to the infants during the sensorial saturation intervention is not fully described other than to say that the words used should be gently but firmly spoken (C. V. Bellieni et al., 2001).

The rationale for its effectiveness is based on 'gate control theory' which suggests that non-painful stimuli are able to 'shut the gates' to the brain, preventing noxious stimuli from reaching it (Melzack & Wall, 1996). It focuses on three main senses: taste, touch and hearing. A fourth sense, smell, was found to be unnecessary to the effectiveness of the intervention. The sensorial saturation procedure is described as follows:

1. Talk to the baby to attract his/her attention
2. Massage his/her face while administering some drops of sugar and water on the tongue to obtain regular sucking
3. When the baby is evidently concentrated on sucking (regular suction) perform the heel prick
4. Continue to stimulate the baby throughout the procedure. (Carlo Valerio Bellieni et al., 2012)

The sensorial saturation intervention with preterm infants includes an oral sweet solution, known to reduce pain responses, consisting of 0.2-0.3ml of 10% glucose solution, administered for 30 seconds prior to and during the heel prick (C. V. Bellieni et al., 2001).

Bellieni and colleagues found their sensorial saturation intervention enhanced the analgesic effect of the glucose and water solution. Seventeen preterm infants in their first 10 days of life and less than 35 weeks GA participated in five heel prick procedures, each with a different form of analgesia. Mean PIPP scores were found to be significantly lower in the sensorial saturation condition than in the sweet solution alone condition (C. V. Bellieni et al., 2001). A similar result was found with term infants, for whom a 33% glucose solution was used to assess the effectiveness of the sensorial saturation intervention (C Bellieni, 2002). With only 17 subjects and five different interventions in the preterm infant study, its statistical power may be questionable. However a Bonferroni correction was applied to compensate for the higher chance of a type 1 error (false positive) and the level of significance was clear with a p value <0.01. The PIPP analysis was not blinded in this study. The observers who rated the infant's reactions to the heel prick could see on the video whether or not they were receiving the sensorial saturation intervention, which may have meant that their conclusions were influenced.

A review by Bellieni in 2012 found eight studies assessing the full sensorial saturation intervention published between January 2001 and January 2012 (Carlo Valerio Bellieni et al., 2012). Seven of the studies used a heel prick as the painful procedure and, using a variety of pain measurement methods, all found that the use of sensorial saturation was effective in reducing newborn infant pain. The same search was conducted for the period January 2012 – January 2016 (Medline Ovid and Medline ProQuest with keywords 'sensorial saturation' 'multisensory stimulation' and 'newborn') and no additional studies were found. Table 7.1 below summarises the methods of six of these studies as the seventh was unable to be sourced (C Bellieni, 2002; C. V. Bellieni et al., 2001; Carlo Valerio Bellieni et al., 2003; Carlo V. Bellieni, Cordelli, Marchi, & Ceccarelli, 2007; Bernardini, De Liso, Santoro, Allemand, & Allemand, 2011; Gitto et al., 2012).

**Table 7.1: Sensorial saturation studies with heel prick procedures**

Year	Author	Pain measure	Within or between subject design	PMA of infants	Number of infants in the study	Results of PIPP scores only
2001	<i>Bellieni et al.</i>	PIPP	Within	≤ 35 weeks	17	Null vs SS 11.1±2.5 vs 4.1±1.4
2002	<i>Bellieni et al.</i>	DAN & Crying time	Between	Term	120 (20 in each condition)	
2003	<i>Bellieni et al.</i>	Intracranial pressure	Between	35-41 weeks	51 (17 in each condition)	
2007	<i>Bellieni et al.</i>	ABC	Between	Term	66 (22 in each condition)	
2011	<i>Gitto et al.</i>	CRIES	Between	27-32 weeks	150 (50 in each condition)	
2011	<i>Bernardini et al.</i>	PIPP	Between	30-35 weeks	28 (14 in each condition)	Null vs SS 14.69 vs 6.52 (p<0.001)

DAN = Douleur Aiguë du Nouveau-né (a behavioural pain scale)

CRIES = a behavioural and physiological pain scale

ABC scale = a crying scale

Crying time = in seconds

One of these studies assessed increase in intracranial pressure (measured using a tonometer placed on the anterior fontanelle) while the remaining five used behavioural measures for assessing pain in infants. The PIPP was utilised in two of the studies. Both of the studies using the PIPP assessed a population of infants less than 35 weeks PMA, one using a within subject design and the other a between subject design. However, the study that used a within subject design (assessing five different conditions on the same infant over time) analysed their results according to the intervention groups, not in relation to the control condition for that particular infant. None of the studies assessed the cortisol response of the infants to the intervention. Sensorial saturation is therefore an intervention that appears to be successful in reducing the pain behaviours of infants during a heel prick procedure, but there is currently little information about the impact of the intervention on cardiorespiratory or endocrine response to infant distress.

The authors of the sensorial saturation intervention, Bellieni et al. (Carlo Valerio Bellieni et al., 2012) stress the importance of treating human infants with empathy and maintain that their intervention is consistent with this (C Bellieni, 2002; C. C. Bellieni, 2005; Carlo Valerio Bellieni et al., 2003; Carlo Valerio Bellieni et al., 2012). One could imagine this is so on a number of levels. Firstly this is an intervention that aims for the infant to be well regulated before the heel prick is performed, meaning that the caregiver has to be attuned and responsive to the behavioural state of the infant in order to help them reach this state of regulation. Secondly, the instruction to talk to the infant suggests that the infant is considered to be responsive to social and emotional communication. Anand and Hall describe sensorial saturation as involving "...focussed human attention and sincere commitment to the infant's comfort." and suggest that the application of sensorial saturation "...expresses empathy for infants who are undergoing painful experiences during neonatal intensive care" (K. J. S. Anand & Hall, 2008, p.826). This suggests that this group of researchers view the premature infant as a feeling and communicating being. The unanswered question is whether the success of their sensorial saturation intervention is actually down to the flooding of the senses, as they suggest, whether it may be because the infant senses an empathic human offering them reassurance in their distress, or whether it is a combination of both.

While sensorial saturation works across the three distractors of talk, touch and taste, infant led singing focuses on just talk and touch. Infant directed singing is provided by a trained music therapist who must be attuned and empathic to the infant.

### **7.1.3 INFANT DIRECTED SINGING**

Over the past 25 years there have been many studies looking into the impact of music therapy for premature infants. It has been criticised for potentially being too stimulating for premature infants, but a 2012 meta-analysis, which included thirty studies, found that overall it was an effective intervention for premature infant health (Standley, 2012). Filippa and colleagues found that there were benefits to preterm infants beyond 29 weeks GA with both maternal singing and maternal vocalisations (Filippa, Devouche, Arioni, Imbert, & Gratier, 2013). A review in 2009 reported on three studies where infants were exposed to music during a heel prick procedure, which showed some impact of music on behaviour and pain, but judged these to be studies of poor methodological quality (Hartling et al., 2009). One of these studies, involving 27 infants found music to have a significant positive effect on

heart rate during heel prick procedures (Bo & Callaghan, 2000). Another smaller study with 14 infants found 'Brahms lullaby' to have a positive effect on behavioural state, heart rate and pain response for infants over 31 weeks of age (Butt & Kisilevsky, 2000). The third study, involving 60 infants, found no difference between a pacifier activated lullaby and a pacifier without lullaby on infant behavioural states and stress levels (Whipple, 2008).

Live music therapy has been found to be more beneficial than pre-recorded music (Standley, 2012). In live music therapy, a trained music therapist offers infant directed singing to the infant, adjusting the pitch and contours of their voice in a way that aims to physiologically regulate the infant (Shoemark, 2006). The spontaneous nature of the singing means that the therapist is led by the infant's immediate responses and aims to connect with the infant's emotional experience (Shoemark, 2006). This is seen to be particularly important given the hospital experience being largely non-contingent with the infant's psychological needs (Shoemark, 2006).

Malloch and colleagues, have investigated the impact of live infant led singing on premature infants (S Malloch et al., 2012). The aim was to bring the infant to a state of regulation, either a quiet alert state or sleep state, through attuned interaction, that included singing and touch. Although the sample size for the intervention infants was small (ten infants) they found that infants performed better than control infants on the NAPI (Neurobehavioural Assessment of the Preterm Infant) scale, which they used to assess the infant's ability to 'relax, trust and enjoy' the interaction with the music therapist. They did not find statistically significant results for their measure of socioemotional functioning, the *Alarme Détresse du Bébé* (Alarm Distress Baby Scale, ADBB) and suggested that this may have been due to either the small sample size or because the scale was designed for use with infants over two months of age. They based their interaction on part of the ATVV intervention and replaced the 'talking' aspect with singing because of the evidence that hospitalised infants prefer singing over talking. However, the studies they quote as evidencing this claim were from the 1990s and research since has suggested this is not true. Filippa's research in 2013 suggested that speech and singing each have a similar impact on hospitalised preterm infants, with the only difference being that speaking tended to lead the infants to a quiet alert state, while the singing led the infants to an active sleep state (Filippa et al., 2013). Filippa and colleagues suggest that "meaningful and relational-based maternal vocal stimulation can positively activate the infant's state, avoiding or dampening the risks of non-contingent

overstimulation” (Filippa et al., 2013, p.1020). Music therapy studies to date have used assessment measures that have looked at how the infant is doing generally - for example how they handle a social interaction or their general physiological response to the music therapy. At the time of writing, no study had yet assessed infant led singing as a specific pain management intervention.

#### **7.1.4 SUMMARY**

The ATVV intervention is based on aspects of the typical mother-infant interaction and there is evidence for its effectiveness in improving alertness, feeding behaviours and earlier hospital discharge for preterm infants. There is evidence that Sensorial Saturation reduces infant pain during a heel prick procedure, although this has been tested with behavioural measures only. Levels of stress as evidenced by cortisol levels, heart rate or oxygen saturation have not been tested with this intervention. While the authors of sensorial saturation claim that their intervention is designed to be empathic, they claim that the method through which it offers relief to infants can be explained by Gate Control Theory. They make no direct claims that their intervention ‘works’ through offering an empathic presence. Researchers of infant-led singing do suggest that it is the empathic attunement of the singer that has the positive effect on preterm infant health. However, there is no good quality evidence that this intervention reduces stress or pain during a painful procedure. The question still remains as to whether an attuned empathic presence, conveyed through the use of human voice, can help a preterm infant tolerate and recover from a painful procedure. While the research conducted by Filippa and colleagues focused on maternal vocal stimulation, they suggest “social interaction based on vocal stimulation is now at the heart of new approaches in NICU interventions” (Filippa et al., 2013, p.1019). The present study aims to assess a new intervention in the NICU; the impact of a non-parental attuned vocal intervention on premature infant pain and stress.

## **7.2 RESEARCH QUESTIONS, AIMS AND HYPOTHESES**

The short-term aim of this study was to assess the impact of a *vocal intervention* on premature infant pain and stress during a routine painful procedure. Specifically:

*Does talking empathically to premature infants during a heel prick procedure have a beneficial effect on infants’ behavioural and physiological responses to pain and stress?  
Or in other words, does a ‘soothing voice’ actually soothe?*



If effective, the results of this intervention could be easily applied across a range of painful interventions and could have the potential to improve psychological and physiological outcomes for premature infants in the long term.

Based on previous studies that have shown the benefit of non-pharmacological interventions on stress in preterm infants, it was hypothesized that *behavioural and physiological pain and stress responses for the infant in the talking condition would be less pronounced and would return to baseline more quickly than for the infant in the silent condition.*

## **7.3 METHODS**

### **7.3.1 PARTICIPANTS**

Preterm infants on no respiratory support were recruited in their first 2-10 days of life. Gestational age at birth was between 32-35 completed weeks and each infant was to have a heel-prick blood test, as part of their usual care, on two separate occasions. See section 3.1.1 for further details regarding the infant population for this study. Figure 7.1 illustrates the study set up, with infant, equipment and researcher.



Figure 7.1: Study set up: infant, equipment and researcher<sup>1</sup>

### **7.3.2 STUDY DESIGN AND POWER CALCULATION**

The feasibility study utilised a ‘between subject’ design, but the decision was made to use a randomised cross-over design for this study in order to reduce the potential impact of confounding variables such as temperament or level of infant health. The cross over design was also advantageous because it meant a smaller sample size was required for the statistical analysis. As this study assessed the impact of a soothing intervention on discrete noxious stimuli approximately 24 hours apart, there was very little likelihood of carryover effect from the condition that the infant was first exposed to. For example, the infant being soothed or not as an outcome of the first condition was thought to have little influence on the outcome of the second condition.

Sample size calculations were performed using a non-parametric test approach, as information was not available regarding standard deviations for salivary cortisol levels in this population. Noether’s sample size formula for the Wilcoxon signed ranks test was used (Noether, 1987). The non-parametric sample size was thought likely to be slightly larger than

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<sup>1</sup> All the photographs used in this chapter were posed using the researcher’s nephew for the purposes of illustrating the study set up and did not involve a real heel prick procedure.

the sample size required for the proposed analysis - the comparison of log-transformed salivary cortisol levels using a paired t-test.

Sample size was predicated on detecting whether at least 70% of infants had lower peak cortisol levels for the talking intervention compared to the silent condition. This gave a sample size of 50 infants (with  $\alpha = 0.05$  and power of 0.8) measured under both conditions. Allowing for 20% drop-out or failure of data collection (for example not being able to collect sufficient saliva to determine cortisol levels) this gave a target sample size of 63 infants.

This sample size was considered sufficient for analysis of other outcomes, for example detecting a mean difference of two points on the PIPP-R score with a power of 0.8 would require a total sample size of 32 infants.

### **7.3.3 STUDY PROTOCOL**

The study was located in the Neonatal Intensive Care Unit of Wellington Hospital and was approved by the Central Health and Disability Ethics Committee (appendix IV). The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000882820).

All infants in this randomised controlled study were exposed to each of the two study conditions - vocal soothing by a non-parental adult during a routine heel prick procedure (intervention) and no vocal soothing during a routine heel prick procedure (control). Vocal soothing was undertaken by the researcher for this study, as described in chapter three. Given the low incidence of nurses talking to babies found in the observational audit, it is reasonable to assume that the control condition was akin to usual care in most cases.

The recruitment processes for this study are described in chapter three and the information sheet and consent form for parent of infants in the study is provided in appendix V. Infants were randomly allocated by block randomisation to the order of conditions using a computer package (R 2.15.1, R Foundation, Vienna, Austria) so that there were equal numbers of voice first/silent first infants in the list.

Environmental sound and infant behavioural state were documented prior to each cortisol measurement and at regular intervals throughout each study. Figure 7.2 illustrates the typical set up of the vocal soothing for infants that were in open cots.



**Figure 7.2: Study set up: offering vocal soothing**

### **7.3.4 DATA COLLECTION**

There were four outcome measures for this study: salivary cortisol, heart rate, oxygen saturation, and the Premature Infant Pain Profile - Revised (PIPP-R). The rationale for the use of these measures and the methods for data collection are described in detail in chapter three. Figure 7.3 shows an infant being monitored for heart rate and oxygen saturation, Figure 7.4 shows the research trolley and Figure 7.5 provides a close up of the physiological monitoring with the heel prick marked.

*Salivary cortisol:* Each saliva sample was collected following the administration of 0.01ml of a 5% aqueous solution of citric acid to increase saliva volume. For saliva cortisol analysis two control samples (low and high) were run in each analysis with values of 7 nmol/l and 21 nmol/l and the overall inter-assay coefficient of variation was 13.9% and 8.3% respectively. The intra-assay coefficient of variation was 8.6%, calculated from the mean of the duplicates of the saliva samples. See chapter three, section 3.4.1 for further details of salivary cortisol methods. The baseline data were collected over a period of three minutes 22-25 minutes before the heel prick procedure. The peak data were collected over a period

of three minutes, 20 minutes after the heel prick and the recovery data collected over a three minute period, 50 minutes after the heel prick (see chapter three, Figure 3.1).

*Heart rate and oxygen saturation:* Infant stress was measured by continuous heart rate and oxygen saturation monitoring. Oxygen saturation as measured by pulse oximetry (SpO<sub>2</sub> - 1 sample/second) and electrocardiogram (ECG) were recorded simultaneously. See chapter three, section 3.4.2 for further details of heart rate and oxygen saturation methods. Mean baseline oxygen saturation and heart rate data were collected for one minute prior to nurse touch, minimum oxygen saturation and maximum heart rate were collected in the 30 seconds following the heel prick for peak data and mean recovery data were collected over one minute, two minutes after the heel prick (see chapter three, Figure 3.2).

*Premature Infant Pain Profile - Revised:* The physiological measures for 'baseline' and 'peak stress' were used to complete the relevant components of the Premature Infant Pain Profile – Revised (PIPP-R). The infant's behavioural response was assessed retrospectively using a video recording of the procedure. Each video was assessed with the sound turned off so that the primary investigator was blind to the intervention/control condition for each study.



**Figure 7.3: Heart rate and oxygen saturation monitoring**

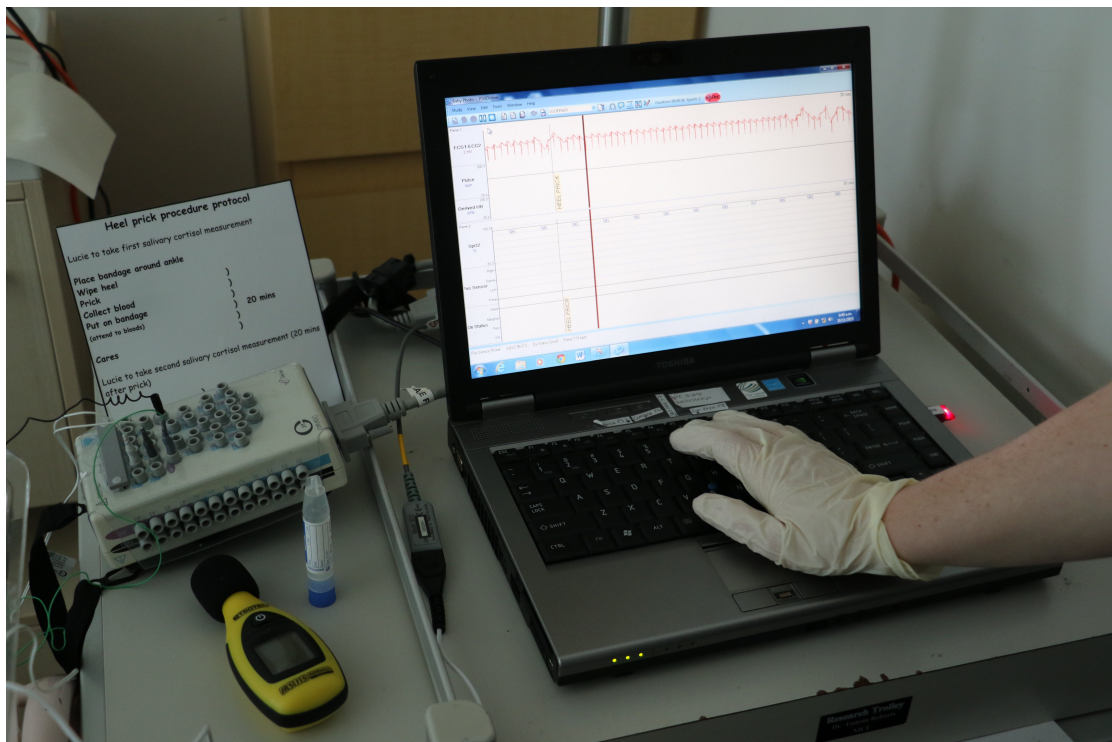


Figure 7.4: Research trolley set up with physiological monitoring, salivette swab and sound recorder.

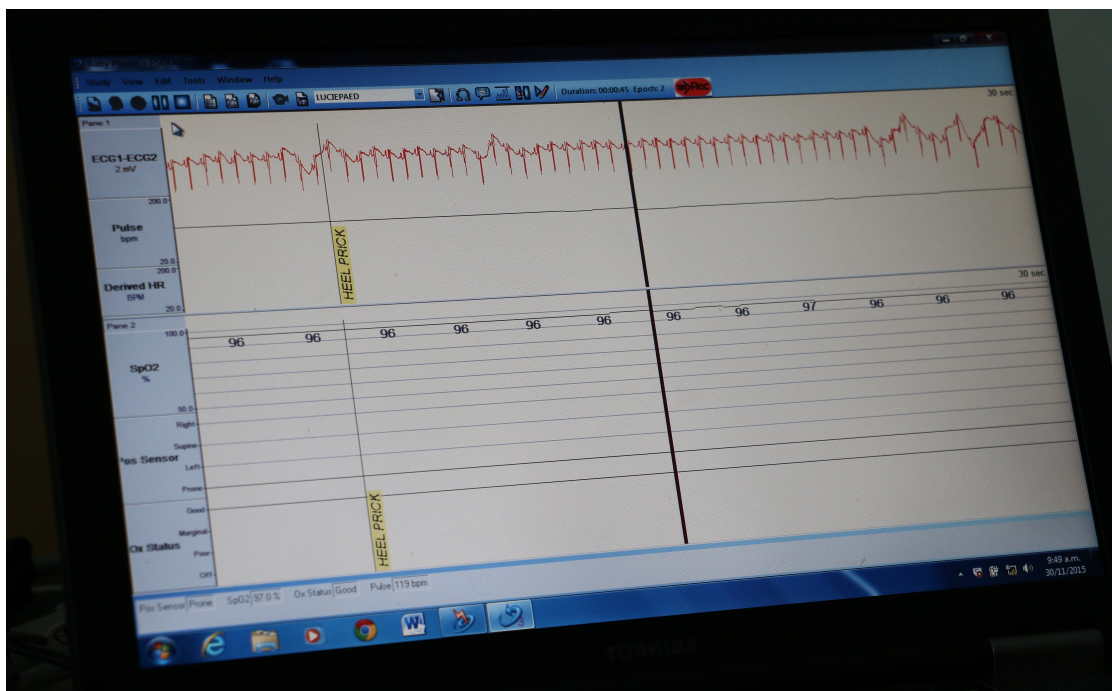


Figure 7.5: Close up of physiological monitoring with heel prick marked.

### 7.3.5 STATISTICAL METHODS

Data were first analysed for comparability to a normal distribution in SPSS. Cortisol and oxygen saturation data were found to be skewed and kurtotic, with Shapiro-Wilk p values

below 0.05 suggesting the data differed significantly from normality. The histograms, QQ Plots and Boxplots did not appear normal (see Appendix VII). Log transformed cortisol and SpO<sub>2</sub> values however gave a good approximation to a normal distribution and were used for analysis. The heart rate data were less skewed and kurtotic with most p values above 0.05 and histograms, QQ plots and Boxplots that looked more near normally distributed (based on histograms, QQ plots, Boxplots and Shapiro-Wilk p values above 0.05). The Premature Infant Pain Profile - Revised (PIPP-R) results were also normally distributed (see appendix VII for skewness, kurtosis, shapiro wilk and histograms). Parametric tests were therefore used for analysis of these data, log-transformed as necessary. For all analyses a p value of less than 0.05 was considered statistically significant.

First the hypothesis that talking empathically to infants reduces the cortisol response to heel prick procedures was tested. Cortisol levels were log-transformed and compared using a linear mixed model in SPSS. Given the paired nature of the data and the fact that the baseline value for each condition was different, the test accounted for changes in the cortisol values and then estimated the differences between conditions of these change values. The clinical question being considered was whether infants in the voice condition recovered any more quickly than infants in the silent condition and so the values of interest were the recovery values for each condition and also the peak minus recovery figure for each condition.

The linear mixed model included parameters for timing, condition and their interaction. Timing was analysed to ascertain whether there were any differences between peak and recovery, on average across conditions. Condition was analysed to ascertain whether there were differences by condition, on average across both study periods. The interaction of timing and condition was examined to answer the question of whether the changes in cortisol were a function of both timing and condition. This statistical analysis also produced confidence intervals, that is the plausible bounds as to what the true difference might be. The cortisol results presented below have been back transformed to the original scale of nmol/l. Back transformation required exponentiating the log values, which meant that the differences are expressed as a ratio of means. Heart rate and oxygen saturation data were also analysed using the mixed model in SPSS described above.

## **7.4 RESULTS**

### **7.4.1 PARTICIPANTS**

A total of 137 infants were eligible for the study during the recruitment period, 86 of these infants were not studied for reasons outlined in Figure 7.6. The full sample size of 63 infants was unable to be reached due to time restraints on data collection during this PhD programme. Fifty-one infants participated in this study and all families were offered and sent a summary of the results (appendix VI). The descriptive statistics are presented in Tables 7.2 and 7.3. The behavioural states of the infants at the beginning of each heel prick procedure are presented in Table 7.4.



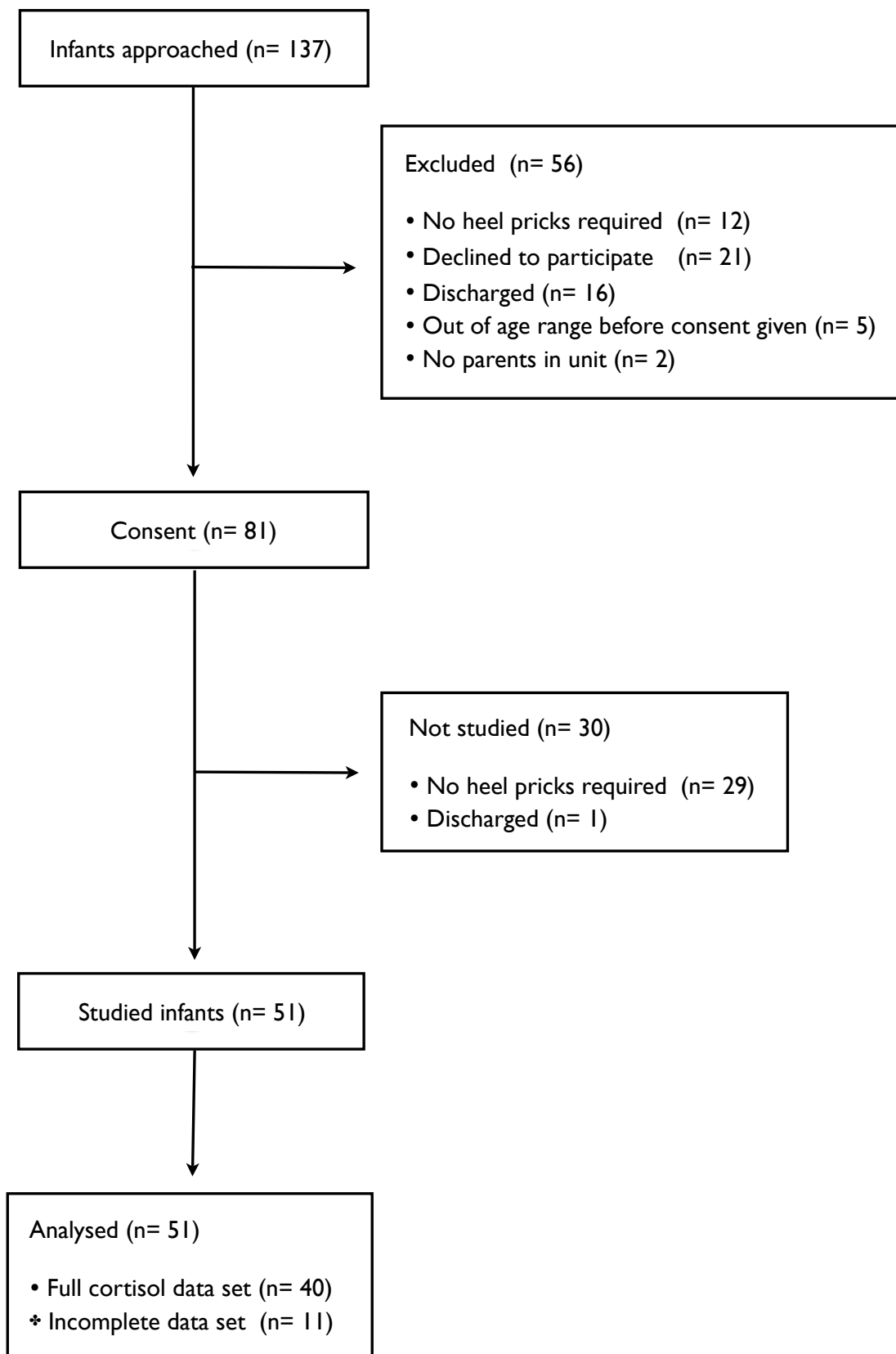


Figure 7.6: Flow diagram of participant recruitment

**Table 7.2: Participants in the Main Study**

<b>Participants</b>	<b>N (%) or median (range)</b>
Male infants N(%)	24 (47%)
Gestational age at birth (weeks)	33 (32-35)
Ethnicity N(%)	
- NZ European	21 (41%)
- NZ European/other	10 (19.6%)
- NZ European/Māori	6 (11.8%)
- Māori	1 (2%)
- Māori/Other	1 (2%)
- Pacific	4 (7.8%)
- Pacific/Asian	1 (2%)
- SE Asian	2 (3.9%)
- Indian	2 (3.9%)
- African	1 (2%)
- Other	2 (3.9%)
Delivery method N(%)	
- Emergency caesarean section	23 (45%)
- Normal vaginal delivery	20 (39%)
- Elective caesarean section	5 (9.8%)
- Forceps	2 (3.9%)
- Ventouse	1 (2%)
Positive pressure ventilation at birth N (%)	33 (65%)
Apgar at	
- 1 min	8 (2-10)
- 5 min	9 (7-10)

**Table 7.3: Participants in the Main Study according to condition**

Participants	Intervention study (n=51)	Control study (n=50)^
Post menstrual age (weeks) †	34 (32-36)	34 (32-36)
Age (days) *	5.9 ±1.9	5.8 ±2
Weight (gms) *	1899 ±487	1909 ±489
No previous heel pricks †	11 (2-28)	11 (3-26)
State before heel prick °		
- Quiet sleep	12 (23.5%)	7 (14%)
- Active sleep	17 (33.3%)	11 (22%)
- Awake	19 (37%)	29 (58%)
- Missing data	3 (5.8%)	4 (8%)
Environmental sound before heel prick (Decibels)*	56±4.5	56 ±5.5
- Incubator°	21 (41%)	22 (44%)
- Cot°	25 (49%)	24 (48%)
- Missing data°	5 (10%)	4 (8%)

†Median (range). ^There were only 50 infants in the control study as one infant participated in the voice condition only.

\*Mean ±SD. ° N (%).

**Table 7.4: Behavioural states prior to heel prick of infants in each condition**

Control condition						
Intervention condition		Quiet sleep	Active sleep	Awake	No data	
		Quiet sleep	3	1	7	1
		Active sleep	4	3	10	0
		Awake	0	7	12	0
		No data	0	0	0	3

#### **7.4.2 DOES TALKING EMPATHICALLY TO INFANTS DURING HEEL PRICK PROCEDURES DECREASE THEIR CORTISOL RESPONSE TO PAIN?**

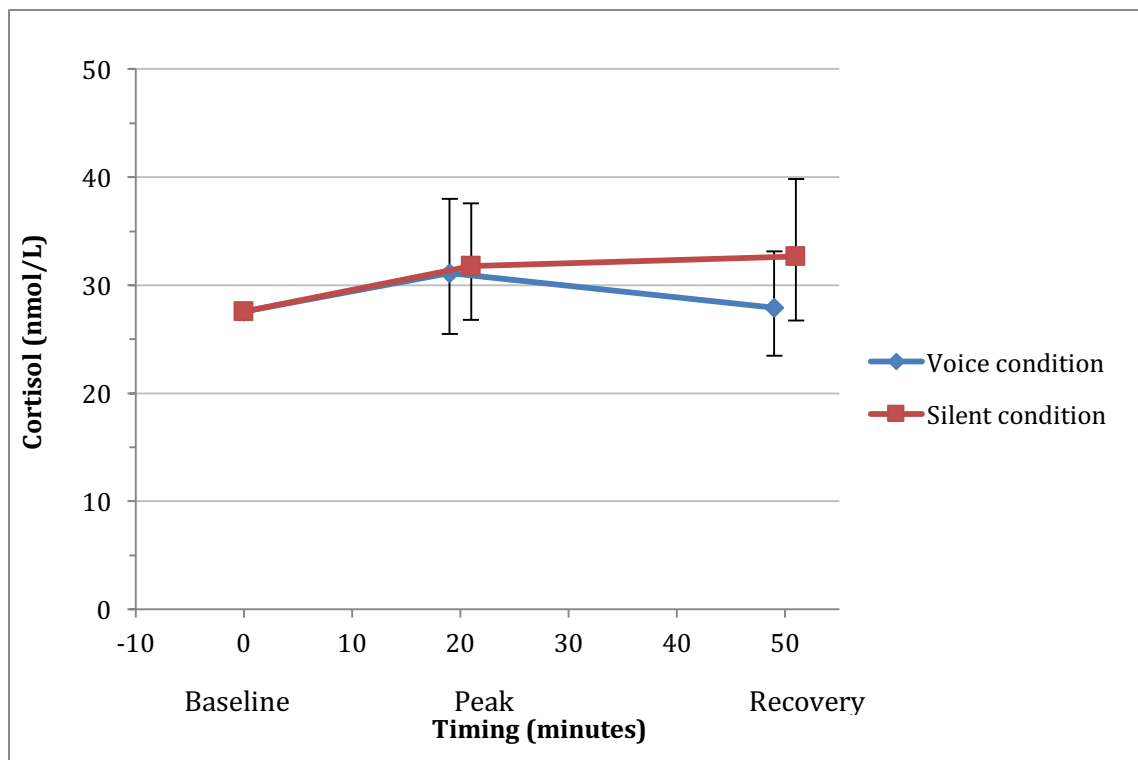
Of the 51 infants studied, data from 50 infants (98%) were able to be included in the analysis. Full cortisol data sets were obtained for forty of the infants. Four infants had one cortisol value missing, three infants had two cortisol values missing, two infants had three cortisol values missing and one infant had four cortisol values missing. One infant was unable to be included in the analysis due to insufficient saliva for cortisol analysis in all six of their samples. Table 7.5 presents descriptive statistics for the salivary cortisol data in each of the voice and silent conditions at baseline, peak and recovery. The median and inter quartile

ranges are presented because they are immediately interpretable. The means and standard deviations are provided in appendix VII, as these may be of interest to other researchers who wish to compare results.

**Table 7.5: Median and Inter quartile range for salivary cortisol data in original units (nmol/l)**

	<b>Voice</b>	<b>Silent</b>
	Median (Inter quartile range)	Median (Inter quartile range)
Baseline	24 (14, 42)	27.5 (17.5, 38.5)
Peak	34 (19, 46)	31.5 (22.5, 42)
Recovery	27 (19, 44)	32.5 (25, 44)

Figure 7.7 presents the mean differences with the 95% confidence intervals for the back-transformed values. The baseline figure for both conditions was set by the statistical method (analysis of covariance) to be equal which allows the plotting of changes across time and condition adjusted for baseline values. The data points have been offset by one point each on the x-axis, for ease of reading. At 'recovery' the log transformed cortisol level in the voice condition was 0.85 (95% CI, 0.66 – 1.11,  $p=0.232$ ) that of the mean in the silent condition. This is a 15% reduction in the voice condition with a confidence interval that suggests that the true difference could lie (with 95% confidence) somewhere between a 34% reduction and an 11% increase in cortisol for infants in the voice condition compared to the silent condition. The change from peak to recovery in the voice group was 0.87 (95% CI 0.61 – 1.25,  $p=0.458$ ), which equates to a 13% reduction for the voice condition with a 95% confidence interval of a 39% reduction to a 25% increase in cortisol for the voice condition.



**Figure 7.7: Change in cortisol across time and between conditions. The mean differences are presented with the 95% confidence intervals. The baseline measurements were taken 25 minutes prior to the heel prick but are represented here at time zero to illustrate the changes across time and condition adjusted for baseline values, which were set by the statistical method (analysis of covariance) to be equal. The data points have been offset by one point each on the x-axis, for ease of reading**

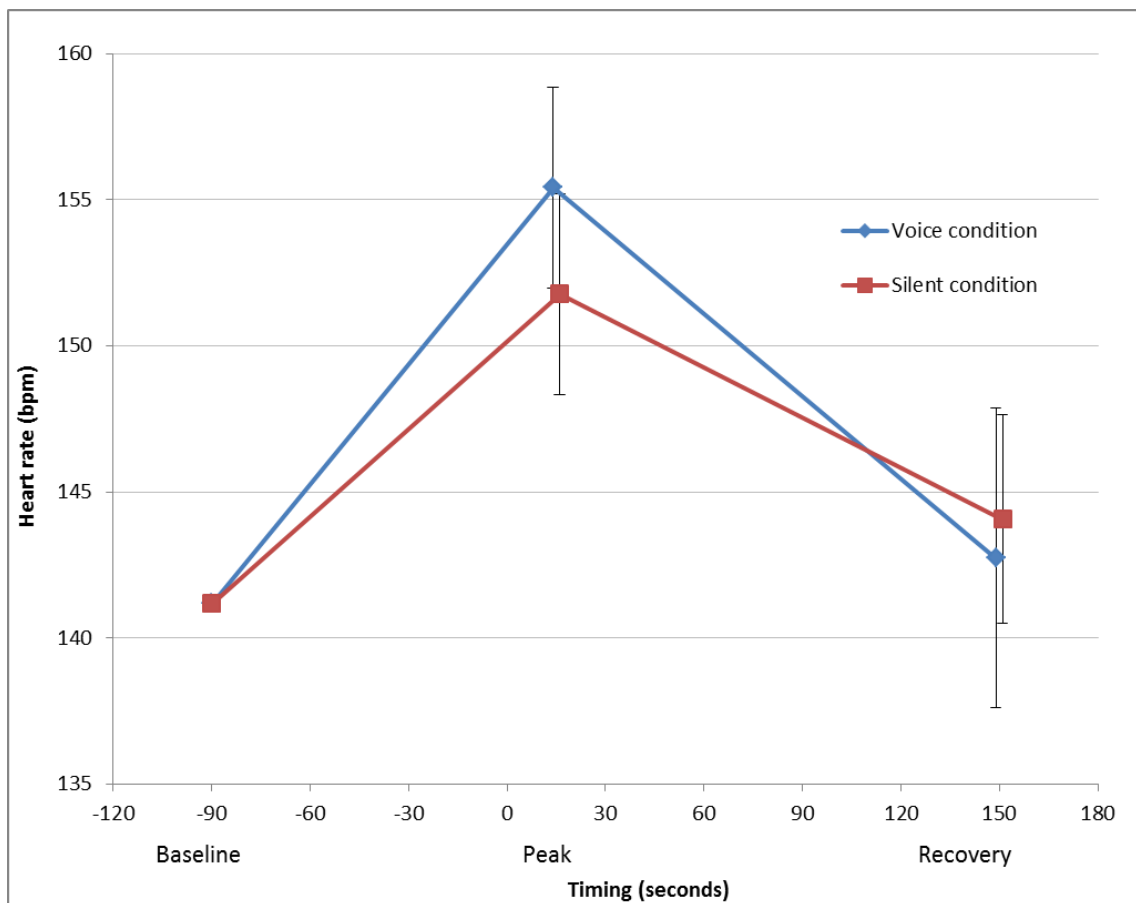
### **7.4.3 DOES TALKING EMPATHICALLY TO INFANTS DURING HEEL PRICK PROCEDURES IMPACT ON INFANT HEART RATE RESPONSES TO PAIN?**

Data from all of the 51 infants studied were able to be used in the analysis. Full heart rate data sets were obtained for forty-six of the infants. Three infants had one heart rate value missing, one infant had two heart rate values missing and one infant had three heart rate values missing. Table 7.6 presents the descriptive statistics for the heart rate data in each of the voice and silent conditions at baseline, peak and recovery. For this normally distributed data, the median and inter quartile range are presented as well as the mean and standard deviation for baseline, peak and recovery.

