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CITATION

Aminudin, Nurul (2021): Neonatal Noise Exposure and Noise Reduction During Transport. Royal College of Surgeons in Ireland. Thesis. https://doi.org/10.25419/rcsi.13637558.v1

DOI

10.25419/rcsi.13637558.v1

URL

https://repository.rcsi.com/articles/thesis/Neonatal_Noise_Exposure_and_Noise_Reduction_During_Transport/13637558/1

Neonatal Noise Exposure and Noise Reduction During Transport

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A thesis submitted to the School of Postgraduate Studies, Faculty of Medicine and Health Sciences, Royal College of Surgeons in Ireland, in fulfilment of the Medical Doctorate degree by research.

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January 2020

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Abbreviations

- ANC: Active Noise Cancellation
- bpm: beats per minute
- dB: decibel
- dBA: decibel A weighted
- dBC: decibel C weighted
- dBZ: decibel Z weighted
- EAM: External Auditory Meatus
- FiO_2: Fractional Inspired Oxygen Concentration
- HR: heart rate
- HSE: Health Service Executive
- ICU: Intensive Care Unit
- Leq: Total Sound Pressure Level cumulative energy
- Lpeak: Peak Sound Pressure Level
- MRI: Magnetic Resonance Imaging
- NAS: National Ambulance Service
- NICU: Neonatal Intensive Care Unit
- NIHL: Noise Induced Hearing Loss
- NIPS: Neonate and Infant Pain Score
- NNTP: National Neonatal Transport Program
- NPEM: Noise Protective Ear Muffs
- O_2: Oxygen
- O2 Sats: Oxygen Saturation
- RCT: Randomised Control Trial
- RMS Root mean square
- SC: Standard Care
- SPL: Sound Pressure Level
- TRIPS: Transport Risk Index of Physiological Stability
- WHO: World Health Organisation

Abstract

Inter-hospital transport of sick neonates for specialist care is often necessary, but older studies suggest it may expose them to high levels of noise that may cause distress, autonomic instability and even noise induced hearing loss (NIHL). There have been advances in transport equipment standards, but little effort to address this issue. There is paucity of data on the effects of noise levels experienced by neonates undergoing inter-hospital nor on the effects it may have on infant stability or behaviour. MRI scans, which are known to generate potentially hazardous noise levels, are not performed without conventional noise protection headphones, and newer active noise cancelling equipment that is available may provide additional protection. Standard neonatal transport clinical care does not include noise protection as such for patients during road transfers, and minimal protection is provided for air transport.

This research quantified the noise levels experienced by neonates undergoing interhospital transport by both air and ground ambulance, with the national neonatal transport service. Baseline noise levels were obtained to ascertain feasibility of research equipment prior to demonstrating the physiological effects of noise among neonates during transport in an observational patient cohort. The research subsequently evaluated the effect of the application of noise protective equipment during neonatal interhospital ground and air transport by demonstrating differences in noise exposure and the effect on the neonatal heart rate, oxygen saturations and behavioural responses. A convenience sample of neonates who underwent clinically indicated inter-hospital transfer was recruited following parental consent. A multichannel noise meter recorded noise levels at the infant external auditory meatus (EAM), within the incubator and in the ambulance cabin concurrently. Simultaneous

recording of infant heart and oxygen saturations was obtained and video footage was taken for behavioural analysis by 4 separate examiners. Demographic and routine transport monitoring data was documented. The patient observational study to determine the extent of noise exposure and its physiological effects during standard neonatal ground transport care i.e. without noise protection was followed by a sequence if intervention studies which included a crossover design that compared the application of noise protective devices with standard care. The noise protective devices that was used in the interventional patient studies were MRI grade noise protective earmuffs and an electronic active noise cancelling headphones. Two patient studies are still on-going due to paucity of suitable cases during the research period. One is randomized controlled trial of stable infants undergoing elective repatriation transfers was carried out to compare standard care with active noise cancelling headphones. The other is an observational study to compare the effectiveness of noise protective earmuffs versus active noise cancellation headphones in single journey neonatal air transfers.

Noise levels was measured underneath the noise protective equipment near the patients ear along with concurrent heart rate, oxygen saturation and infant behaviour recording. All the data was downloaded to a password protected computer and analysed using specialist software for analysis. Statistical analysis was performed using SPSS version 26.

This research demonstrated the quantity of neonatal noise level exposure in the NICU, but more pertinently during neonatal transport. Results of noise levels in baseline studies in NICU, ground ambulance transport and air transport can reach above 80 decibel-A and occasionally stretch near to and above 100 decibel-A. This surpasses international recommended limits of which should not exceed 60 decibel-

A during transport. The degree of noise reduction offered by the selected noise protective modalities evaluated, indicate the need for foreseeable improvement in delivery of care to the vulnerable neonate undergoing transport. While various analysis throughout the research demonstrated changes in physiology and behaviour moreover, with the application of noise protection; there is still huge variability within small population groups that was studied.

Thesis Acknowledgment

I would like to express my sincere gratitude to my academic and clinical supervisor **Professor Naomi McCallion** who relentlessly provides me with continuous support from the very beginning of my career in neonatology. “Naomi, your experience, patience, understanding, positivity, motivation and immense knowledge has helped me immeasurably throughout my time as a clinician, educator and most pertinently as a researcher. I could not have imagined a better supervisor and mentor in this MD research and even in my professional career as a whole. I feel deeply honoured having completed this fantastic project with you.”

I would also like to express my heartfelt gratefulness to my clinical supervisor in this research; **Dr. Jan Franta** who continues to support me since I found a spark of interest in neonatal medicine and neonatal transport. “Jan, this research with such a title has come to life from your idea. You let me become independent in doing this research while still being within reach for advice about anything and everything. You also opened doors of opportunities for me during my time as a researcher, and this doesn’t go unnoticed. I am grateful to you and your transparency and honesty that has given me direction in this career journey. Thank you, to both you and Naomi for selecting me out of many; and putting the trust in me to see this research through.”

I would also like to thank my other co-supervisors who have also helped me in this research**; Professor Afif Elkhuffash** and Dr**. David Corcoran** for their insightful comments, encouragement and who have also agreed to assist me with publications from this project.

I would also like to convey my sincere thanks to the following for assisting me in any shape or form; as the MD thesis completion would not surface without these persons, organisations and teams:

- Miss Ann Bowden, NNTP Coordinator
- The Rotunda Foundation
- National Children's Research Centre, Ireland (NCRC)
- National Neonatal Transport Programme (NNTP): The Rotunda Hospital, Coombe Women and Infant's University Hospital and National Maternity Hospital Holles Street. This includes all consultants, registrars and nurses that I interacted with during my time doing this research
- Mr. Mark Hollywood, Dr. Susan Harvey, Ms., Mairead McMorrow and Ms. Tara Moore
- Dr Dermot Doherty, National Clinical Programme in Transport Medicine.
- National Ambulance Service
- Irish Air Corp
- All Research and Ethics Committees from The Rotunda Hospital, Coombe Women and Infant's University Hospital and National Maternity Hospital Holles Street
- Ian McFarlane (Svantek Ltd UK) for Noise and Vibration software tutorials.
- School of Postgraduate Studies, RCSI, Dublin
- All my colleagues and friends in all 3 maternity hospitals and everywhere, who have given me unconditional support, you know who you are.
- The collateral support and understanding I received during my clinical fellowship; from my colleagues and seniors in Cambridge UK. They continuously encouraged me while I was writing the thesis in the final few months.

Finally, my eternal gratitude and love goes to my family: Zaidi, my husband and my children; Lily 15, Ilyaas 13, Nidal 9 and Azlan 7. You guys are the best team in my universe. Nobody has made me realise who I really am more than you. I will be ‘home’ soon!

Nurul H. Aminudin

Chapter 1 Introduction

Background 1: The Neonate

A neonate is a newborn child or infant in the first 28 days of life. This is a critical phase in human life as they adapt to the extra-uterine environment, experience rapid physiological changes and adjust to appropriate feeding and care for survival. Although the word neonatology wasn't used until 50 years ago, its core practices as a clinical specialty were recognized more than a century. Neonatology, is one of the most progressive fields in medicine, specializing in the care of neonates, including those who encounter difficulties going through physiological adaptive changes and require medical or surgical treatment to successfully transition. Modern neonatology has integrated with and bridged the different disciplines of obstetrics with paediatrics, intensive care and primary care. The on-going care provided to neonates involves teams of skilled professionals including the neonatologist (physician), neonatal nurse, midwife, obstetrician, perinatologist and often other allied health professionals. (1,2) As a subspecialty of paediatric medicine, the craft of the neonatologist encompasses caring for neonates delivered both full term and prematurely; who are well and unwell, during their first 28 days of life or until 42 weeks corrected gestational age[1]. (3) In addition to this, neonatal care also includes follow-up and monitoring of neonatal patients who have been affected from adversity during delivery and in their first few weeks of life, transitioning some to other paediatric services. In keeping with international reference, the World Health Organisation (WHO) has defined a term neonate as a newborn delivered after 37

[1] A neonate is a newborn infant in the first 28days of life. A full-term neonate is an infant delivered from 37 gestational weeks post conception.

completed weeks of gestation, i.e. from the mother's first date of her last menstrual period. Any infant delivered prior to this gestational age is categorized as preterm. Standard definitions of the varying subcategories of neonatal gestation at delivery exists for extremely preterm, late preterm, early term, full term and post term neonate. (Figure 1.0) The degree of infant maturity impacts on infant severity of illness and need to special or intensive care support, with extremely premature infants requiring full and prolonged; initially intensive and further dependent care in a neonatal unit.

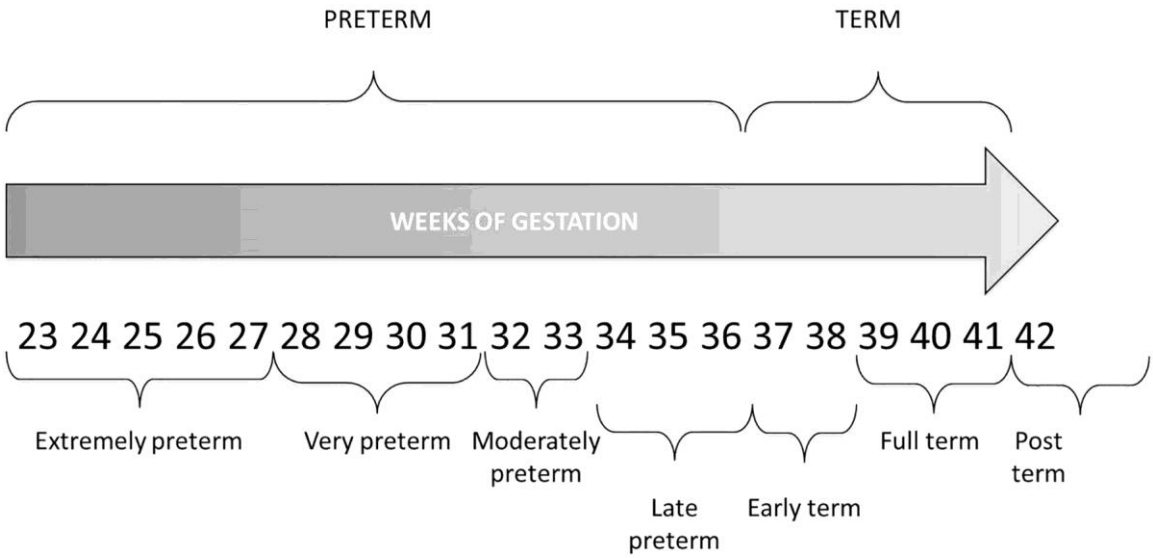

Figure 1.0

NEWBORN INFANT

Preterm: Less than 37 completed weeks of gestation
Term: 39 to 41 completed weeks of gestation
Post-term: 42 completed weeks of gestation
Low birth weight (LBW): Less than 2500 gm
Very low birth weight (VLBW): Less than 1500 gm
Extremely low birth weight (ELBW): Less than 1000 gm

MORTALITY

Maternal mortality ratio: The number of maternal deaths (during pregnancy and within 42 days post- partum) per 100,000 live births
Stillbirth: Variable definitions. In the United States, fetal death (no signs of life) less than 20 weeks' gestation. For international comparison, WHO recommends defining stillbirth rate as fetal deaths greater than 1000 g or more than 28 completed weeks per 1000 total births.
Perinatal mortality rate (PMR): Stillbirths plus early neonatal deaths (up to 6 completed days of life) per 1000 live and stillbirths (adjusted as in the preceding for international comparisons).
Neonatal mortality rate (NMR): Deaths at less than 28 days per 1000 live births.
Postneonatal mortality rate: Deaths from 28 days until 1 year per 1000 live births.
Infant mortality rate: Deaths in the first year of life per 1000 live births

Figure 1.1 : Definitions of the neonatal age, weight and mortality categories (4)

Overall, there has been significant progress in reducing mortality and morbidity in key groups and age ranges in neonatology with a shift over the decade in optimizing treatment for the extremely premature infants, the hypoxic infant requiring therapeutic hypothermia and the haemodynamically unstable neonates i.e. pulmonary hypertension of the newborn. However, increasing resuscitation of extremely premature infants at the border of viability and active management of increasingly complex congenital anomalies means that overall mortality rates remain

largely static. Preterm birth is still the leading cause of death in children under the age of 5 years globally. (5) The transition from life in the uterine environment to the environment outside the mother's womb is usually an immediate complete physiological transition for the full-term neonate who has reached anatomical and physiological maturity, as the infant establishes breathing, cardiovascular autonomy, independent nutrition and waste clearance. Approximately, 1 in 10 of these neonates may need some form of assistance as they transition to independent life ,whilst 1 in 100 full term infants will require major resuscitative measures for a variety of reasons (maternal, feto-maternal or fetal effects of pregnancy or delivery).(6)

For the premature neonate (Figure 1.1), who has not developed the capacity or systems for the required rapid changes during, after and beyond delivery, resuscitation and stabilisation is more challenging. The risks that the premature neonates encounter increase with lower gestational ages, and the care and treatment that they require usually becomes more intensive and more demanding. Extreme prematurity at the limits of intensive care feasibility is challenging because of differing definitions of the threshold of viability in different jurisdictions. International networks and databases from developed countries have identified extra-uterine viability to as early as 23 weeks gestation, however this is at a cost of extremely low survival rates, and morbidity including severe physical and cognitive disability in this fragile group. The Vermont–Oxford Network have reported that 30%–50% of neonates born at less than 25 weeks' gestation will have moderate to severe disability, including blindness, deafness, developmental delay and/or cerebral palsy (6). In Ireland, survival is reported in neonates delivered as early as 23 weeks of gestation when cared for in a tertiary level neonatal intensive care unit. (2,4,7)

Transfer of care is required to level 3 units for all infants under 28 weeks corrected gestational age, in keeping with international guidelines.(8)

1.1 The Neonate ï System of Care

High standard specialist neonatal care involves services that include neonatal special care, high-dependency care, neonatal intensive care, neonatal surgical care and neonatal transport. The neonatal care provided by hospitals with a maternity unit may differ according to location, population, local and national policy, as well as the workload and skill mix that tailor the levels of care available. The quality of neonatal services can also be affected by socio-economic and political influence, education and advances in research and development. Overall, the aim of neonatal services is the provision of safety, quality, accessible, appropriate and relatively cost-effective care to newborn patients. In Ireland, the levels of neonatal service provision nationally are currently three tiered; level 1 (local) neonatal unit, level 2 (regional) unit and Level 3 (tertiary) units. The levels of care provided by these units are patently described in the National Clinical Programme for Paediatrics & Neonatology: Model of care for Neonatal Services in Ireland, 2015. Currently, there are nineteen neonatal units in Ireland, which are classified according to number of births. (1)

1.1.1 Level 1 Neonatal Unit

These units provide maternity services that also include personnel skilled in effective resuscitation of low risk neonates after delivery, when required. If a higher level of care for the neonate is anticipated prior to delivery, in-utero transfer of the mother to a higher-level unit should be arranged. Special care is usually provided for neonates

who are delivered at and more than 32 weeks of gestation that are stable and do not require any form of high dependency or intensive care. Neonates delivered at less than 32 weeks of gestation will usually need to be transferred to higher level units and term neonates who become unwell after birth in level one unit will usually require transfer to a regional or tertiary unit by a neonatal transport team.

