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Neonatal Pain Assessment:

The Development of a Pain Assessment Scale for Neonatal Transport

by

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Thesis for the degree of Doctor of Philosophy

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ABSTRACT

FACULTY OF HEALTH SCIENCES

Thesis for the degree of Doctor of Philosophy

NEONATAL PAIN ASSESSENT: THE DEVELOPMENT OF A PAIN ASSESSMENT SCALE FOR NEONATAL TRANSPORT

by Lavinia Emily Raeside

The aim of this study is to develop a pain assessment scale for use during neonatal transport. Underpinned by the rights of the child to have appropriate assessment and management of pain and the important deleterious effects pain can have on the physiological stability of the neonate, this study utilises a qualitative consensus paradigm of enquiry to inform the content and structure a pain assessment scale specific to the transport setting.

The study was conducted in three Phases, the first Phase consisted of a nominal group meeting with transport clinicians to ascertain their views on items to include in a pain assessment scale for transport. Phase Two utilised the Delphi technique to gain consensus from a large cohort of clinicians experienced in the field of neonatal transport on the content, structure and design of a transport pain assessment scale. Results of the first two Phases of the study were then applied to the adaptation of an existing pain assessment scale. Face validity of the newly developed Neonatal Transport Pain Assessment Scale (NTPAS) was then tested in Phase Three by semi-structured interviews with transport clinicians. Results of initial face validity testing suggested positive results in relation to feasibility and clinical utility of the scale, however further testing is strongly recommended.

Currently there are no pain assessment scales developed for use in the transport setting, and little evidence on the effects of transport on pain and pain assessment. This study offers a unique approach in adding to the body of knowledge on neonatal pain assessment and facilitated the development of a scale adapted to transport. Further research is suggested to undertake psychometric testing of the scale and establish validity and reliability in the clinical setting.

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DECLARATION OF AUTHORSHIP

I, Lavinia Emily Raeside declare that the thesis entitled:

"The Assessment of Neonatal Pain: The Development of a Pain Assessment Scale for Neonatal Transport" and the work presented in the thesis are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- where I have consulted the published work of others, this is always clearly attributed;
- where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- parts of this work have been published as:

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Definitions and Abbreviations

ECMO- *Extracorporeal Membrane Oxygenation*

HFO- *High Frequency Oscillation*

iNO- *Inspired Nitric Oxide Therapy*

IUGR- *Intrauterine Growth Retardation*

IVH- *Intra ventricular Haemorrhage*

LBW- *Low Birth Weight*

PPHN- *Persistent Pulmonary Hypertension of the Newborn*

RDS- *Respiratory Distress Syndrome*

(Gomella et al. 2004)

1. Chapter One

1.1 Introduction to the Thesis

Neonatal transport is a highly specialised service which transfers critically ill neonates between hospitals for on-going care. The aim of this specialist team is to function as an extension of the Neonatal Intensive Care Unit (NICU), providing a similar quality of care during transport (Barry and Leslie 2003). Pain assessment and management is a crucial element of care in the NICU, however currently there is little evidence on pain assessment during neonatal transport and no available pain assessment scales validated for use in the transport setting (Harrison and McKechnie 2011). The central focus of this study is therefore to review neonatal pain assessment during transport and facilitate the development of a valid and reliable means of assessing pain within the challenging environment of neonatal transport. Pain assessment and management is one of the most fundamental aspects of care which health professionals can provide, it can be argued that every individual has a basic human right to adequate pain assessment. However despite significant advances over the last 20 years in relation to our understanding of pain mechanisms in the neonate, the immediate long and short term consequences of neonatal pain and a proliferation of pain assessment measures, there continues to be reports of neonates in a variety of settings who suffer needlessly from acute, prolonged, persistent and chronic pain (Anand et al. 2007).

Pain is a subjective experience and therefore is difficult to measure. The challenge of how to assess pain when the individual is unable to communicate is paramount.

The International Association for the Study of Pain (IASP) published an addendum to their definition of pain in 2003 which stated:

> *"the inability to communicate verbally in no way negates the possibility that an individual is experiencing pain and is in need of appropriate pain relieving treatment".*

(IASP Task Force on Taxonomy 2003)

This addendum for the first time integrated non-verbal communication into the general definition of pain and therefore facilitated a more inclusive definition of pain in infancy. The importance of pain assessment in neonates was also highlighted by the Royal College of Nursing (RCN) in their clinical practice guidelines on the recognition and assessment of acute pain in children (RCN 2009), where clear practice guidelines were outlined on the assessment and management of pain in children and neonates. The guidelines recommended that pain assessment should be an integral part of total pain management and not an isolated element, with appropriate pain assessment scales being utilised (RCN 2009).

This study was therefore set on the backdrop of controversies and complexities surrounding neonatal pain assessment and management. The specific focus of pain assessment during neonatal transport added a dimension to the research which had generated little evidence in the literature. The current study was therefore informed by personal experience of the researcher in the area of neonatal transport, current practice within the transport environment and a lack of validated pain assessment measures specific to neonatal transport.

Background to the Thesis

The initial strategy which was considered in the development of the research proposal involved selecting one of the existing pain assessment scales adapted for the neonatal unit and testing it within the transport setting for validity and reliability.

However due to difficulties in gaining access to conduct the research within a transport service, the focus was shifted from testing an existing scale to adapting or developing a new scale. On reviewing the evidence it became apparent that there was little to support the content and structure of a transport pain scale, therefore it was decided to harness the expertise of clinicians in the field to establish current practice and inform the study.

1.1.1 Research Question and Objectives

Informed by background knowledge, a dearth of evidence on pain assessment during neonatal transport and lack of transport pain assessment scales, the next logical step was to consider issues around pain assessment and the development of an appropriate method of assessing pain during transport.

The research question is therefore:

"Can a valid neonatal transport pain assessment scale be developed?"

The study aims to:

- *Make a unique contribution to the body of knowledge and evidence-base relating to the assessment of pain during neonatal transport.*
- *Critically review how pain is assessed during a transport event.*
- *Report face validity of a pain assessment scale adapted to neonatal transport by means of consensus methods.*

The primary research questions (**PRQs**) associated with the study are:

1. *Which neonatal pain indicators should be included in a transport pain assessment scale?*
2. *What are the practicalities of using a neonatal transport pain assessment scale?*
3. *Has a transport pain assessment scale developed within the current research study by consensus methods achieved face validity?*

The research questions and study aims have been developed from the academic and professional literature and further supported by current clinical practice. The primary research question and study aims are worthwhile exploring primarily due to the lack of validated measures of neonatal pain assessment specific to the transport setting.

Despite the vast amount of literature on pain, pain assessment and pain management, the area of pain assessment during neonatal transport remains an area with limited evidence-based research. This study will therefore enhance knowledge, education and ultimately clinical practice with the potential to positively impact on direct patient care.

1.2 Overview of the Thesis

Chapter Two of the Thesis is an introductory chapter which sets the background with an overview of the complex issues around pain during neonatal transport. Health policy in relation to pain assessment and management within the neonatal population is reviewed, with dilemmas in relation to policy development and its effect on clinical practice being explored. This leads on to consideration of the vast ethical issues which surround neonatal pain assessment and management. The second section of Chapter Two builds on issues around the specialised area of neonatal transport, the complexities of the environment (Barry and Leslie 2003), the physiological effect of the environment on the neonate (Lawler 2000a) and the potential effect on pain and pain assessment.

Chapter Three further develops the Thesis by considering development of the research by evidence-based practice, leading on to the formulation of a PICO question to search the literature. This led on to searching the evidence by means of a comprehensive review of the literature on neonatal pain assessment scales using systematic methods to identify scales available at the time of writing the Thesis. This highlighted an integrative systematic review by Duhn and Medves (2004) which reviewed all available pain assessment scales up to 2004. This identified no pain assessment scales adapted to the transport environment, the literature review was therefore further developed to review pain assessment scales published since the Duhn and Medves (2004) review, followed by a critical appraisal of selected studies.

Chapter Four presents the study aims and primary research question which is the central focus of the study. An overview of the study design and methodology utilized in execution of the research is then detailed, with reference to the three Phases of the study.

Justification for the use of consensus methods to develop a transport pain assessment scale in the form of Nominal Group Technique (NGT) (Phase One) and Delphi Method (Phase Two) is presented followed by key concepts of each approach as described by Delbecq et al. (1975), Linstone and Turroff (1975), Murphy et al. (1998) and Keeney et al. (2011). A number of methodological strengths and weaknesses of the techniques are identified, with reference being given to the electronic Delphi and development of the Delphi tool. The Chapter moves on to relay application of consensus methods to the current research, including the complex process involved in analysis and issues in relation to rigour within the research process, with potential effects on validity. The third and final Phase of the study is then reviewed. This reports face validity of the pain assessment scale achieved by semi-structured interviews with transport clinicians, providing an overview of development of the data collecting instrument utilised in the semi-structured interviews. The Chapter concludes by considering the limitations of the methods used relating to robustness and integrity of the research design.

Chapter Five presents data analysis and results of the NGT and Delphi study and is structured into two major sections; the first gives an overview of the general organisation and management of raw data, moving on to further develop the study with a presentation of the findings, integrating the first two Phases of the study by linking the emergent priority areas and main results. The second section of the Chapter provides an overview on the integration of results and application of the findings in the development of the first draft of the new transport pain scale. The Chapter concludes with a presentation of the first draft of the transport pain assessment scale.

Chapter Six presents the main findings of Phase Three of the study, reporting the results of the semi-structured interviews to establish face validity of the scale. This is followed by final development and confirmation of definitive Themes and an overview of the development of an effects matrix in the final presentation of results.

Chapter Seven concludes the Thesis by presenting the discussion, conclusion and recommendations. The discussion considers the purpose and conduct of the study including the background, context and unique nature of the research. All three Phases of the study are considered in relation to applied methods, with consideration of benefits and disadvantages of NGT, Delphi process and semi-structured interviews. The paucity of available research in the field of pain assessment during transport is considered, with implications for practice. The major findings of the study and application of results to the development of a pain assessment scale are reviewed, followed by results of the semi-structured interviews to establish face validity. A critique of the findings is then presented with limitations of the study, concluding with possible alternatives to the chosen methods and dissemination of findings with recommendations for future research and practice.

2. Chapter Two

Pain and Neonatal Transport

2.1 Introduction

'Pain is inevitable, suffering is optional....' Anon

This Chapter locates the background concepts and theory on neonatal pain within the practice domain and in doing so informs the study by underlining the challenges and potential benefits to developing a specific measure of pain assessment for the transport environment. The first section of this Chapter begins by reviewing the complex issues around pain and health policy, which have important implications for the assessment and management of pain in the neonatal period. This leads on to consideration of the extensive ethical issues around neonatal pain assessment and how this influences practice. Do neonates have a right to appropriate assessment and management of pain in the immediate new born period? Furthermore do clinicians have a moral obligation to appropriately manage pain within this specialised population?

The sections that follow examine the concept and effects of pain within the dynamic neonatal transport environment in order to elucidate the implications of appropriate pain assessment within this population. Does the transport environment expose the neonate to specific challenges not experienced within the neonatal unit therefore necessitating the development of a method of pain assessment specific to transport?

2.2 Pain and Health Policy

How important is it to improve outcomes in the neonatal period? In a study reporting the costs of preterm birth alone throughout childhood in England and Wales, the largest contribution to the economic implications of preterm birth are hospital inpatient costs after birth (Mangham et al. 2009). The implementation of effective pain assessment strategies will lead to improved pain management and reduce the reported long-term effects of pain such as decreased pain sensitivity (Taddio et al. 1997), attention deficit disorders (Bhutta et al. 2002), stress disorders (Jacobson et al. 1987), impaired cognitive/social skills (Curtis et al. 2002), self-destructive behaviours (Jacobson et al. 1990) and all the costs associated with these outcomes. Appropriate assessment and management of pain should therefore be a fundamental element of care within this population. Neonatal pain however presents unique challenges to health policy. The recognition of pain as an important element of neonatal care is a relatively recent phenomenon, therefore it is crucial that consensus is reached on the most appropriate methods of evaluating, measuring and treating pain.

2.3 Health Policy and Implications for Clinical Practice

Assessment and management of neonatal pain is rarely reported as an element of public health or hospital statistics, receiving low priority from clinicians and policy makers (Glasziou 2002). As neonates do not verbalise pain in the same way as adults it is difficult to reach agreement on the best method of assessing and treating neonatal pain. Furthermore it should be acknowledged that early literature reflected the view that babies have no recollection of events and therefore pain during this period is irrelevant (D'Apolito 1984, Shearer 1986).

However current neonatal practice recognises the physiological and long term neurodevelopmental effects of neonatal pain and strives to minimise pain and stress within the neonatal population (Anand et al. 2007). Practical advice on the management of pain by means of a joint consensus statement was reported by the American Academy of Pediatrics and the Canadian Pediatric Society (American Academy of Pediatrics et al. 2000). This document emphasised the ethical mandate to treat pain and suffering, and also the importance of anticipating and recognising pain with the emphasis on the individual needs of the baby. In the UK the Department of Health published a national service framework for children, young people and maternity services which included guidance on pain assessment and management for young people and children who are ill (Department of Health 2007).

In relation to pain management the document states:

> *"Historically, pain has been underestimated and under treated in children and particularly babies. There is still evidence that pain is inadequately dealt with for children, requiring better prevention, assessment and treatment".*

(Department of Health, Department for Education and Skills 2007)

In the UK this view is also supported by the Royal College of Nursing (RCN) who acknowledge the importance of pain assessment in neonates and children (RCN 2011). In a policy document outlining health care service standards in caring for neonates, children and young people (RCN 2011), the RCN states that:

> *"evidence-based policies and procedures related to the assessment and management of pain drawn from national clinical guidelines should be in place".*

(RCN 2011, Section 2, 2.2)

The Royal College of Paediatrics and Child Health (RCPCH) also support recommendations for good practice in the management of post-operative and procedural pain, reflecting that children's pain should be assessed, documented and appropriate action taken to prevent and relieve pain. Furthermore they recommend that health care professionals should receive information, education and training in pain assessment (RCPCH 2008).

Health policy therefore appears to support the assessment and management of pain, providing a structured framework on which to develop clinical practice. However despite neonatal pain being acknowledged widely in the medical, nursing, ethical, political and legal literature, deficiencies in the assessment and management of neonatal pain are still reported (Stevens et al. 2007a). In a fifteen year follow-up of neonatal pain assessment in Sweden, authors reported that the number of units attempting to assess pain increased from 64% in 1993 to 83% in 2008. Within this group 44% used a structured method in 2003 compared to 3% in 1998 (Gradin and Eriksson 2010). However a descriptive survey conducted by Akuma and Jordan (2011) in seven neonatal units in the UK reported that clinicians were knowledgeable about neonatal pain however gaps between knowledge and practice remains.

The report suggested that this bridge could be resolved by providing research evidence for the efficacy of guidelines utilising validated pain assessment scales. In relation to neonatal transport, there is little available data on discomfort and stress of the infant undergoing transport (Harrison and McKechnie 2011) and no available policy guideline. This reflects a crucial deficit in knowledge which requires more research and debate.

2.4 The Transport Environment

Within the transport environment there is little available evidence in relation to the assessment or management of pain in patients of any age group (Fast and Newton 2008). Harrison and McKechnie (2011) in an audit reviewing levels of discomfort experienced by neonates during transport reported that all neonates in the study showed higher levels of discomfort during transport compared to baseline recordings. It is acknowledged that neonatal pain is associated with multiple adverse effects which include tachycardia or bradycardia, alterations in blood pressure, apnoeic episodes and oxygen desaturation (Stevens et al. 2007b). Furthermore within the NICU, reports state that basic procedures such as suctioning and repositioning may cause pain to neonates' (Mathew and Mathew 2003).

It would therefore seem reasonable to assume that neonates requiring transport may be subjected to pain not only as a result of being transported but also due to their illness. Transporting the neonate involves firstly preparing them for movement into portable intensive care equipment and then loading of the equipment into vehicles for transfer, which could be an ambulance, a helicopter, fixed wing plane or military helicopter (Figure 1). As a result of these modes of transport fluctuations in temperature, noise, movement, vibration and barometric pressure can potentially be areas of stress, pain and discomfort. The assessment of pain in these dynamic environments is both difficult and challenging however essential to ensure a safe, optimum transfer.

Figure 1 **Modes of Neonatal Transport**

Helicopter

MOD Air Transfer

Ambulance

Fixed Wing Plane

With permission of West of Scotland Neonatal Transport Service

Recent innovations in clinical management of the critically ill neonate during transport such as Extracorporeal Membrane Oxygenation (ECMO), High Frequency Oscillation (HFO) and Inspired Nitric Oxide Therapy (iNO), have resulted in the need for highly technical and specialised transfers. It has been recommended that pain assessment should be a routine part of the transport nurses' initial assessment of the patient (Holleran 2003, Association of Air Medical Services 2004), therefore the application of appropriate pain assessment strategies in order to manage pain effectively is crucial.

Pasero and McCaffery (2002) stated that self-report of pain is the single most reliable indicator of the severity of patient pain, however as neonates are unable to verbally report pain, it is even more essential to identify a method of pain assessment which is appropriate for this population and also takes into account the transport environment.

Prior to selecting a method of pain assessment for neonatal transport, it was important to review the environment within which the assessment tool will be used. This would elucidate the difference between the NICU environment and the transport environment and reflect on how these differences may influence pain experienced by the neonate.

2.4.1 Challenges to Pain Assessment during Patient Transport

The transport environment presents specific challenges to pain assessment which differentiate it from the clinical setting and therefore influences the selection of an appropriate pain assessment scale. McLean et al. (2003) attempted to elucidate the perceptions of transport nurses on issues around barriers to patient pain assessment during transport. Their comments identified multiple barriers which could be extended to any patient in the transport setting, including:

- Transport vehicles are loud, making conversation difficult.
- Vehicles are small, access can be difficult.
- Patient contact is short-term making assessment of subtle signs of discomfort difficult to ascertain.
- The transport nurse may be busy managing life-threatening conditions and must stabilise the patient before pain assessment can be considered.
- The nurse and pilot in air transfers wear helmets to communicate with each other making it difficult to hear conversation outside of the helmet.

- The priority is safety during fight transfer, which may divert attention from the patient to potential hazards outside the aircraft.

These comments highlight clinical utility, feasibility, reliability and validity as being crucial aspects in the development of a transport pain assessment scale (Streiner and Norman 1995). During transport patients frequently need to be transferred quickly due to severity of illness, a pain assessment scale therefore needs to be easy and effective to use.

2.4.2 Physiological Effects of Transport on the Neonate

In order to assess and manage pain within the transport setting it is important to evaluate the additional sources of pain and stress which the neonate may experience. Multiple factors within the transport environment such as vibration, noise or temperature fluctuations may affect pain and stress levels in the neonate. Furthermore, evidence suggests that accelerations and decelerations can also have deleterious effects on the cardiovascular system, resulting in changes in cardiac output and alterations in blood pressure (Skeoch et al. 2005).

2.4.2.1 Movement and Vibration

Increased movement and vibration may be experienced in all modes of transport, this may occur on movement of the baby from the hospital incubator to the transport incubator and also during the journey. Lengthy road transfers by ambulance may be problematic particularly in adverse weather conditions, excessive vibration or movement may dislodge lines and tubes and have an effect on the monitoring equipment such as pulse oximeters and non-invasive blood pressure monitoring devices (Gajendragadkar et al. 2000).

In the case of the surgical infant or the very unstable baby excessive movement may increase pain and discomfort. The greatest episodes of vibration will be experienced on difficult and uneven road surfaces, driving around roundabouts and difficult roads and during take-off and landing during flight transfers (Holleran 2003), it has also been suggested that the risk of intracranial bleed in preterm infants' may be increased (Barry and Leslie 2003).

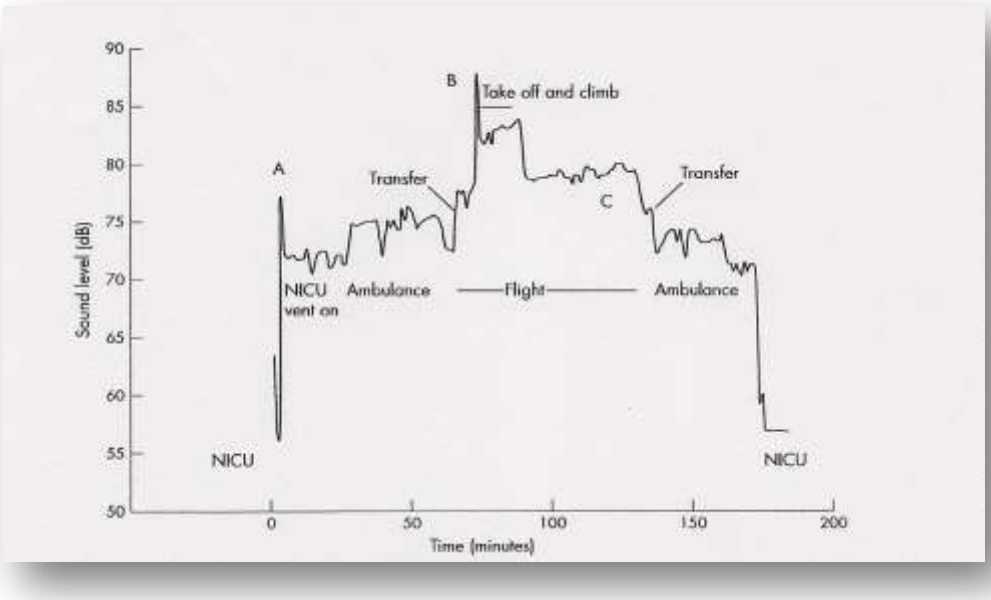
2.4.2.2 Noise Levels

Vibration and sound are a recognised source of trauma encountered in aviation medicine (Fisher 1995). Recommendations have been made that noise levels in neonatal units should not exceed 45 to 50 db. (Committee on Environmental Health 1997), however high noise levels may be encountered both in road transfers and also during air transfers where noise levels of up to 125 db. may be experienced during take-off and landing. Changes in heart rate and peripheral vasoconstriction in preterm neonates have been reported as low as 70 decibels, with exposure to sudden noise in neonates with encephalopathy being associated with desaturation (Gajendragadkar et al. 2000). Significantly recent evidence suggests increased noise levels in the NICU may result in potentially adverse effects on the physiological stability and future neurodevelopment of neonates (Wachman and Lahav 2011).

In a study analysing sound levels during neonatal transport, it was reported that sound levels during road ambulance transfers were all significantly higher on country roads than on city roads (Buckland et al. 2003), this was related to poor road surfaces and increased speed.

The same authors reported the highest sound levels in air transfers with no significant difference between helicopter and fixed wing aircraft (Figure 2). However all modes of transport have been stated to exceed recommended levels of sound exposure for neonates (Committee on Environmental Health 1997).

Figure 2 **Changes in Exposure to Noise during Road and Air Transport**



Buckland et al. (2003) With Permission.

2.4.2.3 Fluctuations in Ambient Temperature

Low birth weight, very preterm or critically ill neonates are particularly vulnerable to cold which therefore presents particular challenges to transport (Barry and Leslie 2003). Thermal stress can occur at various stages throughout the transport, during the initial movement into the transport equipment or when the neonate is in the transport vehicle.

In a cool environment or their body temperature drops, the neonate has to increase their cardiac output in order to deliver the oxygen required to increase their body heat. In a stable neonate this may not be a problem, however in an unstable or preterm neonate this can cause an acute deterioration. The extremely preterm neonate may be unable to maintain their body temperature and rapidly become hypothermic (Ellis 2005).

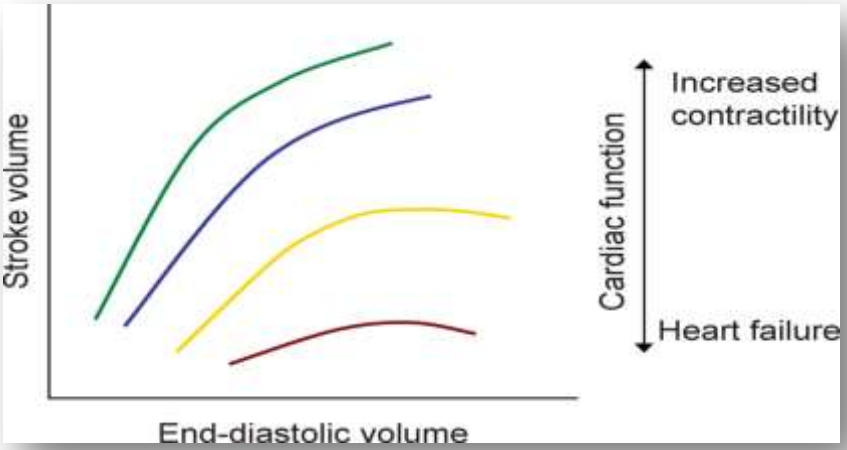
The profound effects of hypothermia on the neonate have been recognised for over 40 years in the literature and range from respiratory compromise such as tachypnoea or apnoea (Elliot and Mann 1957), to further physiological symptoms such as hypoglycaemic, hypoxic and metabolic acidosis (Gandy et al. 1964, Kumar et al. 2009). It is recommended that neonates should be nursed in a thermo neutral environment, which is an environment that keeps body temperature at an optimum point at which the least amount of oxygen is consumed for metabolism, enabling the neonate to maintain body temperature without expending more energy (Ellis 2005). This is of particular importance during air transfers where there is a temperature drop of 2 degrees centigrade for every 300m of altitude (Skeoch et al. 2005), therefore potentially compromising the clinical stability of the neonate.

2.4.2.4 Physiological Effects of Acceleration and Deceleration

In the mobile transport environment rapid acceleration and deceleration may occur in the ambulance or aircraft which may result in acute physiological changes in the neonate (Skeoch et al. 2005). Rapid acceleration rarely occurs, however rapid deceleration due to braking in an ambulance can result in forces up to 7G, which can have significant effects in the neonate (Barry and Leslie 2003). Rapid acceleration and deceleration can cause pooling of blood, and may lead to sudden fluctuations in venous return and changes in cardiac output (Barry and Leslie 2003).

The Starling curve plots stroke volume against end diastolic volume in the heart, reflecting some of the physiological effects that may occur (Figure 3). The normal curve (green) shows an increase in cardiac output with increasing filling pressure up to the point where the myocardium fails and no further increase is seen. In heart failure (brown line) or in the normal heart in hypervolemia, an increase in filling pressure will not be accompanied by an increase in cardiac output.

Figure 3 **Filling Pressure in the Heart**



Lawler (2000a) with permission

The position of the baby in the ambulance or aircraft can affect their physiological stability during transfer. If the patient is positioned with their head towards the front of the ambulance rapid acceleration in speed will reduce venous return, reduce filling pressure and result in reduced cardiac output. During rapid deceleration venous return to the heart will increase which may then lead to an increase in cardiac output or in the failing heart my cause heart failure and reduce cardiac output (Barry and Leslie 2003). Pulmonary blood flow in the neonate can also be affected by motion changes. If the patient is laying head first and the vehicle rapidly accelerates, blood is diverted towards the lung base and away from the anatomical apex, the reverse will occur in deceleration.

This may lead to an increase in ventilation-perfusion mismatch. Physiological changes may also be caused by movement of large organs. The diaphragm separates the abdomen and thorax, acceleration and deceleration will displace the abdominal contents and move the diaphragm. This may again cause under ventilation, hypercapnoea and hypoxia (Barry and Leslie 2003). Therefore neonates should be positioned if possible in a transverse position in the vehicle (Barry and Leslie 2003).

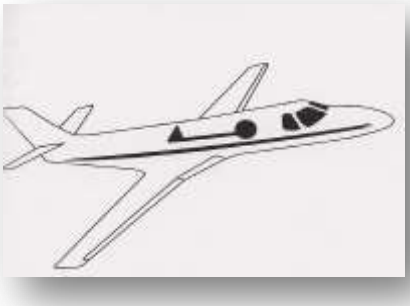
Air transfer requires specific considerations to be assessed in relation to patient position. Sudden increases in venous pooling in the head can lead to increases in intracranial pressure, which is of particular importance due to reports that low birth weight neonates may be at increased risk of intraventricular haemorrhage (IVH) during transfer (Towers et al. 2000, Mohammed and Aly 2010). The rotary wing aircraft fly "head down or tail up" (Figure 4), therefore the optimum position of the patient is with the head in the direction of travel. However the fixed wing aircraft fly "nose up" (Figure 5) and patients positioned in the head first position are at increased risk, therefore feet first is optimum. Ideally the patient should be positioned across the direction of travel, however this position is rarely possible due to limitation of space within the aircraft.

Figure 4

Rotary Wing Aircraft (head down tail up)

Figure 5

Fixed Wing Aircraft (nose up)

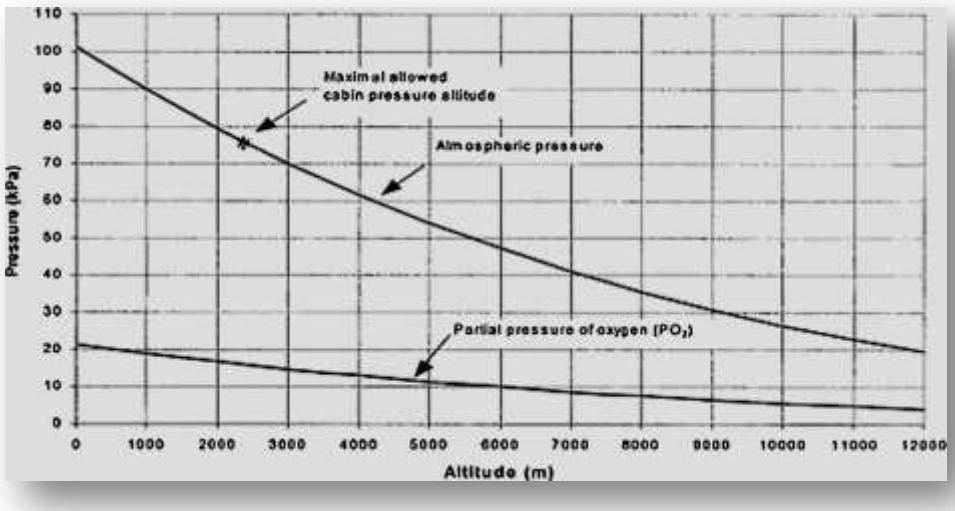


(Lawler 2000b) With permission

2.4.2.5 Effects of Changes in Atmospheric Pressure during Air Transport

Barometric pressure decreases with altitude (Figure 6), potentially leading to major effects on oxygen transport across the alveolar capillary membrane causing an increase in inspired oxygen requirements (Martin and Glanfield 2006). This is of most significance in the most compromised patients who require 100% oxygen and are already receiving maximum respiratory support. Helicopters are usually unpressurised, this can be problematic when transferring extremely hypoxic neonates as the reduction in oxygen pressure that occurs at altitude can be clinically significant in the patient with extreme respiratory failure (Barry and Leslie 2003).

Figure 6 Changes in Barometric Pressure at Altitude



Smith et al. (2010) With Permission

Furthermore another important consideration when clinically assessing patients during flight transfers is that gas filled spaces expand with increasing altitude and reduced barometric pressure. This is of particular importance if the patient has a pneumothorax, as this can expand if not drained.

Also the stomach will expand, as will limbs if they are restricted by tight splinting, bandages or blood pressure cuffs. All of these effects may result in increased pain or stress levels in the neonate during transfer (Skeoch et al. 2005).

2.5 Neonatal Pain: Theory and Concepts

The theory and concepts behind neonatal pain within this population is a complex and expansive area and requires an understanding if pain is to be assessed and managed appropriately. This is an important aspect of the study however it is beyond the parameters of this Thesis to cover in depth. As part of this study a review of the literature was carried out in relation to the theory and concepts of neonatal pain. This paper was blind peer reviewed and subsequently published in Working Papers in Health Sciences (Raeside 2013), and can be reviewed in Appendix 1.

2.5.1 The Assessment of Pain in the Neonate

An important area to consider is the assessment of pain and how this could be facilitated during transport. Multiple factors may affect neonatal pain response and therefore pain assessment, including gestational age (Grunau and Tu 2007), severity of illness (Stevens et al. 1994), level of sedation (Ramsay 2000) and specific pathology such as neurological impairment (Stevens et al. 2007b). Also highlighted are the different situations and environments within which the neonate may experience pain and the lack of specificity to this influencing factor in pain indicators (Stevens et al. 2007b). Pain assessment within this population has particular challenges, methods of pain assessment may not have full generalizability to different age groups such as the preterm and term baby.

Therefore a degree of caution should be applied when reviewing various methods of pain assessment with particular reference to their validation sample (Stevens et al. 2007b).

In order to develop a pain assessment scale appropriate to the transport environment, it is important to review existing methods of assessing pain in the neonatal period. Measures of assessing pain are classified as self-report, physiological, behavioural or bio-behavioural, however as self-report cannot be used with the neonate, behavioural, physiological or bio-behavioural measures are commonly used (Stevens et al. 2007b). These measures will be considered in the next section of this Chapter.

2.5.1.1 Physiological Measures of Assessing Neonatal Pain

In the non-verbal patient the most feasible way to assess pain may be the evaluation of physiological parameters. In relation to the neonatal population, assessment of physiological pain response includes changes in heart rate, respiratory rate, blood pressure, oxygen saturation, vagal tone, palmar sweating (Stevens et al. 2007b, Appendix 2) and plasma cortisol or catecholamine concentrations (Van Howe 1999). Physiological indicators of neonatal pain are integrated in many multidimensional pain assessment scales (Duhn and Medves 2004) and are therefore an important element in neonatal pain assessment. It has been suggested that the validity and reliability of these physiological measures are questionable due to the subjective and labile nature of pain itself (McGrath 1996). However physiological measures are proposed as being quantifiable and objective in nature, despite the difficulties in establishing their validity, reliability, specificity, sensitivity and practicality (Stevens et al. 1995).

As part of this study a comprehensive literature review on the physiological measures of assessing infant pain was conducted, peer reviewed and subsequently published (Raeside 2011) and can be reviewed in Appendix 3.

2.5.1.2 Behaviour Indicators Utilised in the Measure of Neonatal Pain

Behaviour has been viewed as being a useful measure and indicator of neonatal pain (McGrath 1996). There are several reasons why behaviour should be considered. Behaviour is often the first sign of pain and may set the template for the developing child's reaction to painful events and later coping strategies (McGrath 1996). Interestingly it has been suggested in early research that a crying child was an important determinant in how nurses rated pain and the level of intervention initiated, researchers observed that a child that did not cry or vocalise pain was less likely to be given analgesics (Hamers et al. 1994).

Behaviour as a reaction to pain can be divided into different phases. The initial phase is the immediate reaction to noxious stimuli, characterised by a range of behaviours such as withdrawal, grimacing, flailing or crying, with this immediate reaction being followed by a more subtle reaction to on-going pain in a shutdown of activity or "non-responsive" phase (McGrath 1998). However as pain is subjective, behavioural assessment is indirect and therefore it can be argued that it is never entirely accurate (Merskey and Bogduk 1994). Furthermore many behavioural measures lack clinical validation and therefore may be problematic in the research setting, furthermore according to Barr (1998) there is dissociation between physiological and behavioural responses. However psychometric testing of behavioural tools is an on-going area of development in order to obtain reliability and validity for these measures.

Several studies have examined the different behavioural responses of both preterm (Stevens et al. 1994, Craig et al. 1993, Grunau et al. 2004) and term babies (Gibbons et al. 2002, Stevens et al. 2004) to painful events such as heel lance or circumcision. Facial expression is viewed as being a reliable and consistent behavioural indicator of pain which can apply across situations and populations (Stevens et al. 2007a). Cry has also been reported extensively throughout the years in assessment of neonatal pain (Wasz-Hockert et al. 1987). It is most frequently described in terms of presence or absence (Owens and Todt 1984), amplitude, pitch and temporal characteristics. In the NICU and the transport setting cry may be of limited value as babies are frequently ventilated and cannot cry or vocalise. Body movements have also been reported as pain indicators in the neonatal period, however gestational age has an important influence on the type and frequency of the body movement, with the preterm or acutely ill infant lacking the energy reserves to display movement. The extremely preterm infant exposed to frequent painful procedures may become limp and flaccid in response to pain, with their movements being more disorganised that the healthy term neonate (Stevens et al. 2007b).

2.6 Strategies in Pain Assessment

Having considered methods of assessing and measuring pain, it is crucial to then consider application of these methods to the clinical setting. Several areas have to be considered when a measure of pain assessment is introduced into clinical practice. Assurance that the measure assesses pain in a reproducible way will be dependent on psychometric properties (Streiner and Norman 2006). However it is important to acknowledge that modifications to a pain measure in an attempt to adapt to different environments or client groups may interfere with psychometric testing and therefore will require further testing.

Neonatal pain assessment measures can be further classified as unidimensional or multidimensional with composite measures (Appendix 4). Unidimensional measures include either a single indicator such as cry, or multiple indicators from one domain, an example being facial actions. However multidimensional strategies utilise more than one type of pain indicator, with composite measures also incorporating contextual strategies such as sleep state (Stevens et al 2007b). The characteristics of each of these measures will now be considered.

2.6.1 Multidimensional Pain Measures

Due to the complexities in pain assessment many adopt the view that multidimensional pain measures (Appendix 4) are the most appropriate (Duhn and Medves 2004). Furthermore it has been reported that correlation between physiological and behavioural indicators is consistently low in unidimensional measurement strategies (Stevens et al. 2007b). However both subjective and objective data are adopted in a multidimensional approach, this can be done by assessing different elements in a particular domain such as facial actions, cry and body movement. Alternatively a composite measure can be used that include multiple domains such as physiological, behavioural and contextual indicators.

There has been a rapid increase in the number of multidimensional pain assessment scales available over recent years (Duhn and Medves 2004). Indicators such as sleep pattern have little theoretical or conceptual foundations and therefore have less supporting evidence than cry, facial expression or body movement (Van Dijk et al. 2002). Behavioural state is however much more clearly defined in the literature and contributes to information on the context in which the pain is experienced. This can be seen in the PIPP (Premature Infant Pain Profile) (Stevens et al. 1996) which is a composite measure including infant behavioural state.

Whereas several composite measures have been established as reliable and valid measures of infant pain, it remains unclear if composite multidimensional approaches are more reliable than unidimensional composite measures (Stevens et al. 2007b).

2.6.2 Unidimensional Pain Measures

A unidimensional measure will utilise one indicator to assess pain such as infant heart rate, or use several indicators from one domain such as heart rate, blood pressure and breathing rate (Appendix 4). Behavioural indicators of infant pain have however traditionally been the most widely utilised, this would include cry, facial expression and activity. However when assessing behavioural indicators non-verbal infants present the challenge of distinguishing between pain and other states such as hunger or agitation. Despite confounding factors influencing behavioural indicators such as severity of illness, neurological influence, pharmacological influence and extreme prematurity, behavioural indicators continue to be reported as reliable in the assessment of infant pain (Hudson-Barr et al. 1998).

2.7 Reliability and Validity of Pain Assessment Scales

Reliability and validity testing is an important element in the introduction of a pain assessment scale to the clinical area (Duhn and Medves 2004) and is crucial in the development of a transport pain scale. However despite the extensive number of available scales all of the assessment related problems in neonates have not been solved, with most scales being validated for acute procedural pain, performing less well for sub-acute or chronic pain (Duhn and Medves 2004).

Thewissen and Allegaert (2011) argue that most scales do not take into account persistent pain which results in a quiet immobile neonate and also the limited capacity of the preterm neonate to mount a consistent and persistent behavioural and physiological response to pain. However newly evolving scales such as the N-PASS pain and sedation scale (Hummel et al. 2008) is an example of a scale which encompasses both pain and sedation with inclusion of the inactive and preterm neonate.

The validation and implementation of a pain scale may be based on intra and inter individual variability, with correlations being made with neuroendocrine markers of pain and stress (Fitzgerald and Walker 2009). However it has been highlighted by Thewissen and Allegaert (2011) that interrater agreement is only reflective of agreement in rating between different caregivers and excludes a systematic error. It has been suggested that pain assessment scales focus on aspects of pain expression which does not necessarily reflect nociception (Fitzgerald and Walker 2009). A further aspect presented by Xavier Balda et al. (2000) is that health professionals under assess infant pain as a coping strategy, reflecting that this occurs during times when health professionals are put in a position when they need to cause varying degrees of pain and discomfort to the neonate as part of their daily job. Furthermore Reyes (2003) expands on this view by highlighting the importance of nurses' appropriate assessment and accurate documentation of pain.

Frequently pain assessment scales are modified and adapted to particular clinical areas where they will be used, however modification of pain assessment scales or application in a new population or environment may interfere with psychometric testing and may necessitate repeat testing (Duhn and Medves 2004).

The issue of clinical utility is important as it has to be appropriate for use in the clinical setting. Scales which are complex, lengthy and require extensive training may not be feasible or practical in the clinical setting. It is important to ascertain if the scale or measure has been developed for research or clinical purposes and the population within which the scale has been developed (Streiner and Norman 2006).

2.7.1 The Psychometrics of Pain Assessment and Measurement

Frequently social and health scientists use subjective judgements as there may be no objective means of measuring the phenomenon. Support for this subjective judgement as a valid approach to measurement is derived from psychophysics (McDowall and Newell 1996). Psychophysical principles which are adapted to address the quality of measurement are known as psychometric properties and include reliability, validity, sensitivity and specificity. Psychometric validation is a means by which an instrument is assessed through the establishment of a series of defined tests on a population group for whom the instrument is intended (Bowling 2004) and is generally conducted within the clinical area.

2.7.2 Clinical Utility, Feasibility and Face Validity

Clinical utility, feasibility and face validity are important elements of pain assessment scales which should be evaluated prior to application in the clinical area (Anand and Craig 1996). Clinical utility refers to the property of a pain scale which facilitates decision making in clinical practice. In order for a measure to have clinical utility it must be viewed by the user as being acceptable and convenient to use, providing the information they require to plan, implement and evaluate care (Stevens et al. 2007b).

Grunau et al. (1998) reflect the view that clinical utility ensures that the needs of the neonate in relation to setting and circumstances are met. Clinical utility has been reported as being the precursor to clinical significance, which relates to the clinically meaningful differences in pain scores and outcomes for the neonate (Stevens et al 2007b).

Feasibility varies from clinical utility in that it relates to whether the scale can be used effectively at the bedside. Therefore feasibility generally refers to length of time taken to complete the scale, simplicity of scoring and interpretation, cost, format and training (Stevens and Gibbons 2002).

In relation to face validity, Streiner and Norman (2006) report that it refers to the appearance of the scale, do the items appear on the surface to actually measure what they are intended to measure? The authors go on to highlight that if the items appear irrelevant then the respondents may omit the items irrespective of its psychometric properties. Face validity generally relates to how the users of the scale perceive it, therefore it has been argued that they should judge face validity and be asked to rate the scale (Nevo 1985). Franck et al. (2000) highlighted that pain assessment scales must be reliable, valid, have clinical utility and be feasible to use. However it has been acknowledged that there are very few multidimensional pain measures which have established adequate psychometric properties and clinical utility for use with infants (Walden 2001).

2.8 Differentiation between Pain and Stress in the Neonate

The terms “neonatal pain” and “neonatal stress” frequently interlink in the literature and are important to consider. The lack of ability to report pain presents challenges in the assessment and management of both stress and pain in the neonatal period (Johnston et al. 1997). Stress has been defined as:

> *“a physical, chemical, or emotional factor that cause’s bodily or mental tension and may be a factor in disease causation”*

(Merrium Webster 1994 p1164).

Stress responses can be specific to a particular source or nonspecific and generalised. McIntosh et al. (1993) reflected that pain is always stressful however stress is not necessarily painful. It is however extremely difficult in a nonverbal neonate to distinguish where stress ends and the painful experience begins. Stokowski (2009) in a review which discussed the quantification of neonatal stress highlighted that there was a great deal of overlap in what was considered to be painful and what was considered to be stressful to the neonate. The author goes on to reflect that there is currently no validated tool to measure neonatal stress levels.

This view was supported by Grunau and Tu (2007 p45), reflecting that with reference to the multiple aspects of bio behavioural reactivity in the neurophysiologically immature neonate, the separation of specific sensory changes which occur as a result of pain, are very difficult to differentiate from the cumulative effects of pain and stress. The American Academy of Pediatrics (AAP) also acknowledge that behaviours associated with pain may also be associated with perceived non painful care-giving procedures, going on to recommend additional research to better differentiate pain and stress be conducted (American Academy of Pediatrics 2000).

2.9 Neonatal Pain Assessment: The way forward?

This Chapter has considered the challenges associated with the assessment of pain in the neonatal period and the limitations of currently available pain assessment scales. The gold standard of pain assessment (verbal report) cannot be used with the neonate, the responsibility lying with the caregiver to interpret the signs of pain and distress displayed by the neonate. What is the way forward for pain assessment in the neonatal period? Pain assessment scales currently focus primarily on pain expression not necessarily reflecting nociception (Fitzgerald and Walker 2009). In a recent study conducted by Slater et al. (2010), corticol evoked response were utilised to assess the effect of sucrose versus aqua during a painful procedure (heel lance). This study reported no difference between the groups, generating much debate in relation to clinical practice and the use of sucrose for pain relief. However the study also received much criticism due to the small sample size and methods used (Lasky and van Drongelen 2010). Nevertheless Thewissen and Allegaert (2011) suggested that the study did however illustrate that pain expression is not equal to nociception, at the same time acknowledging the extensive evidence available in support of sucrose to blunt pain scores in the neonate (Slater et al. 2010, Lasky and van Drongelen 2010).

However on-going innovations within the field of research may potentially lead to the development of tools/scales in the measurement of pain and sedation in neonates. These include bispectral index (BIS) monitor, skin conductance and near infrared spectroscopy (NIRS). Near-infrared spectroscopy (NIRS) evaluates acute changes in cerebral blood flow, volume and oxygenation and is now used in many NICU's with a range of neonates including those with congenital heart disease (Ricci et al. 2010) to those requiring ECMO (Benni et al. 2005).

NIRS works by evaluating acute changes in cerebral blood flow, volume and oxygenation which provides indices of activity in the somatosensory cortex which have been used to evaluate cortical responses to pain for many years (Edwards et al. 1988). However despite this brain-based method providing a novel way of understanding pain, the issue of whether cortical activation is a direct indicator of pain is unclear. When used as a clinical bedside tool NIRS can be challenging as results can be affected by movement artefacts (Wolf and Griesen 2009). However the use of NIRS does provide scope for development in future pain research studies (Holsti et al. 2011).

2.10 Chapter Summary

This Chapter opened with an overview of the important challenges faced by clinicians when considering policies in health care and ethical principles surrounding the management of pain in the sick neonate. It is clear from the literature that health policy now supports the assessment and management of pain in the neonatal period by the provision of structured frameworks, however the question of why deficiencies are still reported in some areas is an important one which should be addressed.

This overview provided a background to the complex issues surrounding neonatal pain assessment and was further developed by reviewing the transport environment and its effect on the neonate. This highlighted the specific issues related to the transfer and management of the neonate which could influence pain assessment and was fundamental when considering the research question.

The Chapter concluded by considering issues around methods of pain assessment in the neonatal period, which highlighted the complexities and possibly assisted in illuminating some the reasons behind inconsistencies in the application of pain guidelines in some clinical areas. The consideration of new and innovative developments in neonatal pain assessment suggested potential ways in which this area may be progressed, however also highlighted these methods were still under review requiring further research.

3. Chapter Three

Development of the Research underpinned by Evidence-based Practice

3.1 Introduction

This Chapter further develops the study with an overview of evidence-based practice and its application to the current study. This is followed by the development of a PICO question to search the literature and a by a detailed review of the literature on neonatal pain assessment scales using systematic methods to identify scales available at the time of writing the Thesis. This cumulated with the development of the research question and methods utilised to undertake the study.

3.1.1 Evidence-based Practice

Evidence-based practice (EBP) requires that health care professionals critically appraise the best available evidence at the appropriate time and if indicated apply the evidence to clinical practice (Greenhalgh 2001).

Evidence-based practice has been described as:

> *"the conscientious, explicit and judicious use of the best evidence in making decisions about the care of individual patients"*

(Sackett et al. 1996 p71-72)

Polit and Beck (2010 p36) highlight that the movement towards evidence-based practice (EBP) has given rise to controversy and debate, reflecting that advocates of EBP argue it offers a solution to providing quality, cost-effective health care within a framework which encapsulates self-directed learning.

Whereas critics are concerned that individual clinical judgement and patent input is being devalued, with insufficient attention being given to qualitative research. Regardless of the controversy, EBP is now considered to be a fundamental element of current practice, prompting clinicians to question scientific evidence and alter practice accordingly (Greenhalgh 2001). The Nursing and Midwifery Council (NMC) code of conduct (2008) requires that nurses, midwives and health visitors utilise best practice or evidence in their delivery of care to patients. Polit and Beck (2010) expand of this by reflecting that clinicians' must now be competent in accessing, evaluating, synthesising and using new research evidence.

The process of evidence-based practice can be relayed in six steps (Box 1). This structures a systematic approach to identifying all appropriate evidence and will be adopted in each Chapter of this study.

Box 1 **Six Step Approach to Evidence Based Practice**

1. **Developing the question**
2. **Searching medical literature for studies most likely to provide the best evidence**
3. **Identifying studies that will answer the question**
4. **Critically appraising studies to determine validity**
5. **Clinical application**
6. **Evaluation of results**

(Mayer 2004)

3.2 Development of the Literature Search Question

In order to implement the recommendations made by the Department of Health (2007) and the RCN (2011), it is crucial that clinicians have an understanding of the immediate and long term effects of pain on the neonate and utilise appropriate pain assessment strategies specific to the individual environment and circumstances of each neonate. Evidence from a systematic integrative review of infant pain assessment scales reported thirty five available scales, with none specifically developed or adapted for the transport environment (Duhn and Medves 2004). Neonatal pain has been widely researched in relation to procedures and ventilation however there is currently little evidence on pain assessment or management during transport (Harrison and McKechnie 2011). Issues around the varying environments within which neonates are cared for are complex, with the transport setting offering particular challenges. Johnston et al. (2007 p183-185) highlight that environmental factors may influence the way infants' perceive pain and also how staff assesses and management pain.

The first and most important element of the EBP is to ask the right question. The PICO framework was therefore utilised in order to formulate a search strategy to answer the research question. The clinical question should have a defined structure, the PICO model is a method which is widely applied to the process of defining a searchable question (Mayer 2004). The PICO framework provided a structured format on which to select the relevant studies to address the research question. It was necessary to break down the question into key words or concepts, with the PICO format being utilised to review population of interest (P), the intervention (I), comparison to the intervention (C), and the outcome of interest (O) (Mayer 2004).

Application of the PICO Model:

a) Population *(neonates being transported who may be in pain)*

b) Intervention *(assessment of pain using a pain assessment scale adapted for neonatal transport)*

c) Comparison *(no measure of pain during transport)*

d) Outcome *(appropriate pain management)*

Population is the patient group to which the information will be applied, neonates during inter-hospital transfer who may be in pain. The **intervention** is the assessment of pain using a pain assessment scale adapted for neonatal transport. The **comparison** is the intervention therapy against which the intervention is measured this should be a realistic alternative to the treatment. In this study the pain assessment scale will be compared with current practice which is no measure of pain. Finally the **outcome** is the endpoint, the most important being the one that matters most to the patient, which in this case would be pain management (Mayer 2004). Following review of the background information a PICO question was formulated to search the literature:

"How does the current practice of not measuring neonatal pain during transport compare with the measurement of pain using a pain assessment scale adapted for neonatal transport".

This facilitated the identification of key words (Box 2) to take forward for the database search which will be discussed in the next section of this Chapter.

Box 2 **Key words to consider for database search**

Population	Intervention	Comparison	Outcome
Neonatal pain. Neonatal pain and transport.	Neonatal pain assessment scale. Neonatal Pain assessment scale for transport.	Keyword search or use limit function in Medline (study type)	Pain management.

3.3 Selection and Identification of the Evidence

3.3.1 Introduction

Following development of the PICO question a detailed review of the literature was initiated, culminating with development of the research question and methods utilised to undertake the study. In order to address the PICO question it was necessary to identify available neonatal pain assessment scales. The process was initiated by reviewing the evidence on all available pain assessment scales developed for the neonatal population with particular focus on neonatal transport.

3.3.2 Literature Search

The first step in utilising an evidence-based approach to answering the question was to identify the sources of evidence available and carry out a broad sweep of the literature to review all available neonatal pain assessment scales. When examining the literature it is important to understand how research integrates with evidence-based practice (EBP). Sackett et al. (2001, p1) described EBP as:

> *"The integration of best research evidence with clinical expertise and patient values".*

Sackett et al. (2001) expands on this by highlighting that best research evidence is clinically relevant research, ranging from patient-centred clinical research to scientific experimental research, diagnostic tests, prognostic markers and preventative regimens. The author further reflects that patient values are the individual expectations and needs that a patient brings which should be included in the decision making process. The integration of these elements should form an alliance between the patient and health care professional with the aim of optimising outcome and quality of life.

3.3.3 Hierarchy of Evidence

There is a wide range of evidence available from a variety of sources including expert based opinion, research-based evidence and from the expertise and experience of health care professionals (Parahoo 2006). However there is some debate over what constitutes usable evidence. Polit and Beck (2010) emphasise that the findings from vigorous research should be paramount, however what constitutes vigorous research and what can be considered best evidence is unclear. The hierarchy of evidence was developed to assist in the evaluation of the effectiveness of evidence (Evans 2003). A hierarchy of evidence ranks evidence sources in accordance with its strength, however as highlighted by Polit and Beck (2010) evidence quality at any level can vary. The authors go on to emphasise that in some areas of healthcare it may be necessary to use evidence based on expert opinion and personal expertise due to stronger evidence being unavailable. There are several hierarchies of evidence available, however the hierarchy presented by Polit and Beck (2010) relates to health care interventions and ranks evidence sources according to strength, Level 1 strongest and Level V11 weakest (Table 1).

Table 1 Hierarchy of Evidence (Polit and Beck 2010)

Level 1	a) Systematic review of randomised control trial (RCT) b) Systematic review of nonrandomised trials
Level 11	a) Single RCT b) Single non-randomised trial
Level 111	Systematic review of correlational/observational studies
Level 1V	Single correlational/observational studies
Level V	Systematic review of descriptive/qualitative/physiological study
Level V1	Single descriptive/qualitative/physiological study
Level V11	Opinions of authorities, expert committees

3.3.4 Selection of the Evidence

With this philosophy as a foundation, a structured process of identifying available sources of information on neonatal pain assessment scales which could be applied in the transport setting was commenced. The literature search is a circular process which can only be complete when the searcher retrieves records they have already identified and no new information is encountered. The process involves identifying the terms, formulating a search strategy, running the search, retrieving a manageable number of results, evaluating the results, saving results, modifying and re-running the search (Rumsey 2004). A broad preliminary search of the literature was carried out by the author in order to identify the depth of available literature. The terms measurement, tool, scale and instrument have been used interchangeably in the literature when referring to pain assessment, however within the context of this study the term 'scale' will be used. This search uncovered a plethora of studies relating to neonatal pain and pain assessment, however there were no studies relating to pain assessment during transport or pain assessment scales developed for transport.

3.3.5 Electronic Sources of Evidence

There are an increasing number of electronic databases which provide clinical evidence from studies on health related problems. However there is reported to be over 22000 journals and 10 million articles in the biomedical literature and still only a small proportion of these are indexed in databases (Mayer 2004). Internet Google search engine (www.Google) provides a wide range of information, however for the purpose of evidence-based practice, frequently it is from an unknown source and not backed up by reliable references. Prior to a full database search, a preliminary search was undertaken using www.Google, on entering the term "neonatal pain assessment" 414,000 hits were made.

This term was further refined to "neonatal pain assessment tools" which received 184,000 hits, and then neonatal pain assessment tools and transport which received 24,700 hits. It was evident from these results that a wealth of information was available requiring further refinement through academic sources.

3.3.6 Bibliographic Databases

Bibliographic databases can be accessed via academic websites on the internet and facilitate journal and publication searches. A comprehensive search of the literature can then be carried out using set search terminology, providing on-line access to the relevant information.

The following databases were accessed:

●**EMBASE** (The Excerpta Medical Database) - Produced by Elsevier. This covers biomedical literature evidence sources including health policy and health management, psychiatry and selective coverage of nursing and dentistry (Sackett et al. 2001).

●**MEDLINE** (Medical Literature Online) - Produced by the United States National Library of Medicine. This is the best known database that indexes health-related literature. It is the world's largest general biomedical database and it indexes one third of all biomedical articles. However due to the size of its literature base it can be difficult to access evidence appropriate to a specific topic (Parahoo 2006).

Databases that provided a more specialised search of information include:

● **CINAHL** (Cumulative Index to Nursing and Allied Health Literature) - produced in the United States. This covers over 4000 journals and over 11 million citations (Parahoo 2006).

● **BNI** (British Nursing Index) - formed between three universities and the Royal College of Nursing. This database claims to be the most current database for UK journals (Parahoo 2006).

●**MIDIRS** (Midwifery resource) - Provides education and practice development resources to assist midwives and student midwives in their practice studies.

A further source which was searched was the **INDEX TO THESES** which provides a list of theses with abstracts accepted for higher degrees by UK universities. This was searched via the university library using key search terms (Southampton University Library 2010). However this provided no studies relevant to the current research. A list of data bases and online resources used can be reviewed in Appendix 5.

3.3.7 Print/Hard Copy

Traditional textbooks have been criticised for frequently being outdated, however textbooks are a useful source for the pathophysiology of clinical problems, providing they are frequently reviewed and referenced with clear evidence to support the statements (Sackett et al. 2001). In relation to neonatal pain, textbook pathophysiology provided a plethora of information. The studies sourced on the electronic databases were obtained on hard copy either from a library search or ordered from inter-library services. Hand checking of peer reviewed journals may potentially highlight studies not identified on the electronic databases. Journal publications in 2009 which were reviewed in this manner included;

- *Pediatrics*
- *Neonatal Network*
- *Archives of Disease in Childhood*
- *Biology of the Neonate*
- *Acta Paediatrica*

Foreign language titles can cause difficulty to the researcher as it limits dissemination, with the reader having to rely on the accuracy of translation.

Publications relating to a symposium, conference or convention can include pre-prints, proceedings and conference records. This sometimes is called grey literature as frequently the organisation hosting the proceedings does not publish all papers within a reasonable time frame. Grey literature and ephemera can include publications that are not easily identified or accessible, as well as conference proceedings they can include theses, company reports, research papers prior to publication and local records.

Ephemera are publications which are disposable or single sheets, and can include pamphlets, leaflets for marketing and forms (Rumsey 2004). Guidelines and local documents can also provide valuable information on current practice. Several interesting documents were reviewed however none were directly relevant to the search.

3.3.8 Key Informants

People can be a very important source of information, providing personal experience and expertise. It can range from expert opinion in a chosen field or a colleague or fellow researcher. However, when obtaining this type of information there is always a risk of personal bias which should always be considered when reviewing results (Rumsey 2004). The author discussed the topic under study with several experts in the field, with the aim of identifying if pain assessment scales were being used on transport. This included a consultant neonatologist who specialised in neonatal transport, neonatal transport nurses currently employed on a transport team, nurse researchers and the clinical nurse pain specialist working in the clinical area. An audit trail of experts consulted can be reviewed in Appendix 6 with an example of correspondence.

An extensive amount of information was obtained which assisted in development of the research question. None of the experts consulted were aware of a pain assessment scale adapted to the transport environment or clinical guidelines relating to pain assessment during transport.

3.3.9 Cochrane Library and CRD

The Cochrane library is an international organisation which aims to facilitate informed decisions about health care by means of systematic reviews of the effects of health care innovations (Polit and Beck 2010). It contains evidence-based databases which provide high quality information (Parahoo 2006). The Centre for Reviews and Dissemination (CRD 2001) is part of the National Institute for Health Research and undertakes high quality systematic reviews. In order to access previous research on the topic under review these databases were accessed regularly over the period of the study.

3.3.10 Government and Professional Initiatives

There are several government and professional initiatives which provide evidence and frameworks to inform practice in relation to the management of pain in infants and neonates. These include the Department of Health (2007) National Service Framework for Children, Young People and Maternity Services and the Royal College of Nursing (2011) care service standards in caring for neonates, children and young people. International organisations such as the International Association for the Study of Pain (IASP Task Force on Taxonomy 2003) provide an invaluable international perspective.

3.4 Main Database Search

Prior to the actual literature search a search strategy was utilised to assist in confirming search terms. This process involved creating a mind map of a variety of words and phrases linked to the proposed question in order to explore and expand ideas. Initial searches included the key words neonatal transport, inter hospital transport, pain assessment and pain assessment scale. The search strategy revealed no scales specifically for use in the transport setting however did produce several articles which were not relevant to the study. Therefore in order to reduce the size of the search inclusion and exclusion criteria were used.

3.4.1 Boolean Logic

When the study question was broken down into compartments they were combined using Boolean logic, using the terms “AND” and “OR” as part of the search. Records containing two terms were retrieved using the “and” operator, this narrowed the search and reduced the number of citations recovered. The “or” operator broadens the search and is used when at least one of the terms must appear, it connects related topics or synonyms (Mayer 2004). Map term to subject heading was used to highlight any relevant search terms from the database thesaurus which would enable a refined search from the subheadings. Truncation and wildcard techniques were used to ensure that all variations of the word were retrieved. The symbol ($) finds the words with a common route such as neonate, neonatal neonatology.

An initial search was conducted in 2009, and a final search was conducted in 2012 to identify recently published neonatal pain assessment scales. Table 2 details the main search to inform the remainder of the study.

Table 2 **Search History Pain Assessment Scales 1996-July 2012**

	Search Term	MEDLINE	BNI	EMBASE	CINAHL	MIDIRS
1	neonatal transport.mp	113	41	186	181	104
2	inter hospital transport	21	2	42	17	4
3	pain assessment.mp	46139	1187	54623	3863	102
4	neonatal pain.mp	154	153	237	295	120
5	infant pain.mp	249	194	354	271	135
6	newborn pain.mp	15	31	27	99	10
7	pain scale	1159	286	3680	4566	83
8	Pain tool	34	253	49	508	4
9	1 or 2	132	42	226	196	106
10	3 or 4	46198	1313	54730	4092	200
11	4 or 5 or 6	386	292	564	563	244
12	7 or 8	2287	494	3719	4951	86
13	9 and 10	1	41	1	0	1
14	12 and 13	0	0	0	0	0
15	10 and 11 and 12	63	33	97	65	17

As a result of this search (Table 2) an integrative systematic review of infant pain assessment tools was identified which was carried out by Duhn and Medves (2004). The authors of this paper reviewed all available pain assessment scales up to 2004. This review identified no pain assessment scales developed or adapted for use in the neonatal transport setting. A search of the Cochrane Library under “neonatal” and “pain control” revealed no systematic reviews on neonatal pain assessment scales, a further source accessed included Clinical Trials.gov. The literature review was then further refined to review all neonatal pain assessment scales published since the systematic review by Duhn and Medves (2004).

This will highlight any pain scales specifically developed for neonatal transport and also enable evaluation of all published scales in relation to their applicability to the neonatal transport environment. An outline of how the inclusion/exclusion criteria were applied to limit the search for appraisal can be reviewed in Table 3 below. The initial search highlighted seven articles which reported the development of pain assessment scales. The final search in July 2012 sourced a further two papers reporting newly developed pain assessment scales which were also included in the review.

Table 3 **Inclusion/Exclusion Criteria for Pain Assessment Scales from 2004**

Exclusion Criteria	Medline 63	Embase 97	Cinahl 65	BNI 33	MIDIRS 17
Not review of existing scale/s	-10	-8	-7	-15	-5
Not review of a pain scale	-43	-75	-47	-10	-5
Not neonatal population	-1	-1	0	0	0
Duplicate	-2	-2	-1	-2	-1
Before 2004	-2	-6	-4	-6	-1
Studies accessed in each database included in the review	7	6	7	0	6

Some studies were accessed on more than one database and are reported in Table 4 below. The systematic review by Duhn and Medves (2004) (Paper 1) and the published pain assessment scales (Papers 2-9) which were included in the review are listed below in Table 4. Details of each paper can be viewed in Appendix 7.

Table 4 **Studies Included in the Review: Pain Assessment Scales**

Study	Author(s)	Pain Scale	Identified Database(s)	Study Outline Included/Excluded
Paper 1	Duhn and Medves (2004)	**Systematic Review of pain scales 1966-2004**	**Medline, Embase, Midirs, Cinahl**	**Systematic integrative review of pain scales** ***Included***
Paper 2	Cignacco et al. (2004)	Bernese Pain Scale **(BPS)**	**Medline, Embase, Midirs, Cinahl**	**Validity/reliability cohort study.** ***Included***
Paper 3	Bellieni et al. (2005)	ABC Pain Scale **(ABC)**	**Medline, Embase, Midirs**	**Validity/reliability cohort study.** ***Included***
Paper 4	Holsti and Grunau (2007)	The Behavioural Indicators of Pain Scale **(BIPP)**	**Medline, Embase, Midirs, Cinahl**	**Validity/reliability cohort study.** ***Included***
Paper 5	Ramelet et al. (2007)	Multidimensional Assessment of Pain Scale **(MAPS)**	**Medline**	**Follow -up validation cohort study.** ***Included***
Paper 6	Hummel et al. (2008)	The Neonatal Pain and Sedation Scale **(N-PASS)**	**Medline, Embase, Midirs, Cinahl**	**Validity/reliability cohort study.** ***Included***
Paper 7	Milesi et al. (2009)	Faceless Acute Neonatal Pain Scale **(FANS)**	**Medline, Embase, Midirs, Cinahl**	**Validation cohort study.** ***Included***
Paper 8	Hand et al. (2010)	**COVERS** neonatal pain scale	**Cinahl**	**Validation cohort study.** ***Included***
Paper 9	Liaw et al. (2011a)	Pain Assessment Scale for Preterm Infants **(PAPSI)**	**Cinahl**	**Scale development and review of psychometric properties. Cohort study.** ***Included***

3.5 Critical Appraisal of Selected Evidence

It has been suggested by Polit and Beck (2010 p95) that critical reading of a paper involves:

> *"a careful appraisal of the researcher's major conceptual and methodological decisions".*

The process should involve a careful and objective appraisal of all the limitations and strengths of a study. Parahoo (2006) highlights that it is important that the process involves making an objective judgement based on what is contained within the research paper.

3.5.1 Critiquing Tools

There are various critiquing tools available to assist in the systematic appraisal of evidence. After considering a range of tools the author decided to use the Critical Appraisal and Skills Programme (CASP) developed by the Public Health Resource Unit (PHRU 2002). This programme has designed a range of tools specific to the methods applied in each study to assist the process of critically appraising the research. The tools were developed to address the epidemiological principles underpinning the study design with particular focus on assessing study validity. The purpose of using an appraisal tool is to review validity, analyse results and appraise applicability and generalizability to clinical practice. The CASP tools address both internal and external validity and therefore were appropriate to this study.

3.6 Critical Appraisal of Evidence using CASP Critical Appraisal for Systematic Review (PRHU 2002)

The systematic review by Duhn and Medves (2004) was appraised by using the CASP Critical Appraisal for Systematic Review. A systematic review provides a summary of evidence contained in a number of articles written on a specific subject, using explicit methods to systematically search and critically appraise the literature (Sackett et al. 2001). A review article will provide an overview of a range of evidence on a selected topic, and keeps the practitioner up to date with current evidence. However Polit and Beck (2010) emphasise the importance of thoroughly critiquing a systematic review before the findings are deemed trustworthy and relevant.

- **Paper 1**: Duhn and Medves (2004) – Integrative Systematic Review

The authors of this paper clearly identified the purpose of the review, which was to examine the issue of infant pain assessment by acquiring all available published pain assessment scales and evaluate their reported reliability, validity, clinical utility and feasibility. The review focused on neonatal scales with the inclusion of unidimensional and multidimensional scales in an attempt to identify all available publications. The method was appropriate to the question as the aim of the review was to identify all studies reporting pain assessment scales. The authors identified 35 studies which they included in the review, 18 unidimensional and 17 multidimensional scales. A detailed review of each study was not included in the paper, however the authors selected samples of each method to discuss within the text.

An overview of the reported validity, reliability, clinical utility and feasibility of some of the scales was provided, however all of the selected studies did not fully report psychometric properties which reflected on presentation of the results. As a consequence meta-analysis of the selected studies was not carried out, the reasons and implications of this for the review were not fully discussed by the authors. The inclusion of meta-analysis would have enhanced rigour within the review, providing additional validity to results. However the authors outlined a clear purpose for the study and methods for accessing the available literature. A wide time frame was selected from 1966 to 2004 with the aim of detecting all available neonatal pain assessment scales. The authors accessed 4 databases and revealed a total of 35 infant pain assessment scales. Limitations of the study include the search being focused on English speaking journals, which the authors acknowledged may have resulted in some studies being excluded. Unpublished scales were identified, however there appeared to be no contact with authors to gain access to unavailable or unpublished scales.

The aim of the review was to compare and contrast scales specifically for their reported reliability, validity, clinical utility and feasibility in a structured systematic manner. The authors did not stipulate if a critiquing tool was applied, an important factor in the assessment of quality. The authors excluded studies which compared scales against each other, with results reflecting in-depth descriptive analysis of the accessed scales. The fact that not all studies reported clinical utility and feasibility was highlighted, however the review gave an overview of scales readily available to clinicians in the field.

It is acknowledged that there is a plethora of scales available, reflecting that six of the multidimensional measures were either published as abstracts only, were not published at all or the original work could not be obtained therefore influencing quality assessment . This clearly affected the ability to review all scales which had been developed. Emphasis was given to psychometric properties of instruments, with the authors giving a detailed overview of key terms used in the description of psychometric properties.

The Cochrane Database of Systematic Reviews (CDSR) is one of four databases in the Cochrane Library which presents structured systematic reviews critically analysing selected studies. The authors however did not apply these methods within this systematic review. A strong systematic review is a structured piece of research, identifying relevant studies in order to appraise the quality of the study and summarise the results using scientific methodology (Sackett et al. 2001). Khan et al. (2003) recommend that the question addressed in a systematic review needs to be defined precisely in order to ensure appropriate selection of papers, highlighting that the recommendations of a systematic review should be based on balanced inferences generated from the collated evidence rather on subjective opinion. However elements of bias can influence the results of a review. Personal interests of the author may motivate the initiation of a review and influence the outcome.

The authors of the systematic review (Duhn and Medves 2004) were based in Ontario, Canada and the review was supported by The Registered Nurses Association of Ontario. There appeared to be no influencing factors in relation to support which would compromise the study, however it can be argued that an element of subjective opinion influences the outcome due to the lack of scientific methodology within the review.

Greenhalgh (2001) highlighted that the manner in which the search for the studies is carried out, the way the evidence is collated and the generation of inferences may reflect on the conclusions and recommendations. When assessing the weight of a review, it is important to evaluate certain elements of the report. Sackett et al. (2001) emphasise that the quality of the methodology can seriously affect outcome as systematic error can occur when an inappropriate design is used. A measurement of precision is important, that is the likelihood of random errors occurring. External validity frequently may not be proven, this is the extent to which the results are generalizable to a particular target group (Khan et al. 2003). The limitations of a systematic review can also include the lack of qualitative evidence which may reflect the practitioners' experience of the treatment and give more in depth and rich analysis. The authors of this review do not include qualitative studies within this population in relation to feasibility and clinical utility however they do reflect on these issues by reviewing the construct of each scale.

The authors clearly differentiated between unidimensional and multidimensional scales, however there is no statistical comparative analysis of the scales reviewed by the authors. The importance of psychometric testing of pain assessment scales is emphasised by the authors, however the use of descriptive comparison limits results. The selected scales were clearly displayed in tables, similar methods of analysis were used in each of the studies, however the authors acknowledge that the level of psychometric analysis between studies varied which prevented meta-analysis. Detailed variation in results is not discussed within the review which therefore prevents comparative analysis.

Acknowledgement is made to the lack of comparative statistical analysis between scales which would be beneficial in reviewing validity, reliability and clinical utility.

A limitation which is acknowledged by the author is the focus on pain scales in the English speaking language, as there may be scales published in other languages not accessed by the author. Conference abstracts were only available when they were referenced in peer reviewed journals which may exclude scales. The authors conclude that none of the selected scales fulfilled the criteria as an ideal measure for neonatal pain, however multidimensional scales appear to be more reliable and valid compared to unidimensional scales. There was no scale identified specifically tested for the neonatal transport population.

This reflects the difficulty in creating a scale which meets all needs. The authors give recommendations and implications for practice which are relevant and appropriate to the clinical area. They highlight the importance of testing scales within the environment that they will be used, and not utilising scales which have not been sufficiently tested. An area also discussed is practitioner satisfaction, reflecting that it is important in the selection of a final scale to ensure that the scale is feasible to use in clinical practice in a meaningful way. The method of design of the scale is also discussed, if it is designed for research purposes or clinical practice. The important point that further testing and validation may be required if a different population is targeted is emphasised. The authors reflect the variations in psychometric analysis within the selected studies. Confidence interval or a p-value is not reported in all of the studies, therefore precision in relation to results cannot be evaluated.

- **Summary of Results**

The neonatal population covered in the review are similar to the local population, however none of the scales were tested in the transport environment and therefore could not be applied to the transport setting. The authors acknowledge that the purpose for which a pain assessment scale has been designed should be considered when applying it in the clinical setting. If the scale is being used in a different population or setting, further testing may be required. The commitment of all health care professionals is recognised as an important factor in ensuring maximum benefit when introducing a pain assessment scale to a clinical area. The selected scale should be perceived by clinicians to be practical and feasible for use in the clinical area.

An outcome not considered was the potential negative effects of utilising a pain assessment scale such as over scoring of the scale resulting in over prescribing, and how this can be avoided. The authors concur that none of the existing scales fulfil all the criteria for an ideal measure, recommending that further testing of existing scales is necessary to enhance pain assessment. Therefore identifying appropriate scales for individual circumstances and undergoing a process of adapting and validating scales to specific settings would be the most appropriate way to progress on-going development.

This study highlights the plethora of scales available and the lack of formal testing of many scales in the clinical setting, therefore the recommendation that scales should be tested within the appropriate setting is an important outcome which should be considered in the clinical area.

3.6.1 Critical Appraisal of Evidence using CASP Appraisal Tool for Cohort Study (PRHU 2002)

The remaining studies (Papers 2-9) were appraised using the CASP Appraisal Tool for Cohort Study (PRHU 2002).

Review of Pain Scales from 2004 to 2011

The search of the selected databases revealed eight pain assessment scales published since the Duhn and Medves (2004) review (Paper 1). All of the neonatal pain assessment scales were published in referenced journals (Appendix 7). They were all published in English, and were affiliated with institutions in Switzerland (**Paper 2**- Cignacco et al. 2004), Italy (**Paper 3**- Bellieni et al. 2005), Canada (**Paper 4**- Holsti and Grunau 2007), Australia (**Paper 5**- Ramelet et al. 2007), USA (**Paper 6**- Hummel et al. 2008), France (**Paper 7**- Milesi et al. 2009), USA (**Paper 8-** Hand et al. 2010) and Taiwan **(Paper 9-** Liaw et al. 2011a).

Each study focused on the validation of a pain assessment scale, with a clear definition of the population under study. Both preterm and term neonates were included in Paper 2, 5, 6, 7 and 8, with Paper 3 including only term babies and Paper 4 and 9 including only preterm babies Two unidimensional pain assessment scales were published in this time period utilising behavioural assessment (Paper 3 and 4). The remaining scales were multidimensional including both physiological and behavioural assessment (Paper 2, 5, 6, 8, and 9) and Paper 7 the study published by Milesi et al. (2009) which validated an acute neonatal pain scale which did not utilise facial expression.

The reason for the development of a new scale varied in each study. Paper 2 stated that there was a paucity of measures to evaluate pain in preterm or ventilated neonates therefore justifying the development of the new scale. This view was also reflected in Paper 4, where a unidimensional measure was developed utilising behaviours to assess pain in the preterm neonate. However in Paper 3 the authors highlighted the complexity of existing scales and the lack of clinical utility, therefore justified the development of a unidimensional measure utilising cry as an indicator of pain.

The assessment of post-operative pain was given as the main objective in Paper 5, with a wider age range of 0 to 36 months. The authors however gave no justification for the development of a new post-operative pain scale. Paper 6 presented an additional element to pain assessment by introducing the evaluation of sedation with pain, reflecting that many preterm and critically ill neonates are routinely sedated.

Paper 7 utilises a novel approach by suggesting that they propose the first scale for the evaluation of acute pain in newborns where the face is not accessible, thereby adapting to the new practices in caring for preterm newborns. The authors go on to reflect that improved neonatal practices such as protection against bright light and non-invasive mask ventilation have made facial observation more difficult, therefore justifying their study. One of the most recently developed scales (Paper 8) claims to have the advantage over other scales in that it is universally applicable to every gestational age and physiological state. However this could be contested as other scales (Paper 6) were developed to cover a similar population. The most recent study (Paper 9) proposes to reflect the weaknesses in existing scales in relation to clinical utility and presents a scale which addresses these issues for the evaluation of pain in the preterm neonate.

In relation to methods repeat measures cohort study is stipulated in Paper 4 as the method of choice which was applied to validate a behavioural pain assessment scale. Polit and Beck (2010) describe a cohort design as a correlational study with a prospective design which starts with a presumed cause and then progresses on to the presumed effect. This can be presented as an appropriate method for a validation study as repeat measures correlation between variables in a population with a common characteristic was required to validate the scale. The remaining studies in the review did not clearly state their selected study design however each applied similar methods to those applied in Paper 4.

In relation to sampling Parahoo (2006) highlights that it relates to the decisions made about data collection and participants. Polit and Beck (2010) expand on this view by emphasising how crucial the effect of the sampling process can be on the validity of the research. The sampling procedure was similar in most of the selected studies. Paper 2 included twelve neonates both term and preterm, however the process for identifying participants for inclusion in the study is not stipulated and would appear to be a convenience sample on admission to the unit. A disadvantage of convenience sampling is that available subjects might be atypical of the population and therefore introduce a risk of bias (Polit and Beck 2010). However this effect may have been limited by the researchers introducing exclusion criteria for participation in the study. Each study identified similar exclusion criteria in order to reduce the effect of confounding factors which may affect results such as congenital anomalies.

Paper 3 studied 50 babies who had been video-recorded for a previous study, details of sampling method used in the previous study was not included. The process applied in paper 4 was similar to that of Paper 2 in that a convenience sample of 92 preterm neonates appeared to be the method of choice however was not stipulated. Convenience sampling was also applied in Paper 5, sample size was estimated on the assumption that a minimum proportion of agreement between two assessors would be between 70% and 90% with 95% CI of $\pm$ 0.1. The remaining studies (Paper 4, 6, 7, 8) also used convenience sampling as their sampling method of choice. Parental consent was obtained for each study. Ethical approval was also obtained for each study apart from Paper 7, as the intervention was deemed to be part of normal procedure and ethical approval was not required in France.

Data Collection

- *Unidimensional Pain Assessment Scales*

Methods of data collection in relation to exposure to a painful event varied in accordance with the aims of each study and the scale under validation. Appropriate methods of data collection are crucial within a study to address the issue of reliability (Polit and Beck 2010). The unidimensional scales focus on one aspect of pain assessment and generally utilise infant behaviour and body movements as opposed to physiological effects of pain. Most frequently they apply a devised coding system for specific facial expressions.

The first unidimensional scale reviewed (ABC Pain Scale) (Paper 3) was developed for term neonates and was based on acoustic features of crying: pitch, rhythmicity, and constancy of intensity.

It is acknowledged in the study that cry is not exclusively applied as an indicator of neonatal pain, however the authors justify using these parameters by referring to previous studies which highlighted identified parameters to distinguish between medium and high levels of pain measured by spectral analysis of crying. The authors validated the scale by using an acute pain episode during heel prick in healthy term neonates. Concurrent validity was tested by comparing this scale against a validated scale called the DAN scale (Carbajal et al. 1997). The sensitivity was also tested by comparing the two scales. Specificity was assessed by comparing the ABC scale and DAN scale during a heel prick with two non-painful events and during the administration of an analgesic. In relation to specificity, the authors reported analgesic non-analgesic comparison as $p < 0.0001$, pain/sham comparison, $p < 0.0001$. Sensitivity was reported as good, with a reported high correlation between scores. In relation to concurrent validity, Spearman $r = 0.91$, and internal consistency was demonstrated with Cronbach's alpha=0.76. Inter-rater reliability was reflected with Cohen's kappa for multiple raters = 0.83, and intra-rater reliability, Cohen's kappa = 0.85. The authors reviewed the practicality of the scale by asking nurses to rate the scale, those who used it stated it was "good".

Paper 4 describes the initial validation of the BIIP scale (Behavioural Indicators of Infant Pain). The authors justify their development of a unidimensional tool using only behavioural measures by reflecting that frequently preterm infants have dissociated physiological and behavioural responses to pain, highlighting that using a multidimensional tool may limit the ability to determine the effects of pain exposure on each individual system. A relatively large sample size of 92 infants between 23 and 32 weeks gestation were included, however no justification for sample size was included. Outcome measures were recorded on video to facilitate interrater reliability, comparing the BIPP (Behavioural Indicators of Infant Pain) with NIPS (Neonatal Infant Pain Score) during blood collection, and heart rate.

- *Multidimensional Pain Assessment Scales*

The remaining scales cited in the search were all multidimensional scales (Paper 2, 5, 6, 7, 8, and 9). The Bernese Pain Scale for Neonates (BPSN) (Paper 2) was developed to bridge the paucity of pain assessment measures for very low birth weight and ventilated neonates in the NICU. The emphasis was on 'acceptability and convenience of use'. The BPSN scale included 9 indicators of pain which were both physiological and behavioural, however the sample size was small consisting of 12 neonates from 32 to 41 weeks gestation (n=6), and 27 to 31 weeks and 6 days (n=6). It can be argued that this small sample size within this population could affect outcome and generalizability. Clear exclusion criteria were defined to reduce the effect of confounding variables. An acute pain episode (heel stab) was the intervention selected to assess acute pain response. The BPSN was used in conjunction with the PIPP scale and VAS (visual analogue scale) to facilitate comparative analysis, with assessments by two bedside nurses at intervals in the procedure. Further video analysis was also carried out by four different nurses to improve validity, however the authors do not elaborate on the training or experience of the raters. This is an important influencing factor which could result in bias if training to ensure interrater reliability was not included.