**Table 7.6: Descriptive statistics for heart rate (beats/min) data**

	<b>Voice</b>	<b>Silent</b>
	Median (Inter quartile range) <i>Mean ± S.D.</i>	Median (Inter quartile range) <i>Mean ± S.D.</i>
Baseline	140 (134, 150) <i>141.78 ± 14.48</i>	143.5 (136, 148) <i>141.24 ± 12.88</i>
Peak	152 (144, 166) <i>154.85 ± 14.27</i>	153.5 (143, 162) <i>151.87 ± 17.59</i>
Recovery	145.5 (130, 154) <i>143.89 ± 15.22</i>	142.5 (133, 150) <i>142.54 ± 13.89</i>

Figure 7.8 presents the mean differences with the 95% confidence intervals. As with the cortisol data, the data points have been offset by one point each, for ease of reading. At recovery, the mean heart rate in the voice condition was 1.33 beats per minute lower than in the silent condition (mean diff = -1.3, 95% CI -7.5, 4.8,  $p=0.669$ ). The heart rate reduced by an additional 5 beats per minute from peak to recovery in the voice condition as compared to the silent condition (mean diff = 5, 95% CI -2.8, 12.7,  $p=0.207$ ). These differences were not statistically significant.



**Figure 7.8: Change in heart rate across time and between conditions. The mean differences are presented with 95% confidence intervals and the data points have been offset by one point each, for ease of reading**

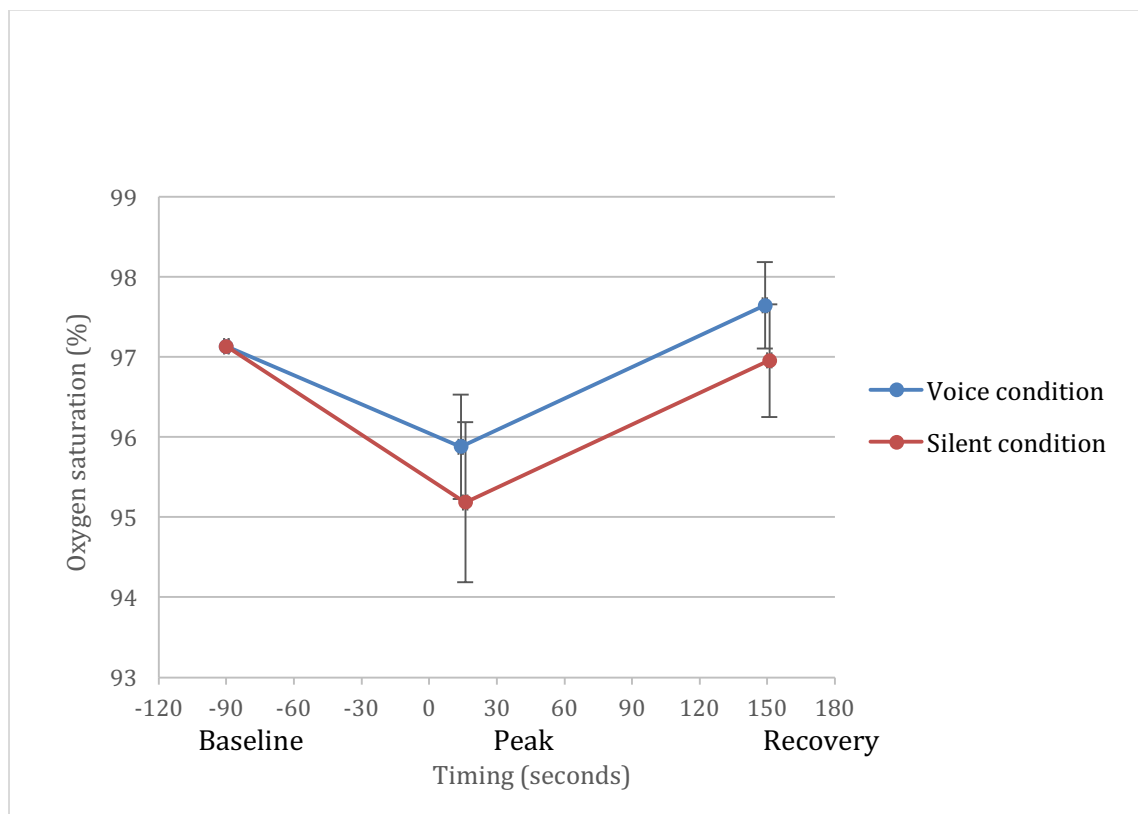
#### **7.4.4 DOES TALKING EMPATHICALLY TO INFANTS DURING HEEL PRICK PROCEDURES IMPACT ON INFANT OXYGEN SATURATION RESPONSES TO PAIN**

Data from all of the 51 infants studied were able to be used in the analysis. Full oxygen saturation data sets were obtained for forty-six of the infants. Three infants had one oxygen saturation value missing, one infant had two oxygen saturation values missing and one infant had three oxygen saturation values missing. Table 7.7 presents the descriptive statistics for the oxygen saturation data in each of the voice and silent conditions at baseline, peak and recovery. The median and inter quartile range are presented for baseline, peak and recovery.

**Table 7.7: Descriptive statistics for SpO<sub>2</sub> (%) data**

	Voice	Silent
	Median (Inter quartile range)	Median (Inter quartile range)
Baseline	97 (96, 99)	98 (97, 99)
Peak	96 (94, 98)	96 (95, 97)
Recovery	98 (97, 99)	98 (96, 99)

Figure 7.9 presents the mean differences in SpO<sub>2</sub> with 95% confidence intervals. As with the cortisol and heart rate data, the data points have been offset by one point each, for ease of reading. At recovery, the mean oxygen saturation in the silent condition was 0.69% lower than in the voice condition (mean diff = 0.69, 95% CI -0.19, 1.56, p=0.121). The oxygen saturation increased by an additional 0.01% from peak to recovery in the voice condition as compared to the silent condition (mean diff = 0.01, 95% CI -1.45, 1.46, p=0.991). These differences were not statistically significant.

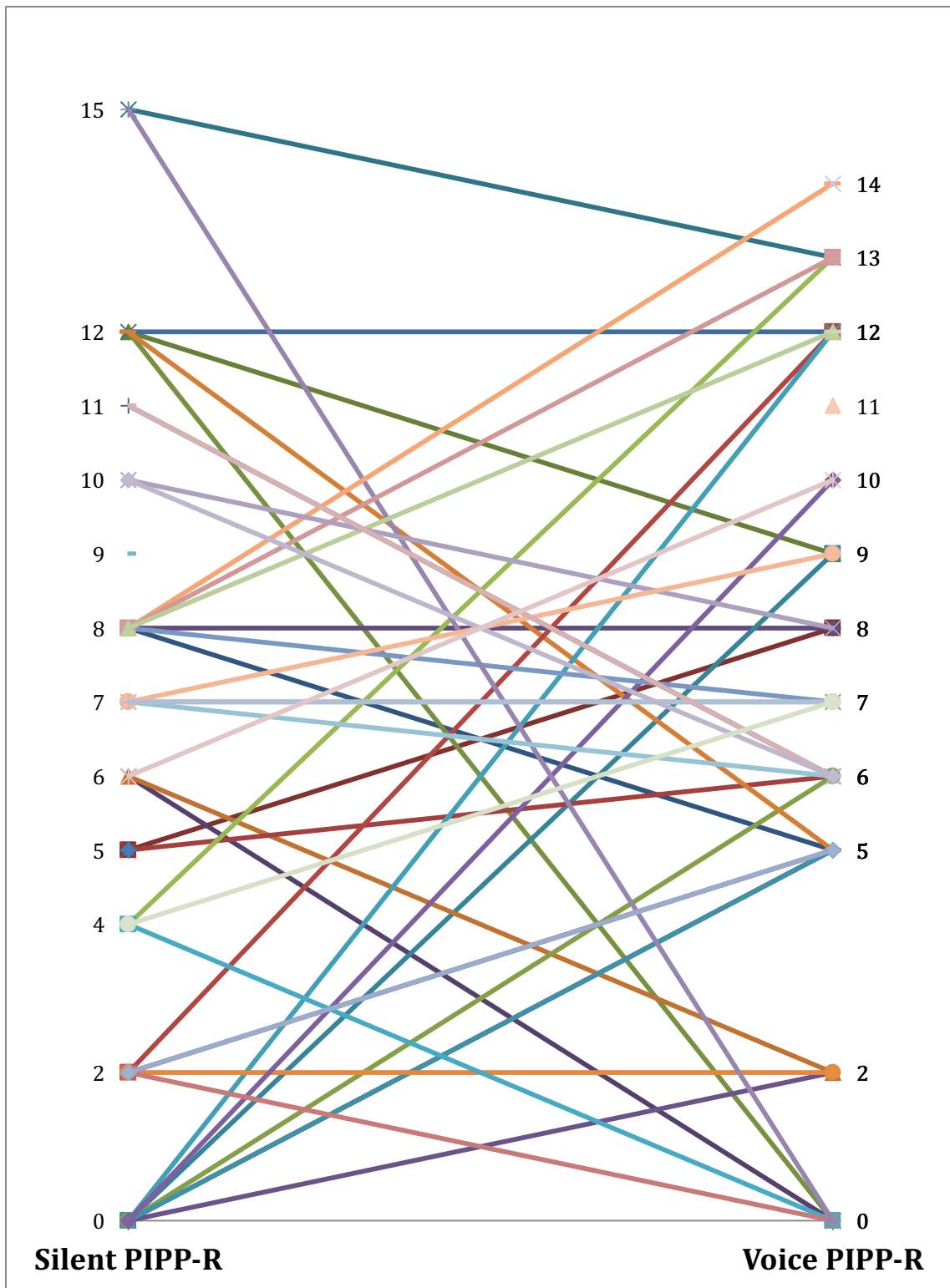


**Figure 7.9: Change in oxygen saturation (SpO<sub>2</sub>) across time and between conditions. The mean differences in SpO<sub>2</sub> are presented with 95% confidence intervals and the data points have been offset by one point each, for ease of reading**



#### **7.4.5 DOES TALKING EMPATHICALLY TO INFANTS DURING HEEL PRICK PROCEDURES REDUCE THEIR PIPP-R SCORES IN RESPONSE TO PAIN?**

Forty full PIPP-R data sets were able to be included in analysis. Eleven (21.6%) were unable to be included: five because the parents refused permission to video their child during the study; five because the infant's face was obscured for the 30 seconds following the heel prick procedure; one child participated in one heel prick study only. The results of the paired t-test comparing the PIPP-R scores for the two conditions were not statistically significant (Mean = -0.65, 95% CI -2.494, 1.194,  $p=0.48$ ). Figure 7.10 presents a slopegraph of the individual differences between the PIPP-R scores in the silent and voice condition. The highest score possible is 21, which indicates the most effect of pain detected, while a score of zero indicates no detectable effect of pain. There was no apparent pattern of results, with big changes for some infants in either direction and minimal change in scores for others.



**Figure 7.10: Slopegraph of the differences between the PIPP-R scores in the silent and voice condition for each infant. The highest score possible is 21 which indicates the most effect of pain detected, while a score of zero indicates no detectable effect of pain. Each line represents one infant, or in four cases, two infants as they had identical PIPP-R scores for each condition.**

There were twelve infants for whom a PIPP-R score of 'zero' (no effect of pain perceived) was allocated based on their lack of behavioural and physical response to one of their heel pricks. Infants who receive a 'zero' score for the PIPP-R during a heel prick procedure have

been referred to elsewhere as 'non-responders (C. Céleste Johnston et al., 1999). Table 7.8 presents the data for the PIPP-R 'non-responders' in this study. Of the twelve non-responding infants seven were in the silent condition and five were in the voice condition. No infant received a zero score in more than one of their heel prick procedures. Eight out of twelve scored a non-response in their first heel prick and four scored their non-response in their second heel prick. Of the eight infants who scored a non-response in their first heel prick, three of them had had one extra un-studied heel prick in between the studied heel pricks.

The difference in cortisol values for each infant between baseline and peak was able to be calculated for eight of the non-responders. Although in small numbers and not statistically significant, the 'increase' in cortisol from baseline to peak was higher for five of the eight infants (62.5%) who scored a zero for pain (no pain) than when they received a score that indicated a pain response (score 1-21). These 'increases' are in bold type in Table 7.8. The other three infants had higher cortisol during their more painful heel prick (as measured by the PIPP-R). There does not appear to be a pattern with PIPP-R scores and sleep state.

Table 7.8: PIPP-R 'non-responders'

Infant ID	PIPP-R test scores	Condition	Timing of condition (1 <sup>st</sup> or 2 <sup>nd</sup> )	Number of heel pricks before each test	Cortisol increase from baseline	Hours between studies	State
4	0	Voice	2	6	Not available	24	Quiet awake
	6	Silent	1	5	Not available		Active sleep
8	0	Silent	1	13	<b>-5</b>	24	Quiet awake
	5	Voice	2	15	<b>-83</b>		Active sleep
9	0	Voice	1	15	<b>27</b>	24	Quiet awake
	12	Silent	2	16	<b>-17</b>		Awake fussing
11	0	Silent	1	6	Not available	46	Quiet awake
	9	Voice	2	7	Not available		Active sleep
15	0	Silent	1	7	<b>21</b>	24	Quiet awake
	6	Voice	2	8	<b>2</b>		Quiet sleep
16	0	Silent	2	9	5	24	Quiet awake
	2	Voice	1	6	6		Quiet awake
17	0	Silent	2	15	<b>77</b>	24	Quiet awake
	5	Voice	1	12	<b>-39</b>		Active sleep
23	0	Silent	1	7	-1	38	Quiet sleep
	12	Voice	2	8	15		Active sleep
28	0	Silent	1	26	<b>11</b>	24	Active sleep
	10	Voice	2	28	<b>1</b>		Quiet awake
29	0	Voice	2	7	Not available	25	Active sleep
	4	Silent	1	6	Not available		Quiet awake
32	0	Voice	1	23	-48	24	Active sleep
	2	Silent	2	24	1		Quiet awake
34	0	Voice	1	14	Not available	96	Active sleep
	15	Silent	2	16	Not available		Awake drowsy

## **7.5 DISCUSSION**

The present study investigated the impact of a non-parental attuned vocal intervention on premature infant pain and stress. Fifty-one infants participated in this cross over design study and data for four separate measures of pain and stress were collected and analysed. In this study a difference in preterm infant physiological and behavioural manifestations of pain and stress during heel prick procedures could not be demonstrated when a non-parental vocal soothing intervention was compared with silence.

Each of the four pain and stress measures will be discussed individually. The choice of statistical approach will then be explained followed by consideration of the strengths and limitations of the study design. The chapter will end with a summary of what these data add to the current literature on preterm infant pain and stress.

### ***7.5.1 STRESS MEASURE: SALIVARY CORTISOL***

The cortisol results suggest that if there is a difference to be found between the voice and silent condition, it may be a reasonably sized reduction, or a small increase, in cortisol in the voice condition compared to the silent condition. While this study was unable to show a statistically significant difference between the cortisol levels in the two conditions, the confidence interval for the recovery data suggests it would be reasonable to assume that vocal soothing is unlikely to have a detrimental clinical effect on preterm infant cortisol levels at recovery. Likewise the recovery rate, reflecting change in cortisol between peak and recovery time periods, was unable to rule out a significant statistical advantage or disadvantage.

Salivary cortisol analysis, using the protocol developed for this study, is a feasible method with this age group with 98% of the infants able to be included in the analysis and 80% of infants had full cortisol data sets in both conditions.

### ***7.5.2 STRESS MEASURES: HEART RATE AND OXYGEN SATURATION***

This study found infants to have a lower heart rate (by 1.33 beats per minute) at recovery in the voice condition compare with the silent condition. This study also found the heart rate 'recovery rate' (peak minus recovery) was lower by a further 5 beats per minute in the voice condition than the silent condition. However, these results were not statistically significant. The confidence interval for the difference in scores at recovery was (-7.5, 4.8) which means

that the true difference between conditions could be anywhere between a reduction of 7.5 beats per minute to an increase of 4.8 beats per minute. In terms of the recovery rate, the confidence interval was (-2.8, 12.7) suggesting that the true difference may be between a 2.8 beat difference increase and a 12.7 beat decrease. While this confidence interval may indicate a possibility that vocal soothing could be more likely to be advantageous rather than detrimental to preterm infant heart rate during heel prick procedures, the data in this study suggest that there is no difference between the two conditions.

The oxygen saturation data suggest that a heel prick with vocal soothing leads to a recovery figure that is 0.69% higher than a heel prick in silence. The recovery rate in the vocal soothing condition was 0.01% higher than in the silent condition. These results were also not statistically significant and do not give a useful indication of whether vocal soothing may be of benefit or detrimental to oxygen saturation levels.

The measurement of physiological data from infants is fraught with difficulties. Although the plan for extracting data for this study was fairly robust, there were a number of situations arising that may have impacted upon the accuracy of the heart rate and oxygen saturation data. For example, it could be seen in 23 of the studies that the infants displayed a lot of movement and there was evidence of oxygen desaturation of up to 6% just prior to the heel prick, likely as a response to the handling required just prior to a heel prick. This often led to an artefactual loss of oxygen saturation and heart rate data. It would also have been useful to have recorded the end of the heel prick as some infants noticeably desaturated a few minutes after the heel prick.

For 22 of the studies for which a peak measurement could be calculated, the heel prick epoch had some data missing, meaning that the maximum heart rate or minimum SpO<sub>2</sub> may have appeared more settled than they actually were. It was also difficult to ensure accuracy with the recovery measurement. Although the rule was to take the first clear 60 second epoch at two minutes post heel prick, this was a time that some infants may have already been receiving the rest of their cares (e.g. face wash, nappy change) while others may have been resting. Given the naturalistic setting of the research, it was difficult to find a way around this. The feed start and end times were recorded, so there is certainty that the recovery measurement did not fall into this period. Further to this, preterm infants are prone to respiratory pauses, which may be followed by a fall in oxygen saturation and this was observed in some of the data in this study (Elder, Campbell, Larsen, & Galletly, 2011).

### **7.5.3 PAIN MEASURE: PREMATURE INFANT PAIN PROFILE (PIPP-R)**

There were no significant differences to be found in PIPP-R scores between the conditions. These results are likely to be reliable. The PIPP-R is designed to be carried out at the cot side during painful procedures meaning that observers are required to calculate the proportion of time the infant displays facial characteristics of pain (brow bulge, naso-labial furrow and eye squeeze) at the same time as noting the maximum heart rate and minimum oxygen saturation. In the current study, the infant's face was video recorded and continuous physiological measurement available to extract data, meaning that the results were less likely to be susceptible to observer error as there was time available to make the observation.

The scoring of the PIPP-R may mean that a larger sample is required in order to establish whether there are differences between conditions. When the PIPP was used in the sensorial saturation studies (see Table 7.1), the difference between the intervention and the control groups was large, for example  $11.1 \pm 2.5$  versus  $4.1 \pm 1.4$  respectively (C. V. Bellieni et al., 2001) and  $14.69$  versus  $6.52$  respectively (Bernardini et al., 2011). The adjusted scoring of the PIPP-R means that scores are overall lower, with zero figures possible, so the PIPP-R validation study reported a difference in means of only two points between painful and non-painful procedures (S. Gibbins et al., 2014). Gibbins et al. found a mean of  $6.3 \pm 2.5$  for painful procedures and a mean of  $4.1 \pm 2.8$  for non-painful procedures for 32-36 week infants. Considering the standard deviations for the PIPP-R results in the study by Gibbins et al., it would appear that the real difference between the groups may be up to three points in either direction. If the meaningful difference between a painful and non-painful procedure is as little as two points then it cannot be ruled out that there is a difference between the conditions that may be found with a bigger sample size.

The paired nature of the PIPP-R data (and also of the stress data) is useful because we have information about individual infants in a short time frame of 24 hours (or at most 96 hours, in one case). Of the sensorial saturation PIPP studies reported in the literature only one could be found that related to a heel prick procedure and also used a within subject design, however even this paper analysed the results by group and did not consider the paired nature of the data (C. V. Bellieni et al., 2001). A strength of the design of the current study is that it adds to the literature around infant responses to pain, and in particular how they can vary within a subject.

Of particular interest are the infants who did not respond behaviourally or physiologically to the heel prick and thus scored a zero in the PIPP-R. Twelve infants in this study received a score of zero (non-response) in one of the conditions and not in the other. These infants have been referred to by others as 'non-responders' and as yet no conclusions have been made as to why this may be so (Bonnie J Stevens et al., 2014).

### **'Non-responders'**

Some of the authors involved in the development and validation of both the PIPP and PIPP-R, collaborated on a paper in 1999 that considered the lack of response to heel prick procedures in preterm infants (C. Céleste Johnston et al., 1999). They performed a stepwise logistic regression analysis with infants born at 27-31 weeks GA and found that behavioural and physiologic responses were less likely to be present for younger infants (both post conceptual age and postnatal age), if an infant had undergone a painful procedure recently (5 hours as opposed to nearly 10 hours) and if they were asleep. The authors suggested that there were two possible explanations for non-responders: 1. That these infants do not feel the pain or 2. That they feel the pain but cannot respond. They discounted the idea that infants cannot feel the pain based on studies that have shown that infants at 26 weeks PMA have been able to demonstrate a pain response (C Celeste Johnston, Stevens, Yang, & Horton, 1995; McIntosh, Van Veen, & Brameyer, 1993). They also rejected the idea that endorphins from a recent painful procedure might have an analgesic effect, as the average time since the last procedure was 5 hours, too long for an endorphin response to remain in the infants' system. However, they concluded the association with time since last painful procedure in non-responders could occur because the infant has not had sufficient time to rest in order to be able to put together a co-ordinated response to pain. They thought that these young infants were actually under extreme stress and exhaustion and unable to display the behaviours that are assessed by the PIPP. The authors of the PIPP-R make the argument that some weighting in the PIPP-R needs to be available for these younger preterm infants given the evidence that they don't display as strong a behavioural response to pain, but they acknowledge that it is still unclear as to how much weighting is required. This is an area that is still developing in the premature infant pain literature. The present study adds some interesting data to this evolving area.

In this study, there were 12 infants at 32-35 weeks PMA who were both responders and non-responders. The idea that the infant is too young to be able to mount a co-ordinated



response to pain is not supported in these cases, because in most cases the infant only differed in age by 24 hours). The time since the last painful procedure is unlikely be a factor here, as none of the infants had heel prick procedures less than nine hours before the studied heel prick, as the study set up began six hours prior to the infant's studied heel prick and this was three to four hours following the infants last feed and six hours following the infants last 'cares'. Heel pricks in this unit were usually done during the cares time, although occasionally they were done during a feed time if it was necessary.

How is it that an infant can be both a non-responder and a responder in a time period of 24-96 hours? Not one of the non-responders in this current study had a non-response in both conditions and the conditions were spread pretty evenly, with five non-responders in the vocal soothing condition and seven non-responders in the silent condition. There did not appear to be an association with sleep state.

An important question is whether it is actually desirable for an infant to have a non-response? Sixty-two percent of the non-responding infants had a higher cortisol response to the heel prick when their PIPP-R score was zero than when their PIPP-R score was not zero. If infants are not able to mount a physiological or behavioural response then perhaps they can mount a cortisol response instead. Studies that do not consider all three of these stress responses may not be giving an accurate picture of the level of stress experienced by preterm infants during painful procedures.

The reason for non-response may not relate to gestational age, or time since last painful procedure or even to sleep state, but rather something else happening that causes an infant to respond or not. For example, do factors such as the technique used or handling by the nurse impact on infant response to heel pricks? Were there other stressful/soothing aspects of the environment that may have impacted upon the infant being able to mount a behavioural response in pain one day and not the next? The infants in this study were not generally unwell and the heel pricks took place at the same time of day (or within an hour of the same time) for all except infant number 23. More research is required in this area using infants with more than one painful procedure to focus on contextual factors rather than the factors arising from within the infant themselves. It may be useful for nurses to be aware of non-responders potentially having a stress response that they can't see (e.g. cortisol) so that pain management interventions are offered regardless of whether the infant cries or not.

#### **7.5.4 STRENGTHS AND LIMITATIONS OF STUDY DESIGN**

This study has a number of strengths. The crossover design and the fact that the studies usually took place in a 24-hour period meant that the two conditions could be compared with limited interference from infant variables. Factors such as infant age, severity of illness and history in the unit were unlikely to have impacted upon results. Further to this, the statistical methods were able to account for the differences in baseline values for the cortisol, heart rate and oxygen saturation data by measuring the changes in the values and then estimating the differences between conditions based on these values. The PIPP-R data calculates the physiological data as a percentage change from baseline, which also goes some way to ensuring that the two conditions can be accurately compared.

The overall research programme described in this thesis included three feasibility studies which were essential for refining the methods for this study. For example the decision to use a polygraphic system for recording the time of the heel prick as well as the physiological data was made after the feasibility study highlighted the difficulties in collecting accurate data around the moment of the heel prick. Problems with obtaining enough saliva for cortisol analysis in the feasibility study were investigated in subsequent feasibility studies and were able to be rectified in this study.

The feasibility study highlighted the difficulties in asking nursing staff to deliver the vocal soothing intervention as the nurses offered vocal soothing that was too variable to be able to reliably test the intervention. The decision to use the voice of the researcher became another strength of this study as the intervention was consistent for all infants and each had had no prior exposure to the researcher's voice.

There were some limitations of this study design that may have impacted upon results. The sample size was intended to be calculated based on data from the feasibility study. However because so few of the cortisol samples in the feasibility study were able to be analysed, this calculation was could not occur. Instead, sample size was based on calculations using assumptions which were conservative. A bigger sample size may have led to statistically significant results given the distribution of the data.

There were 137 infants who were approached to participate in the study of whom only 51 were able to eventually participate. It is important to consider whether the results of the group of 51 infants are generalisable. Seventeen of the infants approached were soon after

transferred out of the NICU back to their regional centres so it is unknown whether they would have been able to be included in the study. Twenty-eight infants were not studied because their parents declined or did not give consent within the infant's first ten days of life. The largest group of infants not studied were the forty-one infants who did not end up requiring two heel pricks in their first ten days of life as part of their standard care. This may suggest that the infants who did participate were those with conditions that required heel pricks such as jaundice or low blood sugar and that these infants may not be representative of the total 32-35 week gestational age population. However, they are likely to be representative of the 32-35 week gestation population that required repeated blood tests.

There were environmental factors that may have impacted upon the results. For example, the study took place in the open plan NICU meaning that it was not possible to account for extra noises or environmental conditions that may have impacted upon the stress levels of the infants in the study or lead to unexpected arousal. Having said this, the mean environmental sound levels (measured in decibels) for each condition were the same and this was another strength of the study. Different nurses carried out each heel prick however, and no one nurse carried out both the control and the intervention heel prick meaning that the style of administration and length of time taken for the heel prick could not be controlled for. Grunau and Craig observed that the term infants in their study displayed different facial and cry pain behaviours depending on the clinician administering the heel prick procedures (R. V. Grunau & Craig, 1987). All of these extrinsic variables reflect the real world of neonatal care and it could be argued that the effectiveness of an intervention should be able to be demonstrated despite them.

### **Impact of sleep state on results**

Sleep state at the beginning of the heel prick could not be controlled for. The timing of the heel prick was determined by the nurse; there was nothing about the infant's state that determined when the heel prick would happen. Most of the heel pricks occurred at 23 minutes to the hour, in order to allow for two salivary cortisol samples to be taken before the feed that began on the hour. While a clear research protocol was in place, it was necessary to also fit in with usual caregiving procedures for the infant. This decision was made in order to limit the disruption to the infants, families and staff in the NICU.

With this study design there was no guarantee that the infant would be in a comparable sleep state between the two study conditions, which may have had an impact on the results.

For example, in preterm infants oxygen saturation is lower in active sleep than in quiet sleep, indicating that state does have an impact on the physiology of the infant (Elder et al., 2011). The vocal soothing intervention was tested for its impact on an infant in any state undergoing a heel prick procedure. Perhaps if a decision had been made to wait until the infant was in a calm state before undertaking the heel prick, there may have been a greater likelihood that a difference could be shown between the intervention and control conditions. The sensorial saturation intervention, for which statistically significant results for its effectiveness were found, included getting the infant to a calm state and occupied with regular sucking (Carlo Valerio Bellieni et al., 2012). The authors do not report the behavioural state of the infant when the heel prick was undertaken in the control conditions, but as the control condition was essentially no intervention, and a big part of the intervention was to soothe the infant prior to the heel prick happening, it is not possible to be sure that the infant wasn't in more of a distressed state at the time of the heel prick in the control condition.

#### ***7.5.5 WHAT THESE DATA ADD TO THE CURRENT LITERATURE ON PAIN AND STRESS***

These data add to the literature on pain and stress in the following ways:

1. There is no evidence from these data that vocal soothing has any beneficial effects on the parameters studied
2. Vocal soothing is unlikely to have a detrimental effect on infant stress as assessed using salivary cortisol levels
3. Reliable physiological data is difficult to collect from preterm infants especially during times when they are being actively handled for a heel prick procedure or routine cares
4. Infants can produce both a 'pain' and a 'no pain' response to noxious stimuli within a 24 hour time period, meaning that there may be reasons other than infant age, state or time since last procedure that contribute to a behavioural and physiological expression of pain
5. Given that some infants did not exhibit behavioural or physiological manifestations of pain or stress, yet still responded with a cortisol increase, it would be important to consider that it is not always obvious to a caregiver that preterm infants are in distress

### **7.5.6 CONCLUSION**

The main study for this research programme assessed the use of a vocal soothing intervention with preterm infants during a routine heel prick procedure. Fifty-one infants participated in this crossover study, which included three measures of stress (salivary cortisol, heart rate and oxygen saturation) and one measure of pain (Premature Infant Pain Profile – Revised). None of the results were found to be statistically significant when exposure to the two conditions was compared. However, the cortisol results of the study indicated that vocal soothing may not be contra-indicated. Reliable measurement of physiological data in preterm infants is difficult to achieve. The results of the pain measure indicated that infants can be both apparent ‘responders’ and ‘non-responders’ to painful stimuli. More research is required to understand what might be the factors involved in pain responses. Some infants displayed distress behaviourally and physiologically and some did not, yet they had an increased cortisol response. This suggests that it may not always be obvious when a preterm infant is in distress.

## 8 DISCUSSION

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*One of the best bits of teaching I ever heard when I was a medical student was from a consultant, on the difference between worry and concern. "Try not to worry about patients", he said, "and certainly don't ever take **worry** home with you overnight. Be concerned for the patients, always – you will find that with true concern, you can leave them behind when you aren't with them. Work out the difference."*

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(Coltart, 1996, p.142)

Psychoanalyst Nina Coltart initially trained in medicine and reflects above on the wise words of her consultant. The model of vocal soothing developed and tested in this research programme was designed as a tool to promote concern. 'Worry' may well get in the way of NICU nurses attuning to the emotional experience of their infant patients, the idea of getting too emotionally invested could feel overwhelming. 'Concern' on the other hand, suggests both attuning to the emotional experience of the infant while also keeping a safe psychological distance. The vocal soothing model developed in this research programme may serve as a guide for how to attune to an infant in a deliberate and emotionally safe way and as such avoid being overwhelmed, rather than potentially avoiding the infant.

The model of vocal soothing was designed for two reasons. At its face value it was intended to be a pain management intervention that was simple, cost effective and able to be undertaken by any person caring for the preterm infant. The focus of this research programme has been on determining whether the model of vocal soothing proposed is effective in reducing preterm infant pain and stress during a heel prick procedure. The wider aim was to develop and test an intervention that might enhance the emotional care of preterm infants in the NICU.

There is a focus on nurses in this discussion because they are the ones who provide the most direct care in the NICU, although it is acknowledged that these ideas could apply to any caregiver who may be in direct contact with preterm infants in the NICU, including medical and allied health professionals. In this discussion the terms 'caregiver' and 'nurse' will be used interchangeably. There are some ideas in this discussion that will also apply to parents caring for their infants in the NICU.

This discussion will consider pain management and companionship in the NICU in more detail. Preterm infant pain and stress and the problem of the underuse of pain management interventions will be considered through a psychoanalytic lens and the idea of a 'psyche-education' will be proposed. The findings in this research programme that nurses did not often speak to infants during caregiving activities will be explored; it will be suggested that talking to preterm infants is an essential aspect of infant mental health care in the NICU and that 'companionship' may be a concept to promote this. Conclusions and recommendations for future research are provided at the end of this chapter.

This chapter will begin with an outline of the advances in knowledge that have been able to be made during this research project followed by an analysis of the strengths and potential limitations inherent in testing this intervention with a preterm infant population.

## **8.1 VOCAL SOOTHING AS A PAIN MANAGEMENT INTERVENTION**

This research programme developed and tested an intervention that was designed to enhance the emotional care of infants in hospital, by reducing their manifestations of stress and pain. There were some important advances in knowledge that will contribute to the fields of both infant mental health and to nursing. The specific aims of the research, as presented in chapter one, will each be discussed separately followed by consideration of the strengths and limitations of this programme.

### **Aim 1: To develop a model of vocal soothing that could be used by non-parental caregivers during a routine painful procedure**

Knowledge from parent infant psychotherapy and other emotional theories of development were brought together in this project to form a model of vocal soothing to be investigated. The model was developed to provide psychological containment to preterm infants during painful and stressful experiences by offering infant-directed speech and matching the vocal tone to the perceived infant emotional and physical experience. It included warning about being touched, acknowledgement of the pain experienced and it required the caregiver to remain truthful and attuned to the infant. The model supports communication between the infant and non-parental caregiver and given the importance of 'serve and return' experiences for brain development (described in chapter two), this model of vocal soothing could be considered an important aspect of infant mental health care.

**Aim 2: To investigate the current use of voice by neonatal nurses to soothe preterm infants during routine painful procedures**

An observational study was conducted in order to ascertain baseline levels of vocal soothing. Despite nursing recommendations that nurses speak soothingly to infants and be mindful of the infant's experience, the observational study found that nurses in this NICU spoke very little to infants during heel prick procedures and those who spoke to their colleagues instead may not have been attuned to the infant's experience. The results of this study raise important questions about why nurses may not speak to infants during painful procedures, particularly as painful procedures are likely to be occasions in which infants potentially need the most soothing. The absence of other studies investigating this phenomenon suggest that it is not a question that has been asked or considered by other researchers.

While the main focus of the feasibility study was to test and refine the methodology for the main study, it also highlighted the differences in nurses' abilities to use their voice empathically towards the infant during a painful procedure. There may have been logical reasons for this, for example participating in a research study may have meant that the nurse felt unable to speak as freely as usual and they may not have been sure what was expected of them with the loose instruction to 'speak soothingly' to the baby. Or perhaps it really is difficult to concentrate on a heel prick and talk at the same time.

**Aim 3: To investigate the current use of voice by neonatal nurses to soothe preterm infants during routine non-painful procedures**

The results of the second baseline study suggested that in the NICU studied nurses speak fewer words to infants during painful procedures than they do during non-painful procedures. Overall, 'vocal soothing' does not appear to be an intervention that is used regularly during either painful or non-painful procedures. It cannot be discounted that there may be something about talking to the infant in general that is difficult to do. If this is the case then the instruction to speak soothingly to the infant as prescribed by developmental care may not be as easy to follow. Perhaps further investigation into the use of voice with preterm infants might go some way to understanding the reasons why some nurses do not speak to infants they are caring for. If vocal soothing is found to be an effective intervention in the future then training in how to vocally soothe would need to be an integral part of implementation.



**Aim 4: To test the feasibility of the proposed methodology for assessing the effectiveness of a model of vocal soothing in reducing manifestations of pain and stress in preterm infants during painful procedures**

The feasibility studies were an integral part of this research programme and provided information that led to important revisions of the planned main study design. It became clear that being able to document the exact moment of the heel prick and correlate it with the physiological data was needed to ensure accuracy of the data extracted for analysis. The research protocol was further refined to include heel prick blood tests with capillary tubes only and problems with obtaining sufficient saliva for cortisol analysis were able to be rectified.

**Aim 5: To assess the effectiveness of a vocal soothing intervention in reducing manifestations of pain and stress in preterm infants during painful procedures**

This study was unable to provide evidence that vocal soothing is an effective pain management intervention. There is some indication in the cortisol results however, that vocal soothing is unlikely to be detrimental to an infant. The main study did provide valuable information about non-responders and the importance of assessing more than one aspect of pain and stress in preterm infants, for example a low score in the premature infant pain profile might occur at the same time as a rise in cortisol suggesting that one measure is unable to provide a complete picture of response to pain and stress.

The discussion in the main study (chapter seven) highlighted the difficulties encountered in this research in objectively measuring preterm infant pain and stress. The methodology was thorough in using four different aspects of infant physiology and behaviour to assess pain and stress (cortisol, heart rate, oxygen saturation and the premature infant pain profile) but there were a number of limitations of the research protocol that may have impacted upon the results of the main study. The strengths and limitations of this research project are discussed further below.

**8.1.1 STRENGTHS AND LIMITATIONS OF THIS RESEARCH PROJECT**

Strengths of this research project include the cross fertilisation of infant mental health theories and nursing practice which led to the development of a model of vocal soothing that was tested with thorough methodology under ordinary NICU conditions.