1.1.2 Level 2 Neonatal Units

These units will care for neonates who are born at 28 completed weeks of gestation and above. The care of infants in these units is provided by neonatologists and neonatal nurses and short term invasive ventilatory support, non-invasive ventilator support, parenteral nutrition, paediatric radiology services and neurodevelopmental follow up can be provided. In addition to this, paediatric health and social care professionals (allied health professionals: dietetics, pharmacy, physiotherapy, occupational therapy, speech and language therapy and social work) may be available. Preterm infants born at or less than 28 completed weeks of gestation will require a higher level of care and therefore should be transferred to a tertiary unit when possible. Higher level of intensive care is sometimes needed for term and preterm neonates who become critically unwell and are transferred by a dedicated neonatal transport team.

1.1.3 The Level 3 Tertiary Neonatal Unit

These units provide highly specialized care to critically ill term and preterm neonates. To sustain this expertise these units are typically the centre of maternity and neonatal referrals and therefore will usually provide care to more than 100 very low

birth weight neonates (≤ 1500 grams) and/or more than 100 infants who require assisted ventilatory support. Neonatal intensive care is provided by a full tier of neonatologists, skilled neonatal nurses, clinical and research fellows and resident physicians who are training in paediatrics and neonatology. Level 3 units also have a more enhanced health and social care professional teams with special interest in neonatology and are often linked with active fetal medicine departments. Occasionally, the neonates in level 3 units will require specialist surgical treatment in other level 3 hospitals e.g. cardiothoracic or paediatric surgery which also involve inputs from a neonatal transport service.

Currently there are 11 local units, 4 regional units and 4 tertiary units that provide nationally a total of 300 neonatal cots: 193 special care, 52 high dependency care and 55 intensive care. The integration of provision of the multi-level neonatal services is fundamental to the delivery of high-quality care for neonates in need of specialist neonatal service. International best practice is the centralization to tertiary or quaternary care of extreme prematurity, surgical neonates, high risk neonatal patients needing intensive haemodynamic support and also neonates requiring therapeutic hypothermia. In-utero transfers are safer than postnatal transfer. Nevertheless, the unpredictable nature of infant deliveries in general makes a neonatal transport service vital.

1.2 Neonatal Transport

Evidence from previous studies shows that early in-utero transfers of high-risk obstetric patients to tertiary centres reduces morbidity and mortality for mothers and infants. However, births of high-risk neonates continue to occur in non-tertiary

centres, these babies are often referred to as ‘out-born infants’ and potentially experience higher morbidity and mortality. A logistic regression analysis study of 3,769 out-born and inborn neonates born at ¢32 weeks of gestation reported that out-born infants had a higher risk of death, severe intraventricular hemorrhage (IVH), patent ductus arteriosus, respiratory distress syndrome (RDS), and nosocomial infections, even after adjusting for perinatal risks and illness severity. (9,10) Fetal scans help to identify patients requiring early in-utero transfer of the mother or fetus to tertiary centres, especially those term neonates with an antenatal diagnosis of a major congenital anomaly, including surgical abdominal defects and complex or critical cardiac conditions needing care in a tertiary unit. However, it can be difficult to predict whether delivery will happen where and as planned. The transport of high-risk neonates plays an essential role in facilitating expert and specialist care for preterm and/or critically unwell infants. This has been recognised since the 1970s and the start of regionalisation of peri-natal and neonatal specialist centres was when neonatal transport became essential. This led to early development of specialist transport equipment including incubators with a built-in ventilator and monitoring. (2) Today, neonatal transport services provide out-reach neonatal intensive care and pretransfer stabilisation in addition to initiation of specialist care during mobilization to tertiary centres.

National Neonatal Transport Programme (NNTP)

There is widespread recognition of the necessity for neonatal transfers as regionalization of paediatric and neonatal services increases. In Ireland, the National Neonatal Transport Programme (NNTP) is an established organisations that transfers neonatal patients between primary, secondary and tertiary neonatal and

paediatric units nationally and internationally. Established since March 2001, this organisation provides critical and intensive care, initiates surgical and urgent cardiac care and integrates the link between the referring units and tertiary or quaternary centres. This organisation maintains multi-specialty connections in all relevant critical care units.(11) Currently, the NNTP is a national service operating out of the 3 tertiary neonatal centres of Dublin (National Maternity Hospital Holles Street, the Rotunda Hospital and the Coombe Women and Infants University Hospital). (Table 1.0)

Level	Hospital	Level	Hospital
3	National Maternity Hospital, Holles Street, Dublin	1	Wexford
3	Rotunda Hospital, Dublin	1	Portlaoise
3	Coombe Women and Infants University Hospital	1	Cavan
3	Cork University Maternity Hospital, County Cork	1	Kilkenny
2	Limerick Maternity Hospital	1	Letterkenny
2	Drogheda	1	Castlebar
2	Galway	1	Sligo
2	Mullingar	1	Tralee
2	Waterford	1	Clonmel
		1	Ballinasloe

Table 1.0: Neonatal Units in Ireland (1)

The NNTP transport team staff are employees of these 3 centres. Any transport organisation requires governance, expertise, research and education. NNTP has developed each role since it evolved from being a 9am-5pm service to a 24-hour service in December 2013. This high acuity service transfers approximately 600

neonates per annum for each of the last 5 years. (1,11) This 24-hour service is provided by consultant neonatologists, specialist transport consultants, a

skilled transport coordinator, neonatal transport nurses who are also experienced neonatal intensive care nurses, junior paediatric trainee physicians, neonatology clinical fellows, neonatal ambulance drivers and clinical engineering. The NNTP works closely with the National Ambulance Service (NAS) and operates in conjunction with NAS paramedic and ambulance drivers for the mobilization in any retrievals.

For the most part, neonatal transfers take place via ground ambulance. Infrequently, time critical and distance of referral from accepting centres will necessitate the need for transfers by air. The Irish Air Corps facilitates air ambulance for the NNTP through a service level agreement with the Health Service Executive (HSE). The NNTP air transport module and pathway of air ambulance referral is well established. Approximately 10-15% of critical neonatal air transfers occur through air ambulance utilizing military aircrafts (rotary wing i.e. helicopter, fixed wing maritime aircraft and the government Lear jet) or with the cooperation of the Irish Coast Guard Services.

1.2.1 Transport of the neonatal patient

The ideal transport of a neonatal patient involves meeting the physiological, psychological and social needs of the infant and their families during their separation due to critical illness, one of the most stressful times of a mother and her newborn's lives together. In a well-organized and established transport service detailed attention is given to transport equipment, transport team competency and education, communication with families and, importantly, the neonate's stability, comfort and

safety. All efforts are made to ensure that the neonatal patient is physically stable prior to transfer from the referring centre.

A typical NNTP transport team in a neonatal transport shift will comprise of:

- a neonatal transport physician (if this is a junior neonatal trainee either a consultant neonatologist or neonatal specialty fellow with an interest in neonatal transport medicine may accompany the team)
- a neonatal transport nurse (an experienced neonatal tertiary level intensive care nurse)
- an NAS ambulance driver assigned with the team.

Patient clinical information is communicated to the retrieval team, the accepting neonatologist and the receiving centre by the referring unit prior to transfer. Effective communication is the cornerstone for successful and safe patient transfer.

1.2.2 Neonatal Transport Equipment

The transport equipment centres around a neonatal incubator affixed to a metal frame/ trolley on wheels. Included on the transport incubator trolley is equipment that fulfills the requirements for a ‘mobile neonatal intensive care unit’, ideally in its most uncomplicated, compacted but practical form. The primary appliances attached to the transport incubator trolley are the ventilator, battery operated suction pump, intravenous infusion pumps, patient vital signs monitor, gas tanks (air, oxygen and nitric oxide) and an active cooling device for therapeutic hypothermia where indicated. (Figure 1.2) Emergency equipment in the event of sudden patient deterioration is always available in the ambulance; e.g. airway equipment, positive pressure ventilation masks and connections and cardiac defibrillation device. All

loose equipment, including procedural apparatus and medications are kept in specially designed transport luggage.

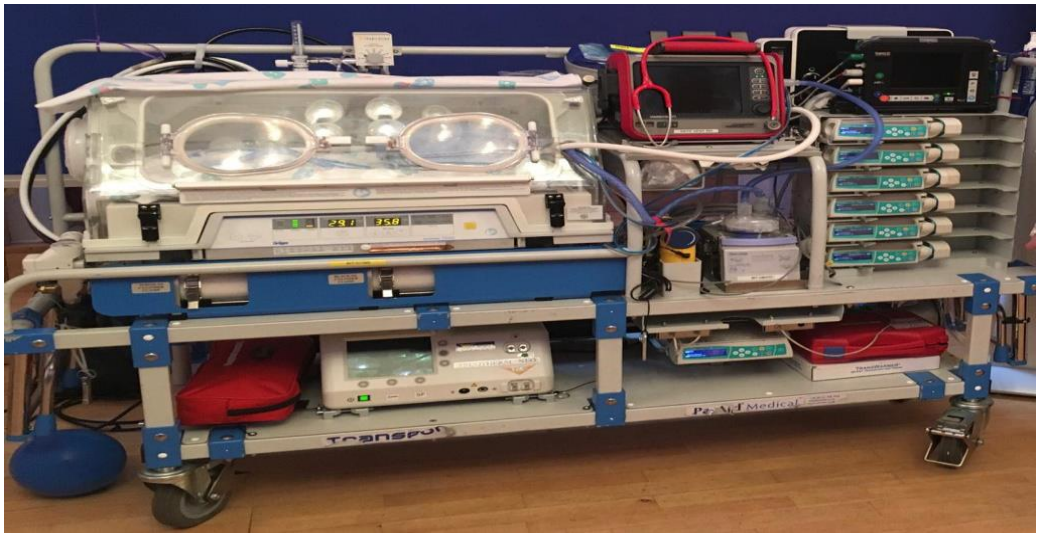

Figure 1.2: NNTP Transport Incubator and Transport Equipment *(Courtesy of Ms. Anne Bowden; NNTP Coordinator, Dublin Ireland)* (11)

The neonatal transport incubator is made of double walled durable, impact resistant polycarbonate that forms an entirely enclosed containment system for the neonate. Access to transfer the patient in and out of the incubator is through 2 side doors, if any patient contact is needed during inter hospital transfer. A series of ports are available to provide access while preventing heat loss. A thermal mattress can be sited for neonates who are at particular risk of adverse hypothermia, such as premature newborns. In most cases, the incubator ambient temperature can be adjusted to optimise the patient's body temperature. Neonatal patients are secured in the transport incubator with adjustable straps prior to mobilization. Loading and unloading the transport incubator trolley in the ground ambulance requires skill, coordination and understanding of effective and secure locking mechanism in the

ambulance cabin. Staff are extremely careful that incubators are securely locked prior to any vehicle movement.

1.2.3 Stressors during neonatal transport

NNTP transfers encompass a range of infants from premature infants delivered at 23 completed weeks of gestation and weighing an approximate minimum of 500 grams; to 6 weeks of age, i.e. when an infant's age reaches the equivalent of the full 40 weeks of gestation + a further 6 weeks after that. The service provided is limited by a maximum weight for optimal equipment function. The maximum weight for the patient is usually is 5.5 kilograms. The wide age ranges and ten-fold differences in weights provide unique challenges to staff providing neonatal care during transport. Premature infants in particular are particularly vulnerable as they are designed for the in-utero environment. They often develop apnoeas and cardiorespiratory instability with handling or illness. Stressors imposed on term neonates being transferred may affect physiological stability but more vulnerable premature infants may experience greater difficulty. Transport potentially exposes infants to significant stress including handling, thermoregulatory challenges, noise and vibration. These stressors may be exacerbated if transfers involves stress from altitude i.e. air transfers in addition to air expansion and hypoxia. (10,12)

We can learn from what staff have reported when considering a neonatal patient's experience during transport. Furthermore, the neonatal patient is not the only one affected by the transport environment. The effects of transport also result in discomfort for transport staff, who have reported issues such as motion sickness, irritability, hypoxia and headaches. Therefore, as babies are particularly vulnerable, it is important that the team understand the physiological stressors of neonatal

ground transport and altitude physiology in order to avoid or alleviate problems that could arise. Reducing the impact of stressors has remained a challenge for transport teams, equipment designers and engineers.