Paper 5 reported on the clinical validation of the Multidimensional Assessment of Pain Scale (MAPS). This scale was also developed due to a perceived lack of assessment scales for critically ill infants. The scale was developed specifically for postoperative critically ill infants from 0 to 36 months, therefore could not be applied to the wider neonatal population. The scale was tested in response to analgesics in the postoperative period as opposed to an acute event such as heel stab in a convenience sample of 19 critically ill infants. Authors reported convergent and concurrent validity by testing the scale against the FLACC scale (Faces Legs Activity Cry Consolation) and Visual Analogue Scale Observer (VAS *obs*).

In order to ensure compliance the authors stated that all staff involved in data collection attended a one hour tutorial and practice application of MAPS. Clinical utility was assessed using a questionnaire completed by the bedside nurses, with descriptive statistics being used to analyse the responses to the questionnaires. The use of analgesics provided an additional dimension to assessment of the amount of pain the neonate was exposed to postoperatively, facilitating comparative analysis.

Paper 6 reviews the clinical reliability and validity of the N-PASS (Neonatal Pain Agitation and Sedation Scale). This scale is the only sourced scale which combines the assessment of pain and sedation. This study reviews the assessment of prolonged pain in ventilated or postoperative neonates as opposed to an acute pain event such as heel stab. The authors justify assessing both pain and sedation by explaining that infants in the NICU commonly receive analgesics and sedatives, with the assessment of both analgesia and sedation levels having the potential of improving overall assessment of the sick neonate in the clinical environment. The emphasis of this scale appears to be clinical application as opposed to research. However sedation is a concept less well studied in the neonatal population with no available sedation assessment tool available. The N-PASS included the 5 indicators of pain which are well established for validity and reliability, clinical application and ease of assessment: crying/irritability, behavioural state, facial expression, extremities/tone, vital signs. Sedation was assessed utilising the same five indicators, which were consistent with the State Behavioural Scale (Curley et al. 2006) and Modified Glasgow Coma Scale (Reilly et al. 1988). The authors selected 10 nurses to train in the N-PASS scale for data collection. Ventilated and /or postoperative neonates were assessed before and after pharmacological intervention.

Paper 7 reviews the "Faceless" Acute Neonatal Pain Scale (FANS), assessing an acute pain event in the form of heel stab. This scale differs in that it does not depend on facial expression in the assessment of pain, the justification being that in current neonatal practice facial observation of the infant is more difficult due to greater protection against bright lights and non-invasive mask ventilation. The authors conducted a multi-centre study of 24 to 40 week gestation neonates during heel prick. Three raters then scored the pain using FANS and a validated scale DAN (Douleur aigue du Nouveau-ne). The FANS scale is based on autonomic reactions, cry and limb movement. The study recruited a larger sample of 53 neonates 30 to 35 weeks gestation over an 18 month period infant reactions were videotaped to facilitate more accurate analysis of pain reaction.

The final two studies were sourced from in the final literature review in July 2012. Paper 8 was a validation study of the COVERS scale which evaluated 21 newborns gestational age 27 to 40 weeks during two procedures, these were heel stick and diaper change. A crossover design was used so that each patient included in the study was assessed during both procedures. A single observer rated pain at the patient's bedside at three different points; a baseline, during the procedure and after a recovery period. Pain responses were measured using three different existing validated scales and compared with the COVERS scale. It can be argued that the use of a single observer relies on the skills of one observer in the use and application of the scales, multiple observers can assist in establishing interrater reliability. The final study (Paper 9) also applied an acute pain event in the form of heel stab in the development and validation of the PAPSI scale. Content validity was evaluated by 10 neonatal clinicians who answered two questions on the effectiveness of the scale and clarity of the scale. Responses were rated on a Likert Scale and items were then removed from the scale as indicated by results.

The feasibility was tested by asking the 10 clinicians on how frequently they thought staff would use the scale in the clinical area. The reliability and validity of the scale was then tested by video recordings. Data was collected by video tape around a heel stick procedure, with 4 periods around the procedure being monitored. The video tapes were reviewed by 3 nurses, who compared the pain score to the PAPSI with two other pain scales. The nurses were trained by the researcher in use of the scales to reduce the risk of bias.

- ***Analysis***

The primary analysis in each study focused on the reliability and validity of the scores derived from the pain assessment scales. The studies selected existing scales with reported validity and reliability to test the newly developed scales. In relation to analysis of the BPSN in Paper 2, the authors applied tests of normal distribution, with two-tailed tests for all statistical comparisons. Statistical significance was defined as a p value of <0.05. Construct validity between the BPSN and two other scales were compared for each neonate in each situation and were subject to variance analysis. Interrater and intrarater reliability was analysed with Cronbach's Alpha reliability coefficient. Results reflected a highly significant difference between events. When only behavioural indicators were considered, results reflected a significant difference ($F=34.45$, $p<0.0001$). To determine concurrent validity the BPSN was compared to the visual analogue scale (VAS) and there was good correlation between the two scales (Cronbach's Alpha, $r = 0.855$, $p<0.0001$). Convergent validity was determined by comparing the BPSN and the PIPP score) $r=0.907$, $p<0.0001$). Reliability was assessed calculating interrater reliability, the results of pain assessment using BPSN did not vary over time.

Paper 5 which reviewed the MAPS scale used a slightly differing approach in that responses to analgesics were evaluated using a hypothesis testing approach, with the assumption being that pain score drops after analgesia. Pain scores were averaged across number of bolus analgesics administered at baseline at regular time intervals. The nonparametric Friedman test was used to determine significant decreases in median pain score between baseline at the specified time intervals after administration of morphine. Concurrent validity was also assessed in this study by comparing the scale with the VAS.

Convergent validity was assessed by comparing MAPS and FLACC pain scale. Reliability analysis consisted of assessing the MAPS internal consistency by calculating Cronbach's coefficient for each subjects pain score at each time point. A coefficient of > 0.50 was indicative of internal consistency. Twenty infants participated in the study, all were over 36 week's gestation, aged between 4 days and 31 months, with all scoring raking place in the first 24 hours after surgery.

In reviewing the N-PASS, Paper 6 also applied intraclass correlation coefficient (ICC) as a measure of interrater reliability and Cronbach's alpha as a measure of internal consistency. Spearman's rank correlation between the N-PASS and the PIPP as a measure of convergent validity and Wilcoxon signed-rank test to compare the distribution of N-PASS scores before and after pharmacological intervention as a measure of construct validity. Result reflected interrater reliability measured by intraclass coefficients of 0.85 to 0.95 was high (<0.01 to 0.0001), convergent validity was demonstrated by correlation with PIPP scores. The Spearman's rank correlation coefficient at high pain scores was 0.83, and 0.61 at low pain scores. Internal consistency as measured by Cronbach's alpha was evident with pain scores (0.82) and with sedation scores (0.87).

Construct validity was reflected with the Wilcoxon signed-rank test which compared the distribution of N-PASS scores before and after morphine, showing pain scores of 4.86 (3.38) and 1.81 (1.53) mean and (SD) $p < 0.0001$. Sedation scores of 0.85 (1.66) and -2.78 (2.81) $p < 0.0001$ for pre and post intervention.

In Paper 7 reliability of the FANS scale was assessed by interrater agreement and internal consistency (Cronbach's alpha). Validity was established by agreement between scales - intraclass correlation coefficient (ICC). Effects of differences between conditions when using the FANS score was evaluated by the Wilcoxon test. Cronbach's alpha was 0.72, ICC was 0.92 for interrater agreement and 0.88 for agreement between scales. Data analysis in Paper 8 established concurrent validity by comparing scores on the COVERS scale to three other validated scales. Construct validity scores on the COVERS scale for each of the two procedures were compared. Data was analysed using Pearson correlation coefficients and the Wilcoxon signed-rank test.

On reviewing the PAPSI (Paper 9), data analysis included content validity measured with the content validity index (CVI) (Lynn 1996), a numerical value reflecting the level of each items content relevance as rated by clinical experts. Also interrater reliability between observer scores and concurrent validity of the scale with the other validated scales were determined by intraclass correlation coefficients. Internal consistency was assessed by Cronbach's alpha and item-total correlations. Further testing included construct validity using repeated- measures analysis of variance, reviewing whether the scale measures the construct (pain) adequately.

Overview of Results

- *Unidimensional Pain Assessment Scales*

Paper 3 concluded that the ABC scale is simple and reliable for assessing pain in healthy non-intubated term neonates. Clinical utility and feasibility is however questionable, it is unclear how much training would be involved in the use and application of the scale. Due to the nature of the observations its use would be limited in the special care setting as it can only be used in non-ventilated term patients. However the authors go on in a later study to validate the scale with preterm neonates by comparing it with the PIIP scale which is a validated scale for the preterm population (Stevens et al. 1996).

Paper 4 describe the initial validation of the BIIP scale, reporting that scores on the BIPP changed significantly across all phases of blood collection. The internal consistency of BIPP was evaluated with Cronbach's alpha. Internal consistency (0.82) and interrater reliability (0.80-0.92) were high. To assess changes in BIPP, NIPS, and mean heart rate repeated measures ANOVA was carried out across the phases of blood collection. Correlation between the BIPP and NIPS were modest ($r=0.64$, $p<0.01$) as were correlations between the BIPP and mean heart rate ($r=0.45$, $p<0.01$). This may be due to the NIPS scale being multidimensional and includes physiological measures. The number of infants included which were less than 29 weeks gestation was small, however the authors acknowledge the difficulty in assessing this population due to levels of analgesia and sedation. Feasibility is also questionable as recording was carried out by video and not direct bedside observation. Also in relation to feasibility, newborns are frequently swaddled in the neonatal unit to promote containment and neurodevelopment, observational pain measurement in these circumstances can be problematic.

- *Multidimensional Pain Assessment Scales*

Paper 2 reported that in the BPSN Scale pain expression in gestational age 27 to 32 weeks was statistically not significantly different from those with a gestational age between 32 and 41 weeks. This reflected a lack of sensitivity within the scale specific to gestational age. However construct validity was stated to be very good ($F=41,3$, $p<0.0001$), with high coefficients for interrater ($r=0.86-0.97$) and intra-rater reliability ($r=0.98-0.99$). Main limitations of the study is the small sample size, in that only 6 infants in each gestational age category were included, therefore it would be difficult to suggest results are generalizable. The authors acknowledge a limitation is the small numbers of ventilated sick neonates within the sample. There was no indication of training of raters or level of training required to use the scale, therefore feasibility and clinical utility are questionable. The authors concluded that the BPSN was shown to be a valid and reliable tool for assessing pain in both term and preterm neonates who were both ventilated and non-ventilated.

In relation to Multidimensional Assessment of Pain Scale (MAPS) (Paper 5) results indicated that the MAPS score decreased significantly (40% of total score) after analgesia ($p< 0.001$). Agreement measurements demonstrated that there was little risk of measurement error between MAPS and FLACC and MAPS and VAS. However results indicated an improvement in internal consistency of the MAPS if the item "vital signs" (physiological parameters) was removed. This was reflected in the observation that after the administration of morphine, Cronbach's alpha ranged between 0.80 and 0.26, reflecting widely varying internal consistency of the 5 point MAPS at the different time periods after analgesia. The authors refer to reports in the literature which demonstrate a poor correlation between behaviour and physiological parameters (Van Dijk et al. 2002), however go on to report that correlation increases with intensity of pain, reflecting that physiological parameters are a reliable measure of intense pain.

As a result of this the MAPS was refined to change the scoring system of the vital signs. A limitation of this study for application to the neonatal population is the small sample size, being conducted in a paediatric intensive care environment and being focused on term neonates.

Paper 6 reviews the clinical reliability and validity of the N-PASS (Neonatal Pain Agitation and Sedation Scale). A strong correlation between the PIPP (Premature Infant Pain Profile) and N-PASS is reported particularly at high pain scores. The mean scores for each gestational age were similar, this was before the points were added for prematurity. Therefore the authors conclude that this element of the scale which adds on points for prematurity may be unnecessary. The authors reflected that these results provide initial evidence that the N-PASS is a reliable and valid tool for assessing pain and agitation in post-operative patients. The main limitations of the study were that the tool was studied in the clinical setting and not videotaped which therefore implies that bias cannot be excluded.

The “faceless” acute neonatal pain scale (FANS) reported in Paper 7, does not depend on facial expression in the assessment of pain. In order to validate the scale the authors compared it to another validated scale or “reference scale” called the DAN (Douleur aigue du Nouveau-ne) scale The authors reported that the FANS is a reliable scale which correlates well with an established pain scale and is able to discriminate reliably between painful procedures and non-painful stimulation. In order to validate the FANS authors assessed reliability in the interrater agreement and internal consistency by calculating Cronbach’s alpha. The coefficient varied from 0 to 1 and served to determine the contribution of each item to the totality of the scale. The interrater reliability was high and comparable to reference scale. A Bland and Altman analysis assessed the agreement between the two scales, estimated by the 95% confidence interval.

Pain scores provided by the FANS tended to be higher than those provided using DAN for moderate pain events. However the difference between the FANS and DAN remained stable whatever the gestational age. A limitation of this scale is that it is reliant on vocalisation and therefore cannot be used in ventilated infants, limiting its use in the neonatal intensive care setting.

Paper 8 reported that when the COVERS pain scale score for the premature infant was compared to the PIPP score results were similar, as were results when the COVERS scale was used with term neonates and compared to the NIPS scale. During painful procedures there was a significant increase in each pain score, with a significant decrease in the score after the recovery period. Similar results were reflected in Paper 9 when reviewing the PAPSI scale, where similar construct validity was demonstrated between the new scale and the PIPP scale and VAS. However the authors acknowledge that the scales may not discriminate between painful and non-painful procedures in the extremely low birth weight neonate (below 27 weeks gestation).

- *Discussion and value of results*

Results reflected the increasing numbers of scales available in the literature for measuring pain in the neonate. However many have not had rigorous psychometric testing in the clinical area, and have not included items which are theoretically derived or are developmentally relevant to both term and preterm neonates. The population and environment within which the tool will be used is a crucial element in the interpretation of pain and behaviour and in utilising a pain assessment scale (Hummel and van Dijk 2006). Clinical areas frequently adapt existing scales without adequate testing to ensure validity and reliability.

The motivation for scale selection may be ease of use as opposed to being appropriate to the particular patient or circumstance. The post-operative period is frequently used to evaluate pain, however it is crucial to acknowledge the different types of pain that can be experienced such as acute and chronic, and the varying effects of the neonate. It has to be noted that the included studies examine both acute (Paper 2, 3, 4, 7, 8, 9) and chronic pain (Paper 5, 6) which may influence results.

The value of some pain indicators utilised in neonatal pain scales may be questionable. Cry (Paper 3) is frequently used as an indicator of pain, however neonates do not always cry during skin breaking procedures (Holsti and Grunau 2007). Neonates who are ventilated do not cry and therefore tools utilising this item are not appropriate with this population. The more preterm or unstable the neonate the less likely they are to cry vigorously, furthermore some infants may appear to be sedated without medication having been administrated such as babies who are septic or lethargic or have a degree of neurological compromise. It has also been reported that premature infants may exhibit a "shut down" reaction to overwhelming pain and appear sedated (Johnston et al. 1999). Cry can be very subjective in that neonates cry for various reasons which may not be pain related, possibly dependent on the temperament of the baby and cannot always be used in isolation as an indicator of pain.

Facial response is a further behavioural characteristic which is not always displayed by the neonate who is experiencing pain (Holsti and Grunau 2007), however it is also utilised in many pain assessment scales (Paper 4, 6). Some infants do not respond to tissue damaging events (Johnston et al. 1999). This effect is problematic for clinicians as it may be difficult to distinguish between the absence of pain and the neonate who is in such acute pain that they are non-responsive. Body

movement can also be subjective as is reflected by Milesi et al. (2009). Often neonates are contained in nests and protected from light therefore observational tools can be difficult to use in the clinical area and impractical when transporting the patient during transfer. Also when the neonate is being transferred by ambulance or by air visibility of the neonate in the incubator may be reduced relying more on physiological parameters to assess pain.

It has been reported that pain should also be assessed with sedation (Ramsay 2000). Paper 6 is the only scale which applies both pain and sedation, it can be argued that this element of assessment is particularly relevant to the transport environment as many neonates will be sedated therefore influencing pain assessment. Pain assessment may be regarded as being one of the most crucial elements in the management of the neonate during transport in order to ensure a safe and stable transport. However the utilisation of pre-emptive analgesia in known painful events in any nonverbal population is also an area of debate and should be addressed with caution. The N-PASS scale presented in Paper 6 is unique in its combination of pain and agitation however it has only minimal reporting of psychometric properties. The differentiation between pain, agitation and sedation is problematic due to the complex nature of neonatal pain assessment and requires further research.

It is clear from the review that each scale has both strengths and weaknesses, largely dependent on the context within which the scale is utilised. However none have been validated in the transport setting and have limitations in relation to clinical utility and feasibility. An overview of the strengths and weaknesses of each scale can be reviewed in Table 5 below.

Table 5 **Strengths and Weaknesses of Reviewed Pain Scales**

Study	Strengths	Weaknesses	Appropriate for Transport
Bellieni et al. 2005 (ABC scale)	Simple and easy to use.	Unidimensional scale. Cry is pain measure. Used in healthy term babies.	Not validated for use during transport. Concerns regarding clinical utility/feasibility
Holsti and Grunau 2007 (BIPP scale)	Includes both term and preterm.	Unidimensional pain assessment scale. Behavioural measures only. Combines sleep/wake states.	Not validated for use during transport. Concerns regarding clinical utility/feasibility
Hummel et al. 2008 (N-PASS scale)	Multidimensional. Both term and preterm. Uses both pain and sedation.	Complex to use. Time consuming. Requires training.	Not validated for use during transport. May be adaptable.
Cignacco et al. 2004 (BPSN scale)	Multidimensional. Includes term, preterm and ventilated babies.	Does not include sedation.	Not validated for use during transport. Concerns regarding clinical utility/feasibility
Milesi et al. 2009 (FANS scale)	Multidimensional.	Does not include facial expression. Does not include sedation	Not validated for use during transport. Concerns regarding clinical utility/feasibility
Ramelet et al. 2007 (MAPS scale)	Multidimensional.	Does not include sedation.	Not validated for use during transport. Concerns regarding clinical utility/feasibility
Hand et al. 2010 (COVERS scale)	Multidimensional.	Does not include sedation.	Not validated for use during transport.
Liaw et al. 2011a (PAPSI scale)	Multidimensional.	Does not include sedation.	Only valid for preterm infants over 27 weeks gestation

3.7 Conclusion

It appears from the available literature that there is no pain assessment tool ideal for every situation; many have limited psychometric testing. Establishing validity and reliability can be a lengthy process, requiring test and re-test with different populations and in different environments. It is important that the selected tool is applicable to the setting within which it will be used. In relation to the neonatal transport setting, the tool has to be practical, easy to use, applicable to the term and preterm neonate, ventilated and non-ventilated patients and patients who are sedated with analgesia.

Results reflect the characteristics of some scales which would make them impractical in the transport setting. The scale published by Bellieni et al. (2005) was developed for term neonates and was based on acoustic features of crying, therefore this could not be adaptable to the transport setting as preterm babies would be excluded and also ventilated or heavily sedated babies. The BIIP scale (Holsti and Grunau 2007) measures behavioural indicators of infant pain, this also could not be adapted to transport due to the problem of assessing only behaviour during transport. Subsequently unidimensional tools which assess only one pain indicator would be problematic and impractical in this setting. Multidimensional tools appear more appropriate to this population. However no scale has been tested in this environment with the specific issues of movement, noise, temperature control, altitude, light being considered in their development.

The tool developed by Hummel et al. (2008) is the only tool which includes both pain and sedation, encompasses both term and preterm neonates and appears to have a degree of flexibility in relation to different patient groups and diagnosis.

The N-PASS was however developed within a North American model and may have some problematic areas in relation to terminology which may require adaptation to a UK setting.

Overall results however reflect the deficiencies which exist in the literature in relation to the specific needs of the transport setting and also the practicality of use in this complex environment.

3.8 Chapter Summary

The literature review on neonatal pain assessment scales presented in this Chapter clearly identified gaps in the literature in relation to pain assessment during neonatal transport, with no available scale developed specifically for the neonatal transport environment or an existing scale which could be readily applied to the transport setting. The implication was therefore that a new scale specifically adapted to the transport setting would be the most appropriate for this population.

Therefore informed by the broad range of information presented in Chapter Two highlighting the challenges imposed on pain assessment by the transport environment, combined with the literature review on available pain assessment scales, the next Chapter of this Thesis utilises evidence-based methods to develop a new pain assessment scale appropriate to this specialised population.

4. Chapter Four

Methodology

4.1 Introduction

This chapter begins by stating the study aims and primary research questions, progressing on to outline the major methodological theme of the study which serves to fuse together the three distinct Phases of the research into a collective unit. Justification for the use of consensus methods will be presented, linking the design to the framework, building on the main concepts of the research with the purpose of answering the primary research question (PRQs). A major component was to structure an operational plan which would address potential difficulties, ethical concerns and any potential bias which may present during the study. A crucial element was to clearly outline procedures and methods utilised in the implementation of the research process (Parahoo 2006).

4.2 Primary Research Question

After a critical review of the literature using the previously formulated PICO question, gaps in the knowledge base were identified. Principally there was no evidence of a specific neonatal transport pain assessment scale in existence.

Therefore the following research question was posed:

"Can a valid neonatal transport pain assessment scale be developed"?

The study aims to:

- *Make a unique contribution to the body of knowledge and evidence-base relating to the assessment of pain during neonatal transport.*
- *Critically review how pain is assessed during a transport event.*
- *Report face validity of a pain assessment scale adapted to neonatal transport by means of consensus methods.*

The primary research questions (**PRQs**) associated with the study are:

1. *Which neonatal pain indicators should be included in a transport pain assessment scale?*
2. *What are the practicalities of using a neonatal transport pain assessment scale?*
3. *Has a transport pain assessment scale developed within the current research study by consensus methods achieved face validity?*

The research questions and study aims have been developed from the academic and professional literature, and further supported from clinical practice. The primary research question and study aims are worthwhile exploring primarily due to the lack of validated measures of neonatal pain assessment specific to the transport setting.

Despite the vast amount of literature on pain, pain assessment and pain management, the area of pain assessment during neonatal transport remains an area with limited evidence-based research. This study will therefore enhance knowledge, education and ultimately clinical practice with the potential to positively impact on direct patient care.

4.3 Contribution of this Study

This study contributes a comprehensive review of pain assessment specific to the neonatal transport environment. The evidence from this study highlights the lack of available literature in this specialised field, emphasising the current lack of assessment measures validated and tested in the neonatal transport setting. This study therefore adds to the limited evidence on transport pain assessment and offers the development of a pain assessment scale specific to neonatal transport setting.

4.4 Research Methodology

4.4.1 Consensus Methods

Consensus method is a process of group decision-making aimed at gaining the consent of participants. In professional terms this may be defined as reaching an acceptable resolution to an issue which is supported by participants, however acknowledging that it may not be the favourite of one of each. Health care providers may be faced with the problem of attempting to make decisions where there is little information or alternatively a plethora of contradictory information. Consensus methods therefore provide an alternative means of synthesising information by means of encapsulating the insights of experts to enable effective decision making.

Consensus methods are increasingly being used in healthcare research (Cantrill et al. 1996) and are acknowledged as an effective approach within collaborative problem solving (Burgess and Spangler 2003). This approach to decision making has been described as a complex process involving decision making at both the individual and group level (Black et al. 1999).

Three principal consensus methods are described (Black et al. 1999);

•**Nominal Group Technique (NGT):** consists of a highly structured format utilising weighting and ranking methods that enables a group to generate and prioritise issues within an environment. The method gives everyone an equal voice, resulting in a set of prioritised solutions representing group preferences.

•**Delphi Method**: consists of postal or online questionnaires which assist panellists in prioritising predetermined categories, utilising an iterative approach until consensus is reached.

•**Consensus Development Conference:** debates current scientific evidence and expands understanding of issues and their relationship to policy and practice.

All of these methods share the common objective of synthesising judgements when a state of indecision or uncertainty exists, initiating the generation of ideas and understanding of complex issues (Keeney et al. 2011). Consensus methods have been utilised in a variety of settings including education and training programmes (Farley 2005, Williams et al. 2006) and to facilitate the production of clinical guidelines (Cornick 2006). Fink et al. (1984) purport that the main purpose of consensus methods is to define levels of agreement on controversial subjects, going on to reflect that when used appropriately consensus methods can facilitate structured environments within which experts are given optimum information enabling their decision making to be credible and justifiable.

The Delphi Method and NGT are two of the most common consensus methods used to synthesise data from conflicting evidence and emerged as the most appropriate for the current study. Both methods offer a transparent, structured and replicable way of synthesising individual judgements, and have been extensively used for guideline development and priority setting in health care (Glasier et al. 2003, Zeitlin et al. 2003). They are primarily concerned with deriving quantitative estimates by means of qualitative approaches.

4.4.2 Justification for Choice of Methods

The methods selected for this study was based on the nature of the research, the data required to answer the primary research questions and importantly availability and access to participants. The initial approach which was considered for this study adopted a quantitative methodology with the aim of testing the validity and reliability of an existing pain assessment scale in the transport environment. However this approach was not possible due to barriers in relation to accessing neonates during transport. Therefore the research aims and objectives were reconsidered.

The following issues informed the approach adopted in execution of the research:

1) Barriers in accessing the vulnerable neonatal population in the transport setting.
2) Lack of available evidence on pain assessment during transport.
3) No current pain assessment scales developed for the transport setting.
4) Plethora of neonatal pain assessment scales for the NICU setting.
5) Current practice within the transport setting.

Due to the lack of structured methods of pain assessment during transport, current practice generally consists of utilising the transport clinicians' experience and judgement. Therefore due to the lack of available evidence and no existing transport pain scale it was decided to harness the knowledge and perceptions of experts in the field. The ultimate aim of this approach was to inform the content and structure of a pain assessment scale, the first draft of which would be developed within the course of the research. Therefore the most appropriate choice of methodology which met the needs of the study fell within a qualitative consensus paradigm, utilising expert opinion to develop or adapt a pain assessment scale to the transport setting.

The views and opinions of experts in the field of neonatology were sought in each Phase of the research in order to inform, structure and evaluate the newly developed scale. Qualitative methods were utilised with a combined sequential approach in order to generate structured data for development of the scale, concluding with an evaluation of the newly developed scale by semi-structured interviews with neonatal transport clinicians to establish face validity. The research process was therefore primarily concerned with ensuring that the most appropriate methods were utilised for the topic under investigation, utilising a systematic, rigorous approach to explore, confirm and facilitate comprehension of the topic being studied (Cormack 2000, Clarke and Reed 2006).

This study was therefore divided into three distinct Phases:

1. **Phase One**- Focus group meeting utilising the Nominal Group Technique (NGT). Results of Phase One taken forward to inform the content of the Delphi tool utilised in Phase Two.
2. **Phase Two**- Two round Delphi study with transport clinicians throughout the UK to gain consensus on the overall content, structure and design of a transport pain assessment scale.
3. **Phase Three**- Semi-structured interviews with transport clinicians to establish face validity of the first draft of the newly developed transport pain scale.

The main objective of the methods utilised in this study was firstly to identify specific pain indicators to include in a pain assessment scale which would inform development of the Delphi questionnaire, secondly to gain overall consensus on the content, design and structure of a pain scale and thirdly to establish face validity of the developed scale. The first Phase of the study required a specific question to be addressed. The highly structured format of the NGT can only review one question or issue at a time and is a single purpose technique (Delbecq et al. 1975), therefore this method appeared to be an ideal means of addressing Phase One.

Furthermore it has been suggested that NGT can be used to develop consensus without the limitations of methods such as committee meetings which are prone to domination by strong individuals and personalities, resulting in effective decision making within a group setting (Delbecq et al. 1975).

Phase Two required consensus to be achieved on the overall content, design and structure of a pain scale. The Delphi technique is aimed at measuring levels of consensus between a panel of experts by controlled feedback (Powell 2003), involving 'collaboration' as opposed to 'compromise' in the decision making process, providing the ideal platform for development of the pain scale. Transport clinicians are dispersed throughout the UK; therefore Delphi method also addressed the difficulties in participants being located in different geographical areas. This study has therefore been designed to be flexible but rigorous in methods of data collection to capture the views of clinicians and address the study aims and primary research question.

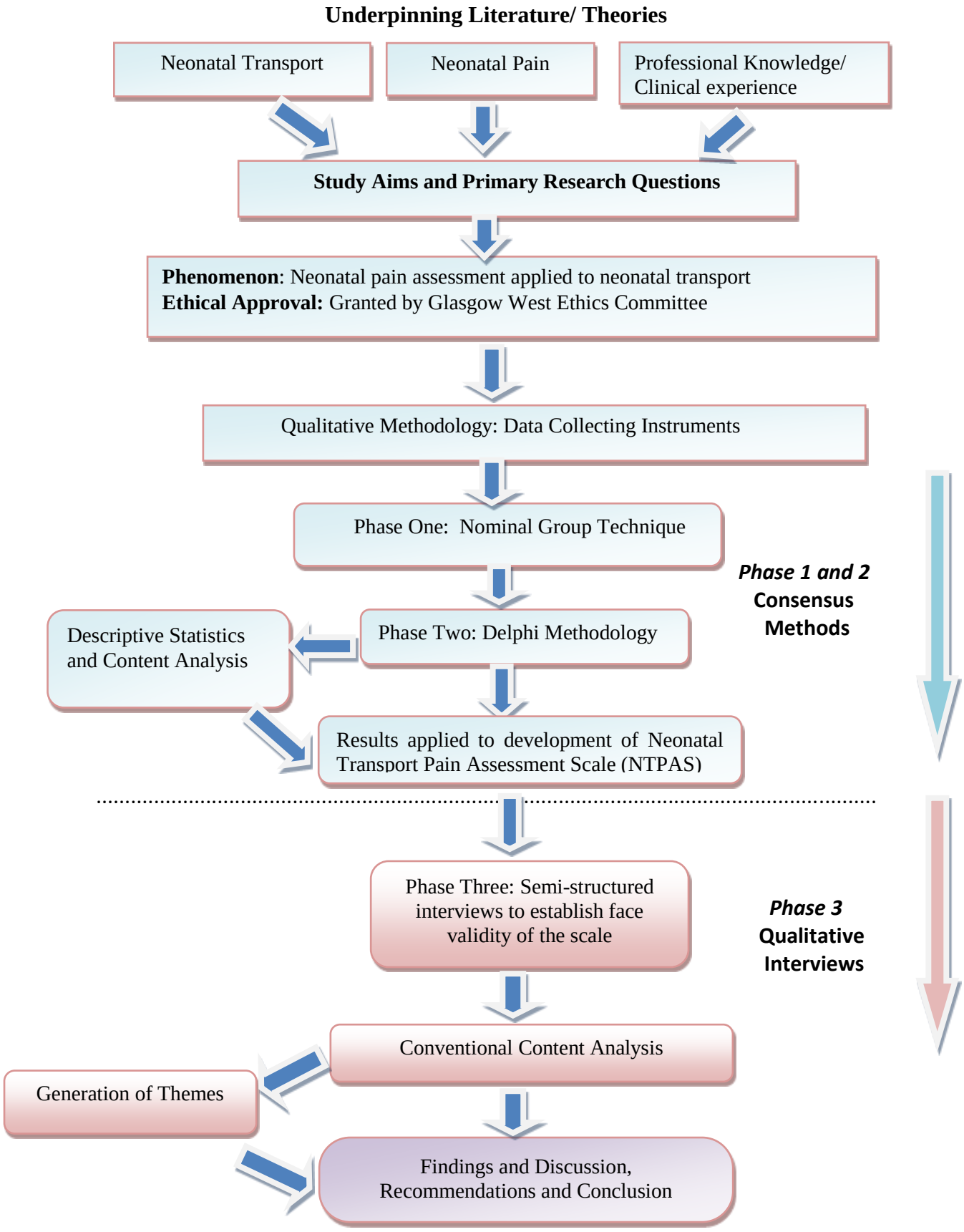
Turoff (2006) reflected that the Delphi approach is a suitable means to pursue any of the following objectives:

- To seek out information which may generate a consensus on the part of the respondent group and to determine or develop a range of possible alternatives
- To explore underlying assumptions or information leading to differing judgements
- To correlate informed judgements on a topic spanning a wide range of disciplines
- To educate the respondent group as to the diverse and interrelated aspects of the topic.

Each of the above objectives linked into the concepts of the current study, furthermore by giving each participant time to formulate their own opinion independently of others, Delphi method also helps to avoid problems related to "groupthink", at the same time overcoming barriers of communication such as intimidation and disagreement (Keeney et al. 2011).

Application of consensus methods in this study can be further justified by the concept of the 'expert' nurse, encapsulated in the landmark work by Patricia Benner (Benner 1984) which introduced the effect and value of their wealth of experience and education to patient care. Practitioners within the clinical area acknowledge the importance of expertise and knowledge base in the management of the acutely ill patient (Keeney et al. 2011). This resonates with the current study in that the utilisation of expert opinion is an important element in the development of clinical practice within neonatal nursing and the expertise involved in the assessment and management of pain required within the transport environment. Furthermore Lopez (2003) highlighted the main reason for utilising Delphi is a lack of knowledge on the subject area, relating to the current study in that there is a lack of published literature on pain assessment or management during neonatal transport. Therefore in relation to available evidence the application of consensus methods can be justified in the execution of this study. An important element in the design of this research project was integrating structural organisation in order to facilitate systematic navigation through the study. A thematic map (Polit and Beck 2010) was developed in the form of a schematic representation of the principal concepts and processes central to the study. Rosenberg and Yates (2007) describe this process as useful in facilitating a 'visual map' of the various aspects of the study, directing a route through the study which links to the audit trail. A schematic representation was therefore developed in order to elucidate the processes intrinsic to the study in order to assist in execution of the research (Figure 7).

Figure 7 **Study Schematic Representation**
Adapted From: Lemaire and Wallace (2010)



The next section will review the NGT and Delphi process in more detail and by doing so highlight the congruence and cohesion between the two approaches in the application of the research, providing an overview of the strengths and weaknesses of each method.

4.4.3 Nominal Group Technique (NGT)

The NGT is a highly structured format which is aimed at gathering information from a group of participants about a given issue. It is a decision making method for use among groups of varying sizes who want to make their decision quickly by a vote, but ensure everyone's opinions are taken into account (as opposed to traditional voting where only the largest group is considered).

The NGT has been described by Moore (1994 p10) as:

> *"A method for structuring small group meetings that allows individual judgements about a topic or an issue to be pooled effectively and used in situations in which uncertainty or disagreement exists about the nature of a problem and its possible solutions"*

The NGT was initially developed in the late 1960's from an analysis of group decision making in aerospace, environmental and industrial fields. The technique was first described by Van de Ven and Delbecq (1972), who reported the method's applicability to group settings and health care policy as an effective method of facilitating problem exploration in a group setting. NGT is now utilised in a wide array of health care research with a variety of aims, ranging from end of life care (Shipman et al. 2008, Aspinal et al. 2006) to professional education (Williams et al. 2006).

Van de Ven and Delbecq (1972) stated that the nominal group process is 'problem centred', however Cooper (1982) argued that the process can also be 'solution centred' in some circumstances. Delbecq et al. (1975) highlight that this method is not appropriate for routine meetings where the focus is on information exchange and coordination, furthermore this technique can only review one question at a time and is therefore a single purpose technique (Delbecq et al. 1975).

A main consideration of using this method is that it involves no preliminary preparation, however provides a forum to generate a substantial amount of work in a relatively short period of time (Williams et al. 2006). Meetings generally last around 90 minutes and the results are immediate with no further input required from participants, an important aspect when working with clinicians who are busy with limited time to offer. The NGT also facilitates a democratic style of meeting which may not be evident in other formats where individuals may dominate the discussion resulting in bias. Flaherty and Glasper (2003 p32) reflect that the NGT emphasises impartiality by:

"giving each subject a voice which is not drowned"

4.4.3.1 Structure of the NGT

The format of the NGT (Delbecq et al. 1975) is a highly organised process guided by a facilitator, whose role it is to ensure the smooth running of the session within the structured format (Figure 8 below). The NGT is a weighted ranking method which enables a group to generate and prioritise issues within a structure which allows everyone to have an equal voice.

Figure 8 **Stages of the NGT**

The Six Stages of the NGT	
1	Silent generation of ideas in writing
2	Round robin recording of ideas
3	Serial discussion for clarification
4	Preliminary vote on item importance
5	Discussion of Preliminary Vote
6	Final Voting

(Delbecq et al. 1975)

The structure of the NGT is fundamental to the effectiveness of the process, with each stage playing an important part in achieving an optimum outcome (Delbecq et al. 1975). It is therefore important that the facilitator understands the purpose of each NGT stage and both the participants and facilitator follow each stage of the process, resulting in an effective and time efficient means of integrating the views of clinicians on a specific topic.

The first step in the NGT is to present a nominal question to the group in written format, the facilitator then asks the group members to write their key ideas silently and independently. This stage of the process is important as it gives participants time to think and reflect, it avoids interruptions and undue emphasis on an individual idea or train of thought. It also avoids competition between participants, prevents status pressure and pressure to conform with other group members. It is important at this stage that the facilitator does not provide answers to the question for the group or get involved in detailed clarification, as evidence shows that this will focus the group on the facilitator's frame of reference (Delbeq et al. 1975).

It has been suggested that the fact that the list is written is of particular importance, as an idea expressed in writing is more objective and less personal, furthermore if the idea is written down participants are more able to separate it from the personality or position of the individual contributing it. This process also allows the group to consider a large number of ideas during the process (Delbeq et al. 1975).

The aim of the second stage is to record a rapid, accurate list of ideas in brief phrases or words on a flip chart which is visible to the entire group. The round-robin recording during this stage means going around the table, asking for one idea from one member at a time. The facilitator writes the idea on the flip chart and then proceeds to the next group member, allowing equal participation in the presentation of ideas to provide an increase in open mindedness. It also facilitates depersonalisation of ideas from individual group members and increases the ability to deal with a large number of ideas. This method leads to an increased tolerance of conflicting ideas within the group and encourages hitchhiking (stimulates an idea from another group member). The written list also has the benefit of providing an early group reward, presenting a range of ideas generated by the group.

The third stage in the process takes each idea listed on the flipchart in order and gives a short period of time for the discussion of each item. The primary objective of this stage is to clarify not to gain consensus on arguments. However Delbeq et al. (1975) highlight that this stage is not restricted to the meaning of words or phrases, but can also convey logic or analysis behind them.

Following group discussion the participants have come to understand the meaning of each item, with arguments for and against each one. The fourth stage must now aggregate the judgements of group members in order to highlight the relative importance if each item. The simplest and most frequently used method of voting in NGT is rank-ordering, a process which can increase judgemental accuracy by having group members express these judgements mathematically. The process involved in the preliminary vote relies heavily on clear instruction by the facilitator. The group are asked to select five priority items from the list and write each on the upper right hand corners of a 3x5 index card. Delbeq et al. (1975) justify the reason for the selection of five items by reflecting that as a rule individuals are able to accurately rank or rate about seven (±2) items, furthermore using the visual example of flip chart and index cards helps eliminate confusion. When each group member has selected five priority items they are then asked to rank them in order of importance one card at a time, with 5 being the most important and 1 the least. This process slows the procedure down encouraging them to make careful iterative decisions rather than hasty decisions.

Stage five involves a discussion of the preliminary vote with the purpose of increasing judgemental accuracy. This step provides the opportunity to discuss again items which are perceived to receive too many or too few votes and also any inconsistencies. The final step (stage six) in the process consists of the final vote which combines individual judgements into a group decision, the outcome of the meeting is determined providing a sense of closure and documentation of the meeting.

4.4.3.2 NGT: Strengths and Weaknesses

When selecting the most appropriate methods to utilise it is important to consider both the strengths and weaknesses. Jones and Hunter (1995) suggest that group based research are methods of last resort, regarded more as a means of structuring group communication than as a means of producing answers. The authors argue that unless the findings can be tested against observed data, they remain uncertain in relation to producing the "correct" solution. However Burtunek and Murninghan (1998) dispute this assumption by reflecting that NGT is one of the best processes for reaching effective and accurate decisions on structured problems.

Delbecq et al. (1975), the main proponents of NGT, concur with the view that NGT ensures equal participation of each member of the group during decision making or ranking, highlighting that it builds on the commitment from members on the decisions made due to everyone having been given a fair chance to participate. Furthermore the authors reflect that it eliminates peer pressure in the ranking process and prevents dominant members controlling the group, importantly consensus is visible and allows major points of disagreement to be settled objectively. This democratic style encourages all participants to freely express their opinions preventing domination by individual participants (Potter et al. 2004). A further strength of the NGT is that there is no interference or interpretation from the moderator or facilitator, participants make their own independent judgements during the process (Delbecq et al. 1975). Carney et al. (1996) however argue that the question of power is relevant to the relationship between the group facilitator and the nominal group. Some group members may not fully co-operate with the facilitator if they feel they have a more powerful position in the organisation than the facilitator.

Williams et al. (2006) discuss the issue of bias in relation to the selection of participants, reflecting that pre-determined criteria to select group members may lead to an objective and credible process. The authors go on to state that this method facilitates the generation of data directly related to the clinicians work environment and practice, which is important if the findings are to be considered reliable. Flaherty and Glasper (2003) allude to a further strength of the technique in that it encourages participants to make fine judgements on the overall importance of each generated item, resulting in only topics which were considered relevant being allocated votes.

A further advantage to the NGT is that it requires a minimal amount of analysis after the group session has been conducted (Carney et al. 1996). The participants generate ideas and identify priorities, resulting in a feasible and practical method in the clinical area where time may be limited. However it is important that a clear question should be devised before the session. In relation to calculation of the extent of agreement, various levels of rigour are reported, frequently related to time limitations and scope of the research. Straightforward consensus agreement methods may be applied as reported by Williams et al. (2006), or alternatively a more detailed analysis for ranking using a Likert scale which allows for a measure of the level of agreement between groups may be utilised (Jones and Hunter 1995). It has also been argued that the immediacy of group consensus may mask strong minority agreement (Carney et al. 1996). Williams et al. (2006) however reflect that this may be overcome by individual interviews with a sample of participants to discuss any contentious issues. Aspinal et al. (2006) reported on issues relating to examining topics involving potentially sensitive areas which may cause upset or distress to participants. The authors modified the NGT due to the sensitive nature of the study topic and deemed it inappropriate to ask the group participants to undertake in-depth preparation before the meeting.

The researchers also felt that participants may have found it difficult to see statements that they found important discarded by the group, therefore the NGT was further modified in relation to ranking of statements in order to minimise the effect. This issue was also addressed in a study related to bereavement conducted by Addington-Hall et al. (2004). The sensitivity of the topic had the potential of causing upset or concern to bereaved relatives, however pre-testing allowed the identification of questions which participants found upsetting, these were removed or reworded. The authors also identified some issues in relation to the Punjabi translation of some of the interview questions, which highlighted a potential problem in relation to NGT and consensus methods in general, as a working knowledge of the common language being used during the session is essential if all participants are to fully contribute. However NGT has been reported as being applicable and commonly used to examine the appropriateness of clinical interventions (Hunter et al. 1994, Ziemba et al. 1991), it has also been used in areas related to practice development (Justice and Jang 1990) and for identifying measures for clinical trials (Felson 1993).

4.4.3.3 Summary of Justification for use of Nominal Group Technique (NGT) for Phase One

The decision to utilise NGT in the first Phase of the research was based on the following:

- The Nominal Group Technique (NGT) which is grounded in social-psychology studies (Van de Ven and Delbecq 1972), can be utilised by small groups with the aim of reaching consensus on key problems. The NGT is designed to promote group participation in the decision-making process and can assist participants in the process of combining their knowledge.

- NGT has a highly structured format which reviews one question at a time, being a single purpose technique. The primary aim of Phase One of the current study was to inform development of the Delphi tool which would be utilised in Phase Two, therefore NGT was an ideal method to apply.

- A major consideration in selection of this method was that data collection in Phase One was time limited in that the transport team who participated was a small group of clinicians who had a limited amount of time to participate in the research. This method involves no preliminary preparation, provides a forum to generate a substantial amount of work in a relatively short period of time and facilitates decision making quickly by a vote, therefore further justifying this choice of method.

- The NGT provides semi-quantitative, rank ordered feedback about participants perceptions on a selected topic with each participant having an equal say in generating and rank ordering evaluation items. It is a consensus-planning tool that can assist in the prioritization of issues by means of an iterative process (Dobie et al. 2004), encouraging participants to contribute their individual thoughts on the selected topic, leading to a clear set of prioritized solutions or recommendations.

- The NGT offers a democratic style of meeting frequently not seen on other types of group meeting, ensuring that all participants' opinions are taken into account, preventing domination by strong personalities or senior members of the group, encouraging the more passive members of the group to participate, with each contribution being of equal value. These aspects were particularly relevant to the study as the small group of transport clinicians were from the same team and were varying grades of seniority within the team. The NGT is an ideal method for working in small groups and brainstorming ideas, leading to decisions on potential solutions to problems or the development of strategies to implement.

- Each participant has the opportunity to write down their ideas without coercion, with the opportunity to explain and rank their ideas and recommendations. Furthermore the face-to-face nature of NGT facilitates a range of opportunities to understand the opinions and judgments of other participants (Campbell 2010).

4.4.4 Delphi Process

In contrast with the NGT the Delphi method is an iterative process used to assemble and refine the judgments of experts using a series of questionnaires interspersed with feedback (Linstone and Turoff 1975). The main premise of the Delphi process is based on the assumption that the opinion of a group is of more value than that of an individual (Keeney et al. 2011). It is a method of reaching consensus of a group of experts after eliciting their opinions on a defined issue and relies on the "informed intuitive opinions of specialists" (Helmer 1983 p134).

Linstone and Turoff (1975 p3) stated in relation to the objective and technique of the Delphi process:

> *"Delphi may be characterised as a method for structuring a group communication process, so that the process is effective in allowing a group of individuals, as a whole, to deal with complex problems"*

The use of the term "Delphi" originates in Greek mythology. It is recorded in the ancient Greek legends that Pythia, the resident priestess at the temple complex Delphi, became known as the Delphi oracle for her skills of interpretation and ability in making predictions about the future (Everett 1993). Researchers now use this technique to examine past, present and future trends.

The Delphi technique was originally developed by Dalkey and colleagues at the RAND Corporation in the United States (Linstone and Turoff 1975), where the process was applied to reviewing future trends within the defence industry. Since its original development a number of Delphi techniques have evolved.

4.4.4.1 The Delphi Process: Characteristics and Structure

The unique structure of the Delphi technique consists of a series of sequential questionnaires, combined with controlled feedback, with the aim of gaining reliable consensus from a group of experts (Linstone and Turoff 1975).

The Delphi method involves identifying experts in the area under investigation to participate and form a panel. The process is co-ordinated by a facilitator(s), who manages return of the questionnaires and analysis of results.

The principle features of Delphi have been defined by Zami and Lee (2009) as:

- Expert opinion
- Systematic
- Questionnaire
- Iterative process
- Feedback- individual opinion mediated by group
- Anonymity of individuals

Rowe and Wright (1999) expand on these features by identifying characteristics of the classical Delphi process:

1. ***Anonymity:*** Delphi participants are anonymous allowing free expression of opinions without social pressures to conform from other members of the group.
2. ***Iteration:*** facilitates refinement of views by participants as a result of the progress of the group's work from round to round.

3. *Controlled feedback*: informs all participants of the other participant's responses, and therefore gives them the opportunity to consider their responses and change them.
4. *Statistical aggregation of group response*: facilitates quantitative analysis and interpretation of data.

It has been suggested that only those studies true to their origins that have the four characteristics should be classified as Delphi studies (Rowe and Wright 1999). However others (Adler and Ziglio 1996, Delbeq et al. 1975; Linstone and Turoff 1975) suggest that the technique can be effectively modified to meet the needs of the individual study.

The process is initiated by sending the issue which requires consensus to members of the panel whose role it is to generate solutions to each of the statements, which are returned by mail or electronic means and subsequently collated centrally by the facilitator. All generated solutions are then redistributed to panel members in order to allow them to reconsider their responses in light of the overall results. The Delphi continues to operate until a predetermined consensus between respondents is reached. The process stops when either consensus is reached, the research question is answered, saturation is achieved, or when sufficient information has been exchanged (Keeney et al. 2011). This generally takes up to three rounds of questionnaires. It is recommended that a minimum of 70% return rate per round is reached to maintain rigour (Sumison 1998). This process has the benefit of facilitating debate between experts who are geographically unable to meet however can share opinion and reach consensus on difficult issues. The questionnaires are designed to focus on problems, solutions, development opportunities or forecasts, with each subsequent questionnaire being developed based on the results of the previous questionnaire. Mitroff and Turoff (1973) highlight that the distinguishing element of Delphi from other polling procedures is the process of feedback and refinement of views which occurs between rounds.

The Delphi technique has evolved over the years from its original form known as the *classical Delphi*, to many different modifications and techniques. Frequently researchers who utilise both NGT and Delphi do not always adhere to the basic procedures and principles, many studies refer to a 'modified' Delphi technique (Hartly 1995, Oranga and Nordberg 1993).

The most common deviation in Delphi is in the conduct of the first round, which may be developed by literature review, NGT, idea writing or communications with stakeholders (Jairath and Weinstein 1994).

4.4.4.2 The Expert Panel

The role of the expert panel is core to the success of the Delphi process (Baker et al. 2006). Adler and Ziglio (1996) reflect that Delphi panellists should meet four requirements which include:

- Having knowledge and experience of the issues under investigation
- Willingness and ability to participate
- Sufficient time to participate
- Effective communication skills

However Sackman (1975 p703) criticise the use of the word "expert" claiming that:

> *"it is almost impossible to find current psychometric or social science literature on experts"*

Strauss and Zeigler (1975) also support the criticism on claims that one group represents valid expert opinion, stating that it is scientifically untenable. However the Delphi technique does not call for expert panels to be judged as representative sample for inferential statistics, Linstone and Turoff (1975) argue that Delphi is not a scientific tool answerable to criteria to ensure reliability but a useful method for structuring communication in the exploration of issues.

It has been suggested by Delbecq et al. (1975) that participants should be sought from groups likely to have the necessary experience and information on the selected topic. However the authors go on to reflect that heterogeneous groups with members from a wide range of perspectives on a problem produce a higher proportion of high quality solutions compared to a homogenous group.
Jones and Hunter (1995) reflect that the subject matter is of most importance with specialists in the field generating the most useful perspectives.

This view was also reflected by Oranga and Nordbeg (1993) highlighting that the optimum number and qualifications of the panel members depends on the subject under study and the likely variance and sensitivities in the community under study. In relation to panel numbers, Delbecq et al. (1975) suggest that there should be no limit to the number of participants and that it should be representative of the general population being studied. Murphy et al. (1998 p37) state:

> *"there is very little actual empirical evidence on the effect of the number of participants on the reliability or validity of consensus processes"*

With reference to published studies the size of the panel varies greatly, numbering from 10 to 1685 participants (Reid 1988). In postgraduate research, sample sizes range from 8 to 345, with sample size being related to the population under study (Skulmoski et al. (2007). Factors which should be considered to determine sample size include:

- **Internal or external verification**: the larger the group the more convincingly the results can be said to be verified.
- **Decision quality compared with Delphi manageability**: as sample size increases there is an increase in decision quality. However increasing numbers makes analysis more time consuming with limited benefits.

▪ **Homogeneous or heterogeneous sample**: a smaller sample size of between ten to fifteen is sufficient in a homogeneous group. If disparate groups are involved then a larger sample size will be require which may be several hundred people (Skulmoski et al. 2007).

In relation to number of rounds utilised in the Delphi process, Delbecq et al. (1975) suggest that a two or three iteration Delphi will be sufficient in most studies. Skulmoski et al. (2007) expand on this by stating that if the sample is heterogenous and group consensus is required, then three or more rounds may be necessary. Where the sample is homogenous and the aim is to understand nuances, fewer than three rounds may be sufficient to reach consensus between participants, achieve the information required or reach theoretical saturation. However Alexander (2004) highlights the fall in response rates as the number of rounds increase and the input required by respondents increase.

4.4.4.3 Computer Based Delphi Process

The traditional Delphi method involved questionnaires being sent out using standard mail, however during recent years email has become more and more commonly utilised to mediate the Delphi process. These studies are usually named "e-Delphi" or "Real-time Delphi" (Wiersma and Jurs 2005, Chou 2002). The e-Delphi involves the administration of the Delphi by email or alternatively by completion by means of an online form (Avery et al. 2005). Several methodological strengths and weaknesses can be identified in the computer based Delphi process. However, in the currently expanding technological environment within which research is frequently conducted, it can be an extremely user friendly medium, therefore this was the selected choice of format for the current study. There are important characteristics of a computer based Delphi which should be considered if this method is utilised.

- *Characteristics of a Computer Based Delphi*

Turoff and Hiltz (2008) purport that a particular benefit of computer-based Delphi is that it enables group members to select when they would like to participate and formulate their answers or responses. This can be more conducive to working within an intense work schedule, however it can be argued that electronic language is less structured and not planned to the same extent as written language, it is more uncontrolled and spontaneous (Markham 2004, Mann and Stewart 2005). The method of communication is therefore transformed into a format which resembles the spoken language, responses are expected rapidly and written quickly in an informal and concise manner which can lead to less restraint and caution amongst respondents. Importantly there is no need for transcription which reduces time and elements of bias. Reminder emails are sent out automatically, with no increased cost involved in the postage and package of questionnaires (Keeney et al. 2011). However a disadvantage to the computer based Delphi may be that not all members of the panel will have email accounts, alternatively some busy participants may not take part in the process or complete it in a casual manner. A further concern may be that some computer firewalls may block e-Delphi questionnaires or they may be directed into a junk folder therefore affecting participants' ability to participate (Keeney et al. 2011).

Turoff and Hiltz (2008) suggested that a good Delphi is structured to facilitate tackling the problem from a variety of perspectives. The computer based Delphi can allow members of the panel to focus on the approach to problem solving with which they feel most comfortable. A particular advantage of working within a group system is that members with differing experience, perspectives and cognitive abilities can contribute to those parts of the problem they feel they have the ability to influence. Benbasat and Taylor (1982) highlighted that individuals differ greatly in their ability to deal with various aspects of problem solving based on their cognitive abilities.

It has been argued that the Delphi process should allow the group members to decide which part of the problem to deal with at any time in the problem solving process and that it is easier to facilitate this with a computer-based Delphi (Turoff and Hiltz 2008). An important consideration in the design of the e-Delphi is that it is organised and structured in a way which is understood by the panel members (Turoff 1991). In a paper Delphi the design team must process the results and provide feedback to the group. In the e-Delphi this is replaced by a process of continuous feedback which may or may not require human intervention for processing.

- *Anonymity*

Anonymity is an important concept in the Delphi process. The e-Delphi process is anonymous in the sense that the researcher does not exert an influence by being present at the interview. However Markham (2004) highlighted that email interviews establish a type of contract for social interaction between the researcher and participant. A primary factor in encouraging participation in the Delphi process is that participants feel that the other members of the group are able to make a valuable contribution. The value received by the participants has to be equal to the effort made in participating in the Delphi process. The e-Delphi offers more options in the organisation of anonymity in the Delphi process (Keeney et al. 2011).

- *Computer-Based Delphi Facilitator*

The role of the facilitator in the e-Delphi is slightly different to that of a paper Delphi. In the paper Delphi it is necessary that each contribution goes back to the individual who is facilitating or coordinating the process, this then enables a combined end of round report for each participant (Keeney et al. 2011). However in the e-Delphi this is frequently not necessary.

Screening of particular contributions is dependent on the content, however group members can update themselves online before making a contribution, therefore reducing the amount of duplication. In topics where there are strong controversies the facilitator may have to edit or screen the wording of some results before making them available to the whole group. A large proportion of the material contained in the e-Delphi can be relayed directly to the group, however the Delphi facilitator still needs to make specific decisions on these aspects specific to the individual study (Turoff and Hiltz 2008), therefore it can be argued that the role of the facilitator may be crucial in the success of the computer mediated Delphi.

4.4.4.4 Delphi Process: Strengths and Weaknesses

When utilising Delphi it is important to consider the reported strengths and weaknesses of the method. The Delphi technique is based on the principle that groups perform better than their best member resulting in more accurate data than that obtained from individuals or by interacting groups (Rowe et al. 1991). Additionally one of the key advantages widely reported in Delphi is that the technique can prevent the effect dominant powerful individuals may have within a group situation, which can lead to conformity and poor decision making (Moeller and Shafer 1994). However a range of advantages and disadvantages to the Delphi process have been reported in the literature and should be considered. The Delphi technique has been subjected to extensive criticism with particular reference to its scientific value. Sackman (1975) strongly criticised the approach for its lack of both professional and scientific guidelines with reference to the design, administration, application and validation. However the leading proponents of Delphi (Linstone and Turoff 1975) responded to this by asserting that Delphi was more of an art than a science.

Conflicting reports suggest that psycho-social influences may affect the outcome of the Delphi process (Bardecki 1984, Sackman 1975), panel members who have contradictory views may conform with strong group pressure or withdraw from the process (Rowe and Wright 1999).

Anonymity is reported by Rowe et al. (1991) to be an important advantage of the Delphi process, however Keeney et al. (2011) argue that complete anonymity cannot always be guaranteed, reflecting that the facilitator will frequently be aware of the identity of the panel members and responses. It is also argued that the Delphi method includes experts in the field, therefore panel members may know each other to the extent that they can attribute responses to specific individuals. Furthermore Sackman (1975) suggested that anonymity may result in lack of accountability of views expressed and encourage snap decisions. However it can be argued that this issue is a limitation of other methods such as postal questionnaire, and that the sequential nature of the Delphi process may discourage this. Delbecq et al. (1975) reflect that the main advantage of Delphi is to achieve consensus in an area of controversy, also the feedback between rounds can widen knowledge base and stimulate new ideas with the potential of being highly motivating and educational (Stokes 1997). Everett (1993) has described the technique as quick, cheap and efficient, however response rate is an important issue in that frequently participant response reduces with each Delphi round.

Attrition in a Delphi study can be high, possibly due to the necessity for experts to participate in several rounds. Panel members withdraw due to fatigue, constraints of time, distraction between rounds or disillusionment with the process (Donohoe and Needham 2008). McKenna (1994) suggested that high dropout rates characterise the final round of most Delphi studies.

However Evans (1997) reflected that a high attrition rate is often associated with large Delphi panels, with a small panel experiencing small dropout rates. Makaya and King (2002) reported that they had to limit their Delphi study to one round due to the panel members being unwilling to participate in subsequent rounds. If attrition is substantial, dropout can lead to a response bias therefore the researcher should make every attempt to reduce the level of attrition. Murphy et al. (1998) reflect that the process of interaction facilitates consideration of a wide range of options and has the potential of filtering out idiosyncrasies. The benefits noted by Jones et al. (1992) of being cheap, and quick (Everett 1993) has to be compared with the potentially extensive time commitment required by the research staff (Williams and Webb 1994).

Delbecq et al. (1975) described the temporal aspects as being time consuming for the researcher but time saving for the participant when compared to other consensus methods. However Sackman (1975) stated that the consensus approach may potentially lead to a watered down version of best opinion, with Jones and Hunter (1995) highlighting that there may be a risk of achieving collective ignorance rather than wisdom by attempting to encapsulate opinions of a given population. In contrast Lindeman (1975) highlighted that the systematic approach adopted in the Delphi process has the potential of providing a degree of objectivity to the outcome, combining knowledge and skills. Importantly it has been suggested by Jones and Hunter (1995) that the existence of consensus does not necessarily mean that the correct answer has been found. The reported advantages and disadvantages of the Delphi method appear to vary in accordance with the views and experiences of different researchers and authors, however should be considered in execution of the study.

4.4.4.5 Summary of Justification for use of Delphi Method in Phase Two of the Study

The decision to utilise the Delphi Process in the second Phase of the research was based on the following:

- Development of the pain assessment scale required consensus from a group of experts spread geographically throughout the UK. Utilising a computer-based Delphi process facilitated the recruitment of participants who may otherwise have been difficult to recruit and enabled a consensus process between experts covering a wide geographical area.

- Expert opinion on content and structure of the pain tool was a fundamental element of this Phase of the study. Therefore application of the Delphi process can be further justified in that the main premise of the Delphi process is based on the assumption that the opinion of a group is of more value than that of an individual. It is a method of reaching consensus of a group of experts after eliciting their opinions on a defined issue and relies on the 'informed intuitive opinions of specialists'.

- It was crucial that participants were allowed to freely express their opinions and views without any pressure to conform form other members of the group. The Delphi participants are anonymous, therefore allowing free expression of opinions, further justifying this choice of method.

- The generation of considered, practical views which would inform development of the pain assessment tool was an important element of this Phase. The Delphi method contained a process of iteration and therefore refinement of views by participants as a result of the progress of the group's work from round to round. This was further enhanced by controlled feedback which informed participants of other participant's responses providing them with the opportunity to consider their responses and change them.

- The computer-based Delphi enabled participants to select when they would like to participate and formulate their responses which is more conducive to working in an intense work schedule which is the case with clinicians participating in the study

- Further justification for use of the computer-based Delphi method was that administration of the Delphi questionnaire was quick and easy, with the timely generation of reminders being forwarded to participants. Statistical aggregation of group response facilitates quantitative analysis and interpretation of data, further justifying this choice of method.

4.4.4.6 Design of the Delphi Questionnaire

The Delphi technique is a methodologically complex process which requires the researcher to coordinate various aspects of the process to ensure it is applied appropriately. This includes designing the questionnaire, sending an initial letter of invitation to potential panel members, cover letter, developing coding systems, creating file systems for responses and creating and maintaining databases. An important aspect of the Delphi process is design of the questionnaire. Within the current study the Nominal Group process generated ten priority items, 5 physiological and 5 behavioural items (named NGT Items 1- 10) for inclusion in the Delphi questionnaire. The NGT items were expanded and developed to gain a deeper generation of views with the aim of reaching consensus from the Delphi panel. As the purpose of the Delphi process was to gain consensus on the content of pain assessment scale for neonatal transport, it was essential to include all relevant aspects in relation to what to include in the scale and also design of the scale.

Pain assessment is an immense subject area, which is further complicated by the effects of neonatal transport, therefore it was necessary to structure a method of focusing on important aspects of pain assessment during transport in order to incorporate them into the questionnaire. This process involved reviewing the literature on how to develop a pain scale (Duhn and Medves 2004, Debillon et al. 2001) and on the appropriate content of a health measurement scale (Streiner and Norman 2006). Therefore main focus areas appropriate to the aims of the study were developed around which questions could be structured for inclusion in the Delphi questionnaire. As reflected by Duhn and Medves (2004) when developing a pain scale areas of importance should encompass feasibility, clinical utility, purpose of the scale, also consideration of the area and population within which the scale is being utilised.

The questionnaire was developed within a framework of priority focus areas in order to ensure that all important aspect of transport pain assessment are addressed. These include:

1) Safety

The issue of safety is threaded throughout the literature in relation to patient transport (Barry and Lesley 2003, Fast and Newton 2008), appearing to be a crucial factor to consider when embarking on transport. This area is focused on considering if a pain assessment scale is an appropriate method of pain assessment during transport and if so when should it be used? Is a pain assessment scale safe and appropriate for every baby and in every circumstance during transport?

2) Content

The consideration of content is also important as a pain scale should be relevant to the environment (Duhn and Medves 2004) in this case neonatal transport, also crucially that it appropriately assesses pain. Which indicators of pain should be included in the scale? Furthermore are they appropriate to include in a transport pain assessment scale?

3) Clinical Utility and Feasibility

Clinical utility and feasibility can be viewed as the most important aspects in relation to transport as a pain scale would have to be appropriate to use within this specialised area. Which environmental factors would influence pain assessment and therefore outcome, should these be considered when developing a pain assessment scale? Furthermore at what time during transport is it appropriate and feasible to use the pain assessment scale?

4) Design

Design of the scale is related to the practicalities of how the scale appears and is structured. This is also an essential element to consider as it would have to include all important aspects of pain assessment but not be cumbersome or over complicated. Therefore feasibility and clinical utility (Duhn and Medves 2004) are encompassed in design of the scale.

5) Outcome

Outcome is related to purpose of the scale (Duhn and Medves 2004) which within the context of the current study is pain assessment during transport. This can be viewed as one of the most important areas in relation to reliability and validity to ensure pain was assessed appropriately. An important element of using the pain scale was ensuring that it was used appropriately and that clinicians were trained in use of the scale. Furthermore consideration of who should be using the scale during transport?

Having considered important focus areas for inclusion in the questionnaire, further development of the questionnaire was similar to any survey with careful attention being made to the length of the questionnaire, wording and design. It was important to ensure that the content of the questionnaire was not too complex or lengthy in order to encourage returns and prevent participant fatigue (Edwards et al. 2002).

Of particular importance was to meet the aims and objectives of the study, while minimising response bias and respondent misunderstandings. When designing the questionnaire principles such as using short questions with simple vocabulary and avoiding double barrelled or hypothetical questions to prevent ambiguities (Siniscalco and Auriat 2005) were applied. Participants were also asked to rate the confidence in their answers by utilising a Likert format with a "no judgement" option for those who did not have an opinion (Turoff 2006).

A Likert scale is a psychometric scale which is frequently used in many types of questionnaires. It allows participates to indicate their level of agreement or disagreement with a statement, which is an ideal means of working towards consensus within a panel. When design of the Delphi tool was finalised, the questionnaire was hosted by "SurveyMonkey" (www.SurveyMonkey.com), which will be discussed later in this Chapter.

4.4.4.7 Analysis of the Delphi Process

The process of the analysis in a Delphi study is a fundamental element in the quality of the results. Computer mediated systems have the potential to facilitate this and expedite analysis. The electronic process can be fed into SPSS, or basic analysis can be conducted by sites such as "SurveyMonkey" www.SurveyMonkey.com) which are becoming increasingly popular (Keeney et al. 2011). Turoff and Hiltz (2008) presented specific objectives for the analysis of a Delphi study which can be easily facilitated by a computer mediated system. These include:

- Facilitate the analysis of subjective judgements to produce a clear presentation of the range of views and considerations, and by doing so improve the understanding of the Delphi panel participants.

• Highlight hidden judgemental biases and disagreements.

• Detect information which is missing, or any ambiguity in interpretation by members of the panel.

• Facilitate the analysis of examination of complex situations that can only be summarised by a process of analysis.

• Detect patterns of data and of sub-group positions.

• Highlight critical items which need to be focused on.

The computer mediated method therefore provided an ideal means of administering the Delphi process within the current study. A more detailed overview of the process involved in analysis will be reviewed later in the study.

4.4.5 Phase Three: Semi-Structured Interviews

The final Phase of the study consisted of semi-structured interviews with transport clinicians to establish face validity of the new transport pain assessment scale. Face validity is a form of content validity (Parahoo 2006) and involves asking participants to review the new transport pain scale in order to ascertain if 'on the face of it' the scale reflects the phenomenon being studied, in this case pain assessment during transport. Streiner and Norman (2006p 66) reflect that the advantages of achieving face validity include:

> *"it reduces dissatisfaction among users*" and also "*makes it more likely that policy makers and others accept the results".*

It was therefore essential to utilise an appropriate method of data collection in order to review the perceptions and views of clinicians. Semi-structured interviews were an ideal means of initiating communication with the reference group of transport clinicians.

They are used when researchers have a list of questions or areas which must be addressed in an interview (Polit and Beck 2010). In order to ensure all questions are covered an interview schedule is used, the main objective being to encourage participants to talk freely. The use of pre-determined questions provides a structure to the interview, resulting in the interviewer being in control of the interview process.

Barriball and While (1994) purport that the semi-structured interview provides:

"the opportunity to change the words but not the meaning of the questions".

Respondents can be helped to understand the questions posed to them and interviewers can ask for clarification therefore increasing validity. Furthermore respondents are not presented with multiple choice answers to choose from but can formulate their responses in their own words. Importantly the questions are the same for all respondents with variations in the wording to assist clarity (Parahoo 2006). It is crucial that the interviewer does not lead the respondent or influence their responses, however the presence of the researcher can enhance the study and improve validity by increasing clarity on the questions. An additional reason for the application of semi-structured interviews is that they can provide quantitative and qualitative-type responses which allow comparisons between respondents in the same study. They can increase response rates and also can be useful for complex or sensitive subject areas.

Within the context of this study, semi-structured interviews provided participants with the opportunity to review the first draft of the transport pain scale and reflect on various aspects of the content and structure in relation to the transport environment. Participants were encouraged to openly and freely give their views and perceptions to gain rich and meaningful data. Semi-structured interviews were well suited to studying the perceptions and views of transport clinicians on complex areas and enabled probing for more information. Development of the tool applied in this Phase of the study will be described in the next section of this Chapter.

4.4.5.1 Summary of Justification for use of Semi-Structured Interviews in Phase Three of the Study

The decision to utilise semi-structured interviews in Phase Three of the research was based on the following:

- The main purpose of this Phase of the research was to establish face validity of the pain tool by eliciting the views of a small group of clinicians. The use of semi-structured interviews allowed the development of a list of questions or subject areas which had to be addressed during the interview process in order to establish face validity.

- The Semi-structured interview facilitated individual interviews with participants, encouraging them to talk freely, with the additional benefit of pre-determined questions providing structure and control to the interview process.

- This method can be further justified in that the interviewer has the ability to provide clarification for the participant therefore increasing validity.

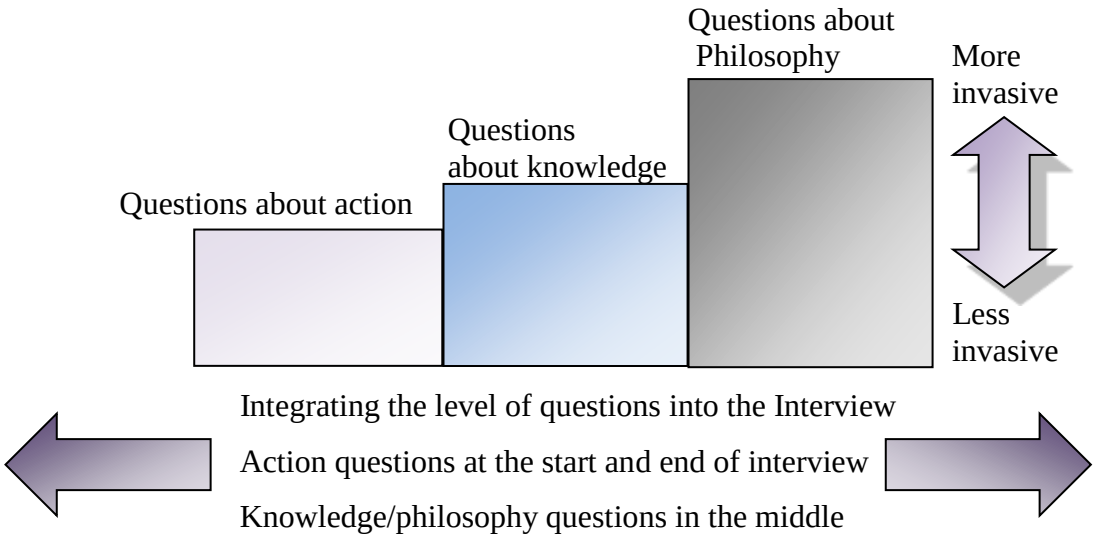
- The assessment of pain is a complex area which may be perceived as a sensitive subject area, semi-structured interviews can help overcome this by the interviewer providing clarity to questions and allowing the participant to express themselves in their own words.

4.4.5.2 Semi-Structured Interviews: Data Collecting Instrument

An interview schedule was developed to facilitate data collection by tape-recorded semi-structured interviews, combining open and closed questions. Cormack (2000) reflected that when compared to conversation, semi-structured interviews differ in that the research interview focuses on the purpose of the interview and anticipated outcomes.

With this aim a level of standardisation was structured in the interview schedule, however a degree of flexibility was included in that the participants were asked the same questions, sometimes with the order altered and re-ordered. The key to obtaining rich data is in asking good questions which have been prepared beforehand to reflect the basic research question. Price (2002) reported a technique of "laddering", which was integrated into the interview schedule. Laddered questions are a method of selecting the most appropriate level of question based on the knowledge that we share a common idea of what is likely to seem most intrusive during conversation. Price (2002) reflects that conversations on actions or behaviours are less invasive than those about knowledge, and that both are less invasive than questions on feelings, beliefs and values (Figure 9). Laddered questions were therefore incorporated into the interview guide.

Figure 9 **Laddered Questions**



Adapted from Price (2002)

These operated at three levels: 1) Action, 2) Knowledge, 3) Values. Therefore at the beginning of the interview it was appropriate to ask an "action" question such as:

"Have you used a pain assessment scale during neonatal transport"?

Questions about knowledge were included later when the participant is more relaxed. Knowledge questions often challenge the respondent as they may risk the respondent discovering that they did not know something that they felt that they should have known. Knowledge questions prompted responses on "what do you know" or "what do you think" such as:

"Should any other item be included in the scale?"

This method facilitated the transition into deeper and more probing questions, therefore integrating the link between actions knowledge and beliefs. Questions about personal philosophy or beliefs are the most invasive (Price 2002), and are deemed to be core to the individual's personal identity. However these questions may leave the participant feeling that the interviewer is judging them. This may include questions such as those probing the participants in relation to their own beliefs on the influencing factors on the management of pain during transport, as this has the potential to illuminate their own practice and philosophy on pain assessment and management. The main aim of the interview schedule was to establish face validity of the NTPAS scale, therefore questions were structured to highlight the clinician's views on how effectively the scale appears to measure pain during transport. In order to enhance rigour and test the interview guide for clarity, ambiguity and repetitiveness, a volunteer sample of three participants were selected as a pilot sample. Information obtained from the pilot interviews was presented in a data matrix grid, issues and problems were identified and the appropriate questions modified accordingly and integrated into the interview schedule.

4.5 Data Collecting

4.5.1 Introduction

This section of the Chapter will describe the journey followed in relation to setting, sample and the processes encompassed in the data collection phase. The use of pilot studies and responsibilities in relation to ethical concerns will also be addressed.

4.5.2 Setting and Sample

Setting and sample are an important part of the research process. Eligibility criteria for inclusion in the study should be clearly identified, with the distinction between target population and accessible population being clarified (Polit and Hungler 1993). The basic principle of sampling is the selection of a portion of the population which is representative of the entire population (Polit and Beck 2010). A sample which is carefully selected can provide data which is representative of the population from which the sample is drawn (Parahoo 2006). However information obtained from samples can lead to erroneous conclusions, an aspect which is of particular concern in qualitative studies.

An important criterion of adequacy is the samples representativeness, a representative sample being one whose main characteristics are similar to those of the population (Polit and Beck 2010). Sampling bias may occur unless the sampling method ensures that all members of the population of interest have a calculable chance of being selected in the sample.

The purpose of Phase One of the study was to identify items for inclusion in a transport pain assessment scale which would be taken forward to structure the content of the Delphi questionnaire. Therefore a reference group of neonatal transport clinicians working in a dedicated neonatal transport team was identified. A group meeting utilising NGT was conducted to identify items to take forward to inform the Delphi questionnaires. The concept of a reference group is that it is a group of individuals that is used as a standard for evaluation. It can be viewed that reference groups provide the benchmarks and contrast needed for evaluation. It is a term used frequently by sociologists, Thompson and Hickey (2005) reflected that reference groups are groups that people refer to when evaluating their qualities, circumstances, attitudes, values and behaviours.

In Phase Two of the study (Delphi Technique) purposive homogenous sampling was utilised encapsulating snowball sampling. Purposive homogenous sampling is based on the concept that the sample has similar characteristics which are of particular interest to the researcher. A purposive sample is when individuals are sought from a pre-specified group. This is based on the belief that researchers' knowledge about the population can be used to select sample members (Polit and Beck 2010). This method should enable the researcher to satisfy the aims and objectives of the study, establishing a trusting relationship between researcher and participant, being a type of sampling method commonly associated with flexible designs (Robson 2004). In snowball sampling early sample members are asked to refer other people who meet the eligibility criteria, providing the benefit of reaching participants who may be difficult to identify or locate (Polit and Beck 2010). Phase Three of the study consisted of semi-structured interviews with clinicians from the original reference group of neonatal transport team members, with the purpose of establishing face validity of the newly developed pain assessment scale. Inclusion and exclusion criteria were developed (Figure 10 below) to satisfy the specific needs of the study and optimise internal validity (Humphreys and Weisner 2000).

Figure 10 **Study Inclusion / Exclusion Criteria**

Phase of Study	Inclusion Criteria	Exclusion Criteria
Phase One: **NGT** **Reference Group**	Transport Team Clinicians working on a neonatal transport team Subset of the sample population	Clinicians with no neonatal or transport experience
Phase Two: **Delphi Process** **Purposive Homogenous Sample**	Participants selected on the basis of "perceived experience" as there is no formal academic qualification for transport clinicians. Perceived experience classified as: 1) Professional background (medicine, nursing) 2) Employed in the area of neonatology within the UK 3) Experience of transporting neonates 4) Recommended by a professional group/association 5) Recommended by other members of the Delphi panel if they meet the other criteria	
Phase Three: **Semi-structured Interviews** **Reference Group**	Transport Team Clinicians working on a neonatal transport team Subset of the sample population	

4.5.2.1 Sample Size

Sample size of the reference group utilised in Phase One and Three of the study was in line with the recommended sample size of the NGT which is generally advocated as optimum sample size from 7 to 12 participants (Bowling 2004). Therefore seven transport clinicians were recruited to participate. In relation to the Delphi study, there is no one identified sample size (Keeney et al. 2011). There are a wide range of sample sizes presented in the literature. Jones and Twiss (1978) suggested 10 to 50 participants whereas Wild and Torgersen (2000) proposed 300 to 500 participants for representative information. The number of participants is essentially dependent on the topic under investigation, design selected, complexity of the problem, resources available and range of expertise required (Powell 2003, Turoff 2006, Whitman 1990). If the sample size is homogenous then a smaller sample size may be sufficient as you could infer that results are generalizable (Delbecq et al. 1975), however if the sample is heterogeneous more subjects may be required. As the Delphi sample consisted of a specialised group of neonatal clinicians a minimum number of 100 participants was sought for the first Delphi round. Attrition is an important factor in Delphi samples, however there are no criteria for acceptable response rates and attrition for Delphi studies. Literature reflects response rates which vary from 8% (Cooney et al. 1995) to 100% (Owens et al. 2008). However several authors recommend a 70% response rate to maintain rigour (Bork 1993, Sumison 1998) which can be a difficult percentage to achieve.

4.5.2.2 Recruitment Process and Access to Participants

Access to the participants is crucial and should be clarified early on in the research process (Robson 2004). Denscombe (2007 p71) described it as a continual process whereby the gatekeepers can exercise influence over the research process in terms of access to participants, places or events. Participants recruited in this study were neonatal staff with experience of working in neonatal transport.

This is a small specialised group of clinicians who are dispersed throughout the United Kingdom, therefore gaining access was challenging and required careful planning throughout each Phase of the study. The setting where participants could be accessed varied from dedicated neonatal transport teams which were based in various health authorities in the UK, to clinical neonatal units based in maternity hospitals or sick children's' hospitals. Phase One of the study required access to a group of transport clinicians (n=7) working on a dedicated neonatal transport team. Phase Three consisted of semi-structured interviews with the same reference group of transport clinicians (n=7) to evaluate the content of the newly developed scale. In both Phase One and Three an appropriate transport team was identified and access was sought and gained from the gatekeepers within the appropriate department of Nursing, Midwifery and Healthcare who consented to accessing participants.

The procedure to obtain ethical approval was both lengthy and complex and will be reviewed later in this section. Phase Two of the study consisted of a UK wide Delphi study, which required access to a large sample of neonatal staff throughout the UK in various settings. It was not practical to gain ethical approval to access every health authority where clinicians were based, access was therefore sought via non-National Health Service (NHS) sources such as special interest groups. The groups approached included the Scottish Neonatal Nurses Group (SNNG), the Neonatal Nurses Association (NNA), Neonatal Transport Special Interest Group (NTSIG), the Association of Chief Children's' Nurses (ACCN) and University sources in the form of Advanced Neonatal Nurse Practitioner (ANNP) ex-students at the University of Southampton. The Association of Chief Children's' Nurses (ACCN) agreed to post information on the Delphi study and access to the Delphi questionnaire on the ACCN website. The audit trail for the stages of recruitment can be reviewed below in Figure 11.

Figure 11 **Recruitment Process**

Month and Year	Recruitment Process
2008	
November	Ethical Approval received for Phase One and Two: Glasgow West Ethics Committee
2009	
March	Permission to recruit from local stakeholders
May	Study Information to local transport team inviting participation in study
June	**Phase One: NGT meeting-** N=7 recruited from transport team
2010	
January – July	Letters of invitation via special interest groups: 1) Scottish Neonatal Nurses Group 2) Neonatal Nurses Association 3) Association of Chief Children's Nurses 4) Neonatal Transport Special Interest Group
February	Approval from Southampton University to access student database to recruit participants for Phase Two
July 23rd	Update student data base
July	**Phase Two: Pilot Delphi Round 1** – volunteer sample of 3 neonatal nurses
August	Letter of invitation to Southampton student database
August 1st –	**Delphi Round1:** available via ACCN website or via email.
August 1st- October 31st	Three reminders to participants via ACCN : **102 participants recruited**
2011	
March 21st to May 31st	**Delphi Round 2**
April to May	Three reminders to participants via ACCN or email
June	49 recruited to Delphi 2
May	Ethics approval for Phase Three
June	Information to transport team on Phase Three requesting volunteers to participate
July-August	**Phase Three: Pilot interviews**: volunteer sample of 3 clinicians
September	**Phase Three: Semi-structured interviews-** volunteer sample of 7 transport team clinicians

4.6 Ethical Responsibility

An important element in development of the research project was consideration of the complex ethical issues around neonatal pain, both in relation to pain management and conduct of the research study. Researchers have a responsibility to ensure that research is not more intrusive than it needs to be, that the privacy of participants is maintained throughout the study and issues around data protection are addressed ensuring that data is kept in strict confidence.

Polit and Beck (2010 p121) reflected that there are:

> *"primary ethical principles on which standards of ethical conduct in research are based: beneficence, respect for human dignity, and justice".*

The principle of beneficence is one of the most fundamental principles in research, imposing a duty on researchers to minimise harm and to maximise benefit, also of importance are the principles of respect for autonomy, justice and confidentiality (Royal College of Nursing (RCN) 2004). Therefore the next section of this Chapter will firstly consider ethical issues around the treatment of neonatal pain, leading on to the process of gaining ethical approval and informed consent.