The basis for this research project has been synthesis of knowledge from the fields of infant mental health and nursing. Traditionally the emotional care of infants has been considered

the domain of the parents, but this programme of research has gone one step further by considering the role that non-parental caregivers have with infants in their care. Developmental Care and Sensorial Saturation include the instruction to talk to infants as part of their intervention, yet have not defined what is meant by this, nor how to do it. The model of vocal soothing developed in this thesis has provided guidelines for a way in which a care-giver could speak to an infant in the NICU that may meet their emotional needs when this interaction occurs during a nursing intervention. A strength of this study has been in the bringing together of these two fields of knowledge in a way that supports a more holistic view of infant care in the NICU.

This model of vocal soothing was thoroughly investigated. First, it was ascertained that nurses do not speak very often to infants in this NICU during procedures. Then a plan for testing the effectiveness of the intervention was developed and initially tested during three feasibility studies. The final study was a randomised, controlled cross over design, which assessed four separate aspects of infant stress (salivary cortisol, heart rate and oxygen saturation) and infant pain (PIPP-R). It was a strength of this study that so many measures were included, especially as it highlighted the fact that some infants can respond to pain across one measure and not in another. The vocal soothing intervention was assessed during usual day-to-day bedside conditions in the NICU. The limitations of this approach are discussed below, but it is also a strength of this study because it is an intervention that is designed to be used by nurses at the cot side as part of routine care.

There are five main limitations of this research project that may have had an impact on the results. These include recruitment difficulties, the fact it was 'infant oriented' research as opposed to research under strictly regulated conditions, the potential impact of the infant's health status at the time of study, the research assistant not always being available to assist and also the specific difficulties faced in doing research in the NICU. Each of these issues will be discussed in turn.

### **Recruitment**

It is possible that if the planned numbers of participants were able to be recruited for this project, the increase in data may have led to statistically significant results. There were difficulties in recruitment that may have been related to the following issues.

The age range of the infants in the research population was deliberately restricted to the 32-35 week gestation age range and in their first ten days of life in order to try to ensure that the clinical events being studied were comparable. However in doing this recruitment may have been made more difficult. The infants in the age range then needed to be having two consecutive heel prick procedures as part of their usual care approximately 24 hours apart. These infants were usually those with jaundice or requiring blood sugar monitoring and not all of the infants in the age range were in these categories. In trying to keep the research population as homogenous as possible, the pool of potential participants became smaller. Researchers vary in terms of their reporting on recruitment, for example of the six sensorial saturation studies analysed in chapter seven (Table 7.1), only two of the studies reported on their recruitment success rate, both of which were above 95% and were conducted by whole research teams as opposed to one researcher (C Bellieni, 2002; C. V. Bellieni et al., 2001).

There were other factors that impacted on recruitment. The parents needed time to consider their responses and sometimes this meant that the window of opportunity for studying a particular infant was lost. It was important to allow the parents time to come to their decision to take part as they were likely to still be in a period of adjustment and coming to terms with the fact that they had an infant in the NICU and it was unlikely to be an ideal time to approach them to take part in a study. A systematic review involving nine qualitative studies of parent experiences in the NICU provided evidence that parents of preterm infants are more psychologically distressed than parents of term infants (Al Maghaireh, Abdullah, Chan, Piaw, & Al Kawafha, 2016). This review identified that parents of preterm infants experience symptoms of stress, anxiety and depression, as well as sleep disturbance, grief and isolation. Erin Currie discusses the issues involved in recruiting bereaved parents for research and highlights the importance of building trust with parents in the consent seeking process, specifically recommending spending time talking with the parents and being a good listener (Currie, Roche, Christian, Bakitas, & Meneses, 2016). The researcher in the current project, a registered parent infant psychotherapist, was comfortable providing this kind of support to parents and often spent time building trust before consent was given. The question of how ethical it is to ask parents to participate in studies when they may be unable to think clearly has been raised and has to be considered alongside the alternative of not advancing knowledge and achieving better outcomes for infants (Modi, 1994).

Having said this, it is possible that the nature of this study may have meant that parents perceived their babies to be getting something 'good' and could have been more inclined to take part. In this study each infant received the intervention as they were their own controls so there was no question of any infant receiving placebo or 'no treatment'. This was also a study in which infant participation resulted in no extra pain and they were being offered more attention and a potentially soothing intervention. Parents still required time to decide however and although they may have been amenable to taking part they then needed to remember to bring back their signed consent forms and sometimes these were not returned in the time frame required to study the infant. There was an ethical dilemma in terms of knowing how much to 'chase' parents for consent while also respecting their right to take as long as they needed to make a decision, especially given their circumstances of having an infant in the NICU.

There was much reliance on nurse assistance to explain the study and obtain consent as the researcher was unable to be on the unit 24 hours a day. Although the nurses were phoned at the beginning of each shift to alert them to a family who were considering the study, there were other priorities for the nurses on each shift to attend to. The most reliable method of gaining consent was when the researcher met the parents for a second time. Most parents visited the NICU only once or twice a day to coincide with the infant's caregiving procedures, which were typically every six hours. This made it difficult to coincide with the researcher being there at the same time. The researcher was in the NICU almost everyday, but was unable to be there all of the time, which may have been what would have been required to ensure adequate recruitment. As it was, the researcher was operating on two to four hours sleep most days during the recruitment period in order to do the recruiting well, and it was not feasible to be in the NICU for more hours.

Recruitment difficulties led to only 51 out of a planned full sample size of 63 infants able to be included. However, given that the final results were not even close to statistical significance, it is unlikely that having the full sample size for this study would have led to the achievement of statistically significant results. The sample size for this study was based on assumptions that were conservative as a result of the feasibility study being unable to provide data that could guide sample size more accurately.

### **Infant oriented research**

This was infant-oriented research in that the research protocol was designed to slot into their regular caregiving procedures rather than the infant being studied at a set time or away from their usual environment. This decision was made in the best interests of the infants, but may not have been in the best interests of the research. It meant that the studied environment was unable to be controlled, the timing between heel prick procedures was unable to be formally standardised and the infants received their heel prick regardless of their behavioural state immediately prior to the procedure. Other interventions such as sensorial saturation involve ensuring the infant is in a particular state of quiet alert before beginning the heel prick procedure and it may have been that the decision in this project to fit in with the timings of the unit made it harder to get an optimal outcome and answer to the main research question. As mentioned above, the decision making in the planning stages of this research was based on the fact that the intervention would only be really useful if it was able to be effective in ordinary NICU conditions and not be dependent on carefully controlled research conditions for its effectiveness. It is therefore both a strength and a limitation of this study. With hindsight it might have been better to first establish whether the intervention had any merit under more controlled conditions and then to work out how to adapt it for use under ordinary conditions in the NICU.

### **Impact of infant health status**

While it was likely that each of the infants involved in the study was having a heel prick for either high bilirubin (jaundice) or low blood sugar levels, this information was not gathered at the time of the study and it is possible that these conditions may have had an impact on the results of the study. Both low blood sugars and high bilirubin levels could theoretically affect an infant's response to pain because of decreased arousability. If consent had been given regarding accessing the NHI numbers of each studied infant in order to obtain information about the infant's health then this information could have been gained retrospectively. In future studies it would be worth ensuring that the consent form has this option agreed to in case other questions arise that require checking back on health information.

### **Research assistant not always available**

The vocal intervention was designed to be provided with support from the research assistant who was responsible for the note taking and the physiological recording and timing of the

various aspects of the intervention, thus leaving the researcher free to focus on the vocal soothing. However the assistant was not always available to take part in the studies. The heel prick procedures were often performed with 6 hours notice and many times it was after midnight. The assistant was able to be present for the studies that took place in the evening, but the researcher had to manage both roles in the studies that took place after midnight. This may have meant that in these studies the infants did not get the full benefit of the attuned vocal soothing as the researcher was concentrating on the computer beside the cot as well. This of course raises another question regarding implementation if vocal soothing was found to be effective. Would it be feasible for a nurse to vocally soothe while simultaneously trying to attend to a heel prick procedure? It may be easier for a nurse to vocally soothe while not providing physical care so it might be important to consider whether someone else could do the soothing, such as another nurse or a parent if they were able.

### **Difficulties doing research in NICU**

There was an effort made in the current programme of research to communicate well with staff in order to gain their support, as has been recommended following an investigation into NICU nurses perceptions of research (Reynolds et al., 2013). Senior staff were consulted widely and their approval and support of the project may have made it more easily acceptable to the staff. There were regular presentations to the staff psychosocial days about infant mental health and many, many informal conversations with the staff about this research and the point of it. It was important to make these personal connections with individual nurses and to take the time to explain the infant mental health viewpoint. The researcher became known as 'the baby whisperer' and for some it seems that this was a term of endearment and for others perhaps more of a mockery. The researcher was a psychotherapist without medical or nursing training and not all nurses may have been convinced that there was a place for psychological interventions in the NICU. While for the most part the nurses were extremely obliging and accommodating to the research protocol, there were also occasions when some nurses were quite obstructive to the research. These were either in relatively minor ways such as not passing on messages to or from parents about their consent or in more serious ways such as performing the heel prick ahead of the arranged time meaning that the baby was unable to be studied. On the occasion that this happened, there was a higher than usual level of tension on the unit due to medical acuity.

### **8.1.2 SUMMARY**

Each of the studies in the research project have been represented in terms of their individual contributions to the advancement of knowledge. Vocal soothing does not appear to be used regularly and even when nurses are asked to do it, they find it difficult. A model of nurse vocal soothing was developed and tested. Although the results have not shown this intervention to be effective, the research methodology was thorough and has provided valuable information regarding 'non-responders'. The strengths of this research project were in its cross fertilisation of two fields, the thorough methodology and the testing of the intervention under ordinary NICU conditions. There are a number of methodological limitations that may have impacted upon the results of this project. These include recruitment difficulties, the fact it was 'infant-oriented' research, lack of information about the infant's health status at the time of study, the research assistant not always being available to assist and also the specific difficulties faced in doing research in the NICU.

The next two sections of this thesis will look in more detail at some of the findings in this thesis. Firstly, the issue of pain management and how ideas from psychoanalysis might guide further research on this.

## **8.2 THE MANAGEMENT OF PRETERM INFANT PAIN AND STRESS: A PSYCHOANALYTIC PERSPECTIVE**

While there are still gaps in knowledge around the impact of painful and stressful experiences on preterm infants in later life, there is convincing evidence of the long-term impact on brain development and stress sensitivity (Grunau, 2013). The reduction of pain and stress for preterm infants has been recognised as a priority by the American Academy of Pediatrics (Keels et al., 2016). Chapter two discussed some of the adverse consequences of preterm infant experiences of pain and the evidence for interventions to help mitigate these. This section will describe the international problem of the under-use of pain management interventions and what has been done in an attempt to address this issue. Possible interpersonal and intrapersonal factors that may contribute to this will be considered and drawing from the field of psychoanalysis, a new approach to improving pain management is proposed.

It has been reported that the majority of preterm infants are not offered pain relief during painful procedures in the NICU (Carbajal et al., 2008; Jeong, Park, Lee, Choi, & Lee, 2014; Roofthoof, Simons, Anand, Tibboel, & van Dijk, 2014), despite it being raised as a serious issue of concern a decade and a half earlier (B. Stevens et al., 1999). A large French study reported in 2008 recorded all painful and stressful procedures for infants in the NICU in their first 14 days and found that they received a median of ten (range, 0-51) painful procedures per day of hospitalisation and only 20.8% of these were performed with any analgesia (pharmacological or non-pharmacological) (Carbajal et al., 2008). In a U.K. study involving 92% of all NICUs it was found that 75-80% of Units did not use any form of analgesia for heel prick procedures and only 55% used analgesia for more painful procedures such as chest drains or lumbar punctures (Robins, 2007).

The nurses observed in the heel prick observational study, described in chapter four, used at least one comfort intervention in 96% of the heel prick procedures in which the infant was awake. However, only two of the interventions offered (sucrose and non-nutritive sucking) were evidence-based and recommended by the international guidelines distributed by the American Academy of Pediatrics (Keels et al., 2016). Both sucrose and non-nutritive sucking are described in the parent/caregiver information brochures as being available for infants in this NICU, yet out of 50 heel prick procedure sucrose was only provided on 11 (22%) occasions and non-nutritive sucking on 10 (20%) occasions. This suggests that non-pharmacological interventions are also under used in this NICU.

There are pain management guidelines available. The most recent update on the prevention and management of procedural pain was published by the American Academy of Pediatrics in February 2016. Seven recommendations are made and are summarised below (Keels et al., 2016):

1. All Units should have written pain management guidelines
2. Pain assessment tools should be used before, during and after painful procedures
3. Recommended non-pharmacologic strategies to be consistently used for short term mild-moderately painful procedures are facilitated tucking, non-nutritive sucking, breastfeeding or expressed human milk or 'Sensorial Saturation'
4. Oral sucrose and/or glucose can be used but should be tracked as a medication.



5. Potential and actual benefits and burdens for pharmacologic treatment methods should be weighed
6. Medical staff and families should receive ongoing education regarding recognition, assessment and management of pain in neonates
7. More research is required on pain assessment tools and strategies to reduce or prevent pain

The data accumulated in the present study add to the literature in terms of difficulties around pain assessment. It was found that some infants displayed a behavioural response to pain without a corresponding increase in cortisol and some infants had the opposite, an increase in cortisol but without a behavioural response. A routine salivary cortisol measurement would not be practical in the NICU and nor would it provide information at the time it was needed, meaning that there are likely to be infants who are hard to assess for pain and stress accurately. The paired nature of the data in this study has also highlighted how infants can respond very differently to the same procedure over a 24 hour time period which provides support for the idea that factors external to the infant, such as the technique used or type of handling by the nurse may also be important to consider in terms of pain management.

Even if more accurate pain assessment and management strategies can be found, there is still a problem with the under-use of these strategies. The Committee that produced the guidelines above on behalf of the American Academy of Pediatrics acknowledges this problem and states clearly that treating infant pain is an ethical issue (Keels et al., 2016). In addition to this, the ethical principles of non-maleficence and beneficence in relation to neonatal nursing hold that nurses are required to ensure that their actions are not doing harm and that they are actively doing good (Boxwell, 2010). Bellieni and colleagues have gone one step further and found it to be against the law in Italy to not provide analgesia for infants (CV Bellieni, Buonocore, Perrone, & Gabbrielli, 2011). This is perhaps an indication of how difficult a problem this has been to solve if researchers are looking into the legal aspects of providing appropriate care to infants to improve clinician compliance with established clinical guidelines.

Research in this area has moved beyond the developing and testing of techniques and interventions to alleviate pain and is now focused on the problem of getting NICU staff to

use them (Harrison, Bueno, & Reszel, 2015). Efforts to improve the rates of pain management have included a focus on education and parental participation.

### **Education**

The Academy of Pediatrics pain management guidelines state explicitly the recommendation to have 'ongoing education'. There is also an education focus in terms of how the guidelines are presented. The message is to 'do these things to address pain in your NICU', and thus the guidelines themselves are another form of education. This is not sufficient, it would seem, as one study that reported low pain management rates also reported that 92.2% of the nurses were actually aware of the guidelines in their unit (Jeong et al., 2014). It would appear that knowledge of guidelines is not enough to change practice.

Specific education for nurses on the topic of infant pain has also been recommended.

Registered nurses Howard and Thurber acknowledged the difficulty for professionals in the NICU in confronting the reality of inflicting pain, but insisted that they must be made aware of the infant's pain and their contribution to it in order to provide the necessary pain relief (Howard & Thurber, 1998). Howard and Thurber suggest that the way forward with increasing pain management is to heighten pain awareness. However, a Korean study asked 141 nurses from five university affiliated hospitals across Korea to complete a survey about their perceptions of how painful certain procedures are for infants, how appropriate pharmacological and non-pharmacological interventions are and whether they use them across certain procedures, including heel prick procedures (Jeong et al., 2014). The study found that although the nurses believed pain management interventions to be necessary, they rarely used them. From a psychoanalytic viewpoint, it could be speculated that a reason for this discrepancy in knowledge versus practice could be because it is emotionally safer to think about infant pain in the abstract, that is 'babies feel pain in general' rather than in the here and now moment when the nurse is actually faced with an infant in pain. The comments by nurses during this research project, described in chapter four, provided support for this idea. The nurse who said 'I do it very quickly (the heel prick) because the sooner it is over the quicker I can pretend it didn't happen', appeared to be consciously aware of the pain in the infant but described a process of denial of these feelings, rather than using them to help manage the infants pain. The nurses who said 'you are ok, it doesn't hurt', or 'nothing is happening', despite the infant showing signs of pain (squirming and

crying) provide another example of a situation where the knowledge of infant pain was present, but quickly pushed away at the time of the painful procedure.

It would seem that education, both in the form of general guidelines and also in terms of nurse knowledge of infant pain, has not been particularly effective in improving rates of pain management in the NICU. Parental involvement with infant pain management is another option that has been explored.

### **Parental involvement**

The results of the baseline heel prick observational study presented in chapter four suggest that parents are rarely present for painful procedures in the NICU (occurring in 4% of the heel prick procedures observed). Chapter four of this thesis offers some initial thoughts around nurses' decisions to include parents in the pain care or not. It was suggested that factors involved in this decision may include the nurse wanting to protect the parents from witnessing the infant in pain, it being harder for the nurse to disengage emotionally from the pain if the parent is present, that it may be more of an emotional burden on the nurse to have to consider the parent's feelings about the painful experience for their infant or perhaps that the nurse may feel a performance anxiety performing heel prick procedures in front of parents. There is an acknowledgement that parents often would like to be more involved in their infant's pain care (Franck, Oulton, & Bruce, 2012) and a Canadian study found that infants were more likely to receive pain management interventions if their parents were present (Johnston, Barrington, Taddio, Carbajal, & Fillion, 2011). This study found that the presence of the parent in painful procedures was the one factor that predicted the use of any pain reducing intervention. The authors suggest that the presence of the parent may give the infant more of a 'persona' and consider that parents should be encouraged to be present at the painful procedures. There may be other reasons for including parents in this way, but the issue of whether it is appropriate for parents to be encouraged to be there so that nurses are more likely to give pain relief needs more consideration. It is interesting to consider the possible reasons for the parental presence being the motivating factor in nurses providing pain relief. Is it possible that the nurse is forced to consider what she looks like to the parent in doing the painful procedure and with this 'mirror' it makes her wish to be seen as kind and caring so offers the infant analgesia? Or perhaps the nurse is somehow reassured by the presence of the parent, who may somehow relieve the nurse of the burden of psychologically supporting the infant and then

is more free to acknowledge the infant's pain and therefore do something about it. These are of course speculations about unconscious processes in the nurse and they would be difficult to research.

The issue of facilitating optimal partnerships between parents and staff is currently a focus in the nursing literature (Franck et al., 2012; Franck et al., 2011), although it may be complicated at times as NICU parents are often under stress and not always able to emotionally regulate themselves around nursing staff. During the researcher's time in the Unit situations occurred where there became a breakdown in the relationships between parents and staff. At these times there appeared to be an 'us and them' mentality (split) when under stress. More than one nurse was overheard saying 'what makes our job hard is the parents. When parents were 'difficult' (for example 'firing' nurses) they were demonised by the group of nurses, which, while feeling supportive to the nurse in the firing line, left no space to wonder about the parents' experience and what may have caused them to lash out in that way. These parents were likely to be the ones who needed the most help, yet they were the ones who were avoided or dismissed. A psychoanalytic understanding of this process is referred to as 'splitting' (Hinshelwood, 1998). It occurs when there is an emotionally difficult dynamic between people and it feels easier to distance oneself from the pain of a negative interaction by assuming that we are in the right and the other person is in the wrong. While this may keep the 'hurt' person feeling emotionally safe, it does not attend to the needs of the other 'hurt' person that felt the need to lash out in the first place. This dynamic can be seen happening between colleagues as well as with parents.

Parents are also encouraged to provide the pain relief themselves and one research group has made a 'you tube' video to teach parents how to do this (Harrison et al., 2015). Parents have been found to be better raters of their children's pain than health professionals (Schneider & LoBiondo-Wood, 1992). Franck and colleagues have put forward a conceptual model that considers the opportunities and barriers to parental involvement with pain management. The model suggests three main influencing factors: whether the parents have a strong sense of parental role, whether the staff provide instruction to the parents on how to comfort their infant and thirdly, whether the parent is able to be physically present for the painful procedures (Franck et al., 2012). While a useful model, it does not provide a consideration of the individual nurse factors. The latter two factors will be influenced by the nurse as they will be the ones providing the information (or not) and deciding when to do

the procedures. Their decisions may depend on their own subjective experience of pain and how comfortable they are with acknowledging it. The next section will consider in more detail the subjective nature of decision-making.

### **8.2.1 SUBJECTIVE NATURE OF DECISION MAKING**

When viewed through a psychoanalytic lens the subjective experience of the nurse is inextricably linked with the resulting decision-making around care of infants. This is an area that is largely unaddressed in the nursing literature, where the focus has mainly been on the dissemination of information to encourage changes in practice. Even standardised tools may not be wholly exempt from an observer bias. Two studies have found that nurses will score pain differently depending on whether they are observing or performing the procedure and that these scores are different to an observer scoring by video clip (Carlo V Bellieni et al., 2007; Spasojevic & Bregun-doronjski, 2011). Bellieni and his team at the University of Siena, Italy have thus made a case for focussing on pain *detection* during clinical practice rather than scoring the level of pain (Carlo Valerio Bellieni, Tei, & Buonocore, 2015). They advocate for a method in which the caregiver is aware of the interventions that will activate nociceptors and assume that the infant is in pain if their heart rate increases or they cry. In their view all detectable pain should be addressed and the formal assessment of levels of pain should be reserved for research. This approach asks the caregiver to be more empathic towards preterm infants and offers a framework in which to guide decision-making. It remains to be seen whether this method is effective in increasing the rates of active pain management for preterm infants.

It has been suggested that a focus on 'knowledge translation' should be the next step for research in terms of addressing the issue of the underuse of pain management interventions (Harrison et al., 2015). Knowledge Translation focussed research aims to identify ways to bring evidenced based interventions or knowledge into practice. An exploratory study in 2004 looked at the factors that influence getting evidence into practice but did not consider the inter- or intrapersonal factors that may be also part of the equation (Rycroft-Malone et al., 2004). Researchers have now called for more examination of the intrapersonal and interpersonal dynamics for health care professionals involved in pain management (Carter, 2004; Franck & Bruce, 2009; Goubert, 2005; B. J. Stevens et al., 2014).

Franck and Bruce present evolutionary ideas; that humans are wired to both engage with and help other humans in distress but are also wired to underestimate the other human's distress in order to protect the self (Franck & Bruce, 2009). They suggest that while the tendency to under estimate pain may have been adaptive in evolutionary terms, it is a problem in the healthcare sector if pain is underestimated and not adequately managed. A very similar process can be explained using psychoanalytic literature in terms of a cutting off or denial of the pain in order to not feel the brunt of it.

### **8.2.2 THE USE OF PSYCHOLOGICAL DEFENCE IN NICU**

The psychological defence of 'denial' when faced with an infant in pain was introduced in chapter four as an explanation for why nurses may not acknowledge pain verbally to an infant. This idea will be elaborated on in this section by considering the role of psychological defence in decision-making around pain management. Some researchers are 'perplexed' by the findings that nurses' knowledge of how to treat pain and their levels of empathy seem to have little, if any, bearing on their decisions to provide pain relief (Campbell-Yeo, Latimer, & Johnston, 2008). It would appear that there is something else that is governing the decision to engage with and soothe the pain of patients. Through functional magnetic resonance imaging (fMRI) researchers have shown that there is similar activation in the neural system of both the person experiencing pain and the observer (Botvinick et al., 2005; Carr, Iacoboni, Dubeau, Mazziotta, & Lenzi, 2003; Jackson, Brunet, Meltzoff, & Decety, 2006; Singer et al., 2004). This means that there is likely to be some transmission of discomfort from patient to observer. How does it impact on the observer if the observer is also the provider of pain? Psychoanalytic theory would hold that this discomfort can be managed with the use of psychological defence.

An interesting study in 2011 investigated nurse experiences of caring for children in pain (Ljusegren, Johansson, Gimbler Berglund, & Enskär, 2012). The authors found that the nurses did not become distressed when the situation was predictable, but that they became emotionally dysregulated whenever the child's pain deviated from an expected pattern. At these times the nurses described feeling that they had lost control and felt fearful, powerless, abandoned and distrustful. When the nurses felt this way they stopped being in connection with the patient and instead became distanced. Becoming distanced from the patient when experiencing emotional dysregulation may be a way for the nurses to psychologically defend themselves against these uncomfortable feelings. Also, when

emotionally dysregulated it can be more difficult to remain in connection with another person.

The underestimation of pain is another way in which psychological defence of denial may be being used by health professionals. The phenomenon of health professionals' underestimation of patient pain is well documented (Teske, Daut, & Cleeland, 1983). It is also suggested that the underestimation of pain may be a coping mechanism for nurses to be able to do their jobs well under emotionally difficult conditions (Prkachin, Solomon, & Ross, 2007).

Franck and Bruce suggest that there may be other factors that impact on a healthcare professional's response to pain, such as desensitisation or suppression of empathic reactions, seeing the other aspects of clinical care as being more important or as a result of interpersonal power issues that override the individual motivation to provide pain relief (Franck & Bruce, 2009). These reasons could all be categorised as a psychologically defensive use of denial, they serve to give the healthcare professional relief from the discomfort of seeing an infant in pain. This is achieved by either disconnecting from the infant's pain or by providing some sort of justification for why it is acceptable to not treat it.

Psychological defences can be useful in the NICU. For example superstitions such as never saying the 'H' word (home) for fear of an infant then never getting to go home or the 'Q' word (quiet) for fear of a sudden influx of infants into the unit, may actually serve an important purpose on the unit. These particular superstitions hold an important omnipotent fantasy, that somehow if it is not said it will not happen, which holds onto a wish for the ability have some control over variables that are ultimately uncontrollable. A baby's death or a sudden influx of too many babies to care for at once are both unwanted possibilities to consider and if superstitions such as these give the nurses the illusion that they can make them happen or not, it may introduce a sense of control to this essentially hopeless situation. The reality is of course that saying 'home' or 'quiet' is not going to jinx these situations, but having it as a superstition may be beneficial because it offers psychological protection. They are relatively benign superstitions to hold and on balance probably do more good than harm in a high stress unit such as the NICU.

### **8.2.3 A 'PSYCHE EDUCATION'**

If it is true that the decision-making surrounding the use of pain management techniques is determined by the individual nurse and their emotional capacity to identify and tolerate pain in the infant, then it would make sense to consider an intervention that seeks to enhance the emotional capacity of the nurse. Enhancing the emotional capacity of the nurse may mean that they are more able to attune to the infant's experience.

Franck and Bruce suggest that it remains to be seen whether a health care professional's avoidance of pain can be helped with training or psychological therapy and in fact they question whether any improvement in pain recognition for healthcare professionals can be made at all (Franck & Bruce, 2009). Perhaps a combination of both training and psychological therapy in the form of a 'psyche-education' might be a way forward. Not a personal therapy, nor an information session on pain management, but instead a training on the system of defence in the human psyche and the ways in which it can help or hinder the practise of healthcare professionals.

In psychoanalysis, a behaviour can be changed when the unconscious reasons for it are discovered. The behaviour can usually be traced back to a defensive response against something too emotionally painful to bring into consciousness. In psychoanalytic psychotherapy the patient is helped to understand what unconscious factors may be driving their behaviour and when they have a conscious understanding about themselves it becomes integrated into their conscious self-knowledge and they lose the need to defend against it.

These principles could be applied in the NICU to answer the question of why analgesia is under-used and to facilitate more conscious use of these pain management interventions. It is not enough to just put up more signs around the unit to remind staff to give analgesia, this has been done and the problem still exists. An education session that focuses on the defence mechanisms that have been discussed may help staff understand how some behaviour can be understood as a defence against unconscious worries. For example, nurses could be told that it is human nature to defend against painful things, that the concept of an infant being in pain is by its nature a painful thing to have to face (unconscious worry) and one way that our minds help us manage this is to pretend that it is not happening (the defence of denial). If we believe that the infant is not in pain then we are less likely to use analgesia (the



behaviour). Nurses could be educated on the psychoanalytic theory of how the mind works to protect an individual against painful experiences. There may be an unconscious need within them to deny the infant's experience of pain in order to protect themselves psychologically. This may mean they are less likely to realise that the infant may need analgesia and will need to try to be more consciously aware of it. In this way the information is presented to the nurses in a way that acknowledges their inner emotional state, bringing into consciousness thoughts that are likely to be unconscious. This is psyche-education: theoretical knowledge about how the inner psyche may work. This theory could be explained to nurses by suggesting that there may be a denial mechanism within them that propels them away from fully realising the negative experience of the infant. While it is not their job to connect deeply with the infants in their care, like a parent would, it is their job to provide infants with the pain interventions that are recommended in the evidence-based guidelines developed by international working groups on premature infant pain. The hypothesis would be that once staff became aware that this is likely how their mind would process this experience under stress they would have another way to manage their response that hopefully would not result in avoidance or denial.

Using a psychoanalytic understanding of the caregiver 'psyche' and looking at how it interfaces with the physical and emotional experience of the infant may lead to more sensitive and attuned care. Developmental Care promotes the idea of adjusting care to be more mindful of the infant, but it doesn't teach nurses to be more mindful of themselves, particularly under stress. A good reflective capacity in parents leads to better care of children, perhaps supporting the reflective capacity of nurses might lead to better pain management for preterm infants (Fonagy, Gergely, Jurist, & Target, 2002).

#### **8.2.4 SUMMARY**

Despite guidelines and education, preterm infant pain is undertreated in the NICU, including the unit in which this research programme was based. This is an ethical issue and researchers have turned their focus to knowledge translation – the ways in which evidence can be translated into practice. It is acknowledged that the presence of parents encourages the use of pain management interventions. The pain detection method has been suggested as a way to address the subjective nature of pain management decisions. Nurse participation in painful procedures could be emotionally painful for nurses and the psychological defences that they employ to help them manage this may also mean that they deny the infant's

experience of the pain. A 'psyche-education' may be worth investigating for its potential effectiveness in improving pain management in the NICU.

The next section considers how infant mental health needs in general could be met by non-parental caregivers in the NICU through companionship.

### **8.3 INFANT MENTAL HEALTH IN NICU: COMPANIONSHIP**

The finding in the observational studies that nurses spoke infrequently to infants in their care is worth investigating further. Why is it that nurses do not offer vocal soothing in general? Why did they speak less to infants during painful procedures than during non-painful procedures? The answers to these questions are outside the scope of this thesis and would require qualitative research. Although the main study findings did not provide evidence of a beneficial effect of vocal soothing on infant manifestations of pain and stress, there was some indication that it was unlikely to have a detrimental effect on cortisol levels. In this section it will be suggested that talking to infants is an integral part of infant mental health care and that 'companionship' may be a useful concept to encourage more attuned and sensitive care.

Both the infant mental health literature and the nursing literature thus far have focused on the support parents may need in order to better meet their infant's mental health needs. This thesis has investigated an intervention designed to help non-parental caregivers meet the mental health needs of infants. While this programme of research has not provided a definitive answer regarding whether this intervention is useful for reducing manifestations of preterm infant stress, it has provided evidence that nurses in this unit do not currently speak very often to infants during caregiving activities. In this section, an argument is made for vocal soothing being an integral aspect of infant mental health care. The importance of companionship for meeting the emotional needs of preterm infant in the NICU is discussed, followed by a consideration of the emotional health needs of nurses in the NICU.

#### ***8.3.1 VOCAL SOOTHING: AN INTEGRAL ASPECT OF INFANT MENTAL HEALTH CARE IN THE NICU***

The baseline observational studies in this research programme have provided data that suggest that NICU nurses speak infrequently to their infant patients and that they speak more to infants during non-painful procedures than painful procedures. Vocal soothing does

appear to be feasible as the nurses were able to talk to their colleagues more, suggesting that concentrating on a heel prick and talking can be done at the same time. The researcher provided the vocal soothing for the main study because the results of the feasibility study suggested that nurses could not do it. While this may have been due to the nurse feeling self-conscious under research conditions, it also may not be and warrants further exploration. This research programme has not only raised questions about frequency but also the issue of content of vocalisations to infants in the NICU. In the observational studies when words were offered they were usually soothing, but sometimes they were punitive towards the infant. More research is required to ascertain the factors involved in how a nurse speaks to an infant in their care and the optimal duration of the interaction.

What might be the impact on infants in the NICU if they are not spoken to by the people providing them care? Is it possible for their emotional care needs to be met without being spoken to? History suggests it may not. Frederick II, the King of Sicily and Holy Roman Emperor in the middle ages, designed an experiment in which 40 infants were taken from their families and raised by nurses who were to feed and clothe the children but were forbidden to speak to them. The experiment was designed to discover the true language that the infants would speak without outside influence, however these children never spoke and all had died by the time they were eight years old (Coulton, 1907; Vanier, 2015).

The theory of innate primary intersubjectivity proposed by Colwyn Trevarthen and described in chapter two holds that infants are born to expect to communicate meaningfully with others (Trevarthen, 1977). Meaningful communication is required to achieve the important infant mental health goals of affect attunement and affect regulation and this includes the use of voice. Through vocal soothing reassurance can be offered to the infant that they are not alone and that they are in empathic company.

A 'miracle baby' born at 27 weeks in Australia was pronounced dead by doctors who had worked for 20 minutes to save his life and was having kangaroo cuddles with his mother when he came 'back to life' (Crane, 2015). The story focussed on the benefit of skin-to-skin care in this case, but it was also reported that during the time he was being cuddled, he was told his name, that he had a twin sister and the hope his parents had for his life. While it seems perhaps more plausible that the physical warmth and regulating heartbeat of his mother had a big part to play in this, one cannot discount the potential 'psychological resuscitation' (as described by Psychoanalyst Catherine Vanier) that also took place (Vanier,

2015). This boy was lovingly attended to and treated as a person through the use of voice and he turned six years old in March 2016. Psychoanalysts working in maternity wards and NICUs in France report many examples of infants who were failing to thrive being spoken to directly and then thriving (Szejer, 2005; Vanier, 2015).

Developmental Care goes some way to promote the idea of talking to and being 'mindful' of infants, but does not offer specific strategies in order to achieve this aspect of care. It may be an expectation that nurses do this anyway, but given the data obtained in the course of this research programme regarding the lack of talking to infants, this is an area that needs more research attention. There may be a case for introducing the model of vocal soothing developed in this research programme as a tool to encourage the nurses to talk more.

If infants are not spoken to in the NICU how can they know that there is a sensitive and attuned adult available and waiting to get to know them? How can they feel accompanied in their painful and stressful experiences if they cannot hear a voice that seems to rise and fall in line with their experiences? Although this research programme was unable to demonstrate a particular effectiveness of vocal soothing over silence during painful procedures, could it be considered unethical not to speak to preterm infants in the NICU? As the results of the main study in this research programme suggested that there is unlikely to be a detrimental effect on infant stress as measured by salivary cortisol if they are spoken to, perhaps a focus on increasing the emotional care of infants through talking to them is worth pursuing.

One of the ways in which talking to preterm infants may be able to be supported could be in the introduction of the concept of 'companionship' as a direct infant mental health intervention in the NICU. Chapter two of this thesis provided a discussion around how infant mental health in the NICU appears to be restricted to parent infant relationships, despite nurses usually being the primary caregivers of the infants during their time in the NICU. It may be time to take a closer look at the quality of care provided by non-parental caregivers if infant mental health needs are to be attended to fully in the NICU environment.

### **8.3.2 MEETING INFANT MENTAL HEALTH NEEDS THROUGH COMPANIONSHIP**

Emotional care of infants has been recognised as essential for the healthy social and emotional development of humans (Harvard, 2004; Panksepp, 1998; Perry, Pollard, Blakley, Baker, & Vigilante, 1995; Schore, 1996). A lack of responsive relationships in early childhood

has adverse effects on brain development (Harvard, 2012). Harry Harlow's experiments in a rhesus monkey model showed that even mammals choose comfort over nutrition when given a choice (Harlow, 1958). There is already evidence that from 32 weeks PMA, infants have an expectation for and ability to communicate with others (van Rees & de Leeuw, 1993).

Meeting infant mental health needs in the NICU requires care that promotes the mental health and healthy brain development of the infant and includes reducing stress as well as attuned caregiver-infant interactions. The social capacities of infants and their needs for 'serve and return' experiences in order to support good mental health were described in chapter two and these aspects of care can be provided by anyone caring for an infant. Supporting infant mental health in the NICU is of particular importance because they are experiencing more painful and stressful experiences than infants at home and often do not have their parents physically or emotionally available to soothe them through these experiences.

The World Association for Infant Mental Health (WAIMH) acknowledges that the needs of infants have often been overlooked in favour of decisions that prioritise older children or parents and that there is enough evidence now that infants need special nurturance and caregiving in order to meet their needs and facilitate normal development. The Association's 2016 position paper states "(t)he Infant has the right to be given nurturance that includes love, physical and emotional safety, adequate nutrition and sleep, in order to promote normal development". Infants born preterm who have to undergo painful and intrusive interventions for the sake of their physical health, have a right to emotional care at this time also. It is encouraging that the model of Family Integrated Care (described in chapter two) is undergoing further research. This may be one important way in which premature infant's emotional needs can be better met in the NICU. In the unit in which this research took place, nurses still provide the majority of the care for the infants so the way in which these nurses interact with infants in their care is important.

There have been calls in the literature for more empathic care in the NICU. Various methods for increasing empathy in the NICU have been suggested, for example, in order to be motivated to provide better pain relief for infants, Walden and Carrier suggest that nurses should follow the guiding principle of 'Do unto others' infants as you would want them to do for your own' (Walden & Carrier, 2009) - in this way perhaps emphasising the human nature

of the infants to try and encourage nurses not to objectify their patients. Anand and Hall suggest that NICU staff suppress their empathic responses to infants in order to remain 'professional' and in an attempt to encourage staff to be more empathic they advocate for paying attention 'not just to what you do in caring for infants but in how you do it' (Anand & Hall, 2008).