Background 2: Noise

Noise is defined as an unpleasant and unwanted sound. It is a well-recognized pollutant studied extensively in occupational health and environmental sectors internationally. Noise, when sensed as unpleasant, can lead to either disturbance or habituation over time. Habituation or acclimatization to noise exposure tends to be ignored and underestimated by human behaviour and attitudes, although it remains a major environmental health risk. When the exposure to noise is becomes repetitive and exceeds certain safe levels, negative health outcomes are observed. The health effects from noise exposure were recognised in the occupational and public health settings in the 1960's. Today, research in the study of social, occupational and environmental noise exposures continues to expand and has generated scientific evidence that supports health and environmental policies of noise control. (13,14)

1.3 Basic Concepts of Acoustics: Sound and noise

The ability to grasp the concept of noise requires an understanding of the physics of sound and sound propagation. A sound wave is a longitudinal or transverse wave, and the movements of particles involved in the sound transmission are parallel to the direction of energy being transferred. A sound wave is an air pressure disturbance that results from vibration of particles from solid, liquid or gas state that is audible to

the human listener at approximate hearing range of 20-20,000 Hz (Figure 1.3). The generation of audible sound requires vibratory disturbances and an elastic medium. Sound is propagated when the vibration source is placed in an elastic medium and the phenomenon of compression and rarefaction occurs. The outward propagation of compression and rarefaction waves travel at the speed of sound which is affected by the environmental elasticity and medium density. At room temperature of 20 degrees Celsius, sound travels at approximately 348meters/second (m/s).

In acoustic science, noise is an aperiodic sound that does not show a pattern. It remains an unpleasant stimulus to the perceived ear, although the threshold for hearing can potentially vary among individuals. Noise measurements, involves calculation of intensity and pressure levels.

$$\text{Noise Intensity Level in dB} = 10 \log_{10} I_x / I_r$$

As the range of intensities between silence and painful noise is about 10^{12} or 1,000,000,000,000 (a trillion times) larger than the threshold level sound, a logarithmic scale is needed to simplify calculations; particularly when considering the effects of noise reduction. Therefore, noise that is measured as sound pressure levels (SPL) quantified in units of decibel (dB) are logarithmic scales of 10 i.e. 'Deci' meaning 10. Therefore, a doubling in loudness corresponds to an increase in 10dB whether it is from 10dB to 20dB or from 100dB to 110dB. The weakest audible sound is roughly 0 dB in intensity level and a whispered voice is 1000 times more intense or 30 dB higher. A loud rock concert, close to the threshold of pain might have an intensity ratio of 10^{12} , or 120 dB. (Figure 1.3, Table 1.1).

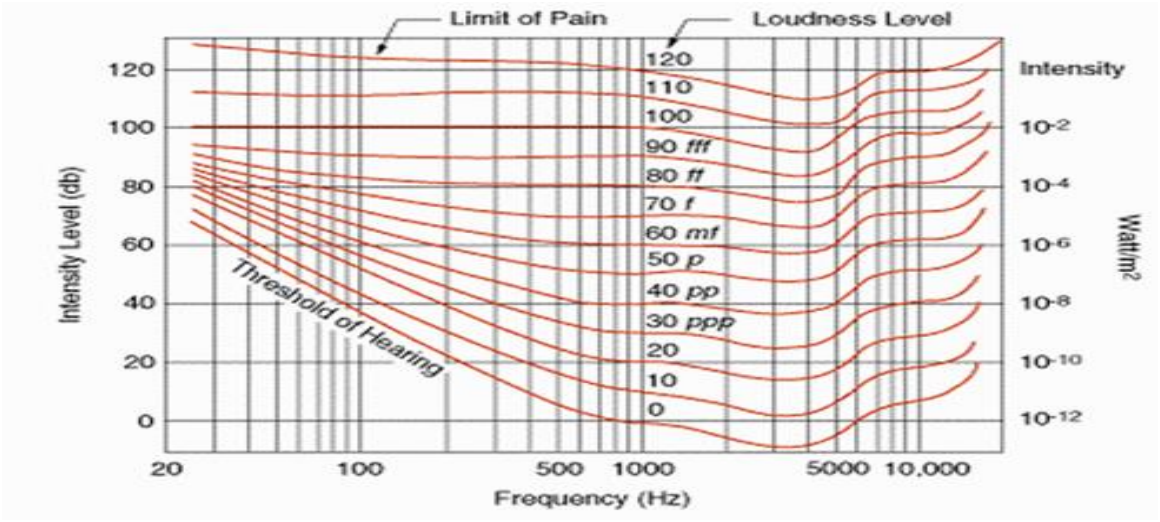

Figure 1.3: Thresholds of human hearing

Sound level **dB SPL**	**Intensity ratio** **I / I_r**	**Example**
140	10^{14}	Gunshot at close range
120	10^{12}	Loud rock show
100	10^{10}	Shouting at close range
80	10^{8}	Busy city street
70	10^{7}	Normal conversation
50	10^{5}	Quiet conversation
30	10^{3}	Soft whisper
20	10 2	In the woods at night
6.5	4.5	Mean absolute threshold at 1 kHz
0	1	Reference level

Table 1.1: examples of sound in units of decibel and sound intensity

The propagation of sound differs with time of the day and difference in temperature gradient. Sound waves travel faster in higher temperature and slower in lower temperature. However, when a temperature gradient exist, sound waves are refracted. Sound waves are louder at night due to change in the direction of sound refraction caused by the reversal of temperature gradient where sound waves bend towards the ground. The opposite phenomenon occurs during the day. (15)

The relevant quantification of noise in environmental and occupational health sector is called Sound Pressure Level (SPL), represented in units called decibel (dB). The field of study of different aspects of sound and noise in acoustic science and the physics of noise is potentially immense and complex. Therefore, as discussed above, one has to be mindful that the quantification of SPL at any given time is through a logarithmic scale and not simple subtraction or addition.

1.3.1 Basic Concepts of Acoustics: The relation between sound and vibration

The study of mechanical vibration is closely related with that of sound. The production of sound and noise cannot exist without the vibration of particles in a frequency range that the listener can appreciate. Vibration is the term used to describe alternating motion of a mass or body with respect to a reference point. Measurement of vibration is in terms of displacement, velocity and acceleration jerks. In relation to noise and sound, the motion may involve tiny air particles that produce sound when the rate of vibration is in the audible frequency range (20 to 20,000 Hz), or it may involve, wholly or in part, structures found in machinery, bridges, or aircraft. Vibration is therefore a source of noise, annoyance and even discomfort. Thus,

during neonatal transports vibration of the ambulance vehicle (either during ground transport and in the helicopter during air transfers) can be transmitted to the incubator structure and hence exposed to the patient, is another cause of stress. It is also important to note for this work that it additionally acts to amplify noise levels and hence noise exposure. (16,17)

1.4 Noise as a Health Pollutant

The WHO has considered noise to be a community health problem since before the 1980's, and a taskforce and guidelines on community noise were developed in 1992. Noise is one of the most prevalent health risks addressed by the occupational and public health sectors. Occupational noise is the most frequently studied type of noise exposure, with research extending to social and environmental noise. (14,18) In the occupational health setting, regulatory limits of noise exposure have been set at 85 dBA in developed; and 90 dBA in many developing countries when exposure is anticipated for an 8-hour day. Exposure to noise at an A-weighted sound level of 70 dB or less is not likely to cause significant hearing damage, and <85 dBA level is considered acceptable. As a practical compromise a limit of 90 dBA for 8-hours exposure every working day has been in effect in the USA for some years. It is recognized that this level of exposure over a long period will lead to measurable hearing loss in some susceptible people, and because of this an 85 dBA limit may be safer. (17) As a major public health problem, studies have shown that noise in these environments have been linked to a range of auditory and an even wider range of non-auditory health effects. Basner et al in 2014 summarised knowledge and research related to noise exposure and reviewed auditory effects (noise induced

hearing loss) and non-auditory effects health effects such as annoyance, sleep disturbance, cardiovascular effects and cognitive performance. (14)

1.4.1 Auditory effects of noise

Acoustic trauma to the cochlea has been studied for more than half a century. Research into the anatomical and physiological components of inner ear damage has been extensive. Hearing damage from excessive noise exposure, i.e. noise induced hearing loss (NIHL), is a cumulative process. On the other hand, individuals are not equally susceptible to NIHL. While high intensity impulsive sounds (e.g. explosion or gunfire) cause direct mechanical damage to the cochlea, SPL at lower intensity (e.g. an industrial setting or airport runaway) with repeated exposure induces a metabolic change in these sensory cells, which can then either recover or trigger cell apoptosis. Any noise exposure of more than 130 dB damages the organ of Corti and its supporting structures e.g. Reisner's tectorial membrane, which can result in degeneration of hair cells. Animal studies have also found mixing of the perilymph and endolymph in the organ of Corti causes free radical release, and damages the sterocilia responsible for the mechanical transduction of sounds. (19) NIHL damage to the cochlea and auditory pathway is complex and relatively prevalent, but preventable, and is influenced by both environmental and genetic factors. (20)

Hearing loss from noise exposure can be temporary or permanent. Acute exposure to a SPL level of approximately 100 dBA, causes a subsequent increase in hearing threshold immediately following exposure. This is a "temporary threshold shift" that undergoes gradual recovery of hearing ability. However, repetition of this noise

exposure over extended periods ultimately leads to permanent hearing loss with incomplete recovery i.e. permanent threshold shift. (17)

Although studies have shown that mild damage to sterocilia and the vestibular sense organs can recover, the cochlear hair cells are fixed in number in humans and mammals, and neither recover nor regenerate. There is a surplus of cochlear hair cells, however cumulative exposure to noise can lead to cumulative redundancy of cochlear hair cells, and NIHL may only surface in later life.

Although patterns of environmental noise propagation and exposure lead to both reversible changes and irreversible noise induced hearing loss (NIHL), there are also other recognized auditory effects from excessive noise exposure including changes in hearing threshold shifts and tinnitus, which causes considerable morbidity.

1.4.2 Non-auditory effects of noise

Peterson et al mentioned the work or previous colleagues that summarized the knowledge on non-auditory effects of noise exposure. Very high levels (120 to 150 dB), at certain resonant frequencies of the body structure, can produce noticeable symptomatic reactions. Even moderate noise levels produce temporary changes in the size of some blood vessels, but it is not clear that these effects eventually produce permanent changes. The production of stress and fatigue by noise exposure is difficult to verify in a meaningful way.(17)

There is also a systematic description of the evidence of environmental and occupational noise on health. (21) Studies have described noise impacting on sleep, cognitive performance, heart rate, blood pressure and the risk of developing mental illness. As a result, noise pollution can potentially lead to an increased physiological

and hormonal effort for adaptation and a chronic sympathetic arousal state as a consequence. (22)(21)

“*The auditory system and physiological responses to sound are inseparably connected. Therefore, all of the effects of noise on the body mediated by the ears are "auditory" effects. More precisely, the effects of sound on the body through vibration of structures other than those of the auditory system are "non-auditory" or "extra-auditory."*(23)

1.4.3 Effects of noise in adults and hospital in-patients

The impact of noise on health is being increasingly recognized beyond its effects on the auditory system. The physiological and psychological effects of increased noise levels the have been studied with an aim to increase public awareness of the significant harm from noise exposure. (22) Extensive studies of adult populations experiencing environmental, occupational and hospital noise (experienced by patients) have shown that it leads to a heterogeneous group of effects. (23) Healthy subject volunteers were studied and found that the impact of noise quality affected heart rate variability. (24) Evidence that these responses to noise are mediated by increased level of stress hormones, e.g. catecholamines, that are involved in the fight, fright, flight response have also been demonstrated. Biochemical studies of the endocrine effects in adults of increase exposure to both acute and chronically elevated noise levels in different settings found elevated cortisol and catecholamine levels in patients when ,exposed to the noise stimuli. (25,26)

In the hospital setting the sickest patients are generally located in the intensive care unit, and these are critically ill and subject to increased physiological instability. The

World Health Organisation (WHO) recommend that average sound levels in hospitals should not exceed 35dBA through the day, and the maximum peak SPL overnight is 40 dBA. (As described in a previous section, that noise is [perceived to be louder at night due to changes in atmospheric temperature gradients). (15,27) A study of noise levels in 5 ICUs in the UK revealed that the average SPL was always above 45dBA, and more than half of the SPL recordings were 52-60 dBA. Patients in the ICU may be sleep deprived, or confused (ICU related delirium). They are exposed to multisource noise generation from the ventilator apparatus, equipment handling (dropping, opening or closing of doors), telephones and staff conversation.(28) Each of these noise events have been shown to trigger a sympathetic nervous system response, increasing cardiac workload and adversely affecting respiratory function. A typical response to these events is to increase patient sedation, haemodynamic and respiratory settings, rather than address the underlying cause. (29)

In summary, there is good evidence that noise not only causes annoyance, sleep disturbance, and reduction in quality of life, but may also contribute to arterial hypertension and cardiovascular morbidity. The rationale for this is supported by both experimental laboratory and observational field studies, as well as a number of epidemiological studies. Noise-induced sleep disturbance constitutes an important mechanism on the pathway from chronic noise exposure to the development of adverse health effects. The evidence strongly supports initiatives aimed at reducing environmental noise exposure levels to promote cardiovascular and public health.(30) Recent studies indicate that people's attitude to and awareness of air-craft noise in particular has changed over the years. Noise mitigation policies have to consider the medical implications of environmental noise exposure. Noise mitigation

strategies to improve public health include noise reduction at the source, active noise control (e.g. noise- optimized take-off and approach procedures), optimized traffic operations (including traffic curfews), better infrastructural planning, better sound insulation in situations where other options are not feasible, and safe, enforced maximal noise limits.