4.6.1 Ethical Issues in the Treatment of Neonatal Pain

Numerous areas of controversy encompass ethical issues in the NICU, involving both decision making and management (Raeside 1997). The assessment and management of pain is one aspect which generates great debate, with clinical practice being influenced by the attitudes and perceptions of staff towards pain assessment (Polkki et al. 2010). In response to the lack of unanimous guidelines pertaining to ethical issues, The Union of European Neonatal and Perinatal Societies proposed a 10-point charter about the ethical rights of the neonate.

This document was designed to be complementary to other Charters such as the United Nations Charter of Children's Rights, however it expands on and debates specific points such as enrolment in research and end of life decisions (Guimaraes et al. 2011). Gillon (1994) describes four primary ethical principles plus concern for their scope of application which form the foundation on which standards of ethical conduct both in research and in clinical practice are based, these are beneficence, non-maleficence, respect for autonomy and justice. These important principles have particular resonance with the neonatal population and will be further discussed in relation to issues around pain assessment and management.

- **Beneficence and Non- Maleficence**

Beneficence and Non-Maleficence is one of the most fundamental ethical principles in health care, imposing a duty on health care professionals to minimise harm and maximise benefit (Polit and Beck 2010). Beneficence refers to acting from a spirit of compassion and benevolence to benefit others, however as reflected by Gillon (1994), when clinicians try to help others we inevitably risk causing harm. Therefore clinicians must consider the overall principles of beneficence and non-maleficence together with the overall aim of producing net benefit over harm (Gillon 1994). However in certain circumstances where clinicians have no recognised obligation of beneficence to others, the two principles should be considered separately as there is still a moral obligation to cause minimal harm. The fundamental principle of responsible medical care is not 'do no hurt' but 'do no harm'. This underlines the major ethical challenge to clinicians, in that harm occurs when the amount of hurt or suffering is greater than necessary to achieve the required benefit. Therefore as pain appears harmful to babies, electing to not utilise all available means of relieving pain effectively should always be fully justified. A central ethical issue in pain control is the question of balancing the risks against the benefits of treatment. It is important to review empirical information on the benefit and harm of various treatments which may be available through research and current literature.

This view is supported by Gillon (1994), who professes the importance of clarity in relation to risk and probability when assessments are being made in relation to harm and benefit, highlighting the need for empirical information about the probabilities of harm and benefit by means of medical research.

There are no risk free pharmacological interventions to ameliorate pain in neonates, with most being of uncertain efficacy, having both cost and risk implications (Lantos and Meadow 2007). This is a particularly challenging aspect in the neonatal population as they cannot tell clinicians how much pain they are experiencing. The use of opiates within the NICU for pain relief is a common occurrence, however opiates have been reported as having several side effects including hypotension and respiratory depression (Menon and McIntosh 2008). Nevertheless a major area of concern is the painful nature of many interventions within the NICU and the reported lack of analgesia during these procedures (Stevens et al. 2007a, Lago et al. 2005). Of primary importance is the clinicians' judgement on how much pain the neonate is suffering and the appropriate analgesia (Akuma and Jordan 2011). However it has been suggested that personal opinion can influence how pain research is interpreted and applied, for example in view of the potential disadvantages to some analgesics, is it optimum to have a slightly higher mortality rate and less pain or a slightly lower mortality rate and more pain (Lantos and Meadow 2007). Gillon (1994) suggests that these moral obligations can be achieved by comprehensive and effective education and training throughout each health professionals career. This particularly resonates with pain assessment and management, as effective training and education is essential if a pain assessment scale is to be applied appropriately within the clinical area.

Respect for Justice and Autonomy

- **Respect for Justice**

The ethical right to justice encapsulates the issue of fair treatment, ensuring that vulnerable patients are not exploited with fair distribution of risks and benefits. Gillon (1994) argues that obligations of justice can be divided into three categories, these include; fair distribution of scarce resources (distributive justice), respect for morally acceptable laws (legal justice) and respect for an individual's rights (rights based justice). Several moral conflicts arise within the context of each of these categories, these include; the criteria for just and fair allocation of health care resources, equal access to health care, offering as much choice as possible and allow health care workers to prioritise their patients. Each of these can be morally justified, however within the challenges of current health care resources not all can be fully met at the same time. These issues are of particular relevance in neonatal intensive care as the costs of neonatal care are both emotional and financial. Neonatal intensive care for sick babies can be lengthy and very expensive, therefore considerations of costs should encompass a range of aspects. Gillon (1994) highlights that health care workers need to be aware of these opposing moral concerns, ensuring that their own personal or professional views on justice are not imposed on other individuals.

The issue of the rights of the neonate to analgesia for painful procedures in the NICU has been an area of controversy for many years (Rouzan 2001). Akuma and Jordan (2011) in their review of pain management in neonates within seven UK neonatal units reported that less than 30% of doctors always used either analgesia or comfort measures for procedures including lumbar puncture, arterial stab or long line insertion, with even lower figures for preterm neonates. When compared with adult intensive care clear differences in practice are evident.

The adult intensivist readily uses analgesia and sedation for the intensive care patient whereas in the neonate practice is less consistent. It has been suggested that:

"In neonates many see pain relief as a goal that is only worth pursuing if it can be achieved without any trade-offs in survival" however in adult ICU *"pain relief is seen as primary and the side effects of analgesia are seen as tolerable".*

A controversial view expressed by Lantos and Meadow (2007 p215) in relation to differences in pain research within adult and neonatal intensive care stated;

"in adult ICU's it would be considered morally intolerable to do the sort of placebo-controlled trials that have been carried out in NICU's".

A further example is the use of premedication prior to intubation, as traditionally intubation was performed in the NICU with no analgesia (Carlson et al. 1996). However many clinicians now recognise the pain and distress that intubation can potentially cause to the neonate and routinely use sedatives, analgesics and muscle relaxants for elective neonatal intubations (Carbajal et al. 2007).

- **Respect for Autonomy**

The important ethical principle of the respect for autonomy and human dignity includes the right to self-determination and the right to full disclosure (Polit and Beck), including issues such as veracity, disclosure or informed consent, confidentiality and promise keeping. This principle cannot be completely applied to the neonate due to the fact that the neonate cannot express views opinions or beliefs, therefore decisions should be made by parents or extended to others such as health care professionals (Merenstein and Gardner 1993). The main priority in the decision making process is that the "best interests" of the baby should take precedence.

Within the principles of autonomy, it is agreed that disclosure of evidence-based information in relation to treatment options and consideration of family values is a reasonable approach to adopt. As reflected by Gillon (1994) in order to demonstrate respect for autonomy, health care workers must be able to communicate effectively with their patients and clients.

In relaying the most current evidence-based knowledge about the neonate's condition and prognosis and by assuming parents will act in the best interests of their child, providers demonstrate respect for autonomy. However conflicts can arise when clinicians and parents disagree about the best interests of the neonate. During the crisis of the acutely ill neonate or preterm birth, clinicians can address the ethical principle of autonomy by facilitating the disclosure of objective evidence to aid parent decision-making while also respecting the cultural and moral beliefs of parents in making autonomous decisions. Difficult and challenging decisions on the management of critically ill neonates should be made by parents or carers in conjunction with health care providers, parents should consider all the information presented to them and treatment options in terms of the best interest of the neonate.

4.6.2 Summary of the Process of Gaining Ethical Approval in each Phase of the Study

In order to comply with ethical principles, written ethical approval for the study was sought and therefore granted from West Glasgow Ethics Committee 2 (Appendix 8). As this was a multi-centre site study further approval was obtained at stages throughout the research process from Southampton University (Appendix 8.1) and Lothian Ethics Committee, details of which are included in the next section of this Chapter.

- **Phase One: NGT**

Ethical Approval to conduct the study was sought prior to approaching departments who potentially would be involved in the study. A detailed summary of Ethical approval can be reviewed in Appendix 8. Ethical approval was gained for Phases One and Two from West Glasgow Ethics Committee 2 in November 2008. Approval for Phase Three was deferred pending results of the first two Phases of the study. Approval was then sought and obtained in March 2009 from NHS Lothian Research and Development Department to conduct Phase One with the transport team clinicians. Letters of invitation to participants (Appendix 8.2) and consent forms (Appendix 8.3) were approved by the Ethics committee.

- **Phase Two: Delphi Process**

In order to access University students for Phase Two, permission was sought and gained from the University of Southampton Chair of the School of Health Science Ethics Committee on February 2010 to access ex-student Advanced Neonatal Nurse Practitioners who were on a student database held by the University. It was deemed unnecessary to submit for ethical approval to the University Ethics Committee as the study had already been reviewed by Glasgow West Ethics Committee 2. In order to meet with ethical requirements it was necessary to ensure that all students on the Southampton University database consented to remain on the database and also consented to being contacted for the purpose of research. The University posted letters to each student to update their details and obtain consent to remain on the database (Appendix 8.4). This was followed by information on the study to those who consented to being contacted (Appendix 8.5).

- **Phase Three: Semi -structured Interviews**

When Phase One and Two were completed and Phase Three was structured, substantial amendment Ethical approval was sought and obtained in May 2011 from Glasgow West Ethics Committee 2 and Lothian Research and Development Department (Appendix 8.6) and approval gained for the Phase Three participants information sheet (Appendix 8.7) and consent form (Appendix 8.8).

The gatekeepers within the department of Nursing, Midwifery and Healthcare who consented to accessing participants included:

Phase One: Neonatal Transport Co-ordinator and Head of Department within Lothian Neonatal Services, Clinical Director Edinburgh Royal Infirmary, Edinburgh Royal Infirmary Research and Development Department.

Phase Two: Greater Glasgow and Clyde Research and Development Department, Chair of the University of Southampton School of Health Science Ethics Committee, Chairperson Scottish Neonatal Nurses Group (SNNG), Chairperson Neonatal Nurses Association (NNA), Chairperson Association of Chief Children's Nurses (ACCN).

Phase Three: Glasgow West Research and Development Department, Neonatal Transport Co-ordinator and Head of Department within Lothian Neonatal Services, Clinical Director Edinburgh Royal Infirmary, Edinburgh Royal Infirmary Research and Development Department.

The study did not access or recruit patients or clients from any clinical settings. There were no conditions put in place in order to access participants.

4.6.2.1 Summary of the Process of Gaining Informed Consent in each Phase of the Study

In both Phase One and Three an appropriate transport team was identified and access was sought and gained from the gatekeepers within the appropriate department of Nursing, Midwifery and Healthcare who consented to accessing participants.

- **Phase One: Nominal Group Technique**

An information pack was given to each participant prior to the nominal group meeting containing a research information sheet which relayed information on the study and also informed the participants that they could opt out at any point during the study. Written consent was then obtained from each participant prior to commencement of the nominal group meeting.

- **Phase Two: Delphi Study**

Phase Two of the study, the Delphi process, was conducted online therefore written informed consent could not be obtained. Generally implied consent is assumed with a questionnaire as the return of the completed questionnaire reflects the respondents' voluntary consent to participate. However a section was included in the online Delphi tool for participants to indicate their consent to participate in the Delphi process. Information on the study was available online in the ACCN website for participants to review prior to participation in the study. Written information sheets were also available and were forwarded to potential participants when participation was sought via the Southampton University student database.

- **Phase Three: Semi structured Interviews**

In Phase Three of the study an information pack was given to participants containing information on this final Phase of the study. Written informed consent was obtained from each participant prior to commencement of the interview.

4.7 Risk / Benefit Analysis

A strategy utilised by many researchers to protect participants is to undertake a risk-benefit assessment, aimed at determining whether the benefits of participating in a study are in line with the cost. The cost may be social, physical, financial or emotional (Polit and Beck 2010). It can be viewed that all research involves an element of risk, however frequently the risk is minimal. The definition of minimal risk is as a risk which is expected to be no greater than those encountered in everyday life. When the risk is not deemed as minimal researchers must proceed with caution ensuring that they attempt to minimise risk and maximise benefit.

Therefore in nursing research it is important to assess the risk / benefit ratio and determine if the research has the potential to improve patient care (Polit and Beck 2010). A risk / benefit analysis can be viewed below in Figure 12.

Figure 12 **Risk / Benefit Analysis**

Risk/Benefit Analysis Associated With the Study.

Potential Benefits to Participants

- Feeling that their views are valued
- Giving participants a voice through the study
- A sense of satisfaction that they are contributing to a substantive research study which may contribute to the assessment of pain during neonatal transport
- Escape from routine and excitement of being part of a study

Potential Risks to Participants

- Fatigue or boredom
- Loss of time
- Fear of feeling inadequate

4.8 Data Collecting

Data were collected on three separate occasions from April 2008 to October 2011 (Figure 13). This was dependent on the availability of participant and Ethical approval being obtained prior to each phase of the study.

The data collecting instruments developed for this study include:

Phase 1- Nominal Group Technique (NGT)

Phase 2- Delphi Questionnaire

Phase 3- Semi-structured Interviews

A pilot study preceded each phase of the study and this is discussed further in this Chapter. The main aims of each pilot study were to:

- Test if the instruments were collecting the type of data required to answer the primary research questions.
- Provide the opportunity to clarify areas of ambiguity in the instruments.
- Review the design and content of the data collecting instruments for each Phase of the study.
- Provide the opportunity for the researcher to gain experience of engaging the data collecting instruments with the participants.
- Identify any potential ethical concerns, dilemmas or distress on the part of the participants.
- Consider contingencies for unexpected events.

Figure 13 **Data Collection Activities**

Month and Year	Data Collection Activities
2008	
January to October	*Review of Literature and Development of Research Question*
November	*Ethical approval received for Phase 1 and 2*
2009	
May	*Development of NGT question and pilot*
June	***Phase One-*** *NGT Meeting (n=7)*
July-August	***Phase One****- Data analysis*
2010	
February	*Additional Approval from Southampton University for Phase Two*
February to June	*Development of Delphi Questionnaire*
July	***Phase Two****- Pilot Delphi Round 1 (n=3)*
August 1st to October 31st	***Phase Two****- Conduct Delphi Round 1 (n=-102)*
November	***Phase Two****- Analyse Delphi Round 1*
2011	
March 21st to May 31st	***Phase Two****- Conduct Delphi Round 2 (n=49)*
June	***Phase Two-*** *Analyse Delphi Round 2*
July	***Phase Three****- Pilot Study Semi Structured Interviews (n=3)*
August	***Phase Three*** -Amend interview schedule
September	***Phase Three-*** Conduct semi-structured interviews *(n=7)*
October	Commence Data Analysis and Write -up

4.9 Consensus Methods as Applied to this Study

This section describes the application of consensus methods in the form of the NGT and Delphi Technique in the current study. The choice of expert panel members, the data collection procedure and the identification of justifiable consensus levels are reported. The aim is to demonstrate a clear decision trail which justifies the choice of the method in investigating the problem.

4.9.1 Background

The selected methodology required the generating of information on items for inclusion in a transport pain assessment scale from clinicians in the field. The number of clinicians who transfer neonates in the United Kingdom is very small and represent an extremely specialised group. The NGT meeting facilitated the generation of views and opinions from all participants in a specialised reference group without bias. This data was taken forward to structure content of the Delphi questionnaire for distribution to the wider Delphi panel. This method provided a structured means of identifying specific items to include in a scale which clinicians believed were important in pain assessment during transport.

4.10 The Process and Application of Phase One: Using the NGT with a Group of Key Informants

Following review by the regional ethics committee and the local research and development department a neonatal transport team was identified and approached to participate in the study. The transport team co-ordinator invited clinicians to attend and a mutually convenient date was agreed. The main issues involved with the organisation were the constraints of the transport service in that it provided an emergency response and therefore clinicians provided on call cover and could be called away at short notice. The group is very small and specialised therefore facilitating a number of clinicians to attend was challenging. However the group were very enthusiastic to participate and seven clinicians attended on the day. The meeting took place in June 2009 over a one and a half hour period. For the purposes of the study and with the prior consent of participants the group session was audio taped.

In preparation for the meeting information sheets outlining the study and the question of which items to include in a pain assessment scale for neonatal transport was forwarded to the transport team co-ordinator for distribution to those interested in participating. A room was prepared with table, chairs, flip chart and refreshments for the group. A pack was given to each participant containing a research information sheet, a sample of four validated neonatal pain assessment scales, consent form, 5 pink and 5 blue scoring cards. Seven transport clinicians attended the hour and a half session which was facilitated by the researcher.

- **Opening Statement**

This was used by the group facilitator to set the scene for the meeting. A warm welcome was given and thanks to all for attending and participating. The overall task and the contribution of the group members were described.

The procedure was relayed and how the results will be used. An overview of the research was presented and importance of carrying out the project. The format and length of the meeting was relayed and importance of all to contribute as much as they feel able to do. The group participants were requested to sign the consent form and briefly review pain assessment scales independently.

- **Stage 1: Silent Generating of Ideas**

The first step requested that group members write ideas silently and independently, this time was for thinking and reflecting. A question was written on the flip chart and presented to the group in writing (Figure 14). The group were then asked to write their responses, they were encouraged to include both broad and specific issues. However the facilitator had to encourage the group to 'silently' reflect their answers which proved challenging for some of the group members.

Figure 14 **NGT Question**

"Which indicators of pain should be included in a Neonatal Transport Pain Assessment Scale"

Ten minutes was given to the group to write ideas silently and independently.

- **Stage 2: Round Robin- using flip chart**

The group were then asked for items to include in the scale divided into behavioural and physiological items. This method facilitated and generated participation from each group member and involved all group members sharing their ideas.

The facilitator invited each participant consecutively in the group to put forward a physiological item which they then numbered and was written on the flip chart. The facilitator ensured that the flip chart was visible to the entire group. The group were encouraged to state one idea at a time in the form of a short statement or phrase and not to elaborate, members were informed that they could miss a turn if they chose to however each member participated. The facilitator continued to go around the table until all ideas were exhausted which took several rounds. The same procedure was followed for the behavioural items again until all suggestions were exhausted.

This process is intended to provide objectivity and equity ensuring that ideas are a product of the group rather than an individual, with the fact that ideas are written down being less personal and more objective than a verbal statement (Delbecq et al. 1975 p47). This stage took around 30 minutes to complete and facilitated depersonalisation of items for inclusion in the scale, resulting in individuals not being associated with certain items. It also allowed a large numbers of ideas to be generated with a problem solving approach. Ideas which were generated also stimulated other participants to think of additional solutions (hitchhiking). This method also provided written guidance and a record of the meeting, all items were recorded verbatim on flip chart paper. Detailed results can be reviewed in Chapter Five. The pages were each displayed around the classroom in numerical succession. This facilitated each page of paper to be in full view of each nominal group participant so that they could see all the items that were collectively generated.

This process ensured both objectivity and equity, with the items generated being regarded as a product of the group rather than being owned by the individual who initially generated them (Williams et al. 2006).

- **Stage 3 – Serial Discussion/Clarification of Ideas**

A serial discussion then took place as the group reviewed items which had been included on the flip chart. It enabled further generation of ideas and consideration of other colleague's views with any group member being able to comment on items. The task of the facilitator at this point was to ensure that there were no judgemental comments and the process was as neutral as possible. Duplication had occurred on some items due to rewording; with the agreement of the group they were combined. It was important at this point not to condense items into broad categories as some of the specificity of the original item may have been lost.

- **Stage 4 – Preliminary Vote on Item Importance**

This step involved a rigorous two step voting procedure which asked members to identify independently their own top five items from the behavioural and physiological list for inclusion in the scale. A preliminary vote then took place to identify the most important items for inclusion in the scale. The group were asked to use the pink cards for physiological items and blue cards for behavioural items.

Participants were then requested to carefully select their five most important items from the physiological group and write them on the pink cards with their corresponding number, and then their most important behavioural items placing them on the blue cards. The group were then asked to place all the five pink and blue items in front of them on the table.

A process of ranking then took place in order to highlight the most important item in each category, 5 most important to 1 which was the least important. Again the procedure began with physiological items and when this was complete behavioural items. The process was confusing for some participants and required careful explanation. Participants were firstly requested to select the most important item and write the number 5 in the lower right hand corner. They were asked to turn that card over and review the remaining four cards. Of the remaining four cards they were asked to consider which was the least important and then write the number 1 in the lower right hand corner.

The remaining cards were reviewed and the most important given number 4 and the least important of the remaining two cards number 2, the group were asked to write number 3 on the last remaining card. The purpose of this method of ranking one card at a time was to slow the group members into making careful iterative decisions and help maintain interest. A tally was then made on the flipchart with the numbers down the side of the chart corresponding to the ideas from the round-robin list. The final scores for each item were then put on the flip chart for the group to view. The importance of this stage was that it encouraged participants to make judgements on the overall importance of each item in the list. Therefore only the topics considered to be highly relevant were allocated votes. This process facilitated reinforcement of the judgements of the group in a democratic manner. The remainder of the data was available and all items were used to facilitate further discussion. This led to a process resulting in consensus on complex issues whilst collecting a range of opinion from clinicians facilitating the generation of items for inclusion in the Delphi questionnaire.

- **Stage 5: Discussion of the Preliminary Vote**

The next stage offered time for clarification and brief discussion in order to increase judgement accuracy of the preliminary vote which had been recorded on the flip chart. The discussion was intended to review inconsistent voting patterns and provide the opportunity for items to be discussed again if they were perceived to have too few or to many scores.

It has been suggested by Delbecq et al. (1975 p62) that using a three-step-wise process including preliminary voting of item importance, followed by discussion and re-voting is a more precise method than preliminary voting alone. However the discussion phase was short, to ensure that judgments were not distorted or influenced in the final vote.

- **Stage 6: Final Vote**

This was the final stage in the NGT process, which combined individual judgements into group consensus. This stage determined the outcome of the meeting and provided a sense of closure. The group decision was documented which also provided a sense of accomplishment for the group. The same voting procedure as applied in Stage 4 was adopted.

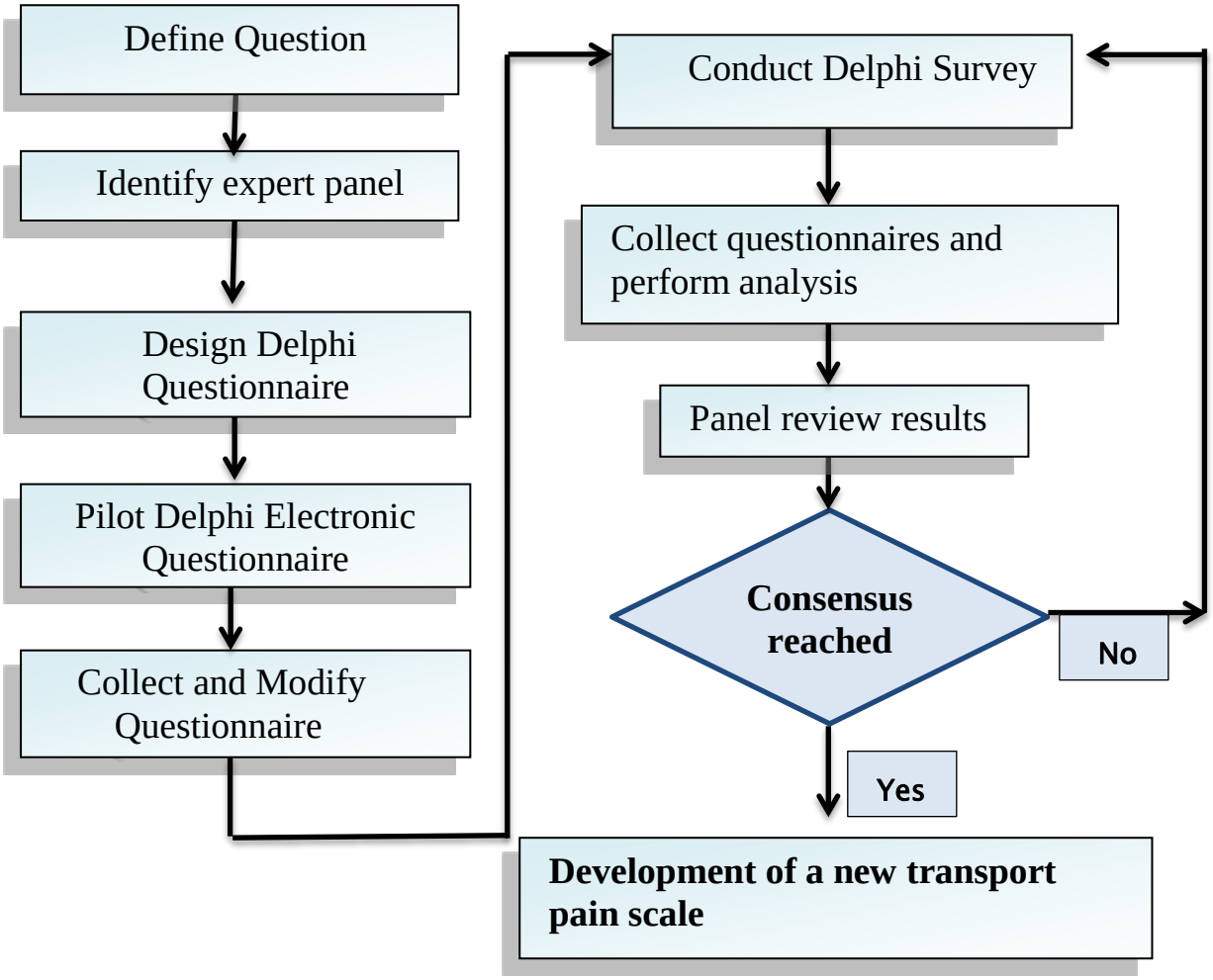
At the end of voting participants were thanked for their time and input and the meeting was concluded.

4.11 The Process and Application of Phase Two: the Delphi Method

Modified Delphi Technique

Within the context of the current study, the Modified Delphi approach was selected, utilising results of the NGT for development of the Delphi tool. Application of the Modified Delphi Technique to the current study can be viewed in the following Figure (Figure 15).

Figure 15 **Modified Delphi Technique Applied to this Study**



4.11.1 Pilot Study

It has been suggested that pilot testing is an important element of a good Delphi design (Gordon 1994, Novakowski and Wellar 2008). This can facilitate identification of ambiguities in wording (Turoff 2006) and provide information regarding reliability and validity (Jairath and Weinstein 1994). Therefore a pilot test was carried out with a draft of the Delphi questionnaire using a small sample panel. This panel consisted of 3 clinicians with neonatal experience and therefore would have background knowledge of neonatal topics. Results of the pilot questionnaires were then presented in a Data Matrix Grid (Appendix 9) and the appropriate questions modified accordingly and integrated into the Delphi questionnaire (Appendix 9.1, 9.2). A detailed breakdown of items included in the Delphi questionnaire can be viewed in Appendix 9.3.

4.11.2 Invitation to Participate

Invitations to participate were provided in both written format and by electronic means in the Association of Chief Children's Nurses (ACCN) Website (Appendix 10). The initial cover letter provided a brief outline of the project, with particular emphasis on the importance of undertaking the research. An explanation of the Delphi process and the anticipated number of rounds, format of the responses and time commitment required of participants. Assurances of confidentiality were included, contact details for the researcher and external sources of information.

4.11.3 Administration of the Delphi Questionnaire

In relation to the practical aspect of administering the Delphi, electronic methods by means of email was utilised by accessing a web based survey facility (www.SurveyMonkey.com) to structure, format and administer the questionnaire. The advantages of utilising this method included that delivering the questionnaire by email to participants was quick and easy to administer. It also can be argued that it was not threatening to participants as they could have chosen not to respond or elected to delete the email. Furthermore participants were able to complete the Delphi at their own convenience and at their own pace giving as much time as they needed to consider responses. Anonymity to other participants while also having the benefit of being sent group responses to questions was a further advantage in the Delphi process. However a disadvantage may have been that participants had to be computer literate and have the facility to respond by email.

The SurveyMonkey (www.SurveyMonkey.com) provides an online facility which enables the development of a survey style questionnaire in a variety of formats including open ended, closed and Likert-style questions. The author can therefore develop the content and structure of the questionnaire in order to meet the needs of the study. The website also analyses the data utilising descriptive statistical analysis which the author can easily access. Data is protected by password access and is available only to the author. In order to further protect the data the study was administered by means of Southampton University email. Access to the Delphi questionnaire was made available to participants via the ACCN website.

4.11.3.1 Return of Delphi Questionnaires

Due to the nature of the Delphi process and the on-going commitment required by the Delphi panel, it was important to maintain panel enthusiasm and motivation. The first Delphi questionnaire was made available to participants in August 2010, with a final return date set for one month. Reminders were sent to the panel one week, two weeks and one month after each questionnaire was distributed (Dillman 1978). The reminders were sent by email, thanking panel members for their participation in the study, reminding those who had not already done so that there was still time to return their questionnaire. The deadline date was extended by two months for each questionnaire to encourage returns.

Following return of the first Delphi questionnaire results were analysed by means of The SurveyMonkey (www.SurveyMonkey.com), which presented a summary of results dependent on the type of survey question. A tally of the response totals, per cent and response counts for each question was presented. It was possible to view individual responses and also text responses to open ended questions, however it was not possible to perform advanced statistics such as standard deviation and chi-square tests on this package. Results were therefore exported to an excel spread sheet for further analysis and presentation.

As with all modifications, content analysis was carried out following the first Delphi round. There is no standard approach to contents analysis for a Delphi study. It has been suggested by Jairath and Weinstein (1994) that analysis is affected by purpose of the study, the structure of the rounds, the types of questions and number of respondents. Content analysis identified major focus areas for Delphi Round 2 (Powell 2003), where similar topics were combined and items which occurred infrequently reviewed for inclusion or exclusion.

Summary statistical analysis was carried out on data to determine the number of statements which had reached consensus of 75% at this stage. There is an option at this point to eliminate the statements that had reached consensus from the next questionnaire. The advantage of this is that the next questionnaire will be shorter and less onerous for participants to complete. However some researchers choose to include all statements in the next round in order to give all statements an even chance of gaining consensus at the highest level. This decision must be made on consideration of ensuring a high response rate from participants, which may be encouraged by a shorted questionnaire, and gaining consensus at the highest level (Keeney et al. 2011). For the purposes of this study it was decided to include all questions in the second questionnaire in order to reach the highest level of consensus. The second Delphi questionnaire was made available electronically to participants in March 2011 and included feedback from the previous round. Participants were asked to review results and reconsider their responses. The method of returning feedback to participants can facilitate motivation and rapid accumulation of results from participants. McKenna (1994) reflected that the process involves panel members in the development of the instrument and can lead to a perception of ownership and acceptance of findings. In relation to the number of rounds the basic principle is to have as many rounds as are required to achieve consensus or until the law of diminishing returns occurs (McKenna 1994). Overall final analysis was conducted following the second Delphi questionnaire. The 75% overall consensus was achieved in the main subject areas, with the return rate in the second questionnaire being 48% of the initial Delphi panel. Detailed results are presented in Chapter Five.

Results of the of the Delphi questionnaire were then taken forward to inform the content and structure of the transport pain assessment scale, and subsequently to Phase Three of the study, the aim of which was to establish face validity of the scale.

4.12 The Process and Application of Phase Three: Semi Structured Interviews with a Group of Key Informants

Phase Three of the research was initiated by a pilot study conducted with three clinicians to review the interview schedule. Results were then presented in a data matrix grid (Appendix 11) and the interview schedule revised accordingly (Appendix 11.1). Semi-structured interviews were then conducted with seven transport clinicians from the initial reference group utilised in Phase One of the study. The data collecting instrument was carefully designed to establish face validity of the newly developed transport pain scale. This provided participants with the opportunity to give their perceptions on the 'face value' of the scale, to review if 'on the face of it' the scale appeared to measure neonatal pain during transport. The management and analysis of qualitative data can be particularly challenging, primarily due to the immense amount of data which can be retrieved from qualitative methods, also due to the absence of standard analytical procedures in handling data and the difficulty in presenting data to ensure validity is transparent in the analysis (Polit and Beck 2010).

Qualitative content analysis was utilised in this Phase of the research, a method reported as being very flexible, requiring researchers to judge which variations are most appropriate for their particular study (Miles and Huberman 1994). Qualitative content analysis was utilized for the subjective interpretation of the content of text data and was applied through the systematic classification process of coding and identifying themes or patterns highlighted in the data (Hsieh and Shannon 2005). The method involved deriving codes from the data, which are read word for word and structured into categories (Miles and Huberman 1994).

Words were highlighted in the text capturing key concepts or thoughts which were consequently reflected in emerging labels or codes (Riley 1990), these codes reflected the primary ideas and eventually formed part of an initial coding system (Hseih and Shannon 2005). The codes were then arranged into categories utilized to organize and group sections of data into meaningful clusters, enabling categories to be structured into major themes. This method of conventional content analysis was therefore applied to this Phase of the study utilising open colour coding (Riley 1990) and identification of themes, with the aim of establishing face validity of the newly developed transport pain scale. A particular feature of qualitative research is that data collection and data analysis are carried out concurrently, encapsulating examination, categorisation, tabulation and combination of the evidence in order to draw conclusions (Parahoo 2006). Computer assisted software such as SPSS for the analysis of quantitative data is now widely available, however qualitative data analysis packages are still not universally accepted to the same extent as quantitative packages.

Within the context of the current research consideration was given to the use of computer assisted qualitative data software (CAQDAS, N-Vivo) which have been described as being useful in eliminating the labour intensive element of qualitative data analysis (Parahoo 2006, Bryman 2008). However as was highlighted by Parahoo (2006), the appropriate use of these software packages requires that the researcher is experienced and perceptive in the analysis of qualitative data. This view was also reflected by Webb (1999) who suggested that new researchers undertaking small-scale studies would be advised to use a manual approach in order to gain insight into the intuition aspects of analysis. As the essence of the data analysis within this study was to focus on the participants' views and experiences on the pain assessment scale it was necessary to remain close to the data at all stages in order to remain true to the study. An informed decision was therefore made to reject the use of software and therefore manual procedures were employed.

The first stage of open text analysis of semi-structured interviews conducted in Phase Three involved reading through transcripts of the interviews, key words or concepts were identified and assigned colour codes which facilitated the emergence of key concepts from the raw data, then all the open codes were listed and grouped manually. Initial Themes emerged during analysis, through word based techniques including word repetitions, indigenous categories or key- words- in- context, numerical codes were subsequently applied to statements in order to facilitate further analysis and facilitate confirmation of definitive Themes. For the purpose of analysis, each statement was allocated a number which was listed in sequence within each transcript.

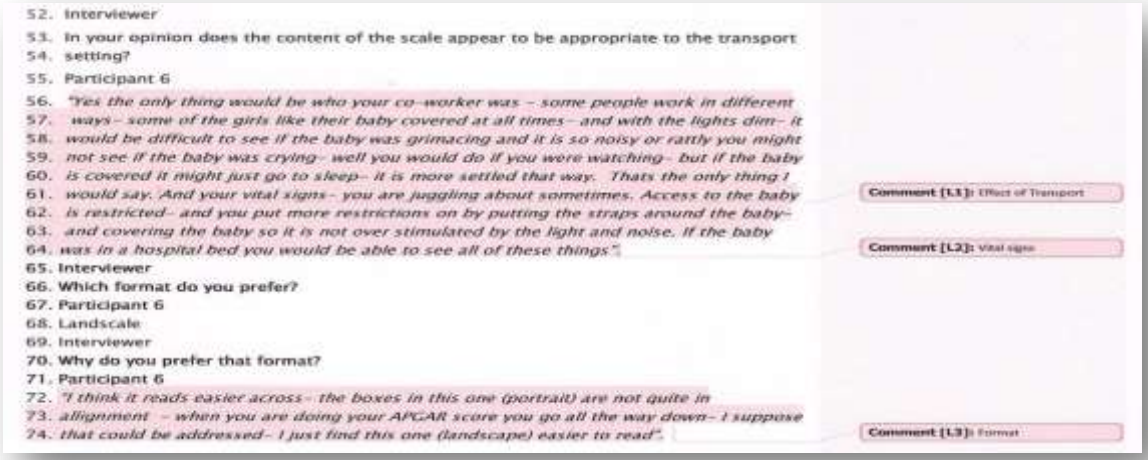
- **Audit Trail: Semi-Structured Interviews with Transport Clinicians**

This section will provide an overview of the audit trail of data collection and analysis throughout Phase Three of the study.

1. A semi-structured interview schedule was developed to establish face validity of the pain scale based on the areas of focus highlighted during development of the Delphi questionnaire.
2. Three pilot interviews were conducted with volunteer participants from a dedicated transport team, any required amendments were made to address issues of ambiguity or wording.
3. Semi-structured interviews then were conducted in September 2011 with seven transport clinicians from the reference group in Phase One.
4. The researcher listened to each audio-recording and stored them in the researcher's laptop computer, protected by a security password. In addition to this a backup of the audio-recording file was made.
5. Each audio-recording was transcribed verbatim by the researcher using computer word processing to allow computerised storage and organisation of data. To preserve anonymity of the participants no names were included with participants numerically identified on the transcriptions.
6. Transcribed copies of their interview were given to each participant for verification of content.
7. The researcher read through the transcriptions on several occasions to provide an overview of the information and gain familiarity with the content.

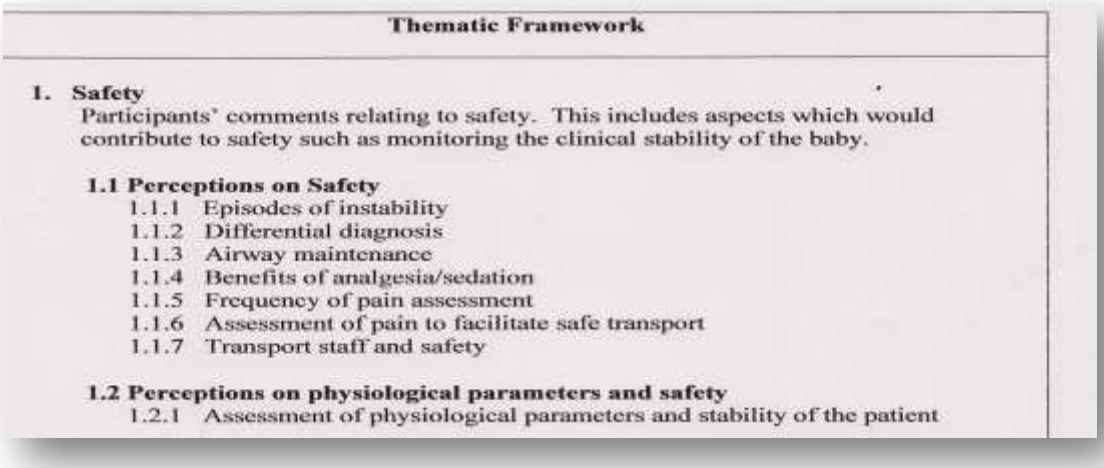
8. The researcher then read the transcriptions line by line to identify key words or meaningful concepts related to the research question and aims of the study, these sections were assigned codes to highlight a particular segment which is known as open coding. This method facilitated key concepts or words to emerge from the data.
9. Computer word processing (Track Changes) was applied at this stage to assist the process (Figure 16). At this point the coded transcriptions were cross checked by an outsourced neonatal education practitioner, experienced in qualitative analysis.

Figure 16 **Example of Open Coding using "Track Change" Word Processing Programme**



10. The open codes of the transcriptions were all listed, sorted and grouped manually into categories; overlap and redundancy among categories were therefore decreased. As a result of this process four main Themes were developed together with sub-themes. The list of Themes and sub-themes were then assigned numerical codes (see Figure 17 below for example of thematic framework assigned numerical codes).

Figure 17 **Example: Thematic Framework assigned numerical codes**



Thematic Framework

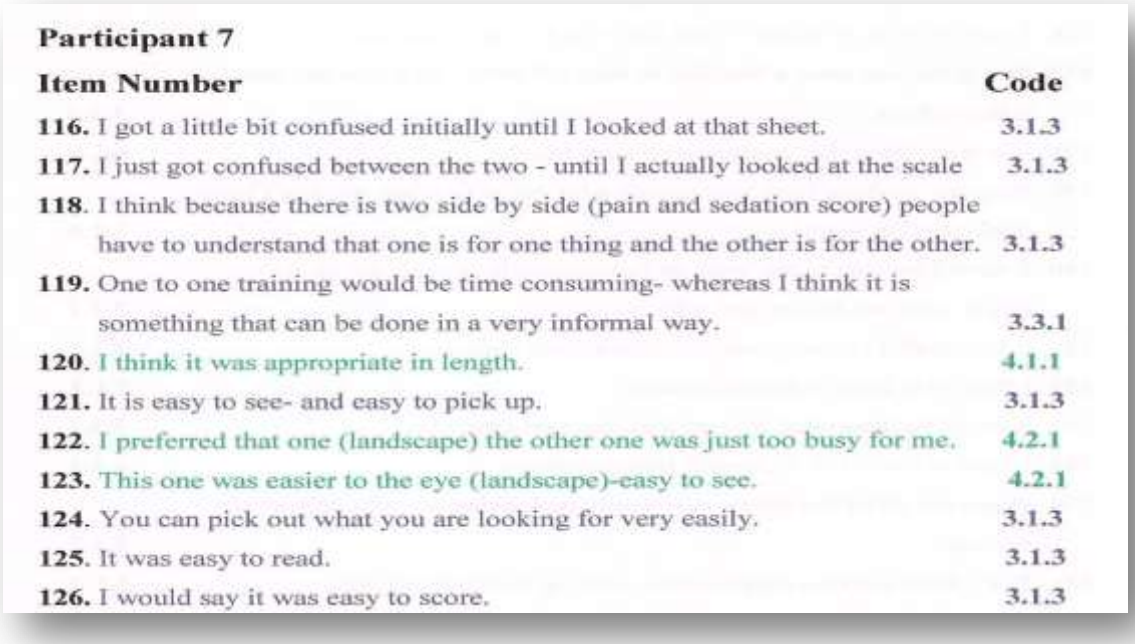
1. Safety
Participants' comments relating to safety. This includes aspects which would contribute to safety such as monitoring the clinical stability of the baby.

1.1 Perceptions on Safety
- 1.1.1 Episodes of instability
- 1.1.2 Differential diagnosis
- 1.1.3 Airway maintenance
- 1.1.4 Benefits of analgesia/sedation
- 1.1.5 Frequency of pain assessment
- 1.1.6 Assessment of pain to facilitate safe transport
- 1.1.7 Transport staff and safety

1.2 Perceptions on physiological parameters and safety
- 1.2.1 Assessment of physiological parameters and stability of the patient

The thematic framework assigned codes were then carefully and systematically applied to all of the transcriptions. Item numbers were then allocated to each statement, which allowed the researcher to view and analyse data within all interviews under the themes developed (Figure 18).

Figure 18 **Example: Semi-structured Interviews with Item Numbers and Codes**



Participant 7

Item Number	Code
116. I got a little bit confused initially until I looked at that sheet.	3.1.3
117. I just got confused between the two - until I actually looked at the scale	3.1.3
118. I think because there is two side by side (pain and sedation score) people have to understand that one is for one thing and the other is for the other.	3.1.3
119. One to one training would be time consuming- whereas I think it is something that can be done in a very informal way.	3.3.1
120. I think it was appropriate in length.	4.1.1
121. It is easy to see- and easy to pick up.	3.1.3
122. I preferred that one (landscape) the other one was just too busy for me.	4.2.1
123. This one was easier to the eye (landscape)-easy to see.	4.2.1
124. You can pick out what you are looking for very easily.	3.1.3
125. It was easy to read.	3.1.3
126. I would say it was easy to score.	3.1.3

In order to reduce the data and make it more manageable without losing their substance, thematic charts were created applying the main themes and sub-themes from the thematic framework. The charts were structured to display each theme within its own chart with entries from all participants. In each chart the themes and sub-themes were in columns with the participant number, the itemised comments were placed in the appropriate column. The process culminated with data being combined into each appropriate theme. This process allowed the researcher to visualise and analyse the data under the developed themes, for an example of a thematic chart see Figure 19 below.

Figure 19 **Thematic Chart**

Theme 3 **Transport clinicians perceptions on what to include in the pain assessment scale and how it shoul**							
Participant Number	**3.1 Items to be included in a pain scale**			**3.2 Effects of content on outcome**			**3.3 Content and staff education**
	3.1.1 Physiological and behavioural indicators of pain	3.1.2 Items relating to pain management	3.1.3 Clarity of content and ease of application	3.2.1 Appropria te to neonate and transport	3.2.2 Depth of content and ability to apply to transport setting	3.2.3 Utility within the transport environment	3.3.1 Requirements of staff education and application of the scale
4	Item	Item 22,	Item 2, 8, 10, 11, 13, 14, 34	Item 21,		Item 1,	Item
5	Item	Item 55	Item 39, 43, 44, 45, 46, 63	Item	Item 36, 37, 38, 65	Item 50	Item 62

4.13 Effects Matrix

An important aspect of any change in practice in the implications it may have on clinical care of the patient. Within the context of this research consideration of the potential influence implementing a pain assessment scale may have in the transport setting was of particular interest. Therefore an effects matrix was utilized to draw together and display data from all Phases of the study which represented the changed in people, groups or organizations (Miles and Huberman 1994).

The important aspect of an effects matrix is that there is always focus on dependent variables, with a clear independent or intervening variable such as the pain assessment scale in this study (Miles and Huberman 1994). The dependent variable of interest was the concept of pain assessment during neonatal transport. When an organization such as the neonatal transport service implement an innovation it can be expected that there will be some change as a consequence. This may lead to additional demands on the system necessitating organisational change, new guidelines, new procedures, changing attitudes or extended roles. It was necessary to build up the data in a clear structured manner. Outcomes were bundled according to their directness. Some outcomes can be classified as direct effects such as the immediate impact on the baby, whereas others may be more general and can be termed as 'meta-effects'.

An example of 'meta-effects' may be a change is clinical guidelines within the transport service. Finally the occurrence of 'side-effects' is considered, these are outlying effects which can occur as a result of the intervention, an example may be that the intervention may have an outlying effect on funding of the service, highlighting that effects can be positive or negative.

Outcomes can be reported by individuals in the service, or they can be attached to different roles or aspects of the service, such as changes in clinicians practice during transport.

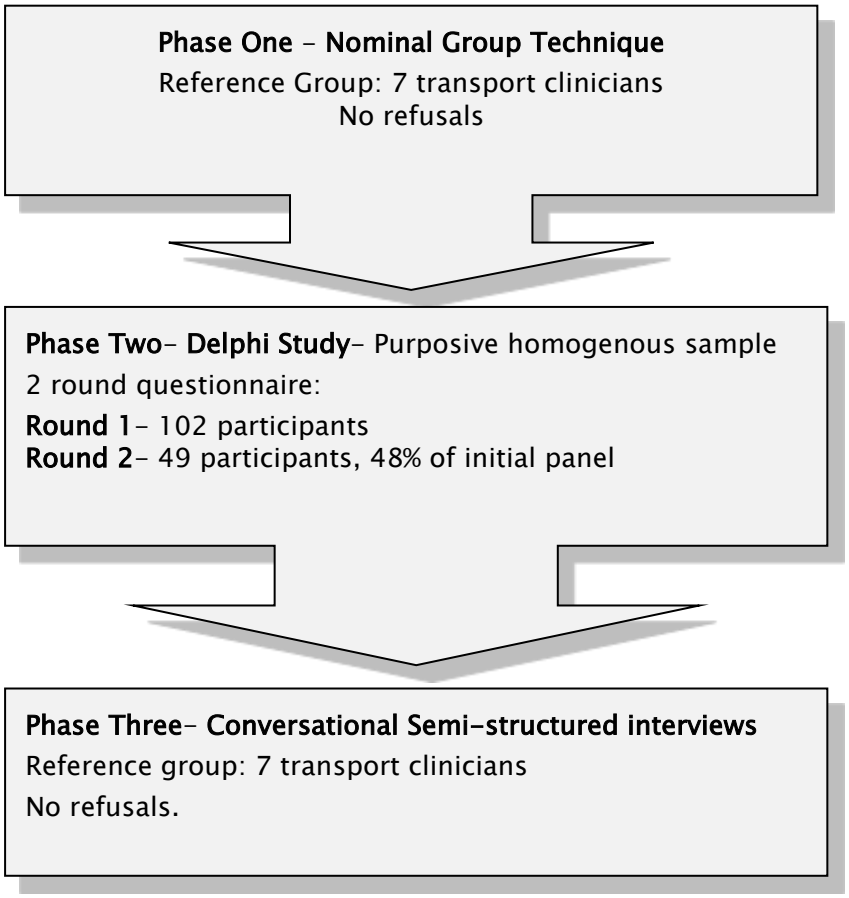
Data was entered in the matrix by summarizing phrases. Those phrases which received strong emphasis by the respondent were marked with an asterisk (*) and those which represented an inference by the researcher were highlighted (☼). This process involved several attempts to re-allocate data and develop definitive categories within the matrix from the phases of the study. The resulting effects matrix will be presented in Chapter Six.

4.14 Achieved Study Samples

The required sample for each Phase of the study was achieved by means of the previously described inclusion and exclusion criteria and the recruitment procedure. The first and third Phase of the study utilised a reference group of seven clinicians within a neonatal transport team. Phase Two of the study utilised purposive homogenous sampling.

This is a non-random method of sampling, aimed at sampling a group with a particular characteristic. It is also called judgement sampling, as respondents are selected due to their specific knowledge which is valuable to the research (Bowling 2004). The achieved sample sizes for each Phase of the study can be reviewed below in Figure 20.

Figure 20 **Achieved Samples for Each Phase of the Study**



4.14.1 Confidentiality

Participants have the right to expect that their data will be kept and applied in the strictest confidence. Anonymity is rarely possible in qualitative studies as the researcher frequently interacts with the participant in the form of interviews or focus group meetings. In relation to the Delphi Phase of the study, the issue of anonymity can present problems. Complete anonymity during a Delphi cannot always be guaranteed due to the fact that the researcher will provide feedback to the participants.

However the researcher can ensure that responses cannot be attributed to any individual panel member by the group (Keeney et al. 2011). Therefore maintaining the rights and anonymity of the participants were addressed by various means throughout the study.

This included informed consent and the following measures:

- Sensitivity to cultural and linguistic diversity
- Questions phrased tactfully, presented in a polite sensitive manner
- Transparency of consent procedures
- Emphasise the participants' right to withdraw at any time
- Ensuring balance between paternalism and autonomy
- Awareness of the risk of manipulation or coercion
- Ensuring anonymity in the final written report
- Continued assessment of vulnerability
- Study data/materials are locked in a secure location and electronic data password protected, and data destroyed within the accepted timeframe

4.14.2 Limitations of the Methods

This section of the Chapter will address issues relating to rigour which correspond to the robustness and integrity of the research design. Within the context of this study consideration has been given to those elements ensuring validity (Polit and Beck 2010), reliability (Bryman 2008) generalizability (Yin 2009) and objectivity (Parahoo 2006, Denscombe 2007). Therefore by highlighting the potential limitations associated with the study methods, the following methods were utilised to increase confidence in findings.

4.14.3 Validity (Credibility)

The validity of the study is an important reflection of the trustworthiness of the findings (Yin 2009, Polit and Beck 2010). The validity or credibility refers to the:

> *"ability of the instrument to measure the attributes of the construct under study"*
>
> (De Von et al. 2007 p155)

Validity is divided into external, which is an indication of generalizability of the findings and internal which refers to the confidence placed on the cause and effect relationship.

- *Content Validity*

There are several ways in which validity can be measured, these include content and criterion- related. In relation to content validity De Von et al. (2007 p155) states that it estimates if:

> *"the item in the tool sample the complete range of the attribute under study".*

It is reported by several authors that Delphi provides evidence of content and face validity (Sharkey and Sharples 2001, Morgan et al. 2007, Huang et al. 2008), this view is linked to the structure of the Delphi which is based on group opinion rather than an individual which is deemed to be more valid. Also both the Delphi process and NGT within this study is generated from expert opinion which provides confirmative judgements (Cross 1999, Spencer-Cooke 1989). This is also strengthened by the fact that the Delphi process within this study has a qualitative first round in the NGT which generates scale items from an expert group with the ability to review and judge the appropriateness of the scale through the consecutive Delphi rounds.

- *Criterion-related Validity*

There are two types of criterion-related validity: concurrent and predictive. Concurrent validity can be demonstrated when a test is correlated with a measure that has been previously validated.

Criterion-related validity is established when:

> *"a test is shown to be effective in predicting criterion or indicators of a construct".*
>
> De Von et al. (2007 p100).

However predictive validity is where one measure occurs earlier and is meant to predict a later measure (McIntire and Miller 2005). The Delphi process contributes to concurrent validity due to the successive rounds (Sharkey and Sharples 2001, Hasson et al. 2000) and also by achieving consensus from the expert panel, which is demonstrated in both the Delphi and NGT. However predictive validity is frequently measured in terms of accuracy, which is often viewed as evidence of validity (Keeney et al. 2011, Streiner and Norman 1995).

There are however challenges in establishing external and internal validity in any study, generalising results to the wider population may be inappropriate if the study was undertaken with a specific sample at a specific time. The Delphi and NGT experts may not be typical of the general population (Keeney et al. 2011), however it can be argued that neonatal transport is a specialised specific population.

4.14.4 Factors which may Influence Validity

There are a variety of influencing factors which can present a threat to the validity of consensus methods. These include:

- *The Sample*

The selected sample may have certain characteristics which may influence results. It has been highlighted that validity is affected by the number of experts, the extent of expertise and the level of consensus (Rowe et al. 1991). Furthermore due to the difference in backgrounds and experience within a panel results may not be replicated in another group of similarly qualified individuals (Sandrey and Bulger 2008).

In the Delphi process due to anonymity there may be a lack of accountability in responses from panel members which can influence results (Simoens 2006). Alternatively in a small panel members may be aware of other panel member identity and this potentially could sway the arguments by others discounting their views.

- *Modified Techniques*

It has been argued that the various modifications to the Delphi process threaten the validity and reliability of the process (McKenna and Keeney 2008). This can refer to various aspects of the Delphi method including number of rounds, timing and lack of consensus. However it has to be acknowledged that successive Delphi rounds may lead to fatigue which can affect response rates, panel members may drop out before the end of the process which may affect results (Simoens 2006).

- *Researcher Bias*

As the researcher is responsible for ensuring that the content is manageable and in the Delphi process there is no opportunity to engage with participants, the risk of researcher bias is always a potential risk (Walker and Selfie 1996, Sumison 1998).

Most Delphi studies use an open qualitative first round which then is reduced by utilising content reviews, this then informs the remainder of the Delphi process. However it has been argued that many Delphi studies have not fully addressed issues of validity (Rowe et al. 1991). As each Delphi study is unique it is unclear how these issues should be established (Engles and Kennedy 2007). It has been suggested that additional research to validate findings could be undertaken (Engles and Kennedy 2007, Van Dijk 1990). This may be in the form of pilot studies with special interest group members (Van Zolingen and Klaasen 2003) or face to face interviews prior to commencement of the Delphi (Delbecq et al. 1975).

However in response to claims criticising reliability of consensus methods such as Delphi, it was recommended that establishing guidelines by which the quality of the method can be tested would facilitate reliability. These would include:

- Applying the method to a specific problem
- Appropriate selection of respondents and their expertise
- Design and administration
- Feedback
- Consensus
- Group Meeting

(Van Zolingen and Klaassen 2003 p329)

4.15 Chapter Summary

This chapter discussed the research design applied to the study, detailing the methods utilised to collect data. The aim was to collect evidence which would provide consensus on the design and content of a pain assessment scale specific to neonatal transport in an ethical and robust way whilst remaining true to the study aims and research questions.

Issues of rigour have been addressed in the research process to ensure credibility and robustness in the study findings. The best interests of participants has been a priority therefore ethical principles have been transparent and applied throughout each phase of the study process.

5. Chapter Five

Data Analysis and Results:

NGT and Delphi Study

5.1 Introduction

This study explores the complex issue of pain assessment during neonatal transport, with the aim of harnessing expert opinion to gain consensus on the content and structure of a pain assessment scale for use in the transport environment, this culminates in a review of face validity of a newly developed transport pain assessment scale by semi-structured interviews. The three primary research questions (PRQs) were developed from the academic and professional literature and were further sourced from clinical experience. This facilitated the study and informed the collection of empirical evidence. The findings which are reported in this study have been derived from the analysis of raw data which contributed to answering the research questions.

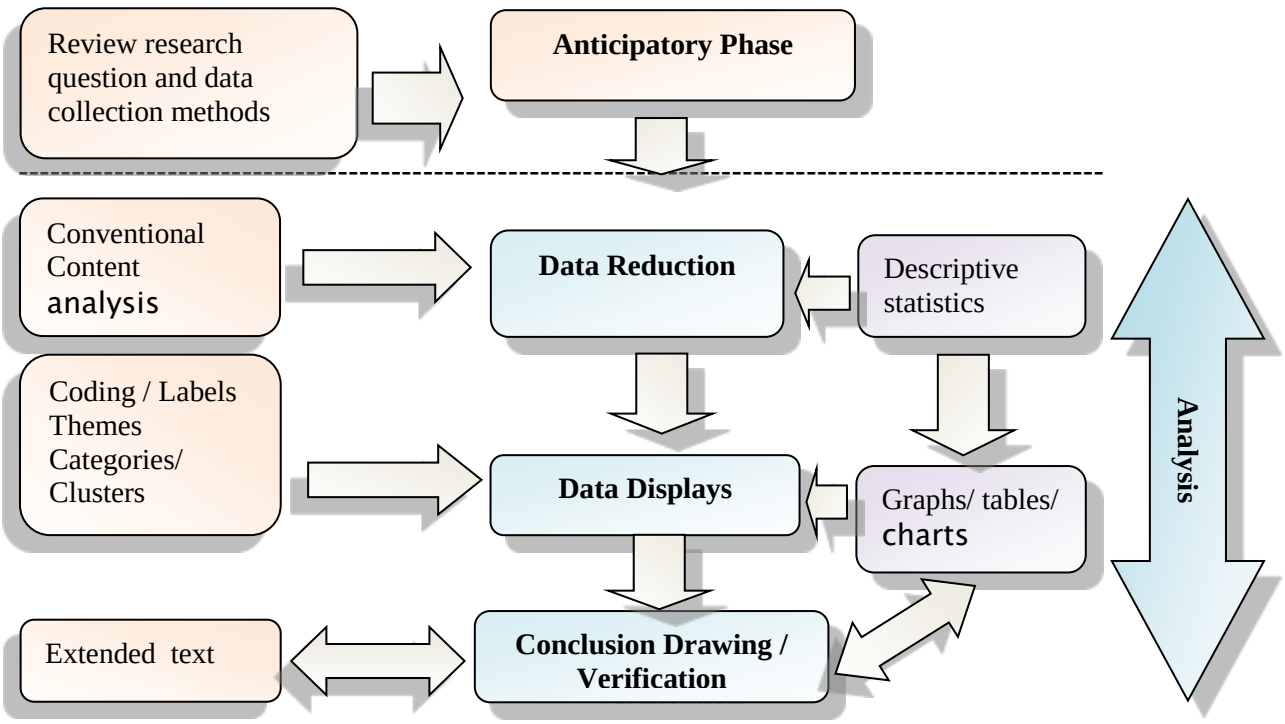
This Chapter presents the general organization and management of raw data, followed by a description of the processes inherent in the analysis of the data within each Phase of the study and presentation of results. The first draft of the new transport pain assessment scale (NTPAS) will be included at the end of this Chapter.

5.2 Management of Data

This section will provide an overview of how data from the first two Phases of the study was managed in order to facilitate analysis. The aim and purpose of data analysis is to extract as much information as possible that is pertinent to the subject under consideration. This is facilitated by eliciting meaning from the data, which is an integral part of the research design (Polit and Beck 2010). Analysis occurred through each Phase of the study, it was therefore crucial to organize and manage data in a structured manner while maintaining the principles of the study. Management and analysis of qualitative data followed a diverse approach based upon conventional qualitative content analysis supported by a framework suggested by Miles and Huberman (1994). Conventional content analysis (Riley 1990) was integrated with the "flows of activity" suggested by Miles and Huberman (1994 p12), which outlined three major components of data analysis: data reduction, data display and conclusions and verifications which are displayed below in Figure 21.

Figure 21 **Data Collection Flow Chart**

(Adapted from Miles and Huberman, 1994 p 10)



5.3 Results: Phase One- Nominal Group Technique (NGT)

The NGT followed a structured six-step format which facilitated analysis of data in the form of scoring and ranking methods (Delbecq et al. 1975), this format concluded the meeting process and identified group priorities in the form of physiological and behavioural indicators of pain. The serial group discussion (NGT Step 3) was outlined by Delbeq et al. (1975) as being the disclosure of thinking and analysis of generated items and not the resolution of differences of opinion. The group discussion enabled verification of data collected during the meeting process with individual comments by participants being checked against information gained by the facilitator on the flipcharts. The use of audiotape enabled the accurate recording of data and identified priority items to be taken forward to development of the Delphi Tool.

The following section of the Chapter will review results of data generated from each stage of the NGT process.

- **Stage 1: Opening Statement**

Stage 1 of the NGT consisted of presenting the opening statement to the group and silent generation of ideas, stages 2 to 6 incorporated the data collection stages.

- **Stage 2: Round Robin (Data Collection)**

Following Round Robin stage of data collection, the group collectively generated a total of 30 statements which were recorded on flip charts. Within this total number, 14 were physiological items (Figure 22) and 16 were behavioural items (Figure 23).

Figure 22 **Nominal Group Statements: Physiological Items Generated in Stage 2**

1. Heart Rate	8. Lactate
2. Respirations	9. Temperature
3. Blood Pressure	10. Increased Oxygen
4. Saturation	11. Apnoea
5. Colour	12. Bradycardia
6. Activity	13. Tachycardia
7. Blood Sugar	14. Toe/Core

Figure 23 **Nominal Group Statement: Behavioural Items Generated in Stage 2**

15. Facial Grimace	23. Withdraw to painful stimuli
16. Eyebrow Furrow	24. Facial Expression
17. Posture	25. Lethargy
18. Cry	26. Gestational Age
19. Tone	27. Previous/Current sedation
20. Alertness	28. Diagnosis
21. Startle	29. Interventions
22. Activity	30. Synchrony with ventilator

- **Stage 3: Serial Discussion and Clarification of Ideas**

This stage of the NGT involved a group discussion on the recorded statements/items (Appendix 12). The process of member checking clarified any ambiguities, and also helps facilitate internal validity of the study. Any item or statement which the group felt to be similar in meaning, were combined into one statement. This helped prevent any repetition in the final votes.

Therefore, the 30 original items which were generated by the group were combined to 23 statements/items (Figure 24).

Figure 24 **NGT Stage 3: Combined Items/Statements**

Combined Items / Statements	New Statement/Item Number and Order	New Statement /Item
1,12,13	1	Variations in Heart rate
11, 30	2	Variations in respiratory rate
4	4	Oxygen Saturation
15, 24	11	Facial Grimace
6, 22, 25	18	Activity level
27	21	Sedation

Following group discussion a new order of items/statements was generated, and is listed in Figure 25.

Figure 25 **NGT Stage 3: New Order of Items/Statements**

1. Variations in Heart rate	
2. Variations in Respiratory Rate	13. Posture
3. Blood Pressure	14. Cry
4. Oxygen Saturation	15. Tone
5. Colour	16. Alertness
6. Blood sugar	17. Startle
7. Lactate	18. Activity Level
8. Temperature	19. Withdraw to painful stimuli
9. Increased Oxygen	20. Gestational age
10. Toe/Core Differential	21. Sedation
11. Facial Grimace	22. Diagnosis
12. Eyebrow Furrow	23. Interventions

- **Stage 4: Preliminary Vote of Item/Statement Importance and Discussion of Results**

This stage required participants to vote independently using their specially prepared voting cards, and identify their own top five statements which best answered the NGT question. The voting and ranking process described in Chapter Four was applied. The voting cards were collected and shuffled to retain anonymity and results recorded and tallied on the flip chart in front of the participants (Figure 26).

Figure 26 **NGT Stage 4: Preliminary Voting**

Order of Statements	Individual Votes per Participant	Collective Total	Total Number of Votes
1	5, 5, 5, 5, 5, 5, 5	35	7 votes
2	2, 1, 2, 3, 1, 4, 4,	17	7 votes
3	3, 4, 3, 4, 4, 2, 1,	21	7 votes
4	4, 3, 2, 3, 3,	15	5 votes
5	1, 2, 1,	4	3 votes
6	1, 2,	3	2 votes
7	0	0	0 votes
8	0	0	0 votes
9	1, 3, 4, 2	10	4 votes
10	0	0	0 votes
11	5, 5, 5, 5, 2, 5, 5	32	7 votes
12	4	4	1 vote
13	2, 3, 3, 3	11	4 votes
14	4, 4, 4, 4, 1, 3, 1	21	7 votes
15	5, 2, 4, 4	15	4 votes
16	5	5	1 vote
17	2	2	1 vote
18	1, 3, 3, 2, 2	11	5 votes
19	1	1	1 vote
20	1, 1, 1	3	3 votes
21	0	0	0 votes
22	0	0	0 votes
23	2	2	1 vote

Results of the preliminary vote are displayed in Figure 27 (Physiological Items) and Figure 28 (Behavioural Items). Variations in heart rate and blood pressure received most votes in the physiological category and facial grimace and cry received most votes in the behavioural category.

Figure 27

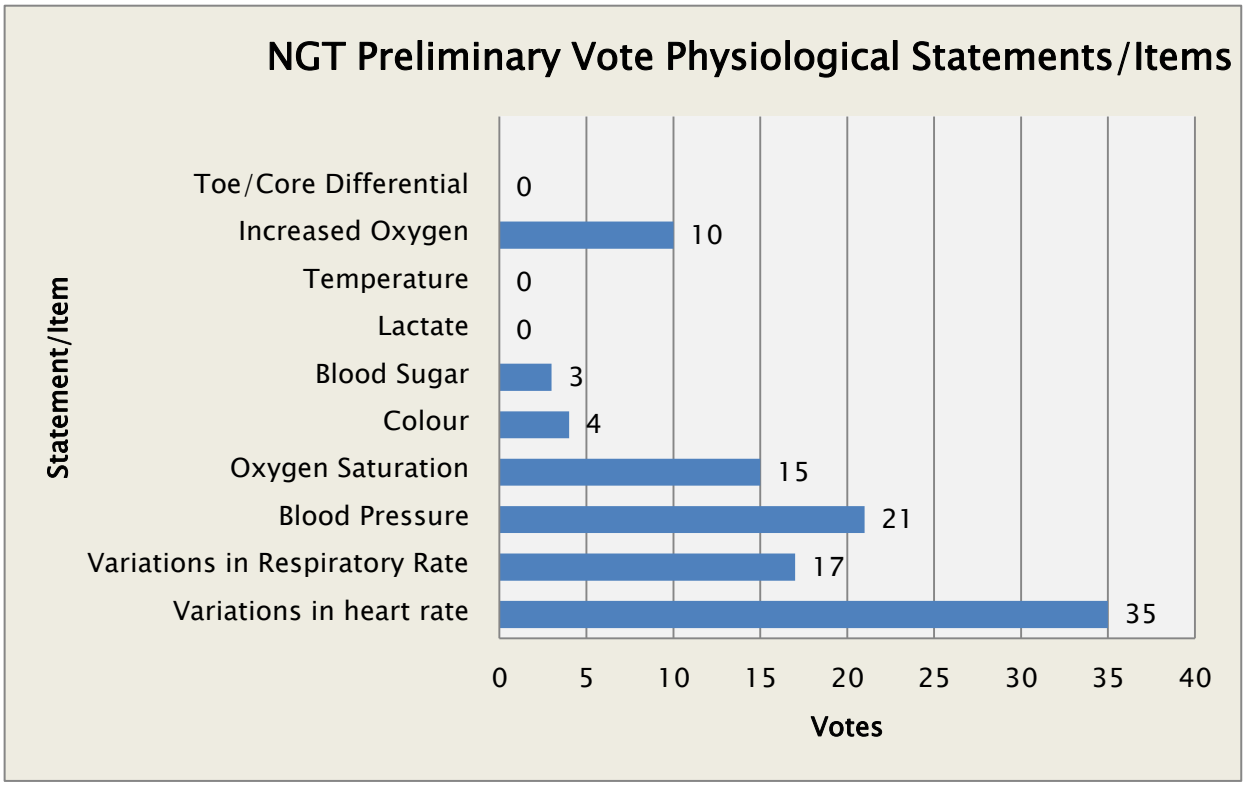
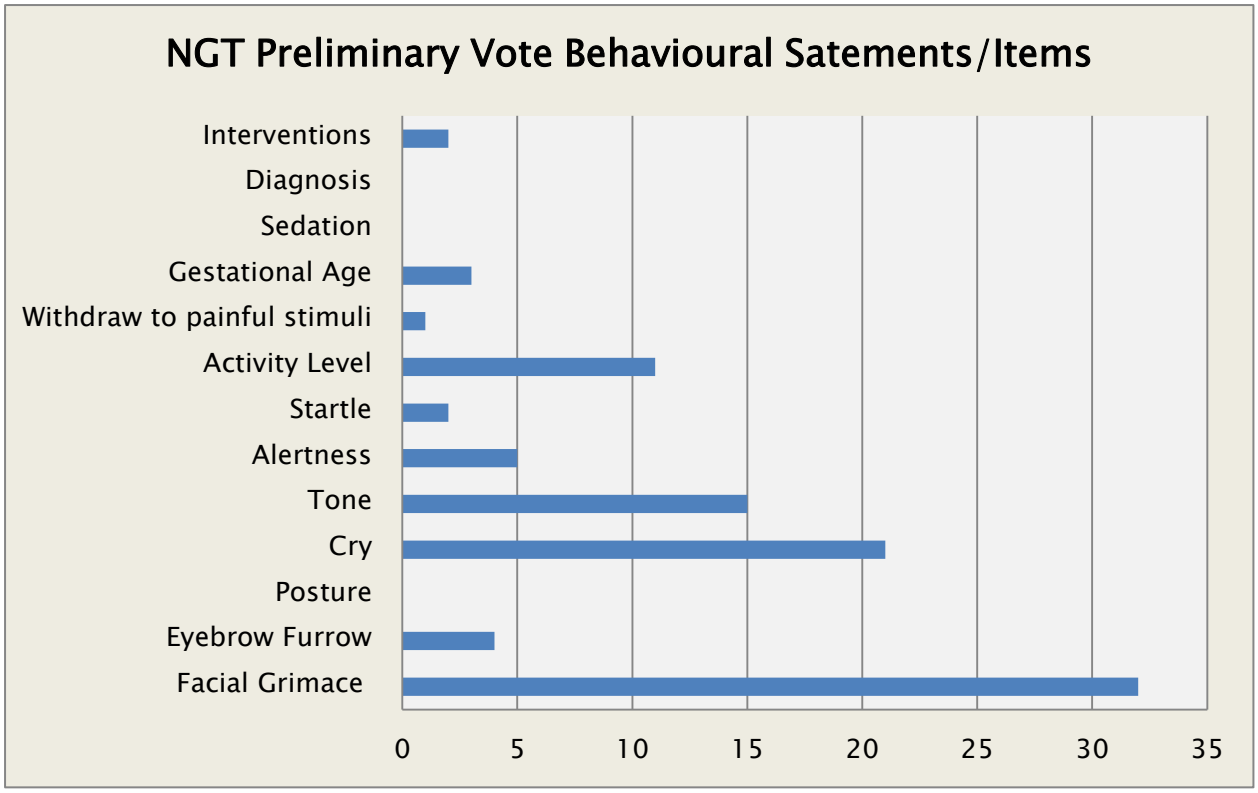


Figure 28



- **Stage 5: Discussion**

This discussion stage gave participants the opportunity to review any perceived inconsistencies in voting patterns and provided the opportunity for items to be discussed again if they were perceived to have too few or to many scores. This offered time for clarification and brief discussion in order to increase judgement accuracy of the preliminary vote which had been recorded on the flip chart.

- **Stage 6: Final Voting**

The final voting phase was aimed at providing a more accurate indication of preference. The participants followed the same procedure as in Stage 4 and final judgments were consolidated for the group. When completed, the definitive lists were discussed briefly and displayed for the group (Figure 29, 30).

Figure 29 **Final Voting- Physiological Items/Statements**

Rank Order	Item Number	Collective Total	Total Number of Votes
1	1	35	7 votes
2	3	21	7 votes
3	2	17	7 votes
4	4	15	5 votes
5	9	10	4 votes

Figure 30 **Final Voting- Behavioural Items/Statements**

Rank Order	Item Number	Collective Total	Total Number of Votes
1	11	32	7 votes
2	14	21	7 votes
3	15	15	4 votes
4	13	11	4 votes
5	18	11	5 votes

The top five agreed statements which answered the nominal group question for behavioural and physiological items are displayed in Figure 31 and 32 respectively.

Figure 31

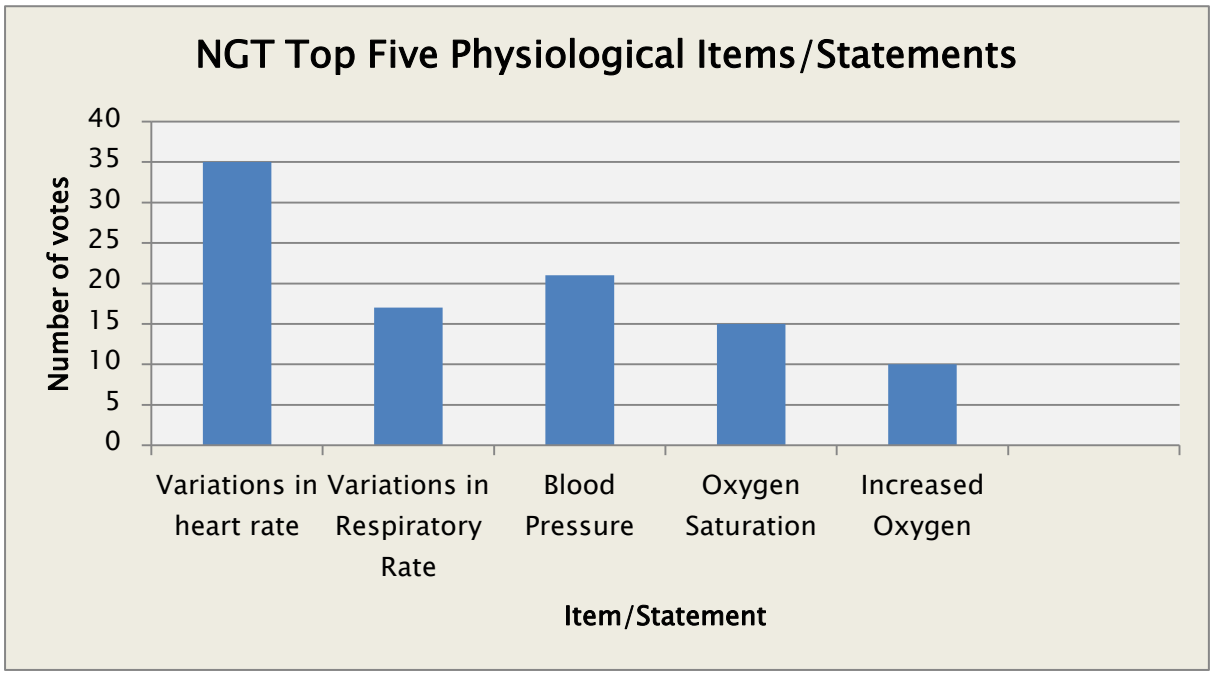
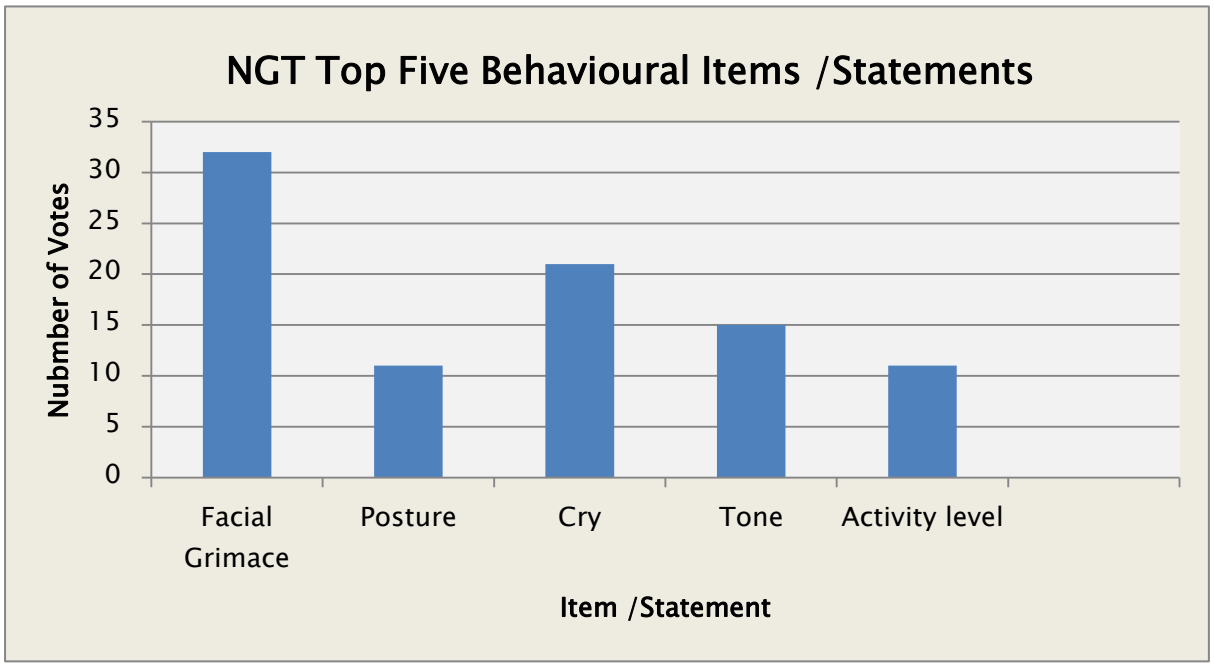


Figure 32



For the purposes of further analysis the top five physiological and top five behavioural items from results of the NGT (Appendix 12.1) were coded as follows:

- **NGT Item 1**: Variations in Heart Rate
- **NGT Item 2**: Blood Pressure
- **NGT Item 3**: Variations in Respiratory Rate
- **NGT Item 4**: Variations in Oxygen Saturation
- **NGT Item 5**: Increased Oxygen
- **NGT Item 6**: Facial Grimace
- **NGT Item 7**: Cry
- **NGT Item 8**: Tone
- **NGT Item 9**: Posture
- **NGT Item 10**: Activity Level

These 10 NGT items were taken forward for inclusion in the Delphi Questionnaire, facilitating development of the tool. Quantitative analysis of data emerged from ranking and scoring items/statements. This identified group priorities which involved group participants reaching agreement on priority statements, rank-ordering or rating also enhanced the accuracy of judgments. Further analysis of the data derived from the NGT process involved several rounds of scrutinizing the NGT statements (Round Robin), the agreed statements following clarification (definitive list of agreed statements) and the top agreed statements, this included comparing and contrasting the data and searching for commonalities.

5.4 Results: Phase Two- Delphi Study

Introduction

This section of the Chapter reports the findings of the second Phase of the study which applies the Delphi method. The aim of the Delphi Phase is to capture empirical data which is quantified together with emerging qualitative data. Where appropriate data produced by the Delphi process is summarised in the form of descriptive statistics and charts which reflect participants' experiences and perceptions on pain assessment and the development of a transport pain assessment scale. The Delphi technique encapsulates a staged, sequential process which facilitates the revision of initial participant responses as a result of emerging findings. It is a common modification of the Delphi process format to use a structured questionnaire in Round 1 that is based upon an extensive review of the literature. Kerlinger (1973) reflected that the use of a modified Delphi process is appropriate if basic information concerning the target issue is available and usable. Therefore the modified Delphi process executed in this study was informed by results of the NGT and from an extensive review of the literature relating to neonatal pain assessment scales (Chapter Three) and physiological measures of assessing pain (Appendix 3).

For the purpose of reporting, the Delphi Items included in the Delphi questionnaire will be referred to as "Delphi Items" (DI), where participants added text statements in the questionnaire this will be referred to as "Delphi Statement" (DS). The section begins by highlighting the Delphi Items (DI) included in the questionnaire, followed by a summary of the Delphi findings including the demographics and experience of the Delphi panel. Summary tables display results according to strength of percentage agreement followed by a more detailed breakdown of findings following Round 2. It has been suggested that swings of opinion between rounds (Duffield 1993) and contradictions (Murphy et al. 1998) should be noted and may be an important factors in the credibility of findings.

5.4.1 First Round Delphi Questionnaire

The Delphi process consisted of two rounds in the form of questionnaires distributed electronically. The first Delphi questionnaire which had been developed from results of the NGT was analysed when the participant reminder process had been completed and the return date reached. Descriptive statistical analysis was facilitated by The SurveyMonkey (www.SurveyMonkey.com) (described in Chapter Four) which presented a tally of the response totals, per cent and response counts for each statement. The median, mode and range were also calculated, with the level of consensus for each question.

This process highlighted when the 75% consensus agreement level had been reached and also facilitated the feedback process to participants in the second Delphi questionnaire. Demographics for sampling profile were analysed to give an overall profile of the expert panel. The Delphi questionnaire also contained open text responses to questions which generated in-depth qualitative data which provided further insight into the perceptions of clinicians on development of the pain assessment scale.

5.4.2 Second Round Delphi Questionnaire

Each statement/question was included in the second questionnaire in order to enable each one to reach the highest level of consensus (Keeney et al. 2011). The second questionnaire was analysed utilising similar methods to the first questionnaire, resulting in the pre-determined consensus level being reached in the majority of statements, therefore a third questionnaire was not deemed to be necessary. Statements which reached consensus were then ranked in order of importance. Results of the Delphi analysis enabled development of the content and structure of the transport pain assessment scale (NTPAS).

5.4.3 Delphi Process: Results

A total of 102 participants completed the first Delphi round questionnaire, with 49 participants completing the second questionnaire by the deadline date given. Consensus was defined as 75% or more of the participants who completed the second questionnaire agreeing or strongly agreeing, or 75% or more disagreeing or strongly disagreeing with the statement or suggestion that an item should be included in the pain assessment scale (Delbecq et al. 1975, Murphy et al. 1998).

- **Major Questions**

The Delphi process was composed of 3 major overriding questions with a specific focus.

1. Which neonatal pain indicators should be included in a transport pain assessment scale?
2. Clinical utility and feasibility of a transport pain assessment scale.
3. Design of a transport pain assessment scale.

- **Delphi Questionnaire**

A detailed list of questions included in the Delphi questionnaire can be reviewed in Appendix 9.3. Sections 2 to 5, generated background information on participants neonatal transport experience and qualifications. Delphi items which reflected participants' views were included in section 6 to 13 of the questionnaire. For reporting purposes Question 1 and 2 of Section 3 were included in the Delphi items as they reflected participants' views on pain assessment.