Theodore Stickley and Dawn Freshwater provide an interesting discussion on the use of 'love' in general nursing. 'Love' is referred to in this paper as a word to describe empathy or emotional care for the patient. Stickley and Freshwater suggest five ways in which love can be integrated into the nursing role; through discipline, concentration, patience, concern and activity (Stickley & Freshwater, 2002). The art of practicing love is seen as requiring *discipline*. Nurses are encouraged to be reflective of their own emotional experiences and to be looking after themselves emotionally. *Concentration* refers to being focused on providing love, to make a determined conscious decision to do it. *Patience* is asked of nurses in terms of realising that this way of being with patients will take more time but that the benefit to the patient is worth it; that love is more valued than material or financial values. Stickley and Freshwater consider that engaging in *concern* for their patients encourages the provision of healing for the physical and the emotional aspects of their patients and as such results in more holistic care. *Activity* refers to an awareness that student nurses appear to be more loving than experienced nurses who have had the art of loving professionally suppressed and that this may be an art that has to be actively developed in order to reduce the risk of suppression. Stickley and Freshwater believe that nurses in general may carry a fear of over-involvement, that if they become too attached to their patients they will more keenly feel their loss upon discharge (or death). However, while their framework does challenge nurses to enter into a more emotionally caring relationship with their patients, the fact that it is a framework also provides protection against nurses becoming over-involved. For example, if a nurse is practicing the professional 'skill' of loving, then perhaps this encourages a way of being genuine in the moment with patients while also holding onto a sense of themselves as separate. They are just 'doing their job'. In this way the nurse remains professional by using a framework for offering emotional care. In this model, empathy is not suppressed in order to be professional, as was described by Anand and Hall above (Anand & Hall, 2008).

Professional supervision, that is the opportunity for nurses to reflect either one on one or in a group on the emotional impact of their work, is recommended to be able to effectively introduce this kind of empathy into a medical setting (Stickley & Freshwater, 2002). NICU

nurses do not have to lose their professionalism if they are to offer emotional care and a deliberate intervention makes it clear that in offering this care the nurse is not taking on the full parental emotional tie of love for the infant.

Wilfred Bion's concept of psychological containment (described in chapter two) has its origins in the emotional care offered to an infant by their parent, but is also understood as the process by which psychotherapists can help their adult patients (Bion, 1984). The infant or patient has a distressed feeling and the parent or psychotherapist recognises it, accepts it and responds to the infant or patient in such a way that lets them know that the feeling is manageable and they will get through it. The psychoanalyst Johan Norman's approach when working with infants (also described in chapter two) was to communicate directly with the infant and offer a response that could be experienced as attuned and soothing. There may be a place for this kind of care in the NICU. A case has been made in this thesis for non-parental caregivers taking responsibility for the emotional care as well as physical care of the infants in their charge. As suggested in chapter two, this could be in the form of companionship rather than trying to emulate parental love.

The concept of 'companionship' was introduced in chapter two; it is different to 'relationship' because it is not as emotionally heavy or invested, but it is invested enough to see that the interaction that caregivers have with preterm infants is an important aspect of their mental health care. Infant mental health in the NICU is currently seen as the supporting of the parent-infant relationship with the infant and in this way the infant's experience may be being missed. Meeting infant mental health needs in the NICU means considering the interactions on a moment-to-moment basis; how is this baby experiencing this moment with this caregiver at this time? How can care be offered that ensures that adequate soothing is offered to the infant at a time of stress? Infants born preterm are likely to require more assistance from the caregiving environment to regulate themselves, particularly during painful and stressful procedures.

Knowledge from the field of infant mental health may help provide a framework for interacting with infants in the NICU. It could also help nurses recognise how the care they are already providing is supportive to infant mental health. Perhaps if NICU nurses received more education in infant mental health they could find other ways to consciously apply the emotional care in a professional way. In the early weeks and months of life any person giving

the infant care is building their emotional health and contributing to their brain development.

### **8.3.3 THE EMOTIONAL HEALTH NEEDS OF NURSES**

What would it 'cost' nurses to provide companionship? It has been shown that depressed mothers are at risk of not being able to provide the sensitive attuned care that infants need in the early weeks and months and years (Murray, Halligan, & Cooper, 2010). This is largely understood to be due to the fact that it requires psychological effort to connect with an infant. If this is so, then could it be considered too much of a burden for nurses to ask them to engage in this way while also providing the physical care? What about the emotional experience of nurses in the NICU?

NICU nurses have been found to have higher fatigue, anxiety and depressive mood than general ward nurses (Fujimaru et al., 2012). In a recent study in Ireland, 98% of NICU nurses reported that treating and caring for infants in the NICU was emotionally stressful (Twohig et al., 2016). Further to this, it was reported in 2015 that most NICUs in England (64%) did not have enough nurses to meet national standards on safe staffing levels, which would create additional stress for nurses (Cleland, 2015). Issues of burnout and compassion fatigue have been identified in adult Intensive Care Unit (ICU) settings, which may be symptoms of unaddressed emotional distress and may also be relevant to the NICU setting. A systematic review on burnout and compassion fatigue amongst adult ICU professionals reported the prevalence of compassion fatigue to be between 7.3% and 40%, while burnout was thought to occur in up to 70% of adult ICU professionals (van Mol, Kompanje, Benoit, Bakker, & Nijkamp, 2015).

Is it reasonable to ask NICU nurses to attune more to infants in their care when they are themselves under emotional stress? This probably needs to be addressed first. It would be interesting to measure nurse cortisol levels or heart rate and blood pressure changes in NICU. Is there a link with the nurse's level of emotional stress and how much they talk to the infants in their care? It would seem prudent to better understand the emotional experience of nurses in the NICU before asking them to focus on the emotional experience of infants. Why is it that there are such low levels of talking to infants during painful and non-painful procedures? If this is understood well enough, then more effective ways to increase the amount of vocal soothing could be investigated.



Despite the lack of knowledge around the emotional experiences of NICU nurses it has been found that attuning to the infant's experience using the 'neonatal resuscitation model' has positive effects on the emotional state of the nursing staff. The 'neonatal resuscitation model' has been developed within the field of pre and perinatal psychology (PPN) (Landon-Malone, 2005). In this field there is an acceptance of the idea that infants are born with a consciousness and awareness of their surroundings and therefore traumatic experiences (Chamberlain, 2003). Obstetrician Dr Robert Oliver, in describing the 'ideal caesarean birth', stresses the importance of informing the infant calmly about what is going on, talking quietly and reassuringly alongside a calm resuscitation team without bright lights and loud noises (Oliver, 2000). In the 'neonatal resuscitation model' nurses are taught the medical aspects of a neonatal resuscitation and are then guided through a visualisation in which they are asked to imagine being in an emergency situation with a baby in which they soothe, speak to and reassure the infant directly. The nurses who participated in this visualisation reported feeling calmer in a real emergency situation, less afraid and more able to think about the job in hand (Landon-Malone, 2005). From a psychoanalytic perspective, the nurses may have been using the imagery as a soothing focus for themselves in the actual emergency to help them get through it as well as offering a containing presence for the mother/father/infant by not becoming fearful or stressed. This is perhaps an example of where medical and psychological practices have come together in the service of everyone – the infant, the parents and the staff.

#### **8.3.4 SUMMARY**

This section has considered what non-parental caregivers may be able to do to support infant mental health in the NICU. Companionship has been proposed as one way in which nurses might be able to connect with infants in the moment-to-moment interactions, while still remaining 'professional'. NICU nurses are likely to be emotionally stressed and it would be important to understand this better before asking them to emotionally attune to infants in their care. The 'neonatal resuscitation model' is one example of where both families and nurses have benefited from psychological care in the medical environment.

The final section in this thesis will present conclusions and recommendations for further research into the mental health aspects of care in the NICU.

## 8.4 CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

The original aim of this doctoral research was to develop and test a model of vocal soothing that could be used as a non-pharmacological intervention with infants during painful procedures. Along the way, this programme of research has found that nurses in the NICU do not often speak to infants in their care and that they are less likely to speak to them during painful procedures than non-painful procedures. In addition, there is support for the findings internationally that interventions to reduce preterm infant pain and stress are under-used. This thesis has offered a psychoanalytic understanding of psychological defence mechanisms that may be contributing to the under-use of pain management interventions and proposed a 'psyche-education' that may help address this issue. The idea of 'companionship' has been suggested as a way of conceptualising the care that nurses could provide in the NICU that is more attuned to an infant's mental health needs yet not emotionally overwhelming for the NICU nurse. To return to the quote that began this chapter, this has been a programme of research designed to facilitate nurse 'concern' for infants, rather than 'worry'.

There will be many things that nurses are already doing that support infant mental health in the NICU and the proposed concept of 'companionship' is a way of acknowledging this important role that non-parent caregivers have with hospitalised infants. There were instances of companionship that were observed by the researcher and are not captured by the formal data in this study. For example:

*One night a nurse asked me to come and look at twin boys who reacted differently to heel prick procedures. She was interested because one of the boys had Down syndrome and he did not appear to become distressed during heel prick procedures, while his twin brother, who did not have Down syndrome, did display distress during the heel prick procedure. I observed both boys undergoing heel prick procedures with this nurse. The twin without Down syndrome cried during his heel prick and the nurse rather briskly told him there was no need to cry. The twin with Down syndrome did not cry yet his fingers splayed, his body stiffened and his eyes took on a startled look. The nurse spoke to him gently and soothingly during the procedure. At the end of the procedure she was surprised when I suggested that the child who had not cried looked more stressed than the other child. She was even more surprised when I observed that she had been*

*more soothing in her response to this child. Although she had not been consciously aware of it, she knew on one level that this baby needed more comfort than the other child.*

This nurse was surprised to learn she had offered companionship to the infant who needed it more, without even thinking about it. This example highlights the often unconscious nature of human behaviour.

#### **8.4.1 CONCLUSIONS**

The conclusions that can be drawn from this research are as follows:

1. It is possible to develop a model of vocal soothing that can be used with preterm infants in the NICU
2. Nurses do not often speak to infants during a nappy change and are even less likely to speak to infants during a heel prick procedure
3. This study did not provide evidence of the benefit of vocal soothing as a pain management intervention
4. It may not be feasible to design a study that can objectively measure an infant's response to vocal soothing while in their usual environment given the inability to control for aspects of the environment and the infant's sleep state
5. Vocal soothing is unlikely to have a detrimental effect on the infant pain response as measured by salivary cortisol levels
6. Infants can produce both a 'pain' and a 'no pain' response to noxious stimuli within a 24-hour time period, meaning that there may be reasons other than infant age, state or time since last procedure that contribute to a behavioural and physiological expression of pain.
7. Given that some infants did not exhibit behavioural or physiological manifestations of pain or stress, yet still responded with a cortisol increase, it would be important to consider that it is not always obvious to a caregiver that preterm infants are in distress.

#### **8.4.2 RECOMMENDATIONS FOR FUTURE RESEARCH**

There are a number of questions that have been raised over the course of this research programme that warrant further investigation.

*What factors impact on nurse decisions to offer vocal soothing?*

This research programme has provided evidence to suggest that nurses do not provide enough vocalisations to an infant to consider it vocal soothing during either painful procedures or non-painful procedures. Further, the results of the feasibility study raise the possibility that nurses might not know how to talk to infants, given that even when instructed to speak soothingly to the infant during the heel prick procedure, they were unable to do so. An exploration of why nurses do/do not speak to infants might go some way to understanding what might influence whether or not a nurse provides vocal soothing.

*Is it stressful for nurses to speak to infants while performing painful procedures?*

It would be worth investigating what providing vocal soothing might 'cost' a nurse, in terms of emotional investment. If it is true that avoiding talking to an infant helps a nurse to manage their own emotional response to their work, then it would be important to understand what extra support a nurse may need in order to provide this intervention without feeling overwhelmed. The literature suggests that NICU nurses are stressed and if asking nurses to attune more closely and provide vocal soothing to infants in their care means they become more stressed, other alternatives may also need to be explored.

*Can a 'psyche-education' improve pain management in the NICU?*

Given the international problem with provision of adequate pain management in the NICU, it would be worth exploring the intra-personal aspects of this issue. An argument has been made in this thesis for providing a psyche-education to help nurses understand the potential unconscious reasons for their avoidance of analgesia and it would be interesting to assess whether this idea has any merit in terms of addressing this issue.

*Does the concept of 'companionship' encourage nurses to offer attuned care with vocal soothing?*

It would also be interesting to know whether the concept of 'companionship' can help improve the vocal soothing rates by nurses in the NICU. 'Companionship' is just one way in which infant mental health knowledge could be conceptualised and shared with nurses, with the aim of raising awareness of their role in providing emotional care to their infant charges.

*Are there ways to measure infant mental health in the NICU?*

This research programme focused on the soothing of a painful and stressful experience, the reduction of stress in the infant being one element of infant mental health. This was assessed using behavioural and physiological measures, but there are other aspects of infant mental health that may be applicable in the NICU, such as the quality of the caregiving relationship. It would be interesting to see if a tool such as the Adult Attachment Interview is useful for understanding how a nurse's past relationships may impact on their current provision of care to infants in the NICU (van Ijzendoorn & Fox, 1995).

This is a new frontier for infant mental health and nursing care. It is time to consider the role that non-parental caregivers have in supporting the mental health of our youngest and most vulnerable citizens. A number of healthcare providers in NICU who had had their own personal experience with children in NICU reflected on what support parents may need. They suggested a number of things for healthcare providers to keep in mind when interacting with parents in NICU, one of which was that *"We can be there for parents at tough moments or avoid them. Be there"* (Janvier et al., 2016, p.3).

This thesis argues that the support focus has to be on infants as well as their parents. So let's extend the same courtesy expected for parents to their preterm infants. The purpose of this research has been to encourage NICU caregivers to 'be there' for infants during those tough moments. Let's also ensure that both parents and non-parental caregivers are fully fit for the important but often under-valued task of ensuring that the emotional needs of these vulnerable infants are fully accommodated for and met.

## REFERENCES

- Abram, J. (2007). *The Language of Winnicott: a dictionary of Winnicott's use of words* (2 ed.). London: Karnac Books
- Acquarone, S. (2004). *Infant - Parent Psychotherapy: A Handbook*. London: H. Karnac (Books) Ltd.
- Al Maghaireh, D. a. F., Abdullah, K. L., Chan, C. M., Piaw, C. Y., & Al Kawafha, M. M. (2016). Systematic review of qualitative studies exploring parental experiences in the Neonatal Intensive Care Unit. *Journal of clinical nursing*.
- Alegria, J., & Noirot, E. (1978). Neonate Orientation Behaviour towards Human Voice. *International Journal of Behavioral Development*, 1(4), 291-312.  
doi:10.1177/016502547800100401
- Allegaert, K., Simons, S. H., Vanhole, C., & Tibboel, D. (2006). Developmental pharmacokinetics of opioids in neonates. *Journal of opioid management*, 3(1), 59-64.
- Als, H. (1982). Toward a synactive theory of development: Promise for the assessment and support of infant individuality. *Infant Mental Health Journal*, 3(4), 229-243.  
doi:10.1002/1097-0355(198224)3:4<229::AID-IMHJ2280030405>3.0.CO;2-H
- Als, H., & B McAnulty, G. (2011). The newborn individualized developmental care and assessment program (NIDCAP) with kangaroo mother care (KMC): Comprehensive care for preterm infants. *Current women's health reviews*, 7(3), 288-301.
- Als, H., & Brazelton, T. B. (1981). A New Model of Assessing the Behavioral Organization in Preterm and Fullterm Infants: Two Case Studies. *Journal of the American Academy of Child Psychiatry*, 20(2), 239-263.
- Als, H., Duffy, F. H., & McAnulty, G. B. (1996). Effectiveness of individualized neurodevelopmental care in the newborn intensive care unit (NICU). *Acta Pædiatrica*, 85, 21-30. doi:10.1111/j.1651-2227.1996.tb14273.x
- Als, H., Duffy, F. H., McAnulty, G. B., Fischer, C. B., Kosta, S., Butler, S. C., . . . Ringer, S. A. (2011). Is the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) effective for preterm infants with intrauterine growth restriction? *Journal of Perinatology*, 31(2), 130-136.
- Als, H., Duffy, F. H., McAnulty, G. B., Rivkin, M. J., Vajapeyam, S., Mulkern, R. V., . . . Eichenwald, E. C. (2004). Early Experience Alters Brain Function and Structure. *Pediatrics*, 113(4), 846-857.

- Als, H., & Gilkerson, L. (1997). The role of relationship-based developmentally supportive newborn intensive care in strengthening outcome of preterm infants. *Seminars in Perinatology*, 21(3), 178-189.
- Altimier, L. (2011). Mother and Child Integrative Developmental Care Model: A Simple Approach to a Complex Population. *Newborn and Infant Nursing Reviews*, 11(3), 105-108. doi: 10.1053/j.nainr.2011.06.004
- Altimier, L., Kenner, C., & Damus, K. (2015). The Wee Care Neuroprotective NICU Program (Wee Care): The Effect of a Comprehensive Developmental Care Training Program on Seven Neuroprotective Core Measures for Family-Centered Developmental Care of Premature Neonates. *Newborn and Infant Nursing Reviews*, 15(1), 6-16. doi: 10.1053/j.nainr.2015.01.006
- Anand, K. J. (2016). Revisiting a dilemma: repetitive pain vs. opioid exposures? *Acta Paediatrica*, 105(7), 736-737.
- Anand, K. J. S. (1998). Clinical Importance of Pain and Stress in Preterm Neonates. *Neonatology*, 73(1), 1-9.
- Anand, K. J. S., & Hall, R. W. (2008). Love, Pain, and Intensive Care. *Pediatrics*, 121(4), 825-827. doi:10.1542/peds.2007-3828
- Anand, K. J. S., & Hickey, P. R. (1987). Pain and Its Effects in the Human Neonate and Fetus. *New England Journal of Medicine*, 317(21), 1321-1329. doi: 10.1056/NEJM198711193172105
- Anand, K. J. S., & Scalzo, F. M. (2000). Can Adverse Neonatal Experiences Alter Brain Development and Subsequent Behavior? *Neonatology*, 77(2), 69-82.
- Anand, K. J. S., Sippell, W. G., & Aynsley-Green, A. (1987). Randomised trial of fentanyl anaesthesia in preterm babies undergoing surgery: effects on the stress response. *The Lancet*, 329(8524), 62-66.
- Armitage, P., Berry, G., & Matthews, J. N. S. (2008). *Statistical methods in medical research*: John Wiley & Sons.
- Axelin, A., Anderzén-Carlsson, A., Eriksson, M., Pölkki, T., Korhonen, A., & Franck, L. S. (2015). Neonatal Intensive Care Nurses' Perceptions of Parental Participation in Infant Pain Management: A Comparative Focus Group Study. *The Journal of Perinatal & Neonatal Nursing*, 29(4), 363-374. doi:10.1097/jpn.000000000000136
- Balbernie, R. (2007). The move to intersubjectivity: A clinical and conceptual shift of perspective. *Journal of Child Psychotherapy*, 33(3), 308-324.

- Ballweg, D. D., & Nepstad, A. E. (2010). Individualised Care: Actions for Individual Staff Members. In C. Kenner & J. M. McGrath (Eds.), *Developmental Care of Newborns and Infants: A Guide for Health Professionals*. Glenview, IL: National Association of Neonatal Nurses (NANN).
- Baradon, T., Broughton, C., Gibbs, I., Joyce, A., & Woodhead, J. (2005). *The practice of psychoanalytic parent-infant psychotherapy - Claiming the Baby*. London: Routledge.
- Barker, D., & Rutter, N. (1995). Exposure to invasive procedures in neonatal intensive care unit admissions. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, 72(1), F47-F48.
- Bateson, M. C. (1971). The interpersonal context of infant vocalization. *Quarterly Progress Report of the Research Laboratory of Electronics*, 100, 170-176.
- Bellieni, C. (2002). Effect of Multisensory Stimulation on Analgesia in Term Neonates: A Randomized Controlled Trial. *Pediatric research*, 51(4), 460-463.
- Bellieni, C., Buonocore, G., Perrone, S., & Gabbrielli, M. (2011). Which legal consequences for those who cause infants to suffer pain? *European Journal of Pain Supplements*, 5(1), 169.
- Bellieni, C. C. (2005). Pain definitions revised: newborns not only feel pain, they also suffer. *Ethics & medicine*, 21(1), 5.
- Bellieni, C. V., Buonocore, G., Nenci, A., Franci, N., Cordelli, D. M., & Bagnoli, F. (2001). Sensorial saturation: an effective analgesic tool for heel-prick in preterm infants: a prospective randomized trial. *Biology of the neonate*, 80(1), 15.
- Bellieni, C. V., Burrioni, A., Perrone, S., Cordelli, D. M., Nenci, A., Lunghi, A., & Buonocore, G. (2003). Intracranial pressure during procedural pain. *Neonatology*, 84(3), 202-205.
- Bellieni, C. V., Cordelli, D. M., Caliani, C., Palazzi, C., Franci, N., Perrone, S., . . . Buonocore, G. (2007). Inter-observer reliability of two pain scales for newborns. *Early human development*, 83(8), 549-552.
- Bellieni, C. V., Cordelli, D. M., Marchi, S., & Ceccarelli, S. (2007). Sensorial Saturation for Neonatal Analgesia. *Clin J Pain*, 23(3), 219-221. doi:10.1097/AJP.0b013e31802e3bd7
- Bellieni, C. V., Tei, M., & Buonocore, G. (2015). Should we assess pain in newborn infants using a scoring system or just a detection method? *Acta Paediatrica*, 104(3), 221-224.
- Bellieni, C. V., Tei, M., Coccina, F., & Buonocore, G. (2012). Sensorial saturation for infants' pain. *The journal of maternal-fetal & neonatal medicine*, 25 Suppl 1, 79-81.
- Berk, L. E. (2006). *Child Development (7th Ed)*. Boston, USA: Pearson Education Inc.



- Bernardini, V., De Liso, P., Santoro, F., Allemand, F., & Allemand, A. (2011). [Procedural pain perception of preterm newborn in neonatal intensive care unit: assessment and non-pharmacological approaches]. *Minerva pediatrica*, 63(4), 247-255.
- Bion, W. R. (1962). *Learning from experience*. London: Karnac Books.
- Bion, W. R. (1984). *Elements of psychoanalysis*. London: Karnac Books.
- Blount, R. L., Corbin, S. M., Sturges, J. W., Wolfe, V. V., Prater, J. M., & Denise James, L. (1989). The relationship between adults' behavior and child coping and distress during BMA/LP procedures: A sequential analysis. *Behavior Therapy*, 20(4), 585-601. doi:10.1016/S0005-7894(89)80136-4
- Blount, R. L., Devine, K. A., Cheng, P. S., Simons, L. E., & Hayutin, L. (2008). The Impact of Adult Behaviors and Vocalizations on Infant Distress during Immunizations. *Journal of Pediatric Psychology*, 33(10), 1163-1174. doi:10.1093/jpepsy/jsn030
- Bo, L. K., & Callaghan, P. (2000). Soothing pain-elicited distress in Chinese neonates. *Pediatrics*, 105(4), e49-e49.
- Botvinick, M., Jha, A. P., Bylsma, L. M., Fabian, S. A., Solomon, P. E., & Prkachin, K. M. (2005). Viewing facial expressions of pain engages cortical areas involved in the direct experience of pain. *Neuroimage*, 25(1), 312-319.
- Bouza, H. (2009). The impact of pain in the immature brain. *The Journal of Maternal-Fetal & Neonatal Medicine*, 22(9), 722-732.
- Boxwell, G. (2010). *Neonatal intensive care nursing*: Routledge.
- Brazelton, T. B., Koslowski, B., & Main, M. (1974). The origins of reciprocity: The early mother-infant interaction. In M. Lewis & L. A. Rosenblum (Eds.), *The effects of the infant on its caregiver*. New York: Wiley.
- Brazelton, T. B., Tronick, E., Adamson, L., Als, H., & Wise, S. (1975). Early mother-infant reciprocity. *Ciba Foundation Symposium*(33), 137-154.
- Bretherton, I. (1985). Attachment theory: Retrospect and prospect. *Monographs of the society for research in child development*, 3-35.
- Burns, E. M. (1990). The effects of stress during the brain growth spurt. *Annu Rev Nurs Res*, 8, 57-82.
- Butt, M., & Kisilevsky, B. (2000). Music modulates behaviour of premature infants following heel lance. *The Canadian journal of nursing research= Revue canadienne de recherche en sciences infirmieres*, 31(4), 17-39.

- Calixto, C., Martinez, F. E., Jorge, S. M., Moreira, A. C., & Martinelli, C. E. (2002). Correlation between plasma and salivary cortisol levels in preterm infants. *The Journal of Pediatrics*, *140*(1), 116-118. doi:10.1067/mpd.2002.120765
- Campbell-Yeo, M., Latimer, M., & Johnston, C. (2008). The empathetic response in nurses who treat pain: concept analysis. *Journal of Advanced Nursing*, *61*(6), 711-719.
- Carbajal, R., Lenclen, R., Jugie, M., Paupe, A., Barton, B. A., & Anand, K. J. (2005). Morphine does not provide adequate analgesia for acute procedural pain among preterm neonates. *Pediatrics*, *115*(6), 1494-1500.
- Carbajal, R., Rousset, A., Danan, C., Coquery, S., Nolent, P., Ducrocq, S., . . . Breart, G. (2008). Epidemiology and treatment of painful procedures in neonates in intensive care units.(Clinical report). *JAMA, The Journal of the American Medical Association*, *300*(1), 60.
- Caron, A. J., Caron, R. F., & MacLean, D. J. (1988). Infant Discrimination of Naturalistic Emotional Expressions: The Role of Face and Voice. *Child development*, *59*(3), 604-616.
- Carr, L., Iacoboni, M., Dubeau, M.-C., Mazziotta, J. C., & Lenzi, G. L. (2003). Neural mechanisms of empathy in humans: a relay from neural systems for imitation to limbic areas. *Proceedings of the national Academy of Sciences*, *100*(9), 5497-5502.
- Carter, B. (2004). Pain narratives and narrative practitioners: a way of working 'in-relation' with children experiencing pain. *Journal of Nursing Management*, *12*(3), 210-216.
- Castro, M., Elias, P. C., Martinelli, C. E., Antonini, S. R., Santiago, L., & Moreira, A. C. (2000). Salivary cortisol as a tool for physiological studies and diagnostic strategies. *Brazilian journal of medical and biological research = Revista brasileira de pesquisas médicas e biológicas / Sociedade Brasileira de Biofísica ... [et al.]*, *33*(10), 1171.
- Chamberlain, D. B. (2003). Communicating with the mind of a prenat: Guidelines for parents and birth professionals. *Journal of Prenatal & Perinatal Psychology & Health*, *18*(2), 95.
- Chugani, H. T., Behen, M. E., Muzik, O., Juhász, C., Nagy, F., & Chugani, D. C. (2001). Local brain functional activity following early deprivation: a study of postinstitutionalized Romanian orphans. *Neuroimage*, *14*(6), 1290-1301.
- Cignacco, E., Denhaerynck, K., Nelle, M., Bührer, C., & Engberg, S. (2009). Variability in pain response to a non-pharmacological intervention across repeated routine pain exposure in preterm infants: a feasibility study. *Acta paediatrica*, *98*(5), 842-846.

- Cleland, S. (2015). *Bliss baby report 2015: hanging in the balance*. Retrieved from [www.bliss.org.uk](http://www.bliss.org.uk) .
- Cohen, M. (2003). *Sent before my time: A child psychotherapist's view of life on a neonatal intensive care unit*. London: Karnac Books.
- Cohen, N. J. (1999). Watch, wait, and wonder: Testing the effectiveness of a new approach to mother-infant psychotherapy. *Infant Mental Health Journal, 20*(4), 429-451. doi:10.1002/(sici)1097-0355(199924)20:4<429::aid-imhj5>3.0.co;2-q
- Coltart, N. (1996). *The baby and the bathwater*. London: Karnac Books.
- Condon, W. S., & Sander, L. W. (1974). Neonate Movement Is Synchronized with Adult Speech: Interactional Participation and Language Acquisition. *Science, 183*(4120), 99-101.
- Cong, X., Ludington-Hoe, S. M., & Walsh, S. (2011). Randomized Crossover Trial of Kangaroo Care to Reduce Biobehavioral Pain Responses in Preterm Infants: A Pilot Study. *Biological Research For Nursing, 13*(2), 204-216. doi:10.1177/1099800410385839
- Cooper, R. P., & Aslin, R. N. (1990). Preference for Infant-Directed Speech in the First Month after Birth. *Child development, 61*(5), 1584-1595.
- Coulton, G. G. (1907). *From St. Francis to Dante: Translations from the Chronicle of the Franciscan Salimbene (1221-1288): with Notes and Illustrations from Other Medieval Sources* (Vol. 25): D. Nutt.
- Craig, J., Glick, C., Phillips, R., Hall, S., Smith, J., & Browne, J. (2015). Recommendations for involving the family in developmental care of the NICU baby. *Journal of Perinatology, 35*, S5-S8.
- Craig, K. D., Whitfield, M. F., Grunau, R. V. E., Linton, J., & Hadjistavropoulos, H. D. (1993). Pain in the preterm neonate: behavioural and physiological indices. *Pain, 52*(3), 287-299.
- Cramer, D. (1998). *Fundamental statistics for social research: step-by-step calculations and computer techniques using SPSS for Windows*: Psychology Press.
- Cramer, D., & Howitt, D. L. (2004). *The Sage dictionary of statistics: a practical resource for students in the social sciences*: Sage.
- Crane, E. (2015). Revived by the power of love. Retrieved from <http://www.dailymail.co.uk/news/article-2992862>
- Cummins, R., Livesey, P., & Evans, J. (1977). A developmental theory of environmental enrichment. *Science, 197*(4304), 692-694.

- Currie, E. R., Roche, C., Christian, B. J., Bakitas, M., & Meneses, K. (2016). Recruiting bereaved parents for research after infant death in the neonatal intensive care unit. *Applied Nursing Research, 32*, 281-285.
- Delafield-Butt, J., & Trevarthen, C. (2013). Theories of the development of human communication *Theories and models of communication. Handbooks of Communication Science* (pp. 199-222). Berlin: Mouton De Gruyter.
- Dibley, A. L., Rydin Orwin, T., Stedmon, J., & Dallos, R. (2016). The feasibility of using "PremieStart", a mother-premature infant interaction program, on a neonatal unit in England. *Infant Mental Health Journal, 37*(4), 440-451.
- Diem-Wille, G. (2011). *The Early Years of Life: Psychoanalytical Development Theory According to Freud, Klein and Bion*. London: Karnac Books Ltd.
- Doane, D. P., & Seward, L. E. (2011). Measuring skewness: a forgotten statistic. *Journal of Statistics Education, 19*(2), 1-18.
- Durie, M. (1998). *Whaiora: Maōri Health Development*: Oxford University Press.
- Egliston, K.-A., McMahon, C., & Austin, M.-P. (2007). Stress in pregnancy and infant HPA axis function: Conceptual and methodological issues relating to the use of salivary cortisol as an outcome measure. *Psychoneuroendocrinology, 32*(1), 1-13.  
doi:10.1016/j.psyneuen.2006.10.003
- Eisenberg, R. B. (1976). *Auditory competence in early life :the roots of communicative behavior*. Baltimore: University Park Press.
- Elder, D. E., Campbell, A. J., Larsen, P. D., & Galletly, D. (2011). Respiratory variability in preterm and term infants: Effect of sleep state, position and age. *Respiratory physiology & neurobiology, 175*(2), 234-238.
- Epstein, R. M. (2003). Mindful practice in action (I): Technical competence, evidence-based medicine, and relationship-centered care. *Families, Systems, & Health, 21*(1), 1.
- Ferguson, C. A. (1964). Baby talk in six languages. *American anthropologist, 66*(6\_PART2), 103-114.
- Fernald, A. (1989). Intonation and communicative intent in mothers' speech to infants: Is the melody the message? *Child development, 1497-1510*.
- Fernald, A. (1991). Prosody in speech to children: Prelinguistic and linguistic functions. *Annals of Child Development, 8*, 43-80.

- Filippa, M., Devouche, E., Arioni, C., Imberty, M., & Gratier, M. (2013). Live maternal speech and singing have beneficial effects on hospitalized preterm infants. *Acta Paediatrica*, *102*(10), 1017-1020.
- Fillion, T. J., & Blass, E. M. (1986). Infantile experience with suckling odors determines adult sexual behavior in male rats. *Science*, *231*(4739), 729-731.
- Fitzgerald, M., Shaw, A., & MacIntosh, N. (1988). Postnatal development of the cutaneous flexor reflex: comparative study of preterm infants and newborn rat pups. *Developmental Medicine & Child Neurology*, *30*(4), 520-526.
- Fitzgerald, M., Millard, C., & McIntosh, N. (1989). Cutaneous hypersensitivity following peripheral tissue damage in newborn infants and its reversal with topical anaesthesia. *Pain*, *39*(1), 31-36.
- Flacking, R., Lehtonen, L., Thomson, G., Axelin, A., Ahlqvist, S., Moran, V. H., . . . The Scene Group. (2012). Closeness and separation in neonatal intensive care. *Acta Paediatrica*, *101*(10), 1032-1037. doi:10.1111/j.1651-2227.2012.02787.x
- Fogel, A. (1993). *Developing through relationships*: University of Chicago Press.
- Fonagy, P., Gergely, G., Jurist, E., & Target, M. (2002). *Affect regulation, mentalization and the development of the self*. New York: Other Press.
- Fonagy, P., Steele, H., & Steele, M. (1991). Maternal representations of attachment during pregnancy predict the organization of infant-mother attachment at one year of age. *Child development*, *62*(5), 891-905.
- Fonagy, P., Steele, M., Steele, H., Leigh, T., Kennedy, R., Mattoon, G., & Target, M. (1995). Attachment, the reflective self, and borderline states: The predictive specificity of the Adult Attachment Interview and pathological emotional development. In S. Goldberg, R. Muir, & J. Kerr (Eds.), *Attachment theory: Social, developmental and clinical perspectives*. Hillsdale, NJ: Analytic Press.
- Fraiberg, S. (1975). Ghosts in the nursery: A psychoanalytic approach to the problems of impaired infant-mother relationships. *Journal of the American Academy of Child Psychiatry*, *14*(3), 387.
- Francis, S., Walker, R., Riad-Fahmy, D., Hughes, D., Murphy, J., & Gray, O. (1987). Assessment of adrenocortical activity in term newborn infants using salivary cortisol determinations. *The Journal of pediatrics*, *111*(1), 129-133.
- Franck, L. S., & Bruce, E. (2009). Putting pain assessment into practice: why is it so painful? *Pain Research and Management*, *14*(1), 13-20.

- Franck, L. S., Oulton, K., & Bruce, E. (2012). Parental involvement in neonatal pain management: an empirical and conceptual update. *Journal of Nursing Scholarship*, 44(1), 45-54.
- Franck, L. S., Oulton, K., Nderitu, S., Lim, M., Fang, S., & Kaiser, A. (2011). Parent involvement in pain management for NICU infants: a randomized controlled trial. *Pediatrics*, 128(3), 510-518. doi:10.1542/peds.2011-0272
- Franck, L. S., & Spencer, C. (2003). Parent visiting and participation in infant caregiving activities in a neonatal unit. *Birth*, 30(1), 31-35.
- Frick, P. J. (2016). Current research on conduct disorder in children and adolescents. *South African Journal of Psychology*, 46(2), 160-174. doi:10.1177/0081246316628455
- Fritsch-deBruyn, R., Capalbo, M., Rea, A., & Siano, B. (1990). Cuddler Program provides soothing answers. *Neonatal network: NN*, 8(6), 45-49.
- Fujimaru, C., Okamura, H., Kawasaki, M., Kakuma, T., Yoshii, C., & Matsuishi, T. (2012). Self-perceived work-related stress and its relation to salivary IgA, cortisol and 3-methoxy-4-hydroxyphenyl glycol levels among neonatal intensive care nurses. *Stress and Health*, 28(2), 171-174.
- Gale, G., & Heffron, M. C. (2010). Developmental Care and Infant Mental Health: Essential Strategies for Optimal Social-Emotional Care of NICU Families. In C. Kenner & J. M. McGrath (Eds.), *Developmental care of Newborns and Infants: A Guide for Health Professionals*. Glenview, IL: National Association of Neonatal Nurses (NANN).
- Gibbins, S., Coughlin, M. & Hoath, S. (2010). Quality Indicators: Using the Universe of Developmental Care Model as an Exemplar for Change. In C. M. Kenner, J. M (Eds) (Ed.), *Developmental care of Newborns and Infants: A guide for Health Professionals*. Glenview, IL: National Association of Neonatal Nurses (NANN).
- Gibbins, S., Stevens, B. J., Yamada, J., Dionne, K., Campbell-Yeo, M., Lee, G., . . . Taddio, A. (2014). Validation of the premature infant pain profile-revised (PIPP-R). *Early human development*, 90(4), 189-193.
- Gitau, R., Modi, N., Gianakoulopoulos, X., Bond, C., Glover, V., & Stevenson, J. (2002). Acute effects of maternal skin-to-skin contact and massage on saliva cortisol in preterm babies. *Journal of Reproductive and Infant Psychology*, 20(2), 83-88. doi:10.1080/02646830220134595
- Gitto, E., Pellegrino, S., Manfrida, M., Aversa, S., Trimarchi, G., Barberi, I., & Reiter, R. J. (2012). Stress response and procedural pain in the preterm newborn: the role of

- pharmacological and non-pharmacological treatments. *European journal of pediatrics*, 171(6), 927-933.
- Goines, L. (2008). The importance of quiet in the home: Teaching noise awareness to parents before the infant is discharged from the NICU. *Neonatal Network*, 27(3), 171-176.
- Goldenberg, R. L., Culhane, J. F., Iams, J. D., & Romero, R. (2008). Epidemiology and causes of preterm birth. *The Lancet*, 371, 75-84.
- Goldstein, R. F. (2012). Developmental Care for Premature Infants: A State of Mind. *Pediatrics*, 129(5), e1322-e1323. doi:10.1542/peds.2012-0511
- Goodfriend, M. S. (1993). Treatment of attachment disorder of infancy in a neonatal intensive care unit. *Pediatrics*, 91(1), 139-142.
- Gordon, M. K., Peloso, E., Auken, A., & Dozier, M. (2005). Effect of flavored beverage crystals on salivary cortisol enzyme-immunoreactive assay measurements. *Developmental Psychobiology*, 47(2), 189-195. doi:10.1002/dev.20081
- Goubert, L. (2005). Facing others in pain: the effects of empathy. *Pain (Amsterdam)*, 118(3), 285-288. doi:10.1016/j.pain.2005.10.025
- Grunau, R. E. (2013). Neonatal pain in very preterm infants: long-term effects on brain, neurodevelopment and pain reactivity. *Rambam Maimonides Med J*, 4(4), e0025.
- Grunau, R. E., Haley, D. W., Whitfield, M. F., Weinberg, J., Yu, W., & Thiessen, P. (2007). Altered Basal Cortisol Levels at 3, 6, 8 and 18 Months in Infants Born at Extremely Low Gestational Age. *The Journal of Pediatrics*, 150(2), 151-156.
- Grunau, R. E., Whitfield, M. F., & Petrie, J. (1998). Children's Judgements about Pain at Age 8–10 Years: Do Extremely Low Birthweight ( $\leq 1000$  g) Children Differ from Full Birthweight Peers? *Journal of Child Psychology and Psychiatry*, 39(4), 587-594. doi:10.1111/1469-7610.00354
- Grunau, R. E., Whitfield, M. F., Petrie-Thomas, J., Synnes, A. R., Cepeda, I. L., Keidar, A., . . . Johannesen, D. (2009). Neonatal pain, parenting stress and interaction, in relation to cognitive and motor development at 8 and 18+ months in preterm infants. *Pain*, 143(1-2), 138-146.
- Grunau, R. V., & Craig, K. D. (1987). Pain expression in neonates: facial action and cry. *Pain*, 28(3), 395-410.
- Gunnar, M. R. (1989). Studies of the human infant's adrenocortical response to potentially stressful events. *New Directions for Child and Adolescent Development*, 1989(45), 3-18.