1.5 Noise and the Neonate

1.5.1 Early development of the auditory system

The human auditory system develops from the first brachial groove. Morphologically this system divided into 3 major components: eternal ear (pinna and external auditory canal), middle ear (tympanic membrane and ossicles) and Inner ear (semi-circular canal, vestibular canal and the cochlea). The Cochlea is the main unit that consists of auditory hair cells responsible in the transmission of sounds in the form of neuronal signals to the brain. (Figure 1.4)

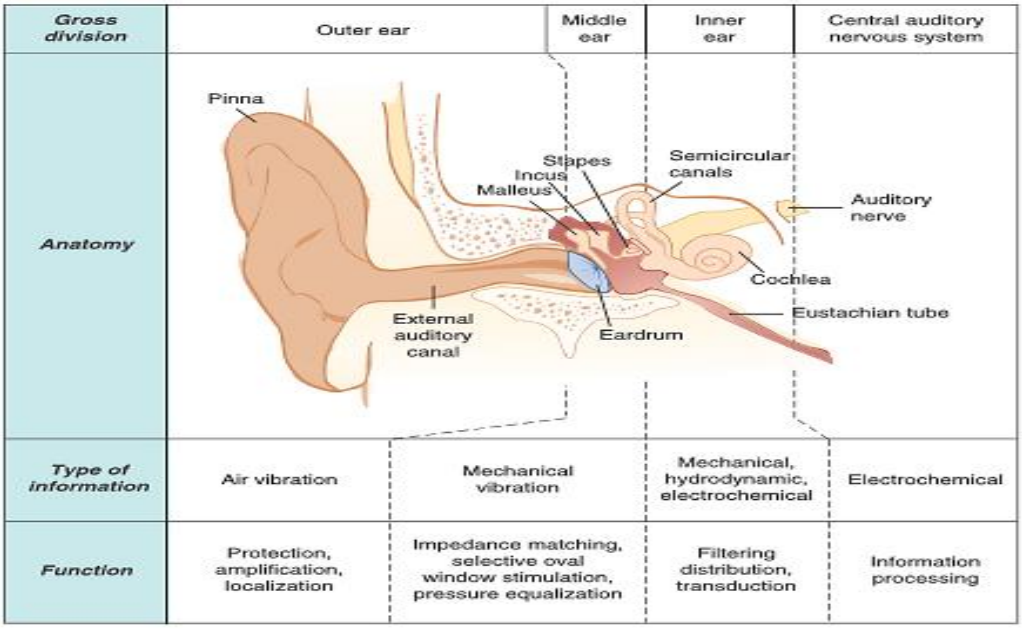

Figure 1.4: Cross-section of the human ear and major functions of each division *(Adapted from Yost W: Fundamentals of hearing, New York, 1994, Academic Press, p 62.)*(31)

The external ear is identifiable from 6 weeks of completed gestation in utero, and the pinna has an adult shape from 8 completed weeks of gestation. The external ear is fully formed and functional at birth, but will continue to mature into adult life. In the middle ear, the ossicles are visible from 5 weeks of gestation and continue to grow from 22-40 weeks of gestation. The tympanic membrane (ear drum) reaches its adult shape at 28 weeks of gestation and the cochlear neuronal development reaches maturity at 28 weeks of gestation, along with other sensory systems e.g. retina, spinal cord, olfactory and limbic system. Maturation of the cochlear hair cells resumes in the third trimester and the synaptic maturation along with central non auditory processing continues post-partum.

The development of the ear is designed to happen while the child is in utero, surrounded by amniotic fluid. The protective fluid filled environment in utero alters sound conduction and much of this reaches the middle and inner ear structures

through bone conduction i.e. the skull, which provides a similar cochlear response to that seen in air conduction. The first fetal motor response to sound has been observed from 26 weeks of gestation with increased response to increasing gestational age and changes in fetal heart rate and behaviour have been seen as early as 25 weeks of gestation. Behavioural responses to sound has been studied and observed in neonates as young as 28 weeks of gestation. (31,32) Therefore it is important to consider the impact of noise exposure towards the neonate especially those born premature e.g. 24 weeks of gestation who will inevitably undergo adversity with conditions related to inflammation and release of oxygen free radicals as it has been studied of its participation in outer hair cell death after noise exposure and lead to sensorineural hearing loss; in animal studies. (33)

1.5.2 Noise in The NICU and the vulnerable neonate

The NICU environment is adapted for neonates but far from natural, and exposes the patient to frequent critical periods that can potentially interfere with the normal sensory development of the auditory system. Critically unwell infants need to be carefully managed in the neonatal intensive care unit while minimising aggravating factors that can adversely affect their physiological stability. The most vulnerable patient group exposed to the pervasive effects of noise in the NICU are the premature infants, and then to a lesser extent those term neonates who are critically unwell. These patients are treated in Neonatal Intensive Care Units (NICU), which aspires to nurture each patient by simulating the in-utero environment. However, the nature of an intensive care unit is that the amount of activity produces high levels of background noise with additional intermittent high intensity peaks during the working day and even during the evening and night shifts. Noise from equipment (ventilator,

suctioning), staff (loud speech), tapping of the incubator and other common activities, including opening and closing doors, alarms from monitors and other electrical equipment all contribute to high noise levels. (Figure 1.5) Neonatal Intensive Care Units (NICU) aim to provide quiet nurturing environments for infant development, but studies of noise levels in NICU have shown sound levels between 7 and 120dBA. (Figure 1.5) Previous studies on ambient noise levels in NICU, incubator noise levels and observational studies on neonatal response to noise have observed that overall noise levels exceed international recommendations. (28,34,35)

The global community of neonatal intensive care units currently targets international recommendation established since 4 decades ago that currently SPL exposure should not exceed 45dBA in the neonatal intensive care units. (36) More recent recommendations on newborn ICU design advised that combination of background SPL and operational sounds should not exceed a total cumulative sound energy of 45 dBA, SPL at 10 % (L10) of the day should not exceed 50 dBA; e.g. during handover times or unit rounds; and transient higher intensity sounds or peak sound should remain below 65 dBA. (37)

TABLE. Noise levels

Quality	Peak Intensity, dBA	Example[2]	Inside Incubator[41]	Effect
Just audible	10	Heartbeat		
Very quiet	20–30	Whisper		<35 dBA desired for sleep
Quiet	40	Average home		
	50	Light traffic	Background	<50 dBA desired for work
Moderately loud	60	Normal conversation	Motor on and off	
	70	Vacuum cleaner	Bubbling in ventilator tubing	Annoyance
Loud	80	Heavy traffic Telephone ringing	Tapping incubator with fingers	
	90	Pneumatic drill	Closing the metal cabinet doors under the incubator	Hearing loss with persistent exposure
Very loud	100	Power mower	Closing solid plastic porthole	
Uncomfortably loud	120	Boom box in car[44]	Dropping the head of the mattress	Pain and distress
	140	Jet plane 30 m overhead		

Figure 1.5: Examples of noise levels in the environment that can be experienced in the incubator(36)

Sound exposure is essential for sensory stimulation of the developing auditory system in the developing fetus, preterm and term neonate. Previous studies of noise levels in various NICUs have shown that neonatal patients are exposed to much higher acoustic noise levels at varying intensity, duration and intervals. There has been extensive research of sound exposure, programs have been developed to improve care and practice within neonatology over 30-40 years, particularly in patient specific individual care e.g. NIDCAP. (38) However, evidence in the literature continues to question how the exposure to sound during early auditory development impacts on the neonate's ability to process sound centrally. On the other hand, a lack of exposure to sound could also impact on the anatomical and physiological function and development of the auditory pathway. (39) The importance of safe sound levels in the fetus and the preterm neonate in the NICU have been studied. The fetus has the developmental advantage of buffering external noise by the maternal abdominal tissue, uterine lining and the surrounding amniotic fluid. Sound

energy travels to the fetus through bone conduction. High frequency sounds are attenuated three times more efficiently (20-30 dB attenuation) than low frequency sounds (5 decibel attenuation). (32,40). On the other hand, the preterm neonate is exposed to critical periods of adversity in the neonatal unit that not just affects auditory development, but also instigates physiological instability. The effects such as the startle response following a loud noise or an unpleasant intervention can trigger changes in physiological parameters such as heart rate, blood pressure and oxygen saturation level have been reviewed in premature neonates in the NICU. An increase in respiratory rate with decreased oxygen saturations have been observed in neonates exposed to high noise levels. The effects of noise on sleep, neurodevelopmental development and hearing were also recognized in several studies with varying results. (41) An interesting randomized controlled trial of very low birth weight neonates in NICU concluded that infants allocated noise protection intervention (ear plugs) had better scores on the Bayley Mental Development index compared with controls ($p < 0.05$).(42)

In all age groups, prolonged continuous noise of 85–90 dBA can lead to a progressive loss of hearing with reduced hearing sensitivity, and irreversible NIHL affects 120 million people worldwide. Term newborn and premature infants are particularly vulnerable as they cannot identify or discriminate important sounds required for normal development if background noise levels exceed 60 dB. Neonatal Intensive Care Units (NICU) aim to provide quiet nurturing environments for infant development, but studies of noise levels in NICU have shown SPL levels that exceed international recommendation for the fetus, neonate, young infant and even in other community settings in the adult cohort.

A combination of noise control, exposure to meaningful sounds and the protection of sleep cycles are all vital for healthy auditory development. (39)

1.5.3 Noise during neonatal transport

In-utero, sound is attenuated by maternal abdominal tissue and the uterine lining, which reduces adverse noise exposure. This is not the case in the extra-uterine environment, as although the recommended safe environmental SPL in NICU should not exceed 45 dB, in reality SPLs range between 50-90dBA, and peak as high as 105dbA. (36,43)Studies have demonstrated that increased noise levels in the NICU affects the neonatal auditory system function and physiology. (41,44) However, the potential for harmful noise exposure is even greater during neonatal transport, when standard NICU care is augmented by road, vehicular and other noise sources, particularly when travelling through metropolitan areas.(45,46) The effect of noise exposure on patients and healthcare providers during inter-hospital critical care transfers have been shown in several observational and interventional research studies. (47,48) The regionalization and networking of different kinds of neonatal units, providing different levels of care according to case-mix complexity, logically requires a neonatal transport service to allow the safe inter-hospital transfer of critically unwell (including the preterm) neonates. Inter-hospital transports to specialist centers, via ground or air ambulance, are needed for treatment and survival. Fragile neonates may require transfer with full intensive care support, which is potentially very noisy. Premature neonates undergoing transport are exposed to potential iatrogenic injury, including temperature instability, exposure to infectious agents, noise, vibration and tactile force, all of which affect the infant. Noise has additional effects – on the immaturity of the auditory system and underdeveloped

processing of auditory stimuli in the brain among premature neonates renders them vulnerable during inter-hospital transfers. (49,50)

1.6 Research in noise exposure during neonatal transport

Researchers investigated noise exposure during patient transfer as far back as four decades ago however there is still limited information available. Studies quantified noise and vibration levels during dummy transfers of ground ambulance and various medically configured aircrafts. (51,52) A study of simulated newborn transports from 2003 suggests that infants may be exposed to levels of noise up to 80dBA, which would be considered harmful to adults and mock neonatal transport scenarios of air and ground transfers from 15 years ago demonstrated excessive noise exposure. Incubators may attenuate sound pressure by approximately 6dBA, but even using liberal noise targets of 60dBA, simulated transports exceeded these levels by 20dB. (45,50) While this research was done with now outdated equipment, few other studies have looked at neonates. Although, research in adult and paediatric intensive care units is promising, little attempt has been made to reduce noise exposure during newborn transport.

1.7 Noise exposure during Neonatal Air Transfers

Transfer of neonatal patients via air typically involves a rotary wing helicopter or a fixed wing air craft, and rarely uses a commercial jumbo jet for international inter-hospital patient transport. For reasons of location and timing of criticality, neonates will occasionally warrant inter-hospital transfer via air rather than road should the facility be available. Aeromedical transfers can potentially expose the neonate to

more exaggerated external stressors of noise and vibration in addition to the effects of altitude on the already compromised physiology of the patient. Air transport exposes the patient to similar average SPL to a conventional MRI scanner, or possibly more. However, infants are not put into MRI scanners without much more extensive noise protection, including ear plugs, foam pads and headphones. (53–55)

Studies have reported that during air transport, noise levels regularly exceed 80dBA. (50) While the transport equipment in current use by the NNTP (National Newborn transport system) is more modern than that used in these studies, there is little to suggest that a significant reduction in noise exposure has been achieved. Current clinical practice is to use no sound protection for road transfer, and to apply a pair of foam mini earmuffs for air transfers. These earmuffs have noise reduction rating between 7-12 decibels.(56,57) A review on practical challenges that included mitigating noise exposure in the neonatal air transfer system in Scotland, UK; recorded SPL up to 150 dB had been experienced during takeoff and landing in the aircraft used by their team. During this period assessment and clinical decision making is usually challenging, particularly when there is turbulence during the flight, and clear communication is paramount. (58)

Sound pressure levels in an infant incubator was studied during actual flight conditions in four common medically configured aircraft. Three noise dosimeters measured time-weighted average noise exposure: one in the infant incubator and the remaining dosimeters recorded noise levels in various parts of the aircraft cabin. It was discovered that the incubator provided a 6-dBA decrease in noise exposure from levels recorded in the crew cabin. Some studies have suggested that incubators can potentially have a much higher SPL compared to the outside environment. This is likely due to the resonance of sound in a hollow cavity and the

increased propagation of sound in higher temperature i.e. the incubator. Moreover, the rigid fixations i.e. transport equipment around that incubator that vibrate during transfer may also amplify sound. The average noise level in the incubator in all aircrafts was close to 80 dB, much higher than proposed safe limits. (51)

1.8 Vibration forces during neonatal transport in and its association with noise.

Vibration(ms^{-2}); is an external physical force experienced during transport where periodic (back and forth) particle movement displaces an object (i.e. the patient) from its equilibrium. This energy comes from vibration due to movement of the transport vehicle and any equipment attached to it, even securely. Any object that vibrates above 20 Hz is potentially audible to the human hearing range. Therefore, vibrational forces during transport also amplify noise. This is frequently the case in the neonatal ground transport ambulance, where vibration is transmitted from uneven road surfaces and the vibratory movement of the equipment on the transport trolley resulting from this vehicular motion. Vibration is also associated with acceleration and deceleration movement that can affect the anatomy of the vulnerable neonate, particularly the premature infant, where intracranial vasculature is vulnerable to shear forces, with potential for intracranial haemorrhage.