Within sections 6 to 13 which examined Delphi items for inclusion in the scale, there were 76 items (Figure 33) included in the Delphi questionnaire which encapsulated the 3 overriding questions.

Figure 33 **Delphi Items**

Pain assessment during transport	8 items
Timing of pain assessment during transport	5 items
Physiological indicators of pain	12 items
Clinical measures	5 items
Behavioural indicators of pain	12 items
Environmental factors	7 items
Non-pharmacological factors	5 items
Pharmacological factors	5 items
Scale design	12 items
Scoring of the Scale	5 items

5.5 Summary of the Delphi Findings

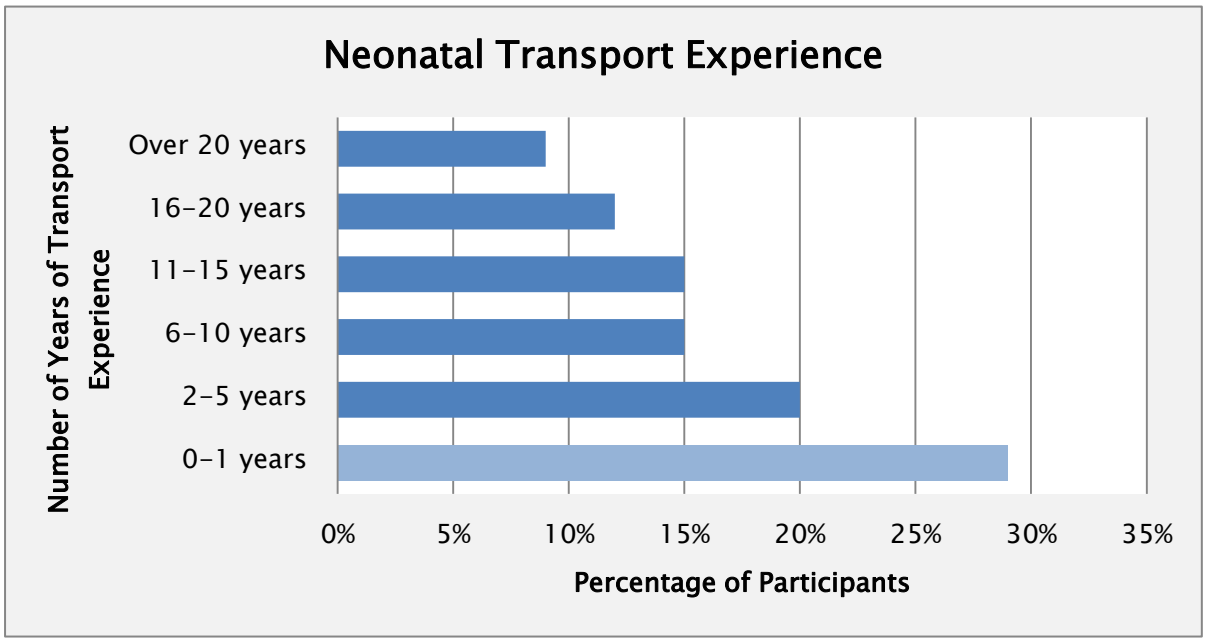
This section reports the demographics and experience of the Delphi panel in Round 1.

Demographics and Experience: Section 2-5

Round 1, Section 2: Question1

How much experience do you have working in neonatal transport?

Figure 34

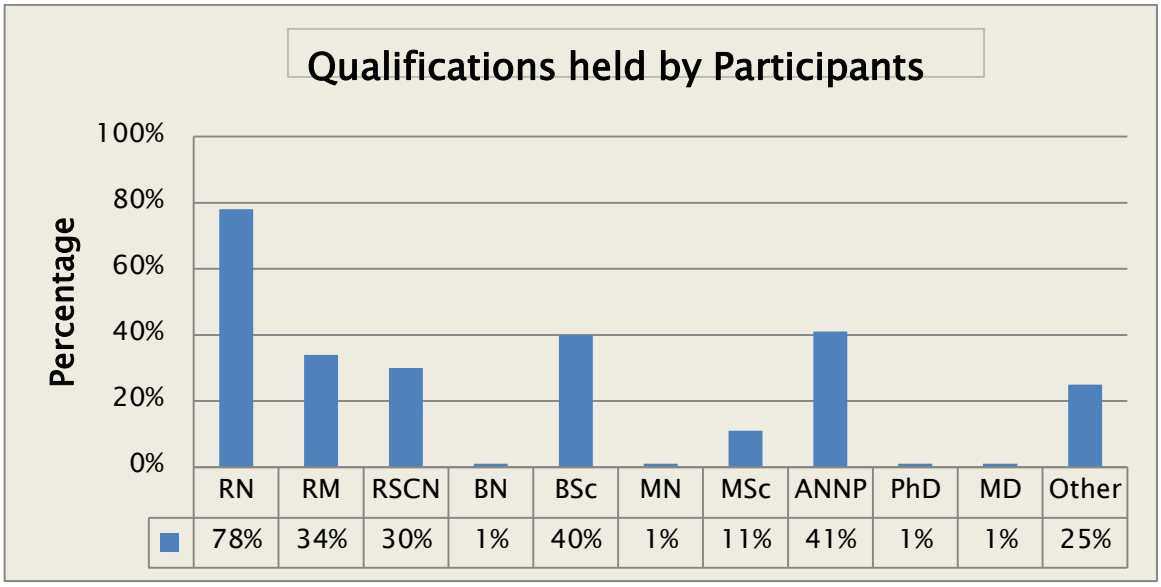


Participants were asked how much experience they had working on neonatal transport. Within the Round 1 sample of 102 participants, 48% (n=49) had up to 5 years' experience working on transport, 29% (n=30) had from 6 to 15 years' experience, and 20% (n=21) stated they had over 16 years' experience on neonatal transport, 2 skipped the question.

Round 1, Section 2: Question 2.

What qualifications do you hold?

Figure 35



In relation to number of qualifications held by participants, 25% (n=26) held one nursing qualification, 22% (n=23) held two qualifications, 27% (n=28) held three nursing qualifications and 24% (n=25) held more than four nursing qualifications.

In relation to nursing qualifications, 79% (n=80) participants held a Registered Nurse (RN) qualification, with 30% (n=31) a Registered Sick Children's Nurse (RHSC) qualification and 41% (n=42) were qualified Advanced Neonatal Nurse Practitioners (ANNP). Within the sample 40% (n=41) held a Bachelor of Science Degree (BSc) and 11% (12) a Master's Degree (MSc/MN). When asked about other qualifications, 26 participants listed other nursing qualifications which ranged from post graduate certificate in education and ENB courses. No other listed courses were directly related to transport or pain assessment.

Round 1, Section 2: Question 3

Have you completed a course/module in neonatal transport?

In order to reflect education and training on transport, participants were asked if they had completed a course in neonatal transport. Within the first questionnaire 30% (n=31) had completed a course/module in neonatal transport and 67% (n=68) stated they had not, 3 skipped the question.

Round 1, Section 3: Question 3

Have you used a pain assessment scale on neonatal transport?

In relation to pain assessment scales participants used on transport, 12% (n=13) stated that they had and 79% (n=80) stated that they had not used a pain assessment scale during transport, 9 participants skipped the question. No participants reported using a scale adapted to neonatal transport.

Round 1, Section 3: Question 4

If you have used a pain assessment scale on neonatal transport which one have you used?

Participants who stated they had used a pain assessment scale on transport were asked which one they had used. Four participants named a scale they had used. One participant used the PIP, one the NIPS, one the NPASS and one the PAT. Two were unsure which score they had used, and twelve stated they had used “other” scales/methods.

Participants were then given the opportunity to expand on "other" scales/methods used. 13 comments were recorded. One participant stated they had used the "FLACC" score and the neonatal facial coding system. Two participants reported that they were planning to use the same pain scale on transport that they used in the neonatal unit, these being the PAT scale and the "*SCREAMS*". A further participant stated that they had adapted the "*dsvni scale (Sparshott)*"and four participants reported having used a locally/in house developed scale or audit tool. One comment reflected that they were:

"currently trying to develop a pain tool for our neonatal unit".

A further participant highlighted that that they used "*personal judgement*", with another participant stating that they:

"Use a common sense approach - if baby asleep, it's not in pain! If I'm sticking tubes in it - it's in pain etc.".

Round 1, Section 4: Question 1, 2

Have you used a pain assessment scale in the clinical area?

When asked if they had used a pain assessment scale in the clinical area, 70% (n=71) stated that they had, 18% (n=19) stated that they had not used one and 12 skipped the question. Participants were then asked which pain assessment scale if any they had used. Within the group 20% (n=21) were unsure which scale they has used, 13% (n=14) used the N-PASS, 10% (n=11) used CRIES, 10% (n=11) NIPS, 2% (n=3) PAT, 1% (n=1) EDIN, 8% (n=9) had never used one, and 31 skipped the question.

Round 1, Section 5: Question 1, 2

Do you have a clinical guideline on neonatal pain assessment in the Neonatal unit or during Transport?

Within the group 63% (n=64) had a clinical guideline for pain in the neonatal unit, 14% (n=15) stated they did not and 8% (n=9) were unsure, 14 skipped the question. In relation to transport none of the participants were aware of a clinical guideline on pain.

5.5.1 Summary of Level of Consensus for Items Included in Round 2 Delphi: Section 6-13

The following data present an overall summary of the level of agreement reflected in Round 2 of the Delphi process. The Delphi questionnaire contained 76 items for which consensus of agreement were sought. Within the 76 items, 19 failed to reach consensus of agreement in the second Delphi round. Consensus of agreement is classified as:

A) Items scoring 75% or higher level of agreement gained consensus.
B) Items scoring 25% - 74% agreement failed to reach consensus.
C) Items scoring 0-24% levels of agreement failed to gain consensus and reached consensus of disagreement (i.e.76% or higher level of disagreement)

Data is presented by level of agreement. A breakdown of the percentage of agreement for each item is displayed below in Tables 6 to 15.

Table 6 **Delphi Process Round 2: Items Scoring 75% or Higher Level of Agreement on Pain Assessment during Transport**

Pain Assessment During Transport 8 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
1) Pain should be assessed during neonatal transport	100%
2) A pain assessment scale should be used in babies requiring analgesia	98%
3) A pain assessment scale should be used in neonatal surgical transfers	98%
4) A pain assessment scale should be used during neonatal transport	94%
5) A pain assessment scale should be used in babies requiring mechanical ventilation	93%
6) A pain assessment scale should be used in babies who are muscle relaxed	91%
7) A pain assessment scale should be used in babies who are neurologically compromised	91%
8) A pain assessment scale should be used during all neonatal transfers	78%

Table 7 **Delphi Process Round 2: Level of Agreement on Physiological Items**

Physiological indicators of pain which should be included in a pain assessment scale **12 Delphi Items**	
Items Scoring 75% or higher level of agreement	Percentage agreement
9) Variations in heart rate	98%
10) Variations in blood pressure	98%
11) Respiratory rate	95%
12) Episodes of instability	95%
13) Work of breathing/respiratory effort	93%
14) Variations in oxygen saturation	91%
Physiological Items that failed to reach consensus of agreement	
Items scoring 74% - 25% agreement	**Percentage agreement**
15) Changes in ventilation requirement	74%
16) Degree of muscle tone	73%
17) Variations in skin colour	72%
18) Temperature	60%
19) Variations in toe/core differential	40%
20) Capillary refill	33%

Table 8 **Delphi Process Round 2: Level of Agreement on Behavioural Items**

Behavioural indicators of pain which should be included in a pain assessment scale 12 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
21) Cry	98%
22) Irritability	98%
23) Level of activity	98%
24) Facial expressions	95%
25) Response to stimuli	95%
26) Eye squeeze during painful stimuli	93%
27) State of arousal	91%
28) Eyebrow furrow	90%
29) Tone	88%
30) Nasolabial furrow during painful stimuli	85%
31) Alertness	81%
Behavioural items that failed to reach consensus of agreement	
Items scoring 74% – 25% agreement	**Percentage agreement**
32) Type of eye movement	60%

Table 9 **Delphi Process Round 2: Level of Agreement on Environmental Factors**

Environmental factors which might influence pain assessment 7 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
33) Light levels	98%
34) Noise levels	98%
35) Type of transfer	95%
36) Environmental temperature	93%
37) Length of transfer	92%
Environmental items that failed to reach consensus of agreement	
Items scoring 74% – 25% agreement	**Percentage agreement**
38) Altitude if flight transfer	69%
39) Infant position in ambulance	61%

Table 10 **Delphi Process Round 2: Level of Agreement on Timing of Pain Assessment**

Timing of Pain Assessment 5 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
40) During transport	98%
41) Prior to leaving the referral unit	89%
42) On arrival at the receiving unit	79%
43) On arrival in the referral unit	77%
Timing of pain assessment- Items that reached consensus of disagreement	
Items scoring 0-24% levels of agreement (i.e.76% or higher level of disagreement)	**Percentage agreement**
44) Pain not assessed at all during transport	**100%**

Table 11 **Delphi Process Round 2: Level of Agreement on Pharmacological Factors**

Pharmacological factors which may influence pain assessment 5 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
45) Type of analgesia	100%
46) Dose during transfer	100%
47) Alterations in dose during transfer	100%
48) Muscle relaxant used	90%
49) Use of sucrose	95%

Table 12 **Delphi Process Round 2: Level of Agreement on Non Pharmacological Factors**

Non-Pharmacological factors which may influence pain assessment 5 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
50) Position e.g. lateral/prone	93%
51) Positional aide used e.g. nest	98%
52) Use of trans warmer	75%
53) Use of pacifier/dummy	95%
54) Containment holds	93%

Table 13 **Delphi Process Round 2: Level of Agreement on Scale Design**

Scale Design -12 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
55) A numerical score should be used to reflect level of pain	98%
56) An algorithm should be incorporated	98%
57) Incorporate diagnosis	95%
58) Limit to one page	95%
59) Include recommendations for analgesia based on pain score	95%
60) Include guidelines on pain scoring system	93%
61) Incorporate history	93%
62) Incorporate pain assessment scale in transport log	84%
63) Document intervention strategies following pain assessment	77%
Scale Design items that failed to reach consensus of agreement	
Items scoring 74% - 25% agreement	**Percentage agreement**
64) Develop separate transport pain assessment chart	30%
65) Limit to 2 pages	18%
Scale Design items that reached consensus of disagreement	
Items scoring 0-24% levels of agreement (i.e.76% or higher level of disagreement)	**Percentage agreement**
66) Unlimited length	**100%**

Table 14 **Delphi Process Round 2: Level of Agreement on Scoring of the Scale**

Scoring of the Scale 3 Delphi Items	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
67) Clinicians should be trained on use of the pain assessment scale	98%
68) The scale should include recommendations on pain management	96%
69) Physician or transport nurse should score scale	75%
Items on scoring the scale which reached consensus of disagreement 2 Items	
Items scoring 0-24% levels of agreement (i.e.76% or higher level of disagreement)	**Percentage disagreement**
70) Physician only should score scale	100%
71) Transport nurse/midwife only should score scale	79%

Table 15 **Delphi Process Round 2: Clinical Measures which Failed to Reach Consensus**

Clinical Measure which Reached Agreement 1 Delphi Item	
Items Scoring 75% or higher level of agreement	**Percentage agreement**
72) Gestational Age	95%
Clinical Measures which failed to reach consensus of agreement 4 Delphi Items	
Items scoring 74% - 25% agreement	**Percentage agreement**
73) Blood glucose measurement	49%
Clinical Measure items that reached consensus of disagreement	
Items scoring 0-24% levels of agreement (i.e.76% or higher level of disagreement)	**Percentage disagreement**
74) Blood gas measurement	91%
75) Blood lactate measurement	91%
76) End tidal carbon dioxide	92%

5.5.2 Detailed Breakdown of the Delphi Findings

Methods of Analysis

- *Ratings Scales*

A ratings scale (Table 16, 17) was utilised to facilitate descriptive statistical analysis. The major statistics used are measures of central tendency and level of dispersion (median, mode and range) this facilitated presentation of information concerning the collective judgements of respondents.

Table 16 **Delphi Process: Rating Scales 1**

Level of Agreement/Disagreement	Score
Strongly Agree	5
Agree	4
Unsure/No opinion	3
Disagree	2
Strongly disagree	1

Table 17 **Delphi Process: Rating Scales 2**

Level of Agreement/Disagreement	Score
Yes	3
No	2
Unsure/No opinion	1

- **Open Text Responses**

Open text responses within the Delphi questionnaire are reported in sequence within the appropriate questions. In order to facilitate analysis and application of results to the new pain scale, statements made by participants were listed and numbered as 'Delphi Statements' (DS), with similar items grouped in accordance with the appropriate focus areas as described in Chapter Four.

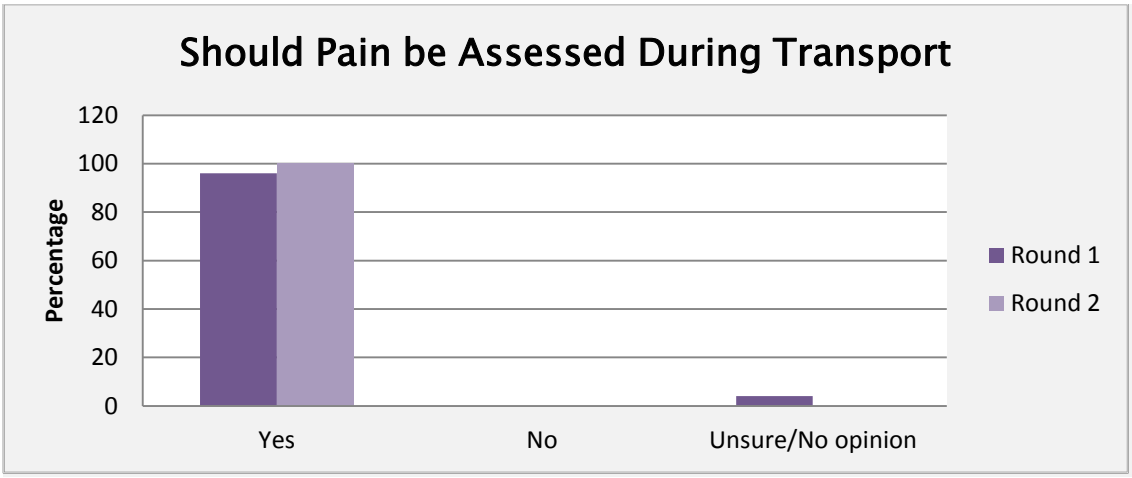
5.5.3 Pain Assessment during Neonatal Transport

This section presents a breakdown of results of section 6 to 13 including where appropriate swings of agreement between rounds. Open text responses are included within the appropriate questions.

Section 6 Question 1

Do you think pain should be assessed during neonatal transport?

Figure 36



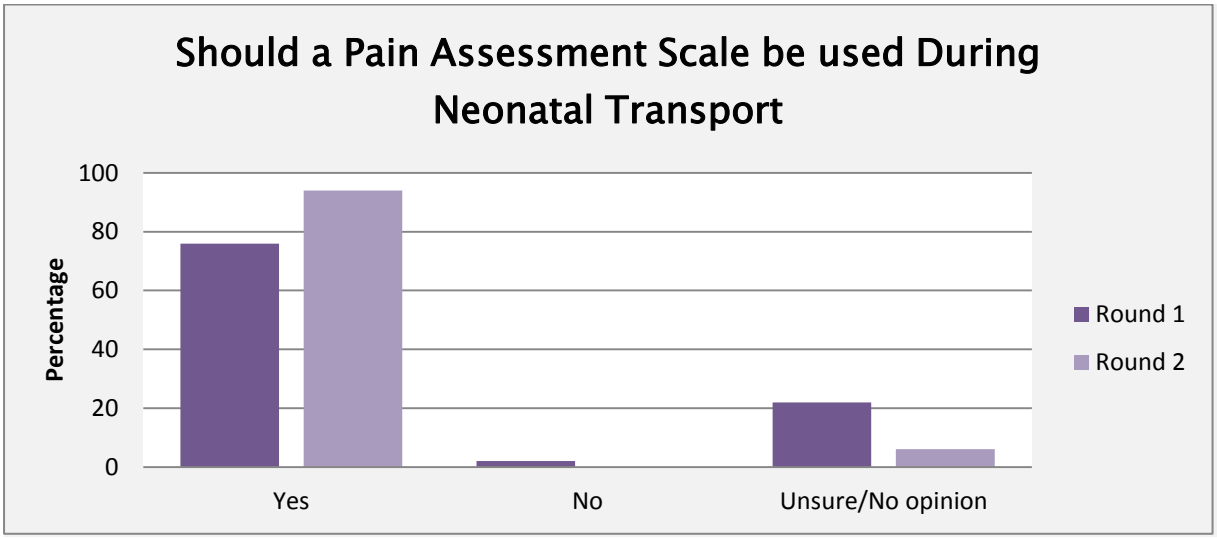
	Responses	Median	Mode	1 U	2 No	3 Yes	Skipped Question
Round 1	**95**	**3**	**3**	**4.2% n=4**	**0% n=0**	**95.8% n=91**	**n=7**
Round 2	**47**	**3**	**3**	**0 n=0**	**0 n=0**	**100% n=100**	**n=2**

Participants were asked if they believed pain should be assessed during transport. In the first round 95.8% of participants stated that pain should be assessed during neonatal transport, with 4.2% being unsure/no opinion. In the second round all participants stated that pain should be assessed during neonatal transport.

Section 6: Question 2

Do you think a pain assessment scale should be used during neonatal transport?

Figure 37



	Responses	Median	Mode	1 U	2 No	3 Yes	Skipped Question
Round 1	**96**	**3**	**3**	**21.9% n=21**	**2.1% n=2**	**76% n=73**	**n=6**
Round 2	**47**	**3**	**3**	**6.4% n=3**	**0 n=0**	**93.6% n=44**	**n=2**

Participants were asked if a pain assessment scale should be used to assess pain during transport. In Round 1, 76% (n=73) stated that a pain assessment scale should be used. In Round 2, 93.6% (n=44) of participants stated that a scale should be used. This indicated a movement of 18% towards an agreement that a pain assessment scale should be used during transport.

The question provided the opportunity to expand on the use of a pain assessment scale during transport. In relation to safety, respondents reflected that pain should be constantly assessed and documented at regular intervals. This was highlighted to be particularly important due to the level of movement of the patient during a transport (Box 3).

Box 3 **Focus Area: Safety**

"Pain is assessed constantly". (**DS** 1)

"This should be the practice observed during transport to ensure safety". (**DS** 2)

"It would be important to use as the baby is being moved more than when in nnu" (**DS** 3)

Respondents also stated that scales can be subjective, and difficult to score. The effects of the environment would also have to be considered in relation to noise and movement (Box 4).

Box 4 **Focus Area: Content**

"The effects of noise, movement and other travel associated factors would need to be taken into account". (**DS** 7)

"Variations in heart rate and BP are useful indicators". (**DS** 25)

How practical the scale/tool would be to use in the transport setting was reflected in several comments. Problems in relation to monitoring and time constraints were highlighted. However it was also stated that pain should be formally assessed regardless of the setting or situation (Box 5)

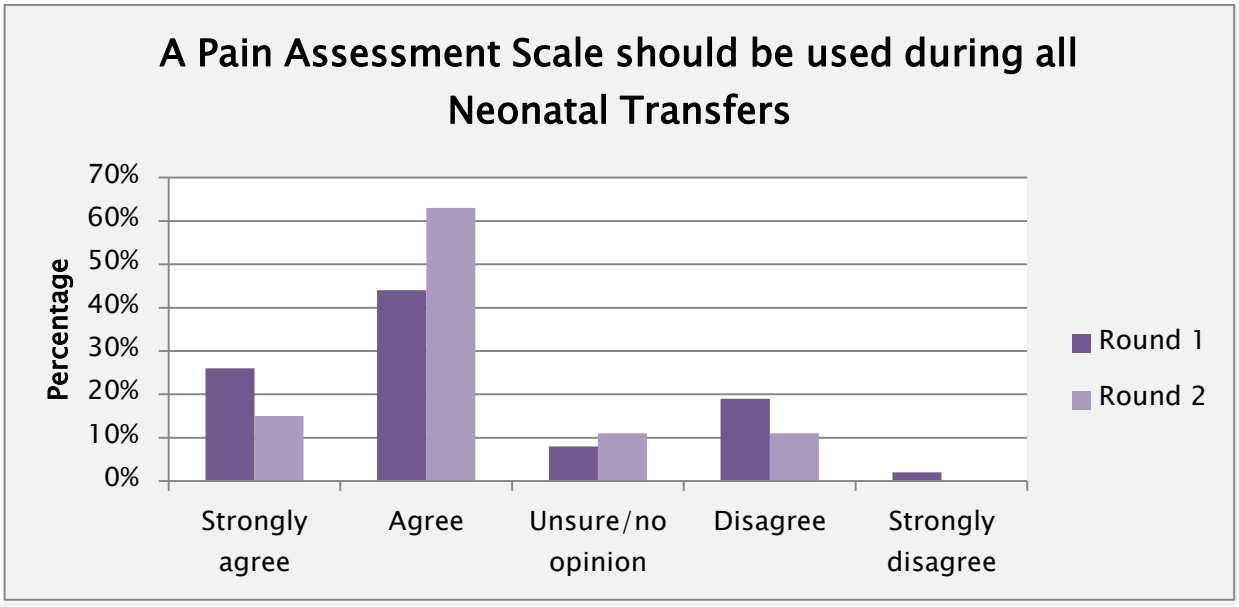
Box 5 **Focus Area: Clinical Utility**

"*This can be difficult and subjective".*	**(DS** 6**)**
"difficult to find pain assessment scores outside of transport which work well & consistently".	(**DS** 8)
" wonder how practical it would be in terms of accessing the infant".	(**DS** 10)
"from a practical point of view not sure how user friendly they would be".	(**DS** 11)
"difficulty of doing this en route, monitoring it and time constraints".	(**DS** 14)
"I will need convincing that it will make a difference and be practical"	(**DS** 9)

Section 6: Question 3

Pain Assessment Scales should be used during all neonatal transfers

Figure 38



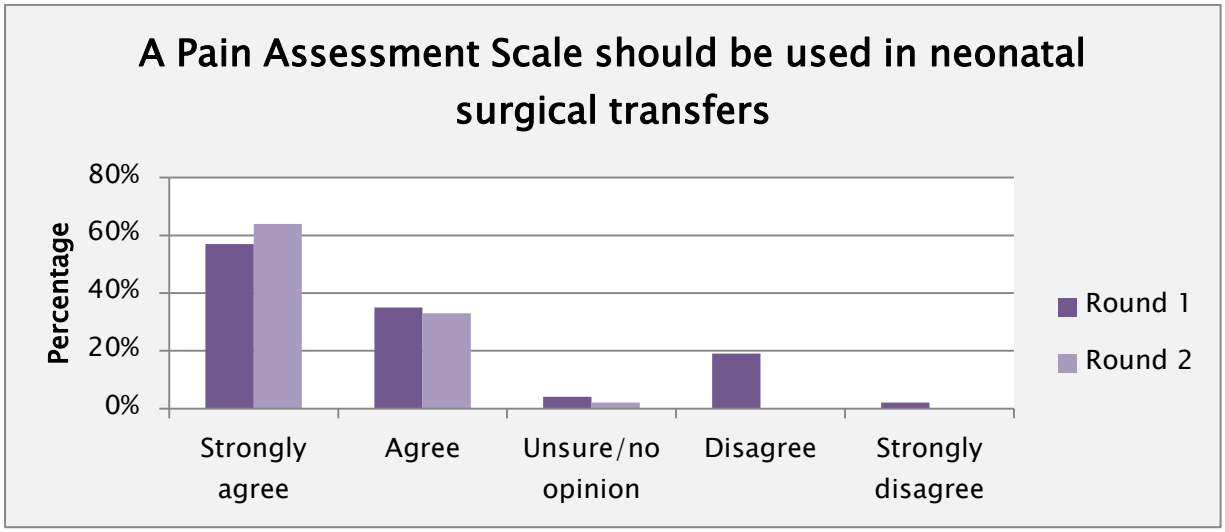
Responses	Median	Mode	Range	1 SD	2 D	3 U	4 A	5 SA	Skipped Question
Round 1 87	3.96	4	5	2.3% n=2	19.5% n=17	8% n=7	43.6% n=38	26.4% n=23	n=15
Round 2 46	4.12	4	4	0 n=0	10.8% n=5	10.8% n=5	63% n=29	15.2% n=7	n=3

In the first round 70% of participants agreed or strongly agreed that a pain assessment scales should be used during all neonatal transfers. In the second round 78% of participants agreed/strongly agreed that a pain assessment scale should be use during all neonatal transfers, reflecting a movement of 8% towards increased level of agreement/strong agreement. This also had the effect of increasing the median score by 0.16. In relation to level of disagreement, in the first round 22% disagreed or strongly disagreed. In Round 2 this decreased by 11% to 11%, indicating a swing from disagreement to agreement.

Section 6: Question 4

Pain assessment scales should be in neonatal surgical transfers

Figure 39



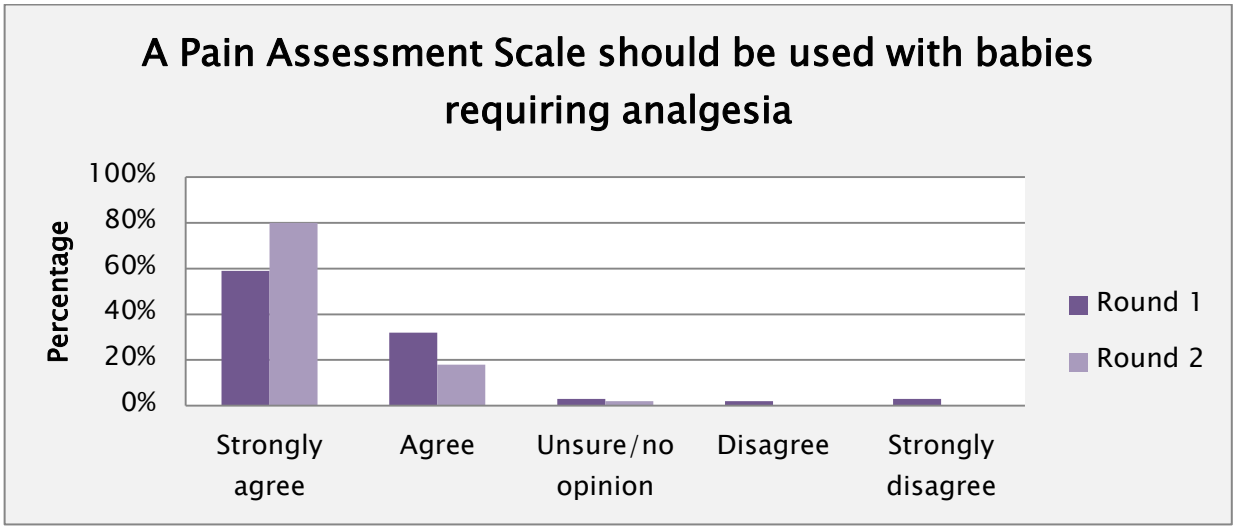
Responses	Median	Mode	Range	1 SD	2 D	3 U	4 A	5 SA	Skipped Question
Round 1 88	**4.62**	**5**	**5**	**3.4% n=3**	**1.1% n=1**	**3.4% n=3**	**35.2% n= 31**	**56.8% n= 50**	**n=14**
Round 2 45	**4.75**	**5**	**3**	**0% n=0**	**0% n=0**	**2.2% n=1**	**33.3% n=15**	**64.4% n= 29**	**n=4**

In total 98% of participants in the second round agreed/strongly agreed that pain should be assessed with a pain assessment scale during all surgical transfers. Results reflected a 6% swing to agreement/strong agreement from the first round. The range of responses decreased from 3 to 5 in the scale, reflecting a swing from disagreement to agreement.

Section 6: Question 5

Pain assessment scales should be used during neonatal transport with babies who require analgesia

Figure 40



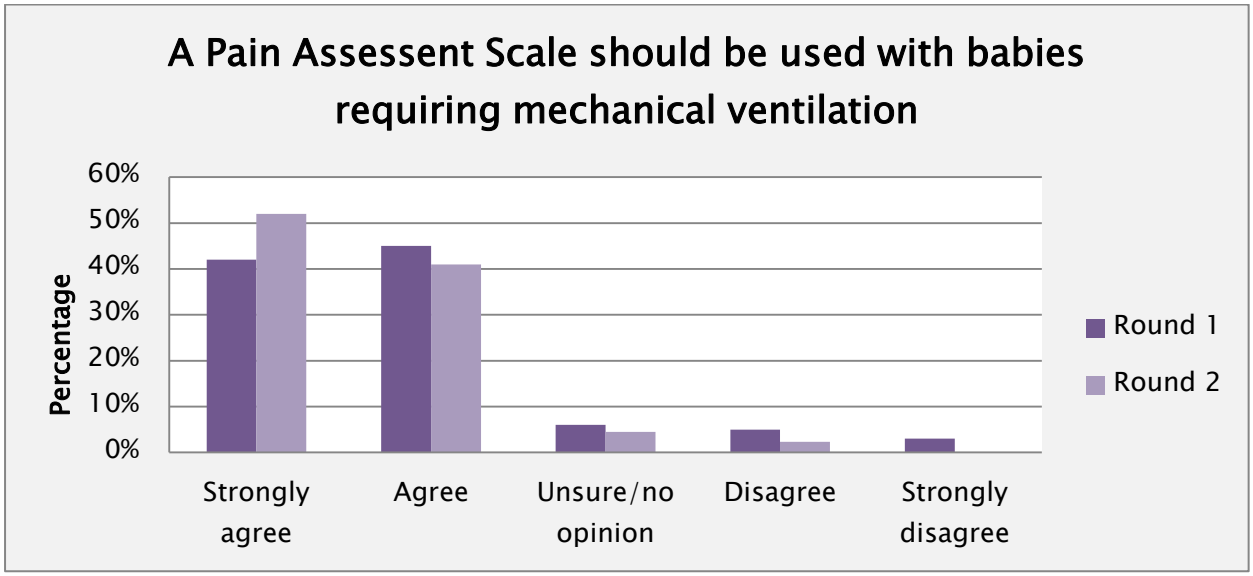
Responses	Median	Mode	Range	1 D	2 SD	3 U	4 A	5 SA	Skipped Question
Round 1 87	**4.64**	**5**	**5**	**3.4% n=3**	**2.3% n=2**	**3.4% n=3**	**32.2% n=28**	**58.6% n=51**	**n=15**
Round 2 45	**4.84**	**5**	**3**	**0% n=0**	**0% n=0**	**2.2% n=1**	**20% n=9**	**77.7% n=35**	**n=4**

A total 90% of participants in Round 1 agreed or strongly agreed on use of a pain assessment scale. In Round 2 there was a swing of 8% towards agreement/strong agreement. There was also a 6% swing away from disagree and strongly disagree, and a reduction in the range of responses to 3, reflecting a swing from disagreement to agreement.

Section 6: Question 6

Pain assessment scales should be used in babies requiring mechanical ventilation

Figure 41



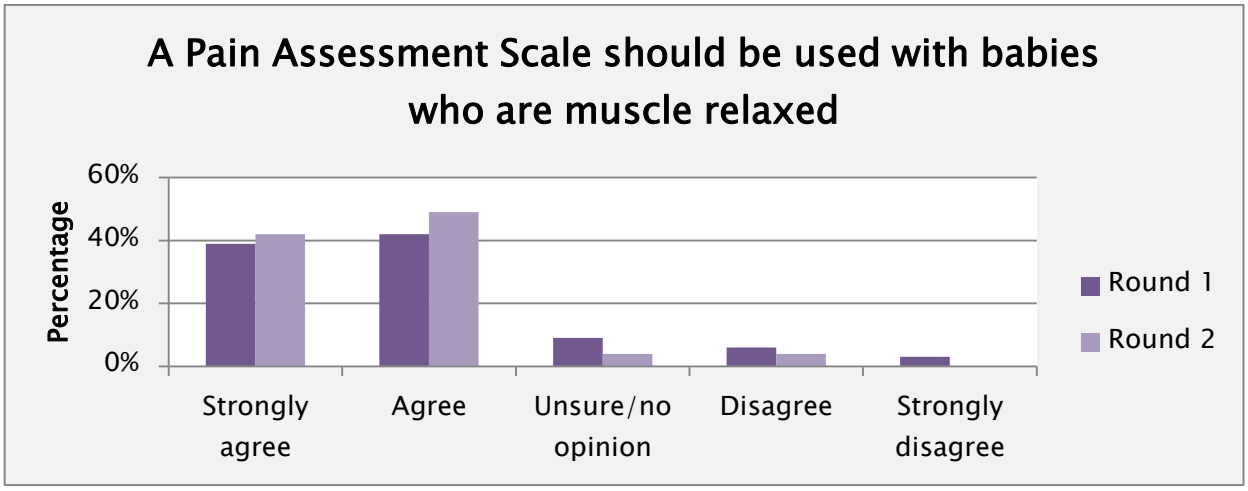
Responses	Median	Mode	Range	1 SD	2 D	3 U	4 A	5 SA	Skipped Question
Round 1 87	**4.32**	**4**	**5**	**3.4% n=3**	**4.6% n=4**	**4.6% n=4**	**44.8% n=39**	**42.5% n=37**	**n=15**
Round 2 44	**4.57**	**5**	**4**	**0% n=0**	**2.3% n=1**	**4.5% n=2**	**40.9% n=18**	**52.3% n=23**	**n=5**

In relation to babies who require mechanical ventilation, a total of 87% of participants in Round 1 agreed or strongly agreed that babies who require mechanical ventilation should be assessed with pain assessment scale during transport. In Round 2 the range of responses dropped to 4 and there was a swing of 6% towards agreement/strong agreement at 93%.

Section 6: Question 7

Pain assessment scales should be used in babies who are muscle relaxed

Figure 42



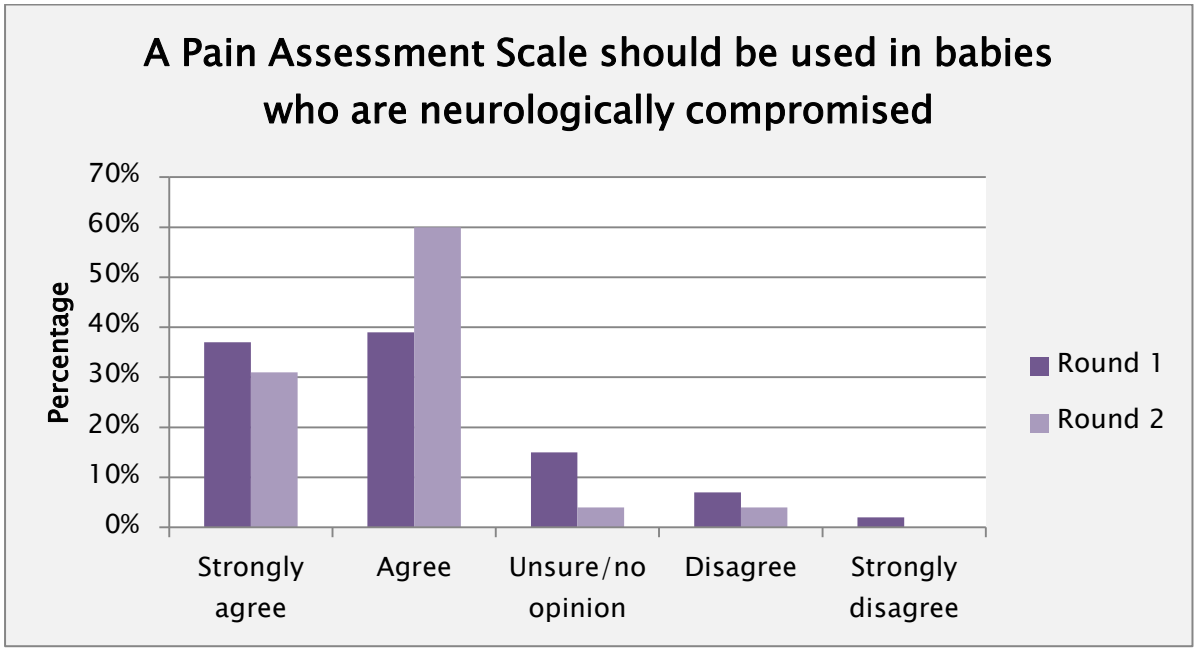
Responses	Median	Mode	Range	1 SD	2 D	3 U	4 A	5 SA	Skipped Question
Round 1 85	**4.23**	**4**	**5**	**3.5% n=3**	**5.9% n=5**	**9.4% n=8**	**42.4% n=36**	**38.8% n=33**	**n=17**
Round 2 45	**4.29**	**4**	**4**	**0% n=0**	**4.4% n=2**	**4.4% n=2**	**48.9% n=22**	**42.2% n=19**	**n=4**

In total 81% of participants in Round 1 agreed or strongly agreed that a pain assessment scale should be used with babies who are muscle relaxed during transport, as opposed to 91% in Round 2. This reflected a 10% swing towards agreement/strong agreement. The range of responses dropped from 5 to 4 and there was a swing of 5% from disagreement to agreement.

Section 6: Question 8

Pain assessment scales should be used in babies who are neurologically compromised

Figure 43



Responses	Median	Mode	Range	1 SD	2 D	3 U	4 A	5 SA	Skipped Question
Round 1 87	**3.86**	**4**	**5**	**2.3% n=2**	**6.8% n=6**	**14.9% n=13**	**39.5% n=34**	**37.2% n=32**	**n=15**
Round 2 45	**3.66**	**4**	**4**	**0% n=0**	**4.4% n=2**	**4.4% n=2**	**60% n=27**	**31.1% n=14**	**n=4**

In relation to babies who are neurologically compromised 77% of participants in Round 1 agreed or strongly agreed that these infants should be assessed with a pain assessment scale during transport. In Round 2 there was an increase of agreement to 91%, with a reduction in the range of responses from 5 to 4 and a swing of 5% from disagreement to agreement.

Respondents were given the opportunity to expand on when pain should be assessed during transport. Comments were made in relation to the use of a pain scale with specific groups of patients. Babies who are neurologically compromised were viewed to be difficult to assess with a pain scale during transport, with current tools not appropriate to use with those babies (Box 6). The importance of baseline assessment was emphasized and the influence on on-going management in the clinical area when the baby is admitted.

Box 6 **Focus Area: Clinical Utility**

"Not possible to use our current pain assessment tool with a muscle relaxed infant". (**DS** 15)

"muscle relaxant would have to be separate tool" (**DS** 16)

"Muscle relaxed and neurologically compromised infants are difficult to assess" (**DS** 17)

Further comments fell into the theme of safety (Box 7). An example of this being importance of monitoring in babies who have received paralytics and do not display behavioural signs of pain.

Box 7 **Focus Area: Safety**

"Signs of pain should still be monitored with babies who have received paralytics but they will not display behavioural signs due to drugs. (**DS** 19)

Analgesics should still be given and physiological signs monitored". (**DS** 21)

Participants reflected on the importance of guidelines on pain assessment, and the effect this would have on the outcome of the baby (Box 8).

Box 8 **Focus Area: Outcome**

"Dedicated transport service with specific guidelines which make assessments and decisions (**DS** 22)

"I'd support the use of the scale in all groups where it made a difference". (**DS** 23)

Section 7: Question 14-25

Physiological items which should be included in a transport pain assessment scale

Results in relation to Physiological Items in Round 1 and 2 are reflected in Figure 44, 45.

Figure 44

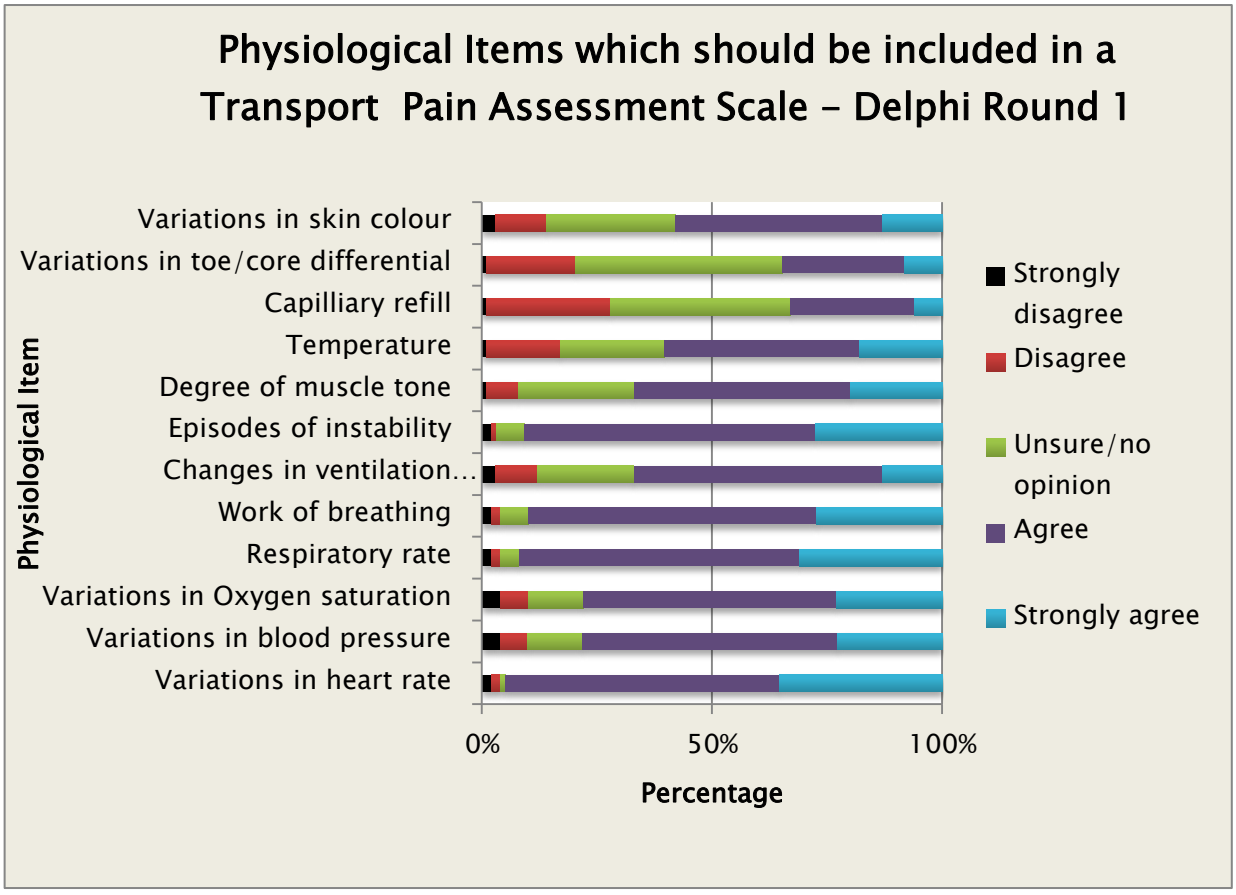
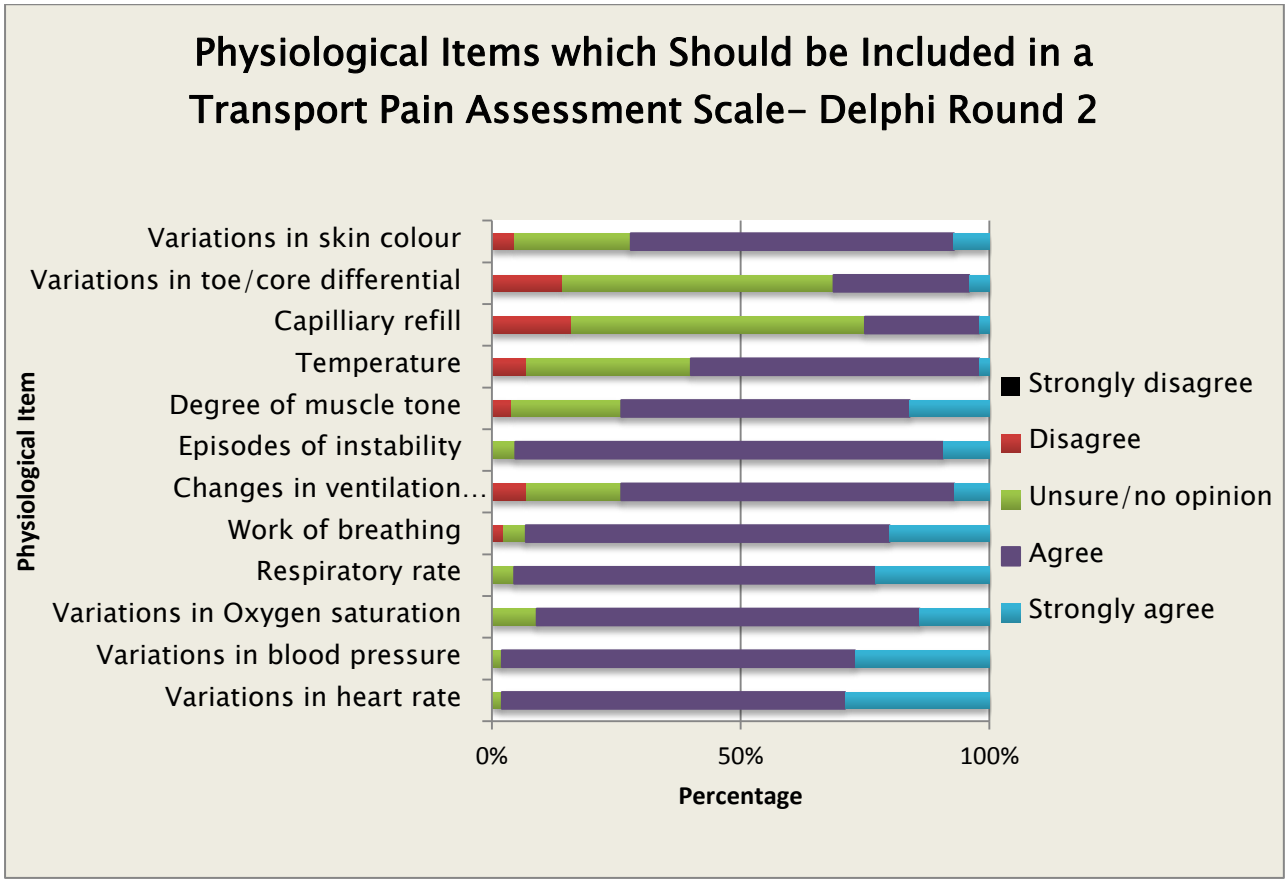


Figure 45



Seven physiological items gained consensus of 75% agreement or above for inclusion in the scale. These items were variations in heart rate, variations in blood pressure, respiratory rate, work of breathing/respiratory effort, variations in oxygen saturation, episodes of instability e.g. apnoea / bradycardia. The swing of consensus from Round 1 to Round 2 ranged from 16% increase (variations in oxygen saturation) to 3 % (respiratory rate). Within the 6 physiological items which failed to reach consensus of 75% or higher, some items gained an increase of agreement for inclusion in the scale. These items were changes in ventilation requirement (increase of 7%), variations in skin colour (increase of 14%), temperature (increase of 6%), degree of muscle tone (increase of 6%).

Items which swung towards disagreement for inclusion in the scale were: variations in toe/core differential (increase in disagreement of 3%) and variations in capillary refill (increase in disagreement of 15%). In the first round each item generated a small amount of strong disagreement for inclusion in the scale. These were variations in heart rate (2%), variations in blood pressure (4%), respiratory rate (2%), work of breathing/respiratory effort (2%), variations in oxygen saturation (4%), changes in ventilation requirement (2%), variations in skin colour (3%), temperature (1%), variations in toe/core differential (1%), variations in capillary refill (1%), episodes of instability e.g. apnoea / bradycardia (2%), degree of muscle tone (1%). In the second round no items generated strong disagreement for inclusion in the scale. Respondents reflected that in relation to physiological parameters, pain may be difficult to quantify as the babies were often very sick and unstable. Different types of transport may affect them differently, with a policy of not touching or opening incubators during movement /transport being important for safety reason (Box 9).

Box 9 **Focus Area: Safety**

"*Pain is difficult to quantify due to the unstable nature of babies at times during transport"* (**DS** 24)

"you must also remember other factors may affect them e.g. heart rate can rise when infant's temp is increased". (**DS** 26)

"Difficulty in assessing pain due to varying clinical conditions/ type of respiratory support etc." (**DS** 31)

"*Containment holds would be difficult from a safety point of view".* (**DS** 39)

"*Pacifier not appropriate in a moving vehicle".* (**DS** 41)

Some comments reflected concerns regarding ability to use a pain assessment scale which uses physiological parameters due to the variable transport environment and method of transport (Box10).

Box 10 **Focus Area: Clinical Utility**

"Some parameters are difficult to assess because of movement during transport". (**DS** 32)

"Difficult to conclude whether physiological changes were down to pain, movement, acceleration/deceleration forces etc." (**DS** 33)

"I feel anything during transport should be 'no touch'- I do not believe there is any 'routine' reason why we should be opening incubator doors during a transport" (**DS** 29)

Respondents also reflected the view that reliable and valid indicators of pain should be used in the scale, highlighting the importance of physiological indicators of pain (Box 11).

Box 11 **Focus Area: Content**

"I would include whatever indicators were shown to be reliable and valid". (**DS** 34)

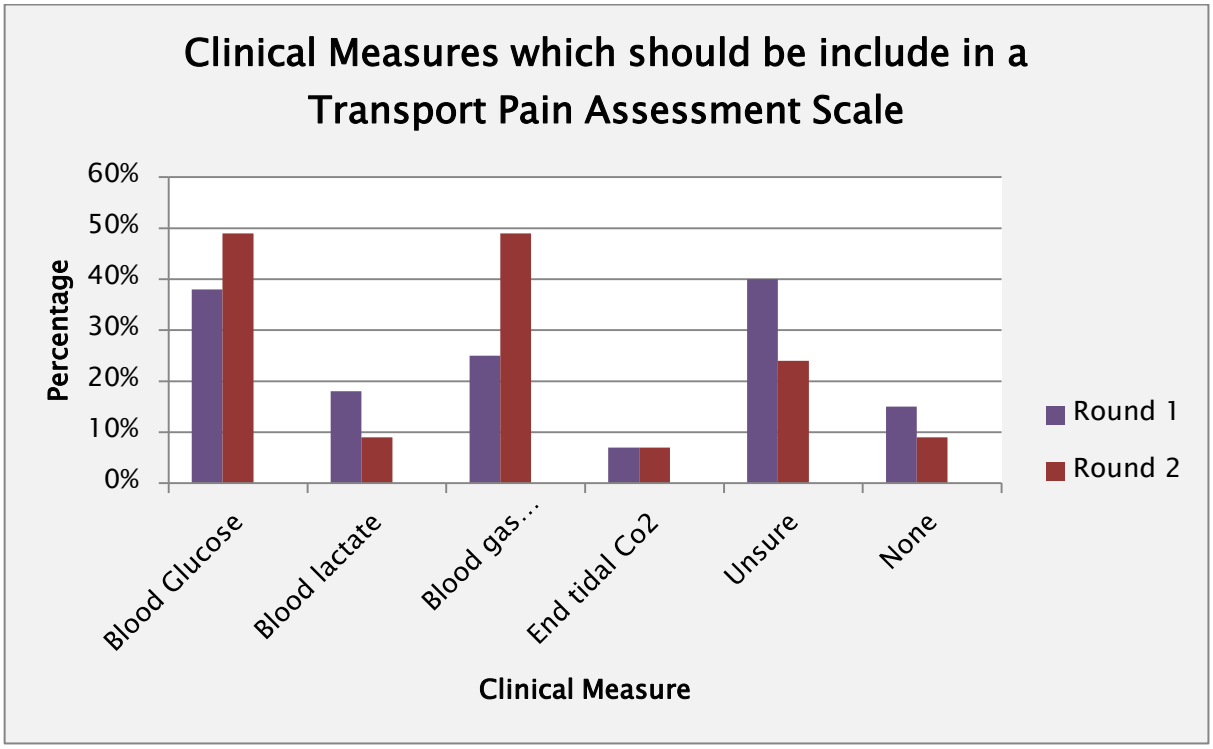
"All (physiological indicators) could be included in a pain assessment depending on the scale used" (**DS** 35)

"obviously taking into account that pain is not the only cause for changes in the above". (**DS** 36)

Section 7: Question 26-30

Which clinical measures should be included in a transport pain assessment scale?

Figure 46

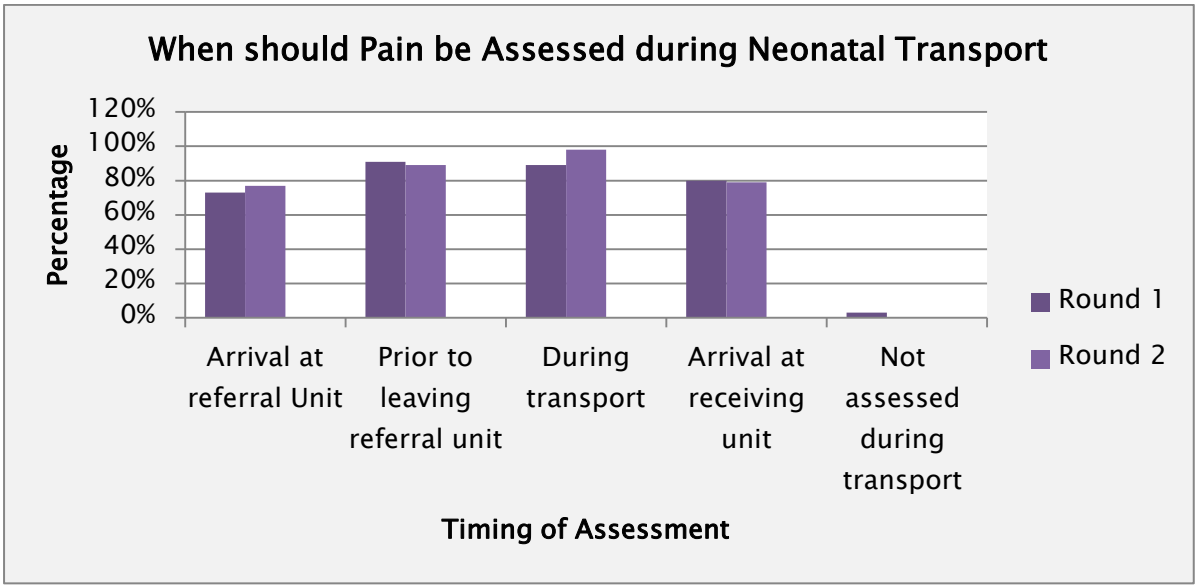


Consensus of 75% or more on clinical measures could not be agreed for items to include in the scale. Blood gas and blood glucose measurement gained a swing towards agreement for inclusion in the scale of 12% and 25% respectively. End tidal CO2 was similar in both rounds. Blood lactate received a 9% swing towards disagreement for inclusion. More participants were unsure which clinical measures to include in Round 2.

Section 6: Question 9-13

When should pain be assessed during neonatal transport?

Figure 47



	Round 1	Round 2
Responses	85	44
Skipped question	17	5
On arrival in the referral unit	73% n=62	77% n=34
Prior to leaving the referral unit	91% n=77	89% n= 39
During transport	89% n=76	98% n=43
On arrival at the receiving unit	80% n=68	79% n=35
Not assessed at all during transport	3% n=3	0% n=0

Participants were asked at which point pain should be assessed during transport. Multiple choices could be selected. When asked when pain should be assessed during transport, there was a 75% or over consensus of agreement that pain should be assessed on arrival at the referral unit, prior to leaving the referral unit, during transport and on arrival.

Section 8: Question 31-42

Behavioural items which should be included in a transport pain assessment scale

Figure 48

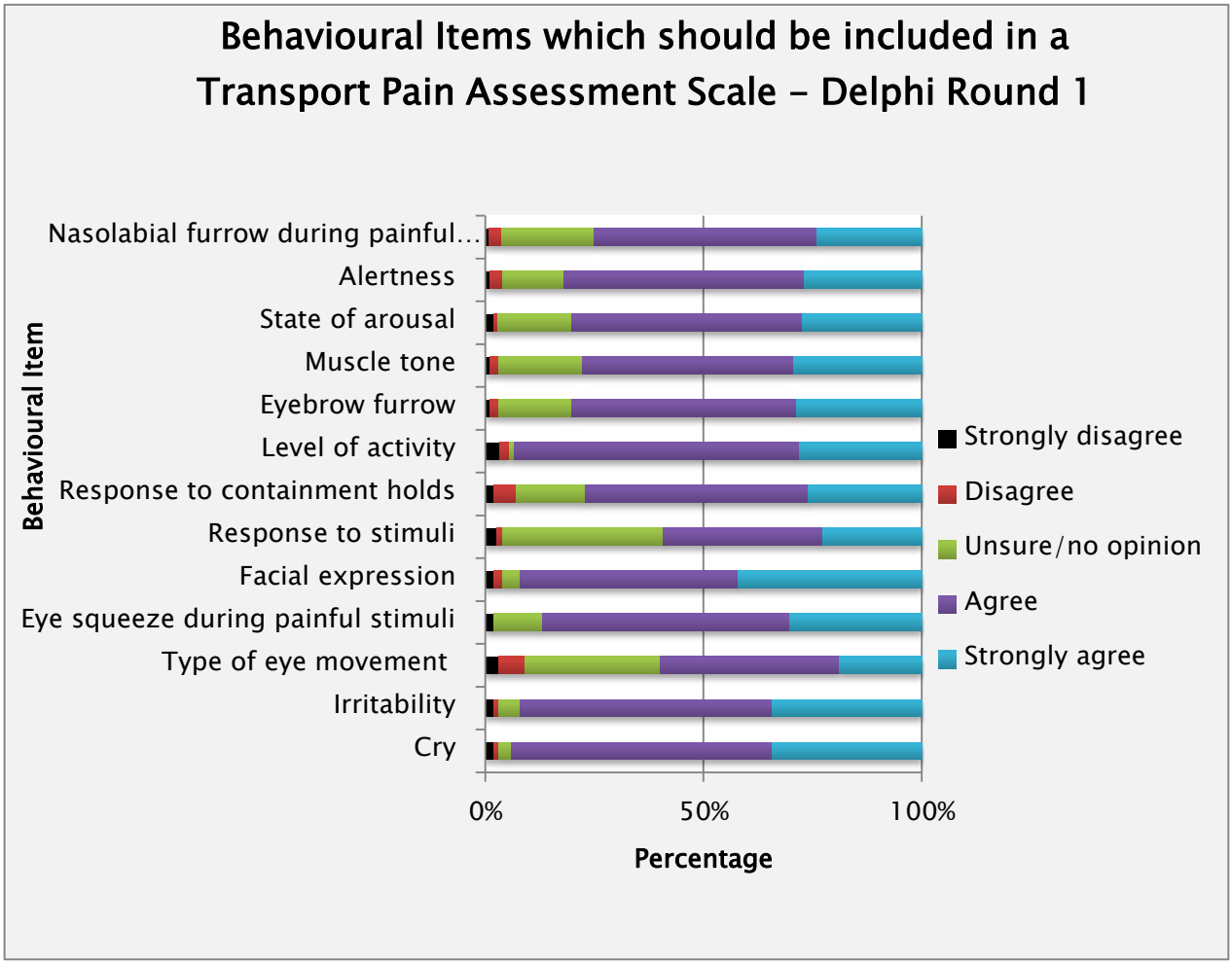
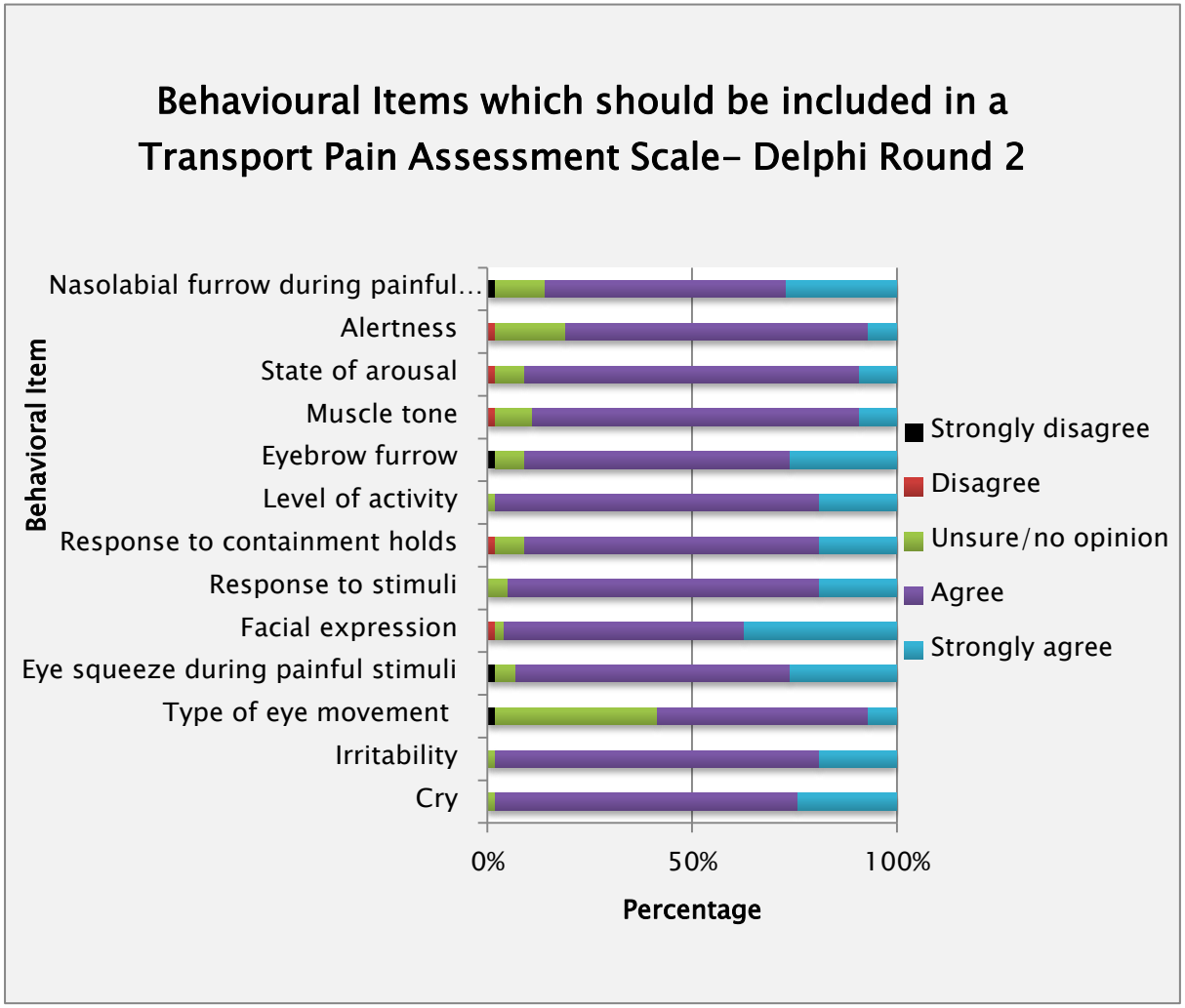


Figure 49



When questioned on behavioural items for inclusion in the scale, 12 items gained 75% or higher consensus of agreement for inclusion. These items were: cry, irritability, level of activity, facial expressions, response to stimuli, eye squeeze during painful stimuli, response to containment holds, state of arousal, eyebrow furrow, muscle tone, nasolabial furrow and alertness. The swing of consensus from Round 1 to Round 2 ranged from 14% (response to containment holds, to 1% (alertness).

One behavioural item did not gain consensus of agreement for inclusion, this was type of eye movement. This item received a 2% increase in swing towards disagreement for inclusion.

Each item received a small level of strong disagreement in Round 1 that they should be included in the scale. These were cry (2%), irritability (2%), facial expression (2%), type of eye movement (3%), eye squeeze during painful stimuli (2%), eyebrow furrow (1%), nasolabial furrow during painful stimuli (1%), response to stimuli (3%), response to containment holds (2%), level of activity (4%), muscle tone (1%), state of arousal (2%), alertness (1%).

In Round 2, there was an overall small swing away from strong disagreement with only 4 items receiving strong disagreement that they should be included. These were type of eye movement (2%), eye squeeze during painful stimuli (2%), eyebrow furrow (2%), and nasolabial furrow (2%).

Section 9: Question 43-49

Environmental factors which may influence pain assessment.

Participants were asked which environmental factors may influence the assessment of pain during transport (Figure 50, 51).

Figure 50

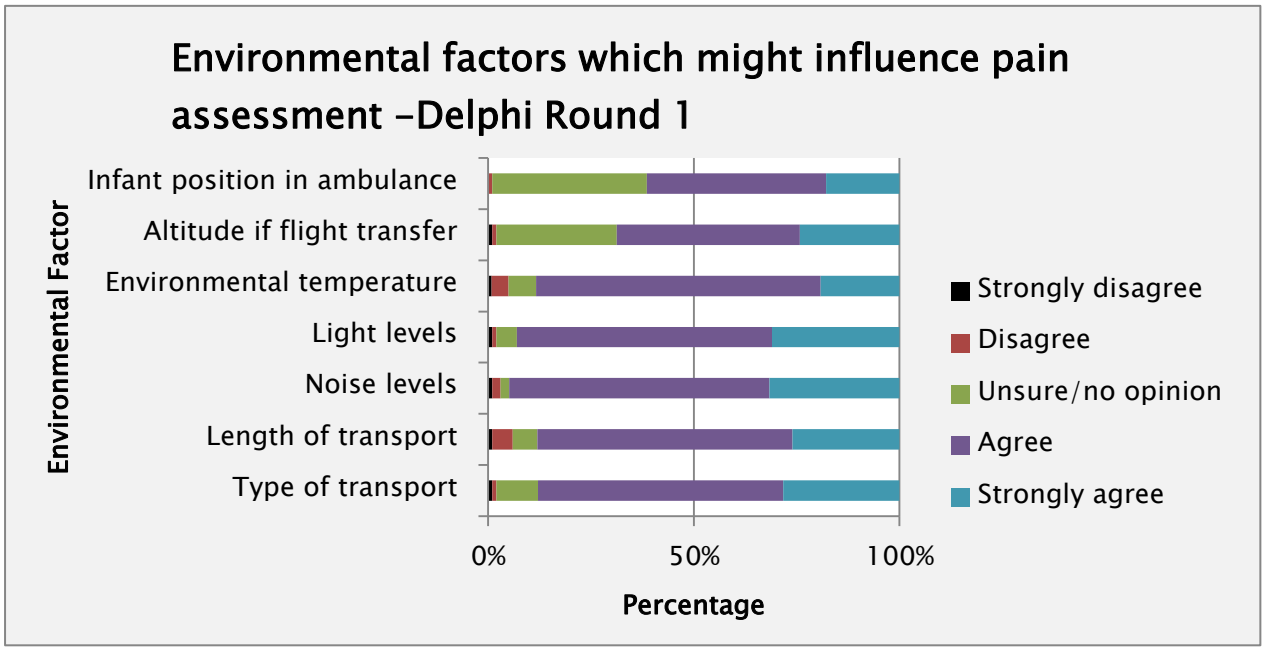
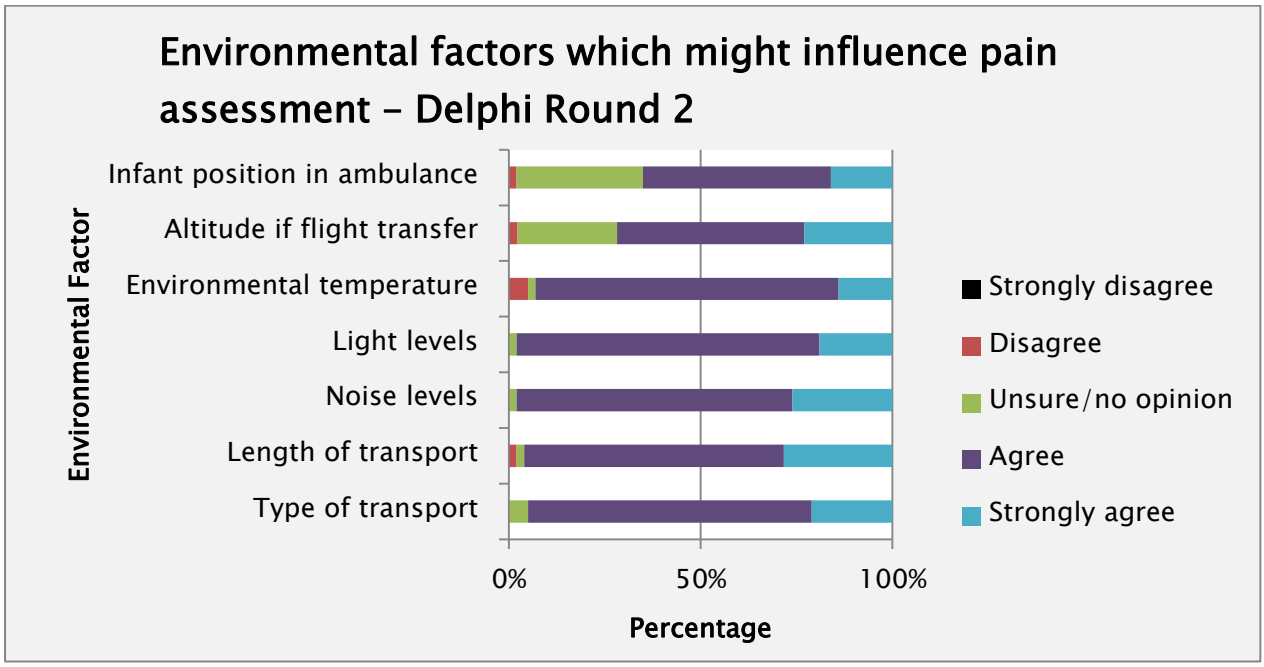


Figure 51



Results reflected a consensus agreement of 75% or more on 5 environmental items that may influence pain assessment. Items which did not gain consensus were altitude in flight transfer which received 69% consensus of agreement, and infant position in ambulance which received 61% consensus of agreement. Both items received high numbers of participants who were unsure, with altitude receiving 26% and infant position 33% of the total number.

The swing towards agreement ranged from 4% (noise levels and length of transfer) to 7% (type of transport and environmental temperature). The median precentage of swing was 5%.

Section 10: Question 50-54

Which non-pharmacological factors may influence pain assessment?

Participants were asked which non-pharmacological factors may influence pain assessment (Figure 52 and 53)

Figure 52

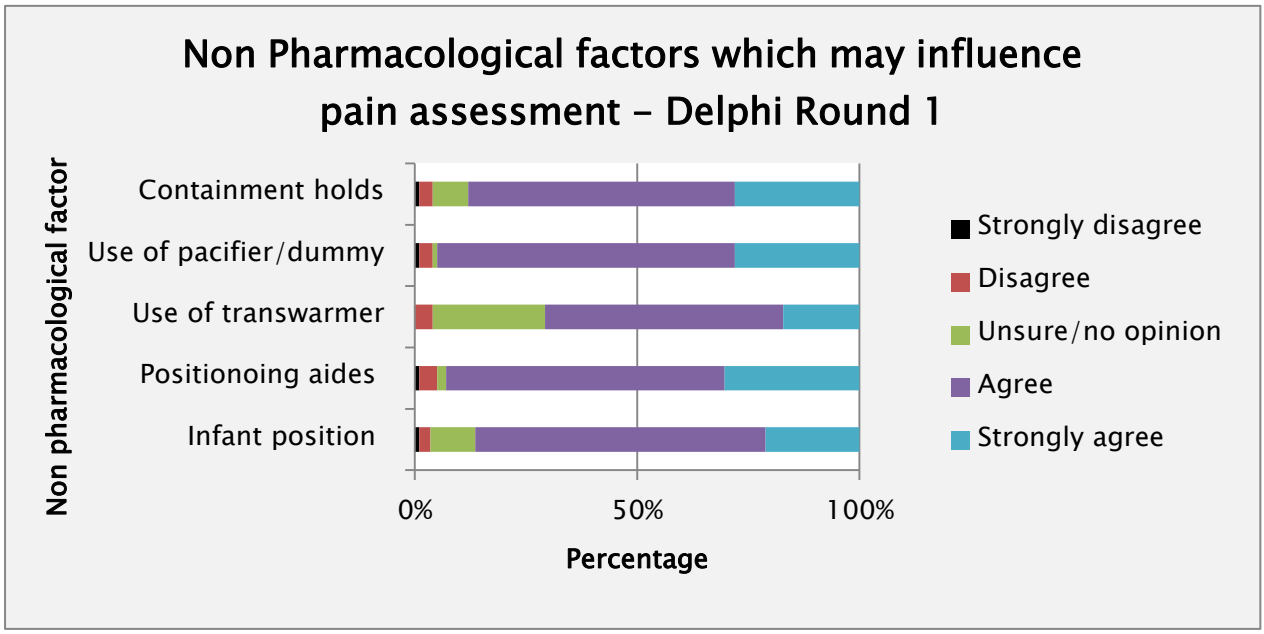
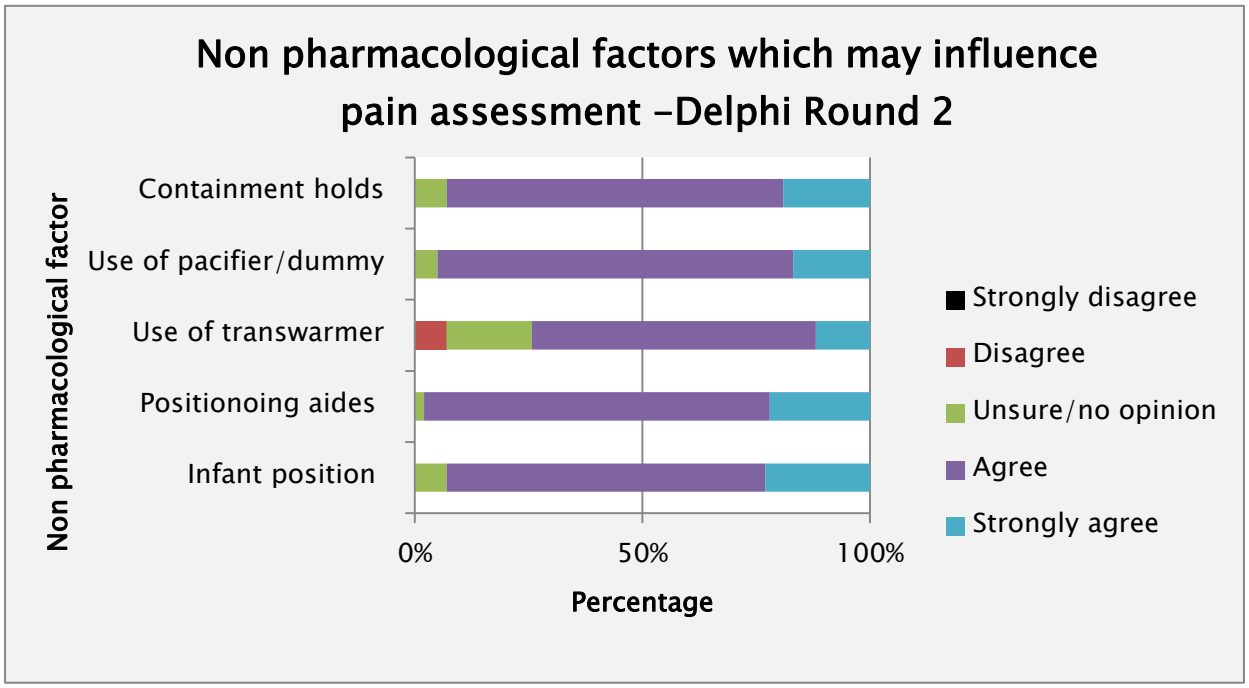


Figure 53



Each of the five items received 75% or higher consensus of agreement. The swing of agreement ranged from no change (use of pacifier/dummy) to 12% (positioning aides used). The number of items which participants disagreed with including in a scale reduced in Round 2, with one item, the trans warmer, receiving 4% level of disagreement.

Participants commented on non-pharmacological factors. The comments fell into the focus area of safety (Box 12).

Box 12 **Focus Area: Safety**

"Containment holds would be difficult from a safety point of view".	(**DS** 38)
"Logistical issues of using containment and nest and being able to visualise the baby especially in helicopter where space is a problem".	(**DS** 40)
"Use of/reliance on a pacifier not appropriate in a moving vehicle".	(**DS** 41)

The main issue surrounded providing containment holds of managing pain during transport due to the movement experienced within the ambulance or plane. This surrounded safety issues for both the baby and staff.

Section 11: Question 55-59

Which Pharmacological factors may influence pain assessment during transport?