- Gunnar, M. R. (1992). Reactivity of the Hypothalamic-Pituitary-Adrenocortical System to Stressors in Normal Infants and Children. *Pediatrics*, *90*(3), 491-497.
- Gunnar, M. R., Hertsgaard, L., Larson, M., & Rigatuso, J. (1991). Cortisol and behavioral responses to repeated stressors in the human newborn. *Developmental Psychobiology*, *24*(7), 487-505. doi:10.1002/dev.420240704
- Halimaa, S.-L. (2003). Pain management in nursing procedures on premature babies. *Journal of Advanced Nursing*, *42*(6), 587-597. doi:10.1046/j.1365-2648.2003.02662.x
- Hall, F. S. (1998). Social deprivation of neonatal, adolescent, and adult rats has distinct neurochemical and behavioral consequences. *Critical Reviews™ in Neurobiology*, *12*(1-2).
- Hall, R. W., Kronsberg, S. S., Barton, B. A., Kaiser, J. R., & Anand, K. (2005). Morphine, hypotension, and adverse outcomes among preterm neonates: who's to blame? Secondary results from the NEOPAIN trial. *Pediatrics*, *115*(5), 1351-1359.
- Hanrahan, K., McCarthy, A. M., Kleiber, C., Lutgendorf, S., & Tsalikian, E. (2006). Strategies for salivary cortisol collection and analysis in research with children. *Applied Nursing Research*, *19*(2), 95-101.
- Harlow, H. F. (1958). The nature of love. *American Psychologist*, *13*(12), 673.
- Härmä, A., Aikio, O., Hallman, M., & Saarela, T. (2016). Intravenous Paracetamol Decreases Requirements of Morphine in Very Preterm Infants. *The Journal of Pediatrics*, *168*, 36-40. doi:10.1016/j.jpeds.2015.08.003
- Harmon, A. G., Hibel, L. C., Rumyantseva, O., & Granger, D. A. (2007). Measuring salivary cortisol in studies of child development: Watch out—what goes in may not come out of saliva collection devices. *Developmental Psychobiology*, *49*(5), 495-500. doi:10.1002/dev.20231
- Harrison, D., Bueno, M., & Reszel, J. (2015). Prevention and management of pain and stress in the neonate. *Res Rep Neonatol*, *5*, 9-16.
- Harrison, D., Johnston, L., Spence, K., Gillies, D., & Nagy, S. (2005). Salivary cortisol measurements in sick infants: A feasible and objective method of measuring stress? *Journal of Neonatal Nursing*, *11*(1), 10-17.
- Hartling, L., Shaik, M. S., Tjosvold, L., Leicht, R., Liang, Y., & Kumar, M. (2009). Music for medical indications in the neonatal period: a systematic review of randomised controlled trials. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, *94*(5), F349-F354.



- Harvard. (2004). *Young Children Develop in an Environment of Relationships: Working Paper No 1. (National Scientific Council on the Developing Child)*. Retrieved from [www.developingchild.harvard.edu](http://www.developingchild.harvard.edu) .
- Harvard. (2012). *The Science of Neglect: The Persistent Absence of Responsive Care Disrupts the Developing Brain: Working Paper No. 12. (Center on the Developing Child at Harvard University)*. Retrieved from [www.developingchild.harvard.edu](http://www.developingchild.harvard.edu) .
- Hei, M., Gao, X., Gao, X., Nong, S., Zhang, A., Zhang, Q., & Lee, S. K. (2016). Is family integrated care in neonatal intensive care units feasible and good for preterm infants in China: study protocol for a cluster randomized controlled trial. *Trials*, *17*(1), 22.
- Herrington, C. J., Olomu, I. N., & Geller, S. M. (2004). Salivary Cortisol As Indicators of Pain in Preterm Infants. *Clinical Nursing Research*, *13*(1), 53-68.  
doi:10.1177/1054773803259665
- Hinshelwood, R. D. (1998). *A dictionary of Kleinian thought*. London: Free Association Books Ltd.
- Holditch-Davis, D., Bartlett, T. R., Blickman, A. L., & Miles, M. S. (2003). Posttraumatic Stress Symptoms in Mothers of Premature Infants. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, *32*(2), 161-171. doi:10.1177/0884217503252035
- Howard, V. A., & Thurber, F. W. (1998). The interpretation of infant pain: physiological and behavioral indicators used by NICU nurses. *Journal of pediatric nursing*, *13*(3), 164-174.
- Howson, C., Kinney, M., & Lawn, J. (2012). Born too soon: the global action report on preterm birth. *Geneva: World Health Organization*.
- Ivars, K., Nelson, N., Finnström, O., & Mörelius, E. (2012). Nasopharyngeal suctioning does not produce a salivary cortisol reaction in preterm infants. *Acta Paediatrica*, *101*(12), 1206-1210. doi:10.1111/apa.12001
- Jackson, P. L., Brunet, E., Meltzoff, A. N., & Decety, J. (2006). Empathy examined through the neural mechanisms involved in imagining how I feel versus how you feel pain. *Neuropsychologia*, *44*(5), 752-761.
- Jacobson, M. (2013). *Developmental neurobiology*: Springer Science & Business Media.
- James, V. L., & Wheeler, W. E. (1969). The care-by-parent unit. *Pediatrics*, *43*(4), 488-494.
- Janvier, A., Lantos, J., Aschner, J., Barrington, K., Batton, B., Batton, D., . . . Cohn, F. (2016). Stronger and More Vulnerable: A Balanced View of the Impacts of the NICU Experience on Parents. *Pediatrics*, e20160655.

- Jeong, I. S., Park, S. M., Lee, J. M., Choi, Y. J., & Lee, J. (2014). Perceptions on pain management among Korean nurses in neonatal intensive care units. *Asian nursing research, 8*(4), 261-266.
- Jessop, D. S., & Turner-Cobb, J. M. (2008). Measurement and meaning of salivary cortisol: A focus on health and disease in children. *Stress, 11*(1), 1-14.  
doi:10.1080/10253890701365527
- Johnson, E. O., Kamilaris, T. C., Chrousos, G. P., & Gold, P. W. (1992). Mechanisms of stress: a dynamic overview of hormonal and behavioral homeostasis. *Neurosci Biobehav Rev, 16*(2), 115-130.
- Johnston, C., Barrington, K. J., Taddio, A., Carbajal, R., & Filion, F. (2011). Pain in Canadian NICUs: have we improved over the past 12 years? *Clin J Pain, 27*(3), 225-232.
- Johnston, C. C., Filion, F., Snider, L., Limperopoulos, C., Majnemer, A., Pelausa, E., . . . Boyer, K. (2007). How much sucrose is too much sucrose? *Pediatrics, 119*(1), 226-226.
- Johnston, C. C., & Stevens, B. J. (1996). Experience in a Neonatal Intensive Care Unit Affects Pain Response. *Pediatrics, 98*(5), 925-930.
- Johnston, C. C., Stevens, B. J., Franck, L. S., Jack, A., Stremler, R., & Platt, R. (1999). Factors Explaining Lack of Response to Heel Stick in Preterm Newborns. *Journal of Obstetric, Gynecologic, & Neonatal Nursing, 28*(6), 587-594. doi:10.1111/j.1552-6909.1999.tb02167.x
- Johnston, C. C., Stevens, B. J., Yang, F., & Horton, L. (1995). Differential response to pain by very premature neonates. *Pain, 61*(3), 471-479.
- Kawakami, K., Takai-Kawakami, K., Kurihara, H., Shimizu, Y., & Yanaihara, T. (1996). The effect of sounds on newborn infants under stress. *Infant Behavior and Development, 19*(3), 375-379.
- Keels, E., Sethna, N., Watterberg, K. L., Cummings, J. J., Benitz, W. E., Eichenwald, E. C., . . . Goldsmith, J. P. (2016). Prevention and Management of Procedural Pain in the Neonate: An Update. *Pediatrics, 137*(2), 1-13.
- Kelly, K., Slade, A., & Grienberger, J. F. (2005). Maternal reflective functioning, mother–infant affective communication, and infant attachment: Exploring the link between mental states and observed caregiving behavior in the intergenerational transmission of attachment. *Attachment & Human Development, 7*(3), 299-311.  
doi:10.1080/14616730500245963

- Kenner, C., & McGrath, J. M. (2004). *Developmental Care of Newborns and Infants: A Guide for Health Professionals*. St Louis, MO (USA): Mosby.
- Kenner, C., & McGrath, J. M. (2010). *Developmental Care of Newborns and Infants: A Guide for Health Professionals (2nd Ed)*. Glenview, IL: National Association of Neonatal Nurses (NANN).
- Kiess, W., Meidert, A., Dressendorfer, R., Schriever, K., Kessler, U., König, A., . . . Strasburger, C. (1995). Salivary cortisol levels throughout childhood and adolescence: relation with age, pubertal stage, and weight. *Pediatric Research*, *37*(4), 502-506.
- Kirschbaum, C., Pirke, K.-M., & Hellhammer, D. H. (1993). The 'Trier Social Stress Test'—a tool for investigating psychobiological stress responses in a laboratory setting. *Neuropsychobiology*, *28*(1-2), 76-81.
- Kitamura, C., & Lam, C. (2009). Age-specific preferences for infant-directed affective intent. *Infancy*, *14*(1), 77-100.
- Kleberg, A., Warren, I., Norman, E., Morelius, E., Berg, A.-C., Mat-Ali, E., . . . Hellstrom-Westas, L. (2008). Lower Stress Responses After Newborn Individualized Developmental Care and Assessment Program Care During Eye Screening Examinations for Retinopathy of Prematurity: A Randomized Study. *Pediatrics*, *121*(5), e1267-1278. doi:10.1542/peds.2006-2510
- Klein, M. (1975). 'Some theoretical conclusions regarding the emotional life of the infant (1952)' *Envy and Gratitude and Other Works 1946-1963*. London: Hogarth Press.
- Klein, M. (1997). *Envy and Gratitude and Other Works 1946-1963*. London: Vintage Books.
- Knitzer, J. (2000). Early childhood mental health services: A policy and systems development perspective. *Handbook of early childhood intervention*, *2*, 416-438.
- Kocak, M., Wilcox, R., Crank, C., & Patra, K. (2016). Evaluation of the relationship between opioid exposure in extremely low birth weight infants in the neonatal intensive care unit and neurodevelopmental outcome at 2 years. *Early human development*, *92*, 29-32.
- Korja, R., Latva, R., & Lehtonen, L. (2012). The effects of preterm birth on mother–infant interaction and attachment during the infant's first two years. *Acta obstetrica et gynecologica Scandinavica*, *91*(2), 164-173.
- Landon-Malone, K. (2005). A Holistic Approach to Neonatal Resuscitation. *Journal of Prenatal & Perinatal Psychology & Health*, *20*(1), 77.

- Legendre, V., Burtner, P. A., Martinez, K. L., & Crowe, T. K. (2011). The Evolving Practice of Developmental Care in the Neonatal Unit: A Systematic Review. *Physical & Occupational Therapy in Pediatrics, 31*(3), 315-338.  
doi:doi:10.3109/01942638.2011.556697
- Lewis, J. G., Manley, L., Whitlow, J. C., & Elder, P. A. (1992). Production of a monoclonal antibody to cortisol: application to a direct enzyme-linked immunosorbent assay of plasma. *Steroids, 57*(2), 82-85.
- Lewis, M., Ramsay, D. S., & Kawakami, K. (1993). Differences between Japanese Infants and Caucasian American Infants in Behavioral and Cortisol Response to Inoculation. *Child development, 64*(6), 1722-1731. doi:10.2307/1131465
- Lewis, M., & Thomas, D. (1990). Cortisol Release in Infants in Response to Inoculation. *Child development, 61*(1), 50-59. doi:10.2307/1131046
- Lickliter, R. (2011). The integrated development of sensory organization. *Clinics in perinatology, 38*(4), 591-603.
- Liew, Z., Ritz, B., Rebordosa, C., Lee, P.-C., & Olsen, J. (2014). Acetaminophen use during pregnancy, behavioral problems, and hyperkinetic disorders. *JAMA pediatrics, 168*(4), 313-320.
- Liu, W., Laudert, S., Perkins, B., MacMillan-York, E., Martin, S., & Graven, S. (2007). The development of potentially better practices to support the neurodevelopment of infants in the NICU. *Journal of Perinatology, 27*, S48-S74.
- Ljusegren, G., Johansson, I., Gimbler Berglund, I., & Enskär, K. (2012). Nurses' experiences of caring for children in pain. *Child: care, health and development, 38*(4), 464-470.
- Lutes, L., Graves, C. D., & Jorgensen, K. M. (2004). The NICU experience and its relationship to sensory integration. In C. Kenner & J. M. McGrath (Eds.), *Developmental care of newborns and infants: A guide for health professionals*. St Louis, MO: Mosby.
- Magnano, C. L., Diamond, E. J., & Gardner, J. M. (1989). Use of Salivary Cortisol Measurements in Young Infants: A Note of Caution. *Child development, 60*(5), 1099-1101. doi:10.2307/1130784
- Malloch, S., Shoemark, H., Crncec, R., Newnham, C., Paul, C., & Prior, M. (2012). Music therapy with hospitalised infants—the art and science of intersubjectivity. *Infant Mental Health Journal, 33*, 386-399.
- Malloch, S., & Trevarthen, C. (2009). *Communicative musicality: Exploring the basis of human companionship*: Oxford University Press, USA.

- Malloch, S. N. (2000). Mothers and infants and communicative musicality. *Musicae scientiae*, 3(1 suppl), 29-57.
- Mares, S., Newman, L. K., & Warren, B. (2011). *Clinical Skills in Infant Mental Health: the first three years*. Victoria, Australia: Aust Council for Ed Research.
- McIntosh, N., Van Veen, L., & Brameyer, H. (1993). The pain of heel prick and its measurement in preterm infants. *Pain*, 52(1), 71-74.
- McIntosh, N., Van Veen, L., & Brameyer, H. (1994). Alleviation of the pain of heel prick in preterm infants. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, 70(3), F177-F181.
- Melzack, R., & Wall, P. D. (1996). Pain mechanisms: A new theory: A gate control system modulates sensory input from the skin before it evokes pain perception and response. *Pain Forum*, 5(1), 3-11.
- Miles, M. S., Holditch-Davis, D., Schwartz, T. A., & Scher, M. (2007). Depressive symptoms in mothers of prematurely born infants. *Journal of Developmental & Behavioral Pediatrics*, 28(1), 36-44.
- Milford, C. A., & Zapalo, B. J. (2010). The NICU Experience and its Relationship to Sensory Integration. In C. Kenner & J. M. McGrath (Eds.), *Developmental Care of Newborns and Infants: A Guide for Health Professionals (2nd Ed)*. Glenview, IL: National Association of Neonatal Nurses (NANN).
- Mitchell, A. J., Chang, Jason., Yates, C., Hall, Richard W. (2012). Challenges, Guidelines, and Systematic Review of Salivary Cortisol Research in Preterm Infants. *e-Journal of Neonatology Research*, 2(1).
- Modi, N. (1994). Clinical trials and neonatal intensive care. *Archives of Disease in Childhood Fetal and Neonatal edition*, 70(3), F231.
- MOH. (2012). *Healthy Beginnings: Developing Perinatal and Infant Mental Health Services in New Zealand*. Retrieved from Wellington:
- MOH. (2015). *Report on Maternity 2014*. Retrieved from [www.moh.govt.nz](http://www.moh.govt.nz) :
- Monnot, M. (1999). Function of infant-directed speech. *Human nature*, 10(4), 415-443.
- Mörelus, E., Theodorsson, E., & Nelson, N. (2005). Salivary cortisol and mood and pain profiles during skin-to-skin care for an unselected group of mothers and infants in neonatal intensive care. *Pediatrics*, 116(5), 1105-1113.

- Murray, L., Halligan, S., & Cooper, P. (2010). Effects of postnatal depression on mother–infant interactions and child development. *Wiley-Blackwell Handbook of Infant Development, The, Volume 2, Second Edition*, 192-220.
- Murray, L., & Trevarthen, C. (1985). Emotional regulation of interaction between two-month-olds and their mothers. In T. Field & N. Fox (Eds.), *Social perception in infants* (pp. 101-125). Norwood, NJ: Ablex.
- Murray, L. A., Liz. (2007). *The Social Baby: Understanding Babies' Communication from Birth*. Richmond, U.K.: CP Publishing.
- Nandi, R., & Fitzgerald, M. (2005). Opioid analgesia in the newborn. *European Journal of Pain*, 9(2), 105-108.
- Nelson, N., Arbring, K. & Theodorsson, E. (2001). Neonatal salivary cortisol in response to heelstick: method modifications enable analysis of low concentrations and small sample volumes. *Scandinavian Journal of Clinical & Laboratory Investigation*, 61(4), 287-291. doi:10.1080/00365510152379012
- Nightingale, F. (1863). *Notes on hospitals*: Longman, Green, Longman, Roberts, and Green.
- Nimbalkar, S. M., Chaudhary, N. S., Gadhavi, K. V., & Phatak, A. (2013). Kangaroo mother care in reducing pain in preterm neonates on heel prick. *The Indian Journal of Pediatrics*, 80(1), 6-10.
- Noether, G. E. (1987). Sample size determination for some common nonparametric tests. *Journal of the American Statistical Association*, 82(398), 645-647.
- Norman, J. (2001). The Psychoanalyst and the Baby: A new look at work with infants. *International Journal of Psychoanalysis*, 82(1), 83-100.
- O'Brien, K., Bracht, M., Macdonell, K., McBride, T., Robson, K., O'Leary, L., . . . Levin, A. (2013). A pilot cohort analytic study of Family Integrated Care in a Canadian neonatal intensive care unit. *BMC pregnancy and childbirth*, 13(1), S12.
- O'Brien, K., Bracht, M., Robson, K., Xiang, Y. Y., Mirea, L., Cruz, M., . . . Alvaro, R. (2015). Evaluation of the Family Integrated Care model of neonatal intensive care: a cluster randomized controlled trial in Canada and Australia. *BMC pediatrics*, 15(1), 210.
- Ogden, T. (1992). *The Matrix of the Mind. Object Relations and the Psychoanalytic Dialogue*. London: H. Karnac (Books) Inc.
- Ohlsson, A., & Jacobs, S. E. (2013). NIDCAP: A Systematic Review and Meta-analyses of Randomized Controlled Trials. *Pediatrics*, 131(3), e881-e893. doi:10.1542/peds.2012-2121

- Oliver, R. J. M. (2000). The ideal cesarean birth. *Journal of Prenatal & Perinatal Psychology & Health*, 14(3/4), 331.
- Pacifici, G. M. (2016). Metabolism and pharmacokinetics of morphine in neonates: A review. *Clinics*, 71(8), 474-480.
- Panksepp, J. (1998). *Affective neuroscience: The foundations of human and animal emotions*: Oxford university press.
- Perry, B. D., Pollard, R. A., Blakley, T. L., Baker, W. L., & Vigilante, D. (1995). Childhood trauma, the neurobiology of adaptation, and use dependent development of the brain: How states become traits. *Infant mental health journal*, 16(4), 271-291.
- Pillai Riddell, R. R., Racine, N. M., Turcotte, K., & Uman, L. S. (2011). Non-pharmacological management of infant and young child procedural pain. *Cochrane database of systematic reviews*(10), CD006275. doi:10.1002/14651858.CD006275.pub2
- Porter, F. L., Grunau, R. E., & Anand, K. J. (1999). Long-term effects of pain in infants. *Journal of developmental and behavioral pediatrics : JDBP*, 20(4), 253.
- Porter, F. L., Miller, R. H., & Marshall, R. E. (1986). Neonatal Pain Cries: Effect of Circumcision on Acoustic Features and Perceived Urgency. *Child development*, 57(3), 790-802.
- Pozzi-Monzo, M. (2007). *Innovations in Parent-Infant Psychotherapy*. London: Karnac Books Ltd.
- Prechtl, H. F. (1974). The behavioural states of the newborn infant (a review). *Brain research*, 76(2), 185-212.
- Price, D. A., Close, G. C., & Fielding, B. A. (1983). Age of appearance of circadian rhythm in salivary cortisol values in infancy. *Archives of Disease in Childhood*, 58(6), 454-456. doi:10.1136/adc.58.6.454
- Prkachin, K. M., Solomon, P. E., & Ross, J. (2007). Underestimation of Pain by Health-Care Providers: Towards a Model of the Process of Inferring Pain in Others. *CJNR (Canadian Journal of Nursing Research)*, 39(2), 88-106.
- Provenzi, L., Giusti, L., Fumagalli, M., Tasca, H., Ciceri, F., Menozzi, G., . . . Montirosso, R. (2016). Pain-related stress in the Neonatal Intensive Care Unit and salivary cortisol reactivity to socio-emotional stress in 3-month-old very preterm infants. *Psychoneuroendocrinology*, 72, 161-165.
- Ramsay, D. S., & Lewis, M. (1995). The Effects of Birth Condition on Infants' Cortisol Response to Stress. *Pediatrics*, 95(4), 546-549.

- Razali, N. M., & Wah, Y. B. (2011). Power comparisons of shapiro-wilk, kolmogorov-smirnov, lilliefors and anderson-darling tests. *Journal of Statistical Modeling and Analytics*, 2(1), 21-33.
- Reddy, V., & Trevarthen, C. (2004). What we learn about babies from engaging their emotions. *Zero to Three*, 24(3), 9-15.
- Rennie, J. M. (2012). *Rennie & Robertson's textbook of neonatology*: Elsevier Health Sciences.
- Reynolds, L. C., Crapnell, T., Zarem, C., Madlinger, L., Tiltges, L., Lukas, K., & Pineda, R. G. (2013). Nursing Perceptions of Clinical Research in the Neonatal Intensive Care Unit. *Newborn and Infant Nursing Reviews*, 13(2), 62-66. doi: 10.1053/j.nainr.2013.04.002
- Robins, J. (2007). "Post code ouch": A survey of neonatal pain management prior to painful procedures within the United Kingdom. *Journal of Neonatal Nursing*, 13(3), 113-117.
- Roofthoof, D. W., Simons, S. H., Anand, K. J., Tibboel, D., & van Dijk, M. (2014). Eight years later, are we still hurting newborn infants? *Neonatology*, 105(3), 218-226.
- Rycroft-Malone, J., Harvey, G., Seers, K., Kitson, A., McCormack, B., & Titchen, A. (2004). An exploration of the factors that influence the implementation of evidence into practice. *Journal of clinical nursing*, 13(8), 913-924.
- Saint-Georges, C., Chetouani, M., Cassel, R., Apicella, F., Mahdhaoui, A., Muratori, F., . . . Cohen, D. (2013). Motherese in interaction: at the cross-road of emotion and cognition? (A systematic review). *PloS one*, 8(10), e78103.
- Salmon, K., McGuigan, F., & Pereira, J. K. (2006). Brief Report: Optimizing Children's Memory and Management of an Invasive Medical Procedure: The Influence of Procedural Narration and Distraction. *Journal of Pediatric Psychology*, 31(5), 522-527. doi:10.1093/jpepsy/jsj081
- Salomonsson, B. (2010). *Baby Worries: A randomised controlled trial of mother-infant psychoanalytic treatment*. Karolinska Institutet, Stockholm.
- Schneider, E. M., & LoBiondo-Wood, G. (1992). Perceptions of procedural pain: parents, nurses, and children. *Children's Health Care*, 21(3), 157-162.
- Schore, A., N. (1996). The experience-dependent maturation of a regulatory system in the orbital prefrontal cortex and the origin of developmental psychopathology. *Development and Psychopathology*, 8, 59-87.
- Schwartz, E. B., Granger, D. A., Susman, E. J., Gunnar, M. R., & Laird, B. (1998). Assessing Salivary Cortisol in Studies of Child Development. *Child development*, 69(6), 1503-1513. doi:10.1111/j.1467-8624.1998.tb06173.x



- Shapiro, S. S., & Wilk, M. B. (1965). An analysis of variance test for normality (complete samples). *Biometrika*, 52(3/4), 591-611.
- Shoemark, H. (2006). Infant-directed Singing as a Vehicle for Regulation Rehearsal in the Medically Fragile Full-term Infant (Vol. 17, pp. 54-63): *Australian Journal of Music Therapy*.
- Singer, T., Seymour, B., O'doherty, J., Kaube, H., Dolan, R. J., & Frith, C. D. (2004). Empathy for pain involves the affective but not sensory components of pain. *Science*, 303(5661), 1157-1162.
- Sizun, J., & Browne, J. V. (2005). *Research on early developmental care for preterm neonates*. Paris: John Libby Eurotext.
- Spasojevic, S., & Bregun-doronjski, A. (2011). A simultaneous comparison of four neonatal pain scales in clinical settings. *The Journal of Maternal-Fetal & Neonatal Medicine*, 24(4), 590-594.
- Spillius, E. B., Milton, J., Garvey, P., Couve, C., & Steiner, D. (2011). *The new dictionary of Kleinian thought*: Taylor & Francis.
- Standley, J. (2012). Music therapy research in the NICU: an updated meta-analysis. *Neonatal Network*, 31(5), 311-316.
- Stern, D. N. (1971). A micro-analysis of mother-infant interaction. Behaviour regulating social contact between a mother and her 3-month-old twins. *Journal of the American Academy of Child Psychiatry*, 10(3), 501-517.
- Stern, D. N. (1985). Affect Attunement. In J. D. Call, E. Galenson, & R. L. Tyson (Eds.), *Frontiers of Infant Psychiatry*. New York: Basic Books.
- Stevens, B., Johnston, C., Franck, L., Petryshen, P., Jack, A., & Foster, G. (1999). The efficacy of developmentally sensitive interventions and sucrose for relieving procedural pain in very low birth weight neonates. *Nursing research*, 48(1), 35.
- Stevens, B., Johnston, C., Petryshen, P., & Taddio, A. (1996). Premature Infant Pain Profile: Development and Initial Validation. *Clin J Pain*, 12(1), 13-22.
- Stevens, B., Johnston, C., Taddio, A., Gibbins, S., & Yamada, J. (2010). The premature infant pain profile: evaluation 13 years after development. *Clin J Pain*, 26(9), 813-830.
- Stevens, B., Johnston, C., Taddio, A., Jack, A., Narciso, J., Stremmler, R., . . . Aranda, J. (1999). Management of pain from heel lance with lidocaine-prilocaine (EMLA) cream: is it safe and efficacious in preterm infants? *Journal of Developmental & Behavioral Pediatrics*, 20(4), 216-221.

- Stevens, B., McGrath, P., Gibbins, S., Beyene, J., Breau, L., Camfield, C., . . . McKeever, P. (2003). Procedural pain in newborns at risk for neurologic impairment. *Pain, 105*(1), 27-35.
- Stevens, B., Yamada, J., Ohlsson, A., Haliburton, S., & Shorkey, A. (2016). Sucrose for analgesia in newborn infants undergoing painful procedures. *The Cochrane Library*.
- Stevens, B. J., Abbott, L. K., Yamada, J., Harrison, D., Stinson, J., Taddio, A., . . . Finley, G. A. (2011). Epidemiology and management of painful procedures in children in Canadian hospitals.(Research)(Report). *CMAJ: Canadian Medical Association Journal, 183*(7), E403.
- Stevens, B. J., Gibbins, S., Yamada, J., Dionne, K., Lee, G., Johnston, C., & Taddio, A. (2014). The premature infant pain profile-revised (PIPP-R): initial validation and feasibility. *Clin J Pain, 30*(3), 238-243.
- Stickley, T., & Freshwater, D. (2002). The art of loving and the therapeutic relationship. *Nursing Inquiry, 9*(4), 250-256. doi:10.1046/j.1440-1800.2002.00155.x
- Stone, L. (1973). Introduction to the capabilities of the newborn. *The Competent Infant. New York, Basic Books, 239-253*.
- Strazdins, L., Meyerkort, S., Brent, V., D'Souza, R. M., Broom, D. H., & Kyd, J. M. (2005). Impact of saliva collection methods on sIgA and cortisol assays and acceptability to participants. *Journal of Immunological Methods, 307*(1), 167-171. doi:10.1016/j.jim.2005.09.010
- Szejer, M. (2005). *Talking to Babies: Healing with Words on a Maternity Ward*. Boston: Beacon Press.
- Teske, K., Daut, R. L., & Cleeland, C. S. (1983). Relationships between nurses' observations and patients' self-reports of pain. *Pain, 16*(3), 289-296.
- Thompson, J. M., Waldie, K. E., Wall, C. R., Murphy, R., Mitchell, E. A., & ABC Study Group. (2014). Associations between acetaminophen use during pregnancy and ADHD symptoms measured at ages 7 and 11 years. *PLoS one, 9*(9), e108210.
- Thomson-Salo, F. (2007). Recognizing the infant as subject in infant-parent psychotherapy. *International Journal of Psychoanalysis, 88*(4), 961-979. doi:10.1516/d67x-384k-9888-210j
- Trevarthen, C. (1977). Descriptive analyses of infant communicative behavior. In H. R. Schaffer (Ed.), *Studies in mother-infant interaction* (pp. 227-270). New York: Academic Press.

- Trevarthen, C. (2000). Musicality and the intrinsic motive pulse: evidence from human psychobiology and infant communication. *Musicae scientiae*, 3(1 suppl), 155-215.
- Trevarthen, C. (2001). Intrinsic motives for companionship in understanding: Their origin, development, and significance for infant mental health. *Infant Mental Health Journal*, 22(1-2), 95-131. doi:10.1002/1097-0355(200101/04)22:1<95::aid-imhj4>3.0.co;2-6
- Trevarthen, C., & Aitken, K. J. (2001). Infant Intersubjectivity: Research, Theory, and Clinical Applications. *Journal of Child Psychology and Psychiatry*, 42(1), 3-48.  
doi:10.1111/1469-7610.00701
- Tronick, E. Z. (1989). Emotions and emotional communication in infants. *American psychologist*, 44(2), 112.
- Twohig, A., Reulbach, U., Figuerdo, R., McCarthy, A., McNicholas, F., & Molloy, E. J. (2016). Supporting Preterm Infant Attachment and Socioemotional Development in the Neonatal Intensive Care Unit: Staff Preceptions. *Infant mental health journal*, 37(2), 160-171.
- van den Anker, J. N., & Allegaert, K. (2016). Treating Pain in Preterm Infants: Moving from Opioids to Acetaminophen. *The Journal of pediatrics*, 168, 13.
- van Ijzendoorn, M., & Fox, N. (1995). Adult attachment representations, parental responsiveness, and infant attachment: A meta-analysis on the predictive validity of the adult attachment interview. *Psychological Bulletin*, 117(3), 387.
- van Mol, M. M., Kompanje, E. J., Benoit, D. D., Bakker, J., & Nijkamp, M. D. (2015). The prevalence of compassion fatigue and burnout among healthcare professionals in intensive care units: a systematic review. *PloS one*, 10(8), e0136955.
- van Rees, S., & de Leeuw, R. (1993). Born too early: the Kangaroo method with premature babies. *Video by Stichting Lichaamstaal, Scheyvenhofweg*, 12, 6093.
- Vanier, C. (2015). *Premature Birth: The Baby, the Doctor and the Psychoanalyst*. London: Karnac Books.
- Ventegodt, S., & Merrick, J. (2004). Clinical Holistic Medicine: Applied Consciousness-Based Medicine. *The Scientific World Journal*, 4, 96-99. doi:10.1100/tsw.2004.8
- Walden, M., & Carrier, C. (2009). The ten commandments of pain assessment and management in preterm neonates. *Critical care nursing clinics of North America*, 21(2), 235-252.

- Weatherston, D. J., & Guy, D. (2015). Infant Mental Health - The Gift of Love. Retrieved from <http://www.tepou.co.nz/resources/iimhl-video-series-infant-mental-health---the-gift-of-love/634>
- Westrup, B., Sizun, J., & Lagercrantz, H. (2007). Family-centered developmental supportive care: a holistic and humane approach to reduce stress and pain in neonates. *J Perinatol*, 27(S1), S12-S18.
- Whipple, J. (2008). The effect of music-reinforced nonnutritive sucking on state of preterm, low birthweight infants experiencing heelstick. *Journal of Music Therapy*, 45(3), 227-272.
- White, R. D. (2011). The Newborn Intensive Care Unit Environment of Care: How We Got Here, Where We're Headed, and Why. *Seminars in Perinatology*, 35(1), 2-7. doi:10.1053/j.semperi.2010.10.002
- White-Traut, R. C., Dols, J. & McGrath, J.M. (2010). Touch and Massage for High-Risk Infants. In C. M. Kenner, J. M (Eds) (Ed.), *Developmental Care of Newborns and Infants: A Guide for Health Professionals*. Glenview, IL: National Association of Neonatal Nurses (NANN).
- White-Traut, R. C., Nelson, M. N., Silvestri, J. M., Cunningham, N., & Patel, M. (1997). Responses of preterm infants to unimodal and multimodal sensory intervention. *Pediatric Nursing*, v23(n2), p169(168).
- White-Traut, R. C., Nelson, M. N., Silvestri, J. M., Vasan, U., Littau, S., Meleedy-Rey, P., . . . Patel, M. (2002). Effect of auditory, tactile, visual, and vestibular intervention on length of stay, alertness, and feeding progression in preterm infants. *Developmental Medicine & Child Neurology*, 44(02), 91-97.
- White-Traut, R. C., Rankin, K. M., Yoder, J. C., Liu, L., Vasa, R., Geraldo, V., & Norr, K. F. (2015). Influence of H-HOPE intervention for premature infants on growth, feeding progression and length of stay during initial hospitalization. *J Perinatol*, 35(8), 636-641. doi:10.1038/jp.2015.11
- White-Traut, R. C., Schwertz, D., McFarlin, B., & Kogan, J. (2009). Salivary Cortisol and Behavioral State Responses of Healthy Newborn Infants to Tactile-Only and Multisensory Interventions. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, 38(1), 22-34. doi:10.1111/j.1552-6909.2008.00307.x

- White-Traut, R. (2004). Providing a nurturing environment for infants in adverse situations: multisensory strategies for newborn care. *Journal of Midwifery & Women's Health*, 49(S1), 36-41.
- Winnicott, D. (1988). 'The Ordinary Devoted Mother'. In D. W. Winnicott, C. Winnicott, & R. Shepherd (Eds.), *Babies and their Mothers*. London: Free Association Books.
- Winnicott, D. (1990). Ego distortion in terms of true and false self (1960). In D. W. Winnicott (Ed.), *The Maturation Processes and the Facilitating Environment: Studies in the Theory of Emotional Development*. London: Karnac Books Ltd.
- Zeedyk, M. S. (2008). *Promoting social interaction for individuals with communicative impairments: Making contact*: Jessica Kingsley Publishers.
- ZerotoThree. (2016). National Center for Infants, Toddlers and Families. Retrieved from [www.zerotothree.org](http://www.zerotothree.org)
- Zwicker, J. G., Miller, S. P., Grunau, R. E., Chau, V., Brant, R., Studholme, C., . . . Stiver, M. L. (2016). Smaller cerebellar growth and poorer neurodevelopmental outcomes in very preterm infants exposed to neonatal morphine. *The Journal of pediatrics*, 172, 81-87. e82.

## APPENDICES

### ***Appendix I: Publications arising from this research***

- (A) This paper was published in the Neonatal, Paediatric and Child Health Nursing Journal in November 2012, it derived from the literature review in chapter two of this thesis. It was co-authored by D Elder, the primary supervisor for this research programme. L Zwimpfer researched the topic and prepared the manuscript, while D Elder provided critical revision of the manuscript.
- (B) This chapter, authored by L Zwimpfer, was published in a book 'Surviving the Early Years: The Importance of Early Intervention with Babies at Risk', edited by Dr Stella Acquarone and published in 2016.
- (C) This is an abstract for an oral presentation given at the combined 17th Congress of the Federation of Asian and Oceania Perinatal Societies (FAOPS) and the 16th Annual Congress of the Perinatal Society of Australia and New Zealand (PSANZ), held in Sydney, Australia in March 2012. It presents the results of the first baseline study, described in chapter four.

### ***Appendix II: Research protocol for heel prick procedures and pain measures***

- (D) Research protocol for heel prick procedures. This protocol was followed by all NICU nurses administering heel prick procedures during the feasibility study and the main study.
- (E) Premature Infant Pain Profile (PIPP) scoring sheet
- (F) Premature Infant Pain Profile–Revised (PIPP-R) scoring sheet

### ***Appendix III: Cultural consultation***

- (G) The University of Otago's Ngai Tahu Research Consultation Committee approval for this programme of study.
- (H) Approval for this programme of study from the Wellington based Research Advisory Group- Maori (RAG-M).

### ***Appendix IV: Ethical Approval***

- (I) Ethical approval from the Central Regional Ethics Committee for the Heel Prick Observational study described in Chapter four.
- (J) Ethical approval from the Central Health and Disability Ethics Committee for the Nappy Change Observational study described in Chapter five.
- (K) Ethical approval from the Central Regional Ethics Committee for the Feasibility study described in Chapter six.
- (L) Ethical approval from the Central Regional Ethics Committee for the Saliva Volume study described in Chapter six.

- (M) Ethical approval from the Central Health and Disability Ethics Committee for the main 'Talking to Babies' study described in Chapter seven.

***Appendix V: Information sheets and consent forms***

- (N) Information sheet and consent form for parents of infants in the Feasibility study.
- (O) Information sheet and consent form for NICU Nurses in the Feasibility study.
- (P) Information sheet and consent form for parents of infants in the Saliva Volume study
- (Q) Information sheet and consent form for parents of infants in the main 'Talking to Babies' study.

***Appendix VI: Summary of study results for participants***

- (R) Summary of study results sent to parents of infants and Nurses in the Feasibility study.
- (S) Summary of results sent to parents of infants in the Saliva Volume study.
- (T) Summary of results sent to parents of infants in the main 'Talking to Babies' study.