Physical stressors have been studied by Bouchut et al 2011, where noise, vibration and shock (i.e.in this case, acceleration and deceleration impulses) were evaluated in ground ambulance and helicopter. Although a helicopter may have mean noise levels, whole body vibration and acceleration forces which are higher to that of

ground ambulance its total body dispersion being in air will make it have less impulsive motions i.e. shock movements compared to the ground ambulance. The ground ambulance has more dynamic effects in terms of breaking, shock and impulsive noise (e.g. intermittent sirens) than a helicopter. (45) (Table 1.2)

	Helicopter	Ground ambulance
Mean noise levels (dB)	86 ± 1	67 ±3
Whole body vibration (ms^{-2})	$0.9^{+12\%; -10\%}$	$0.35^{+40\%; -28\%}$
Acceleration ms^{-2}	$0.7^{+26\%; -20\%}$	$0.45^{+100\%; -50\%}$

Table 1.2 (45)

The most recent study in quantification of vibrational forces during paediatric transfers revealed that air transfer had higher vibration during takeoff and landing, with most vibration exposure during the airborne period consistent around 0.5 ms^{-2}. Ground ambulance transfers had higher vibration readings that ranged from 1.5-2.0 ms^{-2} . This is important as cochlear damage from vibration exposure of industrial settings >1 ms^{-2}has been found in animal studies. Studies have also discovered that vibration forces cause the inner hair cells of the cochlear to undergo oedema and degeneration. (59)

1.9 Noise reduction/ protection strategies

Neonatal transport services are not yet formally addressing the protection of the neonate undergoing transport from potentially harmful effects of noise. Modest

attempts have been made to develop of practical programs that advocate individualistic care. The literature recognising and emphasising the impact of noise on human life outlines 3 points of intervention in noise control: 1) reducing sound from the source, 2) blocking sound from the source and 3) protecting the ear from sound reception. (60,61)

1.9.1 Noise and hearing protection strategies in the NICU

Nearly all studies in NICU measuring ambient noise and noise exposure in term or preterm neonates have demonstrated average SPLs above recommended international standards.(62) Inexpensive practical measures to alleviate the noise exposure and its effect on the neonate have been outlined. These involve simple strategies of avoiding tapping or writing on incubators, closing incubator doors gently and carefully, answering bedside equipment alarms promptly, lowering conversational noise in the patient care area, restricting visitors near patients, stringent adherence to rules of 'Quiet Time in the NICU', and covering the incubators with soft, sound-attenuating fabric covers. (63,64) Measures of environmental noise control can also be incorporated into the building and equipment of the NICU by using of sound absorbing floors, walls and ceilings . (65) Many modern NICU's now have activated noise meters that give visual feedback alerting staff to conduct conversations and other noisy procedures away from the patient care area if possible. Unfortunately these have not been shown to reduce the percentage of time that those in the NICU are exposed to high SPL (63)

Other strategies may be employed in a NICU setting. Incubators that are made of double walled insulated durable polycarbon can be reverberant i.e. sound reflective

rather than sound absorptive. Foam-like sound absorbing panels can be applied externally. These panels reduce reverberations and SPL peaks, but do not lower background noise exposure. (65) On the other hand, a study also showed light and noise protection have for preterm infants in NICU by applying goggles and adhesive MiniMuffs (Natus®) in 54 patients at a mean of 30 weeks of gestation. These interventions caused an increase in heart rate and heart rate variability among the intervention group, and therefore this application was not recommended by the researcher following this study. (66) In a Cochrane review, Almahdoob et al 2015 examined at the effect of noise reduction on long term neurodevelopmental outcome in premature and very low birth weight infants, and found that only one study used a trial of application of ear plugs to reduce noise exposure (Abou Turk et al, 2009); and reported a better mental developmental index in the interventional (ear plug) group who were protected from environmental noise. (42,62)

1.9.2 Noise Protection Strategies During Neonatal Transport

The long-term effects of noise during transport remains unclear. Existing findings from the current literature state that level noise levels should not exceed 60dB; however, they frequently do. Ground transfers average at SPL of >60dBA and peak to 80dBA and neonatal air transfers were found to peak to more than 100dBA during take-off, with an average of more than 85 dBA during the airborne transit. (45,51)

Passive Noise Protection

Passive noise protection/ reduction is the only strategy currently available for neonates during transport. The equipment comprises disposable and practical noise

attenuators, with the MiniMuffs ® Neonatal Noise Attenuators by Natus in use by the NNTP in Ireland. These are soft natural latex foam-like shells which adhere and enclose the neonatal ear. The attenuation provided by these earmuffs is 7-12 dB, which due to the logarithmic nature of the scale reduces experienced noise level by 50%. The utilisation of these noise protectors has been recommended in published literature and research; however, they have not been shown to improve outcomes overall. These studies noted concerns about the attenuating ability of these methods and the amount of noise reduction that can be achieved, particularly during uneven ground transfers and air transfers reaching very high peaks of noise. In some ground transport system these noise attenuators are applied on all neonates being transferred, but not in the majority of services. There is no standardisation of noise protection of patients during neonatal transport. (51,54,66,67)

Active Noise Cancellation

There is interest in active noise cancellation (ANC) as a potentially effective method of noise reduction. Although there is limited reporting of successful use in low birth weight infants, their mechanism of action means they are not as reliant on achieving a snug fit around the ear as many other forms of noise protection. ANC headphones feature a miniature microphone in the earpiece that identifies ambient noise, and then create an opposite, noise cancelling sound wave that is 180°out of phase with the ambient noise. This “cancels out” the environmental noise, so the net sound pressure level reaching the individual approaches zero. It is the microphone, rather than the headphone structure, that delivers the protection, hence a tight fit around the ear may not be necessary. Kajikawa et al, 2012; described the application of ANC a variety of situations including infant incubator systems.(68) Although more

complex and more expensive, ANC equipment offers a potentially interesting and more effective way to reduce noise exposure. (69,70)

There are limited data on noise exposure during modern newborn transport and its physiological and behavioural impact on neonates being transferred, although there is reason for concern. There are no evidence-based guidelines on noise reduction or studies of the effectiveness of noise protection strategies to reduce noise exposure in at risk neonates undergoing inter-hospital transfer. Newer noise protective technologies, such as ANC, have not been studied in this cohort.

No noise protective strategies are currently in use in neonatal road transport in Ireland, and only small ear muffs, providing minimal protection, are used for babies being transported by air. Infants undergoing other noisy procedures, e.g. MRI, are required to wear extensive noise protection equipment. There are no data to date in neonates undergoing transport on more advanced ways of reducing noise, for example electronic active noise cancelling (ANC). ANC monitors sound waves, identifies environmental noise and sends out mirror image sound waves to cancel out noise and stop it reaching the ear. Therefore, this technology could be integrated into headphones of the neonatal transport equipment i.e. the incubator. Clinical research in this domain is required to generate new knowledge and initiate evidence-based guidelines for noise protection practice. This study will add information regarding noise levels and their potential for harm during neonatal transfers under the NNTP, as well as the effectiveness of common interventions to reduce noise exposure, in order to improve the care of critically ill neonates under-going interhospital transport.

1.10 Thesis Outline

1.10.1 Research Hypothesis

Overall, the literature supports the hypothesis that noise induce hearing loss (NIHL) exists and is exacerbated by excessively loud acoustic environments which are particularly detrimental to sick neonates, especially if combined with commonly used ototoxic medications, e.g. aminoglycosides. The exposure of noise affects physiological stability of neonates, essential for safety, growth and recovery. As part of neonatal critical care services, patients frequently require transportation for tertiary or specialist intervention in another centre. Transport potentially exposes these vulnerable patients to increased sound pressure levels at a time when physiological instability is critical, during transfer between safe hospital environments.

The limited evidence mostly on mock patient transfers i.e. mannequins; to date demonstrates that noise levels during neonatal transport may exceed the recommended exposure levels.(45,50) During the transient critical period of transport, implementation of noise reduction modalities could help to achieve greater physiological stability, improve patient safety and prevent potential irreversible damage. The physiological effects of the noise exposure experienced during neonatal transport require further clarification. The implementation of noise reduction modalities routinely used in other patient groups and age ranges could reduce adverse noise exposure, physiological instability and long-term adverse hearing outcomes.

The hypothesis of this research is that noise levels that neonates undergo during interhospital transfers are detrimentally high. This exposure potentially affects the physiological stability of neonates who are critically unstable. It is anticipated that

changes in heart rate, oxygen saturation and behavioural score from noise exposure during transport would eb found when noise levels are high. Therefore, the application of noise protection by applying different modes of hearing protection could potentially reduce the amount of noise exposed to cause injury to the neonatal hearing apparatus, make periods of transport stable in terms of physiology and behaviour and allow for more comfortable transfers.

1.10.2 Rationale

Noise levels during inter-hospital neonatal transport that exceed recommended thresholds potentially cause physiological and behavioural disturbances (q.v.) that may affect neonatal comfort and stability, as shown in studies in many patient care situations. (10) The auditory and non-auditory effects of noise exposure are well-recognized in other groups. (14,47). It is essential to establish the actual noise levels experienced by neonates and the physiological and behavioural effects of these noise levels. By applying noise protection equipment to this patient group, we aimed to demonstrate not merely a reduction in noise exposure during neonatal transport but also improvement in physiological and behavioural parameters.

1.10.3 Thesis Aims and Objectives

This work quantified levels of noise exposure during neonatal transport and described the changes in physiological parameters associated with noise exposure that the neonate encountered during transport. The noise parameter measured was acoustic noise level in decibel-A (dB-A). The physiological parameters that were measured include: heart rate, oxygen saturation and behavioural responses.

The effect of various noise reduction methods during neonatal transport was assessed. and the differences in noise levels experienced by the infant, physiological

and behavioural parameters were compared. Two noise reduction strategies were employed in the patient studies to reduce exposure:

1 Noise protective earmuffs (ems4bubs®): These are MRI grade noise protective ear-muff.
2 Bose ™ Quiet Comfort 35 (QC35) active noise cancellation headphones

The effectiveness of each in reducing noise exposure recorded at the infant's external auditory meatus, and their effect on heart rates, oxygen saturations and behavioural responses were investigated and assessed. The neonatal noise attenuating ear muffs called "Natus MiniMuffs ®" were used in pilot measurements of noise levels both in NICU and during ground transport. (67)

This research is the first to investigate noise exposure and the short-term efficacy of noise protective strategies during newborn transport using simultaneous, synchronized continuous recording of multi-site noise levels and pulse oximetry, downloaded and analyzed using specialist software to allow correlation of noise levels and physiological responses with additional time-synchronized video footage to also assess infant behavioural responses to noise levels.

An initial study looked at a mannequin model. We measured median and peak noise exposure and duration of high exposure (>45dBA) in the NICU and (>60dBA) during routine inter-hospital neonatal transport undertaken by the National Neonatal Transport Program (NNTP) using a mannequin neonate for our pilot data. This includes all ground and air (helicopter) transfers.

The next studies involved real infants being transferred between hospitals. In the study arms involving neonatal patients, we measured median and peak noise

exposure and duration of high exposure (>60dBA) during inter-hospital neonatal transport undertaken by the National Neonatal Transport Program (NNTP) during both ground and air transfers.

I investigated the effect of potentially harmful noise exposure (peak and average) on physiological parameters of neonatal stability including heart rate, oxygen saturation, and fractional inspired oxygen requirement (FiO2) as determined by the clinical team. We used continuous noise exposure readings and simultaneous continuous recording of infant pulse oximetry monitoring data

I further demonstrated neonatal behavioural responses to levels of noise exposure routinely encountered during transport using established and validated infant behavioural scores linked with simultaneous real-time data on environmental noise levels. To investigate the effects of noise protection on physiological stability (heart rate, oxygen saturations and oxygen (FiO2) requirement) and behavioural parameters in the transported neonate; I performed 3 types of study designs in 5 study components using simultaneous physiological and noise level monitoring concurrent with continuous video footage of the patient to determine real-time behavioural effects on environmental noise. The study designs were as follows:

1 A pilot baseline observational study on noise levels using a neonatal mannequin
2 Prospective observational case control studies for both ground and air transfers
3 Three crossover studies on assessing noise protection interventions on ground transfers

4 A randomization study of active noise cancellation (ANC) versus standard care (no protection)

5 An observation of the effectiveness of noise protection (NPEM vs ANC) during neonatal helicopter transfers.

This work provides novel data on the effectiveness of equipment for noise reduction in transported neonates which can guide design of effective safe noise environments for the vulnerable infant during neonatal transfer. The results of this study could be used as a basis for future work looking at hearing exposure and longer-term outcomes (e.g. hearing loss and neurodevelopment). However, this study will be focused on known hazardous noise levels and short-term outcomes.

The idea of this research is to interpret knowledge of noise levels during neonatal inter hospital transfers. This study observed noise levels that neonatal patients are exposed to and explored the behavioural and physiological effects of noise level exposure during this period. The thesis will elaborate on the effectiveness of the application of noise reduction apparatus during neonatal interhospital transfers and established as a result, any variance in neonatal behaviour and physiology during this period. The research is conducted by a neonatal transport clinician and research fellow who has been involved in the initiation, theoretical framework, design, conduct, data collection, data analysis and conclusions of this project. These outcomes/objectives will be met in the following way:

1.11 Summary of Methodology

This research comprised of different study arms that evaluated noise exposure and noise reduction during neonatal transfers using different study designs.

1 Pilot Data on noise levels in NICU and during interhospital NNTP Transport

This mannequin study measured the noise levels in NICU and during mock interhospital NNTP transfers. This was to determine the practicality of the use of the planned research equipment in the clinical situation and to quantify the amount of noise exposure potentially encountered by neonates in the NICU and transported by NNTP is potentially exposed to. Additionally, both noise protective strategies were trialed in a mannequin situation to evaluate their potential effectiveness in attenuating noise exposure.

2 Observational studies

We also performed a prospective observation study of noise exposure and its effects on physiology and behaviour in neonates undergoing NNTP ground ambulance transport. A convenience sampling of research participants was performed with parental consent. Both total sound energy and peak sound pressure levels were quantified during transfer. Simultaneous recording of vital physiological parameters (heart rate and oxygen saturation) and continuous video recording (to assess behavioural responses) were also taken during the transport to assess infant responses to noise.

3 Crossover studies of noise protection strategies during neonatal ground transport

This was a prospective crossover study of neonates undergoing neonatal transport with the NNTP. Infants were randomised to one of three studies

comparing heart rate, oxygen saturations and behaviour with (intervention arm) and without (standard care) noise protection. A convenience sampling of research participants was performed with parental consent, including the application of noise attenuation equipment i.e. MRI grade earmuffs (Noise protection ear muffs –NPEM) or active Cancelling headphones (Bose Active noise cancellation headphones –ANC). The three studies were:

- Crossover 1: Comparison of NPEM versus standard transport care (SC)
- Crossover 2: Comparison of ANC versus standard transport care (SC)
- Crossover 3: Comparison of ANC versus NPEM

Real time noise exposure was quantified with concurrent recording of physiological parameters and video recording for behavioral scoring.

4 Randomisation controlled trial of neonates comparing active noise cancellation (ANC) with standard care i.e. no noise protection (SC) to reduce noise exposure level and physiological instability during transport

This study randomized infants whose parents consented to inclusion in the study to either standard transport care (SC) i.e. no noise protection (control/ P), or active noise cancellation intervention (ANC) (intervention/ I) during newborn transfer. The effects of high-fidelity noise protection versus standard transport care was evaluated by simultaneously recording three channels of noise levels (at baby's ear, in incubator and in cabin), vital physiological parameter (heart rate and oxygen saturation) and continuous video recording of the patient during the transport for behavioural scoring. This study investigated the difference between the modern noise protection technology of active noise

cancelling (ANC) compared with standard practice in stable patients not receiving sedation during transport.