Figure 54

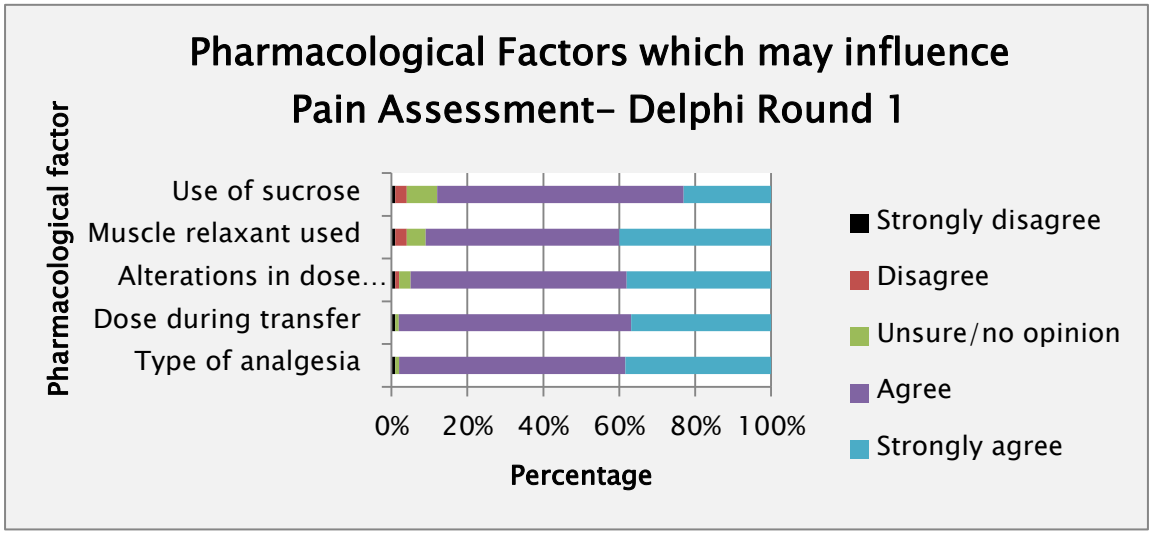
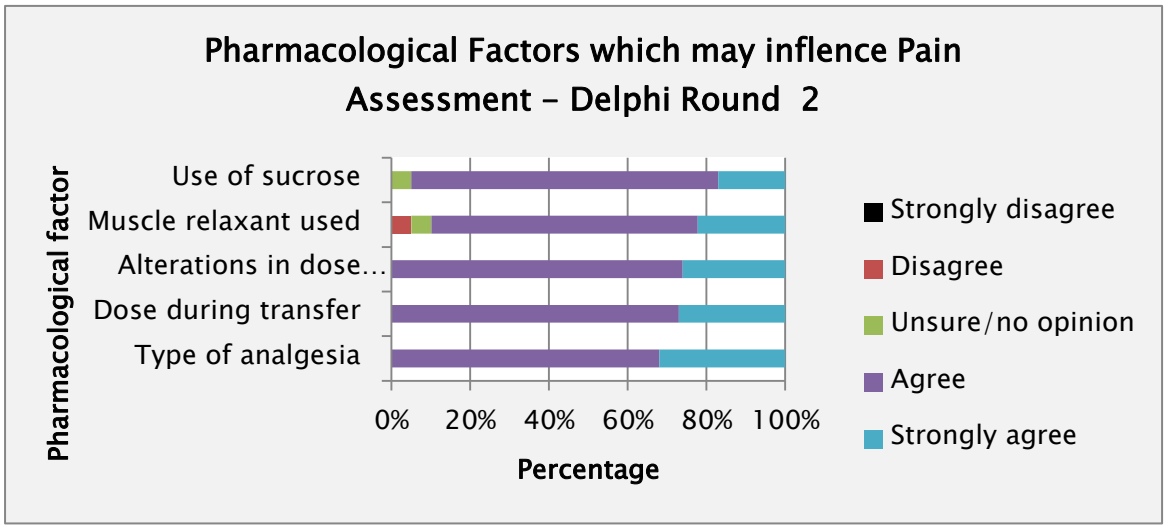


Figure 55



Five Pharmacological items received 75% or higher consensus of agreement. The swing of agreement in Round 2 ranged from 9% (muscle relaxant used) to 1% (dose during transfer). Three items received levels of disagreement in Round 1 (use of sucrose, muscle relaxant used and alterations in dose during transfer). This reduced to one item in Round 2 (muscle relaxant used).

Section12: Question 60-69

Participants were asked for their views on design and structure of the scale (Figure 56, 57).

Figure 56

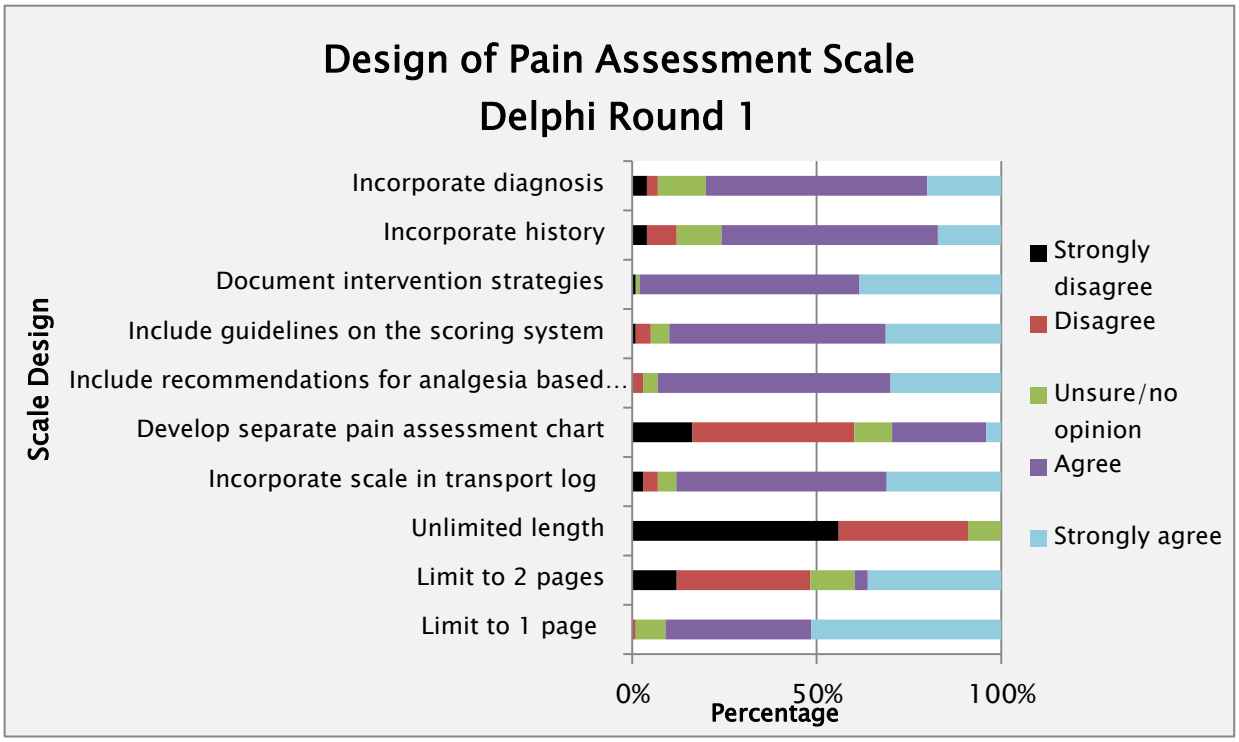
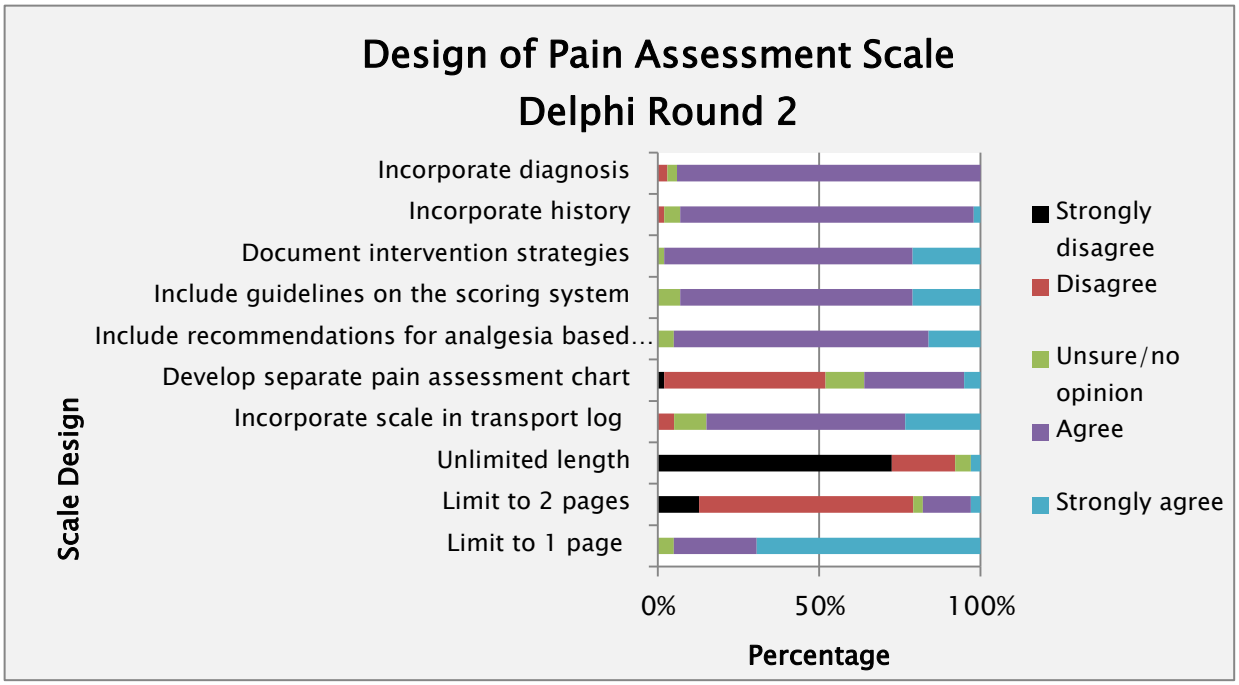


Figure 57



Design of pain assessment scale elicited 75% or more consensus of agreement in 9 of the items. Each item swung towards agreement in the second round. The level of swing towards agreement ranged from 1% (document intervention strategies following pain assessment) to 15 % (incorporate diagnosis). Three items failed to reach consensus, these included "Limit the scale to 2 pages" which gained 18% agreement, with 80% disagreeing with the statement. Also the item "unlimited length" which gained 0% agreement, with 95% disagreeing with the statement, and 5% being unsure. The final item which failed to reach consensus of agreement was "develop a separate transport pain assessment chart" which gained 35% agreement, 52% disagreement and 12% unsure. Participants reflected that a scale should be simple to use due to the environment of neonatal transport and the intensity of some of the patients being transferred (Box 13).

Box 13 **Focus Area: Design**

"Very lengthy pain assessment charts will not be useful". (**DS** 42)

"Documentation must not be so cumbersome as to distract from the general observation and care needs of the infant." (**DS** 43)

There was an emphasis on the content of the scale being "user friendly". There were also comments that some parameters may be affected by transport, but uncertainty that a separate pain scale was necessary (Box 14).

Box 14 **Focus Area: Clinical Utility**

"Documentation should be clear, concise and user friendly" (**DS** 45)

"Reflection/acknowledgement that some parameters (either behavioural or physiological) can be affected by the transport experience but a totally separate tool I am dubious" (**DS** 46)

The importance of history and diagnosis was highlighted, with an important aspect being how assessment will influence on-going management (Box 15).

Box 15 **Focus Area: Outcome**

"Incorporating history & diagnosis is surely fundamental to any plan of care, be it Unit or Transport-based, and should always inform/influence any assessment & subsequent interventions". (**DS** 48)

"Helpful as an intervention indicator" (**DS** 49)

Section12: Question 70

Should a Numerical Score be used to measure pain intensity?

When asked if a numerical score should be included in the pain score there was a consensus of 98% (n=42) agreement in Round 2 that it should, with 2% (n=1) being unsure/no opinion, n=6 skipped the question. In Round 1, 82% (n=66) agreed that a numerical score should be included, 5% (n=4) stated it should not, 12% (n=10) were unsure/no opinion, 22 skipped the question. This reflected a swing towards agreement of 16%. Participants were asked to expand on the use of a numerical score to reflect pain intensity. Responses were conflicting (Box 16, 17,18).

Box 16 **Focus Area: Outcome**

"Should always inform/influence any assessment & subsequent interventions". (**DS** 48)

"Helpful as an intervention indicator" (**DS** 49)

Box 17 **Focus Area: Content**

"Numerical scoring currently appears to offer a quick identifiable guide to pain" (**DS** 52)

Box 18 **Focus Area: Clinical Utility**

"*Pain scoring is subjective during the best of conditions*". (**DS** 53)

"Transport has too many variable factors to base clinical interventions on a set numerical score". (**DS** 54)

"Individualised care would be more appropriate". (**DS** 55)

"Difficult to generalise the type of pain assessment score". (**DS** 58)

Some respondents stated that a numerical score was "too subjective", however others stated that this would provide a trend and ensure consistency. It was also highlighted that scores inform interventions, and are an important part of pain assessment. It was also stated that it was important that clear guidance was given as to on-going management at regular intervals. The importance of individualised care was emphasised, with concern being raised regarding utilising numerical scores for pain management.

Section 12: Question 71

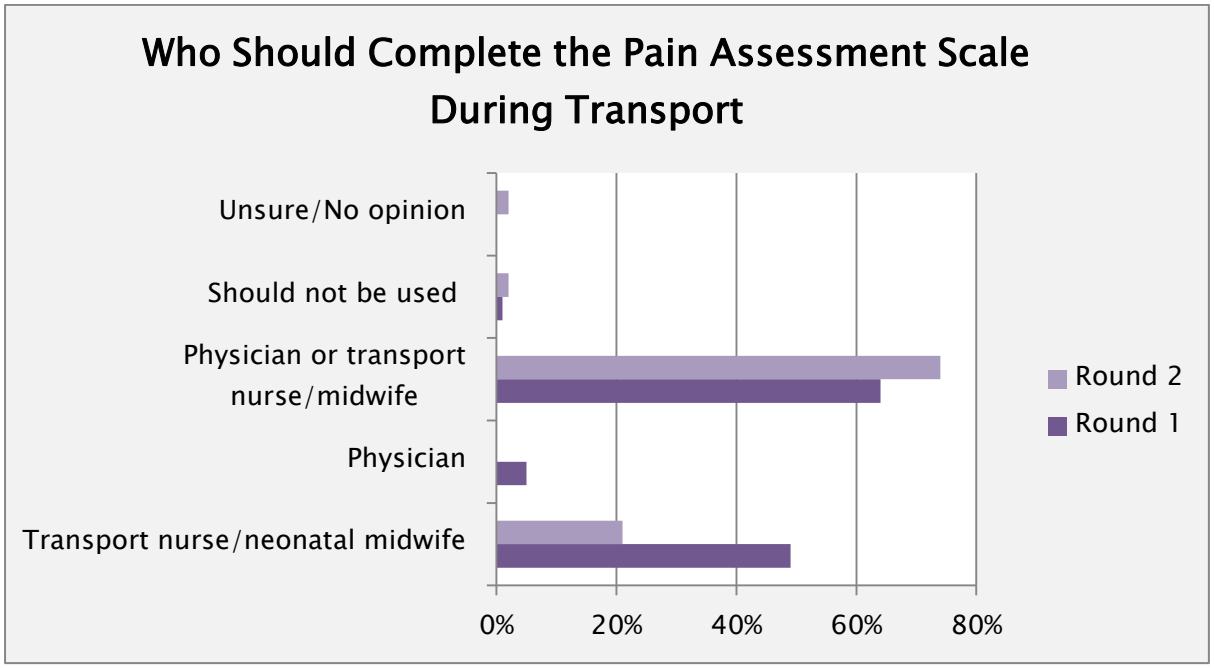
Would an Algorithm to Guide Pain Management be Effective?

In relation to inclusion of an algorithm to guide pain management, a consensus of 98% (n=41) in Round 2 stated that it should be included, with 2% (n=1) unsure, n= 7 skipped the question. In Round 1, 75% (n=58) agreed that it should be included, 10% (n=8) disagreed that it should be included, 15% (n=12) were unsure/no opinion, n=24 skipped the question. Results reflected a swing of 23% towards consensus of agreement that it should be included.

Section 13: Question 72-75

Who Should Complete the Pain Assessment Scale?

Figure 58



In relation to who should complete the pain assessment scale during transport, 75% (n=32) of participants who responded to this question in Round 2 agreed that the physician or transport nurse/midwife should complete the scale, this was a swing towards agreement of 11 % from results in Round 1.

In Round 2, 21% (n=9) of those who responded to this question agreed that only the transport nurse/neonatal midwife should complete the scale, reflecting a swing of 28% towards disagreement from results in Round 1.

Section 13: Question 76

Should Recommendations on Pain Management be Included in the Pain Scale?

When questioned if recommendations on pain management should be included in the scale, a 95% (n=41) consensus of agreement was achieved in Round 2, with (n=1) unsure, (n=1) no, 6 skipped the question. This was a swing towards consensus of agreement of 2% from results in Round 1.

Section 13: Question 77

Should Clinicians be trained on how to use the Scale?

In relation to training on how to use the scale, a consensus of 98% (n=42) in the final round agreed that clinicians should be trained on how to use of the scale, (n=1) unsure and 6 skipped the question. This was a swing towards consensus of agreement of 3% from results in Round 1.

Section 14: Final Comments

Participants were given the opportunity to comment on any aspect of pain assessment during transport or to expand on previous topics.

- **Theme of Safety**

Under the Theme of safety, participants reflected the view that the nature of the transport environment such as movement/noise etc. made clinical assessment difficult for clinicians to achieve safely (Box 19). During transport the infant is secured in the incubator and the transport clinicians are seated for safety reasons in the event of sudden movements in the ambulance or aircraft. This was presented as providing an obstacle to assessment. The question of prioritizing care was also highlighted as an important issue, with infants requiring transfer being frequently very unstable, requiring rapid assessment and efficient transfer. Pain assessment was reflected by some of the participants as not always being the priority during a transfer, with clinical stability such as securing the airway taking priority.

It was also suggested that pain assessment and management should be carried out before leaving the referral unit, and should not be considered during the journey.

Box 19 **Focus Area: Safety**

"Of course pain assessment is always relevant but whether it can be prioritised when stabilisation and tranferring out are the main priorities I think is a difficult question". (**DS** 57)

"majority of infants transported to us are very sick and have come for stabilisation or surgical referral". (**DS** 59)

"I think a pain assessment tool is essential for safe neonatal transport". (**DS** 60)

"I still believe that an assessment of the baby's level of pain should be made before the baby leave the referral hospital and that adequate analgesia be given then". (**DS** 62)

"Transports are not with their own risk and have to consider analgesia mid journey I believe is unacceptable". (**DS** 63)

- **Focus Area: Clinical Utility**

Within the focus area of clinical utility, pain was stated to be difficult to assess within the transport environment. It was reflected that pain tools could not be generalized and therefore not used with every transport, with instability of the infant being emphasized as a precluding factor in pain assessment. Participants reflected that pain tools in the clinical area were unsuitable and not very "user friendly". However some comments adopted a conflicting view in that they stated a universal tool should be adopted for both transport and the clinical area, the success of a pain tool was suggested as being related to how "usable" the tool was, how relevant it is to the population and the extent to which it effects management (Box 20).

Increasing workload and "over formalising " pain assessment was also suggested as potentially being a disadvantage to implementing a pain scale during transport, with a definitive score potentially being too restrictive in the assessment and management of pain.

Box 20 **Focus Area: Clinical Utility**

"difficult area to assess due to minimal handling during transport, with limited access to the baby". (**DS** 56)

"Very difficult to assess due to the multiple influencing factors and levels of instability of the neonates transferred". (**DS** 65)

"I think we do need to assess pain and deal with it, but I don't think we need to make more work for ourselves by formalizing and over-analyzing it". (**DS** 69)

"Use of pain scores and pain management strategies is grossly under used in neonatal units many "tools" are over long complex and confusing & not very user friendly". (**DS** 70)

"Great idea but needs to be succinct as there is usually a lot of paperwork to complete on transports in a limited time". (**DS** 71)

"Choose one of these (existing tools) and test its validity and reliability as well as clinical utility in transport". (**DS** 72)

"Transport is a very different environment and many factors make "classic" pain assessment tools unusable". (**DS** 84)

"*Different circumstances of each transport would make a definitive score and treatment options too restrictive".* (**DS** 86)

- **Content**

Statements which fell into the focus area of content reflected that the content of a pain scale should not be too complex. Expressing concern that pain assessment may become too detailed and complex. Some comments also reflected that the pain scores currently in use in the clinical area are often very confusing and lengthy. Concerns were expressed that a transport pain scale should not be time consuming with overly complex content.

- **Design**

In relation to the focus area of Design, respondents reflected that it may be appropriate to use an existing scale and adapt it to transport (Box 21). This may provide continuity between transport and the clinical area. Further comments expanded on this suggesting that adapting a scale would reduce confusion and ease training, also that a scale may be combined with current observation chart to reduce paperwork and enhance continuity.

Box 21 **Focus Area: Design**

"We already have quite a lot of paperwork so I think it would be best if it was combined onto the observation chart". (**DS** 75)

"It would be helpful to have a similar format of commonly used neonatal pain tools". (**DS** 76)

"Tools need to be transport specific simple to use not just a paring down of existing unit based tools". (**DS** 83)

"Simplicity when designing the scale will help in users using it effectively Training/education of all personnel prior to implementing". (**DS** 78)

- **Outcome**

Participants reflected that pain is often inadequately assessed and managed, emphasising that it should be a formal part of the transport service. Further comments highlight the need for a specifically developed scale for transport, however opposing views expressing the opinion that due to the differences in each transport individualized methods of assessing pain are more appropriate, with a pain scale being too specific and not generalizable (Box 22).

Box 22 **Focus Area: Outcome**

"I strongly believe in good pain assessment and treatment of pain. We have discussed the use of a pain tool within our transport team, but the general feeling was that pain is assessed on transport as part of our overall assessment".

(**DS** 79)

"Should be a universal assessment tool used in all the neonatal units as well". (**DS** 66)

"Enables consistency when the babies are admitted". (**DS** 73)

5.6 First Draft of the Neonatal Transport Pain Assessment Scale (NTPAS)

At this stage in the research process it was important to carefully apply results of the Delphi study in order to inform the content and structure of the transport pain scale. The following section will provide an overview of how results informed development of the scale. For the purpose of analysis, the Delphi Items (DI) from the Delphi questionnaire were numbered (DI 1-76) and can be reviewed in Tables 6-15. The Delphi statements (DS) from the Delphi panel open text responses to the questionnaire were allocated numbers (DS 1-86), a sample transcript of these statements can be reviewed in Appendix 13 and an example of the Delphi Statements presented in order of the allocated Delphi Statement number (DS 1-86) in Appendix 13.1. Both the Delphi Items (DI) and Delphi Statements (DS) were included in the following section within the appropriate text in order to justify development of the transport pain scale.

5.6.1 Integration of Results to Development of the Transport Pain Scale

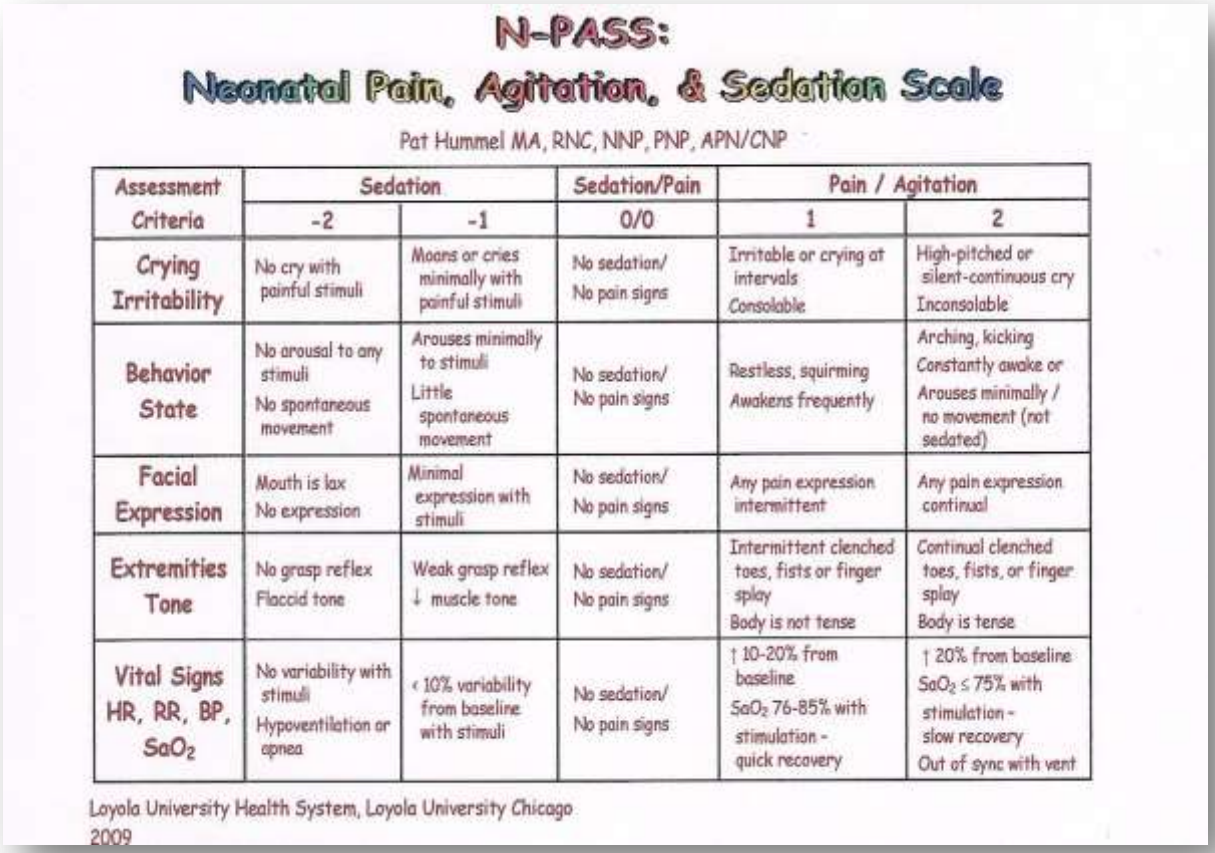
The results of Phase Two of the study and the outcome of Chapters Two and Three were combined and analysed to inform the content, structure and design of a pain assessment scale specific to neonatal transport. Chapter Two provided an overview on the complex issues associated with neonatal pain, highlighting specific challenges in relation to pain assessment during transport such as the physiological effects on the neonate. A review of literature on available pain assessment scales in Chapter Three reported no currently available scale adapted and tested in the transport setting, however multidimensional scales were reported to be the most appropriate to the neonatal population due to the variety of different pathologies which could be encountered in the neonatal period.

Furthermore the benefits of assessing both pain and sedation in this population was also reflected by the Delphi panel (Chapter Five), with the recommendation to adapt an existing validated clinical scale as opposed to structuring a completely new scale. The reasons given were to avoid confusion, promote continuity of pain assessment between the clinical area and transport, and assist reliability and validity.

The literature review (Chapter Three) reported only one neonatal pain assessment scale which assesses both pain and sedation, this was the Neonatal Pain, Agitation and Sedation Scale (N-PASS) (Hummel et al. 2008). This scale had been validated for use in the neonatal setting with both ventilated and non-ventilated, term and preterm neonates, therefore from this perspective would be appropriate for adaptation to transport.

The N-PASS scale (Figure 59) was subsequently taken forward for adaptation to the transport setting utilising results of the Delphi study in Phase Two. It was however important to ensure that the foundations of the NTPAS scale remain constant and true to the original N-PASS scale, which has been validated in the clinical setting.

Figure 59 N-PASS: Neonatal Pain, Agitation and Sedation Scale



N-PASS:

Neonatal Pain, Agitation, & Sedation Scale

Pat Hummel MA, RNC, NNP, PNP, APN/CNP

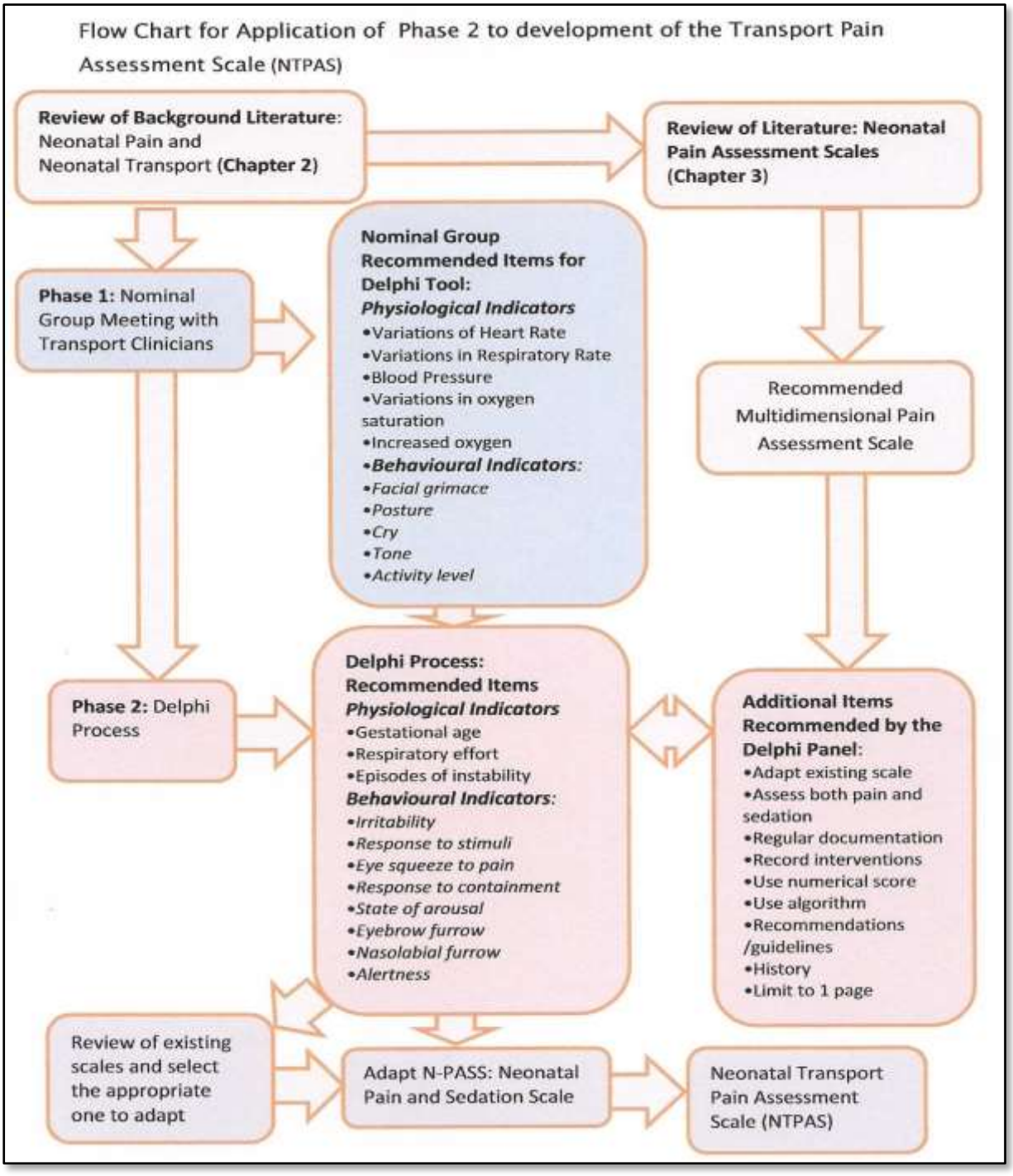
Assessment Criteria	Sedation		Sedation/Pain	Pain / Agitation	
	-2	-1	0/0	1	2
Crying Irritability	No cry with painful stimuli	Moans or cries minimally with painful stimuli	No sedation/ No pain signs	Irritable or crying at intervals Consolable	High-pitched or silent-continuous cry Inconsolable
Behavior State	No arousal to any stimuli No spontaneous movement	Arouses minimally to stimuli Little spontaneous movement	No sedation/ No pain signs	Restless, squirming Awakens frequently	Arching, kicking Constantly awake or Arouses minimally / no movement (not sedated)
Facial Expression	Mouth is lax No expression	Minimal expression with stimuli	No sedation/ No pain signs	Any pain expression intermittent	Any pain expression continual
Extremities Tone	No grasp reflex Flaccid tone	Weak grasp reflex ↓ muscle tone	No sedation/ No pain signs	Intermittent clenched toes, fists or finger splay Body is not tense	Continual clenched toes, fists, or finger splay Body is tense
Vital Signs HR, RR, BP, SaO_2	No variability with stimuli Hypoventilation or apnea	< 10% variability from baseline with stimuli	No sedation/ No pain signs	↑ 10-20% from baseline SaO_2 76-85% with stimulation - quick recovery	↑ 20% from baseline $SaO_2 \leq 75\%$ with stimulation - slow recovery Out of sync with vent

Loyola University Health System, Loyola University Chicago 2009

Hummel et al. (2008)

Permission was obtained to reproduce the scale from the authors of the N-PASS prior to application of the results. An overview of the complex process involved in application of results to development of the scale can be reviewed in the following flow chart (Figure 60).

Figure 60 Development of the Neonatal Transport Pain Assessment Scale



5.6.2 Focus Areas Applied to Development of the Pain Scale

The five primary focus areas applied to construction of the Delphi questionnaire (Chapter Four) were also utilised in development of the first draft of the transport pain scale. This facilitated development of all aspects of the scale in line with the recommendations of the Delphi panel.

The five primary focus areas as describes in Chapter Four included:

- **Safety**
- **Content**
- **Clinical utility and feasibility**
- **Design**
- **Outcome**

The Delphi items (DI) (Tables 6-15) and Delphi statements (Appendix 13.1) from the open text responses to the Delphi questionnaire are referred to within the appropriate text in the next section of this Chapter.

- **Focus Area: Safety**

The focus area of 'Safety' was highlighted in Phase Two and was threaded throughout the study, being perceived as a crucial consideration of a transport pain scale. The Delphi panel reached overall consensus that pain should be assessed during neonatal transport (DI 1) furthermore that a pain assessment scale should be used to assess pain during transport (DI 4), reflecting that pain assessment facilitates a safer transfer for the baby (DS 2).

The Delphi panel reached consensus of agreement that a pain assessment scale should be used to ensure appropriate pain management with all surgical babies (DI 3), those requiring analgesia (DI 2), mechanical ventilation (DI 5), muscle relaxed (DI 6) and those who are neurologically compromised (DI 7).

Therefore a scale selected for adaptation to transport would have to be appropriate for each of these specifications or would require further development for transport. As a result of this specific additions were made to adapt the N-PASS scale to transport (DS 76, 77) in line with results of the Delphi panel. Therefore on review of the N-PASS additional scores (+1) were given in the following circumstances which were perceived to be an additional cause of stress/pain to the baby;

- the baby was within 24 hours post-operative (Figure 40, DS 74),
- the transport was longer than one hour (DS 74)
- the transfer was turbulent or bumpy (DS 7, Figure 51, 52)

This was further expanded by some of the Delphi panel, stating that analgesics should be given during the transport if required to facilitate a safe transfer, with continued monitoring of physiological signs (DS 21). However in relation to babies who are muscle relaxed (DI 6) and those who may be neurologically compromised (DI 7), comments made by some of the Delphi panel suggested that assessing these babies could be difficult (DS 15, 17) primarily due to the potential absence of behavioural indicators of pain, therefore this is referred to in the information sheet which accompanies the pain scale with recommendations. A further element highlighted by the Delphi panel was safety in relation to staff. As transport occurs in moving ambulances and helicopters staff will be mainly seated, therefore would be unable to contain or handle the baby for large periods of time during the transfer (DS 39, 40, 41). Limited access for staff was also reported resulting in minimal handling during the transfer making assessment difficult (DS 61). As a result of these issues the new scale contained only observational assessment requiring no 'hands on' review by clinicians.

The Delphi process also provided the opportunity for conflicting views to evolve. It was reflected that pain assessment is important (DI 1), but not always the priority with some sick babies when stabilisation may take priority (DS 57, 61).

A further view expressed suggested that transport had its own risks and pain should not be assessed mid transport (DS 63) but carried out before leaving the referral hospital (DS 62), however an opposing view stated that using a pain assessment tool throughout transport is essential for a safe transport (DS 60).

Table 18 **Summary of recommendations in relation to focus area of safety**

• Pain scale should be used with: surgical babies / medical babies/ those requiring analgesia / neurologically compromised babies / muscle relaxed babies • Include additional recommendations for those difficult to assess e.g. muscle relaxed/neurologically compromised • Additional (+1) score for: less than 24 hours post-operative transport longer than one hour turbulent or bumpy transfer • Observational assessment only

- **Focus Area: Content**

The focus area of content encompassed both indicators of pain and structure of the pain scale, however the Delphi panel viewed that the issue of content of the scale was potentially difficult as it could be subjective (DS 6). This was also highlighted in the NGT serial discussion (Appendix 12), reflecting that pain assessment may be dependent on individual perceptions of pain. In relation to content, the inclusion of physiological indicators of pain to monitor any variations in the clinical stability of the baby also underpinned safety during transfer. The NGT in Phase One of the study proposed five physiological indicators of pain for inclusion in the Delphi tool (Figure 32, 33). There was less opportunity for participants to conceptualise in the NGT process, with the aim being to identify specific items to include in the Delphi tool. Therefore within these boundaries items selected by the NGT meeting were practical and specific.

The five physiological items suggested by the NGT (Appendix 12.1) were perceived by clinicians to be easy to monitor during transport, and would give an immediate indication of changes in cardiovascular or respiratory status. It would also give an indication of any technical problems during transport with the equipment, as variations would alert staff to troubleshoot for problems. This recommendation was supported by Barry and Leslie (2003), who stated that standard minimal parameters which should be monitored during transport including heart rate with a visible ECG (electrocardiograph), oxygen saturation, temperature and blood pressure. The role of physiological parameters in neonatal pain assessment was also supported in the empirical literature (Chapter Two) and further explored in the review of physiological measures of assessing neonatal pain (Appendix 3). The physiological indicators of pain recommended by the NGT for inclusion in the Delphi tool achieved consensus by the Delphi panel for inclusion in the pain scale (DI 9,10,11,14) with the addition of episodes of instability, gestational age and respiratory. However it was also highlighted that physiological changes may not always be due to levels of pain and that other factors should be take into consideration (DS 26, 31).

The Delphi panel reflected that integration of structured physiological assessment to the scale would ensure clinical stability throughout the transport. The N-PASS scale (Hummel et al. 2008) included a section containing assessment of vital signs, including heart rate, respiratory rate, blood pressure and oxygen saturation. These physiological measures were recommended for inclusion in the transport scale, therefore were included in the new NTPAS scale. The format however was adapted to reflect levels of oxygen desaturation (DI 14) and respiratory effort made by the baby (DI 13). Results of Phase One also recommended five behavioural items for inclusion in the Delphi tool (Figure 32), suggesting that the overall assessment of pain and therefore stability of the baby during transport was enhanced by the inclusion of behavioural items.

The brief serial discussion (NGT Step 3) provided an insight into the group perceptions on issues around the cause of changes in these parameters and how this related to pain (Appendix 12), also the relevance of different disease processes which may cause pain. The Delphi panel expanded on the behavioural indicators of pain, achieving consensus on the addition of irritability (DI 22), response to stimuli (DI 25), eye squeeze to pain (DI 26), state of arousal (DI 27), eyebrow furrow (DI 28), nasolabial furrow (DI 30) and alertness (DI 31, Figure 48, 49). However the Delphi panel reflected that some babies may not display behavioural signs, possibly due to the fact that the baby may be ventilated, or neurologically compromised, also due to the effect of drugs which may be administered during the transport. Type of eye movement was the only item rejected by the Delphi panel for inclusion in the scale (DI 32). A summary of recommendations for the pain scale under the focus area of content can reviewed in Table 19.

Table 19 **Summary of recommendations in relation to focus area of content**

•Pain scale should include physiological indicators: Variations in heart rate (DI 9) Variations in blood pressure (DI 10) Variations in oxygen saturation (DI 14) Work of breathing/respiratory effort (DI13) Respiratory rate (DI 11) Episodes of instability (DI 12)
•Pain scale should include behavioural indicators: Cry (DI 21) Tone (DI 29) Activity level (DI 23) Irritability (DI 22) Response to stimuli (DI 25) Eye squeeze to pain (DI 26) State of arousal (DI 27) Eyebrow furrow (DI 28) Nasolabial furrow (DI 30) Alertness (DI 31)

- **Focus Area: Clinical Utility and Feasibility**

The concepts of feasibility and clinical utility are sometimes used interchangeably (Stevens and Gibbons 2002), however generally feasibility refers to the ease within which the clinicians can apply the tool in the clinical setting whereas clinical utility refers to the ability to use the results of the tool in a useful or informative way in the clinical setting (Duhn and Medves 2004). Issues around clinical utility emerged more frequently in the Delphi process than the nominal group process, this again can be perceived as being due to Delphi providing the opportunity for panel members to conceptualise and review their judgements. This would be relevant to clinical utility as this concept reviews the perception of panel members on the usefulness of the scale during transport.

The Delphi panel perceived clinical utility to be one of the most important elements of the scale due to the extreme environment within which the pain assessment scale would be used (DS 64). Statements from the Delphi panel were conflicting in that the view was expressed that using a pain scale may not be practical or make a difference in the transport setting (DS 9, 10, 11). However it was also stated that pain assessment should be carried out and acted on accordingly whatever the situation (DS 13). The Delphi panel reached consensus that environmental factors such as light levels (DI 33), noise levels (DI 34), type of transfer (DI 35) and length of transfer (DI 37) all may influence pain assessment. However despite the Delphi panel reaching consensus that type of transfer affects pain assessment, they failed to reach agreement that altitude during a flight transfer or the infants' position in the ambulance would influence the stability of the baby and the assessment of pain (DI 38, 39) despite acknowledgment of this in transport literature (Barry and Leslie 2003). This may have been due to a lack of experience of flight transfer or a lack of knowledge on the effects of altitude.

The Delphi panel reached consensus that pharmacological factors may influence pain assessment therefore should be considered and documented, such as the use of sucrose to alleviate pain (DI 49), if a muscle relaxant is used (DI 48), type of analgesia used (DI 45), the dose and any alterations in dose during transport (DI 47, Figure 55, 56).

Delphi provided the opportunity for participants to consider in detail the clinical utility and feasibility of issues such as the frequency of documenting observations (DS 1), the timing of observations and the importance of having baseline observations (DS 18, DI 40-43). The Delphi panel agreed that pain should be assessed prior to leaving the referral unit, during transport, and on arrival at the receiving unit (DI 40-43). Furthermore barriers to utilising physiological indicators was highlighted by the Delphi panel such as the effect of other influencing factors within the transport environment on physiological pain indicators (DS 26), emphasising the difficulty in quantifying pain in an unstable baby during transport (DS 24). Factors such as light, noise and type of transfer were reported by the Delphi panel as being influencing factors on pain assessment (DI 33-37). Therefore with consideration of the above recommendations sections were included in the new scale for documented observations at appropriate times during the transport with space for comments and length of transfer also being included in the scale.

It was stated that it was important that the scale worked well and consistently (DS 8), with the overall success of the scale being directly related to its usability or ease of use (DS 67). It was reflected by the Delphi panel that the scale should be easy to use and applicable to a wide population of neonates due to the diversity of the patients being transferred (DS 45). Assessing both pain and sedation was also highlighted, as many babies would be receiving analgesia and sedation prior to transfer (DS 13). It was also suggested that adapting an existing scale may be more appropriate than developing a completely new scale (DS 72).

The reasons given were the wide diversity of scales available, and that it may be less confusing for staff if a scale they were familiar with was adapted to the transport setting. It was also reflected by the Delphi panel that a scale should be practical, clear and succinct (DS 45). Due to the physical constraints during transport access to the baby is difficult, with observations and assessments being largely visual by means of observing the infant and the monitoring equipment. The Delphi panel also reached consensus that how the baby was positioned in the incubator (DI 50), the use of positional aides (DI 51), use of a trans warmer (DI 52), use of a dummy (DI 53) and containment holds (DI 54) should all be considered. Therefore the area provided in the scale for open text review at regular intervals provided the opportunity for these to be added. As some Delphi panel participants reflected that they were expert at assessing babies and previously used their own judgment and knowledge base to assess pain (DS 80), a visual analogue scale was included as an additional pain marker for comparison or in conjunction with the NTPAS to facilitate application of their perceptions of the pain intensity during transport.

The combination of pain and sedation appeared complex in the N-PASS, therefore to ensure a simple format (DS 70) both pain and sedation were separated as this appeared easier to read and interpret. The NTPAS was also colour coded to separate pain and sedation in order to make reading the scale easier during transport. The scoring system was also simplified for the transport setting, the N-PASS included negative scoring for sedation, this appeared complex and therefore the NTPAS contained only positive scoring.

Table 20 **Summary of recommendations in relation to focus area of Clinical Utility / Feasibility**

- Include type of transfer (DI 35) and length of transfer (DI 37).
- Document the use of sucrose (DI 49), muscle relaxant (DI 48), type of analgesia used (DI 45), the dose and any alterations in dose (DI 47, Figure 55, 56).
- Assess pain prior to leaving the referral unit, during transport and on arrival at the receiving unit (DI 40-43).
- Document position in the incubator (DI 50), the use of positional aides (DI 51), use of a trans warmer (DI 52), use of a dummy (DI 53) and containment holds (DI 54) in the comments section.
- Include a visual analogue scale as an additional pain marker for comparison or in conjunction with the NTPAS to facilitate application of their perceptions of the pain intensity during transport.
- Separate pain and sedation and utilise colour coding to make it easier to read and interpret.
- Simplify the scoring system to include only positive scoring.

- **Focus Area: Design**

Design of the scale encapsulated elements of content and structure, acknowledging the issues of feasibility and clinical utility which have been a constant thread throughout the research. The Delphi panel had the opportunity to consider in detail the design of the scale and reached consensus that the length of the scale was important (DI 58), as a lengthy complicated scale would be impractical in the transport setting. The Delphi panel also reached consensus that the scale should be limited to one page (DI 58) and incorporated within the transport log (DI 62, Figure 57, 58).

It was also important to highlight the importance of a simple, uncomplicated design which is easily completed and applied to the setting (DS 37). An important factor was that the pain assessment scale should not distract clinicians from the general observation of the baby during transport (DS 43). However the Delphi panel reflected that the design should integrate and have sections for important elements such as the history (DI 61), interventions strategies (DI 63) and guidelines for the scoring system (DI 60, Figure 57, 58). It was stated the most critically ill babies need to be observed constantly during transport with on-going documentation of observations, and this should be reflected in the size and design of the pain assessment scale. However the Delphi panel concluded that it would be beneficial to have a similar design to current pain scales in order to reduce confusion (DS 76), with simplicity being an important element (DS 78).

Design of the scale was important for clinical utility and feasibility during transport. Some clinicians preferred a separate transport scale to be used in conjunction with the main transport log (Figure 57, 58), whereas other clinicians stated that the scale should be integrated as part of the transport log to reduce paperwork (DI 62, DS 75). Therefore two options were designed and can be viewed at the end of this Chapter, one landscape (Figure 61) and one portrait (Figure 62), with the option that the portrait would be easier to integrate into the transport log. The content in each of the two options were the same with the layout altered in relation to the page orientation.

Furthermore in relation to design, different colour codes for pain and sedation were included, this was in an attempt to make the different elements of the scale immediately recognizable to the reader. The use of bold text and different fonts were also utilized to make the scale easier to read.

In addition to the physiological and behavioural indicators, the Delphi panel also reached consensus that a numerical score should be utilized (DI 55) which would reflect the level or intensity of pain (DS 52).

Table 21 **Summary of recommendations in relation to focus area of Design**

• limit to one page (DI 58) and incorporate within the transport log (DI 62, Figure 57, 58).
• Include sections for important elements such as the history (DI 61), intervention strategies (DI 63) and guidelines for the scoring system (DI 60, Figure 57, 58).
• Have a similar design to current pain scales in order to reduce confusion (DS 76),
• Use bold text, colour and different fonts to make the scale easier to read.
•Use a numerical score (DI 55) which should reflect intensity of pain (DS 52).

- **Focus Area: Outcome**

Outcome incorporates how the scale has the ability to affect management of the baby, influence the transfer and the potential effect on the transport service.

In relation to patient management the Delphi panel reflected that the scale should be used on all patients where it can influence outcome (DS 23). Also that pain assessment should inform and influence further assessments and interventions during transfer (DS 48, 68). Therefore also included in the NTPAS was a goal of management in relation to recommended levels of pain/sedation (DI 59). Some participants reflected the importance of recommendations on pain management linked with the pain score, however others stated that it was dependent on the baby and transport clinicians, therefore this could be an area for future review. It was also stated that information on how to score the scale should be given to clinicians (DI 60), therefore a scoring guide was constructed for clinicians to review with the scale (Appendix 14).

The Delphi panel highlighted that formal documented pain assessment should be an integral part of a neonatal transport (DS 80), stating that the pain scale should be specific to transport (DS 83), as current clinical pain scales are unusable in the transport environment (DS 84). However it was also reflected that the different circumstance in each transport would make definitive scoring and treatment options too restrictive (DS 86). Documentation was an important element of the scale, with the training of clinicians being perceived as crucial to success of the scale (DI 67).

The Delphi panel reached consensus that all of the team, Transport Nurses, Advanced Neonatal Nurse Practitioners and Medical staff should be instructed on use of the scale (DI 69, Figure 59) and be able to apply it to the baby (DS 48). The Delphi panel recommended that pain should be assessed at regular intervals throughout the transfer to result in optimum pain assessment, including on arrival at the referral unit (DI 43), before leaving the unit (DI 41), during the transport and on arrival at the receiving unit (DI 42, Figure 48). Recommendations on pain management were also stated by the Delphi panel to be an important element of a pain scale (DI 59). Outcome was interlinked within each of the focus areas, as optimal outcome was the main objective during transport. It was important to have clear documentation of scoring and interventions in order to justify outcome (DI 63). Therefore both of the NTPAS options have areas to document assessments and interventions. Inclusion of the visual analogue scale provides additional support to the NTPAS assessment, utilizing the experience of the clinician undertaking the assessment. It was also suggested that an algorithm be included in the scale to assist in the management of pain during transport (DI 56). However as this would have resulted in a lengthy scale it was not included with a view to reviewing this during Phase Three of the study. It was also suggested that there should be clear guidelines on pain assessment linked with the pain assessment scale and instructions of how to use the scale (Appendix 14).

The effect on guideline development within the transport setting was an important consideration (DS 22). A further important element was documentation during transfer and therefore workload for clinicians and overall outcome of the transfer.

Table 22 **Summary of recommendations in relation to focus area of Outcome**

- Include a goal of management in relation to recommended levels of pain/sedation (DI 59).
- Include a scoring guide for clinicians to review with the scale.
- All of the team, Transport Nurses, Advanced Neonatal Nurse Practitioners and Medical staff should be instructed on use of the scale (DI 69, Figure 59).
- Include recommendations on pain management (DI 59).

As a result of the above recommendations the N-PASS scale (Hummel et.al 2008) was adapted, with two formats (Landscape and Portrait) for review in Phase Three of the study. The new NTPAS scale can be reviewed below in Figure 61, 62.

Figure 61 **NPTAS – Landscape Version**

Neonatal Transport Pain Assessment Scale (NTPAS)

Date..... Time..... Observer.....

Patient Sticker

VAS (Visual Analogue Scale) Put a mark on the line below to indicate how much pain you think the baby is in at this moment

No Pain ——————————————————————————— **Worst Pain**

Assessment Criteria	Pain Score			Sedation Score		
	2	1	0	2	1	0
Crying Irritability	High-pitched or silent-continuous cry Inconsolable	Irritable or crying at intervals Consolable	No pain signs	No cry with painful stimuli	Moans or cries minimally with painful stimuli	No pain signs
Behaviour/ State	Arching, kicking Constantly awake or arouses minimally/no movement, not sedated	Restless, squirming Awakens frequently	No pain signs	No response to any stimuli No spontaneous movement	Arouses minimally to stimuli. Little spontaneous movement	No pain signs
Facial Expression	Any pain expression continual	Any pain expression intermittent	No pain signs	Mouth lax No expression	Minimal expression with stimuli	No pain signs
Tone	Continual clenched toes, fists, or finger splay. Body is tense	Intermittent clenched toes, fists or finger play; Body is not tense	No pain signs	No grasp reflex Flaccid tone	Weak grasp reflex Reduced muscle tone	No pain signs
Vital Signs HR, RR, BP, SaO_2	HR, RR and /or BP ↑ 20% from baseline Severe desaturation on stimulation – slow recovery Out of sync with vent	HR , RR, and/or BP ↑ 10-20% from baseline. Minimal desat on stimulation quick recovery	No pain signs	No variability with stimuli Hypoventilation or apnoea	< 10% variability from baseline with stimuli	No pain signs
+1 if baby is less than 30 weeks gestation +1 if transfer longer than 1 hour +1 if turbulent/bumpy transfer +1 if baby is within 24 hours post-operative	The goal of pain management is a score ≤ 3			+1 if baby is less than 30 weeks gestation +1 if transfer longer than 1 hour +1 if turbulent/bumpy transfer +1 if baby is within 24 hours post operative		Deep sedation =6→10 Light sedation =2→5 Goal dependent on pathology

Assessment 1 -Time .....Pain Score .....Sedation Score.....

Treatment.....

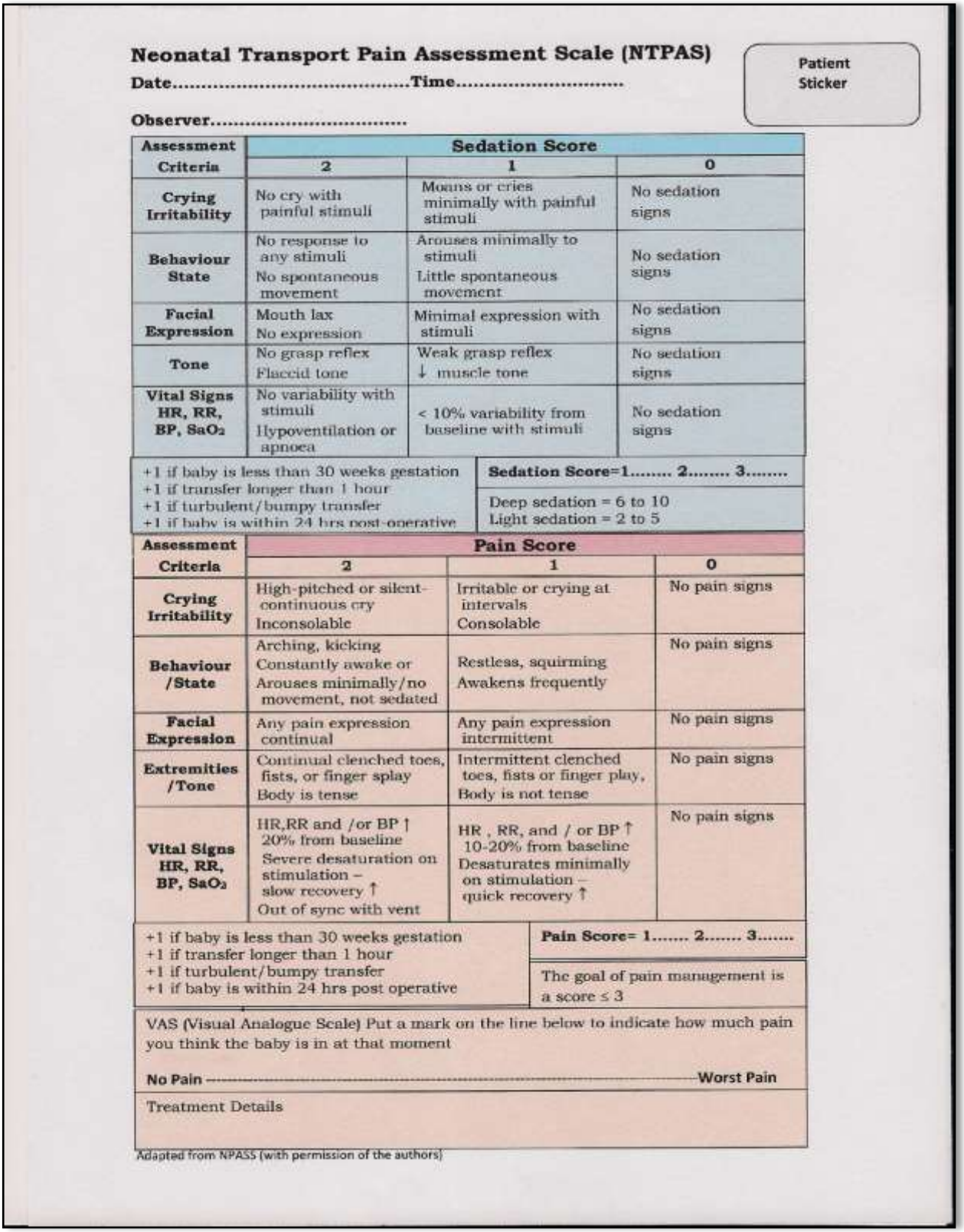
Assessment 2 -Time .....Pain Score .....Sedation Score.....

Treatment .....

Assessment 3 -Time .....Pain Score .....Sedation Score.....

Treatment.....

Figure 62 **NTPAS – Portrait version**



Neonatal Transport Pain Assessment Scale (NTPAS)

Date.....Time.....

Observer.....

Patient Sticker

Assessment Criteria	Sedation Score 2	1	0
Crying Irritability	No cry with painful stimuli	Moans or cries minimally with painful stimuli	No sedation signs
Behaviour State	No response to any stimuli No spontaneous movement	Arouses minimally to stimuli Little spontaneous movement	No sedation signs
Facial Expression	Mouth lax No expression	Minimal expression with stimuli	No sedation signs
Tone	No grasp reflex Flaccid tone	Weak grasp reflex ↓ muscle tone	No sedation signs
Vital Signs HR, RR, BP, SaO_2	No variability with stimuli Hypoventilation or apnoea	< 10% variability from baseline with stimuli	No sedation signs

+1 if baby is less than 30 weeks gestation
+1 if transfer longer than 1 hour
+1 if turbulent/bumpy transfer
+1 if baby is within 24 hrs post-operative

Sedation Score=1..... 2..... 3.....

Deep sedation = 6 to 10
Light sedation = 2 to 5

Assessment Criteria	Pain Score 2	1	0
Crying Irritability	High-pitched or silent-continuous cry Inconsolable	Irritable or crying at intervals Consolable	No pain signs
Behaviour /State	Arching, kicking Constantly awake or Arouses minimally/no movement, not sedated	Restless, squirming Awakens frequently	No pain signs
Facial Expression	Any pain expression continual	Any pain expression intermittent	No pain signs
Extremities /Tone	Continual clenched toes, fists, or finger splay Body is tense	Intermittent clenched toes, fists or finger play, Body is not tense	No pain signs
Vital Signs HR, RR, BP, SaO_2	HR,RR and /or BP ↑ 20% from baseline Severe desaturation on stimulation – slow recovery ↑ Out of sync with vent	HR , RR, and / or BP ↑ 10-20% from baseline Desaturates minimally on stimulation – quick recovery ↑	No pain signs

+1 if baby is less than 30 weeks gestation
+1 if transfer longer than 1 hour
+1 if turbulent/bumpy transfer
+1 if baby is within 24 hrs post operative

Pain Score= 1..... 2..... 3.....

The goal of pain management is a score ≤ 3

VAS (Visual Analogue Scale) Put a mark on the line below to indicate how much pain you think the baby is in at that moment

No Pain ---------- **Worst Pain**

Treatment Details

Adapted from NPASS (with permission of the authors)

6. Chapter Six

Phase Three: Semi Structured Interviews- Results

6.1 Introduction

The aim of Phase Three of the study was to review the new NTPAS scale to establish face validity and work towards answering the primary research questions (PRQ). Therefore the views and perceptions of transport clinicians were sought in relation to the newly adapted scale. Semi-structured interviews provided clinicians with the opportunity to freely give their perceptions on the newly developed scale, to elucidate if in their view the scale appears to be appropriate for the assessment of pain in the transport environment. The aim of this Chapter is therefore to present results of Phase Three of this study and establish face validity of the developed transport pain assessment scale.

6.2 Report of Findings

The reference group of seven transport clinicians from the NGT meeting were given both versions of the NTPAS (Figure 61, 62) and scoring criteria for the pain assessment scale (Appendix 14) to review with a study information sheet (Appendix 8.7) and consent form (Appendix 8.8). A date for interview was set for one week later in order to give them time to review each scale. The interviews were conducted utilising an interview schedule (Appendix 11.1) at a time convenient to the transport clinicians in a quiet office in the transport department and were tape recorded with the prior consent of participants.

The process for management and analysis described in Chapter Four was followed and taped interviews were transcribed (Appendix 15), coded and analysed (Appendix 15.1).

A thematic framework was created by incorporating the most important categories, leading to the development of four main Themes (Appendix 15.1) which will be reported in the next section of this Chapter.

6.3 Emerging Themes

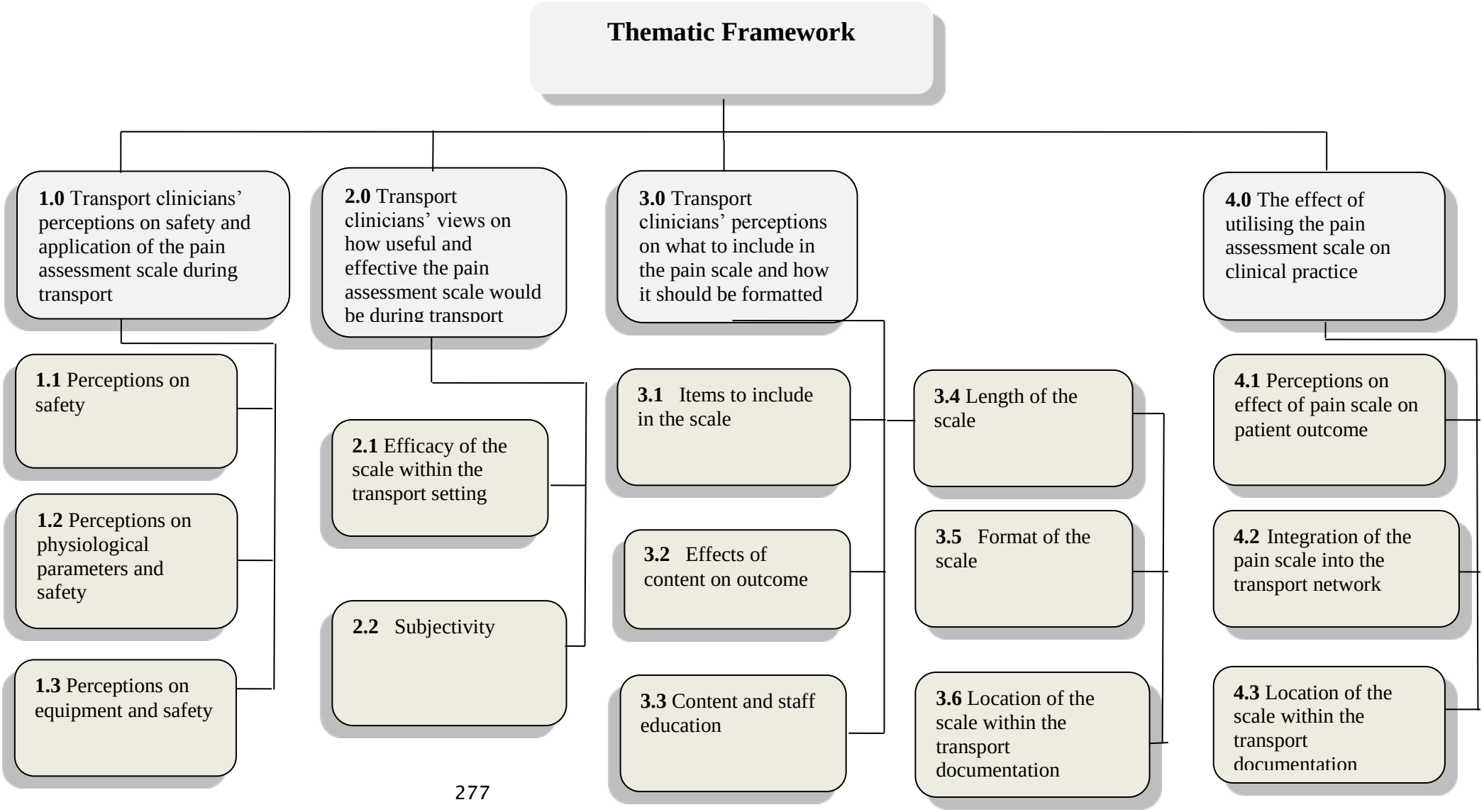
Analysis of the semi-structured interviews revealed data which provided an insight into the clinicians' perceptions on face validity of the NTPAS pain assessment scale. Qualitative content analysis was conducted which involved extracting data utilising the selective highlighting method of colour highlighting (Riley 1990), assigning codes and preliminary labels (Appendix 15.1). This was an inductive process of combining segments of data together into meaningful conceptual patterns. A theme in qualitative research has been defined as:

> *"an abstract entity that brings meaning and identity to a current experience and its variant manifestations. As such, a theme captures and unifies the nature or basis of the experience into a meaningful whole"*

(DeSantas and Ugarriza 2000 p362)

Descriptive analysis and verbatim quotes were incorporated and grouped within the emergent Themes and colour coded in the analysis in order to give a *'voice'* to the participants (Appendix 15.1). In order to protect their anonymity participants were assigned a number 4-10, which is also in keeping with the ethical principles of the study. The four main Themes within the thematic framework can be reviewed in Figure 63 and a detailed breakdown of the thematic framework cane be reviewed in Appendix 16.

Figure 63 **Thematic Framework: Four Main Themes and Sub-themes**



Theme 1 – Transport clinicians' perceptions on safety and application of the pain assessment scale during transport

Within the context of safety during transport, participants' revealed strong views that patient safety was priority during transport. The issue of safety was reflected in several contexts, these included:

- Direct patient care and management
- Control of analgesia and sedation to maximize patient stability
- The ability to utilize monitoring equipment
- Access to the baby
- Constraint of light and noise

The views of participants were particularly related to use of the pain scale and the direct effect on the baby and management throughout the transfer;

> *"Basically it is safer all round...so that they all know we are aware that the baby is as comfortable as possible for a safe journey".*
>
> (Participant 6, Code 1.1.6)

This concept was further developed in relation to management strategies to ensure stability:

> *"If they are needing paralysed we paralyse and sedate them".*
>
> (Participant 5, Code 1.1.4)

In relation to the pain scale, one participant reflected that it highlighted pain assessment, linking physiological stability to pain management;

> *"I think this is good because it makes pain an issue. Whereas if you are noting down clinical numbers all the time sometimes it is a second thought – there are issues for the babies' physiological stability– if you manage the pain properly as well".*
>
> (Participant 9, Code 1.1.1)

The concept of relieving pain and ensuring the baby is as comfortable as possible emerged as an important element of management, both in a safety and an ethical perspective. One participant viewed that the scale could be implemented into transport;

> *"I think it is like anything you can adapt this into your practice to incorporate it in - if your baby is in pain we should be trying to something about it. So it is something you can incorporate in with your observations."*
>
> (Participant 10, Code 1.1.6)

One participant reflected the importance of managing pain during transport, however highlighting that they currently lacked an appropriate method of documenting their interventions.

> *"if your baby is unsettled or in pain you would use swaddling or sucrose we just don't have a format to document it…… we have been told we are a bit barbaric when we don't have pain relief on board"*
>
> (Participant 7 Code 1.1.6)

This led on to control of analgesia and sedation, which was reflected to be a vital component is assuring a safe transfer for the baby, ensuring clinical stability throughout the transfer. An important effect of using the pain scale was suggested to be that it may influence levels of sedation during transfer, leading ultimately to better and safer overall management.

> *"Having both pain and sedation is useful- because sometimes when you think your baby may be in pain - and it has already been sedated -and with the assessment you may need to increase your sedation".*
>
> (Participant 5, Code 1.1.4)

This highlighted the issue of including both pain and sedation in the scale which was perceived as being a useful addition to management, enhancing clinical stability.

Participants reflected that assessing both aspects was a new concept to them, and may require more education and teaching in order to understand the assessment.

> *"I think because there is two side by side* (pain and sedation score) *people have to understand that one is for one thing and the other is for the other".* (Participant 7 Code 1.1.4)

> *"I think sedation is useful to have because they are different- the entities are different- because you could be sedated but still be in pain and vice versa- I think that is good. We should be looking at both"*
>
> (Participant 9, Code 1.1.4)

The use of morphine to facilitate a safe transfer was mentioned by several participants, reflecting that this was an integral part of managing pain in many acute neonatal transfers. The implication emerged from the data that when morphine was used it was an indication to use a structured method of assessing pain such as the pain scale.

> *" I think it will be useful to have a pain scale as we are more aware of pain - babies are on morphine - so that they know we are aware that the baby is as comfortable as possible for a safe journey"*
>
> (Participant 6 Code 1.1.6)

Challenges in relation to safe observation and monitoring were also highlighted by participants. Comments reflected the problems in relation to levels of lighting in the ambulance and helicopter, and also noise levels during transport. This had a direct influence on participants' ability to both access and assess the baby, and also on the stability of the baby.

> *"And your vital signs- you are juggling about sometimes. Access to the baby is restricted- and you put more restrictions on by putting the straps around the baby- and covering the baby so it is not over stimulated by the light and noise".* (Participant 6, Code 1.2.1)

"you will try and make your baby as comfortable as possible without over stimulating the baby or waking it if it is sleeping. It (pain scale) *will just make you more aware of unnecessary interventions or handling. ..basically it is safer all round - so that the baby is not going through additional stress"*

(Participant 6, Code 1.1.6)

"the only thing is that your vital signs can be skewed - if they are going for surgery it might be unpleasant…… you could be getting an unusually high heart rate or resps- that might not be totally true"

(Participant 7, Code 1.2.1)

Monitoring equipment used during transport was stated throughout to be very important in relation to both safety, ensuring stability of the baby, and also facilitating a continuous record throughout the transfer to assess interventions. However the effects of vibration, movement, noise and temperature were influencing factors in the accuracy of equipment and the ability to safely assess the baby with the pain scale.

"*when the lights dim-it would be difficult to see if the baby was grimacing…it is so noisy or rattly you might not see if the baby was crying……also covering the baby so it is not over stimulated by the light and noise*".

(Participant 6, Code 1.2.1)

Effect of environmental influences was stated by several participants to be dependent on the type of transfer and distances involved, air and ambulance transfers offer different challenges to safety and stability for the baby and also for the assessment of pain.

Participants stated that the actual monitoring and documentation of vital signs could be affected due to motion and environmental influences.

> *"vital signs can be skewed a bit….could be getting an unusually high heart rate or resp…. you talk about a turbulent bumpy transfer – you have included these extra things into the assessment"*
>
> (Participant 8, Code 1.3.2)

However it was reported that pain assessment and the pain scale should be used as a continuum throughout the transfer which would help facilitate accurate assessment.

Theme 2 – Transport clinicians' perceptions on how practical and useful the NTPAS scale would be during transport

This Theme reflected how useful the scale was perceived to be within the transport setting. Several concepts emerged under this Theme. These included:

- Ease of use
- Easy to read
- Appropriate length for efficient assessment

It was highlighted throughout that the scale appeared to be easy to use, which was an important consideration for use in the transport setting. This was reflected to be due to the urgency in transferring many acute babies, the emphasis on stabilizing the baby for transfer and prioritizing management strategies to facilitate a smooth efficient transfer.

> *"it should be easy to use on transport"…. needs to be something that is user friendly…….this would be quite practical to use…… it is just as easy to do when you are doing the observations…… pretty self-explanatory*."
>
> (Participant 4, Code 2.1.3)

> *"this is quite visual and you could score and assess it much more easily…… it is quite simple and you could do it quite quickly……..it would be quite practical to use in the transport setting"*
>
> (Participant 5, Code 2.1.2)

Limitation of time was an important consideration, and a constant theme throughout the interviews therefore the time taken to score the scale was a crucial factor. The scoring criteria had to be easily interpreted taking into consideration elements of assessment which would be difficult to apply in the transport setting.

> *"you can pick out what you are looking for very easily….. I would say it was easy to score once you have used it a few times you will be quite familiar with it"*
>
> (Participant 4, Code 2.1.2)

Participants stated that it could be easily adapted into their practice, with particular reference to flight transfers, however several expressed the view that it may take some time to get used to it in the transport environment.

> *"I think you have to use it a few times before you get familiar with it…..I think it is like anything you can adapt this into your practice to incorporate it in….for flights and things like that as well it would be good"*
>
> (Participant 10, Code 2.1.2)

Theme 3 – Transport clinicians' perceptions on what to include in the pain assessment scale and how it should be formatted

This Theme emerged from utilizing the indicators of pain which could be applied to the transport setting to result in a valid and reliably scale. Content encapsulated a fusion of all of the Themes. Participants highlighted that content had to be useful and applicable to transport, therefore also addressing clinical utility.

The issue of safety was a constant theme which was also incorporated into content of the scale. Format of the scale was perceived as being influenced by the content, with clarity and ease of use emerging as an important element.

> *"It was useful…. there was nothing that was ambiguous….. the more I read it – I understood it".* (Participant 4, Code 3.1.3)

> *"fairly short and snappy and concise…there is not a huge amount you have to add up"* (Participant 9, Code 3.3.1)

> *"I think it is appropriate to transport"* (Participant 7, Code 3.2.1)

The information sheet was reported as being a useful reference before applying the scale in the clinical setting.

> *"good explanation of how the scale works"* (Participant 9, Code 3.1.3)

However several participants reflected that the inclusion of both pain and sedation in the scale was new to them and could be confusing. Some stated that further explanation and training on the combination of pain and sedation would be needed, however all participants stated that it was a useful addition to the scale.

> *"I had to keep separating them both, which I am not used to doing…it got me a bit confused the difference between pain and sedation.. …had to keep referring back"*
>
> (Participant 4, Code 3.1.3)

"It is good that you have put sedation as well as that is what you would expect"

(Participant 9, Code 3.2.2)

The addition of an algorithm was stated by most participants to be an unnecessary and would make the scale too complex to score. The inference was that most transport clinicians are experienced and have the ability to initiate individualised management plans specific to each transfer.

"with an algorithm you are telling people what to do it is spoon feeding them"

(Participant 5, Code 3.2.2)

Suggestions of additional elements which may improve the content of the scale included adding type of transfer, as this may influence environmental effects on the baby and therefore the assessment and management of pain. One participant was unsure on what "underlying pathology" referred to and requested additional explanation.

"not sure what underlying pathology means-would need clarified"

(Participant 6, Code 3.1.2)

Guidance on management of pain was reflected by some participants to be essential. This was reflected in including a pain score which would inform management and also guidelines linked to the pain score. However differences in management strategies which can be evident between clinicians were also highlighted, therefore making the introduction of guidelines linked to the pain scale difficult to implement in many areas.

"It is everybody's preference what they use- some places use one thing and others use something else- that would be difficult- think it is something which could be developed"

(Participant 7, Code 3.2.2.)

Several participants reflected that reviewing the scale in the transport area would highlight any problems in relation to content. A participant also stated that staff would have to become familiar with the scale by using it, applying it in the clinical area to fully appreciate how applicable the content is to the transport setting.

" I think I would have to use it to see if there were things that didn't fit…… that would just come with familiarity really" (Participant 10, Code 3.1.3)

In relation to developing management plans, experience using the scale was stated to be an important influencing factor.

"I think it will come hand in hand later on once you start using this"

(Participant 10, Code 3.1.3)

Format of the pain assessment scale was reflected by participants to be a crucial element in how practical and applicable to transport the new scale would be. The method of combining the pain indicators in a format which could be easily read, transcribed and integrated into transport documentation was important. Participants were given the option of a landscape or portrait format, with the same content. The reasoning behind this was that the portrait format could be easily combined with the current portrait format of the transport log used in the clinical area. However each participant stated that the landscape format was easier to read, less fussy and less complex.

"I found this one much easier to read (landscape version). I think it just reads easier" (Participant 4, Code 4.2.1)

"landscape would fit quite neatly on to the clipboard"

(Participant 5, Code 4.3.1)

"I preferred that one (landscape) the other one was just too busy for me…… the portrait would be better for the transport log – however the landscape somehow seems less busy"

(Participant 7, Code 4.2.1)

Some participants felt that the new pain scale should be included in the transport log and not a separate item. This was for both simplicity reducing paperwork and ensuring that the pain scale is utilized.

"The ideal thing would be to have it incorporated and then there is no forgetting to do it" (Participant 7, Code 4.3.1)

The design of the scale incorporated the inclusion of both pain and sedation. It was reflected throughout all of the themes that this was new to participants and may need more explanation and education. Design was important in order to clearly separate each element, however emphasizing the combination of the assessment of pain and sedation in the final score.

"It was just separating pain from sedation that I had to get used to had to read the information several times before I got to understand separating them both" (Participant 4, Code 4.2.1)

Theme 4 – The effect of utilising the pain assessment scale on clinical practice

This Theme included several potential influences that application of a pain scale could have on transport. A major influencing factor was the overall management of pain during transport and to what extent the pain scale could affect management plans. Also highlighted was how the introduction of the scale had the potential to influence guidelines and protocols in the transport environment. Further potential influences emerged such as increasing awareness of pain indicators among staff and therefore their knowledge base on the effects of pain. The overall assessment of the baby was an important factor to participants, and to what extent they are effectively assessing pain.

"when you are looking at the baby you are looking at it as a whole…… it makes you recognise the differences….. I think we transfer enough babies to make it feasible"

(Participant 4, Code 5.1.1)

Participants stated that it had the potential to guide pain assessment and could structure on-going management of the baby.

"it is useful as it would guide you on what to do next….. what your next progress would be" (Participant 5, Code 5.1.1)

"it might change your clinical management" going on to reflect that the pain assessment scale would be.."*a good thing for that baby"*

(Participant 10, Code 5.1.1)

"may even come a time when the baby has a high score you may not move that baby" (Participant 10, Code 5.1.1)

It was also reflected that the diversity of situations and the varying pathologies presenting in the babies may make it difficult to generalize, however one participant stated that a pain scale would:

"Lead to uniform treatment". (Participant 4, Code 5.1.1)

This view also highlighted on-going management and practice, one participant stated:

I think it will jog you into thinking about how to assess and what you are going to do next". (Participant 5, Code 5.1.1)

However it was stated by several participants that it would be good to have a definitive structure to pain assessment.

"this is what we follow and will use" (Participant 7, Code 5.1.1)

"you talk about post op - which is quite pertinent….. you would get some guidance or guidelines" (Participant 10, Code 5.2.2)

Future development in the area of training and induction of the pain assessment scale was highlighted by several participants, with particular reference to education on the content of the pain scale and outcome. The general view was that some form of training would be required however formal training is very time consuming and may not be practical in a clinical setting. As all clinicians have an induction period, several participants stated that it could be implemented as part of that education period and therefore not compromise the service.

"One to one training would be time consuming- whereas I think it is something that can be done in a very informal way…..it could be integrated into an induction" (Participant 7, Code 3.3.1)

In relation to who should carry out the assessments and be instructed on however to use the scale, most participants stated that all of the team should be aware of how to use the scale. However it was highlighted by some participants that only one person should be scoring the scale for each transport episode to facilitate continuity.

> *"I think it has to be the same person who is doing the scoring because some of the things are subjective...although they are subjective they will change on the same basis... so the same person is doing the assessment"*
>
> (Participant 9, Code 2.2.1)

When questioned on future development of pain scales and management of pain during transport, participants highlighted that pain assessment was sometimes not prioritized enough. They also stated that the new scale may make pain assessment more of an issue during transport, encouraging formal assessment and documentation of interventions which currently does not happen on a regular basis.

> *"I think it will draw attention- it will make pain and sedation more of an issue than potentially it is at the moment"* (Participant 9, Code 5.1.1)

> *"there has been a gap in the in service there…… There is obviously a need for it..people should be aware"* (Participant 10, Code 5.1.1)

One participant stated that they felt that staff were managing pain and assessing it, however just not documenting it, that the scale would provide the means of formalizing the assessment.

> *"I think it should be introduced because I think people are doing it anyway they are just not documenting it"* (Participant 10, Code 5.1.1)

It was also stated that clinicians were not always able to remove all painful stimuli for the babies, however they could attempt to reduce or minimize it, and therefore have facilitated as comfortable and stable a transport as possible.

> *"You aren't always able to remove all painful stimuli but you can reduce it"…If you prove that you have tried to reduce it then you have done your job"* (Participant 10, Code 5.1.1)

6.4 Final Development and Confirmation of Definitive Themes

The final stage in analysis was focused on confirmation of definitive themes generated in Phase Three. Thematic Charts (Appendix 17) as described in Chapter Four were developed to facilitate analysis of Phase Three and allowed the researcher to analyse data under the developed Themes.

This process (as described in Chapter Four) culminated in the confirmation of 4 definitive Themes which were cross referenced with the primary research questions (PRQ), these included:

- **Theme 1:** Transport clinicians' perceptions related to safety and application of the pain assessment scale during transport (PRQ1,2)
- **Theme 2:** Transport clinicians views on how useful and effective the pain assessment scale would be during transport (PRQ 3)
- **Theme 3:** Transport clinicians' perceptions on what to include in the pain assessment scale and how it should be formatted (PRQ 1,2,3)
- **Theme 4:** The effect utilising the pain assessment scale would have on clinical practice (PRQ 2, 3)

6.5 Development of the Effects Matrix:

The Effect of a Pain Scale on Neonatal Transport

A final phase of analysis involved developing an effects matrix to review the overall effect a pain scale may have on neonatal transport. This was an important process which allowed the researcher to review data in relation to what effect implementation of a pain assessment scale would have on both the clinical setting and the transport service. The process of summarising and emphasising phrases from participants which received strong emphasis with an asterisk (*) highlighted important issues and facilitated analysis.

The effects matrix included at the end of this section (Figure 64), documented the Themes in one column, linking them to 'positive' and 'negative' direct effects, meta effects and side effects of implementation of a transport pain assessment scale. Phrases which were highlighted (☼), included as an inference by the researcher, were important as this facilitated development of the concept through analysis of the results. The areas which were considered within the effects matrix encompassed:

- Effects on the baby
- Effect on staff
- Effect on the transport environment/service

Each area was considered within the developed Themes for ease of analysis.

Theme 1:

- "*Transport clinicians' perceptions related to safety and application of the pain assessment scale during transport*"

A highlighted direct positive effect of a pain scale for the baby was the constant review of pain throughout the transport and the improvement on safety for the baby. However a direct negative effect was that the baby was frequently difficult to access within the constraints of a moving ambulance or in particular during a flight transfer which could affect pain assessment.

However a highlighted positive Meta effect reflected by participants was that for the transport service implementation of a pain scale was a workable and feasible change in improving pain assessment. In contrast a negative Meta effect as an inference by the researcher was that a pain scale may detract from clinical priorities during transport. This inference was linked to comments made by participants that a complex, time consuming pain scale may be impractical during an acute transport. This factor also related to a negative side effect of a pain scale in that it may lead to longer transport episodes to accommodate pain assessment.

Positive direct effects for staff highlighted that the pain scale was not too time consuming, however they would need educational input on how to use the scale. This also linked to Meta effects in that the service would have to accommodate in-service education which could be time consuming and costly. However a positive effect was highlighted as staff being able to justify their management of pain and ensure a safe transport. In relation to direct effect on transport the overriding view was that a pain scale would made transport safer. However a Meta effect was that it needed to be generalizable to transport teams throughout the UK, which may have implications in relation to funding.

Theme 2: ***"Transport clinicians' views on how useful and effective the pain assessment scale would be during transport"***

Results reflected that utilising a pain scale would facilitate a more comfortable transfer for the baby with an increased awareness of the effects of pain on the baby during transport. However a negative Meta effect may be excessive use of analgesia due to misapplication of the pain scale. It was reflected the pain scale was concise and user friendly for staff and that made pain assessment an essential part of transport. Furthermore results highlighted that the scale added to literature on pain assessment during transport and facilitates further development and research.