***Appendix VII: Data from the main 'Talking to babies' study***

- (U) Tests for Normality: Salivary Cortisol, Heart Rate and Oxygen Saturation data.
- (V) Tests for Normality: PIPP-R data
- (W) Means and Standard Deviations for salivary cortisol based on log transformed data are presented here as they may be of interest to other researchers.

## ***APPENDIX I: PUBLICATIONS ARISING FROM THIS RESEARCH***

- (A) This paper was published in the Neonatal, Paediatric and Child Health Nursing Journal in November 2012, it derived from the literature review in chapter two of this thesis. It was co-authored by D Elder, the primary supervisor for this research programme. L Zwimpfer researched the topic and prepared the manuscript, while D Elder provided critical revision of the manuscript.



# Talking to and being with babies: the nurse–infant relationship as a pain management tool

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## Abstract

**Introduction** The field of infant mental health stresses the importance of attuned caregiver–infant interactions for the development of healthy emotional regulatory capacities in infants.

**Background** "Talking to" and "being with" infants as part of their neonatal care has been identified as an important aspect of pain management. However, the use of the voice and emotional presence alone have not been widely studied.

**The thesis of this paper** Talk and emotional presence are key elements of the psychoanalytic approach to managing psychic pain. Some of the tools of the analyst–infant relationship may be useful for nurses to use with infants during painful and stressful procedures.

**Discussion** We propose a model of nurse vocal soothing that may be an effective non-pharmacological pain management technique in the neonatal intensive care unit (NICU). If a nurse is to offer their voice and emotional presence to an infant during a procedure as a pain management tool, they need to be in an attuned state, thinking about the infant and "being with" the infant emotionally.

**Conclusion** This discussion paper considers the rationale for investigating the effectiveness of attuned, empathic vocal soothing on preterm infant stress.

**Implications for clinical practice** If attuned, empathic vocal soothing is found to be an effective mitigator of preterm infant stress then this will provide evidence for a relationship-based, non-pharmacological, cost-effective intervention that would enable the infant's emotional needs to be met more effectively in the NICU.

**Keywords** Neonatal nursing, relationship-based care, procedural pain management, vocal soothing, empathy, psychoanalysis.

### What is known about this topic

- Talking to infants and offering them a human presence during painful procedures has been identified in the medical literature as being important to neonatal care.

### What this paper adds

- This paper offers a psychoanalytic viewpoint of the nurse–infant relationship, specifically the aspects of "talking to" and "being with" babies. A model of attuned vocal soothing as a pain management tool during painful procedures is proposed.

## Declarations

**Competing interests** Nil.

**Funding** Nil.

**Ethical approval** Not applicable.

**Guarantor** LZ

**Contributorship** LZ – main composition of the manuscript, DE – critical revision of the manuscript and supervisor of PhD project.

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## Introduction

Infant exposure to pain and stress is associated with adverse physical and emotional outcomes<sup>1–5</sup> and later behavioural and emotional problems<sup>2</sup>. Preterm infants are not exempt. For infants born at or less than 32 weeks gestation, poorer cognition and motor function at 8 and 18 months is independently associated with the number of exposures to skin-breaking procedures during their time in the neonatal unit<sup>6</sup>. For these reasons, researchers and clinicians have sought to develop effective pharmacological and non-pharmacological methods to manage pain for preterm infants<sup>7</sup>.

The field of infant mental health, with its focus on infant research, neuroscience and relationship-based interventions, stresses the importance of attuned caregiver–infant interactions for the development of healthy emotional regulatory capacities in infants.

"Talking to" and "being with" infants as part of their neonatal care has been identified as an important aspect of pain management<sup>8,9</sup>. However, although the use of non-pharmacological strategies for managing infant pain is well established, the use of the voice alone has not been as widely studied.

"Talking to" and "being with" infants are key aspects of the parent–infant relationship and also of the analyst–infant relationship in some parent–infant psychotherapies<sup>10–12</sup>. This paper will discuss the importance of relationships for infant development and suggest that knowledge gained from the exploration of psychoanalytic treatment for infants may be useful for the nurse–infant relationship in the neonatal intensive care unit (NICU). A model of nurse vocal soothing will be presented, which is underpinned by the psychoanalytic concept of *containment*.

## Background

### The importance of relationships

There is good evidence available that relationships with adults are critical to facilitate the growth of healthy infant brains that are able to manage stress<sup>13</sup>. It is in moments of stress that the infant most needs the support of an adult caregiver to help them regulate their emotional state. When infants are attended to and soothed by an adult caregiver, their ability to do this for themselves is facilitated through development of the neural pathways for emotional regulation. When this does not happen, the infant is at risk of adverse mental health sequelae later in life<sup>13</sup>. Emotional regulation thus depends on having an emotionally available adult who can tune in and communicate with the infant. Because the NICU is increasingly being seen as a place not just for the physical care of the infant, but also their emotional and developmental care, relationship-based care practices have been developed and are now a routine component of neonatal care in many units<sup>14</sup>.

### Relationship-based care in the NICU

Relationship-based care practices in the NICU include the Neonatal Individualized Care and Assessment Programme (NIDCAP) and infant-led singing. The NIDCAP approach focuses on planning individualised care based on observations of the infant's behaviour, thereby recognising the infant as a person with goals and facilitating the development of a caregiver relationship with the infant<sup>15</sup>. Numerous studies have now been published reporting favourable outcomes for infants using this approach<sup>16–18</sup>. It is, however, an expensive programme to implement fully<sup>18</sup>.

Infant-led singing is an approach in which the infant is offered improvised, infant-led singing, within an attuned relationship, to facilitate self and mutual regulation<sup>19</sup>. The spontaneous nature of the singing means that the therapist is led by the infant's immediate responses and aims to connect with the infant's emotional experience<sup>19</sup>. This is seen to be particularly important given the hospital experience being largely non-contingent with the infant's psychological needs<sup>19</sup>.

The unifying philosophy of these approaches is that the infant is regarded as an individual with emotional as well as physical needs. Relationship-based care practices, such as sensorial saturation, have also been shown to be effective in managing pain and stress<sup>9</sup>. The aim of sensorial saturation is to distract the infant's senses so that pain has less chance of being perceived centrally<sup>20</sup>. Bellieni and colleagues have studied the effectiveness of sensorial saturation extensively and have refined the technique in the "Triple T intervention" using touch, taste and talk as the distractors<sup>9</sup>. This technique has been shown to be effective in reducing behavioural and physiological expressions of neonatal pain<sup>9</sup>.

In reviewing this approach, Bellieni found that the "taste" intervention, oral glucose, was the critical component of their distraction intervention and without this component found touch and talk alone were ineffective<sup>21</sup>. A caveat to this finding is that the measures they used were purely behavioural. It would have been interesting to examine whether effects on physiological measures such as heart rate variability, respiratory rate and variability or salivary cortisol may have been demonstrated in the absence of a behavioural effect. Also the particular kind of talk offered to the infants during the sensorial saturation intervention is not fully described other than to say that the words used should be gently but firmly spoken<sup>20</sup>.

Bellieni *et al.* suggest that an important aspect of sensorial saturation is that the baby should feel accompanied by a human presence during the painful procedure<sup>21,22</sup>. The importance is stressed of the caregiver being caring and attentive and it is argued that effective treatment of neonatal pain can only be realised when the infant is seen as a person and, as such, treated with both dignity and empathy<sup>9,22,23</sup>.

These aspects of the nurse–infant relationship, "talk" and "human presence", have, therefore, been identified in the medical literature as being relevant to medical care. But does it matter what sort of "talk" nurses use with their infant patients? Also what kind of human presence might be required for the effective soothing of neonatal pain and stress?

### The thesis of this paper

Talk and emotional presence are key elements of the psychoanalytic approach to managing psychic pain. Firstly some of the tools of the analyst–infant relationship that may be useful for nurses to use with infants during painful and stressful procedures in NICU will be described. Secondly, a model of nurse vocal soothing that may be an effective non-pharmacological pain management technique in NICU will be proposed.

## Discussion

The field of psychoanalysis has long been interested in the impact of relationships on mental health and theories have been proposed that describe how relationships with primary caregivers (external environment) meet an infant's experience (internal environment) to co-create the infant's emerging sense of self.

Parent–infant psychotherapeutic approaches are generally aimed at recognising and soothing the emotional expressions

of the infant. While some therapists may do this by focusing on helping the parents to "talk to" and "be with" their infant<sup>24-26</sup>, others "talk to" and "be with" the infant directly<sup>10,11,27</sup>.

The approach of psychoanalyst Johan Norman was to focus on the help the therapist could offer directly to the infant<sup>11</sup>. Three important features of his technique, as described by Salomonsson<sup>28</sup>, are that:

1. The analyst seeks to establish a therapeutic relationship with the baby.
2. The analyst assumes the infant will use his primary intersubjectivity<sup>29</sup> (an innate capacity to relate to other humans) to obtain containment<sup>30</sup>.
3. The analyst assumes that the baby processes the non-lexical aspect of interactions.

These will be discussed in turn to consider how they may be relevant for use in the NICU.

#### **The analyst seeks to establish a therapeutic relationship with the baby**

Preterm infants may spend up to three or four months in the NICU, where there are fewer opportunities for intimate interaction with their primary caregiving parents. In the physical and often emotional absence of parents in the NICU, nurses frequently take on the role of primary caregiver for their young patients. The nurse works directly with the infant and takes overall responsibility for their physical care. She or he is important to the baby.

#### **The analyst assumes the infant will use their primary intersubjectivity to obtain containment**

Preterm infants seek communication and comfort from caregivers: that is anyone who offers them care. Even preterm infants are born with an innate primary intersubjectivity, ready to relate to other human beings and expecting a response to their bids for communication<sup>31,32</sup>. Infant researcher Colwyn Trevarthen suggests that it does not necessarily have to be the biological mother that meets the needs of the infant and that infants are born ready to have their needs met by any sympathetic adult willing and able to enter their emotional world<sup>32</sup>.

Within psychoanalysis, the school of object relations is particularly concerned with the relationships, real and imagined, between infants and their primary caregivers. Theorists within this school of thought stress the importance of primary caregivers for helping infants manage "big feelings", both joyful and painful<sup>30,33,34</sup>. This process is often described as "containment"<sup>30</sup>.

Psychoanalyst Wilfred Bion suggested that in infancy we have many raw feelings and experiences, but they cannot be made sense of without a container, without someone else who can "metabolise" them for us and give them back in a digested form<sup>30</sup>. It is a bit like the albatross that chews the fish for their babies then regurgitates it in a way that is digestible to the chicks. Bion said that in this way, through the receiving of thought about thoughts, we develop the capacity to think ourselves<sup>30</sup>. The infant has the emotional experience, the parent recognises it, accepts it and reassures the infant that it is a valid feeling to have and they are not alone.

When Bellieni *et al.* suggested the importance of human presence alongside the infant during painful procedures an empathetic presence was presumed<sup>21,22</sup>. In order for a mother to be able to offer containment to her infant, Bion suggested that she needed to be in a state of reverie, a sort of daydream state, where she is emotionally open to receiving the infant's communications, both good and bad<sup>30</sup>. He postulated that this state of being attuned allows the mother to more accurately understand the infant. It would not be practical for nurses to enter a state of reverie with every infant in their care; however, tuning into the infant during a painful experience would be achievable. Studies have demonstrated that interventions can be more effective when the clinician focuses their attention on the infant<sup>35</sup>. Anand *et al.* stress the importance of clinicians working in the NICU expressing empathy and love for their patients and suggest that this is crucial to "maximise the benefits" of evidence-based medical interventions to reduce stress<sup>8</sup>. Clinicians are urged to be like secure mothers who are sensitive and responsive to the infant's needs<sup>8</sup>.

#### **The analyst assumes that the baby processes the non-lexical aspect of interactions**

The assumption here is that, although infants do not understand the actual words spoken to them, they do understand the emotional intention behind the words. If this is the case, then there may be therapeutic value in nurses offering vocal soothing to infants under stress. This vocal soothing would need to be truthful, that is, recognise and name the infant experience, in order to be meaningful to the infant and help them feel understood and reassured and, therefore, contained.

Infants prefer infant-directed speech to adult-directed speech<sup>36</sup>. Infant-directed speech, also known as "motherese" (although it can be offered by anyone) is characterised by longer sounds in the words, higher pitch, more variation in the pitch and repetition<sup>37</sup>. The falling and rising pitch contours depend on whether the infant is being soothed (falling) or whether their attention is being attracted (rising)<sup>38</sup>. Because of these cadences in the speech, infants can sense the emotions being conveyed<sup>39</sup>.

If nurses are to offer their voice and emotional presence to an infant during a procedure as a pain management tool, they need to be in an attuned state, thinking about the infant and "being with" the infant emotionally. Nurses who speak to their colleagues while carrying out a painful procedure on an infant are physically present with the infant during the procedure but not emotionally present. When nurses say to infants in their care "it doesn't hurt" or "nothing is happening", the infant's experience is, in fact, being minimised or denied and the nurse is clearly neither emotionally present with the infant nor attuned to what they are experiencing. Containment is only possible if the caregiver is open to receiving and accepting the infant's communications and, in particular, their level of stress. The psychotherapeutic viewpoint is that the human presence is about "being with" and "thinking about" the infant emotionally not just physically.

In a recent observational study, we found that despite speaking regularly to their colleagues, nurses did not often

offer vocal soothing to infants during a heel prick procedure<sup>40</sup>. Also, despite being recommended as a standard of care in the NICU there was limited use of other non-pharmacological interventions to relieve pain during the procedure<sup>40</sup>. Others have reported that despite much research demonstrating the effectiveness of these techniques, general implementation of pain management programmes appears to be limited internationally<sup>41</sup>.

It is not likely that nursing staff deliberately withhold pain relief from their patients. However, to be available to talk to infants during a painful procedure, a nurse needs to be attuned to the reality of the painful experience. This, in itself, can be an emotionally taxing thing to do. It is possible that psychological protective mechanisms of which the nurse is not likely to be fully conscious, minimise the perceived effect of the painful procedure on the infant and, therefore, in turn, lead to the underuse of pain management techniques in the nursery. More research is required to establish whether this is, in reality, a barrier to the use of these techniques.

### A model of nurse vocal soothing

Bringing together these elements of "talking to" and "being with" an infant, a model of nurse vocal soothing is proposed. If a nurse is emotionally available to the infant's communications and conveys this to the infant through an attuned, empathic voice, similar to "motherese", it is hypothesised that the infant may achieve containment. In this way, the nurse is responsive to the infant's communications in the moment, leaving the infant feeling that they are accompanied in their pain and, therefore, soothed.

The words used by the nurse are a critical component of this communication. They must be truthful and used in context to help the infant feel that their experience has been well understood. One way to ensure this is to consider the steps suggested for procedural pain management by Halimaa<sup>42</sup>:

1. Creating an environment that is favourable to effective pain management.
2. Safe preparation of the infant for the procedure.
3. Pain alleviation during the procedure.
4. Restoring the infant's sense of security after the procedure.

These steps can be understood in terms of vocal soothing. Firstly, offer a warning about what is about to happen, then talk the infant through the procedure and finally have a time of debriefing afterwards. The aim is to accompany an infant through their experience from the start to the finish: to see it from their point of view, to offer warning or preparation about what is to come, to be aware of how the infant is feeling during the procedure and then to have a review of what has happened before moving on to the next task. Pain management as a process can enhance the emotional health of the infant through making the experience meaningful to them. Someone is thinking about them and how they are feeling and the infant is aware of this.

During this process the nurse must be attuned to the experience of the infant. They need to feel both empathic and confident that the infant will tolerate the procedure well and recover well from any temporary stress that they experience.

The essence of the theory of containment is that when an infant feels that a stronger other person understands how they are feeling and remains calm and supportive, it will be reassuring and soothing for the infant.

Further research is needed to determine whether nurse-provided vocal soothing and emotional availability can be experienced as soothing by infants during painful procedures. Studies such as this will make important contributions to the literature on both empathy and pain management techniques in the NICU.

### Conclusion

This discussion paper has considered the rationale for investigating the effectiveness of attuned, empathic vocal soothing on preterm infant stress. It has been proposed that some of the elements of the parent-infant and analyst-infant relationship can be reproduced in a nurse-infant relationship and that this may be of benefit to the emotional development of the preterm infant being cared for in the NICU.

### Implications for practice

If attuned, empathic vocal soothing is found to be an effective mitigator of preterm infant stress then this will provide evidence for a relationship-based, non-pharmacological, cost-effective intervention that may mean that the infant's emotional needs are met more effectively in the NICU.

### References

1. Anand KJS. Clinical importance of pain and stress in preterm neonates. *Neonatology*. 1998;73(1):1-9.
2. Anand KJS, Scalzo FM. Can adverse neonatal experiences alter brain development and subsequent behaviour? *Neonatology*. 2000;77(2):69-82.
3. Grunau R. Early pain in preterm infants: A model of long-term effects. New York, NY, ETATS-UNIS: Elsevier; 2002.
4. Ozawa M, Kanda K, Hirata M, Kusakawa I, Suzuki C. Influence of repeated painful procedures on prefrontal cortical pain responses in newborns. *Acta Paediatr*. 2011;100(2):198-203.
5. Winberg J. Do neonatal pain and stress program the brain's response to future stimuli? *Acta Paediatr*. 1998;87(7):723-5.
6. Grunau RE, Whitfield MF, Petrie-Thomas J, Synnes AR, Cepeda IL, Keldar A *et al*. Neonatal pain, parenting stress and interaction, in relation to cognitive and motor development at 8 and 18 months in preterm infants. *Pain*. 2009;143(1-2):138-46.
7. Pillai Riddell RR, Racine NM, Turcotte K, Uman LS, Horton RE, Din Osmun L, Ahola Kohut S, Hillgrove Stuart J, Stevens B, Gerwitz-Stern A. Non-pharmacological management of infant and young child procedural pain. *Cochrane Database Syst Rev*. [Internet] 2011 [cited 2012 Feb 20]. Available from: <http://www.mrw.interscience.wiley.com/cochrane/cdsysrev/articles/CD006275/frame.html>
8. Anand KJS, Hall RW. Love, pain, and intensive care. *Pediatr*. 2008;121(4):825-7.
9. Bellieni CV, Tei M, Coccina F, Buonocore G. Sensorial saturation for infants' pain. *J Matern Fetal Neonatal Med*. 2012;25 Suppl 1:79-81.
10. Acquarone S. *Infant-Parent Psychotherapy: A Handbook*. London: H. Karnac (Books) Ltd; 2004.
11. Norman J. The Psychoanalyst and the baby: A new look at work with infants. *Int J Psychoanal*. 2001;82(1):83-100.
12. Norman J. Transformations of early infantile experiences: A 6-month-old in psychoanalysis. *Int J Psychoanal*. 2004;85(5):1103-22.
13. Schore AN. The experience-dependent maturation of a regulatory system in the orbital prefrontal cortex and the origin of developmental psychopathology. *Dev Psychopathol*. 1996;8:59-87.
14. Legendre V, Burtner PA, Martinez KL, Crowe TK. The evolving practice of developmental care in the neonatal unit: A systematic review. *Phys Occup Ther Pediatr*. 2011;31(3):315-38.
15. Als H, Gilkerson L. The role of relationship-based developmentally supportive newborn intensive care in strengthening outcome of preterm infants. *Semin Perinatol*. 1997;21(3):178-89.
16. Als H, Duffy FH, McAnulty GB. Effectiveness of individualized neurodevelopmental care in the newborn intensive care unit (NICU). *Acta Paediatr*. 1996;85:21-30.

17. Als H, Duffy FH, McAnulty GB, Rivkin MJ, Vajapeyam S, Mulkern RV *et al*. Early experience alters brain function and structure. *Pediatr*. 2004;113(4):846–57.
18. Westrup B, Sizun J, Lagercrantz H. Family-centered developmental supportive care: a holistic and humane approach to reduce stress and pain in neonates. *J Perinatol*. 2007;27(51):S12–S8.
19. Shoemark H. Infant-directed singing as a vehicle for regulation rehearsal in the medically fragile full-term infant. *Aust J Mus Ther*. 2006;17:54–63.
20. Bellieni CVC, Buonocore GG, Nenci AA, Franci NN, Cordelli DMD, Bagnoli FF. Sensorial saturation: an effective analgesic tool for heel-prick in preterm infants: a prospective randomized trial. *Biol Neonate*. 2001;80(1):15.
21. Bellieni CVC. Effect of multisensory stimulation on analgesia in term neonates: A randomized controlled trial. *Pediatr Res*. 2002;51(4):460–3.
22. Bellieni CVC, Bagnoli FF, Buonocore GG. Alone no more: pain in premature children. *Ethics & Med*. 2003;19(1):5.
23. Bellieni CVC. Pain definitions revised: newborns not only feel pain, they also suffer. *Ethics & Med*. 2005;21(1):5.
24. Baradon T, Broughton, C, Gibbs, I, Joyce, A & Woodhead, J. The practice of psychoanalytic parent-infant psychotherapy – claiming the baby. London: Routledge; 2005.
25. Cohen NJ. Watch, wait, and wonder: Testing the effectiveness of a new approach to mother-infant psychotherapy. *Infant Ment Health J*. 1999;20(4):429–51.
26. Fraiberg S. Ghosts in the nursery: A psychoanalytic approach to the problems of impaired infant-mother relationships. *J Am Acad Child Psychiatry*. 1975;14(3):387.
27. Thomson-Salo F. Recognizing the infant as subject in infant-parent psychotherapy. *Int J Psychoanalysis*. 2007;88(4):961–79.
28. Salomonsson B. Baby worries: A randomised controlled trial of mother-infant psychoanalytic treatment. Stockholm: Karolinska Institutet; 2010.
29. Trevarthen C, Aitken KJ. Infant intersubjectivity: Research, theory, and clinical applications. *J Child Psychol Psychiatr*. 2001;42(1):3–48.
30. Bion WR. Learning from experience. London: Karnac Books; 1962.
31. Aitken KJ, Trevarthen C. Self/other organization in human psychological development. *Dev Psychopathol*. 1997;9(04):653–77.
32. Trevarthen C. Intrinsic motives for companionship in understanding: Their origin, development, and significance for infant mental health. *Infant Ment Health J*. 2001;22(1–2):95–131.
33. Ogden T. The Matrix of the Mind. Object Relations and the Psychoanalytic Dialogue. London: H Karnac (Books) Inc; 1992.
34. Winnicott D. The maturational processes and the facilitating environment: Studies in the theory of emotional development. London: Karnac Books Ltd; 1990.
35. Ventegodt S, Merrick J. Clinical holistic medicine: Applied consciousness-based medicine. *ScientificWorldJournal*. 2004;4:96–9.
36. Cooper RP, Aslin RN. Preference for infant-directed speech in the first month after birth. *Child Dev*. 1990;61(5):1584–95.
37. Trainor LJ. Infant preferences for infant-directed versus noninfant-directed play songs and lullabies. *Infant Behav Dev*. 1996;19(1):83–92.
38. Fernald A. Prosody in speech to children: Prelinguistic and linguistic functions. *Ann Child Dev*. 1991;8:43–80.
39. Caron AJ, Caron RF, MacLean DJ. Infant discrimination of naturalistic emotional expressions: The role of face and voice. *Child Dev*. 1988;59(3):604–16.
40. Zwimpfer L, Wiltshire, E, & Elder, D. Talking to Babies: A baseline study of vocal soothing by neonatal nurses during painful procedures. *J Paediatr Child Health*. 2012;48(Suppl 1):8–81.
41. Spence K, Henderson-Smart D. Closing the evidence-practice gap for newborn pain using clinical networks. *J Paediatr Child Health*. 2011;47(3):92–8.
42. Halimaa S-L. Pain management in nursing procedures on premature babies. *J Adv Nurs*. 2003;42(6):587–97.

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(B) This chapter, authored by L Zwimpher, was published in a book 'Surviving the Early Years: The Importance of Early Intervention with Babies at Risk', edited by Dr Stella Acquarone and published in 2016.

## Talking to, and being with, babies: the importance of relationship in the neonatal intensive care unit\*

*Lucie Zwimpfer*

### *Introduction*

Talking to, and being with, infants are key aspects of the parent–infant relationship and also of the analyst–infant relationship in some parent–infant psychotherapies (Acquarone, 2004; Norman, 2001, 2004). This chapter discusses the importance of relationships for infant development and suggest that knowledge gained from the exploration of psychoanalytic treatment for infants might be useful for the nurse–infant relationship in the neonatal intensive care unit (NICU). A model of vocal soothing is presented, which is underpinned by the psychoanalytic concept of containment. Ideas for supporting NICU parents to be able to talk to, and be with, their infants are suggested.

Infant exposure to pain and stress is associated with adverse physical and emotional outcomes (Anand, 1998; Anand & Scalzo, 2000; Grunau, 2002; Ozawa et al., 2011; Winberg, 1998) and later behavioural and emotional problems (Anand & Scalzo, 2000). Researchers and clinicians have sought to develop effective pharmacological and non-pharmacological methods to manage pain and stress for preterm infants (Winberg, 1998).

There is good evidence available that relationships with adults are critical to facilitate the growth of healthy infant brains that are able to manage stress (Schoore, 1996). It is in moments of stress that the infant most needs the support of an adult carer to help them regulate their emotional state. When infants are attended to and soothed by an adult carer, their ability to do this for themselves is facilitated through development of the neural pathways for emotional regulation. When this does not happen, the infant is at risk of adverse mental health sequelae later in life (Schoore, 1996). Emotional regulation, thus, depends on having an emotionally available adult who can tune in and communicate with the infant.

The primary carer for preterm infants in a NICU changes daily. When parents are unable to be with their babies, for whatever reason, nurses step in as the temporary keepers of the infant's emotional health. The NICU is increasingly being seen as a place not just for the physical care of the infant, but also their emotional and developmental care, meaning that NICU staff members are taking on the job of helping infants manage their stress. Further, NICU staff members are in a unique position of being able to screen for, and intervene in, relationship difficulties between infants and their parents.

Talking to, and being with, infants as part of their neonatal care has been identified as an important aspect of pain management (Anand & Hall, 2008; Bellieni et al., 2012). Some relationship-based care practices have been developed and are now a routine component of neonatal care in many units (Legendre et al., 2011).

### *Relationship-based care in the neonatal intensive care unit*

Relationship-based care practices in NICU include the neonatal individualised care and assessment programme (NIDCAP), infant-led singing, and sensorial saturation. The unifying philosophy of these approaches is that the infant is regarded as an individual with emotional as well as physical needs.

The NIDCAP approach focuses on planning individualised care based on observations of the infant's behaviour, thereby recognising the infant as a person with goals and facilitating the development of a carer relationship with the infant (Als & Gilkerson, 1997). Numerous studies have now been published reporting favourable outcomes for



infants using this approach (Als et al., 1996, 2004; Westrup et al., 2007). It is, however, an expensive programme to implement fully (Westrup et al., 2007).

Infant-led singing, within an attuned relationship, is an approach aimed at facilitating self and mutual regulation (Shoemark, 2006). The spontaneous nature of the singing means that the therapist is led by the infant's immediate responses and aims to connect with the infant's emotional experience (Shoemark, 2006). This is seen to be particularly important, given the hospital experience being largely non-contingent with the infant's psychological needs (Shoemark, 2006).

Sensorial saturation has also been shown to be effective in managing pain and stress (Bellieni et al., 2012). The aim is to distract the infant's senses so that pain has less chance of being perceived centrally (Bellieni et al., 2001). Bellieni and colleagues have studied the effectiveness of sensorial saturation extensively and have refined the technique in the "Triple T intervention" using touch, taste, and talk as the distractor. Bellieni and colleagues suggest that an important aspect of sensorial saturation is that the baby should feel accompanied by a human presence during the painful procedure (Bellieni, 2002; Bellieni et al., 2003). The importance is stressed of the carer being caring and attentive, and it is argued that effective treatment of neonatal pain can only be realised when the infant is seen as a person and, as such, treated with both dignity and empathy (Bellieni et al., 2003, 2012).

These aspects of the nurse–infant relationship—"talk" and "human presence"—have, therefore, been identified in the medical literature as being relevant to medical care. But does it matter what sort of "talk" is used with preterm infants? Also, what kind of human presence might be required for the effective soothing of neonatal pain and stress?

Talk and emotional presence are key elements of the psychoanalytic approach to managing psychic pain. The field of psychoanalysis has long been interested in the impact of relationships on mental health, and theories have been proposed that describe how relationships with primary carers (external environment) meet an infant's experience (internal environment) to co-create the infant's emerging sense of self. Parent–infant psychotherapeutic approaches are generally aimed at recognising and soothing the emotional expressions of the infant. While some therapists may do this by focusing on helping the parents to "talk to", and "be with", their infant (Baradon et al.,

2005; Cohen, 1999; Fraiberg, 1975), others “talk to”, and “are with”, the infant directly (Acquarone, 2007; Norman, 2001; Thomson-Salo, 2007). In the following section, some of the tools of the analyst–infant relationship that might be helpful to use with infants during painful and stressful procedures in NICU are described. A model of vocal soothing that could be an effective non-pharmacological pain management technique in NICU is also proposed.

### *Talking to, and being with: nurse–infant relationships in NICU*

The approach of psychoanalyst Johan Norman was to focus on the help the therapist could offer directly to the infant (Norman, 2001). Three important features of his technique are discussed in turn to consider how they can be applied to nurse–infant relationships in NICU.

#### *The analyst seeks to establish a therapeutic relationship with the baby*

In seeking to establish a relationship with a baby, the therapist is required to attune to the infant and be open to wondering about how the baby might be feeling. This requires focus and attention, and the adult needs to be calm and unpreoccupied. Typically, analytic therapy occurs in a quiet room, and the therapist focuses on one baby for a significant period of time. Contrast this with a busy NICU where there are constant demands on staff time. Neonatal nurses have multiple babies to attend to, sometimes all at once, and they do not have the luxury of time. However, they do have moments of engagement with individual infants and there will always be a nurse who is with the baby during stressful procedures and caring activities. This nurse can choose to enter into a relationship with the infant at this moment in time.

#### *The analyst assumes the infant will use their primary intersubjectivity to obtain containment*

Preterm infants seek communication and comfort from carers: that is, anyone who offers them care. Even preterm infants are born with an

innate primary intersubjectivity, ready to relate to other human beings and expecting a response to their bids for communication (Aitken & Trevarthen, 1997; Trevarthen, 2001). Infant researcher Colwyn Trevarthen suggests that it does not necessarily have to be the biological mother that meets the needs of the infant as infants are born ready to have their needs met by any sympathetic adult willing and able to enter their emotional world (Trevarthen, 2001).

Within psychoanalysis, the school of object relations is particularly concerned with the relationships, real and imagined, between infants and their primary carers. Theorists within this school of thought stress the importance of primary carers for helping infants manage "big feelings", both joyful and painful (Bion, 1962; Ogden, 1992; Winnicott, 1990). This process is often described as containment (Bion, 1962).

Psychoanalyst Wilfred Bion suggested that in infancy we have many raw feelings and experiences, but they cannot be made sense of without a container, without someone else who can metabolise them for us and give them back in a digested form (Bion, 1962). It is a bit like the albatross that chews the fish for their babies then regurgitates it in a way that is digestible to the chicks. Bion said that in this way, through the receiving of thought about thoughts, we develop the capacity to think ourselves (1962). The infant has the emotional experience, the parent recognises it, accepts it, and reassures the infant that it is a valid feeling to have and they are not alone.

When Bellieni and colleagues suggested the importance of human presence alongside the infant during painful procedures, an empathetic presence was presumed (Bellieni, 2002; Bellieni et al., 2003). In order for a mother to be able to offer containment to her infant, Bion suggested that she needed to be in a state of reverie, a sort of day-dream state, where she is emotionally open to receiving the infant's communications, both good and bad (1962). He postulated that this state of attunement allows the mother to more accurately understand the infant. It would not be practical for nurses to enter a state of reverie with every infant in their care; however, tuning into the infant during a painful experience would be achievable. Studies have demonstrated that interventions can be more effective when the clinician focuses their attention on the infant (Ventegodt & Merrick, 2004). Anand and colleagues stress the importance of clinicians working in the NICU expressing empathy and love for their patients and suggest that this is crucial in order to "maximize the benefits" of

evidence-based medical interventions to reduce stress (Anand & Hall, 2008). Clinicians are urged to be like secure mothers who are sensitive and responsive to the infant's needs (Anand & Hall, 2008).

*The analyst assumes that the baby processes the non-lexical aspect of interactions*

The assumption here is that although infants do not understand the actual words spoken to them, they do understand the emotional intention behind the words. If this is the case, then there might be therapeutic value in offering vocal soothing to infants under stress. This vocal soothing would need to be truthful, that is, recognise and name the infant experience, in order to be meaningful to the infant and help them feel understood and reassured and, therefore, contained. A soothing voice might be particularly important for premature infants who are unable to be cuddled often or touched freely.

Infants prefer infant-directed speech to adult-directed speech (Cooper & Aslin, 1990). Infant-directed speech, also known as "motherese" (although it can be offered by anyone), is characterised by longer sounds in the words, higher pitch, more variation in the pitch, and repetition (Trainor, 1996). The falling and rising pitch contours depend on whether the infant is being soothed (falling) or whether their attention is being attracted (rising) (Fernald, 1991). Because of these cadences in the speech, infants can sense the emotions being conveyed (Caron et al., 1988).

If a nurse offers their voice and emotional presence to an infant during a procedure, they need to be in an attuned state, thinking about the infant and "being with" the infant emotionally. Nurses who speak to their colleagues while carrying out a painful procedure on an infant are physically present with the infant during the procedure but not emotionally present. When nurses say to infants in their care "It doesn't hurt", or "Nothing is happening", the infant's experience is, in fact, being minimised or denied and the nurse is clearly neither emotionally present with the infant nor attuned to what they are experiencing. Containment is only possible if the nurse is open to receiving and accepting the infant's communications, and, in particular, their level of stress. The psychotherapeutic viewpoint is that the human presence is about being with, and thinking about, the infant emotionally and not just physically.

In a recent observational study, we found that despite speaking regularly to their colleagues, nurses did not often offer vocal soothing to infants during a heel prick procedure (Zwimpfer et al., 2012). Also, despite being recommended as a standard of care in the NICU, there was limited use of other non-pharmacological interventions to relieve pain during the procedure (Zwimpfer et al., 2012). Others have reported that despite much research demonstrating the effectiveness of these techniques, general implementation of pain management programmes appears to be limited internationally (Spence & Henderson-Smith, 2011).

It is not likely that nursing staff deliberately withhold pain relief from their patients. However, to be available to talk to infants during a painful procedure, a nurse needs to be attuned to the reality of the painful experience. This, in itself, can be an emotionally taxing thing to do. It is possible that psychological protective mechanisms, of which the nurse is not likely to be fully conscious, minimise the perceived effect of the painful procedure on the infant and, therefore, in turn lead to the underuse of pain management techniques in the nursery. More research is required to establish whether this is, in reality, a barrier to the use of these techniques.

### *A model of vocal soothing*

Bringing together these elements of talking to, and being with, an infant, a model of vocal soothing during painful procedures is proposed. If a nurse is emotionally available to the infant's communications and conveys this to the infant through an attuned, empathic voice, similar to "motherese", it is hypothesised that the infant could achieve containment. In this way, the nurse is responsive to the infant's communications in the moment, leaving the infant feeling that they are accompanied in their pain and, therefore, soothed.

The words used are a critical component of this communication. They must be truthful and used in context in order to help the infant feel that their experience has been well understood. The nurse can accompany an infant through their painful experience from the start to the finish: see it from their point of view, offer warning or preparation about what is to come, be aware of how the infant is feeling during the procedure, and then have a verbal review of what has

happened before moving on to the next task. During this process, the nurse must be attuned to the experience of the infant. They need to feel both empathic and confident that the infant will tolerate the procedure and recover well from any temporary stress that they experience. The essence of the theory of containment is that when an infant feels that a stronger other person understands how they are feeling and remains calm and supportive, it will be reassuring and soothing for the infant.

We are undertaking research to determine whether non-parental vocal soothing and emotional availability can be experienced as soothing by infants during painful procedures. If attuned, empathic vocal soothing is found to be an effective mitigator of preterm infant stress, then this will provide evidence for a relationship-based, non-pharmacological, cost-effective intervention that might mean that the infant's emotional needs are met more effectively in the NICU.

*Talking to, and being with: supporting  
parent–infant relationships in NICU*

Parents of NICU babies are not always able to be emotionally available to their infants. This can be for a variety of reasons. Each family has their own trauma to work through and some parents will be more emotionally equipped and socially supported to manage this than others. How a baby is held in the mind of their parents is a result of complex psychological factors, some conscious and some not. The early weeks of a baby's life are an important part of setting the stage for the kind of relationship they will have with their primary carers. What does having this baby in NICU mean for these parents? How is this baby viewed by their parents? Are they allowing themselves to connect with their baby?

It is becoming more common to see allied health clinicians working alongside medical staff in the service of the premature infant and his or her family. Multi-disciplinary psychosocial meetings provide an opportunity to plan care for families that need extra help. Input from social workers, occupational therapists, speech and language therapists, physiotherapists, lactation consultants, and psychotherapists ensure that families have access to a wide range of support.

As a psychotherapist and infant researcher in an NICU, I have spent many hours working alongside neonatal nurses. I have come to know the detail of their work and, over time, have come to be trusted in this environment. While I am still considered to be in a "fluffy" profession, they see me using equipment that they know—heart rate and respiratory rate monitors—and that has, in a way, served as a bridge between the worlds of psychology and medicine. It means that when I am asked to teach seminars on infant mental health to the nurses, we already have a shared understanding and respect for each other's work. One of the most important aspects of the field of infant mental health is that it is multi-disciplinary. All disciplines that have input into the wellbeing of infants and young children have a responsibility to learn about brain development and the importance of attuned relationships for emotional health. Neonatal nurses can and do promote the principles of infant mental health, whether they realise it or not.

Neonatal nurses are in a unique position to be able to support parent–infant relationships by helping parents to get to know and psychologically claim their baby. They encourage parents to actively participate in the routine physical care of their baby, and kangaroo cuddles are offered when possible. Nurses provide guidance to parents around how to touch and hold their babies. They tell parents about how their baby has been during the shift, as often parents are hungry for as much feedback as possible, perhaps looking for proof that their absence has not been damaging to their child.

Neonatal nurses delight in their infant patients, showing parents that their babies are lovable and unique and special. Many parents will never have had a baby to care for and so take their lead from staff in how to interact with this little person who might seem quite alien to them. All of these things promote the relationship between parents and their babies. It keeps them wondering and interested in their infant's experience.