5 An observation of the effectiveness of noise protection (NPEM versus ANC) during neonatal helicopter transfers.

Current standard practice in the NNTP is the application of neonatal noise attenuators that have a noise reduction rating of 7-12 decibels known as Natus MiniMuffs ®.(67) Based on older simulation data, there is potential for extremely high levels of noise exposure in the harmful range (>80dBA) during neonatal air transfer. Therefore, this study was a prospective observation of the effectiveness of the two noise protection interventions selected for neonatal air transfers; MRI grade earmuffs (ems4bubs®)- NPEM and Active noise cancellation headphones -ANC (Bose QC35™). Neonates whose parents consented to the study had one of the interventions applied throughout the flight. Noise levels were recorded at the patient's ear, in the incubator and in the cabin, and simultaneous physiological monitoring (heart rate and oxygen saturation) and video recording footage were obtained to determine the effectiveness of noise reduction in an air transport situation.

1.12 Project Genesis

The research idea emerged from a clinical supervisor on the research team who observed the lack of world-wide data on noise exposure during neonatal transport, how noise exposure affects neonates and how feasible and effective is noise protection on neonatal physiology and behaviour during neonatal transfers. The project developed through in-depth search of literature, study designs and research

about relevant technologies and available equipment. The decision on selection of equipment was through profound exploration and education with supervision from the principal investigator and senior research supervisors on the research team. The nature of the equipment and study design is easily translatable not just to the neonatal population but to an older or more diverse population.

The dissemination of the findings on this study will involve paediatric transport team, who work closely and share a governance structure with the neonatal service, and the possibility of similar work in their patient cohort.

This is the first formal clinical research study design that involved the National Neonatal Transport Program (NNTP). This program transports 620 patients per annum has a huge potential to improve and guide patient care with well-designed studies. This project will demonstrate the feasibility of studying this neonatal population, and lay the groundwork for future research going forward.

Chapter 2A

Methodology 1: Equipment

The conduct of this research relies heavily on careful detailed handling of both clinical and research equipment. This chapter describes in detail the physical materials used in this research.

2.1 Neonatal Transport Equipment

The safe and stable transfers of neonatal patients is dependent on the effective operation of various types of medical equipment on the neonatal transport trolley. This trolley consists of a standard double walled incubator on a wheeled steel frame. The incubator on the transport trolley provides warmth through radiant heating and protects the neonatal patient from stressors such and light, cold and noise. The transport teams deliver the same support that was provided to the patient in a static environment i.e. NICU, by utilising the correlative equipment from the transport trolley.

All the equipment on the trolley have designated roles to maintain the neonatal physiological stability during interhospital transport. The main equipment on the neonatal transport trolley include a ventilator, intravenous infusion pumps, vital signs monitor, therapeutic cooling machine, suction machine, air humidifier, nitric oxide monitor, air cylinder, oxygen cylinder, nitric oxide cylinder along with cables, wires and tubing necessary. A figure from the previous chapter refers to the transport trolley currently used by the NNTP to deliver intensive care during neonatal interhospital transports. (Figure 1.2)

2.2 The Research Equipment

Research to determine the most suitable noise level meter, physiological monitor and visual recording apparatus was performed. This was followed by cost estimates of the research equipment along with the supporting apparatus involved to conduct the studies. The standard NNTP neonatal transport equipment was used for clinical care. The equipment that was used in the research was separate from the NNTP clinical equipment. The conduct of the research did not interfere with the clinical care received or equipment used in NICU and during NNTP transports. For the studies that involved patient recruitment, the assembly of research equipment to the transport incubator was undertaken once parental consent was obtained.

2.2.1 Noise Measurement Equipment

Noise measurement was obtained by using a noise meter that quantified and recorded noise or sound pressure levels (SPL) in units of decibel (dB). This was performed with a 4-channel sound pressure level (noise) and vibration meter called Svan 958A® by Svantek Ltd. (Figure 2.0) This was the most appropriate noise level meter that allowed simultaneous multichannel recordings during stationary and mobile (i.e. transport) environments. SPL was quantified in varying decibel (dB) weighting units; i.e. decibel (dB), decibel-A (dBA) and decibel-C (dB-C).

The researcher received training by Svantek Ltd., UK personnel for the operation of SVAN 958A® and its correlative data output software Svan PC++ ® via online tutorial sessions prior to its use. The researcher also attended seminars on environmental measurements of noise and vibration to increase own knowledge and understanding in this field of physical sciences.

Figure 2.0: Svan 958A 4 Channel sound and vibration meter (Courtesy of Svantek Ltd®)

In this research, 3 channel inputs were configured for SPL measurement and recording and one channel was configured for vibration recording. 3 designated microphones connected to these input channels were used as receptors to detect and measure environmental noise levels. These 3 microphones were placed at 3 locations in relation to the neonate or mannequin in the incubator (figure 2.1):

- Near the infant's external auditory meatus i.e. ear
- Inside the incubator
- External to the incubator i.e. ambulance cabin

Although the main environmental physical variable quantified in this research was noise, vibration was also measured and recorded into one of the four channel inputs. Vibration was measured through an accelerometer and the vibration units were quantified in meter per second squared (ms^{-2}). The accelerometer was placed on the

surface of the incubator interior and in very close proximity to the patient or neonatal mannequin.

Input channels for sound pressure level recording was set-up to channel 1, 2 and 4. Channel 1 was configured to the microphone near the patient's ear. This microphone dimensions were a small cylindrical shape of 1 cm length and 0.6cm diameter (Figure 2.1).

Figure 2.1:Microphone used in detecti o n o f s o u n d n e a r [p a t i e n t courtesy of GRAS Ltd, Denmark (71)

Channel 2 was configured to record the internal incubator ambient noise. This microphone placement was supported and fixed at the wall of the incubator for steady recording during mobile and stationary environments. Channel 4 was configured to record the SPL outside of the incubator. The microphones used for channel 2 and 4 were similar in their size and dimensions. (Figure 2.2).

The dynamic ranges of SPL recording for all 3 microphones was from 18dB(A) to 138 dB(A). The 4 input channels of SVAN 958A® was used in the following configuration. (Table 2.0; Figure 2.3)

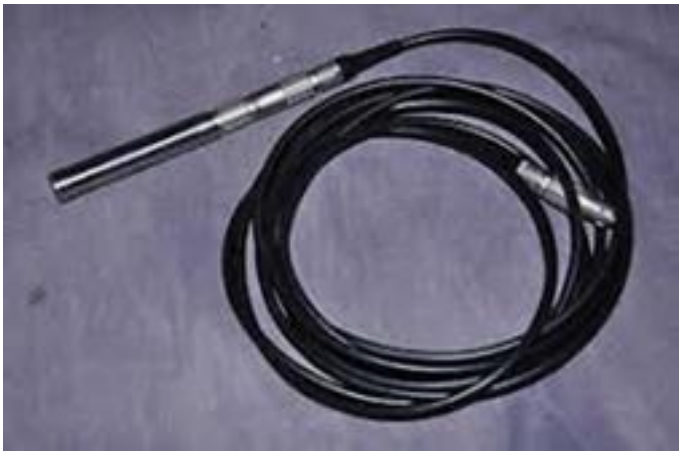

Figure 2.2: Microphone used for channel 2 and channel 4 (GRAS, Denmark Ltd[1])

Input Channel	Type of meter	Receptor input and location	Unit of measurement
Channel 1	SLM	Patient ear	Decibel
Channel 2	SLM	Inside Incubator	Decibel
Channel 3	Vibration	Accelerometer/ Inside Incubator	m/s^2
Channel 4	SLM	Outside Incubator	Decibel

Table 2.0

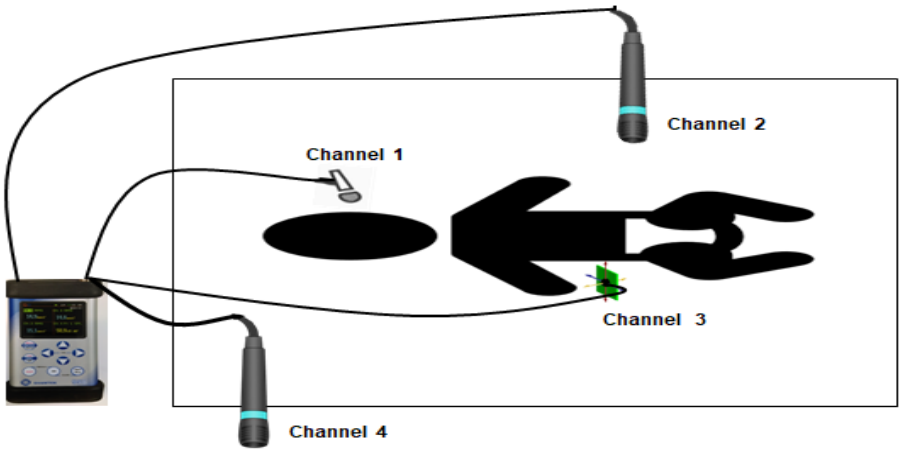

Figure 2.3: Configuration of noise microphone and vibration accelerometer in relation to the neonate in the transport incubator

2.2.2 Recording of vibration

An accelerometer that measures vibration (ms^{-2}) was placed securely on the incubator mattress near to the patient and connected to channel 3 of Svan958A® meter. Recording of vibration was simultaneously and continuously obtained with noise level, heart rate, oxygen saturation and audio-visual (i.e. for behavioural scoring).

The data measured and recorded was stored into the Svan958A®'s internal memory. All recorded noise and vibration data were extracted and transferred using the correlative equipment software Svan PC++®) and subsequently saved in a designated encrypted external computer hard drive. For studies involving patients, data files were named according to the case number assigned. All Svan958A® data was extracted, transferred and saved after every recording event for all studies in the research. Figure 2.4 below, is a sample of data extracted from a noise recording

using the Svan PC++ software. This data was translated to Microsoft Excel to allow for statistical analysis with SPSS version 26

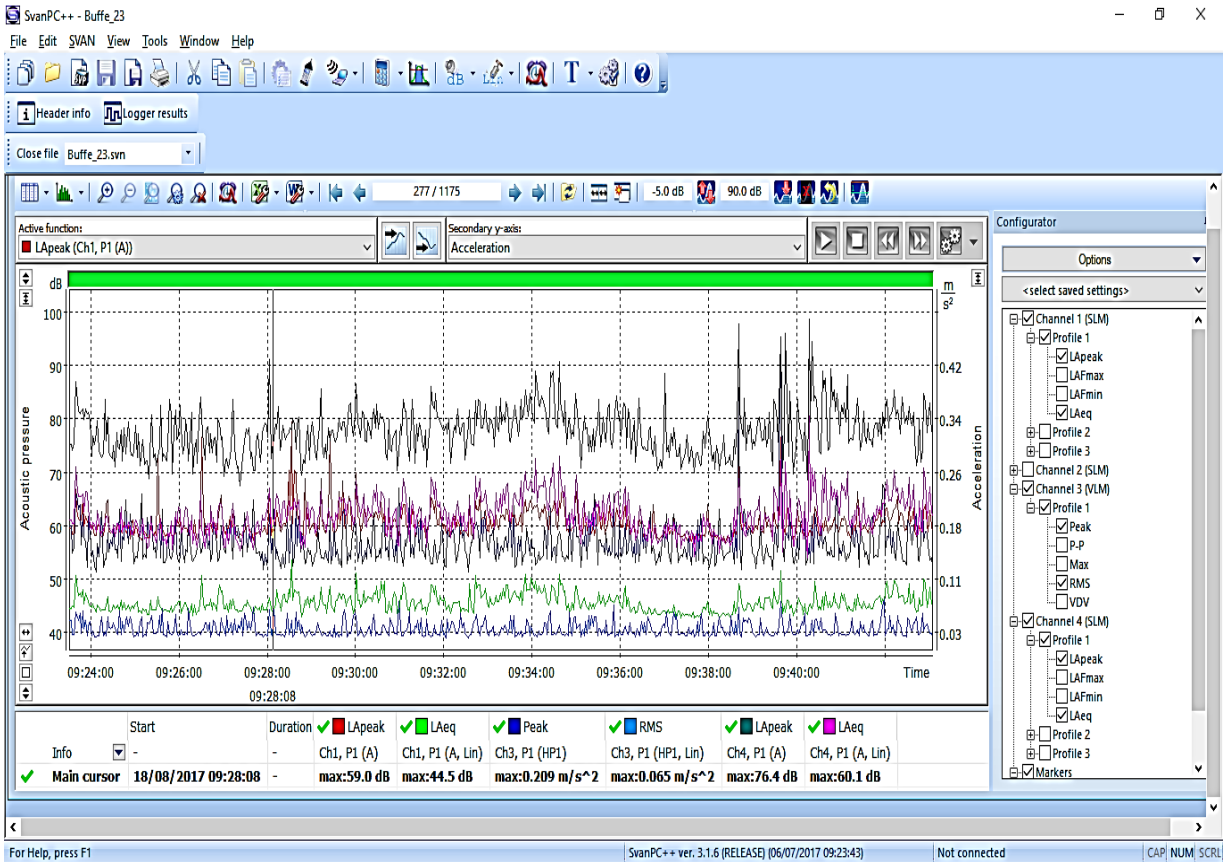

Figure 2.4: Svan PC++®

2.2.3 Physiological Monitoring Equipment

The two physiological variables, heart rate (HR) and oxygen (O2) saturation levels was recorded in order to investigate any changes in relation to exposure to the noise levels recorded during neonatal transport. This was performed by connecting a separate heart rate and O2 saturation monitor (patient monitor) to the neonatal patient being transferred. The monitor used was a portable Masimo® Rad 8 that had an alternate second sampling frequency of both [physiological variables. An adhesive saturation probe was placed at the patient's extremity and connected to the

monitor. Heart rate was recorded in ‘beats per minute’ (bpm). The oxygen saturation level was quantified and recorded in percentage (%). The appropriate value ranges for heart rate and oxygen saturation levels was set to the normally expected neonatal physiological ranges. The monitor’s alarms were also muted to avoid interference with the SPL measurements. The monitor was place securely at the top of the transport incubator using heavy duty adhesive Velcro attachments. The display aspect of the monitor was placed facing the video recording device to allow for added data synchronisation support. The internal time and date were synchronised to the Svan958A® meter. The recording of the patient’s heart rate and oxygen saturation was continuous and simultaneous with the noise and vibration recording. This data was stored into the monitor’s internal memory. After completion of each transfer involved in the research, the physiological data was extracted from the monitor, transferred and stored to an encrypted computer hard drive using the correlative software for Masimo® Rad8 called ViSidownload®. The data files were named according to the case number assigned. This data was translated to Microsoft Excel to allow for statistical analysis with SPSSv26®.