Theme 3: ***"Transport clinicians' perceptions on what to include in the pain assessment scale and how it should be formatted"***

Within this theme the importance of ensuring appropriate assessment of how much pain the baby was experiencing was highlighted with the recommendation that a pain scale should include measurement of both pain and sedation. However a negative effect was that scoring both pain and sedation in the same scale could be confusing for clinicians, therefore the scale should be easy to read and score.

A positive Meta effect was the facilitation of raised awareness of pain and sedation indicators among clinicians, however this would require in-service teaching and education and consequently may require time and input to implement in the clinical area. An important positive Meta effect for staff would be the justification of pain control strategies utilised during transport, furthermore a positive side effect reflected that implementing a pain scale may facilitate a change in practice. A positive direct effect of a pain scale for transport would be that the scale was designed specific to the transport environment, however it would need to be "hands off" due to the dynamic nature of transport and the setting within which pain would be assessed. A positive Meta effect was an overall effective method of assessing pain during transport. However the pain scale would need to be generalizable to transport teams throughout the UK and may require an overall change in practice during transport.

Theme 4: ***"The effect utilising the pain assessment scale would have on clinical practice"***

For the baby it was reflected that a transport pain scale may lead to a safer transport and improved outcome due to more effective assessment and management of pain. However negative perceptions from clinicians on implementing a pain scale highlighted that classic pain tools which clinicians had experienced in the clinical area were unusable and inappropriate for transport. It was acknowledged that a transport pain scale may facilitate further audit and research in this area, deemed important due to the lack of current literature. However an important negative Meta effect was highlighted in that a pain scale may lead to over analysis of pain and excessive use of analgesia. Furthermore a negative side effect may be the increased demands on staff time in an acute setting. However it was reflected that a pain scale may change clinical practice, encourage documented pain assessment, justification of management and promote holistic care.

Figure 64 **Effects Matrix: NTPAS**

Theme		Direct Effects *positive*	Direct Effects *negative*	Meta Effects *positive*	Meta Effects *negative*	Side Effects *positive*	Side Effects *negative*
1	**Effect on Baby**	*Constant pain review. Facilitate safer transfer.	*Difficult to assess on air transfer	* Workable change in improving pain review	☼ May detract from clinical priorities	☼ Add to literature on pain during transport	☼ May lead to longer transport
	Effect on Staff	*Does not take too much time. Can justify management	*Need education on scale and pain indicators	* Able to justify pain strategy and safety during transport	☼Needs in-service education which needs time and input	* Pain and safety is prioritised Increased awareness	☼ May be time consuming
	Effect on Transport	*Safer, more efficient transport.	☼ May lead to longer transport	*Workable change in practice/ Guideline	☼ Needs to be generalizable to transport teams	☼ Transport teams adapt practice	☼ May have an impact on funding of the service
2	**Effect on Baby**	*More comfortable transport	May be difficult in term of access	☼ Increase awareness of pain on transport	☼ May lead to excessive analgesia	☼ Promotes holistic care	☼ May lead to longer transport
	Effect on Staff	*Concise and user friendly.	☼ Forced to assess pain	☼ Better education on pain	☼ May need further development	☼ Staff will have ownership	☼ May be time consuming
	Effect on Transport	*Safer transport. Informs effective transport	☼ May prolong transport	☼ Add to transport pain literature	* May necessitate change in practice	☼ Facilitates further research	☼ May have an impact on funding of the service
3	**Effect on Baby**	* Includes both pain and sedation.	* Scoring both pain and sedation can be confusing	* Raised awareness of pain and sedation indicators	☼ Need in-service teaching	* Pain prioritised	☼ Needs further validity and reliability testing
	Effect on Staff	* Easy to read and score	☼ Need awareness of pain indicators	* Facilitates justification of pain control strategy	☼ Needs time and input to implement	*May facilitate change in practice	☼ May be time consuming
	Effect on Transport	* Score specific for transport	* Needs to be "hands off" pain review	*Overall Effective pain assessment	☼ Needs to be generalizable	*Safer more efficient transfer	☼ May need change in practice

Theme		Direct Effects *positive*	Direct Effects *negative*	Meta Effects *positive*	Meta Effects *negative*	Side Effects *positive*	Side Effects *negative*
4	**Effect on Baby**	*May lead to safer transfer and improved outcome.	*Classic pain tools unusable during transport	☼Facilitate research and audit on pain during transport	*May lead to over analysis of pain on transport	☼Add to Neonatal transport pain literature	☼May lead to increase in use of analgesics
	Effect on Staff	*Should be an integral part of care.	☼ Staff need to justify care plan	☼Improve education on pain	☼Increased time and input into staff education	☼ Transport teams adapt practice	*Increase demands on staff time
	Effect on Transport	*Intervention indicator. May change clinical management	*If lengthy may detract from general obs.	*Recorded pain assessment. Justifies care	☼ Needs to be generalizable	☼ Promotes holistic care	☼ May need change in practice

* = claim made strongly by one person

☼ = inference made by researcher

6.6 Chapter Summary

The aim of this chapter was to organize, interpret, synthesis and represent data from the final Phase of the study to accurately reflect the views of participants in relation to face validity of the newly developed scale. This Chapter was therefore focused on presenting the data and reporting the main findings of the semi-structured interviews. A thematic approach was adopted to bring together results, supported by verbatim quotations to highlight the views and perspectives of participants and give them a voice in the study.

The Themes which emerged were reported independently, however an important element of the results was that they were all interrelated, and linked directly to the evidence. Therefore the Chapter concluded by bringing together and confirming definitive Themes within an effects matrix to elucidate the overall effect utilisation of a pain assessment scale would have on the transport environment. The relationship between the definitive Themes will be discussed in more depth within the following Chapter.

7. Chapter Seven

Discussion, Conclusions and Recommendations

7.1 Introduction

This Chapter presents a discussion on the findings of the study, which culminated in the development of the first draft of a pain assessment scale adapted for use during neonatal transport. This was undertaken within the context of a literature review on neonatal pain assessment and the background environment of neonatal transport. The first section of this Chapter revisits the purpose of the study and provides an overview of the research to date. The findings of the NGT and the Delphi study are then discussed, followed by the application of the findings to the development of a pain assessment scale for transport.

The second section presents a discussion on the semi-structured interviews with transport clinicians the aim of which was to establish face validity of the scale. The Chapter concludes with an overview of the limitations of the study, conclusions and recommendations for future research.

7.2 Discussion: Purpose and Conduct of the Study

The agenda for this research reflected the recommendations of the Royal College of Nursing (RCN) who published guidelines on pain assessment in children (RCN 2009, 2012). In particular the recommendation that clinicians should be vigilant for pain in children and neonates at all times and if pain is anticipated or suspected that a validated pain assessment tool should be used.

7.2.1 Aims and Objectives

The aims and objectives of this study evolved within the backdrop of the dynamic area of neonatal transport. The lack of available literature on pain assessment during transport and the absence of a pain scale developed for transport reflect the difficulty in conducting research within this unpredictable environment.

A key objective of this study was to lead towards the development of a more structured method of neonatal pain assessment during transport, acknowledging that the transport environment provides particular challenges to patient management not encountered in the clinical area (Barry and Lesley 2003, Jaimovich and Vidyasagar 1996). These challenges were also reflected within the current study in relation to difficulties in gaining access to this population. Therefore utilising expert opinion in relation to pain assessment reflected current practice and provided an invaluable insight into the assessment of pain, while answering the primary aims and objectives of the study.

7.2.2 Background and Context

This study is unique in that it is the first of its kind to utilise consensus methods in the development of a neonatal transport pain assessment scale. Currently there is no pain scale developed for use within the transport environment in either the adult or neonate, therefore this study is the first of its kind to examine influencing factors within the complex environment of transport and apply them to a pain scale. Several key influencing factors provided the background and context to this thesis and therefore are central to the selection of consensus methods as the main method of data collection. These factors include a lack of literature on pain assessment during neonatal transport, the absence of a validated scale for transport and the current role of clinician experience and judgement in the assessment of pain during transport. Furthermore the assessment of neonatal pain presents particular challenges encompassing ethical, educational and management issues. However, as reflected by Stevens et al. (2007a p2), it should be acknowledged that despite broad acknowledgement that the neonate experiences pain there continues to be evidence of inadequate pain assessment and management in a variety of settings.

7.2.3 Methodology: Consensus Methods; Strengths and Weaknesses

Consensus methods are reflected in the literature as an increasingly popular means of gaining agreement within health care (Keeney et al. 2011). It provides the opportunity to obtain consensus on a wide range of issues from a specialised group which may not otherwise have the opportunity to collaborate and therefore was an ideal method for execution of this research. Neonatal transport teams are located throughout the United Kingdom, are of varying sizes and geographically cover a diverse area from urban to remote and rural.

Therefore the Delphi process facilitated collaboration between groups with a common purpose who may have little opportunity to meet. However consensus methods have been criticised in several areas, which has to be taken into consideration when applying this method in a research project. Within the context of this study the NGT process was selected to prioritise ideas in a democratic manner and generated items which informed development of the Delphi tool, which was the main purpose of Phase One of the study. It offered a highly structured approach, which generated ideas and established priorities within a group setting. The process resulted in a large amount of work being achieved in a relatively short period of time (Keeney et al. 2011) and achieved a set of priorities for development of the Delphi tool. However it has to be acknowledged that this process generated expert opinion as opposed to being evidence-based (Sackman 1975), furthermore due to the highly structured format the process allowed for little debate and discussion of ideas by participants. Therefore it can be argued that it may be less stimulating for participants compared to other group methods.

The Delphi process conducted in Phase Two of the study however was aimed at achieving consensus or collaborative problem solving as opposed to priority setting from a wide group of clinicians throughout the United Kingdom. The iterative process allowed clinicians to review results and reconsider their responses in a novel approach to problem solving, furthermore it was clear from results that clinicians provided considered responses and had strong views on the subject of pain assessment during transport. As this method also relies on an expert panel to determine whether or not consensus exists, it has been subject to considerable criticism. Examples of this criticism include the view that the Delphi process has a lack of universal scientific or professional guidelines (Sackman 1975), that it is highly labour intensive for the facilitator, administratively complex and requires on-going commitment from participants (Williams and Webb 1994).

In relation to these aspects it has to be recognised that due to the nature of this study, including challenges in accessing participants within the health service spread geographically throughout the UK and the highly specialised field of neonatal transport, administration of the Delphi Process was both challenging and complex. Recruitment was difficult, necessitating access by means of special interest groups and educational establishments. Selection of the Delphi panel is an important element of the process, panel members should be experienced in the field under study with a willingness, ability and understanding of the process in order to participate. Consequently the Delphi method does require a degree of commitment from the panel members, combined with an understanding of the process. However for the purpose of this study the Delphi method helped focus the attention of a large panel on a specific topic, facilitating iterative feedback within a novel approach to information sharing and consensus building. Response rate and attrition can be problematic in any research, the Delphi process in the current study generated a 48% return of questionnaires from participants in the final Delphi round. The reasons for this were not investigated within the context of the research, however Donohoe and Needham (2008) postulate that the Delphi method has a higher potential for experts to withdraw due to distractions between rounds, fatigue or disillusionment with the process, all of which could relate to the current study.

The inclusion of Demographics in the Delphi process provided an overall sampling profile of the expert panel. As highlighted by Keeney et al. (2011) this is not essential and not always included in the Delphi process, however within the context of this study it provided an insight into the experience and background of the panel. A further interesting concept in relation to reporting of results within a Delphi study was presented by Kenney et al. (2011), in proposing the different ideologies between the concepts of agreement and consensus.

The authors question the difference between the extent to which participants agree with other panel members or agree with the issue under consideration? Importantly the extent to which participants agree with each other does not mean that consensus exists or that the correct solution has been found. Evans (1997) supports this view highlighting the difference between the terms consensus and agreement, with few studies reporting findings within the context of these different principles. This may reflect in the current study as participants agree that pain should be assessed in all patients during transport, however some participants suggest that a pain scale may not be the most appropriate method. Furthermore Delphi proponents may argue that panel members can review their responses and change their mind moving towards consensus in the belief that other panel members identified a more relevant viewpoint. However cynics may suggest that panel members are enticed into changing their mind in the belief (possible mistaken) that the majority view must be correct. Therefore the influence of issues around validity and reliability within the Delphi process which were discussed in Chapter Four, are important when reviewing results, highlighting the relevance of incorporating elements such as pilot testing (Mitchell 1991).

On reflection the Delphi method proved to be an administratively difficult, however effective means of gaining consensus from a wide range of clinicians to meet the needs of the research. Consensus methods not only facilitated the development of a transport pain assessment scale but also provided a rich and in-depth insight into the views of clinicians in relation to pain assessment.

7.3 Discussion: Pain Assessment during Transport

In the initial stages of planning this research the wealth of information on neonatal pain and pain assessment quickly became evident, with a broad range of literature on all related aspects of neonatal pain from physiological effects of pain (Anand et al. 2007) to ethical issues around pain management (Lantos and Meadow 2007). Therefore the relative paucity of literature on neonatal pain assessment during transport may be viewed as somewhat surprising, opening up multiple areas for further investigation and research.

The issue of why there is little available evidence in this field has to be considered. Undoubtedly neonatal transport is a dynamic environment, frequently transporting acutely ill unstable neonates (Barry and Leslie 2003). Harrison and McKechnie (2011) allude to the levels of discomfort experienced by neonates during transport in a retrospective audit, however to date there is no large scale research study on levels of pain or pain management during transport. The potential difficulty in conducting research within this challenging environment is undoubtedly an influencing factor. However a further consideration is current practice within the transport environment, which became evident in the initial enquiry stage of the research and was further supported by results of the Delphi process and semi-structured interviews. Transport clinicians in general utilised personal experience and judgement in both assessing and managing pain.

This has several implications for practice, including the recommendation from the Royal College of Nursing that there should be a clear pathway for pain assessment and management incorporating a validated pain assessment tool (RCN 2009). Furthermore that pain should be assessed, recorded and re-evaluated at regular intervals (RCN 2009).

The application of pain assessment scales in the clinical area in itself generates debate and controversy. It has been argued that the selection of a specific pain measure in the NICU may be motivated by the acute environment within which it will be used. However the view expressed by Holsti et al. (2011) that many scales/tools have inadequate psychometric testing is reflected by other authors (Duhn and Medves 2004), furthermore the pain indicators they include may be too generally defined and not based on relevant theories for the population. With reference to the use of pain scales in the clinical area, despite an increased awareness of the effects of neonatal pain, formal pain measures are used inconsistently. There is no recent UK survey of practice, however Foster et al. (2012) report on practice in Australia, reflecting that a pain assessment tool was only used in 21 of 196 units (11%). The authors acknowledge an improvement in practice since a previous survey conducted in 2006 (Harrison et al. 2006), however inconsistencies remain, with only a small rise in the use of pain scales from 6% to 11%.

These views support the concept of this Thesis in that by utilising expert opinion in the development of a transport scale, the population and environment within which the scale will be applied is emphasised as a priority in scale development and a precursor to formal psychometric testing in the transport environment. Furthermore harnessing the support of clinicians potentially may encourage uptake and implementation of the scale in clinical practice.

7.4 Discussion: Delphi Findings

A particular challenge of this study was endeavouring to draw conclusions and make recommendations where there is little empirical evidence and contradictory information. Consensus methods provided an alternative means of synthesising information by encapsulating the views of experts in order to enable decisions to be made (Jones and Hunter 1995). However it has been highlighted that consensus methods are not a replacement for rigorous scientific reviews but a means of reflecting opinion and areas of disagreement. Therefore the key purpose of Phase One of the study (NGT) was to provide a structured foundation by identifying priority areas which would inform the Delphi tool utilised in Phase Two (Delphi study). The highly structured format of the NGT focused on a single goal and was less concerned with generating a range of perceptions or ideas within a focus group process. This resulted in the recommendation of specific pain indicators which could then be taken forward to inform the Delphi questionnaire. The pain indicators were both physiological and behavioural, reflecting the content of other pain assessment scales currently in use in the clinical area (Anand et al. 2007).

7.4.1 Focus Areas

When selecting what to include in the Delphi questionnaire, it was important to consider the issues that needed to be addressed and importantly results of the NGT. The purpose of identifying 'focus areas' for development of the Delphi tool (described in Chapter Four) was to ensure that all of the major aspects involved in development of a health measurement scale specific to pain assessment were considered.

The subsequent Delphi process provided the opportunity for clinicians to expand on the identified pain indicators generated in the NGT, allowing them to consider wider concepts in pain assessment during transport which would affect application of the scale in the transport setting.

- *Focus Area: Safety*

Safety is widely reported as an important factor in all aspects of modern health care (Hughes 2008), with the link frequently being made with quality of care (Grol et al. 2008). In relation to neonatal pain assessment and management, safety has been reported with particular reference to appropriate type, dosage and frequency of analgesia (American Academy of Pediatrics 2006), use of appropriate pain measurement to ensure adequate and safe pain management (Anand et al. 2007) and the importance of ensuring clinical stability and safety during inter-hospital transport (Barry and Leslie 2003). Each of these aspects resonates with results of the current research. The Delphi panel reflected that pain assessment was an important factor in ensuring a 'safe' neonatal transport linking this to pain relief facilitating clinical stability of the neonate during transport with less risk of an acute deterioration and therefore a safer transport. These results support current literature on pain assessment in the neonatal period (Anand et al. 2007) and on clinical management of the neonate during transport (Barry and Leslie 2003). However despite the Delphi panel achieving consensus on the basic principle that a pain assessment scale should be used to assess pain during transport, there were reservations from some panel members in relation to how practical using a pain assessment scale would be during an acute transfer. Comments from some participants reflected the view that the current method of utilising the experience and judgement of clinical staff was a more effective means of assessing pain in this setting, expressing the view that pain scales were often overly complex and time consuming and may compromise care.

As was suggested by a member of the Delphi panel this in itself may compromise safety as it may detract from clinical care. It can be argued that this stance reflects current practice, as pain scales are implemented inconsistently in the clinical area (Foster et al. 2012) despite the importance of pain assessment being widely recognised. However this is in direct opposition to the view that clinicians should utilise evidence-based methods and document assessment and intervention with justifications for treatment (RCN 2009). Furthermore in relation to nurse assessment of pain, Brown and Timmins (2005) in an exploratory study of nurses' knowledge and attitudes towards pain recognition and management, reported pain assessment and management was dependent on the nurses' ability to identify pain cues. The authors go on to reflect that some nurses experience difficulty in recognising pain indicators and do not always demonstrate knowledge of current pain research, therefore reflecting the importance of ongoing education.

The question of prioritising pain assessment is controversial (Breivik et al. 2013). Within the Delphi panel views were contradictory as to how much pain assessment and management was a priority during transport, some participants reflecting that stabilisation of the baby in terms of airway maintenance, ventilation and vascular access should take precedence (Barry and Leslie 2003). However others did not support this view stating that pain assessment should be a priority and was an important element in maintaining safety and stability of the baby. Importantly it has to be acknowledged that pain assessment during transport is not reported with any degree of depth in the neonatal transport literature, being mentioned only briefly with no clear guidance (Barry and Leslie 2003, Jaimovich and Vidyasagar 1996). In a comprehensive manual on paediatric and critical care transport which is commonly used as a reference point for transport clinicians, pain assessment consists of a short paragraph explaining the use of analgesics such as intravenous opiates and femoral nerve blocks with no guidance on pain assessment (Barry and Leslie 2003 p100).

This would therefore support the views expressed by some of the Delphi panel that pain assessment during a transport episode was not a priority, the focus being on management of respiratory and cardiovascular stability of the baby. However it is important to consider if this view is representative of transport clinicians. It has been reflected that clinicians who are willing to participate in expert panels are generally representative of their colleagues (McKee et al. 1991), however it can also be viewed that a small number of participants such as in the NGT meeting may not be generalizable to the wider population (Allen et al. 2004). This was however not reflected in a study conducted by Vella et al. (2000) who utilised the NGT to establish research priorities in critical care and reported that their results were widely representative of the population under study.

The Delphi panel was however a much larger group therefore it can be argued that the group may be more representative of the population. It was important to utilise neonatal clinicians with transport experience for the Delphi panel, as this is crucial to ensure a representative sample (Keeney et al. 2011). Within the Delphi panel over half the members had between 6 to 16 years' experience on transport, therefore were experienced clinicians. However elements of bias due to individual experience or beliefs cannot be excluded. Prior experience of participants in relation to pain management is an important consideration which may affect perspectives on pain assessment. An important finding and one which may influence results was that 86% (n=80) had never used a pain assessment scale during neonatal transport. The remainder who stated they had used a pain scale, reporting using one not tested or validated for transport or they were unsure which scale they had used. This could influence their perceptions on how a pain assessment scale could be adapted to transport and how effective and safe it may be.

However it quickly became apparent within the context of the study that safety was an important consideration for clinicians during transport. This factor is reflected in transport literature particularly with the rapidly expanding use of ground and air medical transport (Reyes and Wesolowski 1996). The literature also highlights the use and maintenance of transport equipment as a major component of safety, in order to ensure that the physiological stability of the baby is monitored throughout the transport (Barry and Leslie 2003). The Delphi panel also alluded to this issue reflecting that it was an important aspect of safety linking it to facilitating appropriate pain assessment.

- *Focus Area: Content and Clinical Utility*

As highlighted by Streiner and Norman (2006) items included in a health assessment scale should be unambiguous and easy to comprehend, if the scale is perceived to be too cumbersome or time consuming staff will not utilise it. Content of the scale was therefore directly linked to clinical utility, as the scale had to be practical to use during transport. Ensuring appropriate content of the pain scale was a crucial element in facilitating appropriate management of pain, addressing validity and reliability and in successfully introducing the scale to the transport environment.

In addressing content the Delphi panel adopted a practical approach to items for inclusion in the scale. The physiological indicators which were selected by the Delphi panel were all assessed by monitoring equipment which was part of standard equipment during transport, such as electrocardiogram to monitor heart rate and oxygen saturation monitor to detect fluctuations in the oxygen saturation levels. This suggested that clinicians were considering safety, clinical utility and feasibility, as these methods of pain assessment required no active handling of the baby during transport.

The behavioural indicators (Figure 32) were also assessed by observation such as tone and activity, again requiring minimal handling of the neonate during transport. The physiological and behavioural items selected by the NGT were also selected by the Delphi panel for inclusion in the scale. In total 60 of the 77 items generated by the Delphi technique reached a pre-determined level of consensus by the second Delphi round. However it was unclear why items were rejected by the panel, it was highlighted by Goodman (1986) that the Delphi technique was not sensitive enough to differentiate reasons for participants grading a topic low. In relation to the current research a parallel could be that participants felt that the item they graded low was either not an indicator of pain or that it was not feasible in the transport setting.

There were differences of opinion in the Delphi panel in relation to the potential causes of elevated pain scores in the scale. Vital signs such as heart rate and blood pressure were selected for inclusion in the scale, however some members of the panel highlighted that there could be other causes of alterations in vital signs such as sepsis, pyrexia or underlying pathology. This highlights the importance of adequate testing of pain assessment scales in the clinical areas within which they will be used, as was recommended by Duhn and Medves (2004) in their review of pain scales.

When undertaking this study it was important to consider the need for a separate pain scale for transport or alternatively could an existing scale be directly utilised in the transport setting? Thewissen and Allegaert (2011) allude to this question by encouraging further research into the effectiveness of existing scales as opposed to developing new scales. However within the context of the current study the Delphi panel suggested additions to a scale which would be specific to transport, with further comments suggesting that simply using an existing scale would be inappropriate to the transport environment.

Sellam et al. (2010) in a systematic review considered the effect of contextual factors on the pain response of preterm infants to heelstick, where contextual factors included aspects such as age, behaviour, therapeutic interventions and handling. The authors concluded that contextual factors play an important role in preterm infants' responses to pain and should be considered in the assessment of pain. Inconsistencies in characteristics of samples and designs of studies reviewed is acknowledged by the authors, however it would seem reasonable to consider the specific effects of influencing factors during transport such as handling, movement and noise as contextual factors which should be considered during pain assessment.

- *Focus Area: Design*

Design of the pain scale has several components which are important to consider if the scale is to be appropriate to the transport environment and also address face validity. Firstly it reflects the purpose of the scale, what it will be used to measure and also the general configuration and layout of the content. The Delphi panel reflected the view that a unidimensional pain assessment scale or one which uses a single pain indicator such as body movement (Craig et al. 1993) or facial movement (Izard 1995) may not provide an accurate assessment of pain and that a multidimensional or composite pain scale would be the most appropriate for this population. This would support the recommendations of Duhn and Medves (2004 p126) who stated:

"because pain is a multidimensional phenomenon, well tested multidimensional instruments may be preferable".

The Delphi panel supported utilising both behavioural and physiological indicators, as well as other influencing factors such as gestational age and type of transport. This would facilitate the inclusion of other factors in the assessment pain specific to transport which may affect the pain or stress levels of the baby.

However an area not addressed by the Delphi panel was the difference between the assessment of acute pain such as in heel stick and chronic persistent pain such as experienced in persistent peritoneal pain caused by necrotising enterocolitis (NEC). It has however been suggested that this issue has not been addressed in pain assessment scales currently used in the clinical area and is a limitation in their effectiveness (Thewissen and Allegaert 2011).

Despite overall results reflecting that the Delphi panel supported the use of a pain assessment scale during transport, there were reservations as to how practical and feasible it would be to utilise in relation to time and workload, as transfers frequently have to be conducted as efficiently as possible. The overriding principle of transport is that the baby is stabilised before being moved from the referring hospital. However in some circumstances the patient has a 'time critical condition' when delaying specialised treatment may be dangerous and the transport has to be conducted as quickly as possible (Barry and Leslie 2003). Therefore concerns regarding utilising a scale which is lengthy, time consuming and cumbersome may be justified. The design of pain assessment scales is frequently reported as being complex and impractical in the clinical area, resulting in their application in the clinical setting being inconsistent. Therefore the clinical experience and views of expert clinicians can be viewed as being crucial in the development of a scale which would address the issues of clinical utility and feasibility in this challenging setting. Also of importance is current practice within the transport area, the Delphi panel reported few transport teams utilising a structured method of pain assessment and documentation, frequently assessment is related to the experience and judgement of individual clinicians. Therefore this study provided a platform for the initiation and further development of structured methods of pain assessment in the transport setting.

However the challenge is to structure content and design in a way that encompasses all the important influencing factors to ensure validity and reliability, considering the important aspect of practicality. The Delphi panel acknowledged this by reflecting that content may be subjective, and also influenced by the length and type of transport. As many acute neonatal transfers require both sedation and analgesia, the Delphi panel indicated that a scale which was designed to include sedation would be beneficial. Sedation is considered in only one pain assessment scale currently available (N-PASS, Hummel et al. 2008), however as sedation is frequently required during transport it can be considered an important factor. This again supported the use of a composite scale adapted to the transport environment. The design and format of the scale was reflected by the panel to be an important factor, with consideration of the setting and population, a point emphasised by Duhn and Medves (2004).

The inclusion of a numerical element to the scale was supported by the Delphi panel, this would reflect the intensity of pain or stress experienced by the baby. There are several existing clinical pain assessment scales which include a numerical scoring system to assist clinicians (Stevens et al. 1996, Hummel et al. 2008). This also related to the outcome of the pain assessment, with Delphi panel reflecting that guidance on pain management in relation to the results of the pain assessment score was a useful addition. This concept can also be found in existing scales where actions are recommended within the scale related to levels of pain scores (Hummel et al. 2008). However some reservations were made by members of the Delphi panel in relation to recommendations or guidance for management due to the differences in practice between practitioners or transport teams.

- *Focus Area: Outcome*

Outcome may be considered one of the most important factors, encompassing what effect the pain assessment scale would have on outcome in relation to pain assessment, management, the transport clinicians and also the overall effect on the transport service.

In relation to effect on the baby, the Delphi panel reached consensus that a pain assessment scale would be beneficial to pain assessment, however as there are no currently existing scales adapted to transport, this cannot be linked to contemporary literature. Recommendations from professional bodies do however recommend the use of appropriate pain assessment scales in order facilitate timely and appropriate pain management (RCN 2009, RCN 2011, International Association for the Study of Pain 2005). Furthermore it is now widely acknowledged that untreated or inadequately treated pain adversely affects the well-being of the baby, influences recovery from surgery and potentially affects long term life experience (Grunau and Tu 2007, Anand et al. 1985). However, conversely the effect of over treatment of pain should be considered (Simons and Anand 2006), where analgesia or sedation is used inappropriately possibly due to either poor application of the scale or use of a scale not validated for the transport environment. The potential effect of pharmacological intervention on the neonate is of primary importance, necessitating careful management. Newborn infants, in particular preterm, are more sensitive to opioids and are at increased risk of respiratory depression, hypotension and urinary retention (Anand et al. 2004). This viewpoint is reflected by the International Association for the Study of Pain (2011 p4), who state:

> *"Clinicians must weigh the short-term and long term consequences of acute neonatal pain against the adverse effects of using analgesia"*

The Delphi panel reflected that education in relation to pain assessment and use of a pain assessment scale was important if the scale was to be used effectively. This view was supported in a recent survey investigating neonatal nurses' perceptions of knowledge and practice in pain assessment and management. The authors reported that nurses' perceptions of well-managed pain correlated with training and use of appropriate pain tools. Furthermore barriers to effective pain management were reported as lack of knowledge on pain assessment, perceived fears of side-effects of pain medication, wrong interpretation of pain signals, lack of trust in pain tools and lack of time (Cong et al. 2013). There is little direct evidence available to assess the effectiveness of training individuals to improve their pain recognition skills, however indirect evidence from research on pain validation studies where researchers were trained in pain observation methods achieved inter-rated reliability and concordance with other pain indicators. Furthermore Williams 2002) suggested that feedback on accuracy of pain recognition can improve individual skills.

Transport teams are comprised of medical staff, transport nurses and neonatal nurse practitioners (Barry and Leslie 2003), all of whom manage and assess pain during transport. The Delphi panel agreed that all members of the team should be able to use the pain assessment scale. However Quinn and Baker (2001) in a study examining staff perception of pain in a neonatal unit reported that doctors and nurses had different perceptions of pain, with more nurses than doctors reporting the need for analgesia in pre-designed scenarios. This would indicate that education on pain assessment may be beneficial in assuring that staff were aware of the structure and content of the scale resulting in consistent and effective pain assessment and management.

The effect of implementation of a pain assessment scale on the transport service is a component which would require consideration due to the previously mentioned necessity for training on pain assessment and use of the scale. This would have implications for time and also finance, furthermore a transport pain scale should be transferrable to all transport teams to ensure continuity of care.

7.5 Discussion: Application of Results and Development of the Scale

Application of results to development of the scale was a complex process requiring careful analysis to ensure that the recommendations of the Delphi panel were taken forward within the construct of the scale. It can be argued however that the recommendations were made on the subjective views of an expert panel raising questions of reliability and validity. The large Delphi panel reached predetermined consensus on content of the scale, however as has been previously highlighted reaching consensus does not necessarily mean that the correct decision has been made (Jones and Hunter 1995). Furthermore Pill (1971) suggested that the results of a Delphi study can be proposed as being at best opinion, however as reflected by Mitroff and Turoff (1975) *truth* rests on widespread agreement and such widespread agreement makes qualitative findings appear factual (Munhall 1989).

7.5.1 Adaptation of the N-PASS Scale

The decision to adapt an existing scale was made following review of the Delphi results where the Delphi panel stated that adapting an existing scale would be easier for clinicians and potentially facilitate a degree of continuity between the clinical area and transport.

The selection of an appropriate scale to adapt potentially could have been difficult and time consuming due to the large number of scales available, however as the Delphi panel recommended including both pain and sedation the N-PASS proved to be the only scale which integrated both elements and therefore was selected for adaptation to transport.

The N-PASS scale was originally developed for the assessment of ongoing infant pain and also sedation in the NICU as opposed to only procedural pain. It was also reported as being consistent, age appropriate and clinically useable (Hummel et al. 2008). However as the scale was developed for a North American unit some of the terminology and layout on the original scale was ambiguous therefore elements were adapted for the transport pain scale to enhance clarity, while maintaining the main philosophy of the scale. As the N-PASS scale had undergone initial psychometric testing maintaining the foundation of the scale may assist in establishment of reliability and validity of the transport scale in future testing in the field.

The strategy of establishing 'Delphi Items' and 'Delphi Statements' highlighted priority areas for development of the transport pain assessment scale. Careful integration ensured that the individual recommendations of the panel were brought through to development of the scale in a clear and systematic manner, considering each of the focus areas. The decision to present two formats (landscape and portrait) for review in Phase Three was an acknowledgement of the specialised environment within which the scale will be used, providing the opportunity for the portrait format to fit easily into the existing transport documentation while maintaining the same content.

7.6 Discussion: Face Validity of the Neonatal Transport Pain Assessment Scale (NTPAS)

7.6.1 Introduction

The key question which structured Phase Three of the study was linked with **PRQ 3**:

> *"Has a transport pain assessment scale developed within the current research study by consensus methods achieved face validity"?*

The aim of this Phase of the study was to establish face validity of the pain assessment scale or to what extent the developed pain assessment scale appears to measure what it is designed to measure, pain assessment during transport. If clinicians considered the scale to be ineffectual, too complex, difficult to use or not reliable then the scale would not be used. The application of semi-structured interviews enabled participants to talk freely and express their views and opinions, with the inclusion of some degree of structure to the process enabling replication of the interviews and examination for consistency (Polit and Beck 2010). This facilitated the generation of perceptions on how feasible the scale would be in the transport setting, generating a large amount of data which was fairly flexible and easy to analyse. However the challenges in utilising semi-structured interviews reported by Parahoo (2006) can be related to this study and will be discussed in this section.

7.6.2 Phase Three Participants

Participants in this Phase of the study were all from the initial reference group utilised in Phase One of the study. The benefit of utilising this group was that they were all experienced transport clinicians and had good background knowledge of the study and associated aims and objectives. It can also be argued that having participated in the initial Phase they had been given the opportunity to develop views and perceptions on what should be included in a transport pain scale, bringing these with them to enhance this Phase of the research. However the disadvantages of utilising this group can be argued as including the introduction of potential bias due to preconceived ideas and views. Furthermore it has also been suggested that the presence of an interviewer may introduce an element of bias due to participants structuring their responses to fit the occasion and giving socially acceptable answers (Parahoo 2006). The personal characteristics of the interviewer such as gender, age, clothing and language or accent can also affect responses (Cartwright 1986). It has also been highlighted that the honesty of participants during the interview process cannot be guaranteed (Bowling 2004), furthermore the fact that the researcher was known by most of the participants may have led to a degree of bias and despite no obvious effects it cannot be excluded.

7.6.3 Analysis of Phase Three

The application of an interview schedule in Phase three assisted analysis by providing a degree of continuity between interviews and also enhanced validity as the interviewer could help respondents to understand the questions and also probe for expansions on answers.

Furthermore the process of undertaking a pilot study prior to the main study enabled any ambiguous questions to be clarified, wording improved where required and also provided the researcher with invaluable experiencing in conducting the interview process. Parahoo (2006) suggested that the extent to which the prepared interview schedule provided a rigid or loose structure may highlight to what extent the topics discussed reflect the respondent or interviewer's perspective.

Within the current study the same questions were asked to each participant, however the sequence altered slightly in some interviews dependent on the respondent's answers in order to assist the flow of the interview. The process of qualitative content analysis utilised within this Phase of the study was complex and time consuming, as evaluation of interviews is an intricate process with no two interviews being the same. Data analysis involved reviewing large segments of data, meticulous analysis followed by combining data together into patterns or categories, facilitating the development of definitive Themes. Weber (1983) described a theme as a cluster of words with different meanings which taken together refer to the same issue or Theme. This relates to the current study in that during analysis words used by the participants could be grouped together and relate to the same issue. Elements of some Themes did overlap, an example being the issue of safety could be threaded throughout each theme as it was a basic foundation of practice in all aspects of care.

7.6.4 Discussion of Main Results: Phase Three

The interview process in Phase Three generated views which were very practical in nature, this may be related to participants being directly linked to the clinical area therefore prioritising aspects which would directly affect operational management of the transport. The main considerations for participants on reviewing the scale included the direct effect on the baby, the efficiency of the transport and their own time and responsibility. However it should be acknowledged that a disadvantage which may have affected results was that as none of the participants had actually used a pain assessment scale or any formal means of pain assessment during transport therefore their views were subjective.

The overall response of participants to the content and design of the scale was positive, with each participant reflecting that the content and design of the scale was appropriate to the transport setting. The view expressed by the Delphi panel that pain assessment was not always a priority during transport was supported in the semi-structured interviews, as clinicians stated that practical considerations such as airways maintenance and cardiovascular stability was the priority. However participants did reflect that pain assessment was important and that using a pain scale would make pain assessment more of an issue during transport. This was partly reflected as being due to an improvement in knowledge base and also the fact that the scale would be part of the documentation and therefore would have to be used. The first Theme which emerged encompassed aspects surrounding safety and was threaded throughout the results. This could be related to the fact that patient transport is perceived as being a volatile, changing environment with specific challenges which need to be considered in all aspects of patient management (Barry and Leslie 2003). This was acknowledged by both the Delphi panel and in the semi-structured interviews, as patient safety was paramount in both selecting the content of the scale and utilising the scale appropriately.

It was also highlighted by participants that practices were changing on transport and that babies were now more frequently transferred on morphine and sedatives, a view supported by Thewissen and Allegaert (2011), who in their review of pain assessment highlighted the emerging use of analgosedatives in neonatology. The authors go on to reflect that these innovations need to be considered and integrated into the changing concepts of neonatal care such as methods of pain assessment. Participants supported this view, reflecting that when patients are being given morphine for pain relief, adequate pain assessment is important from a safety perspective. This concept can be related to integrating pain and sedation assessment in the scale. Participants all stated that this was a useful addition to the scale, however it was a new concept for them and would need further explanation and education. The elements of the transport environment which would influence application of the scale were also reflected in the semi-structured interviews. The influence of portable monitoring equipment was perceived by clinicians to affect their ability to assess the baby, the fact that the movement of the ambulance may affect readings and therefore interpretation of the babies' condition and levels of pain. This reflected an awareness that clinicians needed to utilise their own experience and judgement when using equipment. Furthermore the current practice of protecting the babies from as much light and noise as possible restricted access further and would have to be adapted to facilitate pain assessment.

Theme 2 encapsulated perceptions on how practical and useful the scale was during transport. This concept was highlighted by the Royal College of Nursing (RCN 2009) in their Clinical Practice Guidelines of the recognition and assessment of acute pain in children, with recognition of the importance in selecting a tool relevant to the situation within which it will be used. Participants all stated that the scale appeared to be easy to understand and use during transport, not appearing overly time consuming.

However, it should be acknowledged that the interviews were conducted when the clinicians were out with the clinical setting and able to rationalise each section. Opinions and views may be altered when the scale is applied during an acute transport when time is limited. However it was also speculated that any element of the new scale which may prove to be ambiguous or difficult to apply would become apparent when used in the clinical area and staff become familiar with the scale.

Theme 3 encompasses items to include in the scale and also format of the scale. These again were highly practical elements however extremely important to clinicians if pain was to be assessed appropriately. Issues of reliability and validity apply to this Theme, however for the purpose of this study only face validity of the scale will be established with further testing of the scale being carried out as on-going research in the field. Requirements of a transport scale which were perceived by clinicians as being important such as short, concise, simple to use appear to have been achieved in the scale. These perceptions may not only be due to the acute nature of the transport and possible time limited transports, but also the fact that clinicians had little experience of using a pain scale therefore required a scale easy to understand and use. The use of an information sheet with the pain scale received positive comments, and was stated to be very useful, implying that additional information for clinicians in the field on the scale was important.

In relation to format Participants were given two scales to review both with the same content but one landscape and one portrait. This was a practical method of enabling participants to select the format which they considered most practical to apply in the clinical setting. Despite the portrait version being more appropriate to the design of the current transport log and the content being exactly the same in both formats, participants preferred the landscape format, reflecting that design and layout was important to ease of use.

There were elements of terminology which some participants stated would require further explanation such as “underlying pathology”, highlighting the importance of the scale being simple and easy to understand. The concept of including items which addressed both pain and sedation in the scale was new to participants, however it was perceived to be an important element which participants stated would need further explanation and education before the scale was used. It is important to note that there is only one current pain scale which integrates both pain and sedation (NPASS). This may be due to the difficulty in developing a valid and reliable scale with both measurements. The NPASS had undergone initial reliability and validity testing in the clinical area with positive results however studies are on-going. As the inclusion of both pain and sedation was recommended by the Delphi panel, selection of the NPASS for adaptation to the transport setting can be justified, bringing with the benefit of validity and reliability testing.

The inclusion of an algorithm to assist pain management was suggested by the Delphi panel, however was not included in the first Draft of the transport pain scale as it would have resulted in a larger more complex pain scale. The participants in Phase Three were asked if they would include an algorithm, each participant concluded that it would not be a useful addition and would be overly complex. However participants did reflect that guidance of pain management linked to the pain score would be useful. This was a controversial issue, as it was also highlighted that some transport teams have different management strategies and it would therefore be difficult to implement.

The final Theme 4, integrated all aspects linked to the effect of using a pain scale would have on clinical practice. Participants considered a wide range of aspects including the effect of overall assessment and management of pain on the baby, new guidelines and protocols for the transport service, education and awareness of pain. Participants stated that the pain scale had the potential to influence pain assessment and management. This may be due to improved knowledge of pain or a more formalised process of recording and documenting pain. Accountability appeared to be an important consideration for participants, as currently there appeared to be a lack of documented observation and justification of pain management. This would reflect the recommendations of the Royal College of Nursing (RCN 2009) recommendations that pain in children and neonates should be assessed, recorded and re-evaluated at regular intervals. The issue of documentation is of particular relevance in the intensive care and transport environment. Barry and Leslie (2003 p8) reflect that:

> *"A good doctor or nurse is only as good as the records he or she keeps"*

However the debate in relation to neonatal pain assessment with pain scales includes the consideration of over prescribing analgesia and sedation, with little available information on side effects from repeated opioid administration on neonates (Simons and Anand 2006).

In conclusion this initial review of face validity of the NTPAS provided positive results, with participants reflecting that the scale appeared to be appropriate and feasible to use within the transport environment. The scale appeared to be simple and easy to apply, with content being viewed as appropriate to the transport setting. Importantly participants reflected that the scale should be tested during transport to fully test validity and feasibility and staff would require education on pain assessment and use of the scale.

7.7 Critique of the Findings:

7.7.1 NGT and Delphi Process

As with all consensus methods, the advantages of both NGT and Delphi are heavily dependent on the experience and knowledge base of the participants. What is clear from the results of the study is that pain assessment during neonatal transport is perceived to be important by clinicians who participated, however despite 79% of participants stating they had experience using a pain assessment scale in the clinical area, 86% stated that they had not used one during transport. Therefore this may affect their perceptions on what should be included in a scale or what would be appropriate to the transport setting. This was reflected in the following comments by a member of the Delphi panel:

> *"difficult to find pain assessment scores outside of transport which work well & consistently".* (Delphi panel participant)

The same indicators of pain, both physiological and behavioural are reported throughout each Phase and appear to be consistent with literature on the effects and indicators of neonatal pain (Anand et al. 2007). However results cannot be supported by rigorous statistical analysis as they reflect the views and perceptions of clinicians.

Key comments and views expressed in the Delphi results indicated that there was a range of views and practices in relation to pain assessment during transport. Importantly individual outlying comments and views within the context of the study do not influence overall results, nonetheless are an important aspect of management within the clinical area.

The Delphi technique achieved the required predetermined consensus on 60 items, however as has been reflected widespread agreement does not necessarily mean that the correct answer has been found (Jones and Hunter 1995). Furthermore the application of consensus methods does not in itself assure reliability and validity of the scale in the transport setting, this will be developed in future studies. However Sacket et al. (1996) describes evidence-based medicine as integrating best available external clinical evidence from systematic research practice with individual expertise, which would appear to justify the Delphi method.

One of the main results of the Delphi process was the consensus that a pain assessment scale should be used during neonatal transport. However there were several participants who raised concerns regarding feasibility and clinical utility of a scale for transport which should be considered, expressing that clinical judgement and experience would take priority.

> *"Use a common sense approach - if baby asleep, it's not in pain! If I'm sticking tubes in it - it's in pain etc."* (Delphi panel participant)

However it should be acknowledged that a threat to the credibility (Fink et al. 1991) of the current study is the subjectivity around the assessment of pain, and the range of differential diagnosis and undeniable differing causes of alterations in physiological and behavioural parameters in the neonate.

7.7.1.1 The Rights of the Neonate to Appropriate Pain Assessment and Management

The ethical right of the neonate to appropriate pain assessment is important to consider. The Delphi process highlighted that pain assessment was perceived by the panel to be an important aspect of patient transport, however active implementation of the recommendation made over 10 years ago that pain assessment should be the 'fifth vital sign' (Joint Commission on Accreditation of Healthcare Organizations 2001) appears to be questionable.

Whereas participants recognise the importance of pain assessment they question if it should be prioritised. This is reflected in the comments of one Delphi panel member who stated;

> *"Of course pain assessment is always relevant but whether it can be prioritised when stabilisation and transferring out are the main priorities I think is a difficult question".* (Delphi panel participant)

Some comments reflected the view that with the unstable neonate other issues such as respiratory and cardiovascular stabilisation and management of the transport should take priority over pain assessment. Furthermore that analgesia should not be administered to the neonate during transport.

> *"I still believe that an assessment of the babies' level of pain should be made before the baby leaves the referral hospital and that adequate analgesia be given then".* (Delphi panel participant)

> *"Transports are not with their own risk and have to consider analgesia mid journey I believe is unacceptable"* (Delphi panel participant)

These views may be linked to the potential hazards during a transfer within a transport vehicle (Skeoch et al. 2005, Buckland et al. 2003), furthermore the potential deleterious effects of analgesia (Anand et al. 2004). Motivation to act on pain detected in others has been discussed in the literature (Goubert 2005) and potentially could be an influencing factor in pain assessment. Campbell et al. (2008) purport that empathetic recognition of pain by health care professionals does not necessarily lead to improved pain management in the clinical setting, other factors may moderate or negate sympathetic motivation to act on pain signals from patients. These include decreased motivation in clinicians to detect pain due to desensitisation, suppressing their empathetic reactions or perceiving other elements in their clinical management as being more important (Campbell et al. 2008). Standardising pain assessment for use during all transports also appeared to be problematic for some of the Delphi panel. It has to be acknowledged that neonates requiring transfer have multiple pathologies and specific requirements, a factor which some Delphi panel members stated would make utilising a pain scale difficult;

> *"Different circumstances of each transport would make a definitive score and treatment options too restrictive"* (Delphi panel member)

Furthermore it was suggested that the traditional pain scales were unusable in the transport setting.

> *"Transport is a very different environment and many factors make "classic" pain assessment tools unusable".* (Delphi panel member)

These comments would appear to support the development of a scale specific to transport, taking into consideration all of the influencing factors experienced during transfer. Furthermore it can be argued that the ethical principles of beneficence (the duty to benefit another) and non-maleficence (do no harm) results in an obligation by health care providers to provide pain management to all patients regardless of the circumstance (Franck and Bruce 2009).

7.7.2 Critique of the Findings: Semi-Structured Interviews

Phase Three of the study was aimed at establishing face validity of the developed transport pain assessment scale. Results were therefore based on the perceptions of clinicians reporting if in their view the scale appears to be a valid means of assessing pain during transport. Results are therefore subjective and formulate initial testing of the scale, it is important to emphasise that further reliability and validity testing would be required in the field. However the process of semi-structured interview enabled clinicians to openly discuss pain assessment and the newly developed scale. The success of the semi-structured interview method largely relies on the skills of the interviewer, ensuring that they understand and can competently use the interview schedule, with an awareness of the errors of bias which can arise during the technique of personal interviews (Barriball 1994). Within the current study the researcher conducted and audiotaped each interview, including a pilot study prior to commencement of formal data collection. This assisted in familiarising the researcher with the interviewer providing valuable experience and facilitating continuity in the interview process. The following section will critique the findings of this Phase of the study in greater detail.

7.7.2.1 Transport Pain Assessment Scale: A potentially useful tool or a paper exercise?

This Phase of the research can be viewed as one of the most important as it reflects the views of clinicians on the scale and provides an indication on how well utilised the scale may be in the clinical area. None of the participants currently used a pain assessment scale during transport or were aware of a guideline on management of pain during transport which may have affected their overall perceptions on the application of a scale in the clinical area.

As Franck and Bruce (2009) note, despite numerous guidelines on pain assessment and standards mandating their use, there continues to be poor compliance. Results from both the Delphi process and semi-structured interviews would support this view. Therefore does the developed transport scale appear to have the necessary requirements for the transport environment and would it be used by clinicians? The small scale semi-structured interviews with seven transport clinicians appeared to indicate that the scale achieved a degree of face validity for use during transport. Each participant reflected the overall view that the scale was appropriate for use during transport and would appear to be an appropriate pain measurement tool.

However several participants stated that review of the scale would be easier when they are able to use it and test it during a transport. This view reflects the subjective nature of the research which may be challenged with the current emphasis on evidence-based practice. A comment from one of the Delphi panel with over 20 years of experience reflected doubts over application of the scale;

> *"I will need convincing that it will make a difference and be practical".*
>
> (Delphi panel member)

The very core of the research and development of the scale is based on consensus methods, some may argue that this affects validity. In relation to the use of expert opinion, Kitson et al. (1997) reflect that there are many instances in clinical practice where evidence has to balance with opinion. However the interaction of various perspectives and the involvement of stakeholders advocated by Kitson in the absence of evidence-base would appear to reflect the spirit of consensus methods.

Nevertheless the question of evidence-based practice is important to consider when reviewing the scale as there was a clear lack of existing literature on pain assessment during transport (see Chapter Three). In relation to the assessment of pain in children, Frank and Bruce (2009) support this view by reporting a lack of good quality evidence for the efficacy and effectiveness of standardised pain assessment tools in relation to paediatric or process outcomes. The author's argue that it is impossible to separate the effect of structured pain assessment from the effects of pain treatment on patient outcomes, going on to reflect that there may not be an observed direct effect of structured pain assessment on pain relief. However the authors highlight that an observed effect may be greater documentation of pain which may facilitate more effective treatment and patient outcome. This view was supported in the semi-structured interviews where several participants stated that the scale would improve documentation and make pain more of an issue during transport.

This would also address further concerns relayed by participants in relation to professional accountability, that currently there was no evidence or documentation that they were adequately assessing pain during transport. Each participant reported that the content of the scale was clear and concise, enabling then to easily utilise the scale and document the findings.

The application of evidence-based methods is undoubtedly important in the management of pain, however Sackett et al. (1996) purport that evidence-based practice integrates best available clinical evidence from systematic research with individual clinical expertise, a concept which would appear to support the application of consensus methods within the current study.

7.8 Limitations of the Study

In Chapter Four the abundance of weaknesses in the Delphi technique were identified and discussed, these are likely to hold true with the current study. The Delphi technique as with the NGT has been reported as having one main disadvantage which precedes any other and that is the lack of scientific or professional guidelines upon which it is based (Keeney et al. 2011). It was heavily criticised by Sackman (1975) for failing to meet professional standards relating to such areas as design and administration. As a result of this there are many variations in implementation and format (Linstone and Turoff 1975). A clear advantage for this study was the ability to include participants from a wide geographical area (Allen et al. 2004) as transport teams are scattered throughout the UK. The concept relies on the understanding that consensus is achieved through feedback of other panel members responses. However the format of feedback differs widely between studies from a single number (Jolson and Rossow 1971), complete distribution to participants (Sahal and Yee 1975) and members comments (Clayton 1997). Feedback within this study was given throughout each section of the Delphi tool enabling participants to consider each section and review their responses.

7.8.1 Delphi Rounds: Drop-out Rate and Expert Panel

The number of rounds in the Delphi process is also significant in that two rounds are stated to be necessary to gain consensus (Keeney et al. 2011), however there are reports of single Delphi rounds (Binkley et al. 1993). The crucial aspect is achieving consensus or when convergence of opinion is gained (Cleary 2001). The Delphi process in this study consisted of two rounds, when the pre-determined level of consensus was achieved.

The occurrence of participants dropping out between Delphi rounds is common to all Delphi studies which are of a similar scale to the current study (Lindeman 1975). The effects of this and non-response from the participants who were invited to take part in the second round may have influenced findings. A further limitation may relate to the lack of understanding about the Delphi process, time and work commitment required by panel members despite being given information at the beginning of the process (Landeta 2006). The size of the Delphi panel in this study was large in comparison to other studies (Fink et al. 1991). This resulted in it being difficult and time-consuming to manage. A smaller panel would have been easier to facilitate and may have given the opportunity for increased depth of discussion and evaluation.

The Delphi technique is dependent on the concept of the expert in the field. It is clear in the current study that clinicians who work directly on transport teams are the most experienced within that environment. It should be noted that the second Delphi round had a reduced response rate (48%), which could be attributed to several factors. As the Delphi consists of several rounds there is a higher risk of panel members dropping out of the study due to fatigue, constraints of time or distractions between rounds (Donohoe and Needham 2008). However there may be some disparity between recruiting the clinicians who will be using and applying results in the clinical area (Linstone and Turoff 1975) and those with credibility in the field (Murphy et al. 1998) such as clinical managers, researchers, academics.

7.8.2 The Delphi Questionnaire

On reflection one of the most challenging aspects of the Delphi process was designing the questionnaire. The indicators of neonatal pain and the influencing effects of neonatal transport are extensive, therefore condensing them into a manageable questionnaire was a time consuming process. Piloting the questionnaire with clinicians was aimed at removing any ambiguous areas and clarifying questions. It has been recommended by early Delphi technologists that what they describe as *Delphi Event Statements* have an optimal length of 20 to 25 words (Salancik et al. 1971). However these recommendations appear to relate to the original application of the Delphi process that of forecasting future events rather than the more current contemporary purpose of clinical guidance and decision making (Fink et al. 1991).

Perceptions of pain and pain assessment can be very subjective and may relate to the individual clinicians experience, judgement and possibly qualifications (Brown and Timmins 2005, Thewisen and Allegaert 2011). Therefore there may be differences in interpretation of some of the questions, which potentially could reflect on results. It is apparent some of the participants did not respond to all of the questions. This could be due to fatigue or lack of understanding. It may also be due to each of the Delphi panel not being in position to answer all of the questions due to lack of experience particularly in flight transfers. Technical difficulties could also explain lack of response to some questions, as there is always the possibility with an eDelphi for computer-based problems to influence results. Furthermore the risk of personal bias from the researcher should also be considered and cannot be excluded due to the researchers own prior experience and views.

7.8.3 Alternatives to the Delphi Technique

As with all research studies concluding comments should consider possible alternatives to the methods applied. In relation to the current study, alternatives within the Delphi process could have been applied such as an alternative first round. The generation of a single question to participants is an alternative, however would not have generated structured items for the second round. A single questionnaire would have been simpler to manage, however would not have generated consensus of agreement. A further alternative may have been to conduct individual interviews with transport clinicians throughout different transport teams in the United Kingdom. This potentially would have resulted in more in-depth and personalised data. However gaining ethical approval would have been an extensive and lengthy process in order to gain access to all of the varying hospital establishments.

7.8.4 Limitations of Semi- structured Interviews

The semi-structured interviews were aimed at establishing face validity of the scale, with further validity and reliability testing to be carried by means of on-going research in the clinical area. Importantly results were subjective and reflected the views of individual participants and did not reflect reliability of the scale. The sample size in this Phase of the study was small and from a reference group of clinicians used in the first Phase of the study, therefore results cannot be generalizable. However the choice of methods appeared appropriate as the use of an interview schedule provided structure and direction and also increased validity as respondents were assisted in in understanding the questions where necessary. Furthermore the researcher was in control of the interview with the ability to probe the participant to seek clarification or more in-depth answers as required (Parahoo 2006).

The semi-structured interview however requires preparation and a degree of skill on the part of the interviewer, as various levels of bias can be introduced into the procedure. In the current study the researcher was known by most participants therefore may have led to a degree of bias. Furthermore the interaction between researcher and participant can also be an influencing factor and can affect outcome (Parahoo 2006).

Alternative methods may have included conducting 'unstructured qualitative interviews' where the researcher accumulates experiences and perceptions of participants until a broad understanding is obtained and saturation is reached, when at that point the researcher may stop interviewing (Parahoo 2006). This may have generated in-depth data however would have been lengthy and time consuming and potentially may have generated data which was not as focused on the purpose of this Phase of the research.

7.9 Conclusions

The concluding section of this study highlights the unique contribution made by this Thesis to the field of neonatal transport pain assessment. This study is the first to utilise consensus methods to harness expert opinion on the content and structure of a pain assessment scale for use during neonatal transport. An overview of the contribution to the field of knowledge in relation to pain assessment during neonatal transport follows and leads on to an evaluation of the emerging themes which were developed throughout the study.

7.9.1 Contribution to the Field

This research makes a number of original contributions in the field. This includes a contribution to the knowledge-base on assessment of pain in the transport environment, the application of consensus methods in the development of a pain assessment scale and to academic researchers studying these concepts. The data presented are the product of the research aims and primary research questions all of which have been achieved:

1. Chapter Two focused on the specialised area of neonatal transport by reviewing specific challenges presented by the transport environment and physiological parameters which may be utilised in the assessment of pain.
2. The study elucidates the views of clinicians on which pain indicators should be included in a transport pain assessment scale (PRQ1), highlighting views and perceptions of clinicians on important elements of pain assessment.
3. This study supports the view that a pain assessment scale is a practical and feasible measure of assessing pain during transport (PRQ2), while presenting discussion on aspects of utilising a pain scale which may be challenging in this setting.

4. The development of a pain scale by consensus methods was achieved. To date consensus methods have not been utilised to inform the structure and content of a neonatal or infant pain assessment scale and proved to be an effective strategy.
5. By means of semi-structured interviews the establishment of face validity of the transport pain scale was initiated (PRQ3).

7.10 Emergent Themes

The Themes which emerged in Phase Three of the study were grounded in the specific challenges presented by the transport environment which influences the ability to adequately review and manage pain. The application of the perceptions and views of transport clinicians introduced a practical and structured element to the study. Therefore the Themes which were threaded throughout the results were linked to practical considerations of pain assessment during transport. Issues were highlighted in relation to the safe application of a pain assessment scale to the transport environment (Theme 1), relating also to how effective and feasible it will be to use (Theme 2) importantly the content of the scale (Theme 3) and to what extent it will influence management (Theme 4). The Royal College of Nursing (RCN) in 2009 published comprehensive clinical practice guidelines on the recognition and assessment of acute pain in children. Results of the current study reflected recommendations made in the RCN report particularly in relation to assessment of neonatal pain with the overall consensus that a pain assessment scale should be used to assess pain during transport.

This supported the recommendation (3) by the RCN in relation to pain assessment in neonates which stated:

"If pain is suspected or anticipated, use a validated pain assessment tool; do not rely on isolated indicators to assess pain".

(RCN 2009)

The plethora of neonatal pain assessment scales currently available has to be acknowledged, however they have varying degrees of psychometric and clinical utility testing. This is an issue which should be addressed in future studies in order to ensure that pain assessment scales are appropriate to the infant and setting. The use of a multidimensional pain assessment scale adapted specifically to the transport setting was recommended by the Delphi panel. Results concluded that pain should be assessed at regular intervals, adapted to the individual needs of the baby. This finding is supported by the RCN recommendation (4), the focus being on individualised care specific to the child:

"Assess, record, and re-evaluate pain at regular intervals; the frequency of assessment should be determined according to the individual needs of the child and setting". (RCN 2009)

Clinicians viewed that the inclusion of vital signs in the assessment of pain during transport assured clinical stability and therefore safety during transport. This would support the good practice point (6.2) presented by the RCN (2009) which stated:

"Acknowledging pain makes pain visible. Pain assessment should be incorporated into routine observations (as the fifth vital sign or 'TPRP' – temperature, pulse, respiration and pain".

(RCN 2009)

An overriding message was highlighted by the research in that no one scale or tool is appropriate to all babies or circumstances. Clinicians have a responsibility to ensure that the pain assessment methods are appropriate, valid and reliable to the area or setting in which it is applied. This was highlighted by RCN recommendation 3, which stated:

"No individual tool can be broadly recommended for pain assessment in all children and across all contexts". (RCN 2009)

Outcome was also an emergent theme in the research. Literature on neonatal pain, discussed in Chapter Two of this Thesis, reflect both the short and long term effects of neonatal pain. Abnormal or excessive neural activity related to pain during the neonatal period has been linked with long-term changes in somatosensory and pain processing (Anand 1997, Fitzgerald and Walker 2009). The Delphi panel views also reflect the RCN recommendations that link appropriate pain assessment with optimum outcome for the baby. In relation to outcome the RCN Evidence statement on pain in children reflects that:

"Regular assessment of pain in a systematic framework improves outcomes for children". (RCN 2009)

7.11 Dissemination of Findings

An important aspect of the Delphi technique is effective dissemination of findings (Mead et al. 1997, Fink et al. 1991). A summary of the research findings will be disseminated to those participants who have expressed an interest. A number of the participants have expressed a specific interest in reviewing the new transport pain assessment scale with a view to implementing it into their practice.

An interesting comment from the Delphi panel appeared to suggest that the Delphi process had initiated reflection on current practice with particular emphasis on the priority placed on pain assessment during transport. Concerns related to application of the Delphi methodology in that results may be applied inappropriately or out of context (Powell 2003), were not apparent in the Delphi panel comments. Concerns in this study were largely related to the subjectivity of pain assessment and the difficulty in conceptualising it within the construct of a pain assessment scale.

These concerns will be relayed in future publications of the research. Pain assessment and management is viewed as a continuum from the transferring neonatal unit, during transport to the receiving hospital. Therefore it is important that the issues are disseminated throughout the neonatal community.

In addition to the feedback to participants the researcher has also engaged in some active dissemination of findings of the study by means of a publications in academic journals (Appendix 1, 3) and presented a poster presentation at the International Conference in Nursing 2011 (ICN) in Malta.

7.12 Recommendations

The International Association for the Study of Pain (IASP) in 2005 reported on the IASP first global day against pain in children (IASP 2005 p5). This international association highlighted important principles which were key to this study. They reflected:

"Children's pain must become a priority for all health care professionals. Health professionals must be trained in pain measurement and treatment techniques that are suitable for infants and children. Individual clinicians caring for children have a responsibility to access and apply currently available research and best clinical practice. Most importantly, consumers (children and their parents) should expect that pain will be assessed and managed".

The recommendations for practice, education and research that follow are based upon a cautious approach to the application of the findings of the study. However the recommendations should be reviewed in terms of the best practice guidelines as outlined by the Royal College of Nursing (RCN 2009) in relation to the recognition and assessment of acute pain in children.

- **Recommendations for Practice**

Recommendations directly supported by results of the study include:

● Phase 2 Section 6 of the study supported the recommendation that health care professionals should adopt a proactive approach in the assessment and management of pain. All participants in Phase 2 supported that pain should be formally assessed.

● Phase 2 Section 6 and Phase 3 results reflected that participants perceived pain should be anticipated in all neonates undergoing neonatal transport, furthermore it should be assessed and managed accordingly

● Phase 2 Section 6 and Phase 3 results reflected that a pain assessment scale validated for use during neonatal transport should be used within the transport setting.

● Phase 2 Section 6, 7 and Phase 3 results reflected that participants recommended that pain assessment should be clearly documented and re-evaluated at regular intervals during the transport in accordance with the individual needs of the baby.

- **Recommendations for Education**

As a result of the research general recommendations include:

● Pain assessment and management during transport should be an integral part in the curriculum design of transport courses/modules. It is recommended that the principles of pain management should be included in the basic education preparation of transport clinicians

●Education on the pain assessment method of choice should be available for all transport clinicians with regular in-service updates.

●Pain assessment and management during transport should be evidence-based utilising all available sources such as audit and research.

●There should be structured guidelines within the transport service on pain management specific to the individual needs of the baby.

●Clear and concise communication and documentation is recommended.

This relates to accountability in relation to appropriate assessment and management of pain. Educational processes should engender the development of high levels of critical thinking and reflexive thinking as well as opportunities to develop communication and assessment skills.

- **Recommendations for Further Research**

Empirical research in the area of neonatal pain assessment can be ethically and methodologically challenging. However this small study has suggested a number of areas that may benefit from further research. These include:

1) A validation study utilising psychometric testing of the newly adapted neonatal transport pain assessment scale (NTPAS) in the clinical setting;

- This should entail a multi-centre study applying the NTPAS scale in a variety of transport settings, incorporating psychometric testing of the scale to establish validity and reliability of the scale. This will require the development of a research protocol and support from the transport service, also requiring funding to be sought in order to facilitate the study.

2) Outcome of implementing the NTPAS in relation to the patient, staff and transport service;

- Outcome measures should be reviewed in relation to how the scale effects management during transport, including methods of pain management. This is of particular relevance to highlight any effects on the frequency or dosing of analgesics as a result of the scale. This could be facilitated by retrospective analysis of patient transports by reviewing transport documentation.

- Long term follow-up of neonates included in the NTPAS validation study would be beneficial to review patient outcomes.

- A qualitative study to review staff perceptions of the transport pain assessment scale when used during transport would be beneficial to review feasibility and clinical utility. This could be facilitated by either questionnaires or semi-structured interviews.

3) A review of the effects implementation of the pain assessment scale had on the transport service would highlight any operational issues such as financial effects potentially caused by staff education and training and to highlight how generalisable the tool was throughout the transport service.

4) This study highlighted the lack of research on the effects of pain on the neonate during transport. The NTPAS scale could be utilised in future studies on the effects of different forms of transport on the pain experienced by the neonate.

7.13 Concluding Comments

Although it is hoped that the findings and conclusions of this research will be of interest to the clinicians who participated in the study, it has to be acknowledged that the area of neonatal transport has now become highly specialised, with transport teams being focussed within their individual regions/teams.

To the researchers knowledge this study may reflect the first national study into the development of a pain assessment scale for patient transport undertaken in the UK. This is a surprising finding both due to the plethora of pain assessment scales and literature on neonatal pain. Several reasons can be postulated for this finding. The area of neonatal transport is a challenging area to conduct research both ethically and methodologically. The safety and stability of the acutely ill neonate is of priority and cannot be compromised in the process of conducting research, therefore clinicians are cautious of conducting studies within this setting. Guidelines and practices may be specific to individual transport teams, with research and audit being conducted in-house.

Finally the area of neonatal pain assessment is well acknowledged as a difficult area to research due to the subjective nature of pain in the non-verbal patient. Experienced neonatal clinicians may be considered to be proficient in behavioural and physiological assessment of the neonate and therefore do not perceive a tool or scale necessary to enable pain assessment. However with the increased awareness of the effects of neonatal pain, issues of accountability, and the increasing presence of Advanced Neonatal Nurse Practitioners (ANNP's) as the lead clinicians on neonatal transport, structured methods of pain assessment and documentation should be an area which attracts further research and development within the field.

Glossary

ECMO- *Extracorporeal Membrane Oxygenation: technique which oxygenates the blood via oxygenating system and returns it to the baby*

HFO- *High Frequency Oscillation: ventilatory technique which uses rates of 600-900 cycles/min to maintain oxygenation*

iNO- *Inspired Nitric Oxide Therapy: pulmonary vasodilator used in pulmonary hypertension*

IUGR- *Intrauterine Growth Restriction: infants born below the 10th centile for gestational age*

IVH- *Intra ventricular Haemorrhage: blood within the ventricular system, occurs in preterm infants*

LBW- *Low Birth Weight: infant whose birth weight is 2500grams or less*

PPHN- *Persistent Pulmonary Hypertension of the Newborn: failure of the pulmonary vascular resistance to fall after birth leading to severe hypoxia and acidosis*

RDS- *Respiratory Distress Syndrome: occurs predominantly in preterm neonates due to lack of surfactant in the alveoli*

(Gomella et al. 2009)

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Appendices

Appendix 1

Author Publication: Neonatal Pain Theory and Concepts

Neonatal Pain: Theory and Concepts

Lavinia Raeside

Abstract

Pain assessment and management in the neonatal population is an on-going area of controversy and debate. Historically a lack of knowledge and understanding of neonatal pain has hindered the development of comprehensive pain management strategies in the clinical area. The rights of the child to appropriate pain relief regardless of the environment is paramount, however most pain interventions are of uncertain efficacy and are associated with both risk and cost.
This paper examines current literature on the theory and concepts associated with neonatal pain. The first section will review evidence on the deleterious effect of pain on the neonate. The second section considers to what extent existing evidence had influenced neonatal pain assessment, reviewing the strategies utilised to assess pain within this specialised population.

Introduction

Debate on the management of neonatal pain has evolved over the past three decades. The initial widespread belief that neonates lack complete development of the neuroanatomical and neuroendocrine components necessary to perceive pain, accompanied by concerns over the potentially deleterious effects of analgesia on the respiratory system (Lippmann et al. 1976, Rackow et al. 1961) informed clinical practice at that time, with neonates receiving inadequate or no analgesia for painful procedures.
An era of research in the 1980's established that neonates did demonstrate similar or exaggerated physiological and hormonal responses to pain (Anand and Hickey 1987), highlighting that exposure to pain may increase neonatal morbidity (Anand et al. 1987).
It is now acknowledged that neonates experience pain to a similar extent or possibly more intensely than older children and adults and are at risk of adverse long term behavioural and developmental effects due to inadequate management of pain relief in the newborn period (Mathew and Mathew 2003). However regardless of these views it is still reported that pain is:
"..underestimated and under treated in children and particularly babies. There is still evidence that pain is inadequately dealt with for children, requiring better prevention, assessment and treatment".
(Department of Health, Department for Education and Skills 2007)

Furthermore the intense debate over the dosage of analgesia as well as the risks and benefits of different pain management techniques within the neonatal population continue within the literature (Anand et al. 2004).

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Effects of Pain on the Neonate

The short and long-term effect of pain on the term and preterm neonate is a complex area of discussion. The increasing number of surviving extremely low birth weight and medically fragile neonates has introduced a new population into the Neonatal Intensive Care Unit (NICU) who potentially can be hospitalised for lengthy periods (Grunau and Tu 2007).
It has also been suggested that due to the plasticity of the developing nervous system, the greatest impact of pain may occur in the most immature and sick neonate (Fitzgerald 2005).
Within the NICU environment neonates are frequently exposed to repeated stressful and nociceptive stimulation which can lead to sensitization (Grunau and Tu 2007), with excessive or abnormal neural activity related to pain and injury during the postnatal period also being linked to long-term changes in somatosensory and pain processing (Anand 2000). Procedural pain can induce changes in physiological, behavioural and hormonal response which could influence nociceptive and tactile thresholds, neurodevelopment, stress physiology and behaviour (Anand 2000).
There is also a growing body of evidence which suggests a potential link between pain in preterm neonates (particularly extreme preterm) to later development and behavioural compromise in preterm children (Grunau and Tu 2007). Furthermore Anderson et al. (2004) highlight a correlation between problems in cognitive and behavioural function and birth weight and gestational age. It has also been suggested that the intensity of pain experienced by the neonate in the NICU is another important factor in neurodevelopmental outcome (Grunau and Tu 2007).

Keywords
Neonatal Pain, Pain Assessment, Pain Scales, Pain Indicators.

Differentiation between Pain and Stress in the Neonate

The terms "neonatal pain" and "neonatal stress" frequently interlink in the literature. The fact that the neonate cannot report pain presents challenges in the assessment and management of both stress and pain in the neonatal period (Johnston et al. 1997). Stress has been defined as:

"a physical, chemical or emotional factor that causes bodily or mental tension and may be a factor in disease causation" (Merriam Webster 1994 p1564).

Stress responses can be specific to a particular source or nonspecific and generalised. McIntosh et al. (1993) reflected that pain is always stressful however stress is not necessarily painful. It is however extremely difficult in a neonate neonate to distinguish where stress ends and the painful experience begins. Grunau and Tu (2007 p 45) reflect that: "Consciously pain is on a continuum of aversion from handling to skin-breaking procedures".

Stokowski (2009) in a review which discussed the quantification of neonatal stress highlighted that there was a great deal of overlap in what was considered to be stressful to the neonate. The author goes on to reflect that there is currently no validated tool to measure neonatal stress levels. This view was supported by Grunau and Tu (2007 p45) reflecting that with reference to the multiple aspects of the behavioural reactivity in the neurophysiologically immature neonate, the separation of specific sensory changes which occur as a result of pain, are very difficult to differentiate from the cumulative effects of pain and stress.

The American Academy of Pediatrics (AAP) also acknowledge that behaviours associated with pain may also be associated with perceived non painful care-giving procedures, going on to recommend additional research to better differentiate pain and stress be conducted (American Academy of Pediatrics 2000).

The Assessment of Neonatal Pain: Theory to Practice

The plethora of literature on neonatal pain has undoubtedly had the potential to influence practice, however the extent to which this is reflected in the clinical area is inconsistent. The need to prevent pain wherever possible or have strategies in place to ensure effective pain management is acknowledged as a priority (RCN 2009). Nevertheless despite guidelines for neonatal pain management being aimed at addressing these issues (American Academy of Pediatrics 2000, 2006, Association of Paediatric Anaesthetists of Great Britain and Northern Ireland 2012), non-adherence to guidelines in the clinical area continues to be reported (Hansen and Severinsen 2009, Lagerberg et al. 2009).

However it has to be acknowledged that neonatal pain assessment is a complex and challenging issue, with multiple factors potentially affecting neonatal pain response and therefore influencing appropriate assessment strategies. This may include the gestational age of the neonate (Grunau and Tu 2007), level of sedation (Ramsay 2000) and specific pathology such as neurological impairment (Stevens et al. 2007b). Also highlighted are the different situations and environments within which the neonate may experience pain and the lack of specificity to this influencing factor in pain indicators (Stevens et al. 2007b). Due to variables within the neonatal population, methods of pain assessment may not be fully generalizable to different age groups such as the preterm and term baby. Therefore a degree of caution should be applied when reviewing various methods of pain assessment with particular reference to their validation sample (Stevens et al. 2007b).

Physiological Measures of Assessing Neonatal Pain

There is an increasing body of literature which examines the utilisation of physiological measures as an indicator of pain in the neonate (Sweet and McGrath 1998, Stevens et al. 1999, Reeside 2011). Physiological measures of pain adopt the assumption that changes in physiological variables are indicative of pain (Hester 1993), these measures may include changes in heart rate, vagal tone, respiratory rate, blood pressure, palmer sweating, oxygen saturation, transcutaneous oxygen tension, transcutaneous carbon dioxide tension, and intracranial pressure. However it has been suggested that the validity and reliability of these physiological measures are questionable due to the subjective and labile nature of pain itself (McGrath 1996). Regardless of these concerns, physiological measures are proposed as being quantifiable and objective in nature, despite the difficulties in establishing their validity, reliability, specificity, sensitivity and practicality (Stevens et al. 1999).

Sweet and McGrath (1998) suggest that despite the difficulties in assessing psychometric properties of physiological pain indicators, there may be other characteristics which can be examined to support the reliability, validity and specificity of physiological measures of pain. This includes demonstrating that there is a change in the physiological indicator of pain when analgesics are used as opposed to when they are not, and also differences in physiological indicators when painful and non-painful procedures are compared. The practicality of utilising physiological parameters in various clinical settings should also be considered, with some pain assessment measures being useful in a research setting but not a clinical setting.

A novel approach, Near-infrared spectroscopy (NIRS), measures neonatal pain response at a cortical level and offers opportunities to assess pain and validate neonatal pain assessment tools (Holdefer et al. 2011). NIRS works by evaluating acute changes in cerebral blood flow, volume and oxygenation which provides indices of activity in the somatosensory cortex which have been used to evaluate cortical responses to pain for many years (Edwards et al. 1988). However despite this brain-based method providing an innovative way of understanding pain, the issue of whether cortical activation is a direct indicator of pain is unclear. When used as a clinical bedside tool NIRS can be challenging as results can be affected by movement artefacts (Wolf and Greisen 2009). However the use of NIRS does provide scope for development in future pain research studies (Hoshi et al. 2011).

Behaviour Indicators in the Measure of Neonatal Pain

Behaviour has been viewed as being a useful measure and indicator of neonatal pain (McGrath 1996). There are several reasons why behaviour should be considered, it is often the first sign of pain and may set the template for the developing child's reaction to painful events and later coping strategies (McGrath 1996). Interestingly it has been suggested in early research that a crying child was an important determinant in how nurses rated pain and the level of intervention initiated, researchers observed that a child that did not cry or vocalise pain was less likely to be given analgesics (Holmes et al. 1994). Behaviour as a reaction to pain can be divided into different phases. The initial phase is the immediate reaction to noxious stimuli, characterised by a range of behaviours such as withdrawal, grimacing, flailing or crying, with this immediate reaction being followed by a more subtle reaction to ongoing pain in a shutdown of activity or "non-responsive" phase (McGrath 1998).

However as pain is subjective, behavioural assessment is indirect and therefore it can be argued that it is never entirely accurate (Hemley and Bogdan 1994). Furthermore many behavioural measures lack clinical validation and therefore may be problematic in the research setting, according to Barr (1998). Central is the primary human hormone, however there are conflicting data on cortisol secretion in the neonatal period with reports that cortisol levels are higher in sick rather than healthy preterm neonates (Simmonds et al. 1993).

Scott and Wellenberg (1995) support this view reporting that plasma cortisol levels correlate with gestational age and severity of illness. Stevens et al. (2007b) however highlight that no single biomarker characterises all aspects of neonatal pain, with the pain system having complex interrelationships with other reactivity systems.

Strategies in Pain Assessment

Having considered the effects of pain on the neonate and the measurement of pain, it is crucial to then consider how to achieve appropriate pain assessment in the clinical setting. Several areas have to be considered when a measure of pain assessment is introduced into clinical practice. Assurance that the measure assesses pain in a reproducible way will be dependent on psychometric properties (Streiner and Norman 2008). However it is important to acknowledge that modifications to a pain measure in an attempt to adapt to different environments or client groups may interfere with psychometric testing and therefore will require new testing.

Pain measurement can be classified as behavioural, physiological or self-report, however due to the neonates inability to self-report this method cannot be applied. Neonatal pain assessment measures can be further classified as unidimensional or multidimensional with composite measures. Multidimensional strategies utilise more than one type of pain indicator with composite measures also incorporating contextual strategies such as sleep state (Stevens et al. 2007b).

Multidimensional Pain Measures

Due to the complexities in pain assessment many adopt the view that multidimensional pain measures are the most appropriate (Duhn and Medves 2004). Furthermore it has been reported that correlation between physiological and behavioural indicators is consistently low in unidimensional measurement strategies (Stevens et al. 2007b). However both subjective and objective data are adopted in a multidimensional approach, this can be done by assessing different elements in a particular domain such as facial actions, cry and body movement. Alternatively a composite measure can be used that include multiple domains such as physiology, behaviour and contextual indicators. There has been a rapid increase in the number of multidimensional pain assessment scales available for application within the clinical setting over recent years (Duhn and Medves 2004).

Unidimensional Pain Measures

A unidimensional measure will utilise one indicator to assess pain such as infant heart rate, or use several indicators from one domain such as heart rate, blood pressure and breathing rate. Behavioural indicators of infant pain have however traditionally been the most widely utilised, this would include cry, facial expression and activity.

However when assessing behavioural indicators non-verbal infants present the challenge of distinguishing between pain and other states such as hunger or discomfort. Despite confounding factors influencing behavioural indicators such as severity of illness, neurological influence, pharmacological influence and extreme prematurity, behavioural indicators within pain assessment scales continue to be reported as one of the most reliable indicators of infant pain (Hudson-Barr et al. 1988).

Reliability and Validity of Pain Assessment Scales

Reliability and validity testing is an important element in the introduction of a pain assessment scale to the clinical area (Duhn and Medves 2004). However despite the extensive number

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Appendix 2

Physiological Effects of Neonatal Pain

Measure	Change with Pain	Analgesic Studies	Procedural Phase Studies	Relations to other Measures	Factors that may Affect Measure	Practicality
Heart Rate	Increases	Positive evidence	Positive evidence	Some positive evidence	Age, behavioural state, health, type of measure used	Clinical and Research settings
Vagal Tone	Decreases	ND	Positive Evidence	Weak evidence	Age, behavioural state, recording conditions	Research settings
Respiratory Rate	Increases? Decreases?	Mixed evidence	Conflicting evidence	ND	Health, type of measures used	Clinical and research settings
Blood Pressure	Increases	Positive evidence	ND	ND	ND	Clinical and research setting
Oxygen saturation	Decreases	Mixed evidence	Mixed evidence	Some positive evidence	Behavioural state, type of measure used	Clinical and research setting
TcPO2	Decreases	Mixed evidence	Positive evidence	ND	Age, sucking, skin thickness, pressure on electrodes, type of measure used	Clinical and research setting

tcPCO2	?Increases ?Decreases	Negative evidence	Conflicting evidence	ND	Age, sucking, skin thickness, pressure on electrodes, type of measure used	Clinical and research setting
Palmar sweating	Increases	ND	ND	Some positive evidence	Age, emotional state, behavioural state, measurement procedure	Research setting
Skin blood flow	Increases	Positive evidence	Negative evidence	ND	Take measure from a constant site	Research setting
Intracranial pressure	Increases	ND	Positive evidence	Some positive evidence	Behavioural state	Research setting

Note: ND=no data available

Sweet and McGrath (1998) With Permission

Appendix 3

Research Dissemination- Author Publication

Physiological measures of assessing infant pain: a literature review

Lavinia Raeside

Abstract

Neonatal pain assessment is not standardized. Clinicians may use various parameters in the measurement of pain which can lead to different interpretations. Currently there is no validated biological marker for assessing infant pain in any age group. However, in the non-verbal patient, the most feasible way to assess pain may be by evaluation of physiological parameters. The author conducted a systematic review of the literature using qualitative methods and seven research papers were selected for review, in which physiological measures are used in the assessment of neonatal pain. Heart rate was the most frequently used physiological pain measure in these studies. Oxygen saturation, blood pressure and respiratory rate, lacked sensitivity and specificity and cannot be used independently. These measures may detect pain but cannot quantify it and are, therefore, not useful assessments of chronic pain. The multidimensional approach to pain assessment may be the most appropriate owing to the correlation between behavioural and physiological indicators of pain in the neonate.

Key words: Pain assessment ▪ Neonate ▪ Physiological indicators ▪ Systematic review ▪ Qualitative methods

Infant pain assessment and management is an ongoing area of controversy and debate. Lack of knowledge and understanding on infant pain has hindered the development of comprehensive pain management strategies in the clinical area (Rouzan, 2001).