In our NICU, parent–infant psychotherapy takes place cotside. The work of the psychotherapist is to be alongside the parents in their experience of their baby, to help them process and understand the thoughts and feelings that arise in the presence of their baby. The psychological containment that is offered to parents by the psychotherapist allows the parents then to feel strong enough to be able to wonder about, and be open to, their infant's feelings and experiences.

and wonder about their baby. What is this baby doing? What is this baby's experience in this moment? Nurses can alert parents to their baby's abilities and needs. They can identify and enhance a parent's ability to respond positively to their baby.

*Message four: how do you feel about this baby?*

Nurses are in a key position to be able to sound out a parent's feelings in relation to their baby. What is the parent's experience in this moment? How they are feeling about this baby? What is it like for them having a baby in hospital? What had they hoped for this baby? Did they know their child would be admitted to NICU? The nurse can get a sense of what it is like to be the parent of this baby at this particular time. It is important to listen well to the parent, who might or might not share their own history of abandonment, separation, unresolved loss—all very difficult experiences that could further compound their ability to tolerate having a baby in hospital.

*Message five: this is your baby.*

Nurses can help parents claim their baby. Statements such as "She's your baby", or "He's really listening to you" can be incredibly powerful to parents who are not sure they believe it. To bring their attention back to their baby, a nurse might ask, "How did you choose his or her name?" After they have been with their baby, they might ask, "What was that like for you?" These statements or questions are inherently relational in nature. They serve the purpose of bringing the baby into the parents' mind and helping them claim their baby. Where risk is detected in the relationship, a referral to local parent-infant mental health services might be indicated.

### *Conclusion*

This chapter has made a case for offering attuned, empathic vocal soothing for preterm infant stress. It has been proposed that some of the elements of the parent-infant and analyst-infant relationship are useful to consider in a neonatal intensive care unit setting with nurses, and that this might be of benefit to the emotional development of the



preterm infant. Parents need to be supported to be able to offer containment to their babies, and five key messages for parents can be shared by nursing staff to encourage parents to connect emotionally with their infants.

### References

- Acquarone, S. (2004). *Infant-Parent Psychotherapy: A Handbook*. London: Karnac.
- Acquarone, S. (2007). *Signs of Autism in Infants: Recognition and Early Intervention*. London: Karnac.
- Aitken, K. J., & Trevarthen, C. (1997). Self/other organization in human psychological development. *Development and Psychopathology*, 9(4): 653-677.
- Als, H., & Gilkerson, L. (1997). The role of relationship-based developmentally supportive newborn intensive care in strengthening outcome of preterm infants. *Seminars in Perinatology*, 21(3): 178-189.
- Als, H., Duffy, F. H., & McAnulty, G. B. (1996). Effectiveness of individualized neurodevelopmental care in the newborn intensive care unit (NICU). *Acta Paediatrica*, 85: 21-30.
- Als, H., McAnulty, G. B., Rivkin, M. J., Vajapeyam, S., Mulkern, R. V., Warfield, S. K., Huppi, P. S., Butler, S. C., Conneman, N., Fischer, C., & Eichenwald, E. C. (2004). Early experience alters brain function and structure. *Pediatrics*, 113(4): 846-857.
- Anand, K. J. S. (1998). Clinical importance of pain and stress in preterm neonates. *Neonatology*, 73(1): 1-9.
- Anand, K. J. S., & Hall, R. W. (2008). Love, pain, and intensive care. *Pediatrics*, 121(4): 825-827.
- Anand, K. J. S., & Scalzo, F. M. (2000). Can adverse neonatal experiences alter brain development and subsequent behaviour? *Neonatology*, 77(2): 69-82.
- Baradon, T., Broughton, C., Gibbs, I., Joyce, A., & Woodhead, J. (2005). *The Practice of Psychoanalytic Parent-Infant Psychotherapy—Claiming the Baby*. London: Routledge.
- Bellieni, C. V. C. (2002). Effect of multisensory stimulation on analgesia in term neonates: a randomized controlled trial. *Pediatric Research*, 51(4): 460-463.
- Bellieni, C. V. C., Bagnoli, F. F., & Buonocore, G. G. (2003). Alone no more: pain in premature children. *Ethics & Medicine*, 19(1): 5-9.

- Belliemi, C. V. C., Buonocore, G., Nenci, A., Franci, N., Cordelli, D. M., & Bagnoli, F. (2001). Sensorial saturation: an effective analgesic tool for heel-prick in preterm infants. A prospective randomized trial. *Biology of the Neonate*, 80(1): 15–18.
- Belliemi, C. V., Tei, M., Coccina, F., & Buonocore, G. (2012). Sensorial saturation for infants' pain. *Journal of Maternal–Fetal & Neonatal Medicine*, 25(Suppl. 1): 79–81.
- Bion, W. R. (1962). *Learning From Experience*. London: Karnac.
- Caron, A. J., Caron, R. F., & MacLean, D. J. (1988). Infant discrimination of naturalistic emotional expressions: the role of face and voice. *Child Development*, 59(3): 604–616.
- Cohen, N. J. (1999). Watch, wait, and wonder: testing the effectiveness of a new approach to mother–infant psychotherapy. *Infant Mental Health Journal*, 20(4): 429–451.
- Cooper, R. P., & Aslin, R. N. (1990). Preference for infant-directed speech in the first month after birth. *Child Development*, 61(5): 1584–1595.
- Fernald, A. (1991). Prosody in speech to children: prelinguistic and linguistic functions. *Annals of Child Development*, 8: 43–80.
- Fraiberg, S. (1975). Ghosts in the nursery: a psychoanalytic approach to the problems of impaired infant–mother relationships. *Journal of the American Academy of Child Psychiatry*, 14(3): 387–421.
- Grunau, R. (2002). *Early Pain in Preterm Infants: A Model of Long-Term Effects*. New York: Elsevier.
- Legendre, V., Burtner, P. A., Martinez, K. L., & Crowe, T. K. (2011). The evolving practice of developmental care in the neonatal unit: a systematic review. *Physical & Occupational Therapy in Pediatrics*, 31(3): 315–338.
- Norman, J. (2001). The psychoanalyst and the baby: a new look at work with infants. *International Journal of Psychoanalysis*, 82(1): 83–100.
- Norman, J. (2004). Transformations of early infantile experiences: a 6-month-old in psychoanalysis. *International Journal of Psychoanalysis*, 85(5): 1103–1122.
- Ogden, T. (1992). *The Matrix of the Mind. Object Relations and the Psychoanalytic Dialogue*. London: Karnac.
- Ozawa, M., Kanda, K., Hirata, M., Kusakawa, I., & Suzuki, C. (2011). Influence of repeated painful procedures on prefrontal cortical pain responses in newborns. *Acta Paediatrica*, 100(2): 198–203.
- Schore, A. N. (1996). The experience-dependent maturation of a regulatory system in the orbital prefrontal cortex and the origin of developmental psychopathology. *Development and Psychopathology*, 8: 59–87.

- Shoemark, H. (2006). Infant-directed singing as a vehicle for regulation rehearsal in the medically fragile full-term infant. *Australian Journal of Music Therapy, 17*: 54–63.
- Spence, K., & Henderson-Smart, D. (2011). Closing the evidence-practice gap for newborn pain using clinical networks. *Journal of Paediatrics and Child Health, 47*(3): 92–98.
- Thomson-Salo, F. (2007). Recognizing the infant as subject in infant–parent psychotherapy. *International Journal of Psychoanalysis, 88*(4): 961–979.
- Trainor, L. J. (1996). Infant preferences for infant-directed versus noninfant-directed playsongs and lullabies. *Infant Behavior and Development, 19*(1): 83–92.
- Trevarthen, C. (2001). Intrinsic motives for companionship in understanding: their origin, development, and significance for infant mental health. *Infant Mental Health Journal, 22*(1–2): 95–131.
- Ventegodt, S., & Merrick, J. (2004). Clinical holistic medicine: applied consciousness-based medicine. *Scientific World Journal, 4*: 96–99.
- Westrup, B., Sizun, J., & Lagercrantz, H. (2007). Family-centered developmental supportive care: a holistic and humane approach to reduce stress and pain in neonates. *Journal of Perinatology, 27*(S1): S12–S18.
- Winberg, J. (1998). Do neonatal pain and stress program the brain's response to future stimuli? *Acta Paediatrica, 87*(7): 723–725.
- Winnicott, D. W. (1971). The mirror-role of mother and family in child development. In: D. W. Winnicott, *Playing and Reality* (pp. 111–118). London: Tavistock [reprinted New York: Routledge, 1989].
- Winnicott, D. (1990). *The Maturation Processes and the Facilitating Environment: Studies in the Theory of Emotional Development*. London: Karnac.
- Zwimpfer, L., Wiltshire, E., & Elder, D. (2012). Talking to babies: a baseline study of vocal soothing by neonatal nurses during painful procedures. *Journal of Paediatrics and Child Health, 48*(Suppl. 1): 8–81.

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### **Talking to Babies: A Baseline Study of Vocal Soothing by Neonatal Nurses during painful procedures**

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**Background:** Some Developmental Care guidelines recommend that nurses or parents should speak soothingly to infants during painful procedures, but parents are not always physically or emotionally available. The aim of this study was to gather baseline data on the extent of vocal soothing offered by nurses to babies in a Neonatal Intensive Care Unit (NICU).

**Method:** Fifty heel prick procedures were observed using a standardised data collection form. During each procedure, the number of words spoken to the baby, or to other people, was counted. Demographic data, whether the baby cried and any other soothing techniques were also recorded. 'Vocal soothing' was defined as more than 60 words directed at the baby. Given the small sample size, Fishers Exact Method was used to calculate 95% confidence intervals for the data.

**Results:** Of the 36 male and 14 female babies observed, 17 were born at a gestational age of 24-29 weeks, 23 at 30-35 weeks and ten at 36-41 weeks. Seventeen babies were in their first week of life. Forty of the babies were awake during the procedure. Nurses spoke more than 60 words to another adult during 34% of the procedures (95% CI 21%-49%) and spoke more than 60 words (vocal soothing) to the baby in 4% of the procedures (95% CI 0.5% -14%).

**Conclusions:** In their routine working environment, nurses regularly speak to their colleagues during heel prick procedures, but do not often offer vocal soothing to the babies experiencing the procedure.

## **APPENDIX II: RESEARCH PROTOCOL FOR HEEL PRICK PROCEDURES**

Research protocol for heel prick procedures. This protocol was followed by all NICU nurses administering heel prick procedures during the feasibility study and the main study.

### **Heel prick procedure protocol**

Lucie to take first salivary cortisol measurement

**Place bandage around ankle**

**Wipe heel**

**Prick** )

**Collect blood** )

**Put on bandage** )

(attend to bloods) ) **20 mins**

**Cares** )

Lucie to take second salivary cortisol measurement (20 mins after prick)

)  
**Feed** ) **30 mins**

)  
Lucie to take third salivary cortisol measurement (50 minutes after prick)

## Premature Infant Pain Profile (PIPP) scoring sheet

Infant Study Number: \_\_\_\_\_  
 Date/time: \_\_\_\_\_  
 Event: \_\_\_\_\_

Process	Indicator	0	1	2	3	Score
Chart	Gestational age	36 weeks and more	32-35 weeks, 6 days	28-31 weeks, 6 days	less than 28 weeks	
Observe infant 15 s	Behavioral state	active/awake eyes open facial movements	quiet/awake eyes open no facial movements	active/sleep eyes closed facial movements	quiet/sleep eyes closed no facial movements	
Observe baseline	Heart rate ___ Oxygen saturation ___					
Observe infant 30 s	Heart rate Max ___ Oxygen saturation Min ___	0-4 beats/min increase 0-2.4% decrease	5-14 beats/min increase 2.5-4.9% decrease	15-24 beats/min increase 5.0-7.4% decrease	25 beats/min or more increase 7.5% or more decrease	
	Brow bulge	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more	
	Eye squeeze	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more	
	Nasolabial furrow	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more	
					Total score	_____

### Premature Infant Pain Profile: Development and Initial Validation.

Stevens, Bonnie; Johnston, Celeste; Petryshen, Patricia; Taddio, Anna  
 Clinical Journal of Pain. 12(1):13-22, March 1996.

Premature Infant pain Profile – Revised (PIPP-R) scoring sheet

The Premature Infant Pain Profile: Revised					
Infant Indicator	Indicator Score				Infant Indicator Score
	0	+1	+2	+3	
Change in Heart Rate (bpm) Baseline: _____	0 - 4	5 - 14	15 - 24	>24	
Decrease in Oxygen Saturation (%) Baseline: _____	0 - 2	3 - 5	6 - 8	>8 or Increase in O <sub>2</sub>	
Brow Bulge (Sec)	None (<3)	Minimal (3 - 10)	Moderate (11 - 20)	Maximal (>20)	
Eye Squeeze (Sec)	None (<3)	Minimal (3 - 10)	Moderate (11 - 20)	Maximal (>20)	
Naso-Labial Furrow (Sec)	None (<3)	Minimal (3 - 10)	Moderate (11 - 20)	Maximal (>20)	
* Sub-total Score:					
Gestational Age (Wks + Days)	>36 wks	32 wks - 35 wks, 6d	28 wks- 31wks, 6d	<28wks	
Baseline Behavioural State	Active and Awake	Quiet and Awake	Active and Asleep	Quiet and Asleep	
** Total Score:					
* Sub-total for physiological and facial indicators. If Sub-total score>0, add GA and BS indicator scores.					
** Total Score: Sub-total Score + GA Score + BS Score					
Scoring instructions					
<b>Step 1:</b> Observe infant for <b>15 seconds at rest</b> and assess vital sign indicators [highest heart rate (HR) and lowest O <sub>2</sub> Saturation (O <sub>2</sub> SAT)] and behavioural state.					
<b>Step 2:</b> Observe infant for <b>30 seconds after procedure</b> and assess <b>change</b> in vital sign indicators (maximal HR, lowest O <sub>2</sub> SAT and duration of facial actions observed). * If infant requires an increase in oxygen at any point before or during procedure, they receive a score of 3 for the O <sub>2</sub> SAT indicator					
<b>Step 3:</b> Score for corrected gestational age (GA) and behavioural state (BS) if the sub-total score >0.					
<b>Step 4:</b> Calculate total score by adding <b>Sub-total Score + BS Score</b> .					

**The Premature Infant Pain Profile-Revised (PIPP-R): Initial Validation and Feasibility.**  
Stevens, Bonnie; RN, PhD; Gibbins, Sharyn; RN, PhD; Yamada, Janet; RN, PhD; Dionne, Kimberley; RN, MN; Lee, Grace; RN, MSc; Johnston, Celeste; RN, DEd; Taddio, Anna  
Clinical Journal of Pain. 30(3):238-243, March 2014.

## APPENDIX III: CULTURAL CONSULTATION

The University of Otago's Ngāi Tahu Research Consultation Committee approval for this programme of study.

### NGĀI TAHU RESEARCH CONSULTATION COMMITTEE *TE KOMITI RAKAHAU KI KĀI TAHU*

08/03/2011 - 65  
Wednesday, 09 March 2011

Dr Elder  
Paediatrics and Child Health  
Wellington

Tēnā koe Dr Elder

**Title: Talking to Babies in a Neonatal Intensive Care Unit: The impact of verbal soothing on measures of infant stress during painful procedures.**

The Ngāi Tahu Research Consultation Committee (The Committee) met on Tuesday, 08 March 2011 to discuss your research proposition.

By way of introduction, this response from the Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum, it states "Ngāi Tahu acknowledges that the consultation process outlined in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology; they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

*"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."*

The Committee considers the research to be of importance to Māori health.

The Committee notes and commends that ethnicity data is to be collected as part of the research project and recommends the use of the questions on self-identified ethnicity and descent, these questions are contained in the 2006 census.

The Ministry of Health website <http://www.maorihealth.govt.nz/moh.nsf/indexma/publications> contains a list of Māori health publications. The Committee recommends you review the Māori health publications on this website, eg. Unequal Impact II: Māori and Non-Māori Cancer Statistics by Deprivation and Rural-Urban Status 2002-2006 and Tatau Kahukura: Māori Health Chart Book 2010. Another Publication, Hauora: Māori Standards of Health IV (200-2005), has its own website,

The Ngāi Tahu Research Consultation Committee has membership from:

*Te Rūnanga o Ōtākou Incorporated  
Kāti Huirapa Rūnaka ki Puketeraki  
Te Rūnanga o Moeraki*



NGĀI TAHU RESEARCH CONSULTATION COMMITTEE  
*TE KOMITI RAKAHAU KI KĀI TAHU*

<http://www.hauora.maori.nz/>. These publications provide information on a range of Māori health issues and will assist in ensuring your research has an appropriate Māori health focus.

The Committee suggests dissemination of the research findings to Māori health organisations regarding this study.

We wish you every success in your research and the Committee also requests a copy of the research findings.

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 08 March 2011 to 08 September 2012.

The recommendations and suggestions above are provided on your proposal submitted through the consultation website process. These recommendations and suggestions do not necessarily relate to ethical issues with the research, including methodology. Other committees may also provide feedback in these areas.

Nāhaku noa, nā



PR. NRCC

Mark Brunton  
Kaitakawaenga Rangahau Māori  
Facilitator Research Māori  
Research Division  
Te Whare Wānanga o Ōtāgo  
Ph: +64 3 479 8738  
email: [mark.brunton@otago.ac.nz](mailto:mark.brunton@otago.ac.nz)  
Web: [www.otago.ac.nz](http://www.otago.ac.nz)

The Ngāi Tahu Research Consultation Committee has membership from:

*Te Rūnanga o Ōtākou Incorporated  
Kāti Huirapa Rūnaka ki Puketeraki  
Te Rūnanga o Moeraki*

Approval for this programme of study from the Wellington-based Research Advisory Group- Maori (RAG-M).



Research Advisory Group – Māori  
Māori Partnership Board, Capital & Coast DHB

## RESEARCH ADVISORY GROUP MAORI (RAG-M)

---

02 August 2012

Lucie Zwimpfer  
Department of Paediatrics and Child Health  
University of Otago Wellington  
PO Box 7343  
Wellington South

### **RAG-M 2012/200 – Letter of Endorsement**

Tēnā koe Ms Zwimpfer

On behalf of the Research Advisory Group Māori I write in relation to your study entitled **“Talking to Babies in a Neonatal Intensive Care Unit: The impact of verbal soothing on measures of infant stress during heel prick procedures.”**

*Following your RAG-M Letter of Provisional Endorsement dated: 18<sup>th</sup> July 2012, RAG-M are satisfied that you have read and understood the expectations outlined in this letter. We have received confirmation, acknowledging and addressing these expectations and therefore are happy to endorse this research project.*

You have supplied a RAG-M cover sheet, a study protocol, an ethics application to the Multi-region Ethics Committee, parent information sheet and consent forms.

Our reading of your proposal characterises the research as:

- A randomised crossover trial to investigate whether a non-parent talking empathically to an infant during painful procedures (heel pricks) reduces infant stress, compared to staying silent.
- A study involving 63 healthy babies born between 32 and 35 weeks gestation in Wellington's neonatal intensive care unit of whom 12 may be Māori.
- A study that involves taking six saliva samples from the baby that will be stored for later analysis in Christchurch and completely used during the processing.
- A study in which parents will give consent of their infant's participation.

We note that:

- You have sought approval from the Central Region Ethics Committee, and approval is given pending consultation with local Māori.
- You have registered the study with the Clinical Services Research Centre of the CCDHB.

Given the **likelihood** of Māori babies as participants, we would expect that:

- you would ensure that any Māori parent who is invited to participate is well informed and supported, and offered support from Whanau Care Services;
- you would recognise any cultural expectations and seek to meet these expectations responsively;
- treat any blood and tissue samples taken consistently with the CCDHB policy on human samples which is endorsed by this Committee.

We note that Right 5 of the HDC Code of Health and Disability Services Consumer Rights states that “Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided.” We think your information sheet is well presented. However, we recommend all researchers analyse their information and consent forms for literacy level and consider developing plain language summaries for people with low literacy levels where necessary.

**Whanau Care Services WCS:** You will be aware that WCS operate within the Wellington Regional Hospital. WCS have a responsibility to both patients of the hospital and staff. Given that this research may operate within the hospital campus, or involve CCDHB staff, we would expect that you make participants aware of WCS services and make referrals where appropriate.

We appreciate that you attended the Tikanga Māori training for researchers, and that you have carefully considered the implications of this training for your research.

If all staff involved in the study have not yet completed the cultural training on Tikanga Māori provided by the DHB, we recommend that this be undertaken. We would be interested in receiving a summary of the results of your study. We would also like to know how many Māori participants were recruited.

We welcome this study’s intention to reduce stress for infants experiencing painful procedures at this crucial stage of life. We thank you for consulting RAG-M and wish you well in your study.

Nāku noa nā



**Jack Rikihana**  
Chair RAG-M

## APPENDIX IV: ETHICAL APPROVAL

Ethical approval from the Central Regional Ethics Committee for the Heel Prick Observational study described in Chapter four.



Central Regional Ethics Committee  
Ministry of Health  
No. 1 The Terrace  
PO Box 5013  
Wellington 6145  
Phone (04) 816 2405  
(04) 816 2655  
Fax (04) 496 2340  
Email: central\_ethicscommittee@moh.govt.nz

21 June 2011

Miss Lucie Zwimpfer  
Dept of Paediatrics  
University of Otago  
PO Box 7343  
Wellington

Dear Lucie Zwimpfer

Re: Ethics ref: **CEN/11/EXP/041** (please quote in all correspondence)  
Study title: An Audit of Current Practice around Heel Prick Procedures in Wellington's Neonatal Intensive Care Unit  
Investigators: Miss Lucie Zwimpfer

This study was given ethical approval by the Central Regional Ethics Committee on 16 June 2011.

### Approved Documents

- Audit Study Protocol

This approval is valid 31 August 2011, provided that Annual Progress Reports are submitted (see below).

### Amendments and Protocol Deviations

All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:

- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study
- the method of recruitment
- information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports

The first Annual Progress Report for this study is due to the Committee by 16 June 2012. The Annual Report Form that should be used is available at [www.ethicscommittees.health.govt.nz](http://www.ethicscommittees.health.govt.nz). Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A Final Report is also required at the conclusion of the study. The Final Report Form is also available at [www.ethicscommittees.health.govt.nz](http://www.ethicscommittees.health.govt.nz).

Statement of compliance

The committee is constituted in accordance with its Terms of Reference. It complies with the *Operational Standard for Ethics Committees* and the principles of international good clinical practice.

The committee is approved by the Health Research Council's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990.

We wish you all the best with your study.

Yours sincerely

Sonia Scott  
Administrator  
Central Regional Ethics Committee

Ethical approval from the Central Health and Disability Ethics Committee for the Nappy Change Observational study described in Chapter five.



Health and Disability Ethics Committees

1 The Terrace  
PO Box 5013  
Wellington  
6011

0800 4 ETHICS  
hdec@moh.govt.nz

29 October 2012

Ms Lucie Zwimpfer  
Department of Paediatrics and Child Health  
University of Otago, Wellington  
PO Box 7343  
Wellington South 6242

Dear Ms Zwimpfer

Re: <b>Ethics ref:</b>	<b>CEN/11/EXP/041</b>
Study title:	An Audit of Current Practice around Heel Prick Procedures in Wellington's Neonatal Intensive Care Unit

I am pleased to advise that this amendment has been approved by the Central Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Helen Walker'.

**Mrs Helen Walker**  
Chairperson  
Central Health and Disability Ethics Committee

Encl: appendix A: documents submitted  
appendix B: statement of compliance and list of members

**Appendix A**  
**Documents submitted**

Document	Version	Date
Protocol: study protocol for extension to audit study to include non painful routine nappy changes.	1	17 October 2012
Survey/questionnaire: data collection sheet	1	17 October 2012
Post Approval Form		

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Central Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

### List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	01/07/2012	01/07/2015
Mr Paul Barnett	Lay (the law)	01/07/2012	01/07/2014
Mrs Gael Donoghue	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Dr Ptries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Lynne Russell	Non-lay (observational studies)	01/07/2012	01/07/2014

<http://www.ethics.health.govt.nz>



Ethical approval from the Central Regional Ethics Committee for the Feasibility study described in Chapter six.



Central Regional Ethics Committee  
c/- Ministry of Health  
PO Box 5013  
1 the Terrace  
Wellington  
Phone: (04) 816 2405  
Email: central\_ethicscommittee@moh.govt.nz

10 May 2011

Miss Lucie Zwimpfer

Dept of Paediatrics  
University of Otago  
PO Box 7343  
Wellington

Dear Ms Zwimpfer -

Ethics ref: **CEN/11/04/025** (please quote in all correspondence)  
Study title: Talking to babies in a neonatal intensive care unit: the impact of verbal soothing by a neonatal nurse on measures of infant stress during heel prick procedures. A feasibility study

Thank you for your letter dated the 21<sup>st</sup> of April 2011 enclosing documentation relating to the above named study. This documentation has been reviewed and approved by the Chairperson of the Multi-region Ethics Committee under delegated authority.

**Approved Documents**

- Part 5 attached
- P17, D7. Feedback on why the data would be stored for 36 years.
- Response on the feedback of the committee regarding the possible difference in response to male nurses compared to female nurses

Please do not hesitate to contact me should you have any queries.

Yours sincerely

Elise Agostino  
Administrator  
Central Regional Ethics Committee  
Email: central\_ethicscommittee@moh.govt.nz

Ethical approval from the Central Regional Ethics Committee for the Saliva Volume study described in Chapter six.



Central Regional Ethics Committee  
c/- Ministry of Health  
PO Box 5013  
1 the Terrace  
Wellington  
Phone: (04) 816 2405  
Email: [central\\_ethicscommittee@moh.govt.nz](mailto:central_ethicscommittee@moh.govt.nz)

23 March 2012

Miss Lucie Zwimpfer  
Dept of Paediatrics  
University of Otago  
PO Box 7343  
Wellington

Dear Miss Zwimpfer

Ethics ref: **CEN/11/04/025** (please quote in all correspondence)  
Study title: Talking to babies in a neonatal intensive care unit: the impact of verbal soothing by a neonatal nurse on measures of infant stress during heel prick procedures. A feasibility study

Thank you for your letter dated the 12<sup>th</sup> of March 2012 enclosing documentation relating to the above named study. This documentation has been reviewed and approved by the Chairperson of the Central Regional Ethics Committee under delegated authority.

**Approved Documents**

- Information Sheet for Parents

Yours sincerely

**AWHINA RANGIWAI**  
ADMINISTRATOR  
Central Regional Ethics Committee

Ethical approval from the Central Health and Disability Ethics Committee for the main 'Talking to Babies' study described in Chapter seven.



Health and Disability Ethics Committees  
1 the Terrace  
PO Box 5013  
Wellington  
0800 4 ETHICS  
hdec@moh.govt.nz

13 August 2012  
*Amended 22 August 2012*

Miss Lucie Zwimpfer  
Department of Paediatrics  
University of Otago  
PO Box 7343  
Wellington

Dear Miss Lucie Zwimpfer

Re: <b>Ethics ref:</b>	<b>CEN/12/06/021</b>
Study title:	Talking to Babies in a Neonatal Intensive Care Unit: The impact of verbal soothing on measures of infant stress during heel prick procedures

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the full review pathway.

#### Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

#### After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

#### Participant access to ACC

The Central Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



**Mrs Helen Walker**  
Chairperson  
Central Health and Disability Ethics Committee

Encl: appendix A: documents submitted  
appendix B: statement of compliance and list of members

**Appendix A**  
**Documents submitted**

<b>Document</b>	<b>Version</b>	<b>Date</b>
National Application Form		
Part 4 signed by Lucie Zwimpfer		22 May 2012
Form A		
Letter of acceptance and funding assessment process from Hawkes Bay Medical Research Foundation		
Letter dated from Ngai Tahu Research Consultation Committee		9 March 2011
Maori Consultation Letter from RAG-M (CCDHB)		
Locality Assessment - Wellington Hospital		
Information Sheet for Parents		May 2012
Parent Consent Form		May 2012

**Appendix B**  
**Statement of compliance and list of members**

Statement of compliance

The Central Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	01/07/2012	01/07/2015
Mr Paul Barnett	Lay (the law)	01/07/2012	01/07/2014
Mrs Gael Donoghue	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Dr Ptries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Lynne Russell	Non-lay (observational studies)	01/07/2012	01/07/2014

<http://www.ethics.health.govt.nz>

## APPENDIX V: INFORMATION SHEETS AND CONSENT FORMS

Information sheet and consent form for parents of infants in the Feasibility study.



### INFORMATION SHEET FOR PARENTS

#### Talking to babies during heel prick procedures.

**Principal Investigator:** Lucie Zwimpfer, Registered Parent Infant Psychotherapist and PhD Candidate, Department of Paediatrics, Wellington School of Medicine & Health Sciences, University of Otago, Wellington. Telephone: 918 5062

Dr Dawn Elder, Senior Lecturer, is supervising this research and can be contacted through the Department of Paediatrics, Wellington School of Medicine & Health Sciences, University of Otago, Wellington. Telephone: 385 5999

#### An Invitation

You and your baby (or babies) are invited to take part in a research study looking at the effect that a nurse's soothing voice has on preterm infants in the Neonatal Intensive Care Unit during heel prick procedures. You have as long as you need to consider whether you are willing to take part in this research. Your decision to not take part will not affect you or your baby's continuing health care.

#### What we know already

- Previous studies have shown us that there are interventions other than the use of drugs, that are effective in reducing the pain and stress that babies feel during heel prick and other procedures
- Some of these interventions include 'kangaroo care', swaddling the baby, giving the baby a pacifier to suck and modifying the light and sound environment.

**What do we want to learn from this study?**

We want to learn whether a nurse's voice is effective in reducing the stress experienced by preterm babies during heel prick procedures in the Neonatal Unit.

**Why do we need to do this study?**

We know that preterm babies often have to have many stressful procedures during their time in the Neonatal Unit and research has suggested that this can make them more vulnerable to stress later in life. We know from research the importance of a parent's voice for soothing infants both in hospital and at home. We also know that it is not always possible for an infant's mother or father to be with them during every stressful procedure. The purpose of this research is to see if a nurse's voice is able to soothe an infant in the absence of their parents.

**Who is able to be part of the study?**

All infants born around 32-35 weeks gestation, in their first week of life and who are thought to be well enough are able to take part in the study. Staff in the Neonatal Unit will select infants suitable for the study. Your infant will either be in the group that has nurse's talking to them during their heel prick test, or in the control group where the nurse will be silent during the test.

**Where will the study be held?**

In the Neonatal Intensive Care Unit at Wellington Hospital.

**How much time will it involve?**

The study will involve one 1 ½ hour monitoring period before, during and after a routine heel prick procedure that your baby is having as part of their usual treatment.

**What procedures does the study involve?**

Your baby will be randomly allocated (selected by chance) by a computer to be in the 'talking' group or the control group. In the 'talking' group we will ask the nurse to talk to your baby about what is happening during their heel prick blood test and in the 'control' group we will ask the nurse to remain silent. Over the time of your baby's studied heel prick test, your baby will be videoed and have his/her heart rate, breathing rate and oxygen levels recorded for up to 1½ hours. In addition, we will take three saliva swabs from your baby's mouth; once before your baby's heel prick test and twice afterwards. These saliva samples will be stored at Wellington Hospital and then sent to Canterbury for analysis. The saliva will be destroyed during the analysis process.

**What are the risks and/or inconveniences of the study?**

Your baby will be monitored throughout their participation in this study (as well as by their usual assigned nurse) and the study will be performed in the Neonatal Intensive Care Unit.



There is no extra risk to your infant. We will not do the study if it interferes in any way with the medical and nursing care of your infant and we will stop the study if there are any concerns that it may be having an adverse effect on your baby.

### **What are the benefits of the study?**

- In the short term your baby will have a period of more intensive monitoring during the study. If there are any concerns about your baby's stress response we will pass on information gained from the study to your baby's Doctor.
- The main benefit will be long-term for all the babies cared for in the Unit. We will see if we can find evidence that talking to babies during stressful procedures reduces the stress of the situation for preterm babies. We will use this information to determine how we care for babies in this situation on a day-to-day basis.

### **Will it cost anything to take part in the study?**

No

### **Your decision to participate**

Participation in this study is entirely voluntary (your choice) and you and your partner should both feel comfortable about agreeing that your baby takes part in the study. Please feel free to ask questions about the study before giving your consent. If you choose not to take part in the study you will receive the usual treatment / care.

If you do agree to take part in the study you are free to withdraw your baby from the study at any time without having to give a reason and this will in no way affect you or your baby's continuing health care.

Participation in this study will be stopped should the Doctor feel it is not in the best interest of your baby to continue. The needs of your baby will always come first.

No material that could identify you or your baby personally will be used in any reports on this study. Only the investigators of the study will have access to the information collected about you and your baby.

### **Are you of Maori or Pacific Island ethnicity?**

We have discussed this study with both Maori and Pacific Island Health workers. If you would like one of these workers to meet with you and discuss any aspect of this project with you, we would be happy to arrange this.

### **What will happen at the end of the study?**

The Doctor looking after your baby in the Neonatal Intensive Care Unit will be advised of any ongoing problems that show up in the study. However a full review of all the recordings done on your baby will not necessarily be completed before your baby goes home from the neonatal unit.

You will have the option of receiving a summary of the final results from the completed study.

If you have queries or concerns about your rights as a participant in this study you may wish to contact a Health and Disability Services Consumer Advocate. We would be very happy to help you make that contact.

### **Compensation**

In the unlikely event of a physical injury as a result of your baby's participation in this study, he/she will be covered by the Accident Compensation legislation with its limitations. If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this study.

**This study has received ethical approval from the Central Regional Ethics Committee.**

*Please feel free to contact the researcher if you have any questions about this study.*



## PARENT CONSENT FORM

### Talking to babies during heel prick procedures.

#### REQUEST FOR INTERPRETER

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	loe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	loe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

- I have read and I understand the information sheet dated May 2011 for parents of infants taking part in the study designed to investigate the effect on preterm infants of a nurse's soothing voice during heel prick procedures. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.
- I understand my baby taking part in this study is voluntary (my choice) and that I may withdraw my baby from the study at any time and that this will in no way affect my or my baby's continuing healthcare.
- I understand my baby's participation in the study is confidential and that no material which could identify my baby or me will be used in any reports on this study.
- I understand the compensation provisions for this study
- I have had time to consider whether to take part in the study
- I know whom to contact if I have any questions about the study

- I consent to the researchers storing three specimen of my baby's saliva for its later use as a part of this study. I understand that the analysis will destroy the saliva specimen. YES / NO
- I consent to my baby's data being kept for future research into the impact of soothing voice on babies, subject to ethical approval being given by a New Zealand-accredited ethics committee. YES / NO
- I consent to my baby's heel prick procedure in the study being videotaped YES / NO
- I wish to receive a copy of the results of the completed study YES / NO

I \_\_\_\_\_ hereby consent to my baby  
 \_\_\_\_\_ taking part in the above study.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Witnessed by:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Full name of researcher: Lucie Zwimpfer

Contact number: 385 5999

Project explained by: \_\_\_\_\_

Project role: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

If you have any concerns about this study you may contact: The Central Regional Ethics Committee, PO Box 5013, Wellington. Telephone (04) 496 2405.

Information sheet and consent form for NICU Nurses in the Feasibility study.



## INFORMATION SHEET FOR NURSES

### Talking to babies during heel prick procedures.

**Principal Investigator:** Lucie Zwimpfer, Registered Parent Infant Psychotherapist and PhD Candidate, Department of Paediatrics, Wellington School of Medicine & Health Sciences, University of Otago, Wellington. Telephone: 918 5062

Dr Dawn Elder, Senior Lecturer, is supervising this research and can be contacted through the Department of Paediatrics, Wellington School of Medicine & Health Sciences, University of Otago, Wellington. Telephone: 385 5999

#### An Invitation

You are invited to take part in a research study looking at the effect that a nurse's soothing voice has on preterm infants in the Neonatal Intensive Care Unit during heel prick procedures. You have as long as you need to consider whether you are willing to take part in this research. Your decision to not take part will not affect your employment.

#### What we know already

- Previous studies have shown us that there are non-pharmaceutical interventions that are effective in reducing the stress babies feel during heel prick and other painful procedures
- Some of these interventions include 'kangaroo care', swaddling the baby, giving the baby a pacifier to suck and modifying the light and sound environment.

#### What do we want to learn from this study?

We want to learn whether a nurse's voice is effective in reducing the stress experienced by preterm babies during heel prick procedures in the Neonatal Unit.

#### Why do we need to do this study?

We know that preterm babies often have to have many stressful procedures during their time in the Neonatal Unit and research has suggested that this can make them more

vulnerable to stress later in life. We know from research the importance of a primary caregiver's voice for soothing infants both in hospital and at home. We also know that it is not always possible for an infant's parent to be with them during every stressful procedure. The purpose of this research is to see if a nurse's voice is able to soothe an infant in the absence of a parent.

### **Who is able to be part of the study?**

All nurses caring for infants born around 32-35 weeks gestation, in their first week of life and who are thought to be well enough are able to take part in the study.

### **Where will the study be held?**

In the Neonatal Intensive Care Unit at Wellington Hospital.

### **How much time will it involve?**

The study will not involve any extra time for nurses.

### **What procedures does the study involve?**

During a routine heel prick test we will ask you to either talk to the baby about what is happening throughout the procedure, or to remain silent throughout (control group). The participating infants will be randomly allocated to be in a 'talking' group or control group. During the studied heel prick test, the infant will be videoed and have his/her heart rate, respiratory rate and oxygen levels recorded for up to 1½ hours. In addition, we will take three saliva swabs from the baby; once before the heel prick test and two at intervals afterwards.

### **What are the risks and/or inconveniences of the study?**

We do not anticipate participation in this study to be an inconvenience. The lead investigator, a registered parent infant psychotherapist will be available to speak to at any time during the study, should you wish to.

### **What are the benefits of the study?**

- The main benefit will be long-term for all the babies cared for in the Unit. We hope to find evidence that talking to babies during stressful procedures reduces the stress of the situation for preterm babies. If this is so, it will have implications for the day-to-day care of preterm infants.

### **Will it cost anything to take part in the study?**

No

### **Your decision to participate**

Participation in this study is entirely voluntary (your choice) and you should feel comfortable about agreeing to take part in the study. Please feel free to ask questions about the study

before giving your consent. If you choose not to take part in the study your employment will not be affected.

If you do agree to take part in the study you are free to withdraw your consent at any time without having to give a reason and this will in no way affect your employment.