2.2.4 Video recording of behavioural responses

The assessment of behavioural responses to noise levels during neonatal transport involved the use of an action video camera i.e. GoProHero5® to record visual footage. The camera was placed securely outside the transport incubator using a GoPro® high impact suction cup. The time and date setting on the camera was synchronised with the Svan958A meter and MasimoRad8 monitor. The researcher ensured that the footage included as much as possible the full overhead view of the patient and the display of HR and O2sats on the monitor (Figure 2.5)

Figure 2.5: GoPro camera taking video footage of patient with simultaneous noise, vibration and physiological recording

Video footage was stored in a micro SD storage card during the recording. Recorded data was transferred to an encrypted computer hard drive in mp4 format after every completed transfer. The data files were named according to the case number assigned. Four examiners were invited to view the video recordings separately to assess the patient's responses i.e. to noxious stimuli that included noise. Each examiner assigned behavioural scores to each patient using the Neonatal Infant Pain Score (72,73).

2.2.4 Noise and hearing protection equipment

The current noise and hearing protectors used in neonatal transfers are adhesive foam ear covers called Natus® MiniMuffs. (Figure 2.6). The use of these protectors, although provides a noise reduction rating (NRR) of 7 to 12 dB; is currently not standardised during neonatal ground transfers and its application is primarily during neonatal air ambulance transfers. The use of these Natus® MiniMuffs in this

research was in study 1 which compared baseline noise levels in NICU and during transport using a neonatal mannequin, which is explained in the next chapter.

Figure 2.6:Natus® MiniMuffs (Photo from Natus data specification sheet of MiniMuffs)(74)

We performed wo types of noise and hearing protection in the patient studies:

1. Noise protective ear muffs (NPEM)
2. Active noise cancellation headphones (ANC).

Single use sterile headphone covers were applied to the auricular aspect of both types noise protectors prior to placing them on the patients, in order to avoid cross contamination between patients. The headphone covers are replaced between each patient and patient recording.

Noise Protective Earmuffs (NPEM)

NPEM used in this research were noise attenuators/ protectors called Ems4Bubs® by Ems 4 kids©. Currently, they are commonly used for hearing protection during infant and neonatal MRI scans that expose patients to SPL levels as high as 100dB.(ref) The ear muffs consists of a pair of cup shaped passive noise attenuators (9cm length x 7cm width) with soft foamed margins held by a removable and adjustable elasticated headband which keeps the muffs in place. The channel 1 microphone designated to detect noise levels near the patient's external ear is placed securely through the foam margin of NPEM. (Figure 2.7)

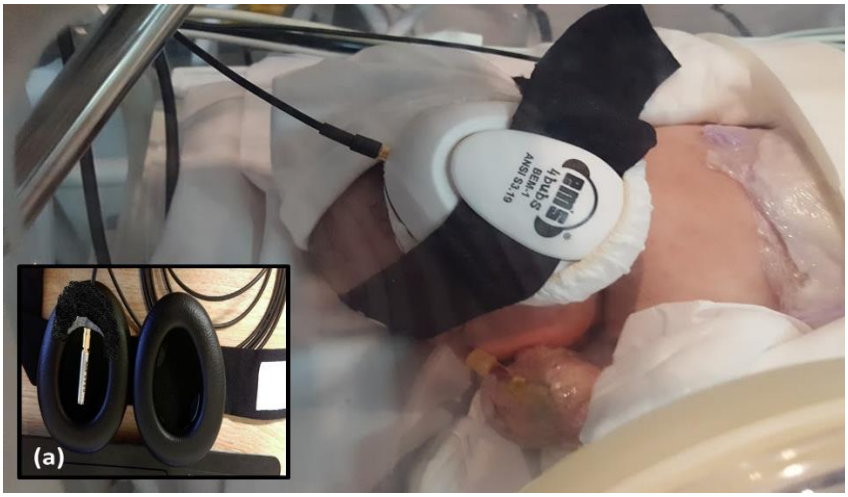

Figure 2.7: Application of NPEM on a research participant; (a) Microphone placed in the foam margin of NPEM

Headphone covers were applied to each side of the ear muffs prior to use to avoid cross contamination. These earmuffs have a mean attenuation of 26 dB at 500Hz and 30 dB at 1000Hz range with a noise reduction rating (NRR) of 22dB. NPEM was

used in the both mannequin and patient studies. Headphone covers were replaced in between patients.

Active Noise Cancellation Headphones (ANC)

Active Noise Cancellation (ANC) technology is the most advanced and current noise attenuation and hearing protection available in the occupational setting and consumer market. An active noise cancellation circuit device that is implanted in a headphone set, is operated electronically via wire adapter or Bluetooth connectivity. An internal microphone is implanted in the cup of the headphone to detect external noise. The amplitude and frequency of the incoming wave is detected by a 'noise cancelling circuit'. This circuit subsequently creates and anti-sound which is 180 degrees out of phase (i.e. opposite wave) with the external sound waves considered being noise. The anti-sound is then transmitted through headphone speakers. This phenomenon is also known as destructive interference. The use of energy to attenuate noise from ANC is via rechargeable cells (battery) or electrical source that differentiates it from the mode of passive attenuation of NPEM. (75,76)

The ANC device used in this research was Bose ©Quiet comfort 35® which has a noise reduction rating (NRR) of approximately 33dB. The channel 1 microphone is taped securely to the convex inner surface of the auricular headphone cup. Single use headphone covers were applied prior to placing the ANC in the best position possible to achieve noise attenuation and hearing protection for the patient. These covers were replaced after each patient. ANC headphones was used in both the mannequin and patient studies. The researcher ensured that ANC headphones were fully charged prior to usage. The blue tooth connectivity was established prior to the

recording of data during the patient studies. These headphones were thoroughly cleaned after, and in between each patient use. Disposable headphone covers were applied prior to the application of this device on the patient.

2.3 Behavioural Scoring Systems

Noise is a noxious stimulus. Most behavioural scoring systems are designed to collect data over a longer period. There are no suitable tools for the assessment of responses to acute noise but there are many for other noxious stimuli including suctioning and pain. Currently, there is no valid or practical behavioural scoring system for the neonatal patient undergoing transport. The use of a neonatal pain score to assess the patient's response to noxious stimulus i.e. noise and vibration was a sensible tool to reflect the neonatal behaviour during interhospital transports. This study used a validated pain score to evaluate infant responses to loud noise. The Neonatal and Infant Pain Sale (NIPS) was chosen for its simple scoring format (72,73,77). This scoring system recommended for children less than one year used the behavioural response that is deemed by the examiner to indicate pain or distress. The examiners observed six aspects of the scoring system which are; facial expression, cry, breathing pattern, upper limb position, lower limbs position and state of arousal. The format of the scoring sheet is displayed below (Table 2.1). A score greater than 3 indicates pain and was considered to be significant. Patients who underwent continuous video footage during the studies were independently scored by four examiners. The examiners consisted of 3 experienced NICU and transport nurses and 1 neonatal doctor who is experienced in neurology. Outcomes included mean scores and episodes of scoring >3. Simultaneous concurrent video recording

with noise level meter and physiological monitor permitted the assessment of responses to potentially concerning noise levels.

Pain Assessment		Score
Facial Expression		
Relaxed Muscles	Restful face, Neutral Expression	
Grimace	Tight Facial muscles; furrowed brow, chin, jaw (negative facial expression-nose, mouth, brow)	
Cry		
No cry	Quiet, not crying	
Whimper	Mild moaning, intermittent	
Vigorous cry	Loud scream; rising, shrill. Continuous (Note Silent cry may be scored if baby is intubated as evidence by obvious mouth and facial movement	
Breathing pattern		
Relaxed	Usual pattern for this infant	
Change in breathing	Indrawing, irregular, faster than usual; gagging, breath holding	
Arms		
Relaxed/ Restrained	No Muscular rigidity; occasional random movements of legs	
Flexed/ Extended	Tense, straight legs; rigid and /or rapid extension, flexion	
State of arousal		
Sleep/ Awake	Quiet, peaceful, sleeping or alert, random leg movements	
Fussy	Alert, Restless and thrashing	

Table 2.1: Neonatal/Infant Pain Scale (NIPS) (Recommended for children less than 1 year old) A score greater than 3 indicates pain (73) **(Department of Nursing, University of Wisconsin, 2014)**

2.4 Data analysis and software

In the mannequin study that investigated baseline levels, data was managed from a single source i.e. Svan958A® sound level meter. SPL and vibration levels were transferred from the its internal memory using the correlative software Svan PC++ and then transferred to the research laptop for encrypted storage and analysis. The data was quantitative numerical value that was exported to Microsoft Excel™ formats which allowed for further statistical analysis using SPSSv25® software. Sound Pressure Levels (SPL) were measured in units of decibel (dB) and decibel-A (dBA). Decibel- A (dBA) is more representative of the human hearing threshold and therefore was the unit of choice for subsequent analysis. Comparison of values of baseline levels between NICU environment and neonatal transport environment was performed. This also included the evaluation of SPL levels during standard (i.e. no noise protection) NICU and transport care (ground and air transfers) compared to the used of noise and hearing protection in these environments. The data were represented as:

- Mean with standard deviation for SPL in NICU and during ground and air transfers in current standard care and during the application of noise and hearing protection.
- The proportion of external noise attenuated by the noise and hearing protection devices (this included no noise protection i.e. incubator protection only) was represented in percentage. The calculation example below:
- Percentage of noise reduction (%) = SPL at infant ear / SPL external of the incubator x 100

In the studies involving neonatal patients, the data sources were from 3 main computes; the sound level meter (Svan958A®), the patient monitor (MasimoRad8)

and the action camcorder (GoProHero6). The internal time and date for the 3 equipment was synchronised prior to each recording. The recording from each of these equipment components i.e. SPL, physiological monitoring and video footage occurred concurrent and continuously for every patient case in the research. The recording procedure and data management for Svan 958A SPL meter was similar to the mannequin study mentioned in the previous section.

The patient monitor (MasimoRad8) records and stores heart rate and oxygen saturation level data in its internal memory that was extracted and analysed using the correlative software called Visi Download® in the research laptop. This quantitative data in numerical form was then exported to Microsoft™ Excel formats that also allowed for further statistical analysis using SPSS v.26 statistical software. The patient's heart rate was represented in beats per minute (bpm). The normal range for neonatal heart rate is 120-160 beats per minute at rest. Oxygen saturation levels were presented in percentage. The normal oxygen saturation level expected for a neonate depending on their gestational age and respiratory support is 93-97%.

Simultaneous to the recording of noise levels and physiological parameters was the continuous visual recording (video) of the patient during the research. This was performed by using an action camera (GoPro Hero5). The video recording was stored into a microSD memory card. After each completed transport, the recorded data was transferred to an encrypted external computer hard drive. The videos of every patient case recruited in the studies were assessed by 4 examiners from a behavioural aspect using the Neonatal Infant Pain Score (NIPS)(72,73) . The behavioural scores assigned to each patient by all 4 examiners was entered into a Microsoft™ Excel spread sheet which was subsequently exported for analysis using the SPSS statistical software.

2.5 Data Analysis

Preliminary data that included studies investigating and observing baseline noise levels in NICU and during neonatal ground and air transport involved numerical values quantified in units of decibel-A (dBA). Vibration levels quantified in units of ms^{-2} was included. The analysis involved comparison of means with standard deviation.

Throughout the research, calculations on mean, standard deviation of mean, median, mode and independent t-test was performed for normally distributed data. In non-normally distributed data, median, mode and non-parametric testing was used. Dichotomous categorical data was analysed using Chi square testing.

The sections described in this represents a guide to understanding the designs of the various studies in this research. In the next chapter, intermittent references are made to refer to the materials that was used to carry out the studies, the study design and the research conduct.

Chapter 2B

Methodology: Study Designs

2.6 Ethics

The initial research proposal was submitted and approved for a Medical Doctorate degree by research to Royal College of Surgeons in Ireland (RCSI), with which whom Rotunda Hospital is affiliated to as part of the RCSI hospitals group. Research and ethical approval were sought for each study involving neonatal patients. Each ethics application was submitted to 3 separate committees in the 3 tertiary maternity and neonatal hospitals; as they are directly involved in providing neonatal transport services affiliated with the NNTP. The standardised research and ethics committee application forms was completed and submitted for all studies involving neonatal patients in this research. The participant and parent information leaflets (PIL) and consent forms were devised for the committee's review. The PIL and consent forms were customised to each specific study that involved patient participants. The research and ethical application for conduct of the studies involving neonatal patients was approved by all 3 research ethics committee in the 3 tertiary maternity/ neonatal hospitals affiliated to the NNTP. The feedback in the form of suggestions following each application and interview was addressed and incorporated. Ethical approval to perform the research was received from all three Dublin maternity hospitals in Dublin affiliated with the NNTP; the Rotunda Hospital, the Coombe Women and Infant's University Hospital and the National Maternity Hospital Holles Street.

2.7 Funding

The purchase for research equipment was kindly provided by the Rotunda Foundation. The salary support to perform this research was from the NNTP Fellow role during year two, and part-time salary support for year one was provided by the RCSI neonatal tutor role in the Rotunda Hospital. The MD candidate and researcher also performed limited clinical work in the NICU and neonatal transport for salary support. Post-graduate fee support for 2nd year of degree was received with thanks from National Children's Research Centre (NCRC), Our Lady's Hospital Crumlin, Dublin. Year one fees were partially supported by the Tutor Fee support in the RCSI, Dublin.

2.8 Patient Recruitment

As there is a high turnover of transfers performed by the NNTP, recruitment of neonatal patient participants was through convenience sampling of suitable patients undergoing either acute time critical, acute but stable and elective or repatriation inter-hospital transfers. The patients were recruited into the studies based on the availability of the research team and equipment. Prior to the recruitment, the researcher approached parents of eligible patients for possible inclusion of their newborn into one of the studies at the referring hospital. The researcher discussed at length the designated relevant study for the patient and provided the parents the corresponding information leaflets. The research team answered all parental queries with regards to the assigned studies. Each parent was given a time of approximately 15-20 minutes to consider the information while the patient was being prepared for transport. Once they had enough time to consider the participation of their infant into the study, a written consent was obtained. The acute nature of many transports services means that there was frequently a clinical urgency to transfer and this was

not delayed by the recruitment process. The patients were only recruited once and was not subsequently ‘re- recruited’ to the research when any such opportunity had arisen.

All neonatal patient participants were managed as per standard NNTP clinical care from the first point of contact with NNTP clinicians at the referring hospital, to the point of arrival in the receiving hospital. The research conducted in all studies did not alter or interfere with the NNTP care and standard transport equipment used to deliver this care.

2.8.1 Inclusion Criteria

We included neonates up to 6 weeks corrected gestational age (i.e. 46 weeks post-conceptual age) who underwent clinically indicated inter-hospital ground or air ambulance transfer NNTP. This included the recruitment of premature neonates with a gestation >23weeks and a birth weight >500 grams at delivery who have required critical transfer to tertiary unit for escalation of care once informed parental consent was obtained.