As neonates do not verbally express pain in the way adults do, it is difficult to reach agreement on the best manner of assessing and treating neonatal pain. In recent years there has been an increase in pain assessment scales and tools reported in the literature. There are over 40 tools currently available for review (Duhn and Medves, 2004). However the interpretation of pain scale and tools can prove to be extremely difficult, as data is frequently extrapolated from adult research; this may not apply to the newborn's developing physiology. Consequently, practice guidelines on pain vary considerably between clinicians.

The appropriate management of pain is an essential element of care. Currently, there is no validated biological marker for assessing infant pain in any age group (Warnock and Lander, 2004). Therefore, as neonates are non verbal, physiological, bio-behavioural and behavioural indicators are used as a replacement for self-report (Duhn and Medves, 2004).

There has been an increasing body of literature examining the use of physiological measures as an indicator of pain in the neonate (Craig et al, 1993; Stevens et al, 1995; Goffaux et al, 2008). Physiological measures of pain such as heart rate, respiratory rate, blood pressure and oxygen saturation, adopt the assumption that changes in physiological variables are indicative of pain (Hester, 1993). However, it has been suggested that the validity and reliability of these measures are questionable because of the subjective and labile nature of pain itself (McGrath, 1996).

In order to evaluate physiological parameters, it is necessary to examine how these indicators are used in pain research and extrapolate how effective physiological parameters are as indicators of neonatal pain.

Physiological indicators are integrated in many multidimensional neonatal pain assessment scales (Cignacco et al, 2004; Ramelet et al, 2007). However, they are often reported as an overall combined score in conjunction with behavioural parameters reflecting pain intensity. It is, therefore, necessary to review research studies which report physiological parameters independently and include comparisons with validated pain scores and tools.

Infant pain and its assessment

It is reflected in the literature that infants feel pain (Anand, 2001). The anatomical structures for pain processing are in place from mid to late gestation, when unmyelinated fibres in the nervous system transport nociceptive impulses throughout the body (Anand, 2000).

However, a recently published report from the Royal College of Obstetricians and Gynecologists (RCOG) concluded that the human fetus is not able to feel pain at 24 weeks and is in an unconscious state while in the womb (RCOG, 2010). The report highlights that after 24 weeks gestation, there is continuing development and elaboration of intracortical networks. It goes on to indicate that when the newborn preterm neonate is exposed to noxious stimuli, the cortical responses, necessary to experience pain, are produced.

Earlier research suggests that the preterm infant may have increased sensitivity to pain compared with older children and adults because of a lack of neurotransmitters in the descending tract. This suggests that inhibitory mechanisms may be lacking (Anand, 2000).

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Physiological measures of pain such as heart rate, respiratory rate and blood pressure are proposed to be quantifiable and objective in the area of infant pain assessment (Stevens et al, 1995). However, they are also reported as being difficult to assess in relation to reliability, validity, specificity, sensitivity and practicality (Stevens et al, 1995). The assessment of psychometric properties of physiological indicators of pain is also problematic. However, several characteristics that may support the validity, reliability, and specificity of physiological measures may be used (Streiner and Norman, 2008).

These measures should demonstrate a greater magnitude of change in relation to painful versus non-painful procedures and a smaller change in relation to pain when analgesics are used versus when they are not used. Also individual physiological pain measures should show a relation with other proposed measures of pain (e.g. main assessment scales) (Sweet and McGrath, 1998).

Background

A review of the literature using systematic methods was necessary to clarify which physiological indicators of pain are reported and how effective these parameters are as indicators of neonatal pain.

Design and methods used in the review

Inclusion and exclusion criteria were determined as indicated in *Table 1*. Randomized controlled trials (RCT) and quasi-randomized controlled trials were reviewed, which focused on physiological indicators of neonatal pain. Systematic reviews and meta-analyses were also included in the search in order to ascertain if this topic had been the subject of a methodological review published recently in the literature. Ongoing clinical trials which indicate current research in the field were also reviewed. Qualitative studies were not included as they would not have demonstrated the effectiveness of physiological parameters as indicators of neonatal pain.

Participants

Term and preterm neonates were included (with a maximum postnatal age of 28 days after reaching 40 weeks corrected gestational age).

Types of interventions

- Any intervention which was considered to cause the neonate pain or discomfort
- Analgesic to alleviate the painful procedure
- Assessment by an alternative proposed pain measure.

Types of outcome measures

The primary outcome was pain assessed by physiological variables, biochemical variables and alternative pain assessment measures (*Table 2*).

Methods used to identify studies

Databases searched include: Cochrane Central Register of Controlled Trials; MEDLINE; CINAHL; PubMed; HPSI; BNI; and MIDIRS. Keywords and medical subject heading (MeSH) terms included infant/newborn; pain assessment; and behavioural/physiological/biological indicators of pain. Reference lists of all articles were screened to identify any additional studies and traditional sources such as online journals were accessed. Language restrictions were not imposed, no attempts were made to identify unpublished studies and thesis reviews were not included.

Table 1. Inclusion and exclusion criteria

Inclusion	Exclusion	Reason for Exclusion
Randomized controlled studies Systematic reviews Meta analysis	Case studies Qualitative reviews	Would not highlight studies which would meet the objectives of the review
Human participants	Animal Studies	Would not reflect all confounding variables in human participants
Term and preterm neonates	Neonates receiving palliative care Congenital anomalies Neurological impairment.	Ethical considerations
Studies reviewing a physiological measurement of neonatal pain	Studies out with the neonatal period	Would not relate to neonatal physiological and behavioural characteristics
English language	Non-English language	Unable to ensure accurate translation
Studies from 1999	Studies published prior to 1999	Review studies carried out in the 10 years prior to search to reflect current evidence

Selection of studies for review

The titles and abstracts of all reports identified other searches were scanned. Full study reports were obtained for those that appeared to meet the inclusion criteria. Study reports were then reviewed for possible inclusion in the review.

Quality of studies reviewed

The quality of all included studies was assessed by the researcher. Standard methods of the Cochrane Neonatal Research Group (CRNG) were used to assess:

- The randomization process
- Concealment of allocation/blinding of randomization

Table 2. Types of outcome measures

The primary outcome was pain assessed by:

- Physiological variables such as:
  - heart rate (HR)
  - respiratory rate (RR)
  - oxygen saturation (Sa02)
  - blood pressure (BP)
- Biochemical variables such as:
  - salivary cortisol levels
  - serum cortisol levels
- Assessment by an alternative proposed pain measure

- Blinding of intervention
- Subject attrition and follow up
- Blinding of outcome measures.

Results of the Review

A total of 17 studies were considered for this review and seven were included. Of the excluded studies, seven did not use independent physiological variables to measure pain, using behavioural measures or a combined pain score as part of a pain assessment tool. Included studies were all RCTs which reviewed the effect of a painful procedure on the pain response of preterm or term neonates.

Outcome measures in each study compared the pain response detected in different pain measures, one of which was an independent physiological measure. Heart rate was the most frequently used independent physiological pain measure and was utilised in each of the selected studies. This was followed by oxygen saturation (Pereira et al, 1999; Brady-Fryer et al, 2004; Catelin et al, 2005; Gradin and Schollin, 2005; Ludington-Hoe et al, 2005; South et al, 2005) respiratory rate (Oberlander et al, 2002; Brady-Fryer et al, 2004; Ludington-Hoe et al, 2005), blood pressure (Brady-Fryer et al, 2004) and serum cortisol (Brady-Fryer et al, 2004).

No study adequately defined the difference between the concept of pain and stress in the neonate and how this could be evaluated.

Description of the studies selected

The systematic review of RCTs conducted by Brady-Fryer et al (2004) was a rigorous Cochrane review of the literature. The paper included studies which evaluated pain relief during circumcision. Inclusion criteria were RCTs which compared pain interventions with placebo or no treatment, or compared two active pain interventions in male term or preterm infants undergoing circumcision.

All of the studies included in the review were reported as RCTs. However, 15 of the 35 studies in the review provided insufficient information on assurance of blinding to randomization. Some of the interventions could not be masked but some of the studies achieved partial blinding through inclusion of a sham or placebo group. The authors highlight that it is no longer acceptable to compare a treatment group with a placebo or no-treatment group because of the acknowledged pain response during circumcision (Brady-Fryer et al, 2004).

This study included the largest number of neonates. The combined number of neonates in all of the studies reviewed was 592. The authors reported the use of pain tools in each of the studies in conjunction with physiological measures (*Table 3*). Three of the trials included in the review which compared dorsal penile nerve block (DPNB) with no treatment or placebo used three different pain scales. However, these scales could not be combined for meta-analysis because of the differences in their conceptual basis. Physiological data, heart rate and oxygen saturation, were consistent with the pain scales and significantly favoured DPNB. However, respiratory rate showed no significant difference. Serum and salivary cortisol levels also showed no significant difference. In the studies examining ring block, both crying time and heart rate were significantly reduced. However, there were no significant differences in respiratory rate or oxygen saturation.

Cry time and heart rate were also reduced with EMLA cream; however, there was no difference in respiratory rate or blood pressure. A similar response was noted with lidocaine, which reduced cry time and heart rate as well. Oral sucrose was difficult to assess as different strategies were used in the administration (e.g different concentrations), however, cry time and heart rate were not significantly different. This study recommended DPND to be the most consistent method in reducing pain experienced during neonatal circumcision.

This review reflected that the effects of pain on heart rate appeared to be the most consistent measure when used with a behavioural tool. However, there were no effects noted in the sucrose trials. The results of other measures such as respiratory rate and oxygen saturation appeared to be inconsistent.

Catelin et al (2005) evaluated environmental and behavioural interventions using the Neonatal Infant Pain Scale (NIPS) and the Schelle Douleur Inconfort Nouveau-Ne (EDIN) neonatal pain and discomfort scale. The results demonstrated a significantly lower score on the NIPS during weighing when the nurse was trained in the use of environmental and behavioural interventions (EBI) to minimize pain. Heart rate was also significantly lower with EBI versus control but no difference was noted in oxygen saturation, salivary cortisol level or total oxygenation index (TOI).

Pereira et al (1999) was the earliest study reviewed and also used two pain scales Neonatal Facial Coding System (NFCS) and NIPS (Neonatal Infant Pain Scale). Results reflected significant differences in the NIPS and NFCS scales in two groups one during skin puncture and the other skin friction by rubbing during cleansing. Comparison of heart rate also demonstrated significant differences at various time periods throughout the procedure. However, most neonates heart rates decreased after puncture. The authors reflected that technical artefacts may be responsible and advise that with their methadology, heart rate assessment could not be useful in detecting pain in the neonate, and should only be a secondary evaluation. Researchers concluded that various pain parameters were analysed separately and their assessment of pain presence often did not agree in the same patient, indicating that the use of multiple parameters can help to establish the presence of pain, confirming the utility of composite measures for pain.

Gradin and Schollin (2005) used the Premature Infant Pain Profile (PIPP), along with crying time and hear rate to assess to pain during heel stick (use of neonatal heel lancet for taking blood samples from the heel of neonates). There were no significant differences in either the pain score or heart rate in either the study group or control group. The lack of contrast may be owing to small sample size or improper sub-therapeutic dose of narcan. Crying time was, however, significantly shorter in latency of first cry and longer duration of crying in the placebo group. The authors suggest it may be because of a calming effect of narcan, although there is no evidence to support this. Therefore, the use of physiological measures to identify pain cannot be substantiated in this study.

Oberlander et al (2002) examined the effect of neonatal acute pain response with prolonged prenatal maternal

psychotropic medication exposure. The study included facial expression via the NFCS in the assessment of pain. Pain response during heel stick was compared in three groups of neonates. The first group were exposed to selective serotonin reuptake inhibitors (SSRIs), the second group SSRIs and clonazepam and the third group were non-exposed neonates. This study focused on the effects of maternal influence in relation to psychotropic medication and infant pain response. However, researchers did not include a non-pharmaxologically treated, but depressed, group of mothers. Therefore, the study could not account for the effects of prenatal stress alone on the developing fetus. The study was also unable to control for unforeseen changes in levels of maternal depression or stress, or changes in medication, over the course of the study. However, the authors did relay the newborn Apgar score which is an indication of the physiological condition of the neonate at birth.

The NFCS increased significantly from baseline to heel stick in all study groups. During lance (i.e. heel stick), reactivity was significantly lower in the study group containing SSRI-exposed infants. Mean heart rate increased with heel stick and fell in recovery in all groups. However, mean heart rate was significantly lower among both SE-exposed infant groups in the recovery period. Power spectral analysis of heart rate variability in both SSRI-exposed infants reflected a significant decrease in low-frequency (reflecting a mixture of parasympathetic and sympathetic activity) and high-frequency (reflecting parasympathetic tone). Total respiratory power also increased significantly from baseline with lance and decreased in the recovery period in both groups. Researchers also reviewed transfer function estimates of respiratory sinus arrhythmia (RSA) and concluded that both exposed and non-exposed infants responded to heel stick with increased sympathetic and reduced parasympathetic modulation. However, SE-exposed neonates responded with maintenance of parasympathetic activity (less parasympathetic withdrawal) with the heel stick and a markedly increased parasympathetic modulation during recovery than control groups. This was noted to be particularly evident in the SE alone group. Therefore, these results are consistent with the lower mean heart rate and increased high-frequency spectral power in the recovery phase. In conclusion, the researchers demonstrated that prolonged second and third trimester prenatal psychotropic medication exposure is associated with an attenuated acute pain response in the newborn period. Both facial expression and cardiac autonomic reactivity were shorter and less intense among the SSRI-exposed infants and SSRI and benzodiazepine-exposed study groups.

The study conducted by Ludington-Hoe et al (2005) also examined heart rate, respiratory rate, oxygen saturation, crying time and behavioural state in relation to heel stick. The researchers randomized infants into two sequences. The first sequence received three hours in an incubator with a heel stick in it. The second sequence had incubator care and a heel stick in the incubator before skin-to-skin contact and skin contact heel stick. Results reflected that heart rate and crying time were significantly reduced during skin-to-skin contact and skin contact heel stick compared with incubator heel stick. This study appears to support the use of heart rate as a method of evaluating pain in neonates. However, the authors reflect that data should be reviewed with caution as data was collected manually and can be subject to error.

South et al (2005) also reviewed pain mediation in the form of non-nutritive sucking during circumcision, measuring heart rate as a primary outcome measure with the PIPP score, crying time and salivary cortisol measures. Results reflected a decrease in crying time during neonatal circumcision, although no change was noted in heart rate or oxygen saturation with non-nutritive sucking. Nonetheless, it can be argued that reduced crying time during sucking may not be reflective of reduced pain. Therefore, this study cannot substantiate physiological measurement of infant pain.

Discussion

The purpose of this review was to examine the literature on the use of physiological measures to assess neonatal pain. Selected studies in the review were all RCTs and therefore rigorous research trials. A variety of pain events and interventions were reviewed in the included studies. The results are generally applicable to current practice, however a number of limitations have been identified. Sample size in the majority of the studies was small (Gradin and Schollin, 2005) which could influence results and lead to bias. However, the difficulty in recruiting subject who were either extremely preterm or clinically unstable may have been an influencing factor.

There were some differences in the characteristics of the study subjects. Ludington-Hoe et al (2005) selected premature infants, whereas Pereira (1999) selected healthy term neonates. The experience and physiology of the preterm neonate may have been different to the term neonate. The preterm neonate potentially experience multiple painful episodes within the intensive care setting. Only one trial was double blinded to the intervention. (Gradin and Schollin, 2005). However, because of the nature of some of the events, such as the environmental interventions, it was not possible to double blind (Catelin et al, 2005). Techniques and methods of measurement of outcomes were variable across the trials, even with a single outcome variable such as heart rate. This was highlighted in the systematic review where the authors found difficulty in combining pain scores within the pain scales in the included studies.

None of the included studies highlighted a clear definition of pain, and none differentiated between painful, stressful or distressing. In general, authors did not identify reasons for selecting specific measures of pain assessment within the context of their research.

Pain scores/scales were used as a means of behavioural assessment of pain in each study with the exception of Lundington-Hoe et al (2005), who used crying time to assess behavioural response. Crying time may be referred to as a controversial method in that it may be subjective with several variables influencing results. Babies can cry for a variety of reasons and the length of crying time may vary widely depending on factors such as the temperament of the baby.

Heart rate and heart rate variability were used in each study to assess pain. Results were confounding in that some studies appeared to corroborate the use of heat rate (Ludington-Hoe

Table 3. Review of the Literature on Physiological Measures of Pain

Physiological Pain Assessment Methods

Study	Pain Assessment Measure	Rationale	Outcome
Ludington-Hoe et al (2005)	Physiological: • Heart rate • Respiratory rate • Oxygen saturation Behavioural: • Crying time • Behavioural state	Previous study utilising PIPP scale (which incorporates these measures) and same intervention.	Heart rate and cry time significantly reduced by pain mediation.
Gradin and Schollin (2005)	• Premature Infant Pain Profile (PIPP) • Cry time • Heart rate	No rationale presented for selecting measures	No significant statistical difference detected between level of pain detected by each measure.
Catelin et al (2005)	• Neonatal Infant Pain Scale (NIPS) • Neonatal Pain and Discomfort Scale (EDIN) • Heart rate • Oxygen saturation • Salivary cortisol • NIRS	No rationale presented for selecting measures	Significant fall in NIPS and EDIN with intervention to mediate pain. Mean heart rate was lower with pain mediation. There was no difference in cortisol or NIRS. No difference in oxygen saturation.
Pereira et al (1999)	• NFCS • NIPS • Heart rate • Oxygen saturation	Feasibility in NICU Sensitive specific tools validated for use with preterm neonates	NFCS and NIPS reflected significant changes with pain event. No change noted in oxygen saturation or heart rate.
South et al (2005)	• PIPP • Heart rate • Oxygen saturation • Salivary cortisol	Reference given to cardiac activity and reactivity for pain measures. Reference given for justification to use oxygen saturation.	No difference in heart rate or oxygen saturation during pain event or intervention to mediate. Reduction in PIPP with intervention.
Oberlander et al (2002)	• NFCS • Heart rate	Reference given for use of heart rate as pain measure.	NFCS increased significantly with painful event. Heart rate increased with pain and decreased after
Brady-Fryer et al (2004)	• Pain scores • Cry time • Heart rate • Serum cortisol • Respiratory rate • Blood pressure • Serum B - endorphin	Systematic Review Rationale not presented	Pain scores were most frequently used with heart rate in studies reviewed

et al, 2005) with the combined use of behavioural measures such as crying. However, other studies demonstrated no change in heart rate in reaction to pain (South et al, 2005).

The studies included in this review reported on various different measures of pain (e.g. physiological, behavioural, biochemical. Methods were dissimilar between studies, which presented difficulties when comparing outcomes. Reasons for selecting particular pain scales were not articulated in the studies. Measurement techniques and conceptual development of selected pain assessment scales varied considerably (e.g. NFCS, NIPS). It can also be argued that some measured behavioural indicators used in the systematic review papers were not conceptually linked to the neonate's experience of pain (Brady-Fryer et al, 2004).

Results of studies reviewed would indicate that physiological measures such as oxygen saturation, blood pressure and respiratory rate can be useful when used in conjunction with other measures or when included as part of a pain tool. However, they lack sensitivity and specificity and cannot be used independently (Pereira et al, 1999; South et al, 2005).

Most of these physiological measures do not change specifically in reaction to painful stimuli (McIntosh et al, 1993). Although they can help in the detection of pain, they cannot quantify it (Stevens et al, 2007). In general, they are easily available in the intensive care setting but should be applied with caution. Most studies relating physiological variables to pain refer to acute painful experiences such as heel stick. However, much of the pain experienced by

neonate is chronic (Anand et al 2007).

The study of neonatal behaviour has been identified as a useful method of evaluating pain in conjunction with physiological parameters, and can help reduce confounding variables in the assessment of pain in neonates.

It has been suggested that the multidimensional approach to pain assessment may be appropriate because of the correlation between behavioural and physiological indicators of pain in the neonate (Stevens et al, 2007).

Conclusion

It appears from the available literature that there is no infant pain assessment method/tool ideal for every situation. Frequently, there is limited psychometric testing in the clinical area. Establishing validity and reliability can be a lengthy process, requiring test and retest with different populations and in different environments. It is important that the selected method/tool is applicable to the setting within which it will be used.

Heart rate was the most frequently used physiological pain measure in the studies reviewed. Results were confounding in that some studies demonstrated no change in heart rate in reaction to pain. Others, however, supported the use of heart rate with the combined use of behavioural measures such as crying.

Physiological measures such as oxygen saturation, blood pressure and respiratory rate lack sensitivity and specificity and cannot be used independently. These measures may detect pain but cannot quantify it and are, therefore, not useful assessments of chronic pain. Further research is required on the identification of a valid and reliable biological or physiological marker for assessing infant pain. As most neonates in the intensive care setting suffer chronic pain, rather than acute pain, further research on the methods of acute pain assessment in the intensive care setting is recommended. NN

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KEY POINTS

- Assessment and alleviation of pain is a vital element of neonatal intensive care
- Pain assessment is not standardized and can be inconsistent
- There is no reliable biological marker for assessing pain
- Physiological measures are used frequently in the assessment of pain but they can lack sensitivity and specificity
- Chronic pain is difficult to assess and quantify

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Appendix 4
Neonatal Pain Assessment Scales

Unidimensional Behavioural Measures of Infant Pain

Measure	Age	Pain	Indicator	Psychometric Properties
Neonatal Facial Coding System (Grunau and Craig 1987)	Preterm Infants >25 weeks gestational age to term infants	Procedural	Eye squeeze Brow bulge Open lips Nasolabial furrow Vertical mouth Horizontal mouth Taught tongue Lips pursed Tongue protrusion Chin quiver	Feasibility Construct validity Convergent validity Interrater reliability (r=0.88) Intrarater reliability (r=0.88)
Infant Body Coding System (Craig et al. 1993)	Preterm infants 32 weeks gestational age to term infants	Procedural	Head movement Torso movement Leg movement Arm movement Foot movement Hand movement	Content validity Face validity Interrater reliability (r=0.83)
Baby Facial Action Coding System (Rosenstein and Oster 1988)	Term infants	Procedural	Facial actions based on data adapted from adult work	Interrater reliability (r = 0.65-0.85)
Maximally Discriminative Facial Movement Coding System (Izard 1979)	Infants 0-2 years	Unclear	Eyes Forehead and brow Nose ridge Mouth	Content validity Construct validity Convergent validity Face validity Interrater reliability (r=0.83)

Multidimensional Pain Measures in Infant Pain

Measure	Age	Pain	Indicator	Psychometric Properties
Flacc Scale (Merkel et al 1997, Manworren and Hynan 2003)	< 3 years of age	Prolonged (Post-operative)	Face Legs Cry Activity Consolability	Content validity Interrater reliability Concurrent validity (P <0.001)
Behavioural Pain Score (Pokela 1994)	28-42 weeks gestational age	Procedural	Body movement Facial expression Response to handling Consolability Rigidity of body	Discriminant validity (P <0.0001)
Behavioural Pain Score (Robieux et al. 1991)	3 months to 3 years	Procedural	Cry Facial expression Body movement	Discriminant validity (P<0.01)
Children's and Infant's Postoperative Pain Scale (Buttner and Finke 2000)	Birth-4 years	Prolonged post -operative	Facial expression Crying Posture of the trunk Posture of the legs Motor restlessness	Content validity Construct and concurrent validity Inrerrater reliability(r=0.64-0.77) Internal consistency(r=0.96)
Douleur Aigue du Nouveau-ne (DAN) (Cabajal et al, 1997, 2005, Bellieni et al. 2002)	25 weeks GA to term newborns	Procedural	Limb movement Facial expression Vocalisation	Content validity Internal consistency (r=0.8) Interrater reliability (r=0.91) Convergent and divergent validity across pain conditions and pain management conditions (P= 0.004-0.0001)
Modified Behavioral Pain Scale (MBPS) (Taddio et al. 1995)	2-6 months	Procedural	Cry Facial expression Body movement	Content validity Construct validity (P<0.01) Concurrent validity (r=0.68-0.74) Interrater reliability (ICC=0.95) Internal consistency (r=0.55-0.66) Test re-test reliability (r=0.95)

Composite Pain Measures in Infant Pain

Measure	Age	Pain	Indicator	Psychometic Properties
Pain Assessment Tool (PAT) (Hodgkinson et al. 1994)	< 3 years of age unable to verbalise pain	Prolonged (post-operative)	Sleep pattern Posture/tone Colour Expression Respirations Cry Oxygen Saturation Heart Rate Blood Pressure Nurse perception	Content validity Convergent validity (r=0.38) Concurrent validity (r=0.76) Interrater reliability (r=0.85)
Neonatal Pain Agitation and Sedation Scale (N-PASS) (Hummel et al. 2003)	<28 weeks -Term Corrected for prematurity	Prolonged Mechanical ventilation or postoperative	Behavioural state Crying/irritability Facial expression Extremities/tone Vital signs	Preliminary reliability and validity in progress.
Neonatal Infant Pain Scale (NIPS) (Lawrence et al 1993)	Preterm and term	Procedural	Cry Facial expression Breathing patterns Leg movement Arm movement State of arousal	Content validity Concurrent validity (r=0.53-0.83) Interrater reliability (r=0.92-0.97) Internal consistency (0.87-0.95)
Premature Infant Pain Profile (PIPP) Stevens et al. 1996)	Preterm and term	Procedural	Behavioural state Gestational age Heart rate Oxygen saturation Eye squeeze Brow bulge Nasolabial furrow	Content validity Construct validity Interrater reliability (ICC = 0.93-0.96) Intrarater reliability (ICC 0.94-0.98) Internal consistency (alpha = 0.59-0.76)
Pain Assessment in Neonates Scale (PAIN) (Hudson-Barr et al. 2002)	26 weeks gestational age -term	Procedural	Cry Facial expression Breathing patterns Extremity movement State of arousal Heart rate	Content validity Concurrent validity (r=0.93)

Composite Pain Measures in Infant Pain (Continued)

Measure	Age	Pain	Indicator	Psychometric Properties
Modified Infant Pain Scale (MIPS) (Bucholz et al. 1998)	4- 30 weeks gestation	Prolonged (post-operative)	Sleep during procedural hour Cry Facial expression Spontaneous motor activity Response to stimuli Flexion Tone Sucking Vital Signs	Interrater reliability (r=0.85) Content validity Convergent validity
The Comfort Scale (Ambuel et al 1992, Van Dijk et al. 2000)	<3 years	Prolonged (post-operative)	Crying Alertness Calmness/ Agitation Movement Tone Facial expression	Interrater reliability (K=0.54-0.93) Internal consistency (r=0.90-0.92) Content validity Convergent validity with clinical judgement
CRIES (Krechel and Bildner 1995)	32 weeks gestational age to Term	Prolonged post-operative	Crying Increased Oxygen Increased vital signs Expression Sleeplessness	Interrater reliability (r=0.72) Content validity Concurrent validity (r=0.49-0.73)
Di Scale for ventilated newborn Infants' (DSVNI) (Sparshott 1996)	Unclear	Unclear	Facial expression Body movement Colour Vital signs	Face validity Content validity
Scale for Use in the Newborn (SUN) (Blauer and Gerstmann 1998)	24 to 40 week gestation	Procedural	State Breathing Movement Tone Face Heart rate Blood pressure	Content validity Beginnings of reliability

Composite Pain Measures in Infant Pain (Continued)

Measure	Age	Pain	Indicator	Psychometric Properties
Riley Infant Pain Scale (RIPS) (Schade et al. 1996)	< 3 years or children unable to verbalise pain	Prolonged	Facial Body Movement Sleep Verbal/Vocal Consolability Response to movement	Intrerrater reliability Internal consistency Content validity Discriminant validity
Liverpool Infant Di Scale (Horgan and Choonara 1996, Horgan et al. 2002)	Neonates	Prolonged	Facial expression Sleep pattern Cry Movement Flexion Tone	Intrerrater reliability Internal consistency Content validity Discriminant validity
Modified Postoperative Comfort Score (Guinsburg et al. 1998)	Preterm	Prolonged	Facial expression Sleep pattern Cry Tone Activity Sociability	Content validity Discriminant validity
Echelle Douleur Inonfort Neouneau - ne (EDIN) (Debillon et al. 2001)	26-36 weeks GA	Prolonged	Facial expression Movement Sleep Consolability	Interrater reliability Content validity Construct validity
Clinical Scoring System (Barrier et al. 1989)	1-7months	Prolonged	Sleep Facial expression Cry Tone Motor activity Excitability	Interrater reliability Content validity Discriminant validity
Bernese Pain Scale	27-41 weeks GA	Procedural	Alertness Crying Colour Posture Eyebrow Bulge Vital signs	Content validity Interrater reliability Construct validity Concurrent validity Convergent validity

Composite Pain Measures in Infant Pain (Continued)

Measure	Age	Pain	Indicator	Psychometric Properties
Napean Neonatal Intensive Care Unit Pain Assessment Tool (NNICUPAT) (Marceau 2003)	27-41 week gestation	Procedural	Facial expression Movement Colour Respiration Vital signs Nurse perception	Pilot data Content validity Interrater reliability Preliminary concurrent validity during procedures
Cardiac Analgesic Assessment Scale (CAAS) (Suominen et al 2004)	Birth upwards	Prolonged	Vital signs Pupillary size	Content validity Interrater reliability Convergent validity

Adapted from: Anand et al (2007 p70-75) (with permission)

Appendix 5
Data Bases and Online Resources:

Electronic Data Bases

EMBASE (European Focussed Index of Pharmacology and Medicine)
MEDLINE (Computerised Version of Index Medicine)
CINAHL (Cumulative Index to Nursing and Allied Health Literature)
BNI (British Nursing Index)
MIDIRS
Index to Thesis
University Library Data Set (Web Cat)

Online Resources

IASP (International Association for the Study of Pain) Task Force on Taxonomy

http://www.iasp-pain.org/terms-p.html

Royal College of Nursing (2011)

http://www.rcn.org.uk

SurveyMonkey

http://www.surveymonkey.com

Neonatal Network (Journal of Neonatal Nursing)

www.springerpub.com/product/07300832

Public Health Research Unit (2002) CASP- Critical Appraisal Support Programme.

www.casp-uk.net

Joint Commission on Accreditation of Healthcare Organizations (2001

http://www.jcaho.org/standard/prn.html

Department of Health, Department for Education and Skills (2007)

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics

Appendix 6

Audit Trail and Example of Correspondence with Subject Specialists

December 9th 2007

Email to Professor Linda Frank, Professor and Chair of Children's Nursing Research, Great Ormond Street, London. Request for any information pain assessment during transport or a pain assessment scale used during transport.

December 10th 2007

Email response from Professor Frank. No pain assessment scales have been evaluated in the transport setting.

December 10th 2007

Email to Dr Anoo Jain, Neonatal Consultant, Bristol.
Request for any information pain assessment during transport or a pain assessment scale used during transport. (No reply)

December 10th 2007

Email to Kaye Spence, Neonatal Nurse Specialist, Westmead Hospital, Melbourne Australia. Request for any information pain assessment during transport or a pain assessment scale used during transport. (No Reply)

January 20th 2008

Email to Mrs C. Horsley Chairperson of The Association of Chief Children's Nurses (ACCN)
Email to Mrs Horsley requesting contact information on transport teams throughout the UK who may agree to provide details on their service in relation to pain assessment.

January 22nd 2008

Meeting with De Lesley Jackson, Neonatal Transport Consultant, West of Scotland Neonatal Transport Service.
Currently services in Scotland have no pain guideline or use a pain assessment scale on transport.

January 23rd 2008
Phone discussion with Mrs Anne Mitchell, Neonatal Nurse Consultant, East of Scotland Neonatal Transport Service.
Currently services in Scotland have no pain guideline or use a pain assessment scale on transport.

January 23rd 2008
Email to Neonatal Transport Service Australia (NETS). Request for any information pain assessment during transport or a pain assessment scale used during transport. (No reply)

January 23rd 2008
Email to Neonatal Transport Service, Cincinnati, USA (Neo Pedtransport) Request for any information pain assessment during transport or a pain assessment scale used during transport. (No reply)

January 24th 2008
Email response from C. Harness, Lead Nurse, Yorkshire Neonatal Transport Team.
The transport team does not have pain guidelines or use a pain assessment scale.

January 28th 2008
Email response from T. Pollard, Clinical Service Manager, Addenbrookes Hospital, Cambridge.
The transport team in this service do not have any guidelines on pain assessment during transport or a current guideline on pain assessment.

February 5th 2008
Email response from L. Kilby, East and North Hants. NHS Trust.
No pain guidelines for transport, a pain assessment scale has just been adapted and implemented in the clinical area which they hope to use on transport

February 15th 2008
Email response from Z. Warren Transport Sister, for South Central Network, Portsmouth.
Offer to participate in the research process.

Example of Correspondence with Specialists

Subj: **Fwd: Neonatal Pain Assessment**
Date: 10/12/2007 20:34:06 GMT Standard Time
From: l.franck@ich.ucl.ac.uk
To: Ler745@aol.com

Dear Lavinia-I think I remember meeting you-were you at Lothian? To my knowledge, none of the pain assessment tools have been evaluated in the transport setting. Perhaps this could be the focus of your PhD. Who is your supervisor? Cheers, Linda
P.S. This is my preferred email address

----- Forwarded message from Ler745@aol.com -----
Date: Sun, 9 Dec 2007 15:57:00 EST
From: Ler745@aol.com
Reply-To: Ler745@aol.com
Subject: Neonatal Pain Assessment
To: linda.franck@kcl.ac.uk

Dear Prof Franck
I am an Advanced Neontal Nurse Practitioner currently working on the West of Scotland Neonatal Transport Team. I am undertaking research for PhD studies at Southampton University on neonatal pain assessment during transport and understand that you have a extensive knoweledge on the topic of neonatal pain.
I would be very grateful if you could inform me of any pain assessment tools you recommend for clinical practice/on neonatal transport or any further information on neonatal pain assessment you think may be useful in the course of
my research.

Yours sincerely

Lavinia Raeside
ANNP
West of Scotland Neonatal Transport Service
Ground Floor Cuthbertson Building
Glasgow Royal Iinfirmary G342HT

----- End forwarded message -----

--
Linda Franck
linda.franck@kcl.ac.uk

--
Linda S. Franck, PhD, RN, RGN, RSCN, FRCPCH, FAAN
Professor and Chair of Children's Nursing Research
Centre for Nursing and Allied Health Professions Research
Institute of Child Health
Level 7, Old Building
Great Ormond Street Hospital for Children
London WC1N 3JH

Appendix 7 Studies Included In Review of Neonatal Pain Assessment Scales

Paper 1

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Duhn and Medves (2004) USA A Systematic Integrative Review of Infant Pain Assessment Tools	To examine the issue of pain assessment in infants by acquiring all available published pain assessment tools and valuating their reported reliability, validity, clinical utility and feasibility	**Sample**	**Design, data collection and analysis, rigour/reliability and validity**	Six multidimensional tools were published as abstracts only, were not published at all or the original work could not be obtained. None of the existing tools fulfilled all criteria for an ideal measure many require further psychometric testing Conclusion: Using an untested tool should not be recommended and should only occur in a research protocol. Well tested multi- dimensional tools may be preferable
		35 pain neonatal assessment tools were identified and evaluated using predetermined criteria. This consisted of 18 unidimensional and 17 multidimensional tools.	Systematic Integrative Review of infant pain assessment tools up to 2004. The critique consisted of structured comparison of the classification and dimensions measured. Reports of validity, reliability clinical /utility and feasibility were reviewed. Meta-analysis was not carried out due different methodologies in the selected studies.	

Paper 2

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Cignacco E, Mueller R, Hamers JPH and Gessler P (2004) Switzertland Pain assessment in the neonate using the Bernese Pain Scale in Neonates	Assessment of pain in preterm and term neonates with or without ventilation on continuous positive airway pressure using the Bernese Pin Scale for Neonates (BPSN)	**Sample**	**Design, data collection and analysis, rigour/reliability and validity**	Construct validity of the BPSN was good F=41.3 p=<0.0001. The study demonstrated coefficients for inter-rater and intra-rater reliability. BPSN was shown to be a valid and reliable tool for assessing pain in term and preterm babies with or without ventilation. A limitation of the study was that it did not include seriously ill neonates who required intubation and mechanical ventilation.
		27-41 weeks GA with or without mechanical ventilation 12 neonates 288 pain assessments: 7 behavioural and 2 physiological indicators	Pain assessment (n=288) performed by 6 health care workers in different situations of term & preterm neonates. Each neonate was observed in four situations. Pain assessments were made by 2 nurses using the BPSN, the PIPP and the VAS. Compared to PIPP and VAS Construct validity: F=41.3 p=<0.0001. Concurrent/convergent validity=0.86, r=0.91 p=<0.0001 Inter-rater reliability (r=0.86-0.97) intra-rater reliability (r=0.98-0.99)	

Paper 3

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Bellieni CV, Bagnoli F, Sisto R, Nero L, Cordelli D and Buonocore G (2005) Italy Development and validation of the ABC pain scale for healthy full term babies	Develop and validate the ABC pain scale for term babies based on the acoustic features of crying.	**Sample**	**Design, data collection and analysis, rigour/reliability and validity**	The ABC scale proved to be simple and reliably for assessing pain in healthy non intubated term newborns. Good sensitivity was demonstrated when the ABC scale was compared to another validated scale. The study also reported that the ABC scale had high specificity demonstrating that it distinguishes different grades of pain. Good inter and intra rater reliability showed the scales clinical utility and reliability, this was also confirmed by nurse's response.
		72 term babies 3 cry parameters	The scale consisted of 3 different cry parameters. The scale was validated using healthy term babies undergoing heel stick. Concurrent validity was tested by comparing it with another pain scale. Specificity was tested by comparing the pain scale during a painful and non-painful event. Compared with PIPP Good correlation with PIPP (r=0.68, r(2) =0.45 p=<0.0001 Good sensitivity and specificity	

Paper 4

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Holsti L and Grunau RE (2007) Canada Initial validation of the behavioural indicators of infant pain (BIPP)	Validation of BIIP scale	**Sample** Sample was 92 neonates 49 males and 43 female between 23-32 weeks gestation	**Design, data collection and analysis, rigour/reliability and validity** Repeat measures cohort study Assessed during 3 one minute phases of blood collection Changes in BIIP and in NIPS scores coded in real time from continuous bedside monitoring Changes in heart rate were obtained from physiological processing software	Scores of BIIP changed significantly across Phases of blood collection. Internal consistency and inter-rater reliability were high. Correlations between the BIPP and NIPS were modest as were correlations between the BIIP and mean heart rate Conclusion: The BIIP is reliable valid scale for assessing acute pain in preterm infants.

Paper 5

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Ramalett A, Rees NW, McDonald S, Bursari MK and Abu-Saad HH (2007) Australia Development and preliminary psychometric testing of the Multidisciplinary Assessment of Pain Scale MAPS	Validation of the aimed to evaluate clinical utility and validity of the MAPS scale	**Sample**	**Design, data collection and analysis, rigour/reliability and validity**	Study reported that the MAPS decreases following rescue morphine and can be recommended for clinical application.
		19 post-operative neonates between 0- 31 months. 5 -category 10 point scale.	MAPS includes 5 categories. And was tested in response to analgesics in a convenience sample. Convergent and concurrent validity were tested by comparison with other validated scales. Compared with FLACC and VAS. MAPS score decreased significantly with analgesia. Risk of measurement error between scales small. Internal consistency represented by Cronbach's alpha coefficient	

Paper 6

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Hummel P, Puchalski M, Creech SD, Weiss MG (2008) USA Clinical reliability and validity of the N-PASS: neonatal pain, agitation and sedation scale with prolonged pain	Preliminary validation of tool. Initial psychometric testing	**Sample**	**Design, data collection and analysis, rigour/reliability and validity**	Inter-rater reliability was high: measured by intraclass coefficients of 0.85 to 0.95 ($p<0.001$ to 0.0001). Convergent validity demonstrated by correlation with the PIPP scores. Internal consistency measured by Cronbach's α was evident with pain and sedation scores. Construct validity established via the Wilcoxon signed-rank test. **Conclusion** Provided the beginning evidence that N-PASS is a reliable tool
		<28-35 weeks gestation (age corrected for prematurity) Convenience sample of 72 observations- 46 ventilated and / or post-operative infants 0-100 days of	Prospective psychometric evaluation Multidimensional tool: • Physiological • Behavioural • Sedation 2 nurses administer tool before and after pharmacological intervention for pain/sedation. One nurse also administered the PIPP score concurrently with the N-PASS	

Paper 7

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Milesi C, Cambonie G, Jacquot A, Barbotte E, Mesnage R, Masson F, Pidoux O, Ferragu F, Thevenot P, Mariette JB and Picaud JC (2009) France Validation of a neonatal pain scale without facial items	To validate a faceless acute neonatal pain scale which does not depend on facial expression	**Sample** Prospective randomised multicentre study. 24 to 40 week gestation neonates.	**Design, data collection and analysis, rigour/reliability and validity** Infants were video-taped during a heel stick. 3 investigators scores pain using the FANS. Scores were compared with a previously validated scale. Reliability was assessed by inter-rater agreement and internal consistency.	FANS is a reliable and valid scale and is the first scale to score pain in preterm newborns when facial expression is not accessible.

Paper 8

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Hand IL, Noble L, Geiss D, Wozniak L, Hall C (2010) USA COVERS Neonatal Pain Scale: Development and Validation	Development and validation of the COVERS scale	**Sample**	**Design, data collection and analysis, rigour/reliability and validity**	Covers scale is a valid pain scale demonstrating both concurrent and construct validity. Can be applied universally regardless of age or physiological state.
		21 Newborns admitted to the neonatal unit were evaluated for pain during 2 procedures	Crossover design was used. Term and preterm babies admitted to the unit were assessed for pain during 2 procedures, a heel stick and diaper change Single observer rated pain at 3 different points. Results were compared with 3 different validated pain scales. To establish construct validity COVERS scores were compared during painful and non-painful procedures.	

Paper 9

Author (Year) Country Title	Aim(s) of study	Methodological Issues		Relevant/key findings
Liaw JJ, Yang L, Chou HL, Chou HL, Chao SC and Lee TY (2011a) Taiwan Psychometric analysis of a Taiwan-version pain assessment scale for preterm infants.	Determine psychometric properties of the PAPSI and to test clinical acceptability and feasibility	**Sample**	**Design, data collection and analysis, rigour/reliability and validity**	Results suggest the PAPSI is a feasible and acceptable instrument. Good psychometric properties were demonstrated.
		Preterm neonates 27 to 37 week's gestation. <30 days post birth and ≤12 points on the National Therapeutic Scoring System for disease severity.	Infants were video-taped to assess pain behaviour during heel stick. Video tapes were reviewed by 3 neonatal nurses to code the infant's pain. Scores were compared with validated pain scales. Psychometric properties included internal consistency, reliability, inter-rater reliability, construct validity, concurrent validity	

Appendix 8

Ethical Approval: Phase 1and 2 - West Glasgow Ethics Committee 2

Acute Services Division

NHS
Greater Glasgow and Clyde

West Glasgow Ethics Committee 2
Western Infirmary
Dumbarton Road
Glasgow
G11 6NT

Telephone: 0141-211-6270
Facsimile: 0141-211-1920

18 November 2008

Ms Lavinia Raeside
Advanced Neonatal Practitioner
Yorkhill NHS Trust
Neonatal Unit
Queen Mothers Hospital
Yorkhill,
Glasgow

Dear Ms Raeside

Full title of study: **The Development of a Pain Assessment Scale for Neonatal Transport**

REC reference number: **08/S0709/116**

The Research Ethics Committee reviewed the above application at the meeting held on 18 November 2008 in the absence of the Chief Investigator.

Ethical opinion

The Committee after some discussion regarding the Study Design are of the opinion that **only Phase 1 and 2 can be given a favourable opinion** at this time.

The Committee are unable to give an opinion on Phase 3 of the study as the content of this phase depends on the outcome of Phases 1 and 2. Therefore these need to be completed and the data analysised before submitting Phase 3 for ethical opinion

The Committee gave a favourable opinion of Phase 1 and 2 of the application only.

Phase 3 was given an unfavourable opinion.

Members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

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40389

Appendix 8.1

Southampton University Ethical Approval

Policy for Students and/or Staff Participating in Research (SP1)

Application Form (SP2)

For requests for students and/or staff in the School to participate in a research Study

* To be completed by the applicant

† To be completed by the Chair of the School of Health Sciences Ethics Committee

Title of Project*	The Development of a Pain Assessment Scale for Neonatal Transport
Type of project*	Student project – Y # If YES, which type of project: MPhil/PhD#
Applicant contact details* *(name, address, telephone number, email)*	Lavinia Raeside 11 Lennox Road, Silverton, Dumbarton, G822ND 01413346113, ler745@aol.com
Project leader/supervisor contact details* *(name address, telephone number, email)*	Professor Alan Glasper Nightinglale Building, Highfield Campus, University of Southampton 07768427412, E.A.Glasper@soton.ac.uk
Ethical committee approval* *(NB please enclose copy of approval letter with this form)*	Y Phase 1 and 2 has been reviewed and received ethical approval. Phase 3 will be submitted when details of the methodology is finalised. Name of Committee: West Glasgow Ethics Committee 2 Date approval received: 18 November 2008 Also approved by Lothian Ethics Committee,

	Edinburgh. The study is sponsored by Yorkhill Hospital NHS Trust, Glasgow. Contact person is Dr Melissa Mcbride, R&D. Southampton University has approved the study for insurance.
Proposed start date* *(mm/yy)*	March 2010
Proposed end date* *(mm/yy)*	October 2011
Number and group of participants to be approached*	200 Advanced Neonatal Nurse Practitioners (ANNP)
Project outline*	*(please complete below so that each aspect is addressed – it is not acceptable to attach a protocol)*
why students and/or staff are required to take part	ANNP's are a group of experienced nurse practitioners many of whom specialise in neonatal transport. As this is a very specialised area with small numbers of practitioners this group will provide most knowledge and experience in this area.
numbers and groups of students and/or staff to be approached	200 Advanced Neonatal Nurse Practitioners who have completed the MSc ANNP course at Southampton University. The participants are therefore past students and would be contacted by means of their personal email.
proposed dates for commencement and completion of data collection (month and year)	Commence date March 2010, completion October 2011.
what they are requested to do *(please enclose copies of any information sheets, letters and consent forms with this application)*	The group will be invited to participate in a Delphi study aimed at developing a new pain assessment scale for neonatal transport. The Delphi tool will highlight items for inclusion in the tool. It is proposed that a three round Delphi will be undertaken dependent on level of consensus. Each questionnaire will be conducted electronically and should take approximately 15 minutes to complete
how and when they will be contacted *(please enclose copy of any advertising material eg poster with this form)*	The participants will be contacted either by their personal email or post if no email address is available. Potential participants would be contacted via Mrs Susan Smith, Lecturer on the Advanced Neonatal Nurse Practitioner Course in Southampton University who has a list of contacts. An outline of the study will also be forwarded to participants stating what they would be required to do if they agree to participate. All students contacted will have given prior consent to be contacted for the purposes of research studies. If they accept invitation to participate , the Delphi questionnaire will be forwarded to them. A reminder email or letter will be forwarded after the initial questionnaire has been sent.
how much of their time will be required	Each Delphi round should take around 15 minutes to complete

will students and/or staff receive any incentive for taking part	No, apart from enhancement of patient care.
any possible disadvantages and risks of taking part	No
actions to be taken if disclosures concerning 'fitness to practice' are made or alleged	This will be discussed with supervisors and taken forward as appropriate
what will happen to the results of the study	Results will be collated and a new pain assessment scale will be devised. Results will be disseminated by publication in professional journals.
procedure for administering the study within SoHS	The research study will be undertaken as part of PhD studies and therefore under supervision. Supervisors for the study are Professor Alan Glasper and Dr Peter Nichols. Participants will be initially contacted and invited to participate by email / post via Mrs Susan Smith, Southampton University tutor. Partcipants who accept the invitation will be forwarded the Delphi questionnaire.
Project outline†	Acceptable: Y YES If NO, why not?
Acceptable given students and/or staff workload? †	Acceptable: YES N # If NO, why not?
Is the plan to access students and/or staff acceptable? †	Acceptable: YES N # If NO, why not?
Any other issues? †	

DECISION

Consent given

Signature: ……

Date: ……23 Feb 2010……....

Appendix 8.2 Phase One: Letter of Invitation to Participants

1

NHS
Greater Glasgow and Clyde

Letter to participants invited to take part in Focus Group Meeting

Development of a Pain Assessment Scale for Neonatal Transport

Dear Colleague
I am a post–graduate student undertaking part-time study into the assessment of pain during neonatal transport.

The aim of this study is the development of a pain assessment scale appropriate for use in the challenging setting of neonatal transport. The study is being supervised within the Faculty of Medicine, Health and Biological Sciences at the University of Southampton.

Pain assessment and management is a crucial element of neonatal transport. Currently there is no validated pain assessment scale/tool for use on transport. Few transport teams adopt a structured method of pain assessment and documentation in the UK.

I believe that achieving consensus from a group of experienced transport clinicians on elements to include in the scale will develop a valid, reliable and feasible tool which will enhance management of the neonate during transport.

The study will be conducted in three stages. The first stage will be a focus group meeting to generate ideas and concepts from transport clinicians for initial development of the scale.

The information obtained from the focus group will then be taken forward to a series of two to three questionnaires distributed to participants throughout the UK. This is sometimes known as Delphi methodology.

The third stage of the study will be a small pilot study with the newly developed transport pain assessment scale.

The end result of the combined data will be the development of new Neonatal Transport Pain Assessment Scale.

I would be extremely grateful if you would consider participating in a focus group meeting and contributing your experience and knowledge to development of the scale.

If you would like to obtain further information on the study I would be delighted to hear from you

Many thanks
Lavinia Raeside

Further information can be obtained from:

Lavinia Raeside
ANNP
NICU, RHSC
Yorkhill, Glasgow
Email: ler745@aol.com

Independent information can be obtained from:

Dr Melissa McBride
Research and Development
R&D Central Office, 1st Floor Tennent Institute,
38 Church Street, Glasgow G11 GNT
Email: melissa.mcbride@ggc.scot.nhs.uk

Academic Supervisors, University of Southampton:
Professor Alan Glasper
Dr Peter Nicholls
Mrs Susan Smith

Version 1 October 2008

Appendix 8.3 Phase One Consent Form

NHS
Greater Glasgow and Clyde

The Development of Pain Assessment Scale for Neonatal Transport

Focus Group Participant Consent Form

I confirm that I have read and understand the information sheet for the above study and consent to participate in the study on the following basis:

- A focus group discussion lasting one to two hours
- The focus group will involve participation in and audio recording of:
  Sharing of ideas and experiences
  Discussing ideas with other participants

I understand that:

Data obtained in the course of the study will be kept securely and destroyed on completion of the study.

I can withdraw from the study at any point

My participation, identity and views will be kept confidential

The study is part of a doctoral study and results will be published

I will be given a summary report of the findings

I hereby consent to participate in the focus group meeting

Signature.....

Raeside:PhD Thesis Appendices

Appendix 8.4

Letter of Invitation to University Student Database

UNIVERSITY OF Southampton
School of Health Sciences

9th August 2010

Dear Colleague,

Re Neonatal research data base.

Further to our letter of the 23rd of July 2010 we are writing to invite you to participate in a research study which seeks to develop a Pain Assessment Scale specifically for use for Neonatal Transport.

Lynn Reaside the post graduate researcher is enclosing an information sheet with this letter which we hope you will find helpful.

We are grateful for any cooperation you can give to this study,

Kind regards

Susan Smith
Alan Glasper
Peter Nichols

School of Health Sciences
Building 67, School of Health Sciences, University of Southampton, Highfield Campus, Southampton SO17 1BJ United Kingdom
Tel: +44 (0)23 8059 7979 Fax: +44 (0)23 8059 7900 www.southampton.ac.uk/healthsciences

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Appendix 8.5

Information for Participants in Phase Two of the Study

UNIVERSITY OF Southampton
School of Health Sciences

9th August 2010

Development of a Pain Assessment Scale for Neonatal Transport

Information for participants invited to take part in a Delphi Study to develop a Neonatal Transport Pain Assessment Scale

Dear Colleague
I am a post-graduate student undertaking part-time study into the assessment of pain during neonatal transport. The aim of this study is the development of a pain assessment scale appropriate for use in the challenging setting of neonatal transport. The study is being supervised within the Faculty of Health Sciences at the University of Southampton.

Pain assessment and management is perceived to be a crucial element of neonatal transport. Currently there is no validated pain assessment scale/tool for use on transport. Few transport teams adopt a structured method of pain assessment and documentation in the UK.

Achieving consensus from a group of advanced neonatal nurse practitioners on elements to include in the scale may help in the production of a valid, reliable and feasible scale. This may potentially enhance management of the neonate during transport.

The study will be conducted in three stages. The first stage which has already been competed consisted of a focus group meeting to generate ideas and concepts from transport clinicians for initial development of the scale. The information generated from the focus group is now being taken forward to the second phase of the study. This will consist of a series of two to three Delphi methodology questionnaires which will be hosted via an online survey instrument.

The content of the questionnaires will relate to items clinicians feel are important for inclusion in a pain assessment scale and also examine issues around design of the proposed sale.

The Delphi technique is a method of achieving consensus from a group of experts in a particular field of study in this case neonatal intensive care and will be used to construct the draft Neonatal Transport Pain Assessment Scale.

School of Health Sciences
Building 67, School of Health Sciences, University of Southampton, Highfield Campus, Southampton SO17 1BJ United Kingdom
Tel: +44 (0)23 8059 7979 Fax: +44 (0)23 8059 7900 www.southampton.ac.uk/healthsciences

Raeside:PhD Thesis Appendices

The third stage of the study will consist of a series of pain assessment scale validation interviews with a small group of practitioners.
I would be extremely grateful if you would consider participating in the Delphi stage of the research and contributing your experience and knowledge to development of the scale.

The Delphi on line questionnaire should take only approximately ten to fifteen minutes of your time to complete,

Subject to your agreement I would be grateful if you would go to the website of the Association of Chief Children's Nurses (ACCN) where a link on their research page will take you directly to the Delphi Questionnaire where you can complete the first round of the investigation. The ACCN can be found at this website link: http://www.accnuk.org/

Following each round the overall anonymised results will be made available to each participant via the ACCN website.

Please complete the online questionnaire no later than Sunday the 19th of September 2010.

I will write to you again in late September letting you know when you can view results.

If you would like to obtain further information on the study I would be delighted to hear from you.

Many thanks
Lavinia Raeside

Further information can be obtained from:

Lavinia Raeside
ANNP
NICU, RHSC
Yorkhill, Glasgow
Email: ler745@aol.com

Independent information can be obtained from:

Academic Supervisors, University of Southampton:
Professor Alan Glasper (eag@soton.ac.uk)
Dr Peter Nicholls (P.Nichols@soton.ac.uk)
Mrs Susan Smith (sls1@soton.ac.uk)

Appendix 8.6

WoSRES Approval for Amendment -Phase Three

WoSRES
West of Scotland Research Ethics Service

NHS Greater Glasgow and Clyde

West of Scotland REC 2
Western Infirmary
Ground floor, Tennent Building
38 Church Street
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4 May 2011

Ms Lavinia Raeside
Advanced Neonatal Practitioner
Yorkhill NHS Trust
Neonatal Unit
Queen Mothers Hospital
Yorkhill
Glasgow
G385J

Dear Ms Raeside

Study title: **The Development of a Pain Assessment Scale for Neonatal Transport**
REC reference: **08/S0709/116**
Amendment number: **2**
Amendment date: **10 March 2011**

The above amendment was reviewed at the meeting of the Committee held on 19 April 2011.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Document listing changes	1.1	
Participant Consent Form	2-March 2011	
Participant Information Sheet	2-March 2011	
Protocol	2.1	15 March 2011

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Raeside:PhD Thesis Appendices

Lothian Research Development Approval for Amendment – Phase 3

University Hospitals Division

NHS Lothian

Queen's Medical Research Institute
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CPP/JK/app-mrecamend

13 June 2011

Ms Lavinia Raeside
NHS Greater Glasgow and Clyde
Neonatal Intensive Care Unit
Royal Hospital for Sick Children
Dalnair Street
Glasgow
G3 8SJ

Dear Ms Raeside

REC No: 08/S0709/116
R&D Project ID No: 2009/R/NE/04
Title of Research *The Development of a Pain Assessment Scale for Neonatal Transport*

I am writing in reply to recent correspondence in relation to the following amendment(s) to the above project.

Amendment: **No.1 dated 10 March 2011**

- **Phase 3 has been amended from a small pilot study utilising the scale in the transport setting, to reviewing face validity of the scale by means of semi-structured interviews with 7 transport clinicians who work on a dedicated neonatal transport team.**
  - **Protocol, version 2.1 dated 15 March 2011**
  - **Information sheet, version 2 dated March 2011**
  - **Consent form, version 2 dated March 2011**
  - **Summary of changes**

We have now received a copy of the amendment(s) and assessed any consequential changes in NHS Lothian resource use. I confirm that NHS Lothian management approval is extended to cover the specific changes intimated. You should be aware that approval for this amendment should be sought from REC before it is implemented.

Yours sincerely

Dr Christine P Phillips
Deputy R&D Director

cc: ***Mrs Anne Mitchell, Neonatology, Royal Infirmary of Edinburgh***

"Improving health through excellence and innovation in clinical research"

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Appendix 8.7
Participant Information Sheet: Phase Three

NHS
Greater Glasgow and Clyde

Development of a Pain Assessment Scale for Neonatal Transport

Information for participants invited to take part in an interview to validate the new transport pain assessment scale

Dear Colleague

I am a post–graduate student undertaking part-time study into the assessment of pain during neonatal transport. The aim of this study is the development of a pain assessment scale appropriate for use in the challenging setting of neonatal transport. The study is being supervised within the Faculty of Health Sciences at the University of Southampton.

Pain assessment and management is perceived to be a crucial element of neonatal transport. Currently there is no validated pain assessment scale/tool for use during transport. Few transport teams adopt a structured method of pain assessment and documentation in the UK. Achieving consensus from a group of clinicans on elements to include in the scale may help in the production of a valid, reliable and feasible scale. This may potentially enhance management of the neonate during transport.

The study will be conducted in three stages. The first and second stages have already been completed. They consisted of a focus group meeting to generate ideas and concepts from transport clinicians for initial development of the scale. These concepts were taken forward to a large Delphi Study with clinicians throughout the UK. Results were then taken forward to develop a pain assessment scale for use in the transport setting. This has been adapted from the N-PASS pain assessment scale.

The third stage of the study will consist of a series of pain assessment scale validation interviews with a small group of practitioners. This will review clinicians' important perceptions of design, content and feasibility of the scale for use in the transport setting.

I would be extremely grateful if you would consider participating in this final phase of the study and taking part in an interview. Should you agree to participate, you will be given the new scale to review and then approximately one week later asked for your perceptions on various aspects of the scale. The interview should take approximately 15 to 20 minutes.

If you would like to obtain further information on the study I would be delighted to hear from you.

Many thanks
Lavinia Raeside

Further information can be obtained from:

Lavinia Raeside
ANNP
NICU, RHSC
Yorkhill, Glasgow
Email: ler745@aol.com

Independent information can be obtained from:

Academic Supervisors, University of Southampton:
Professor Alan Glasper (eag@soton.ac.uk)
Dr Peter Nicholls (P.Nichols@soton.ac.uk)
Mrs Susan Smith (sls1@soton.ac.uk)

Version 2 March 2011

Appendix 8.8

Consent Form: Phase 3

NHS
Greater Glasgow and Clyde

Consent Form

Title of the Proposed Research:
Development of a Pain Assessment Scale for Neonatal Transport

Name of Investigator:
Lavinia Raeside

Address:
Neonatal Intensive Care Unit, RHSC, Yorkhill
Glasgow

Further information is available from:

University of Southampton:
Professor Alan Glasper (eag@soton.ac.uk)
Dr Peter Nicholls (P.Nichols@soton.ac.uk)
Mrs Susan Smith (sls1@soton.ac.uk)

- I agree to participate in Phase 3 Interview stage of this study
- I have read the information sheet and this consent form and had the opportunity to ask questions about them
- I understand that I am under no obligation to participate in this study and I can withdraw from this study at any stage
- The study is part of a Doctoral programme and the findings will be published
- I understand that data will be analysed by the named Researcher
- The interview may be taped with my prior consent

Signature of Participant.....

Name of Participant.....

Signature of Investigator.....

Date .....

Version 2 March 2011

Appendix 9

Delphi Questionnaire: Example of Pilot Study Results

Data Matrix Grid- Delphi Questionnaire Pilot Study

Question Number	Accepted	Accepted but Amended	Question Reject
Section 1. Background Information			
How much experience do you have working on neonatal transport? **0-1 year** **2-5 years** **6-10 years** **11-15years** **16-20 years** **0ver 21 years**	√		
1) What qualifications do you hold?	√		
2) Have you completed training on neonatal transport	√	√ **Re-word and clarify**	
Section 2. Pain Assessment During Transport			
1) Do you think pain should be assessed during neonatal transport **Yes** **No** **Unsure**	√		
2) Do you think a pain assessment scale should be used during neonatal transport? **Yes** **No** **Unsure**	√		
3) Have you used a pain assessment scale on neonatal transport?			
4) If yes which one have you used?		√ **Add Likert scale on difference pain scales**	
Section 3. Pain Assessment in the Neonatal Unit/Clinical Area			
3) If yes which one did you use?	√	√ **Add Likert scale**	

Question Number	Accepted	Accepted but Amended	Question Reject
Section 4. Guidelines on Neonatal Pain Assessment			
1) Do you have a clinical guideline on neonatal pain assessment on transport **Yes** **No** **Unsure**	√	√ **Add question on guideline in the clinical area**	
Section 5. Pain Assessment on Neonatal Transport			
1) In relation to neonatal transport which of the following statements apply- **Pain assessment scales in neonatal transport should be used:** **-During all transfers -** **-Surgical transfers-** **-Ventilated babies--** **-Babies muscle relaxed** **-Other**	√	√ **Re-word** **Add neurologically compromised**	
2) If a pain assessment scale was used at what time would it be used during the transport? **-Arrival in the referral unit** **-Prior to leaving the referral unit** **-During transport** **-On arrival at the receiving unit** **-Not assessed at all during transport**	√		
Section 6. What might be included in a neonatal transport pain assessment scale?			
1) Which physiological indicators of pain should be included? **-Heart rate** **-Oxygen saturation** **-Blood pressure** **-Toe/core differential** **-Skin colour** **-Capillary refill** **- Ventilation requirements** **-Respiratory rate** **-Work of breathing** **-Episodes of instability** **-Degree of muscle tone** **-Temperature** **-Other**	√	√ **Re-word to include variations in parameters and clarify wording**	

Question Number	Accepted	Accepted but Amended	Question Reject
2) Which clinical measures might be included in a neonatal transport pain assessment scale? **-Blood glucose measurement** **-Blood gas measurement** **-End tidal Co2** **-Unsure None**	√		
3) Should gestational age be used? **a) Yes** **b) No** **c) Unsure**	√	√ **Re-word to prevent leading question**	
Section 7. Which behavioural indicators might be included in the scale?			
1) If a neonatal pain assessment scale is used which of the following behavioural indicators of pain should be included: **-Cry** **-Irritability** **-Type of eye movement** **-Eye squeeze during painful stimuli** **-Facial expression** **-Response to stimuli** **-Level of activity** **-Eyebrow furrow** **-Muscle tone** **-State of arousal** **-Alertness** **-Nasolabial furrow** **-Other specify**	√		
Section 8. Environmental Factors which might influence pain assessment			
1) Which of the following environmental factors might influence pain assessment? **-Type of transport SD D NA A SA** **-Length of transport** **- Noise levels** **-Light levels** **-Temperature** **-Altitude if flight transfer** **-Infant position in ambulance** **-Other**		√ **Re-word to include environmental temperature**	

Question Number	Accepted	Accepted but Amended	Question Reject
Section 9. Non-pharmacological factors which might influence pain assessment during transport			
1)Non-pharmacological factors **-Position e.g. lateral/prone SD D NA A SA** **-Positional aides used** **-Use of transwarmer** **-Pacifier/dummy** **-Containment holds** **-Other**	√		
Section 10. Pharmacological factors which might influence pain assessment	√		
1) Which pharmacological factors might influence pain assessment **-Type of analgesia SD D NA A SA** **-Dose during transfer** **-Alterations in dose during transfer** **-Muscle relaxant used** **-Use of sucrose** **-Other**	√		
Section 11. Scale Design			
1)Design of the pain assessment scale **-Limit to 1 page SD D NA A SA** **-Limit to 2 pages** **-Unlimited length** **-Incorporate in transport observation sheet** **-Develop separate pain assessment chart** **-Include recommendations for analgesia based on pain score** **- Include guidelines on the scoring system** **- Document intervention strategies following pain assessment** **-Incorporate history** **-Incorporate diagnosis** **-Other**	√		
2)If used should a neonatal transport pain scale allocate a numerical score to reflect the presence and intensity of pain	√		

Question Number	Accepted	Accepted but Amended	Question Reject
3) If pain is assessed during transport would an algorithm to guide management be effective in pain assessment and management during transport? **Yes** **No** **Unsure**	√		
Section 12. Clinical Utility			
1) Who should complete the pain assessment scale? **-Transport nurse/midwife** **-Physician** **-Physician or transport nurse/midwife** **-Should not be used** **-Unsure**	√		
2) Should a pain assessment scale include recommendations for pain management? **Yes** **No** **Unsure**	√		
3) Should clinicians be trained on how to use the scale? **Yes** **No** **Unsure**	√		
Section 14. Any other comments/suggestions	√ **Important question**		

Appendix 9.1 Modified Delphi First Round Questionnaire

Thank you for participating in this research study. The questionnaire should take approximately fifteen minutes to complete.

2. Background Information

The following questions provide some background information on your neonatal and transport experience

1. How much experience do you have working in neonatal transport?

- ◯ 0 - 1 year
- ◯ 2 - 5 years
- ◯ 6 - 10 years
- ◯ 11 - 15 years
- ◯ 16 - 20 years
- ◯ Over 21 years

If yes please state type

2. What qualifications do you hold?

☐ RN ☐ RM ☐ RSCN ☐ BN ☐ BSc ☐ MN ☐ MSc ☐ ANNP ☐ PhD ☐ MD

☐ Other (please specify)

3. Have you completed a course/ module in neonatal transport?

- ◯ Yes
- ◯ No

If yes please state type

3. Pain Assessment During Neonatal Transport

The following questions will review your experience of pain assessment during neonatal transport

Neonatal Transport Pain Assessment Scale

1. Do you think pain should be assessed during neonatal transport?

- ◯ Yes
- ◯ No
- ◯ Unsure

2. Do you think a pain assessment scale should be used during neonatal transport?

- ◯ Yes
- ◯ No
- ◯ Unsure

Comments

3. Have you used a pain assessment scale on neonatal transport?

- ◯ Yes
- ◯ No

4. If you have used a pain assessment scale on neonatal transport which one have you used?

- ☐ Never used a pain assessment scale on neonatal transport
- ☐ PIPP
- ☐ NIPS
- ☐ NPASS
- ☐ PAT
- ☐ EDIN
- ☐ CRIES
- ☐ Unsure

Other (please specify)

4. Pain Assessment in the Neonatal Unit/Clinical Area

The following questions will review your experience of pain assessment in the neonatal unit/clinical area

1. Have you used a pain assessment scale in the neonatal unit/clinical area?

- ◯ Yes
- ◯ No

Neonatal Transport Pain Assessment Scale

2. If you have used a pain asessment scale in the neonatal unit/clinical area which one have you used?

- ☐ Never used a pain assessment scale in the Neonatal Unit
- ☐ PIPP
- ☐ NIPS
- ☐ PAT
- ☐ EDIN
- ☐ NPASS
- ☐ CRIES
- ☐ Unsure

Other (please specify)

5. Guidelines on Neonatal Pain Assessment

The following questions relate to clinical guidelines on pain assessment

1. Do you have a clinical guideline for neonatal pain assessment in the clinical area/neonatal unit?

- ◯ Yes
- ◯ No
- ◯ Unsure

2. Do you have a clinical guideline for neonatal pain assessment during neonatal transport?

- ◯ Yes
- ◯ No
- ◯ Unsure

6. Pain Assessment on Neonatal Transport

In relation to pain assessment during neonatal transport which of the following statements apply.

Neonatal Transport Pain Assessment Scale

1. Pain assessment scales in neonatal transport:

	strongly disagree	disagree	no opinion	agree	strongly agree
Should be used during all neonatal transfers	☐	☐	☐	☐	☐
Should be used in neonatal surgical transfers	☐	☐	☐	☐	☐
Should be used with babies requiring analgesia	☐	☐	☐	☐	☐
Should be used with mechanically ventilated babies	☐	☐	☐	☐	☐
Should be used with babies who are muscle relaxed	☐	☐	☐	☐	☐
Should be used with babies who are neurologically compromised	☐	☐	☐	☐	☐

Other (please specify)

2. If a pain assessment scale was used at what time would it be used during the transport?

- ☐ Pain assessed on arrival in the referral unit
- ☐ Pain assessed prior to leaving the referral unit
- ☐ Pain assessed during transport
- ☐ Pain assessed on arrival at the receiving unit
- ☐ Pain not assessed at all during the transport

Other (please specify)

7. What might be included in a neonatal transport pain assessment scale?

The following questions review which physiological indicators might be included in the development of a neonatal transport pain assessment scale

Page 4

Neonatal Transport Pain Assessment Scale

1. If a neonatal pain assessment scale is used during neonatal transport which of the following physiological indicators of pain should be included?

	strongly disagree	disagree	no opinion	agree	strongly agree
Variations in heart rate	☐	☐	☐	☐	☐
Variations in oxygen saturation	☐	☐	☐	☐	☐
Variations in blood pressure	☐	☐	☐	☐	☐
Variations in toe/core differential	☐	☐	☐	☐	☐
Variations in skin colour	☐	☐	☐	☐	☐
Capilliary refill	☐	☐	☐	☐	☐
Changes in ventilation requirements	☐	☐	☐	☐	☐
Respiratory rate	☐	☐	☐	☐	☐
Work of breathing/respiratory effort	☐	☐	☐	☐	☐
Episodes of instability e.g. bradycardia / desaturation	☐	☐	☐	☐	☐
Degree of muscle tone	☐	☐	☐	☐	☐
Temperature	☐	☐	☐	☐	☐

Other (please specify)

2. Which clinical measurements might be included in a neonatal transport pain assessment scale?

- ☐ Blood glucose measurement
- ☐ Blood lactate measurement
- ☐ Blood gas measurement
- ☐ End tidal carbon dioxide measurement
- ☐ Unsure
- ☐ None

Other (please specify)

3. If a pain assessment scale is used to measure pain during neonatal transport should be gestational age be included in the scale?

- ◯ Yes
- ◯ No
- ◯ Unsure

Page 5

Neonatal Transport Pain Assessment Scale

8. Which behavioural indicators might be included in the scale?

The following questions review which behavioural indicators might be included in a neonatal transport pain assessment scale

1. If a neonatal pain assessment scale is used during neonatal transport which of the following behavioural indicators of pain should be included?

	strongly disagree	disagree	no opinion	agree	strongly agree
Cry	☐	☐	☐	☐	☐
Irritability	☐	☐	☐	☐	☐
Type of eye movement	☐	☐	☐	☐	☐
Eye squeeze during painful stimuli	☐	☐	☐	☐	☐
Facial expression	☐	☐	☐	☐	☐
Response to stimuli	☐	☐	☐	☐	☐
Response to containment holds	☐	☐	☐	☐	☐
Level of activity	☐	☐	☐	☐	☐
Eyebrow furrow	☐	☐	☐	☐	☐
Muscle tone	☐	☐	☐	☐	☐
State of arousal	☐	☐	☐	☐	☐
Alertness	☐	☐	☐	☐	☐
Nasolabial furrow during painful stimuli	☐	☐	☐	☐	☐

Other (please specify)

9. Environmental factors which might influence pain assessment during neonatal...

Which of the following environmental factors might influence pain assessment during neonatal transport?

Neonatal Transport Pain Assessment Scale

1. Environmental

	strongly disagree	disagree	no opinion	agree	strongly agree
Type of transport e.g. air/road	☐	☐	☐	☐	☐
Length of transfer	☐	☐	☐	☐	☐
Noise levels	☐	☐	☐	☐	☐
Light levels	☐	☐	☐	☐	☐
Environmental temperature	☐	☐	☐	☐	☐
Altitude if flight transfer	☐	☐	☐	☐	☐
Infant position in ambulance e.g. transverse at head of ambulance	☐	☐	☐	☐	☐

Other (please specify)

10. Non-pharmacological factors which might influence pain assessment during ne...

Which of the following non-pharmacological factors might influence pain assessment during neonatal transport.

1. Non-pharmacological factors

	strongly disagree	disagree	no opinion	agree	strongly agree
Position- e.g. lateral/prone	☐	☐	☐	☐	☐
Positioning aides used= e.g. nest	☐	☐	☐	☐	☐
Use of transwarmer	☐	☐	☐	☐	☐
Pacifier/dummy	☐	☐	☐	☐	☐
Containment holds	☐	☐	☐	☐	☐

Other (please specify)

11. Pharmacological factors which might influence pain assessment during neonat...

Which pharmacological factors might influence pain assessment during neonatal transport?

Neonatal Transport Pain Assessment Scale

1. Pharmacological Factors

	strongly disagree	disagree	no opinion	agree	strongly agree
Type of analgesia	☐	☐	☐	☐	☐
Dose during transfer	☐	☐	☐	☐	☐
Alterations in dose during transfer	☐	☐	☐	☐	☐
Muscle relaxant used	☐	☐	☐	☐	☐
Use of sucrose	☐	☐	☐	☐	☐

Other (please specify)

12. Scale Design

The following questions review the potential design of a neonatal transport pain assessment scale

1. Design of Pain Assessment Scale

	strongly disagree	disagree	no opinion	agree	strongly agree
Limit to 1 page	☐	☐	☐	☐	☐
Limit to 2 pages	☐	☐	☐	☐	☐
Unlimited length	☐	☐	☐	☐	☐
Incorporate pain assessment scale in transport observation chart	☐	☐	☐	☐	☐
Develop separate transport pain assessment chart	☐	☐	☐	☐	☐
Include recommendations for analgesia based on pain score	☐	☐	☐	☐	☐
Include guidelines on the scoring system	☐	☐	☐	☐	☐
Document intervention strategies following pain assessment	☐	☐	☐	☐	☐
Incorporate history	☐	☐	☐	☐	☐
Incorporate diagnosis	☐	☐	☐	☐	☐

Other (please specify)

Rana R

Neonatal Transport Pain Assessment Scale

2. If used should a neonatal transport pain assessment scale allocate a numerical score to reflect the presence and intensity of pain?

- ◯ Yes
- ◯ No
- ◯ Unsure

Comments

3. If pain is assessed during transport would an algorithm to guide management be effective in pain assessment and management during transport?

- ◯ Yes
- ◯ No
- ◯ Unsure

Comments

13. Clinical Utility of a Neonatal Transport Pain Assessment Scale

The following questions consider the practical elements of using a pain assessment scale during neonatal transport.

1. If a pain assessment scale is used during neonatal transport who should assess pain and complete the pain assessment scale?

- ☐ Transport nurse/neonatal midwife
- ☐ Physician
- ☐ Physician or Transport nurse/neonatal midwife
- ☐ Should not be used
- ☐ Unsure

Other (please specify)

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Neonatal Transport Pain Assessment Scale

2. If a neonatal pain assessment scale is used during neonatal transport should it include recommendations for pain management?

- ◯ Yes
- ◯ No
- ◯ Should not be used
- ◯ Unsure

Comments

3. If a neonatal pain assessment scale is used during neonatal transport should clinicians be trained how to use the scale?

- ◯ Yes
- ◯ No
- ◯ Should not be used
- ◯ Unsure

Comments

14. Any other comments/suggestions

Do you have any other comments or suggestion in relation to any element of pain assessment on transport.

1. Any other comments/suggestions

15. End of Questions

Thank you for your time in completing Round 1 of this Delphi study.

Overall responses to questions will be forwarded to you with Round 2.

We very much look forward to your input.

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Neonatal Transport Pain Assessment Scale

1. I confirm that I have read the study information sheet and consent to taking part in the Delphi Phase of the study. I understand that I can choose to withdraw from the study at any point

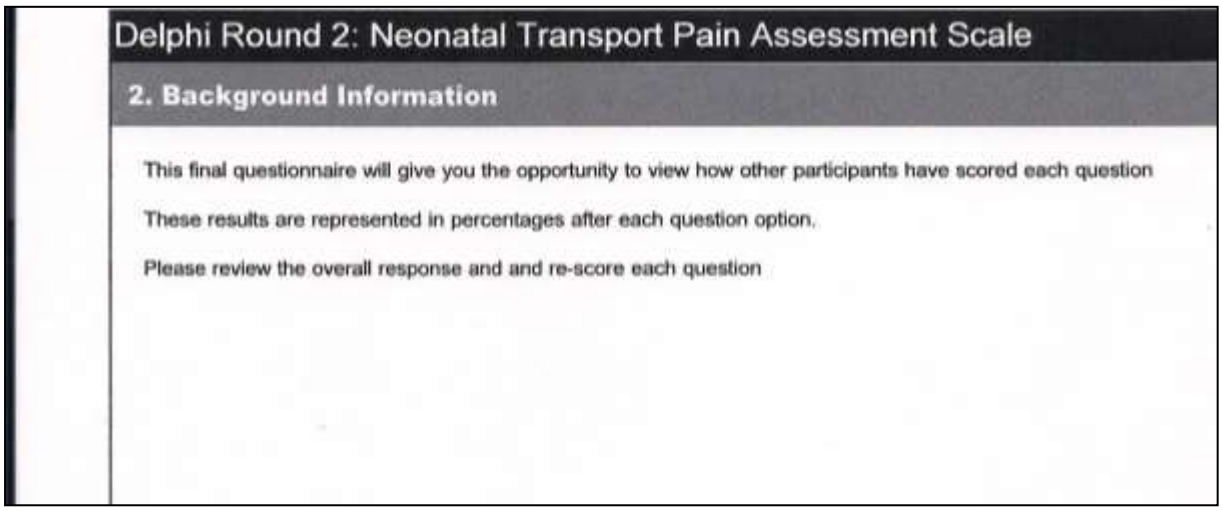
Please tick

◯ I consent to participating in the Dephi Phase of the study

2. Please could you include your email address (non NHS):

Page 11

Appendix 9.2 Modified Delphi Second Round Questionnaire



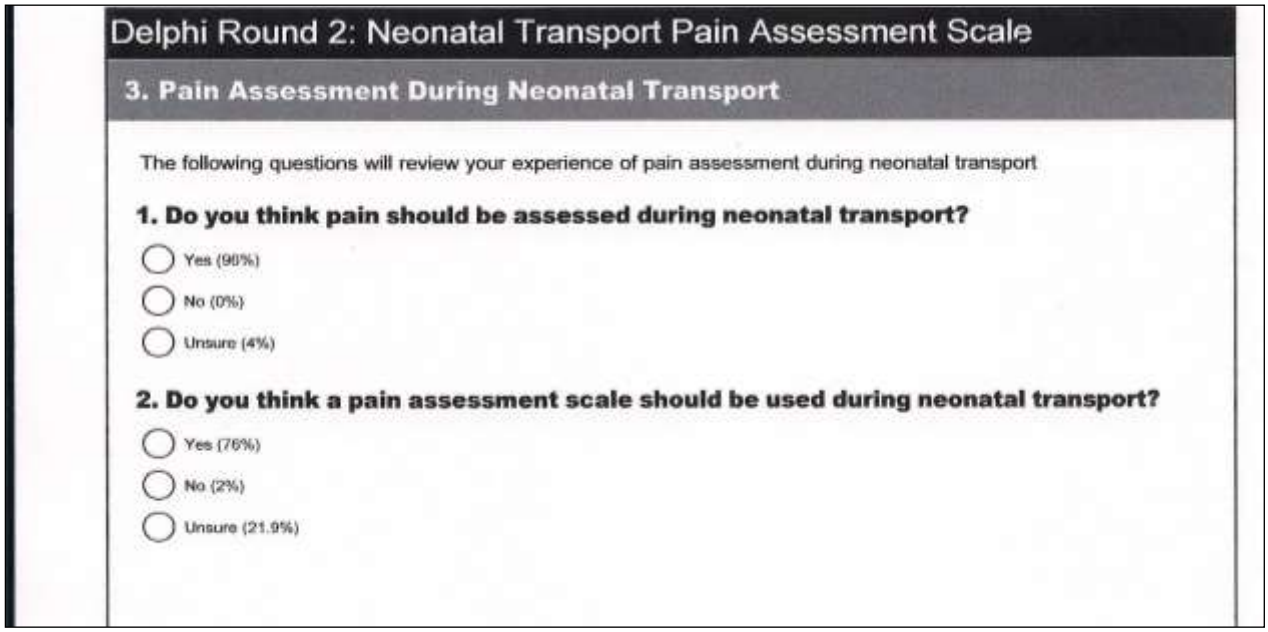
Delphi Round 2: Neonatal Transport Pain Assessment Scale

2. Background Information

This final questionnaire will give you the opportunity to view how other participants have scored each question

These results are represented in percentages after each question option.

Please review the overall response and and re-score each question



Delphi Round 2: Neonatal Transport Pain Assessment Scale

3. Pain Assessment During Neonatal Transport

The following questions will review your experience of pain assessment during neonatal transport

1. Do you think pain should be assessed during neonatal transport?

- ◯ Yes (96%)
- ◯ No (0%)
- ◯ Unsure (4%)

2. Do you think a pain assessment scale should be used during neonatal transport?

- ◯ Yes (76%)
- ◯ No (2%)
- ◯ Unsure (21.9%)

Delphi Round 2: Neonatal Transport Pain Assessment Scale

4. Pain Assessment during Neonatal Transport

In relation to the use of pain assessment scales during neonatal transport which of the following statements apply.