No material that could identify you will be used in any reports on this study. Only the investigators of the study will have access to the information collected about the observed study period.

**Are you of Maori or Pacific Island ethnicity?**

We have discussed this study with both Maori and Pacific Island Health workers. If you would like one of these workers to meet with you and discuss any aspect of this project with you, we would be happy to arrange this.

**What will happen at the end of the study?**

The final results of the study will be available to all participants.

If you have queries or concerns about your rights as a participant in this study you may wish to contact a Health and Disability Services Consumer Advocate. We would be very happy to help you make that contact.

**This study has received ethical approval from the Central Regional Ethics Committee.**

*Please feel free to contact the researcher if you have any questions about this study.*



## NURSE CONSENT FORM

### Talking to babies during heel prick procedures.

#### REQUEST FOR INTERPRETER

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	loe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	loe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

- I have read and I understand the information sheet dated May 2011 for nurses taking part in the study designed to investigate the effect on preterm infants of a nurse's soothing voice during heel prick procedures. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.
- I understand taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and that this will in no way affect my employment at Capital and Coast Health.
- I understand my participation in the study is confidential and that no material which could identify me will be used in any reports on this study.
- I understand the compensation provisions for this study
- I have had time to consider whether to take part in the study
- I know whom to contact if I have any questions about the study



- I consent to my voice being captured on videotape during the heelprick procedure YES / NO
- I wish to receive a copy of the results of the completed study YES / NO

I \_\_\_\_\_ hereby consent to taking part in the above study.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Witnessed by:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Full name of researcher: Lucie Zwimpfer

Contact number: 385 5999

Project explained by: \_\_\_\_\_

Project role: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

If you have any concerns about this study you may contact: The Central Regional Ethics Committee, PO Box 5013, Wellington. Telephone (04) 496 2405.



## INFORMATION SHEET FOR PARENTS

### Talking to babies during heel prick procedures: saliva collection study

**Principal Investigator:** Lucie Zwimpfer, Registered Parent Infant Psychotherapist and PhD Candidate, Department of Paediatrics & Child Health, University of Otago, Wellington.

Telephone: 918 5062

Assoc-Prof Dawn Elder is supervising this research and can be contacted through the Department of Paediatrics & Child Health, University of Otago, Wellington.

Telephone: 918 6145

#### An Invitation

You and your baby (or babies) are invited to take part in a research study looking at the effect that a nurse's soothing voice has on preterm infants in the Neonatal Intensive Care Unit during heel prick procedures. *In this part of the study we are looking at the best way to collect saliva from preterm infants.* You have as long as you need to consider whether you are willing to take part in this research. Your decision to not take part will not affect you or your baby's continuing health care.

#### What we know already

- Previous studies have shown us that saliva is a non-invasive method for assessing stress in premature infants.
- The stress measure that we are hoping to use is salivary cortisol
- However, it can be difficult to collect the volume of saliva needed to measure the cortisol levels accurately.

**What do we want to learn from this study?**

We want to learn whether a drop of 5% citric acid solution (the equivalent of lemon juice) can help stimulate saliva flow in premature infants.

**Why do we need to do this study?**

We know that preterm babies often have to have many stressful procedures during their time in the Neonatal Unit and research has suggested that this can make them more vulnerable to stress later in life. We want to ensure we have a reliable method for assessing salivary cortisol levels in premature infants, so that we can explore the effectiveness of interventions designed to reduce the stress for babies in NICU.

**Who is able to be part of the study?**

All infants born around 32-35 weeks gestation and who are thought to be well enough are able to take part in the study. Staff in the Neonatal Unit will select infants suitable for the study.

**Where will the study be held?**

In the Neonatal Intensive Care Unit at Wellington Hospital.

**How much time will it involve?**

The study will involve two 1 ½ hour monitoring periods before, during and after your baby's cares.

**What procedures does the study involve?**

Your baby will have two saliva collection periods. For one of them we will place a drop of 5% citric acid solution (lemon juice) into your baby's mouth before taking the three samples of saliva, using a swab. In the other period, we will not use any citric acid. Your baby will be randomly allocated (selected by chance) by a computer to decide which of these conditions your baby will have first. These saliva samples will be stored at Wellington Hospital and then sent to Canterbury for analysis. The saliva will be destroyed during the analysis process.

**What are the risks and/or inconveniences of the study?**

Your baby will be monitored throughout their participation in this study (as well as by their usual assigned nurse) and the study will be performed in the Neonatal Intensive Care Unit. There is no extra risk to your infant. We will not do the study if it interferes in any way with the medical and nursing care of your infant and we will stop the study if there are any concerns that it may be having an adverse effect on your baby.

### **What are the benefits of the study?**

- In the short term your baby will have a period of more intensive monitoring during the study.
- The main benefit will be long-term for all the babies cared for in the Unit. We will see if we can find evidence that 5% citric acid is useful for stimulating saliva flow. We will use this information to determine how we can best measure stress for babies in NICU.

### **Will it cost anything to take part in the study?**

No

### **Your decision to participate**

Participation in this study is entirely voluntary (your choice) and you and your partner should both feel comfortable about agreeing that your baby takes part in the study. Please feel free to ask questions about the study before giving your consent. If you choose not to take part in the study you will receive the usual treatment / care.

If you do agree to take part in the study you are free to withdraw your baby from the study at any time without having to give a reason and this will in no way affect you or your baby's continuing health care.

Participation in this study will be stopped should the Doctor feel it is not in the best interest of your baby to continue. The needs of your baby will always come first.

No material that could identify you or your baby personally will be used in any reports on this study. Only the investigators of the study will have access to the information collected about you and your baby.

### **Are you of Maori or Pacific Island ethnicity?**

We have discussed this study with both Maori and Pacific Island Health workers. If you would like one of these workers to meet with you and discuss any aspect of this project with you, we would be happy to arrange this.

### **What will happen at the end of the study?**

You will have the option of receiving a summary of the final results from the completed study.

If you have queries or concerns about your rights as a participant in this study you may wish to contact a Health and Disability Services Consumer Advocate. We would be very happy to help you make that contact.

## **Compensation**

In the unlikely event of a physical injury as a result of your baby's participation in this study, he/she will be covered by the Accident Compensation legislation with its limitations. If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this study.

**This study has received ethical approval from the Central Regional Ethics Committee.**

*Please feel free to contact the researcher if you have any questions about this study.*



## PARENT CONSENT FORM

### Talking to babies during heel prick procedures: saliva study

#### REQUEST FOR INTERPRETER

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Naka i
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	loe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	loe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

- I have read and I understand the information sheet dated May 2012 for parents of infants taking part in the study designed to investigate the best way to collect saliva from preterm infants. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.
- I understand my baby taking part in this study is voluntary (my choice) and that I may withdraw my baby from the study at any time and that this will in no way affect my or my baby's continuing healthcare.
- I understand my baby's participation in the study is confidential and that no material which could identify my baby or me will be used in any reports on this study.
- I understand the compensation provisions for this study
- I have had time to consider whether to take part in the study

- I know whom to contact if I have any questions about the study
- I consent to the researchers storing six specimen of my baby’s saliva for its later use as a part of this study. I understand that the analysis will destroy the saliva specimen.  
YES / NO
- I consent to my baby’s data being kept for future research into the impact of soothing voice on babies, subject to ethical approval being given by a New Zealand-accredited ethics committee.  
YES / NO
- I wish to receive a copy of the results of the completed study YES / NO

I \_\_\_\_\_ hereby consent to my baby  
\_\_\_\_\_ taking part in the above study.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Witnessed by:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Full name of researcher: Lucie Zwimpfer

Contact number: 385 5999 extn 5062

Project explained by: \_\_\_\_\_

Project role: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

If you have any concerns about this study you may contact: The Central Regional Ethics Committee, PO Box 5013, Wellington. Telephone (04) 496 2405.

Information sheet and consent form for parents of infants in the main 'Talking to Babies' study.



## INFORMATION SHEET FOR PARENTS

### Talking to babies during heel prick procedures.

**Principal Investigator:** Lucie Zwimpfer, Registered Parent Infant Psychotherapist and PhD Candidate, Department of Paediatrics, Wellington School of Medicine & Health Sciences, University of Otago, Wellington. Telephone: 918 5062

Associate Professor Dawn Elder, is supervising this research and can be contacted through the Department of Paediatrics, Wellington School of Medicine & Health Sciences, University of Otago, Wellington. Telephone: 916 6145

#### An Invitation

You and your baby (or babies) are invited to take part in a research study looking at the effect that a soothing voice has on preterm infants in the Neonatal Intensive Care Unit during heel prick procedures. You have as long as you need to consider whether you are willing to take part in this research. Your decision to not take part will not affect you or your baby's continuing health care.

#### What we know already

- Previous studies have shown us that there are interventions other than the use of drugs, that are effective in reducing the pain and stress that babies feel during heel prick and other procedures
- Some of these interventions include 'kangaroo care', swaddling the baby, giving the baby a pacifier to suck and modifying the light and sound environment.

#### What do we want to learn from this study?

We want to learn whether a non-parental adult voice is effective in reducing the stress experienced by preterm babies during heel prick procedures in the Neonatal Unit.



**Why do we need to do this study?**

We know that preterm babies experience many stressful procedures during their time in the Neonatal Unit and previous research has suggested that this can make them more vulnerable to stress later in life. We also know from research the importance of a parent's voice for soothing infants both in hospital and at home. However, it is not always possible for an infant's mother or father to be with them during every stressful procedure. The purpose of this research is to see if another adult's voice is able to soothe an infant in the absence of their parents in the same way.

**Who is able to be part of the study?**

All infants born around 32-35 weeks gestation, in their first two weeks of life and who are thought to be well, are able to take part in the study. Staff in the Neonatal Unit will select infants suitable for the study. Your infant will be studied during two of their scheduled heel prick blood tests. During one test the principal investigator will talk to your infant and in the other, the principal investigator will remain silent.

**Where will the study be carried out?**

In the Neonatal Intensive Care Unit at Wellington Hospital.

**How much time will it involve?**

The study will involve one 1 ½ hour monitoring period before, during and after a routine heel prick procedure that your baby is having as part of their usual treatment.

**What procedures does the study involve?**

Your baby will be randomly allocated (selected by chance) by a computer to be first in either the 'talking' condition or the control condition. In the 'talking' condition, Lucie Zwimpfer, the Principal Investigator for this study will talk to your baby about what is happening during their heel prick blood test and how they might be feeling. In the 'control' group, Lucie and the nurse will remain silent. Over the time of your baby's studied heel prick test, your baby will be videoed and have his/her heart rate and oxygen levels recorded for up to 1½ hours. In each condition, we will take three saliva swabs from your baby's mouth; once before your baby's heel prick test and twice afterwards. To help your baby make enough saliva for us to use, we will give them a drop (up to 0.1ml) of 5% citric acid solution (lemon juice) before each saliva swab. These six saliva samples will be stored at Wellington Hospital and then sent to Christchurch hospital for analysis. The saliva will be destroyed during the analysis process.

**What are the risks and/or inconveniences of the study?**

Your baby will be monitored throughout their participation in this study (as well as by their usual assigned nurse) and the study will be undertaken in the Neonatal Intensive Care Unit. There is no extra risk to your infant. We will not do the study if it interferes in any way with

the medical and nursing care of your infant and we will stop the study if there are any concerns that it may be having an adverse effect on your baby.

### **What are the benefits of the study?**

- In the short term your baby will have a period of more intensive monitoring during the study. If there are any concerns about your baby's stress response we will pass on information gained from the study to your baby's Doctor.
- The main benefit will be long-term for all the babies cared for in the Unit. We will see if we can find evidence that talking to babies during stressful procedures reduces the stress of the situation for preterm babies. We will use this information to determine how we care for babies in this situation on a day-to-day basis.

### **Will it cost anything to take part in the study?**

No

### **Your decision to participate**

Participation in this study is entirely voluntary (your choice) and you and your partner should both feel comfortable about agreeing that your baby takes part in the study. Please feel free to ask questions about the study before giving your consent. If you choose not to take part in the study you will receive the usual treatment / care.

If you do agree to take part in the study you are free to withdraw your baby from the study at any time without having to give a reason and this will in no way affect you or your baby's continuing health care.

Participation in this study will be stopped should the Doctor feel it is not in the best interest of your baby to continue. The needs of your baby will always come first.

No material that could identify you or your baby personally will be used in any reports on this study. Only the investigators of the study will have access to the information collected about you and your baby.

### **Are you of Maori or Pacific Island ethnicity?**

We have discussed this study with both Maori and Pacific Island Health workers. If you would like one of these workers to meet with you and discuss any aspect of this project with you, we would be happy to arrange this.

### **What will happen at the end of the study?**

The Doctor looking after your baby in the Neonatal Intensive Care Unit will be advised of any ongoing problems that show up in the study. However a full review of all the recordings done on your baby will not necessarily be completed before your baby goes home from the neonatal unit.

You will have the option of receiving a summary of the final outcome from the completed study.

If you have queries or concerns about your rights as a participant in this study you may wish to contact a Health and Disability Services Consumer Advocate. We would be very happy to help you make that contact.

### **Compensation**

In the unlikely event of a physical injury as a result of your baby's participation in this study, he/she will be covered by the Accident Compensation legislation with its limitations. If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this study.

**This study has received ethical approval from the Central Health and Disability Ethics Committee.**

*Please feel free to contact the researcher if you have any questions about this study.*



## PARENT CONSENT FORM

### Talking to babies during heel prick procedures.

#### REQUEST FOR INTERPRETER

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetahi tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Naka i
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	loe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	loe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

- I have read and I understand the information sheet dated May 2012 for parents of infants taking part in the study designed to investigate the effect on preterm infants of a nurse's soothing voice during heel prick procedures. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.
- I understand my baby taking part in this study is voluntary (my choice) and that I may withdraw my baby from the study at any time and that this will in no way affect my or my baby's continuing healthcare.
- I understand my baby's participation in the study is confidential and that no material which could identify my baby or me will be used in any reports on this study.
- I understand the compensation provisions for this study
- I have had time to consider whether to take part in the study

- I know whom to contact if I have any questions about the study
- I consent to the researchers storing six specimen of my baby's saliva for its later use as a part of this study. I understand that the analysis will destroy the saliva specimen. YES / NO
- I consent to my baby's data being kept for future research into the impact of soothing voice on babies, subject to ethical approval being given by a New Zealand-accredited ethics committee. YES / NO
- I consent to my baby's heel prick procedure in the study being videotaped YES / NO
- I wish to receive a copy of the results of the completed study YES / NO

I \_\_\_\_\_ hereby consent to my baby  
 \_\_\_\_\_ taking part in the above study.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Witnessed by:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Full name of researcher: Lucie Zwimpfer

Contact number: 918 5062

Project explained by: \_\_\_\_\_

Project role: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

If you have any concerns about this study you may contact: The Central Health and Disability Ethics Committee, PO Box 5013, Wellington. Telephone (04) 496 2405.

## APPENDIX VI: SUMMARY OF STUDY RESULTS FOR PARTICIPANTS

Summary of study results sent to parents of infants and Nurses in the Feasibility study.



### **Talking to babies during heel prick procedures: feasibility study.**

**July 2012**

**Dear**

Thank you very much for participating in the 'Talking to Babies' study in Wellington's Neonatal Intensive Care Unit.

The primary purpose of this feasibility study was to assess our method of measuring whether a nurse's voice is effective in reducing the stress experienced by preterm babies during heel prick procedures in the Neonatal Unit.

We found that saliva is a good, reliable measure of stress in infants, however it was difficult to get enough saliva for accurate analysis in this study. A further study has shown that a drop of 5% citric acid solution prior to collecting the saliva is an effective method for increasing saliva volumes, so we are confident that this is still the best way to measure stress in infants. We also gained other information from the feasibility study that has provided important insights into how we should refine our methodology as we continue with this research.

Your participation in this study has taken us one step further in this investigation into the use of a soothing voice as a pain management tool with preterm infants. We are very grateful for your help in finding ways to reduce stress for preterm infants in hospital.

Thank you,

Lucie Zwimpfer

**Principal Investigator**

Registered Parent Infant Psychotherapist and PhD Candidate,

Department of Paediatrics, Wellington School of Medicine & Health Sciences,

University of Otago, Wellington.

Telephone: (04) 918 5062

Summary of results sent to parents of infants in the Saliva Volume study.



## **Talking to babies during heel prick procedures: saliva collection study.**

**June 2012**

**Dear**

Thank you for allowing X to participate in the 'Talking to Babies' saliva study.

The results of this study showed that a drop of 5% citric acid solution (lemon juice) helps to stimulate saliva flow in preterm infants. This means that we now have a much more reliable method for collecting saliva in order to measure the stress hormone cortisol in preterm infants.

X's participation in this study means that we can now go ahead with our research to explore the effectiveness of use of a soothing voice during procedures that are likely to be painful, to reduce this stress for babies in the NICU.

We really appreciate your support for this study which we consider will give us important information about the best ways to care for preterm infants experiencing stress in the NICU.

Regards,

Lucie Zwimpfer

**Principal Investigator**

Registered Parent Infant Psychotherapist and PhD Candidate,  
Department of Paediatrics, Wellington School of Medicine & Health Sciences,  
University of Otago, Wellington. Telephone: 385 5999 extn 5062

Summary of results sent to parents of infants in the main 'Talking to Babies' study.



## Talking to babies during heel prick procedures

**November 2016**

**Dear**

Thank you for allowing X to participate in the 'Talking to Babies' study during your time in Wellington's Neonatal Intensive Care Unit.

The primary purpose of this study was to measure whether a soothing non-parental voice is effective in reducing the stress experienced by preterm babies during heel prick procedures in the Neonatal Unit. In this study we were not able to demonstrate any significant difference in preterm infant pain and stress when a non-parental vocal soothing intervention is compared with silence. However we found that reliable physiological data is difficult to collect from preterm infants especially during times when they are being actively handled for a heel prick procedure or routine cares. Therefore we can still not completely rule out that vocal soothing may help infants in this situation.

There were, however, some important advances in knowledge gained from this study.

Specifically we found that:

1. Non-parental vocal soothing is unlikely to have a detrimental effect on preterm infant cortisol levels. I would encourage you to continue to soothe your infant when you feel he or she is distressed.
2. Infants can produce both a 'pain' and a 'no pain' response to what we would consider to be a 'noxious' stimulus (a heelprick) within a 24 hour time period, meaning that there may be reasons other than infant age, state or time since last procedure that contribute to a behavioural and physiological expression of pain.
3. Given that some infants did not exhibit behavioural or physiological manifestations of pain or stress, yet still responded with a cortisol increase, it is important to consider that it is not always obvious to a caregiver that preterm infants are in distress.



X's participation in this study has taken us one step further in this investigation into how we can better meet the emotional needs of preterm infants. We are so grateful for your help. Doing this research has helped me to think a lot more about this aspect of the care of preterm infants in the NICU and especially how this support can be provided when you their parents are not able to be there. I can assure that I will be making every effort to share this new knowledge with my nursing and medical colleagues who work regularly with preterm infants.

Please feel free to contact me directly if you wish to know anything more about this study.

Thank you again,

Lucie Zwimpfer

**Principal Investigator**

Registered Parent Infant Psychotherapist and PhD Candidate,  
Department of Paediatrics, Wellington School of Medicine & Health Sciences,  
University of Otago, Wellington. Telephone: (04) 918 5062

## APPENDIX VII: DATA FROM THE MAIN ‘TALKING TO BABIES’ STUDY

Tests for Normality: Salivary Cortisol, Heart Rate and Oxygen Saturation data.

The salivary cortisol, heart rate and oxygen saturation data results were not found to be normally distributed. The Skewness, Kurtosis, Shapiro-Wilk test and Histograms upon which this finding was based are presented below.

The data was assumed normal if the z values for the skewness and kurtosis were between -1.96 and +1.96. The cortisol and oxygen saturation data were found to be skewed and kurtotic suggesting that these data were not normally distributed in terms of skewness and kurtosis. The heart rate data was much less skewed and kurtotic (Cramer, 1998; Cramer & Howitt, 2004; Doane & Seward, 2011). The p-values (Sig.) in the Shapiro-Wilk test were all below 0.05 for cortisol and oxygen saturation meaning that the null hypothesis of the data being normally distributed was rejected (Razali & Wah, 2011; Shapiro & Wilk, 1965). The heart rate data was mostly normally distributed in the Shapiro Wilk test. While the heart rate histograms did appear normal, the cortisol and oxygen saturation histograms did not and the decision was made to use non-parametric tests for all these data.

### Salivary Cortisol

#### Skewness and Kurtosis for Cortisol data

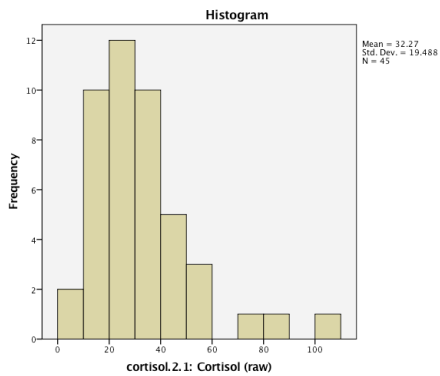
	Skewness			Kurtosis		
	Statistic	Std. Error	Z-score (Statistic/Std. error)	Statistic	Std. Error	Z-score (Statistic/Std. error)
<b>Silent</b>						
-Baseline	1.663	.354	<b>4.698</b>	3.603	.695	<b>5.184</b>
-Peak	2.485	.347	<b>7.161</b>	8.324	.681	<b>12.223</b>
-Recovery	3.488	.354	<b>9.853</b>	16.794	.695	<b>24.164</b>
<b>Voice</b>						
-Baseline	2.537	.337	<b>7.528</b>	6.320	.662	<b>9.547</b>
-Peak	5.490	.350	<b>15.686</b>	33.574	.688	<b>48.799</b>
-Recovery	1.909	.347	<b>5.501</b>	5.118	.681	<b>7.515</b>

## Shapiro-Wilk Test for Normality: Cortisol data

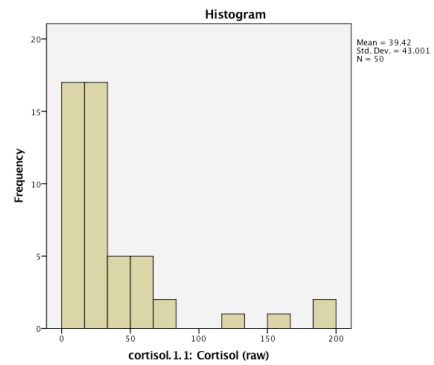
	Statistic	df.	Sig.
Silent			
-Baseline	.864	45	.000
-Peak	.768	47	.000
-Recovery	.676	45	.000
Voice			
-Baseline	.643	50	.000
-Peak	.388	46	.000
-Recovery	.832	47	.000

## Histograms –Cortisol data

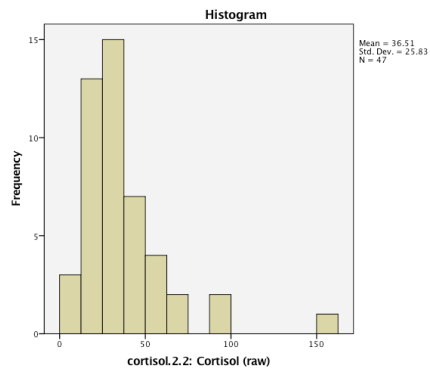
**Silent Baseline**



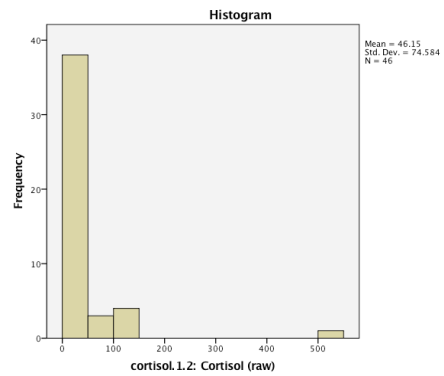
**Voice Baseline**



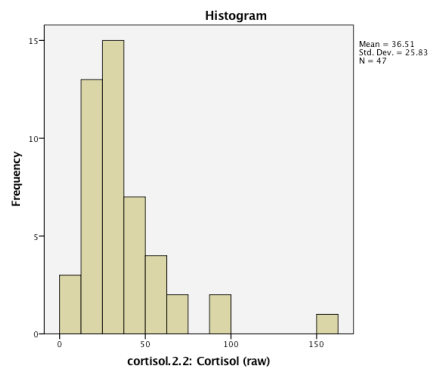
**Silent Peak**



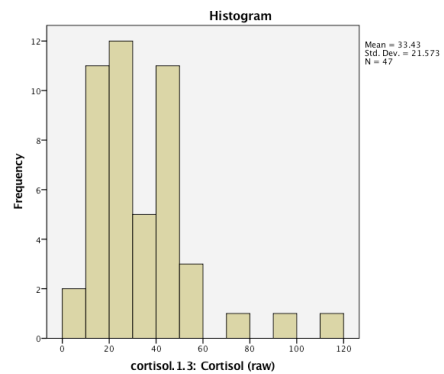
**Voice Peak**



**Silent Recovery**



**Voice Recovery**



## Heart Rate

### Skewness and Kurtosis for Heart Rate data

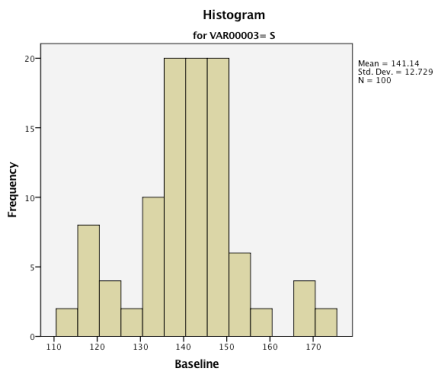
	Skewness			Kurtosis		
	Statistic	Std. Error	Z-score (Statistic/Std. error)	Statistic	Std. Error	Z-score (Statistic/Std. error)
<b>Silent</b>						
-Baseline	-.026	.241	<b>-0.108</b>	.278	.478	<b>.582</b>
-Peak	-.069	.347	<b>-0.199</b>	.572	.681	<b>.840</b>
-Recovery	.226	.337	<b>.671</b>	.440	.662	<b>.665</b>
<b>Voice</b>						
-Baseline	.379	.239	<b>1.586</b>	.444	.474	<b>.937</b>
-Peak	-.343	.340	<b>-1.009</b>	.597	.668	<b>.894</b>
-Recovery	-1.838	.333	<b>-5.520</b>	8.429	.656	<b>12.850</b>

### Shapiro-Wilk Test for Normality: Heart Rate data

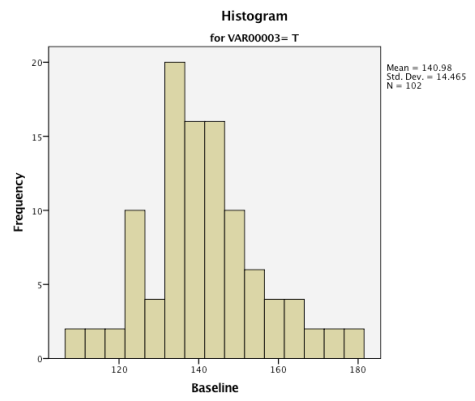
	Statistic	df.	Sig.
<b>Silent</b>			
-Baseline	.971	100	<b>.028</b>
-Peak	.977	47	<b>.491</b>
-Recovery	.989	50	<b>.908</b>
<b>Voice</b>			
-Baseline	.975	102	<b>.049</b>
-Peak	.960	49	<b>.098</b>
-Recovery	.863	51	<b>.000</b>

# Histograms –Heart rate data

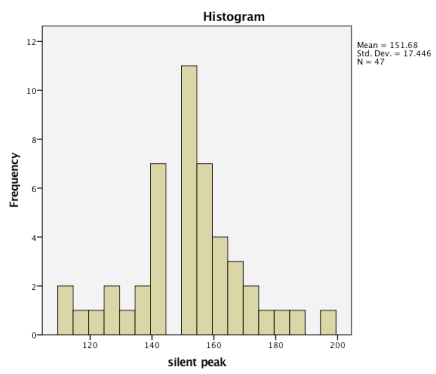
## Silent Baseline



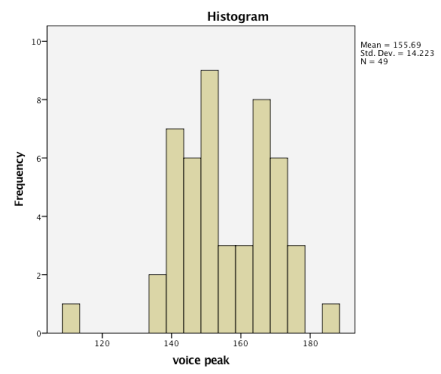
## Voice Baseline



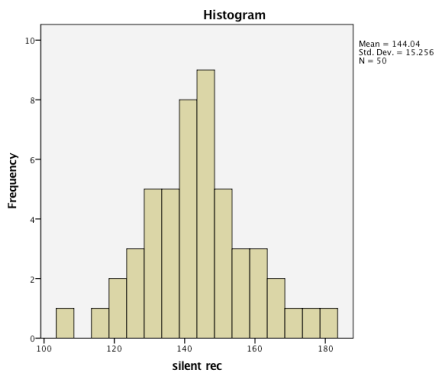
## Silent Peak



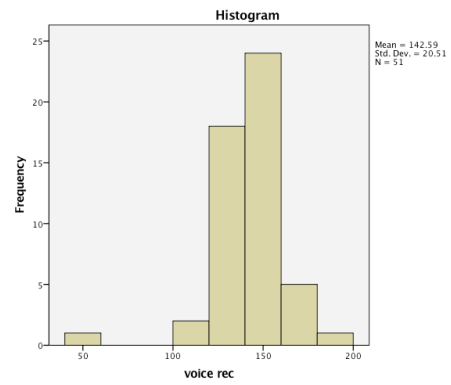
## Voice Peak



## Silent Recovery



## Voice Recovery



## Oxygen Saturation

### Skewness and Kurtosis for Oxygen saturation data

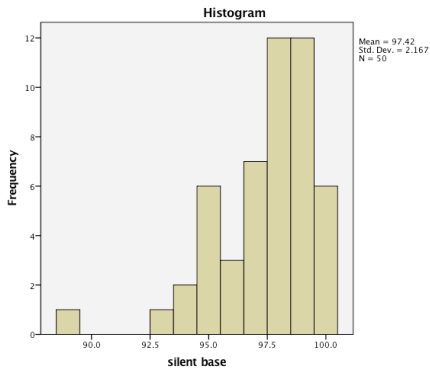
	Skewness			Kurtosis		
	Statistic	Std. Error	Z-score (Statistic/Std. error)	Statistic	Std. Error	Z-score (Statistic/Std. error)
<b>Silent</b>						
-Baseline	-1.471	.337	<b>-4.365</b>	3.332	.662	<b>5.033</b>
-Peak	-3.228	.347	<b>-9.303</b>	14.700	.681	<b>21.586</b>
-Recovery	-1.914	.337	<b>-5.680</b>	5.579	.662	<b>8.427</b>
<b>Voice</b>						
-Baseline	-1.150	.333	<b>3.453</b>	1.345	.656	<b>2.050</b>
-Peak	-.901	.340	<b>-2.65</b>	.816	.668	<b>1.222</b>
-Recovery	-2.792	.333	<b>-8.384</b>	10.901	.656	<b>16.617</b>

### Shapiro-Wilk Test for Normality: Oxygen saturation data

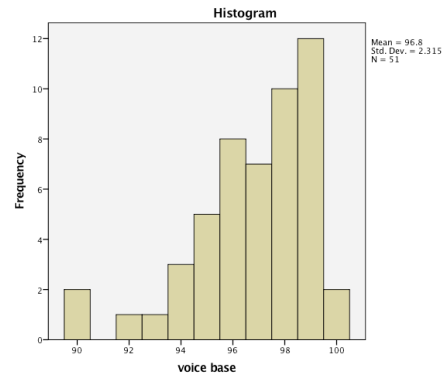
	Statistic	df.	Sig.
Silent			
-Baseline	.869	50	<b>.000</b>
-Peak	.693	47	<b>.000</b>
-Recovery	.826	50	<b>.000</b>
Voice			
-Baseline	.892	51	<b>.000</b>
-Peak	.918	49	<b>.002</b>
-Recovery	.729	51	<b>.000</b>

# Histograms –Oxygen saturation data

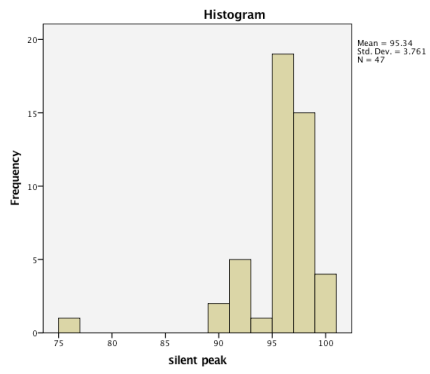
## Silent Baseline



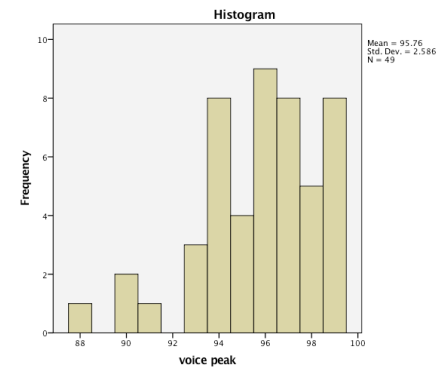
## Voice Baseline



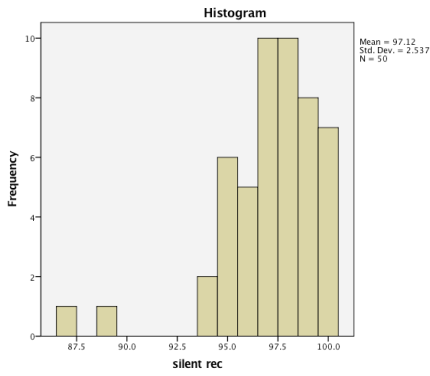
## Silent Peak



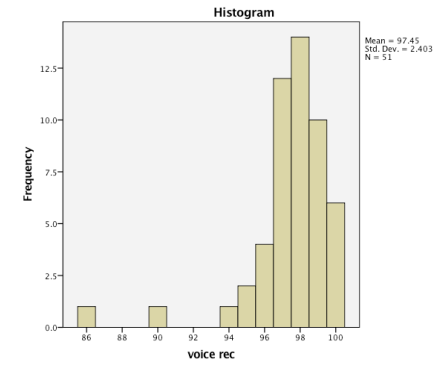
## Voice Peak



## Silent Recovery



## Voice Recovery



Tests for Normality: PIPP-R data.

The Premature Infant Pain Profile-Revised (PIPP-R) results were found to be normally distributed. The Skewness, Kurtosis, Shapiro-Wilk test and Histograms upon which this finding was based are presented below. The data was assumed normal if the z values for the skewness and kurtosis were between -1.96 and +1.96. The data were a little skewed and kurtotic but they did not differ significantly from normality and the assumption made that the data were approximately normally distributed in terms of skewness and kurtosis (Cramer, 1998; Cramer & Howitt, 2004; Doane & Seward, 2011). The p-values (Sig.) in the Shapiro-Wilk test were all above 0.05 meaning that the null hypothesis of the data being normally distributed was kept (Razali & Wah, 2011; Shapiro & Wilk, 1965). The histogram for the silent minus voice data was approximately the shape of a normal curve, although the silent and voice histograms were not. On balance however, with all of the evidence together, it was thought that there was enough evidence that the PIPP-R data were normally distributed and the decision to use a parametric test was made.

**Skewness and Kurtosis for PIPP-R data**

	Skewness			Kurtosis		
	Statistic	Std. Error	Z-score (Statistic/Std. error)	Statistic	Std. Error	Z-score (Statistic/Std. error)
Silent	.173	.374	<b>.463</b>	-.879	.733	<b>-1.199</b>
Voice	-.077	.374	<b>.206</b>	-.714	.733	<b>-0.974</b>
Silent minus Voice	.349	.374	<b>.933</b>	.530	.733	<b>.723</b>

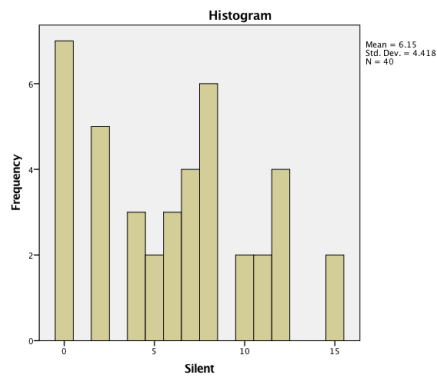
**Shapiro-Wilk Test for Normality**

	Statistic	df.	Sig.
Silent	.941	40	<b>.039</b>
Voice	.945	40	<b>.053</b>
Silent minus Voice	.978	40	<b>.612</b>

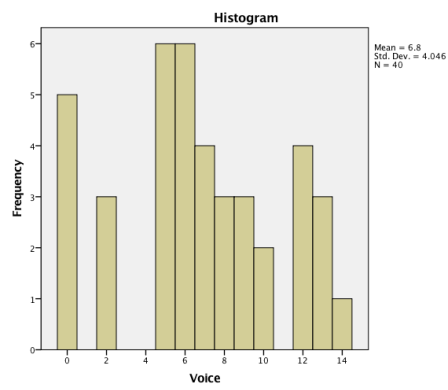


## Histograms – PIPP-R Data

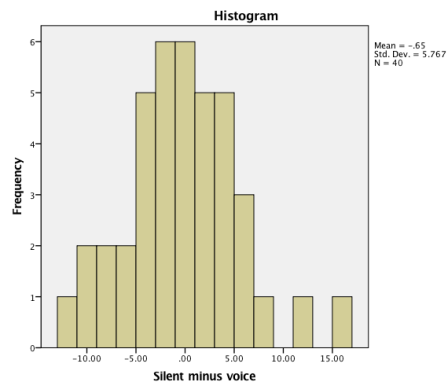
### Histogram – Silent condition



### Histogram – Voice condition



### Histogram- Silent condition minus Voice condition



Means and Standard Deviations for salivary cortisol based on log transformed data are presented here as they may be of interest to other researchers.

**Mean and SD for salivary cortisol based on log transformed data**

	<b>Intervention (Voice)</b>	<b>Control (Silent)</b>
	Mean $\pm$ S.D.	Mean $\pm$ S.D.
Baseline	1.44 $\pm$ .32	1.43 $\pm$ .27
Peak	1.53 $\pm$ .33	1.49 $\pm$ .26
Recovery	1.47 $\pm$ .24	1.51 $\pm$ .29