1. Pain Assessment Scales in Neonatal Transport:

	Strongly Disagree (2%)	Disagree (19%)	Unsure (8%)	Agree (43%)	Strongly Agree (26%)
Should be used during all neonatal transfers	◯	◯	◯	◯	◯

2. -

	Strongly disagree (3%)	Disagree (1%)	Unsure (4%)	Agree (35%)	Strongly agree (57%)
Should be used in neonatal surgical transfers	◯	◯	◯	◯	◯

3. -

	Strongly disagree (3%)	Disagree (2%)	Unsure (3%)	Agree (32%)	Strongly agree (59%)
Should be used in babies requiring analgesia	◯	◯	◯	◯	◯

4. -

	Strongly disagree (3%)	Disagree (5%)	Unsure (6%)	Agree (45%)	Strongly agree (43%)
Should be used in babies requiring mechanical ventilation	◯	◯	◯	◯	◯

5. -

	Strongly disagree (4%)	Disagree (6%)	Unsure (9%)	Agree(42%)	Strongly Agree (40%)
Should be used with babies who are muscle relaxed	◯	◯	◯	◯	◯

6. -

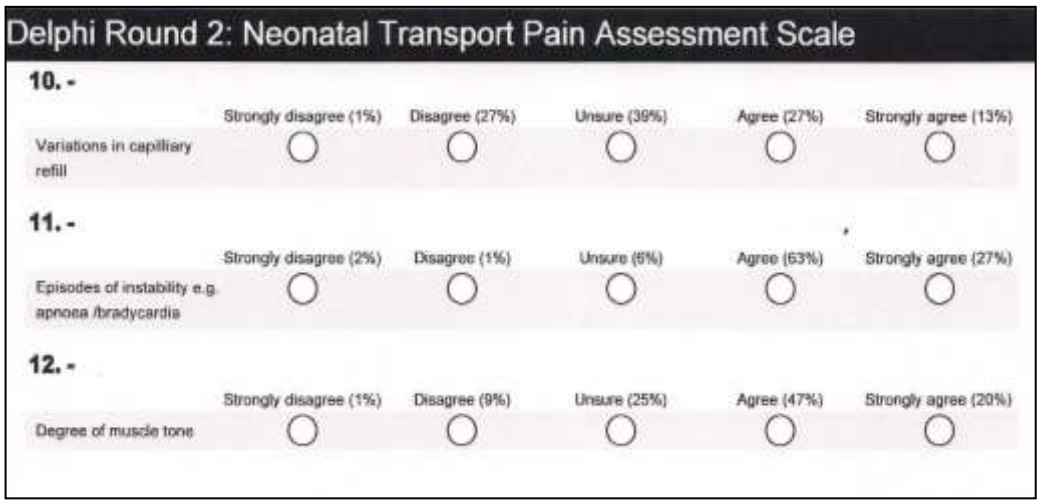
	Strongly disagree (2.3%)	Disagree (7%)	Unsure (15%)	Agree (40%)	Strongly agree (38%)
Should be used in babies who are neurologically compromised	◯	◯	◯	◯	◯

Delphi Round 2: Neonatal Transport Pain Assessment Scale

5. Which items might be included in a neonatal transport pain assessment scale...

Physiological Indicators of Pain should include:

	Strongly Disagree (2%)	Disagree (2%)	Unsure (1%)	Agree (59%)	Strongly Agree (35%)
1. - Variations in heart rate	○	○	○	○	○
	Strongly disagree (4%)	Disagree (5%)	Unsure (5%)	Agree (60%)	Strongly agree (26%)
2. - Variations in blood pressure	○	○	○	○	○
	Strongly disagree (2%)	Disagree (2%)	Unsure (4%)	Agree (61%)	Strongly agree (31%)
3. - Respiratory rate	○	○	○	○	○
	Strongly disagree (2%)	Disagree (2%)	Unsure (6%)	Agree (62%)	Strongly agree (27%)
4. - Work of breathing/respiratory effort	○	○	○	○	○
	Strongly disagree (4%)	Disagree (6%)	Unsure (12%)	Agree (56%)	Strongly agree (23%)
5. - Variations in oxygen saturation	○	○	○	○	○
	Strongly disagree (2%)	Disagree (9%)	Unsure (21%)	Agree (54%)	Strongly agree (13%)
6. - Changes in ventilation requirement	○	○	○	○	○
	Strongly disagree (3%)	Disagree((11%)	Unsure (28%)	Agree (44%)	Strongly agree (14%)
7. - Variations in skin colour	○	○	○	○	○
	Strongly disagree (1%)	Disagree (18%)	Unsure (25%)	Agree (47%)	Strongly agree (7%)
8. - Temperature	○	○	○	○	○
	Strongly disagree (1%)	Disagree (19%)	Unsure (44%)	Agree (26%)	Strongly agree (8%)
9. - Variations in toe/core differential	○	○	○	○	○



Delphi Round 2: Neonatal Transport Pain Assessment Scale

10. -

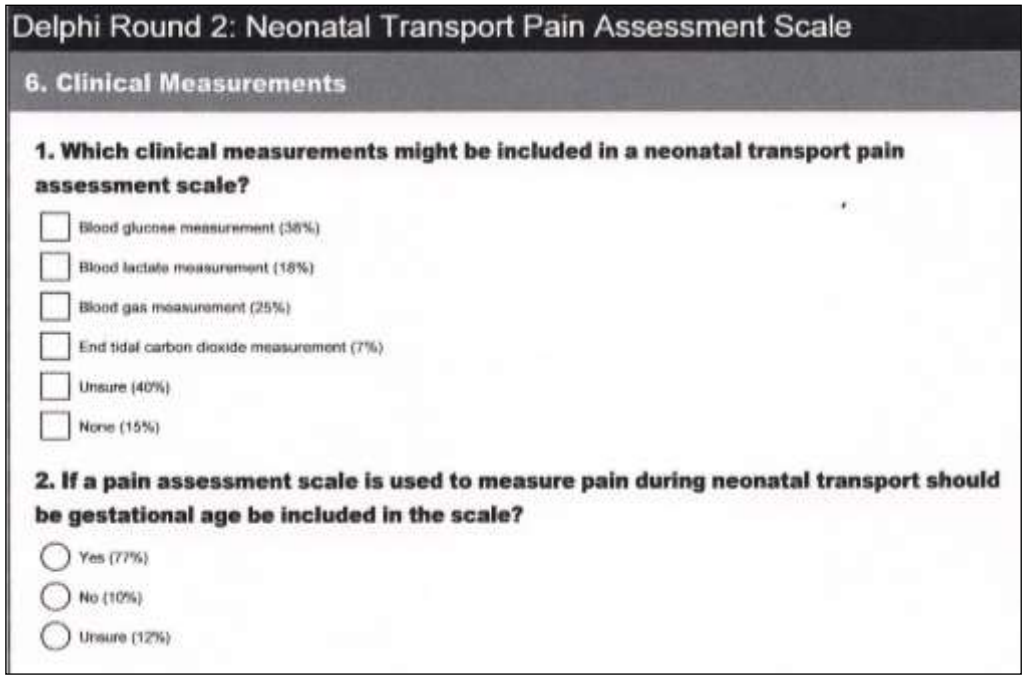
	Strongly disagree (1%)	Disagree (27%)	Unsure (39%)	Agree (27%)	Strongly agree (13%)
Variations in capillary refill	○	○	○	○	○

11. -

	Strongly disagree (2%)	Disagree (1%)	Unsure (6%)	Agree (63%)	Strongly agree (27%)
Episodes of instability e.g. apnoea /bradycardia	○	○	○	○	○

12. -

	Strongly disagree (1%)	Disagree (9%)	Unsure (25%)	Agree (47%)	Strongly agree (20%)
Degree of muscle tone	○	○	○	○	○



Delphi Round 2: Neonatal Transport Pain Assessment Scale

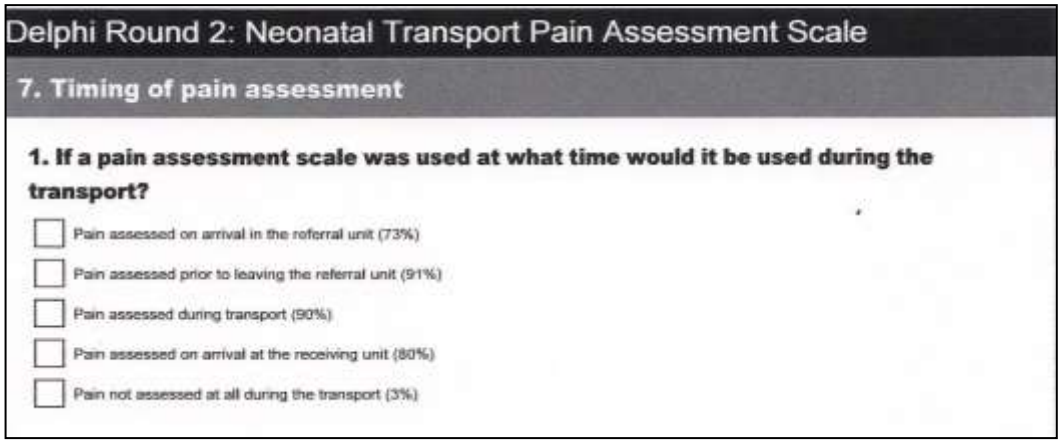
6. Clinical Measurements

1. Which clinical measurements might be included in a neonatal transport pain assessment scale?

- ☐ Blood glucose measurement (38%)
- ☐ Blood lactate measurement (18%)
- ☐ Blood gas measurement (25%)
- ☐ End tidal carbon dioxide measurement (7%)
- ☐ Unsure (40%)
- ☐ None (15%)

2. If a pain assessment scale is used to measure pain during neonatal transport should be gestational age be included in the scale?

- ○ Yes (77%)
- ○ No (10%)
- ○ Unsure (12%)



Delphi Round 2: Neonatal Transport Pain Assessment Scale

7. Timing of pain assessment

1. If a pain assessment scale was used at what time would it be used during the transport?

- ☐ Pain assessed on arrival in the referral unit (73%)
- ☐ Pain assessed prior to leaving the referral unit (91%)
- ☐ Pain assessed during transport (90%)
- ☐ Pain assessed on arrival at the receiving unit (80%)
- ☐ Pain not assessed at all during the transport (3%)

Delphi Round 2: Neonatal Transport Pain Assessment Scale

8. Behavioural Indicators of Pain

Behavioural indicators of pain which might be in a neonatal transport pain assessment scale include:

1. -

	Strongly Disagree (2%)	Disagree (1%)	Unsure (3%)	Agree (59%)	Strongly Agree (34%)
Cry	◯	◯	◯	◯	◯

2. -

	Strongly Disagree (2%)	Disagree (1%)	Unsure (4%)	Agree (57%)	Strongly Agree (35%)
Irritability	◯	◯	◯	◯	◯

3. -

	Strongly Disagree (2%)	Disagree (2%)	Unsure (4%)	Agree (50%)	Strongly Agree (48%)
Facial expression	◯	◯	◯	◯	◯

4. -

	Strongly Disagree (3%)	Disagree (6%)	Unsure (31%)	Agree (41%)	Strongly Agree (19%)
Type of eye movement	◯	◯	◯	◯	◯

5. -

	Strongly Disagree (2%)	Disagree (0)	Unsure (11%)	Agree (56%)	Strongly Agree (30%)
Eye squeeze during painful stimuli	◯	◯	◯	◯	◯

6. -

	Strongly Disagree(1%)	Disagree (2%)	Unsure (16%)	Agree (52%)	Strongly Agree (29%)
Eyebrow furrow	◯	◯	◯	◯	◯

7. -

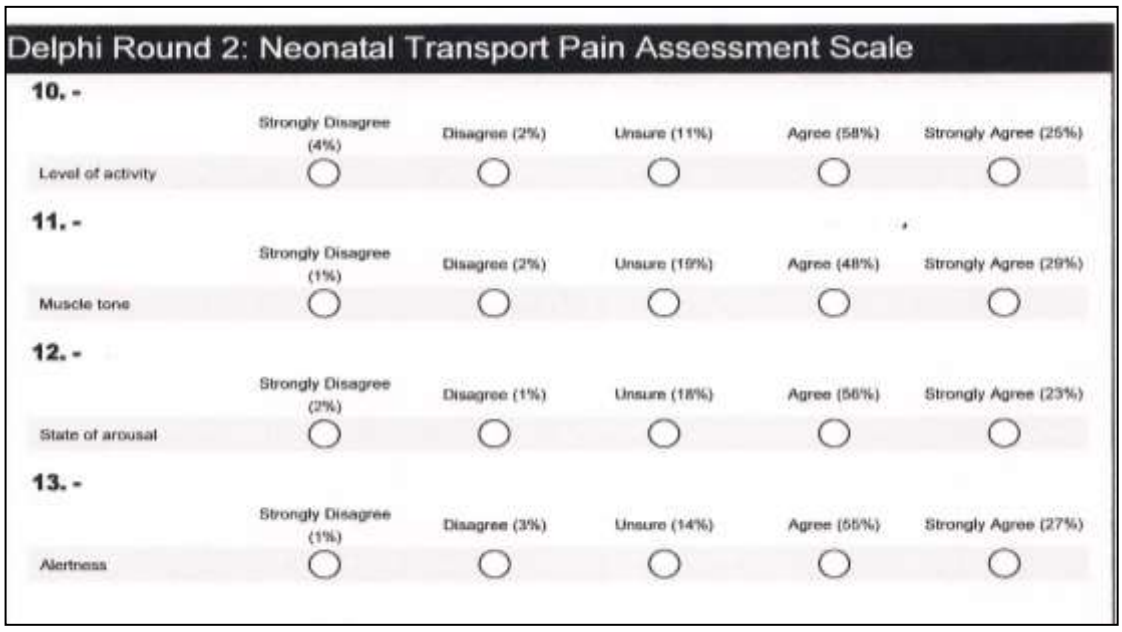
	Strongly Disagree (1%)	Disagree (3%)	Unsure (23%)	Agree (47%)	Strongly Agree (27%)
Nasolabial furrow during painful stimuli	◯	◯	◯	◯	◯

8. -

	Strongly Disagree (3%)	Disagree (2%)	Unsure (5%)	Agree (55%)	Strongly Agree (34%)
Response to stimuli	◯	◯	◯	◯	◯

9. -

	Strongly Disagree (2%)	Disagree (5%)	Unsure (16%)	Agree (51%)	Strongly Agree (26%)
Response to containment holds	◯	◯	◯	◯	◯



Delphi Round 2: Neonatal Transport Pain Assessment Scale

10. -

	Strongly Disagree (4%)	Disagree (2%)	Unsure (11%)	Agree (58%)	Strongly Agree (25%)
Level of activity	○	○	○	○	○

11. -

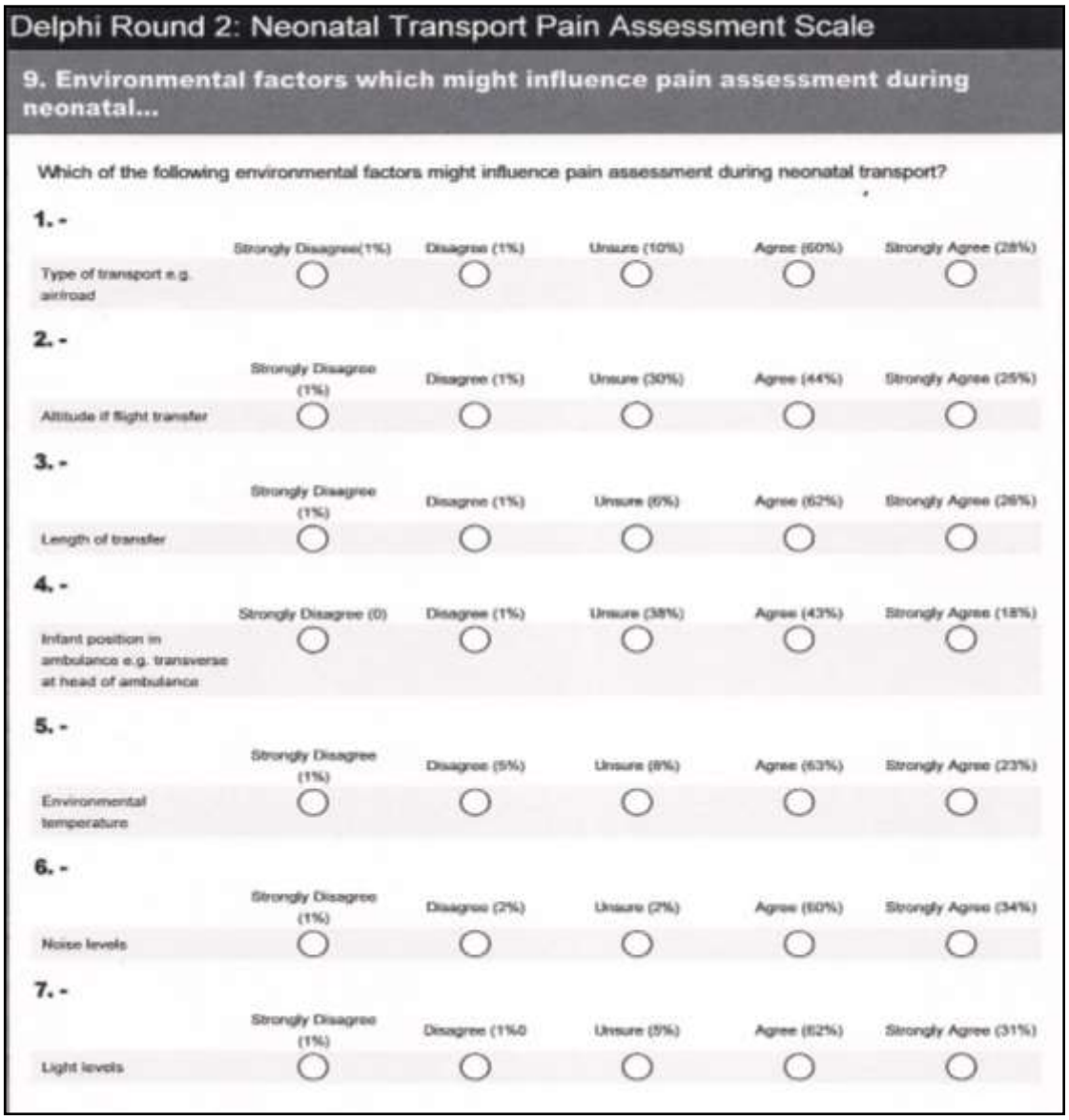
	Strongly Disagree (1%)	Disagree (2%)	Unsure (19%)	Agree (48%)	Strongly Agree (29%)
Muscle tone	○	○	○	○	○

12. -

	Strongly Disagree (2%)	Disagree (1%)	Unsure (18%)	Agree (56%)	Strongly Agree (23%)
State of arousal	○	○	○	○	○

13. -

	Strongly Disagree (1%)	Disagree (3%)	Unsure (14%)	Agree (55%)	Strongly Agree (27%)
Alertness	○	○	○	○	○



Delphi Round 2: Neonatal Transport Pain Assessment Scale

9. Environmental factors which might influence pain assessment during neonatal...

Which of the following environmental factors might influence pain assessment during neonatal transport?

1. -

	Strongly Disagree(1%)	Disagree (1%)	Unsure (10%)	Agree (60%)	Strongly Agree (28%)
Type of transport e.g. air/road	○	○	○	○	○

2. -

	Strongly Disagree (1%)	Disagree (1%)	Unsure (30%)	Agree (44%)	Strongly Agree (25%)
Altitude if flight transfer	○	○	○	○	○

3. -

	Strongly Disagree (1%)	Disagree (1%)	Unsure (6%)	Agree (62%)	Strongly Agree (28%)
Length of transfer	○	○	○	○	○

4. -

	Strongly Disagree (0)	Disagree (1%)	Unsure (38%)	Agree (43%)	Strongly Agree (18%)
Infant position in ambulance e.g. transverse at head of ambulance	○	○	○	○	○

5. -

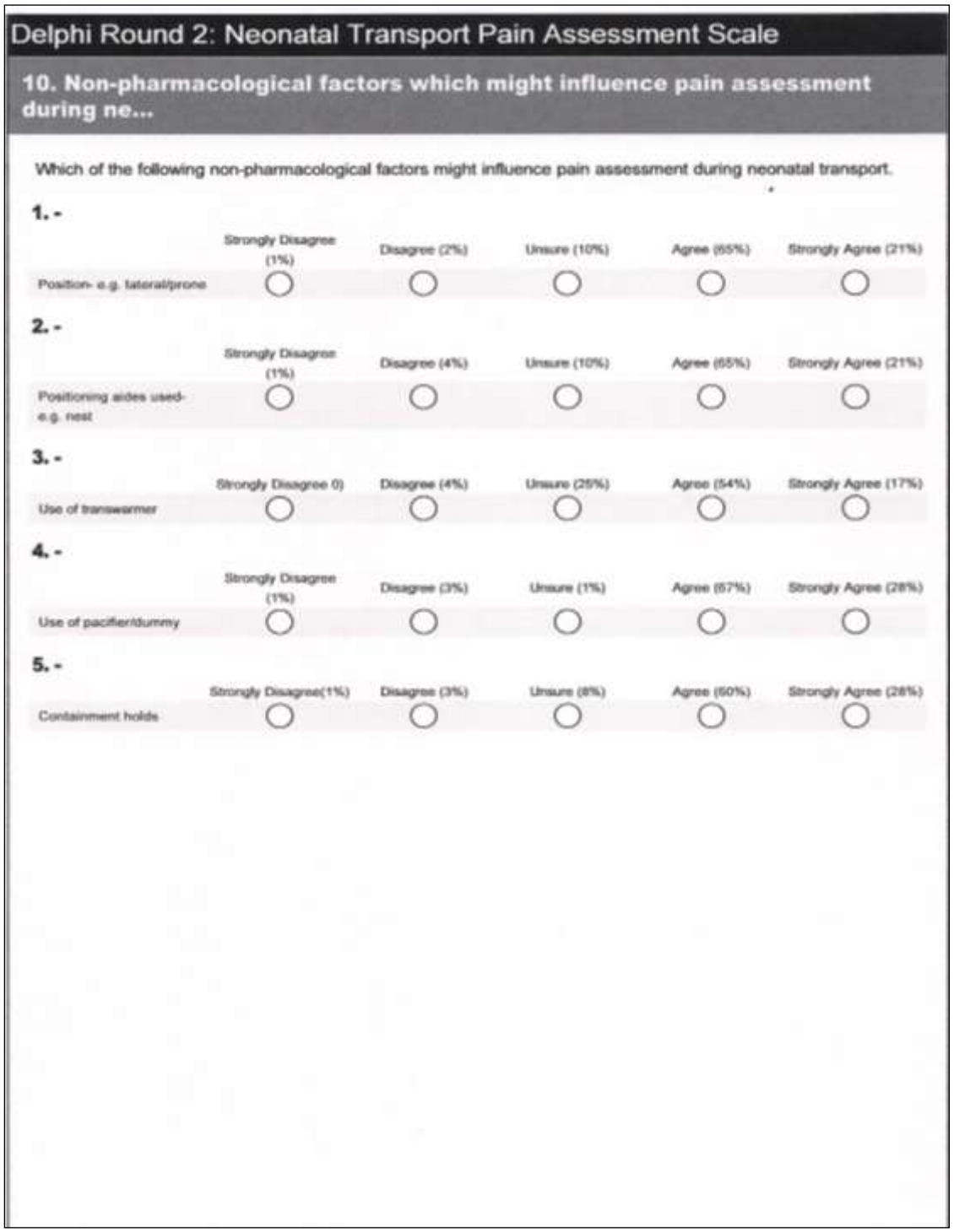
	Strongly Disagree (1%)	Disagree (5%)	Unsure (8%)	Agree (63%)	Strongly Agree (23%)
Environmental temperature	○	○	○	○	○

6. -

	Strongly Disagree (1%)	Disagree (2%)	Unsure (2%)	Agree (60%)	Strongly Agree (34%)
Noise levels	○	○	○	○	○

7. -

	Strongly Disagree (1%)	Disagree (1%0	Unsure (5%)	Agree (62%)	Strongly Agree (31%)
Light levels	○	○	○	○	○



Delphi Round 2: Neonatal Transport Pain Assessment Scale

10. Non-pharmacological factors which might influence pain assessment during ne...

Which of the following non-pharmacological factors might influence pain assessment during neonatal transport.

1. -

	Strongly Disagree (1%)	Disagree (2%)	Unsure (10%)	Agree (65%)	Strongly Agree (21%)
Position- e.g. lateral/prone	○	○	○	○	○

2. -

	Strongly Disagree (1%)	Disagree (4%)	Unsure (10%)	Agree (65%)	Strongly Agree (21%)
Positioning aides used- e.g. nest	○	○	○	○	○

3. -

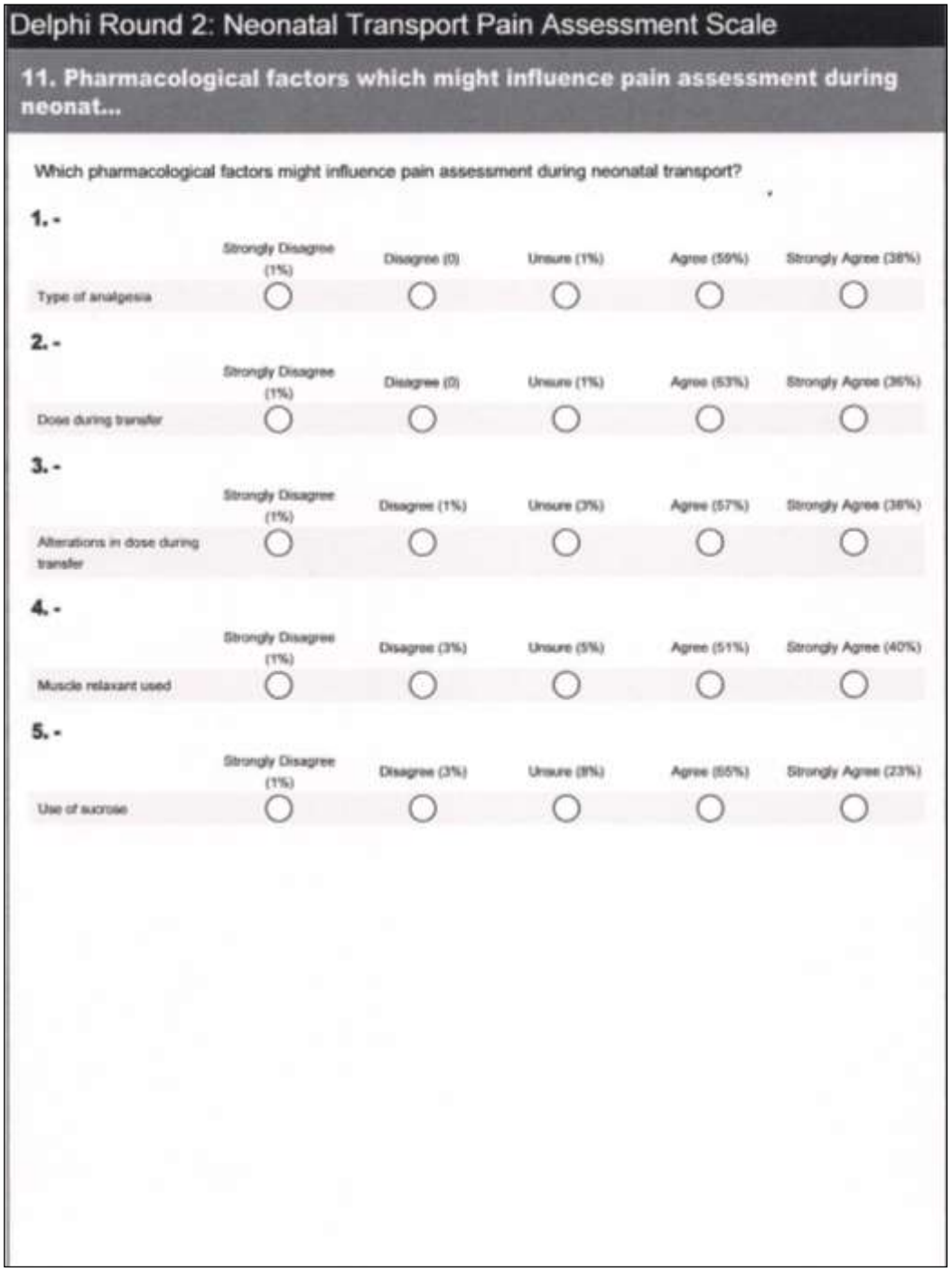
	Strongly Disagree 0)	Disagree (4%)	Unsure (25%)	Agree (54%)	Strongly Agree (17%)
Use of transwarmer	○	○	○	○	○

4. -

	Strongly Disagree (1%)	Disagree (3%)	Unsure (1%)	Agree (67%)	Strongly Agree (28%)
Use of pacifier/dummy	○	○	○	○	○

5. -

	Strongly Disagree(1%)	Disagree (3%)	Unsure (8%)	Agree (60%)	Strongly Agree (28%)
Containment holds	○	○	○	○	○



Delphi Round 2: Neonatal Transport Pain Assessment Scale

11. Pharmacological factors which might influence pain assessment during neonat...

Which pharmacological factors might influence pain assessment during neonatal transport?

1. -

	Strongly Disagree (1%)	Disagree (0)	Unsure (1%)	Agree (59%)	Strongly Agree (38%)
Type of analgesia	○	○	○	○	○

2. -

	Strongly Disagree (1%)	Disagree (0)	Unsure (1%)	Agree (63%)	Strongly Agree (36%)
Dose during transfer	○	○	○	○	○

3. -

	Strongly Disagree (1%)	Disagree (1%)	Unsure (3%)	Agree (57%)	Strongly Agree (38%)
Alterations in dose during transfer	○	○	○	○	○

4. -

	Strongly Disagree (1%)	Disagree (3%)	Unsure (5%)	Agree (51%)	Strongly Agree (40%)
Muscle relaxant used	○	○	○	○	○

5. -

	Strongly Disagree (1%)	Disagree (3%)	Unsure (8%)	Agree (65%)	Strongly Agree (23%)
Use of sucrose	○	○	○	○	○

Delphi Round 2: Neonatal Transport Pain Assessment Scale

12. Scale Design

The following questions review the potential design of a neonatal transport pain assessment scale

1. -

	Strongly Disagree (0%)	Disagree (1%)	Unsure (8%)	Agree (39%)	Strongly Agree (51%)
Limit to 1 page	○	○	○	○	○

2. -

	Strongly Disagree (18%)	Disagree (51%)	Unsure (17%)	Agree (5%)	Strongly Agree (8%)
Limit to 2 pages	○	○	○	○	○

3. -

	Strongly Disagree (56%)	Disagree (35%)	Unsure (9%)	Agree (0)	Strongly Agree(0)
Unlimited length	○	○	○	○	○

4. -

	Strongly Disagree (3%)	Disagree (4%)	Unsure (5%)	Agree (58%)	Strongly Agree (31%)
Incorporate pain assessment scale in transport observation chart	○	○	○	○	○

5. -

	Strongly Disagree (16%)	Disagree (43%)	Unsure (10%)	Agree (25%)	Strongly Agree (4.5%)
Develop separate transport pain assessment chart	○	○	○	○	○

6. -

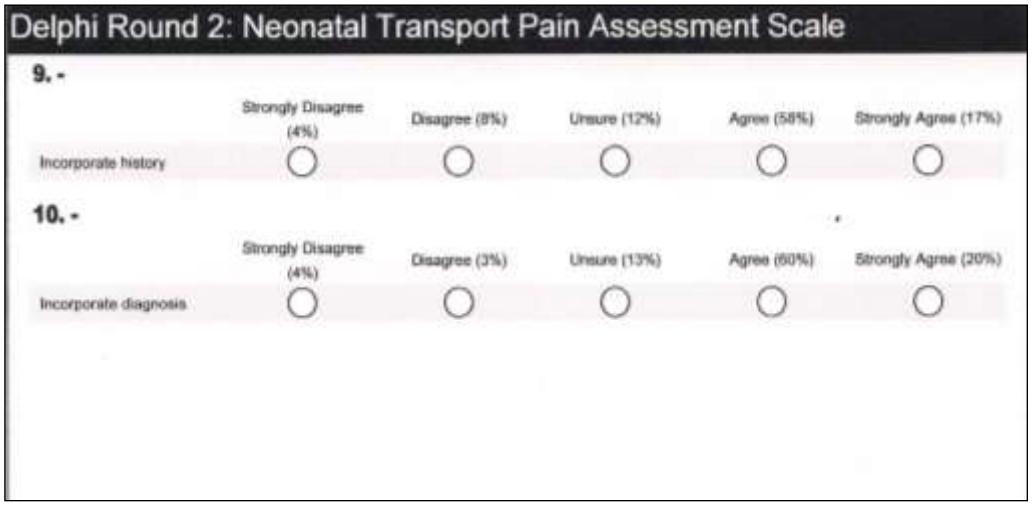
	Strongly Disagree (0)	Disagree (3%)	Unsure (4%)	Agree (63%)	Strongly Agree (30%)
Include recommendations for analgesia base on pain score	○	○	○	○	○

7. -

	Strongly Disagree(1%)	Disagree (4%)	Unsure (5%)	Agree (58%)	Strongly Agree (31%)
Include guidelines on the scoring system	○	○	○	○	○

8. -

	Strongly Disagree (1%)	Disagree (0)	Unsure (1%)	Agree (59%)	Strongly Agree (38%)
Document intervention strategies following pain assessment	○	○	○	○	○



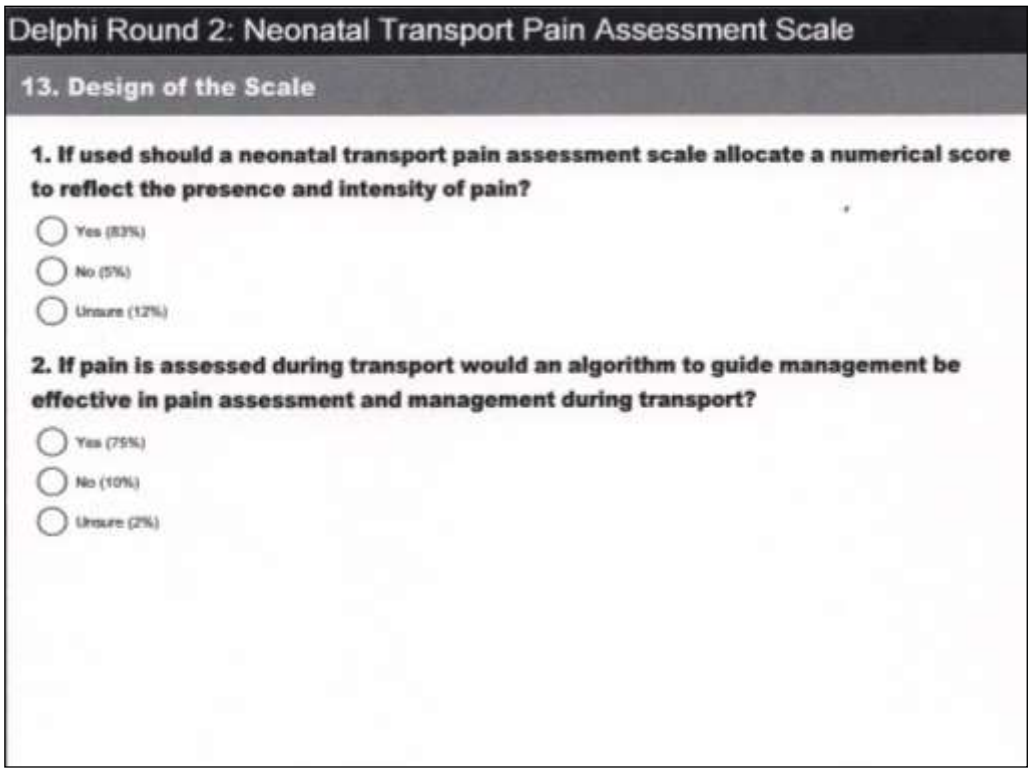
Delphi Round 2: Neonatal Transport Pain Assessment Scale

9. -

	Strongly Disagree (4%)	Disagree (8%)	Unsure (12%)	Agree (56%)	Strongly Agree (17%)
Incorporate history	◯	◯	◯	◯	◯

10. -

	Strongly Disagree (4%)	Disagree (3%)	Unsure (13%)	Agree (60%)	Strongly Agree (20%)
Incorporate diagnosis	◯	◯	◯	◯	◯



Delphi Round 2: Neonatal Transport Pain Assessment Scale

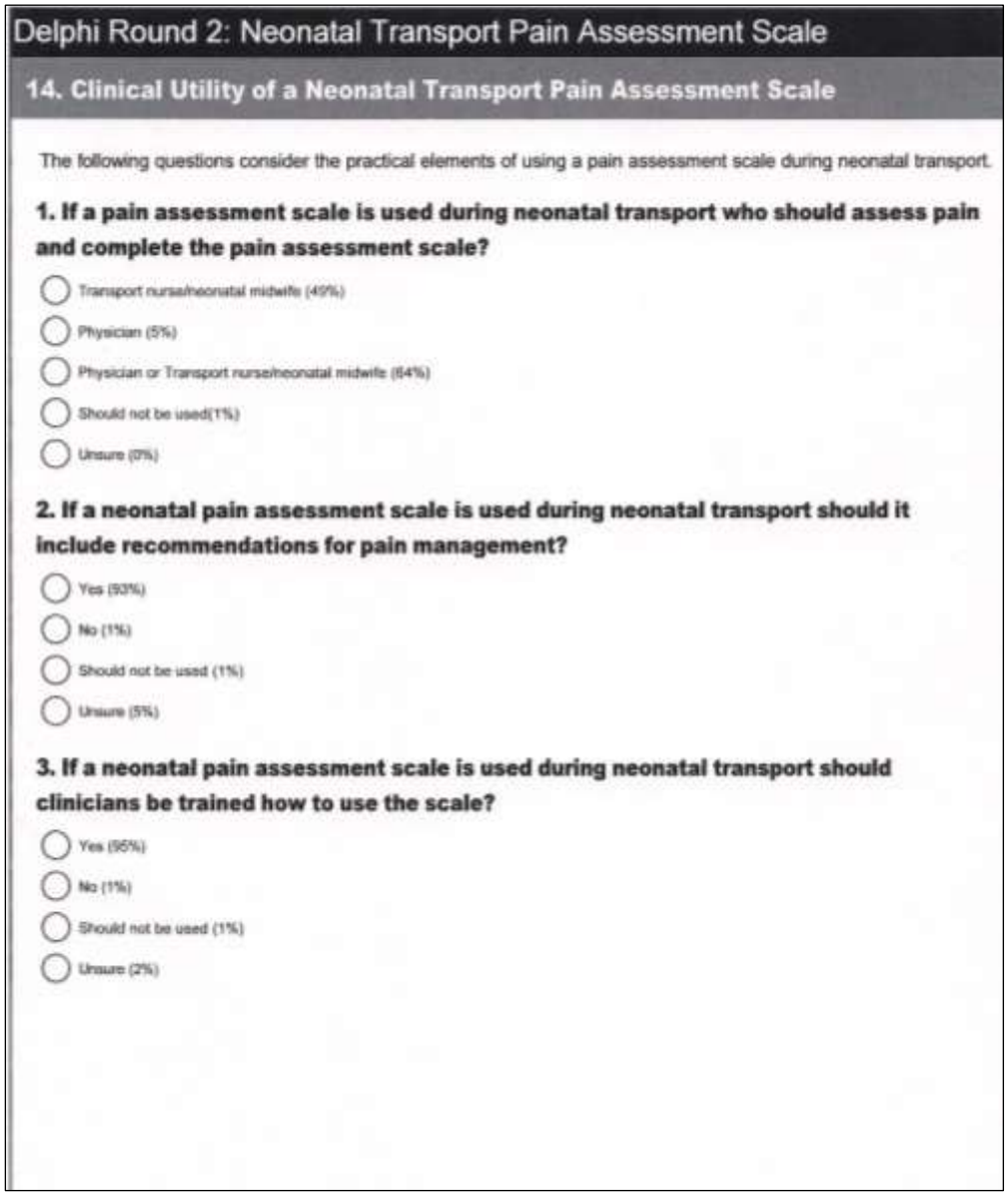
13. Design of the Scale

1. If used should a neonatal transport pain assessment scale allocate a numerical score to reflect the presence and intensity of pain?

- ◯ Yes (83%)
- ◯ No (5%)
- ◯ Unsure (12%)

2. If pain is assessed during transport would an algorithm to guide management be effective in pain assessment and management during transport?

- ◯ Yes (75%)
- ◯ No (10%)
- ◯ Unsure (2%)



Delphi Round 2: Neonatal Transport Pain Assessment Scale

14. Clinical Utility of a Neonatal Transport Pain Assessment Scale

The following questions consider the practical elements of using a pain assessment scale during neonatal transport.

1. If a pain assessment scale is used during neonatal transport who should assess pain and complete the pain assessment scale?

- Transport nurse/neonatal midwife (49%)
- Physician (5%)
- Physician or Transport nurse/neonatal midwife (64%)
- Should not be used(1%)
- Unsure (0%)

2. If a neonatal pain assessment scale is used during neonatal transport should it include recommendations for pain management?

- Yes (93%)
- No (1%)
- Should not be used (1%)
- Unsure (5%)

3. If a neonatal pain assessment scale is used during neonatal transport should clinicians be trained how to use the scale?

- Yes (95%)
- No (1%)
- Should not be used (1%)
- Unsure (2%)

Appendix 9.3

Delphi Questionnaire Round 1: List of Questions

Introduction: Section1

Introduction to questionnaire

Demographics and Experience: Section 2-5

Section 2: Background Information

1) How much experience do you have working on neonatal transport?
2) What qualifications do you hold?
3) Have you completed a course/module on neonatal transport

Section 3: Pain Assessment During Transport

1) Do you think pain should be assessed during neonatal transport
2) Do you think a pain assessment scale should be used during neonatal transport?
3) Have you used a pain assessment scale on neonatal transport?
4) If yes which one have you used?

Section 4: Pain Assessment in the Neonatal Unit/Clinical Area

1) Have you used a pain assessment scale in the clinical area?
2) If yes which one did you use?

Section 5: Guidelines on Neonatal Pain Assessment

1) Do you have a clinical guideline on neonatal pain assessment in the NNU

2) Do you have a clinical guideline on neonatal pain assessment during transport

Questions included in the Delphi Questionnaire: Section 6-13

Section 6: Pain Assessment during Neonatal Transport

- 8 items (Questions 1and 2 included from Section 3)

1. Do you think pain should be assessed during neonatal transport?

2. Do you think a pain assessment scale should be used during neonatal transport?

In relation to neonatal transport which of the following statements apply-

3. A pain assessment scale should be used during all neonatal transfers

4. A pain assessment scale should be used in neonatal surgical transfers

5. A pain assessment scale should be used in babies requiring analgesia

6. A pain assessment scale should be used in babies requiring mechanical ventilation

7. A pain assessment scale should be used in babies who are muscle relaxed

8. A pain assessment scale should be used in babies who are neurologically compromised

If a pain assessment scale was used at what time would it be used during the transport?

-5 items

9. Arrival in the referral unit
10. Prior to leaving the referral unit
11. During transport
12. On arrival at the receiving unit
13. Not assessed at all during transport

Section 7. What might be included in a neonatal transport pain assessment scale?

Which physiological indicators of pain should be included?

- **12 items**

14. Variations in heart rate
15. Variations in oxygen saturation
16. Variations in blood pressure
17. Variations in toe/core differential
18. Variations in skin colour
19. Capillary refill
20. Changes in ventilation requirements
21. Respiratory rate
22. Work of breathing
23. Episodes of instability
24. Degree of muscle tone
25. Temperature

Which clinical measures might be included in a neonatal transport pain assessment scale?

- **5 items**

26. Blood glucose measurement
27. Blood Lactate
28. Blood gas measurement
29. End tidal Co2
30. Should gestational age be included in the scale?

Section 8. Which behavioural indicators might be included in the scale?

If a neonatal pain assessment scale is used which of the following behavioural indicators of pain should be included

- **12 items**

31. Cry
32. Irritability
33. Type of eye movement
34. Eye squeeze during painful stimuli
35. Facial expression
36. Response to stimuli
37. Level of activity
38. Eyebrow furrow
39. Muscle tone
40. State of arousal
41. Alertness
42. Nasolabial furrow

Section 9. Environmental Factors which might influence pain assessment

- 7 items

Which of the following environmental factors might influence pain assessment?

- 7 items

43. Type of transport
44. Length of transport
45. Noise levels
46. Light levels
47. Temperature
48. Altitude if flight transfer
49. Infant position in ambulance

Section 10. Non-pharmacological factors which might influence pain assessment during transport

Non-pharmacological factors

- **5 items**

50. Position e.g. lateral/prone SD D NA A SA
51. Positional aides used
52. Use of transwarmer
53. Pacifier/dummy
54. Containment holds

Section 11. Pharmacological factors which might influence pain assessment

Which pharmacological factors might influence pain assessment

- 5 items

55. Type of analgesia
56. Dose during transfer
57. Alterations in dose during transfer
58. Muscle relaxant used
59. Use of sucrose

Section 12. Scale Design

Design of the pain assessment scale

- 12 items

60. Limit to 1 page
61. Limit to 2 pages
62. Unlimited length
63. Incorporate in transport observation sheet
64. Develop separate pain assessment chart
65. Include recommendations for analgesia based on pain score
66. Include guidelines on the scoring system
67. Document intervention strategies following pain assessment
68. Incorporate history
69. Incorporate diagnosis

70. If used should a neonatal transport pain scale allocate a numerical score to reflect the presence and intensity of pain
71. If pain is assessed during transport would an algorithm to guide management be effective in pain assessment and management during transport?

Section 13. Clinical Utility

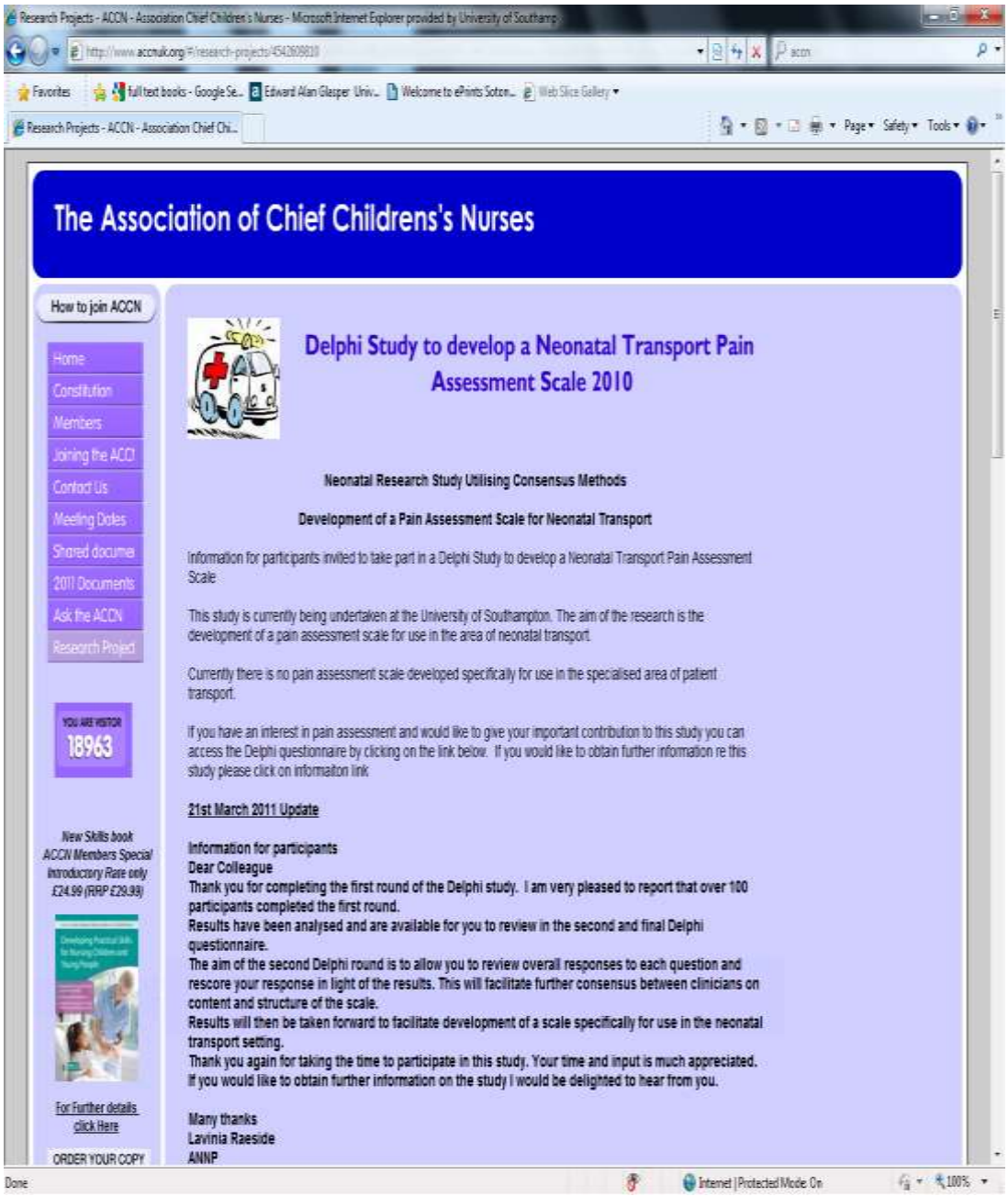
Who should complete the pain assessment scale?

- **5 items**

72. Transport nurse/midwife
73. Physician
74. Physician or transport nurse/midwife
75. Should a pain assessment scale include recommendations for pain management?
76. Should clinicians be trained on how to use the scale?

Appendix 10

Invitation to Participants: Phase 2
Association of Chief Children's Nurses Website



Appendix 11

Data Matrix Grid - Semi-Structured Interview Pilot Study

Data Matrix Grid – Question Number	Accepted	Accepted but Amended	Question Reject
Section 1. Background Information			
5) What is your current post?	√		
6) How much experience do you have working on neonatal transport?			
7) Have you used pain assessment scales in the clinical area or during transport?	√		
8) If yes which scale have you used?	√		
9) Have you reviewed the scale?		√ **Re-word**	
10) Have you reviewed the accompanying information sheet	√		
11) Did you find the information sheet useful?	√		
12) Would additional training be required?		√ **Re-word**	
13) What type of further training do you feel is required?	√	**Additional question on if the training could be included in an induction programme**	
Section 2. Face Validity of the Scale			
1) In your opinion the length of the scale was: **a) Long** **b) Short** **c) Appropriate**	√		
2) Did you find the scale easy to read	√		
3) Did you find the content of the scale easy to understand?	√		
4) In your opinion were items in the scale easy to score?	√	**Additional question on scoring both pain and sedation**	
5) In your opinion does the content of the scale appear appropriate to the transport setting	√		
6) Which format do you prefer? **a) Landscape** **b) Portrait**	√		
7) Why do you prefer this format?	√		

Data Matrix Grid – Question Number	Accepted	Accepted but Amended	Question Reject
Section 3. Feasibility of the Scale			
1) In your opinion is the pain assessment scale practical to use in the transport setting? a) Yes b) No c) Unsure	√		
2) Should the pain assessment scale be incorporated in existing transport documentation?	√		
3) Should any other item be included in the scale? a) Yes b) No c) Unsure	√		
4) Should any item be excluded or removed from the scale?	√		
5) Is a cumulative pain score a useful addition to the pain scale?		√ **Re-word**	
6) Is guidance on management linked to the pain score a useful addition to the pain scale?	√		
Section 4. Clinical Utility of the Scale			
1) Does use of the scale have the potential to influence pain management in the transport setting?	√		
2) In your opinion when should the scale be used during transport?	√		
3) In your opinion who should score the pain assessment scale?	√		
4) Should an algorithm be utilised to guide pain assessment and management during transport?	√ **Interesting question**		
5) Do you have any other comments in relation to pain assessment during transport?	√ **Important question**		

Appendix 11.1

Modified NTPAS Interview Schedule

Review of the Neonatal Transport Pain Assessment Scale (NTPAS)

Interview Schedule
Thank you for taking time to participate in this phase of the study
The purpose of this session is to review your perceptions on the new Neonatal Transport Pain Assessment Scale (NTPAS).
This scale has been developed as a result of a focus group meeting using nominal group technique and a large Delphi study.
Results have been used to adapt the NPASS scale to the transport setting.

1. Background Information

1. What is your current post?
Comments:

2. **How Much experience do you have working in neonatal transport**?
Comments:

The following questions will relate to your experience of pain assessment scales.

3. Have you used a pain assessment scale in the clinical area or during transport?
Clinical Area
Transport
Neither

4. If yes which scale have you used?
Comments:

5. Have you reviewed the neonatal transport pain assessment scale?
Yes
No
Unsure
Comments:

6. **Have you reviewed the accompanying information sheet?**

Yes

No

Unsure

Comments:

7. **Did you find the information sheet useful?**

Yes

No

Unsure

Comments:

8. **In your opinion would additional training be required before using the scale in the transport setting?**

Yes

No

Unsure

Comments:

9. What type of further training if any do you feel is required?

Comments:

10. Could this training be included in a transport induction programme?

Comments:

3. Face Validity of the Scale

These questions will review your perceptions on appearance and design of the scale

1. **In your opinion the length of the scale was:**

a) Too long

b) Too short

c) Appropriate

1. **Did you find the scale easy to read?**

Yes
No
Unsure
Comments:

2. **Did you find the content of the scale easy to understand?**

Yes
No
Unsure
Comments:

3. **In your opinions were the items on the scale easy to score?**

Yes
No
Unsure
Comments:

4. **In your opinion is scoring pain and sedation a useful addition to the scale?**

Yes
No
Unsure
Comments:

5. **In your opinion does the content of the scale appear to be appropriate to the transport setting?**

Yes
No
Unsure
Comments:

7. Which format do you prefer?

Landscape
Portrait

8. Why do you prefer that format?

Comments:

4. Feasibility of the scale

The following questions will review perceptions on how practical the scale is to use in the transport setting

1. **In your opinion is the pain assessment scale practical to use in the transport setting?**

Yes
No
Unsure
Comments:

2. **Should the pain assessment scale be incorporated in existing transport documentation?**

Yes
No
Unsure
Comments:

3. **Should any other items be included in the scale?**

Yes
No
Unsure
Comments:

4. **Should any item be excluded or removed from the scale?**

Yes
No
Unsure
Comments:

5. **Is a cumulative numerical pain score a useful addition to the pain scale?**

Yes
No
Unsure

6. **Is guidance on management linked to the pain score a useful addition to the pain scale?**

Yes
No
Unsure
Comments:

5. Clinical Utility of the Scale

The following questions will review to what extent the scale will facilitate management of pain in the transport setting

1. **Does use of the scale have the potential to influence pain management in the transport setting?**

a) Yes
b) No
c) Unsure

2. **In your opinion when should the scale be used during the transport?**

Comments:

3. **In your opinion who should score the pain assessment scale?**

Comments

4. **Should an algorithm be utilised to guide pain assessment and management during the transport?**

a) Yes
b) No
c) Unsure
Comments:

5. Further comments

1. **Do you have any further comments on pain assessment during transport?**

Appendix 12

Example of Transcription: Nominal Group Technique

Step 3 - Serial Discussion for Clarification

Group Facilitator
"Now we have listed our ideas on a flipchart, I want to take the time to go back and briefly discuss the items. The purpose of this is to clarify the meaning of each item on our flipchart, and give the opportunity to express our understanding behind the ideas. Can we begin with physiological items?".

Participant 2
"We could group some items together 1,12,13 "

Participant 3
"I suppose to variations in heart rate and we could add toe/core to temperature for developing a metabolic acidosis, and combine apnoea and synchrony

Participant 4
"Blood gases even or lactate"

Participant 4
"Would that be in response to pain or stress- would that be in relation to hypotension causing your gap- difficult to differentiate. Are you actually looking at things that cause pain or a response to pain- if you took something like temperature are you saying this is a response to pain or is that causing pain?"

Participant 2
"Do you mean disease processes that would cause pain?"

Participant 4
"Does this reflect the cause of pain or are you looking at responses to pain?

Participant 2
"Is that diagnosis

Participant 4
"If you took something like temperature- or your baby has a temp of 38.5 are you saying that is a response to pain or that's what is causing pain?

Appendix 12.1

Nominal Group Technique (NGT)
Serial Voting /Ranking

NGT Item number for Behavioural and Physiological Priority Items identified from serial Voting and Ranking

Variations in Heart Rate:	**NGT Item** 1
Blood Pressure:	**NGT Item 2**
Variations in Respiratory Rate:	**NGT Item 3**
Variations in Oxygen Saturation:	**NGT Item 4**
Increased Oxygen:	**NGT Item 5**
Facial Grimace:	**NGT Item 6**
Cry:	**NGT Item 7**
Tone:	**NGT Item 8**
Posture:	**NGT Item 9**
Activity Level:	**NGT Item 10**

Appendix 13

Participants Text
Responses to Delphi Questionnaire

Example of open text comments grouped in relation to the appropriate focus area

Focus Areas: **Safety**
Clinical Utility
Content
Design
Outcome

The questions are transcribed and presented in sequence.

Question 2	**Focus Area**
Difficult to find pain assessment scores outside of transport which work well & consistently. Not necessarily scoring tool but definitely needs assessed.	Clinical Utility
I feel that at present pain is assessed constantly and these results are documented hourly within the obs. chart this should be the practice observed during transport. Ideally a neonatal pain assessment should take place at least hourly. It would be important to use as the baby is being moved more than when in nnu.	Safety

Question 2	Focus Area
Depends if stable transfer or very sick neonate.	Clinical
My only concern is subjectivity- This can be very subjective.	Utility
Difficulty of doing this en route, monitoring it and time constraints.	
Depends on the clinical reasons for transfer. I think it is something that many of us assess anyway as part of our routine neonatal care. If we see any signs of the baby appearing to be in pain. I'd like to think it would be addressed prior to transfer. It will be a good tool to have, in the babies' interest. I believe that the assessment should be made prior to the transport commencing and relevant/adequate analgesia given before leaving the unit. Most Transports do not take more than a couple of hours so adequate analgesia can be given before the baby leaves the hospital.	Safety
I will need convincing that it will make a difference and be practical.	Clinical
Pain assessment scores are hard enough to use in neonatal units from a practical point of view not sure how user friendly they would be.	Utility
Only unsure -wonder how practical it would be in terms of accessing the infant	
Neonatal pain assessment should be regarded as the 5th vital sign and therefore assessed and acted upon accordingly whatever the situation. may be hard to judge a neonate during transport.	Safety
Extremely important and like neonatal units we should be actively encouraging the use of them to improve quality of care.	Outcome
Dependent upon the length of time that the transport will take i.e .some flights are only 30 minutes duration. The effects of noise, movement and other associated factors would need to be taken into account	Content

Appendix 13.1

Open Text Delphi Panel Statements:

Example of comments from the Delphi panel, open text statements presented in order of the allocated Delphi Statement (DS) number 1-86.

Delphi Statement number (DS) Number

DS 1 Pain is assessed constantly.

DS 2 This should be the practice observed during transport to ensure safety.

DS 3 Important to use as the baby is being moved more than when in NNU.

DS 4 Should be actively encouraging the use of them to improve quality of care.

DS 5 It will be a good tool to have, in the babies' interest.

DS 6 This can be difficult and subjective.

DS 7 The effects of noise, movement and other travel associated factors would need to be taken into account.

DS 8 Difficult to find pain assessment scores which work well and consistently.

DS 9 I will need convincing that it will make a difference and be practical. practical.

DS 10 Wonder how practical it would be in terms of accessing the infant.

DS 11 From a practical point of view not sure how user friendly they would be.

DS 12 May be hard to judge a neonate during transport.

DS 13 Pain and sedation is assessed and acted upon accordingly whatever the situation.

Delphi Statement number (DS)
Number

DS 14 Difficulty of doing this en route, monitoring it and time constraints.

DS 15 Not possible to use our current pain assessment tool with a muscle relaxed infant.

DS 16 Muscle relaxant would have to be separate.

DS 17 Muscle relaxed and neurologically compromised infants are difficult to assess.

DS 18 Importance of a baseline assessment on transport is to enable continuing assessment.

DS 19 Signs of pain should still be monitored with babies who have received paralytics.

DS 20 They will not display behavioural signs due to drugs.

DS 21 Analgesics should still be given and physiological signs monitored.

DS 22 Dedicated transport service with specific guidelines which make assessments and decisions.

DS 23 I'd support the use of the scale in all groups where it made a difference. a difference.

DS 24 Pain is difficult to quantify due to the unstable nature of babies at times during transport.

DS 25 Variations in heart rate and BP are useful indicators.

DS 26 Must also remember other factors may affect them e.g. heart rate can rise when infants temp is increased.

DS 27 Blood glucose may also aid assessment.

DS 28 Air transport can also affect these physiological parameters.

DS 29 I feel anything during transport should be 'no touch'.

DS 30 I do not believe there is any 'routine' reason why we should be opening incubator doors during a transport.

DS 31 Difficulty in assessing pain due to varying clinical conditions/ type of respiratory support etc.

DS 32 Some parameters are difficult to assess because of movement

Appendix 14

Scoring Criteria for the Neonatal Transport Pain and Sedation Scale (NTPAS)

- The aim of the NTPAS is to assess the infants' response to pain and stimuli.
- Sedation is scored in **addition** to pain for each physiological and behavioural criteria.
- It is **not necessary** to score sedation with each pain assessment.

Pain Assessment

Pain Assessment should take place with every vital signs assessment.

Each behavioural and physiological criteria is given a score of 0 to 2 and them summed

Points are added for:

- Prematurity- infants less than 30 weeks gestation
- Transfers longer than 1 hour
- Turbulent/bumpy transfer
- Baby is less than 24 hours post-operative

The **total** pain score is documented as a number between 0 → 14

Interventions or treatment are suggested for **scores > 3**

The aim of treatment is a score of ≤ **3**

In infants receiving analgesia or sedation assessments should take place every 2 → 4 hours

An assessment should also be made 30-60 minutes after an analgesic is given to assess the infants' response.

If the baby is post-operative the assessment should occur every 2 → 4 hours for 24 to 48 hours and then every 4 hours until analgesia is weaned off.

Oxygen saturation in babies with **cyanotic heart disease** should be assessed with oxygen saturation limits agreed for the baby by the cardiology team/attending physician.

Assessment of Sedation

- Sedation does **not need** to be scored with every pain assessment.
- Sedation is scored for each physiological and behavioural criteria to assess response to stimuli
- Sedation is scored from 0 to 2 for each behavioural and physiological criteria.
- The total score is a score from 0 → 14

Points are added for:

- Prematurity- infants less than 30 weeks gestation
- Transfer is longer than 1 hour
- Turbulent/bumpy transfer
- If the baby is within 24 hours post-operative

If the infant has no signs of sedation and in not non-reactive a score of 0 is given

The required level of sedation is dependent on the circumstances.

- If light sedation is required → a score of 2 to 5 is the goal
- If deep sedation is required → a score of 6 to 10 is the goal

Deep sedation should only be applied with babies who are receiving ventilator support due to the risk of apnoea and hypoventilation.

If a low score is applied without the administration of analgesics this may indicate:

- The response of the preterm infant to prolonged pain/stress.
- Sepsis/neurological depression or other pathology.

Criteria for Scoring the NTPAS

Sedation= blue Applies to both Pain and Sedation= green
Pain = pink

Vital Signs: HR, BP, RR, & O_2 Saturations

Score	If any of the following are observed
2	No spontaneous respiratory effort when on ventilator support. No variability in vital signs with stimuli Hypoventilation or Apnoea
1	There is little variability in vital signs during stimulation. Less than 10% from baseline
0	No sedation signs / no pain signs
1	HR, RR, and/or BP are 10-20% above baseline. Baby desaturates minimally to moderately during stimuli (SaO_2 76-85%) and recovers quickly (within 2 minutes)
2	HR, RR, and/or BP are > 20% above baseline Baby desaturates severely with stimuli (SaO_2 < 75%) and recovers slowly (> 2 minutes) If ventilated baby is out of sync/or fighting the ventilator

Crying / Irritability

Score	If any of the following are observed
2	Baby makes no response to painful stimuli No cry with needle sticks or no reaction to ETT suctioning No response to care giving
1	Cries /moans (audible or silent) minimally to painful stimuli
0	No sedation signs or pain signs
1	Intervals of crying or irritability. Can be consoled. If intubated - intermittent silent cry
2	High-pitched cry or infant cries inconsolably If intubated – silent continuous cry

Score	If any of the following are observed
2	Does not arouse or react to any stimuli. Eyes continually shut or open. No spontaneous movement
1	Little spontaneous movement, arouses briefly and/or minimally to any stimuli. Eyes open briefly, responds to suctioning, withdraws to painful stimuli.
0	No sedation signs or no pain signs
1	Restless, squirming Awakens frequently with minimal or no stimuli
2	Constantly awake, kicking, arching. Or no spontaneous movement / minimal arousal (not sedated and inappropriate for gestational age or situation)

Behaviour / State

Facial Expression

Score	If any of the following are observed
2	No facial expression with stimuli or at rest. Drooling, mouth lax
1	Little facial expression with stimuli or at rest
0	No sedation or pain signs
1	Any observed pain facial expressions are intermittent
2	Any observed pain facial expressions are continuous

Tone/ Extremities

Score	If any of the following are observed
2	No palmar or planter grasp Tone flaccid
1	Weak palmar or planter grasp Tone decreased
0	No signs of sedation or pain
1	Intermittent signs of toes and /or hands clenched or fingers splayed Body is not tense
2	Frequent observation of toes and /or hands clenched or fingers splayed. Body is tense/ stiff

THE PARALYSED NEONATE

The paralysed neonate cannot be behaviourally evaluated.

Pain indicators may include:

- Increases in heart rate
- Increases in blood pressure during or outwith handling
- Analgesics should be administered continuously is the infant is paralysed

Appendix 15

Example of Transcribed Semi-structured Interview with Transport Clinicians

NTPAS Interview Schedule

Interview 7

1. Background Information

1. **What is your current post?**

Comments

"Neonatal Transport Nurse"

2. **How much experience do you have working on neonatal transport?**

Comments

"Over 10 years probably"

The following questions will relate to you experience of pain assessment scales.

3. **Have you used a pain assessment scale in the clinical area or during transport?**

Comments

Clinical Area	□□
Transport	□□
Neither	√

4. If yes which scale have you used?

N/A

4a) Have you used the NPASS scale

N/A

5. Have you reviewed the Transport Pain Assessment Scale?

Yes	√
No	□□
Unsure	□□

Comments

"Yes I have"

6. Have you reviewed the accompanying information sheet?

Yes	√
No	□□
Unsure	□□

7. Did you find the information sheet useful?

Comments

"It was yes - I got a little bit confused initially until I looked at that sheet (pain scale) which clarified this was the pain score and this the sedation score- I just got confused between the two - until I actually looked at the scale".

8. In your opinion would additional training be required before using the scale in the transport setting?

Yes	√
No	□□
Unsure	□□

Comments

"Yes - I would probably say yes to that. A - because with anything that's new you have to kind of - especially if you are auditing it- know what a person wants out of it - I think because there is two side by side (pain and sedation score) people have to understand that one is for one thing and the other is for the other".

9. What type of further training if any do you feel is required?

Comments

"One to one training would be time consuming- whereas I think it is something that can be done in a very informal way ".

2. Face Validity of the Scale

These questions will review your perceptions on appearance and design of the scale

1. **In your opinion the length of the scale was:**

a) Too long □□

b) Too short □□

c) Appropriate √

Comments

"I think it was appropriate in length. It is easy to see- and easy to pick up- I preferred that one (landscape) the other one was just too busy for me- this one was easier to the eye-easy to see- one side is one and one side is the other- and you can pick out what you are looking for very easily".

2. **Did you find the scale easy to read?**

Yes √

No □□

Unsure □□

Comments

"Yes- it was".

3. **Did you find the content of the scale easy to understand?**

Yes	√
No	□□
Unsure	□□

Comments

"Yes- the only thing I had to think about was the NAS [Neonatal Abstinence Syndrome]babies- and how to use this with that- and how to use it with those babies as they have their own scale- however I don't think you would use it with them- you would probably use it for your surgical babies - transferring an NAS baby would be quite difficult having two scores".

4. **In your opinion were items in the scale easy to score?**

Yes	√
No	□□
Unsure	□□

Comments

"Yes -well I tried it out - and yes I would say it was easy".

5. **In your opinion does the content of the scale appear to be appropriate to the transport setting?**

Yes	√
No	□□
Unsure	□□

Comments

"I do actually - A - because you have gone over things like transports longer - bumpy - it can be very bumpy for us - especially if they are a surgical baby- and post-operative - and intubated babies as well- but also it is nice to have a sedation score to see that you have given the appropriate pain relief".

6. **Which format do you prefer?**

Landscape	√
Portrait	□□

7. **Why do you prefer that format?**

Comments

"Landscape", as it appeared easier to read.

4. Feasibility of the scale

The following questions will review perceptions on how practical the scale is to use in the transport setting

1. **In your opinion is the pain assessment scale practical to use in the transport setting?**

Yes	√
No	□□
Unsure	□□

Comments

"Ye s- have already tried it- I think it is because to use it is easy on the eye- and so you can pick it up quite quickly- and once you have used it a few times you will be quite familiar with it".

2. **Should the pain assessment scale be incorporated in existing transport documentation?**

Yes	√
No	□□
Unsure	□□

Comments
"Not all babies will probably need it - however you will not know until you get to the baby- it would be nice to think that you can incorporate it".

3. **Should any other item be included in the scale?**

Yes □□

No √

Unsure □□

Comments

"No -I think you have covered all of them".

4. **Should any other items be excluded or removed from the scale?**

Yes □□

No √

Unsure □□

Comments

"No I think it is just right"

5. **Is a cumulative score a useful addition to the pain scale?**

Yes √

No □□

Unsure □□

Comments

"I think so because if you are using that with the sedation score you can see if it is coming down and if you are using it appropriately"

6. **Is guidance on management linked to the pain score a useful addition to the pain scale?**

Yes □□

No √

Unsure □□

Comments

"It is everybody's preference what they use- some places use one thing and others use something else- that would be difficult- not at the moment but I think it is something which could be developed".

5. Clinical Utility of the Scale

The following questions will review to what extent the scale will facilitate management of pain in the transport setting.

1. Does use of the scale have the potential to influence pain management in the transport setting?

a) Yes √

b) No □□

c) Unsure □□

Comments

"I think it is nice to know you have something to look at and say yes we have made the right decision in giving pain relief- so yes".

2. In your opinion when should the scale be used during transport?

Comments

"Used on a continuum - because you need to have a baseline of pain- because every baby is different - some don't like it and some do- it just depends - so I think you need a baseline to start off with - then you can use it throughout".

3. In your opinion who should score the pain assessment scale?

Comments

"All members of the team".

4. Should an algorithm be utilised to guide pain assessment and management during the transport?

a) Yes √

b) No □□

c) Unsure □□

Comments:
"I think that might be useful".

5. Further Comments

1. Do you have any further comments in relation to pain assessment during transport?

"Because I have never used one before - it is something that is always on your mind - because we have been told we are a bit barbaric when we don't have pain relief on board- and it would be nice to say well we have actually got this set up now - this is what we follow and will use - so yes- I am looking forward to using it".

Appendix 15.1

Semi-structured Interviews: Example Coded Within the Thematic Framework

Colour Code:

Theme 1: Transport clinicians perceptions on safety and application of the pain assessment scale during transport **(Red)**

Theme 2: Transport clinicians views on how useful and effective the pain assessment scale would be during transport **(Blue)**

Theme 3: Transport clinicians perceptions on what to include in the pain scale and how it should be formatted **(Purple)**

Theme 4: The effect of utilising the pain assessment scale on clinical practice **(Green)**

Each quote is allocated an item number to facilitate analysis and a code within the thematic framework .

Participant 4

Item Number	Code
1. It (scoring criteria sheet) was useful**.**	**3.2.3**
2. Had to keep referring back to the scoring sheet.	**3.1.3**
3. It got me a bit confused - the difference between pain and sedation.	**2.2.1**
4. I had to keep separating them both- which I am not used to doing.	**4.2.1**
5. It would not be too lengthy- it is just because you are actually separating it.	**4.1.1**
6. When you are looking at the baby you are looking at it as a whole.	**4.1.1**
7. I found this one much easier to read (landscape version). I think it just reads easier.	**4.2.1**
8. There was nothing that was ambiguous.	**3.1.3**
9. It was just separating pain from sedation that I had to get used to.	**4.2.1**
10. It was easy to score	**3.1.3**
11. Straightforward	**3.1.3**

Participant 4

Item Number	Code
12. I think once you get used to the pain and sedation scoring it will be useful	**2.1.2**
13. The more I read it - I understood it	**3.1.3**
14. I had to read the information several times before I got to understand separating them both.	**3.1.3**
15. Will be useful when you get used to it.	**2.1.2**
16. It should be easy to use on transport.	**2.1.3**
17. It is just as easy to do when you are doing the observations.	**2.1.3**
18. Should be incorporated as a follow on to all the vital signs.	**4.2.1**
19. It should be vital signs and then pain.	**4.2.1**
20. It is simpler and it should be getting done constantly.	**2.1.2**
21. I think it is all pretty much covered.	**3.2.1**
22. I think you need to go through all of these.	**3.1.2**
23. It gives you a guideline- it makes you recognise the differences.	**4.2.2**
24. Leads to uniform treatment.	**4.1.1**
25. It will make you much more aware.	**2.1.2**
26. Make you much more aware of treatment of pain.	**2.1.2**
27. Should be done before the baby has even started the transfer.	**1.1.6**
28. Part of a baseline.	**2.1.2**
29. Pretty self-explanatory.	**2.1.2**
30. Once you get used to it.	**2.1.2**
31. It would just become second nature- and you should be able to do it with your vital signs every 15 minutes.	**1.1.5**
32. Nursing staff will be more concerned with pain.	**1.1.7**
33. Getting used to it- - particularly the layout of it.	**2.1.1**
34. Needs to be something that is user friendly.	**3.1.3**
35. This would be quite practical to use.	**2.1.2**

Appendix 16

Thematic Framework

Thematic Framework

1. **Transport clinicians perceptions on safety and application of the pain assessment scale during transport**
   This includes all comments which would relate to safety such as monitoring the clinical stability of the baby.

   1.1 Perceptions on Safety
   - 1.1.1 Episodes of instability
   - 1.1.2 Differential diagnosis
   - 1.1.3 Airway maintenance
   - 1.1.4 Benefits of analgesia/sedation
   - 1.1.5 Frequency of pain assessment
   - 1.1.6 Assessment of pain to facilitate safe transport
   - 1.1.7 Transport staff and safety

   1.2 Perceptions on physiological parameters and safety
   - 1.2.1 Assessment of physiological parameters and stability of the patient

   1.3 Perceptions on equipment and safety
   - 1.3.1 Benefits of patient monitoring during transport
   - 1.3.2 Appropriate monitoring equipment and patient safety

2. **Transport clinicians views on how useful and effective the pain assessment scale would be during transport**

   Participants' comments relating to application of the scale within the transport environment.

   2.1 Efficacy of the scale within the transport setting
   - 2.1.1 Barriers to application of the scale during transport
   - 2.1.2 Benefits of using the scale during transport
   - 2.1.3 Reliable and valid in the transport setting

   2.2 Subjectivity
   - 2.2.1 Subjectivity and application of the pain scale

3. Transport clinicians perceptions on what to include in the pain assessment scale and how it should be formatted

Participants comments relating to content of the pain scale

3.1 Items to be included in a pain scale
- 3.1.1 Physiological and behavioural indicators of pain
- 3.1.2 Items relating to pain management
- 3.1.3 Clarity of content and ease of application

3.2 Effects of content on outcome
- 3.2.1 Appropriate to neonate and transport
- 3.2.2 Depth of content and ability to apply to transport setting
- 3.2.3 Utility within the transport environment

3.3 Content and staff education
- 3.3.1 Requirements of staff education and application of the scale

Participants comments in relation to format of the pain scale

3.4 Length of the scale
- 3.4.1 Length of the scale and application to transport

3.5 Format of the scale
- 3.5.1 Format of the scale and application to transport

3.6 Location of the scale within the transport documentation
- 4.3.1 Documentation and integration within the transport network

4. The effect of utilising the pain assessment scale on clinical practice

Participants comments relating to application of the pain scale and patient outcome

4.1 Perceptions on effect of pain scale on patient outcome
- 4.1.1 Effect of pain scale on pain management and patient outcome

4.2 Integration of the pain scale into the transport network
- 4.2.1 Benefits and barriers to application of the scale
  Transport guidelines and pain assessment

4.3 Location of the Scale within the transport documentation
- 4.3.1 Perceptions on integration of the scale within current documentation

Appendix 17 Thematic Charts

Semi-structured interview items (statements) within Thematic Framework

Theme 1 **Transport clinicians perceptions on safety and application of the pain assessment scale during transport**										
Participant Number	**1.1 Perceptions on Safety**							**1.2 Perceptions on physiological parameters and safety**	**1.3 Perceptions on equipment**	
	1.1.1 Episodes of instability	1.1.2 Differential diagnosis	1.1.3 Airway maintenance	1.1.4 Benefits of analgesia/sedation	1.1.5 Frequency of pain assessment	1.1.6 Assessment of pain to facilitate safe transport	1.1.7 Transport staff and safety	1.2.1 Assessment of physiological parameters and stability of the patient	1.3.1 Benefits of patient monitoring during transport	1.3.2 Appropriate monitoring equipment and patient safety
4					Item 31	Item 27	Item 32			
5		Item 69		Item 70, 71	Item 61	Item 68				
6								Item 91		

Theme 1(contd) Transport clinicians perceptions on safety and application of the pain assessment scale during transport										
Participant Number	**1.1 Perceptions on Safety**							**1.2 Perceptions on physiological parameters and safety**	**1.3 Perceptions on equipment**	
	1.1.1 Episodes of instability	1.1.2 Differential diagnosis	1.1.3 Airway maintenance	1.1.4 Benefits of analgesia/sedation	1.1.5 Frequency of pain assessment	1.1.6 Assessment of pain to facilitate safe transport	1.1.7 Transport staff and safety	1.2.1 Assessment of physiological parameters and stability of the patient	1.3.1 Benefits of patient monitoring during transport	1.3.2 Appropriate monitoring equipment and patient safety
7		Item 166		Item 153	Item 135, 137, 163	Item 138, 139		Item 157, 158		
8										Item 183, 184
9	Item 216, 227	Item 215, 217		Item 201	Item 220			Item 214		
10	Item 271	Item 243, 248				Item 256				

Theme 2 **Transport clinicians views on how useful and effective the pain assessment scale would be during transport**				
Participant Number	**2.1 Efficacy of the scale within the transport setting**			**2.2 Subjectivity**
	2.1.1 Barriers to application of the scale during transport	2.1.2 Benefits of using the scale during transport	2.1.3 Reliable valid in the transport setting	2.2.1 Subjectivity and application of the pain scale
4	Item 33	Item 12,15, 20, 25, 26, 28, 29, 30, 35	Item 16,17, 53, 54	Item 3
5		Item 47, 56, 59	Item 53, 54	
6	Item 88, 89, 90, 92, 93, 94, 95, 99	Item 107, 112		
7	Item 148, 149	Item 134, 136, 164		Item 128
8	Item 176, 177			
9	Item 209, 210	Item 202, 204		Item 221, 222, 223
10	Item 246	Item 268, 284		Item 236, 237, 251, 273

Theme 3 **Transport clinicians perceptions on what to include in the pain assessment scale and how it should be formatted**										
Participant Number	**3.1 Items to be included in a pain scale**			**3.2 Effects of content on outcome**			**3.3 Content and staff education**	**3.4 Length of the Scale**	**3.5 Format of the scale**	**3.6 Location of the scale within the transport documentation**
	3.1.1 Physiological and behavioural indicators of pain	3.1.2 Items relating to pain management	3.1.3 Clarity of content and ease of application	3.2.1 Appropriate to neonate and transport	3.2.2 Depth of content and ability to apply to transport setting	3.2.3 Utility within the transport environment	3.3.1 Requirements of staff education and application of the scale	3.4.1 Length of the scale and application to transport	3.5.1 Format of the scale and application to transport	3.6.1 Documentation and integration within the transport network
4	Item	Item 22,	Item 2, 8, 10, 11, 13, 14, 34	Item 21,		Item 1,	Item			
5	Item	Item 55	Item 39, 43, 44, 45, 46, 63	Item	Item 36, 37, 38, 65	Item 50	Item 62			
6	Item	Item 81, 103, 104	Item 72, 73, 77, 78, 82, 84, 85, 98	Item 80, 101, 102	Item 86	Item	Item 75, 76, 79, 87, 111			

Theme 3 (Cont) Transport clinicians perceptions on what to include in the pain assessment scale and how it should be formatted										
Participant Number	**3.1 Items to be included in a pain scale**			**3.2 Effects of content on outcome**			**3.3 Content and staff education**	**3.4 Length of the Scale**	**3.5 Format of the scale**	**3.6 Location of the scale within the transport documentation**
	3.1.1 Physiological and behavioural indicators of pain	3.1.2 Items relating to pain management	3.1.3 Clarity of content and ease of application	3.2.1 Appropriate to neonate and transport	3.2.2 Depth of content and ability to apply to transport setting	3.2.3 Utility within the transport environment	3.3.1 Requirements of staff education and application of the scale	3.4.1 Length of the scale and application to transport	3.5.1 Format of the scale and application to transport	3.6.1 Documentation and integration within the transport network
7	Item	Item 132, 145, 152, 154, 160, 161,	Item 116, 117, 118, 121, 124, 125, 126, 130, 131, 141, 142, 146, 147, 150	Item 127, 155, 165, 167	Item 133,	Item	Item 119, 143,			
8	Item	Item 173, 179, 180	Item 169,174, 175,	Item 168, 181	Item 185	Item	Item 170			
9	Item 193	Item 200	Item 187, 188, 189, 190, 195, 198, 199	Item 205	Item 196, 197, 208, 211, 212, 213, 224	Item	Item 191, 192,			
10		Item 252,	Item 228, 229, 233,238, 239, 241,260, 261, 263,	Item 255	Item 240, 242, 259, 262, 265	Item 234, 235,	Item 231, 274, 278			

Theme 4 The effect of utilising the pain assessment scale on clinical practice				
Participant Number	**4.1 Perceptions on effect of the pain scale on patient outcome**	**4.2 Integration of the pain scale into the transport network**		**4.3 Location of the Scale within the transport documentation**
	4.1.1 Effect of the pain scale on pain management and patient outcome	4.2.1 Benefits and barriers to application of the scale	4.2.2 Transport guidelines and pain assessment	4.3.1 Perceptions on integration of the scale into current documentation
4	Item 5, 6	Item 4, 7, 9, 18, 19		
5	Item 40, 48, 49	Item 41, 42, 51		Item 52
6	Item 57, 58, 60, 64, 67, 105, 110	Item 74, 83, 96, 97, 114	Item 113	
7	Item 120, 129, 140, 151, 162	Item 122, 123, 156,		Item 159,
8	Item 171, 178, 186, 194	Item 172, 182		
9	Item 206, 218, 219, 225, 226	Item 203, 207, 232		
10	Item 244, 245, 247, 250, 258, 267, 275, 276, 277, 281, 282, 283, 285	Item 254, 266, 269, 279, 280,	Item 264, 270,	Item 257