2.8.2 Exclusion Criteria

This research excluded any neonate with any external (auricular or peri-auricular abnormality) or known congenital anomalies that can be associated with hearing loss. This included the exclusion of any ear malformations with congenital neurological problems and/or congenital infections or congenital syndromes associated with hearing loss. Any neonatal patient with a family history of inherited hearing loss in any first degree relative was also excluded (31,46,78). Study 4 in this research involved the recruitment of stable neonatal patients in return or repatriation

transfers. For this particular study we excluded infants requiring any form of sedation, neonatal abstinence syndrome or withdrawal syndromes.

This study was not designed to evaluate noised induced hearing loss (NIHL). However, it was necessary to exclude any infant subsequently shown to have a congenital hearing problem. As newborn hearing screening data will not always be available on infants at time of transfer, parental consent to subsequently obtain hearing screening results in the future was included as part of the written consent process.

2.9 Demographics and Documentation

Each patient enrolled in the research was assigned a case number. This case number was also used to label all data recorded in relation to the patient. Each patient had a research participant record that contained demographic and clinical information relevant to the research. The components documented in the research participant record were:

1. Demographic Data: Gender, Weight (at birth and during transport), Gestational age (at birth and during transport), Consent obtained (yes or no)
2. Transport: Type (Ground or air ambulance), Acuity (time critical or stable), final destination (NICU, PICU, HDU, SCBU), Distance (intercity, intercounty or international), Mobilisation time in hours (start and stop of recording)
3. Clinical Data: Area of primary diagnosis (Medical, Surgical, Cardiac, Other), Number of associated co-morbidities, National Newborn Hearing Screen, Family history of congenital deafness, external congenital anomalies,

Congenital infections, Ventilatory support, Fractional inspired oxygen Concentration, Blood Pressure, use of sedation, use of muscle relaxant

4. Relevant to research practicalities: Temperature (ambulance ambient temperature and incubator temperature), Location of accelerometer in relation to the patient (head, shoulder or back, limbs)
5. The assignment of risk score i.e. Transport Index of Physiological Stability score (TRIPS) that assisted in determining the level of instability of the participants involved in a study. (79)

2.10 Study Aims and Outcomes

As mentioned in the introductory chapter this research quantified levels of noise exposure during neonatal ground and air ambulance transport encountered by the neonatal patient. Baseline environmental noise levels was determined prior to conducting the studies involving patients. The observational patient studies investigated changes in neonatal physiology (heart rate and oxygen saturations) and behavioural responses concurrently to the exposed noise levels during ground ambulance transfers. Through crossover and randomised control study, the effect of various noise reduction methods during neonatal transport was assessed. The effect of the differences in noise levels experienced through the application of noise protection, changes in physiology and behaviour during transport was investigated. The research further explored the application of noise reduction and protection during neonatal air transfers and investigated its effects on neonatal physiology and behaviour. (Please refer further to thesis aims and objectives in Chapter 1: Introduction).

2.11 Study 1: Baseline environmental noise levels

This study measured environmental noise in NICU and during mock interhospital NNTP ground and air transfers to determine the practicality of the use of the research equipment in both clinical situations i.e. the NICU environment and the transport environment. This study component involved the use of a neonatal mannequin to simulate the neonatal patient in the incubator.

Baseline environmental noise in the NICU

As described in the previous sections, noise or sound pressure levels (SPL) in the NICU environment was obtained from 3 aspects in relation to the neonatal mannequin in the NICU incubator (Table 5; Figure 9). The measurements were obtained during standard NICU environment which included active periods in the NICU i.e. ward round and during inactive periods i.e. newborn quiet time. Recording times of at least 15 minutes duration was performed over 3 days. SPL was recorded in A-weighted decibel (dB-A). Vibration measurement units was recorded in meters per second squared (ms^{-2})

In order to evaluate the potential effectiveness of attenuating noise exposure, the SPL measurements was taken from:

1. SC: standard NICU practice- SC (mannequin with no noise protectors)
2. Adhesive foam MiniMuffs (Natus)
3. Passive noise protective ear muffs (NPEM)
4. Active noise cancelling headphones (ANC).

Baseline environmental noise levels in neonatal ground and air transport

As described in the section above, the same procedure for measuring baseline noise levels in NICU was repeated in neonatal transport using the neonatal transport incubator trolley. A newborn mannequin was placed in the transport incubator and the baseline measurement was obtained from mock neonatal interhospital transfers with NNTP using Svan958A®. The recording was performed on ground ambulance and air ambulance transfers. The SPL measurement was obtained from ground ambulance transfers that involved recordings in mock intercity and intercounty journeys over a period of eight days. The recording duration was approximately 15 minutes. Similar to the NICU preliminary measurements, the evaluation of the potential effectiveness of attenuating noise exposure was performed. The SPL measurements in ground transfers was obtained from 4 situations:

1. SC: standard transport practice- SC (mannequin with no noise protectors)
2. Adhesive foam MiniMuffs (Natus®)
3. Noise protective ear muffs (NPEM) -ems4Bubs®
4. Active noise cancelling headphones (ANC). BoseQC35™

Measurement of baseline levels during neonatal air ambulance involved recording of noise levels (including vibration levels) in a helicopter (i.e. rotary wing) at different flight phases. The measurements were performed opportunistically due to the paucity of air ambulance transfers during the research period. These recordings were performed on 3 separate air ambulance contact sessions (i.e. air transport training days and electromagnetic testing session for all NNTP air transport clinical and research equipment) which were facilitated by the Irish Air Corpse. The configuration of the research equipment and the use of the mannequin to record SPL

and vibration were similar to ground ambulance baseline studies described above (picture). This study explored the use of 2 noise reduction interventions during neonatal air ambulance transfers in a rotary wing air craft (helicopter).:

1. Noise protective earmuffs (NPEM®)
2. Active noise cancellation headphones (ANC)- BoseQC35™

Study 2: Observation of Physiology and behaviour during standard neonatal ground transfers

This was a prospective observational study of infants who underwent neonatal transfer under standard NNTP conditions. Currently, there is no standardised practise in the application of direct noise protection to the neonate during ground transport. The practise is currently inconsistent in ground transport among neonatal services. The present noise protection available in neonatal transport is the application of the adhesive MiniMuffs Natus®; during ground and air transfers.

Therefore, the component of this research measured noise exposure of neonatal patients during standard interhospital ground transfers and the effects of noise on the stability; which included any changes to heart rate, oxygen saturation level and behavioural responses. There is currently no available published data on neonatal studies in relation to noise exposure and noise reduction during interhospital transfers during the conduct of this research. Therefore, there was no sample size or power calculation performed. This study proposed to recruit convenience sample of ten infants undergoing neonatal air transfers. There was no observational study of this kind in neonatal air ambulance transfers due to the potentially extremely dangerous sound pressure levels in the ambulance aircrafts. Neonatal air ambulance

transfers of patient were not included in this study arm due to the extremely hazardous noise and vibration levels in this environment(51,80).

A convenience sampling of infants undergoing both acute emergency and elective or semi-elective (repatriation) inter-hospital transfers with the NNTP was performed. The research team approached all eligible subjects undergoing NNTP ground ambulance transfers outlined. Patients who have met eligibility criteria with written and informed consent from the parents were included in this study. These patients were managed as per standard NNTP clinical care from the point of departure from the referral hospital to the point of arrival at the receiving hospital. There was no alteration in the NNTP care and standard transport equipment including that of patient monitoring was used.

All demographics, standard transport information including respiratory support, clinical interventions and use of sedation and muscle relaxants was documented and included as part of the research data. (See demographics in previous section). An added risk score i.e. transport risk index of physiological stability (TRIPS) was assigned to the patients recruited in order to categorise level of stability during the recording process and further assess the impact on varying criticality of the patients(79).

The configuration of the research equipment in relation to the patient was as described in Figure 3 and 9 from chapter 1. Svan958A® meter provided continuous recording and data storage from 3 SPL inputs and 1 vibration channel. It is important to emphasis the simultaneous recording of physiology (heart rate and oxygen saturations) through the MasimoRad8 monitor and behavioural reactions through the GoPro camera that occurred concurrently. A three-minute duration was allowed for

the patients to settle other than in response to handling before the recording commences. All research data was transferred and stored into a designated encrypted hard drive and laptop for further statistical analysis. Research equipment was cleaned after a recording is completed to prevent cross contamination between patients.

2.12 Noise Reduction Intervention Studies

Study 3: Effects of noise reduction Interventions through crossover studies of neonates undergoing ground transfers

A crossover approach in the interventional phase of this study explored the effect of neonatal noise protection and explored whether the changes in noise exposure and attenuation led to reciprocal changes in physiology and behaviour of the neonate undergoing transport. As previously discussed, standard neonatal transport care did not include the application of neonatal noise attenuators during routine ground ambulance transfers. This study compared the effects of standard neonatal transport care (SC), noise protective earmuffs (NPEM) and active noise application headphones (ANC) through 3 separate crossover components which was:

- **Crossover 1**: Standard Care (SC) versus noise protective earmuffs (NPEM)
- **Crossover 2**: Standard Care (SC) versus active noise cancellation headphones (ANC)
- **Crossover 3:** Noise protective ear muffs (NPEM) versus active noise cancelling headphones (ANC)

The process of recruitment and the continuous simultaneous recording of noise levels, physiology and video footage were similar to the observational study in the previous section. It was not be possible to blind the study as the interventions were visible.

A computer-generated randomisation application program was used to enrol the patients to one of the crossover components. The starting point of the crossover was also randomised. A crossover compared exposure and intervention alternately at 10 minutes intervals. A three-minute period i.e. ‘washout period’, was allocated for each patient to settle at the beginning of the recording and in between change of exposure/ interventions. Therefore, least 40 minutes of ambulance journey time was required to complete a recording for each patient.

All recorded data was extracted and transferred to an encrypted external hard drive using the compatible equipment software, i.e. SvanPC++® for noise data and Visi Download® for physiological data. Similar to observational studies the data was exported into excel format for further statistical analysis with SPSSv25 software. Video recording was also transferred and saved to an encrypted external hard drive and assessed for behavioural assessments. Previously validated scores for acute noxious stimuli (NIPS) was assessed separately and independently by four separate study investigators to minimise the effect of individual bias(72,73). Diagrams are displayed below to describe the recording phases for the three crossover components.

Crossover 1: Standard Care (SC) versus noise protective earmuffs (NPEM)

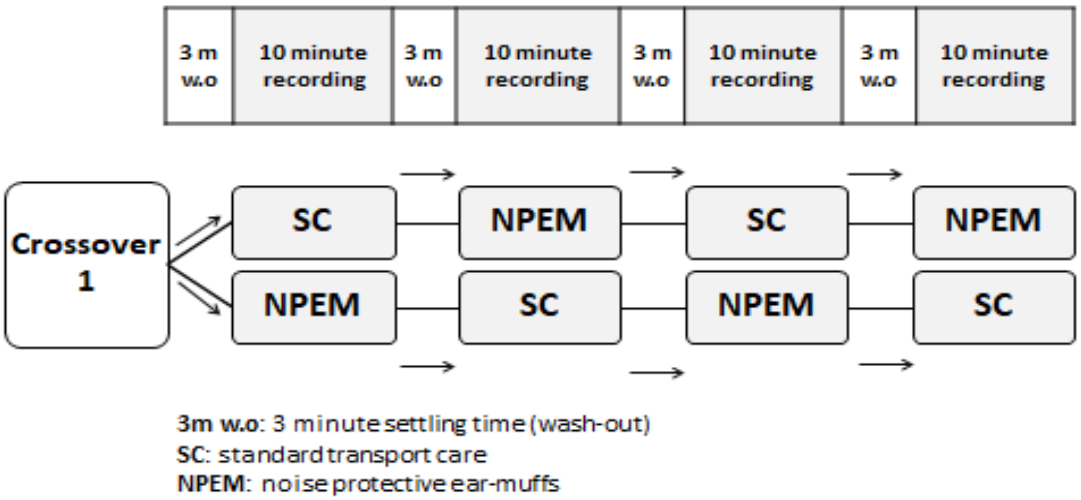

Figure 2.8: Study 3 Crossover 1

Crossover 2: Standard Care (SC) versus active noise cancellation headphones (ANC)

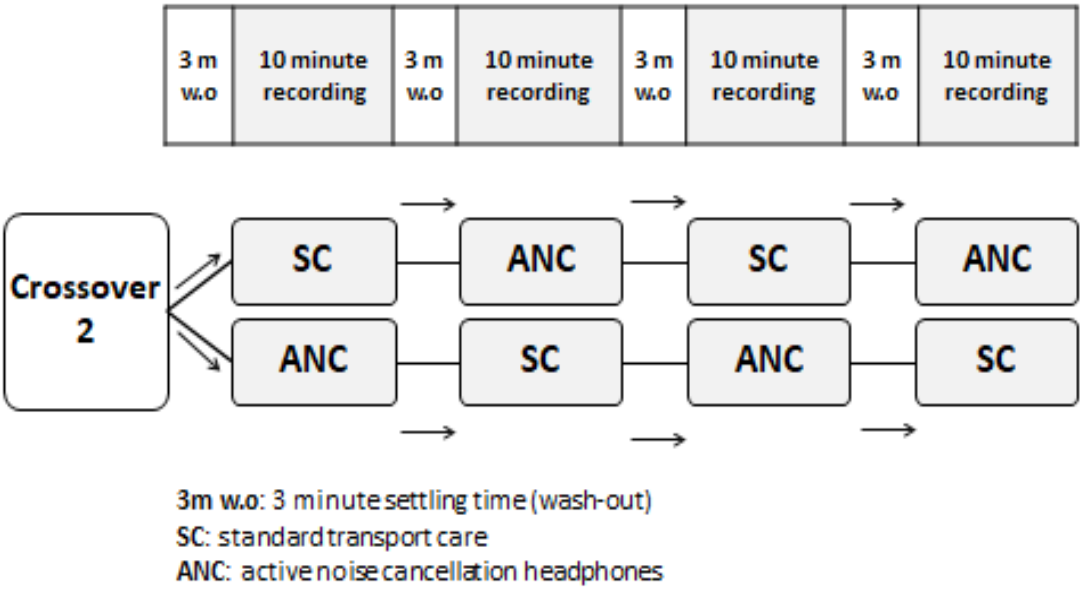

Figure 2.10: Study 3 Crossover 2

Crossover 3: Noise protective ear muffs (NPEM) versus active noise cancelling headphones (ANC)

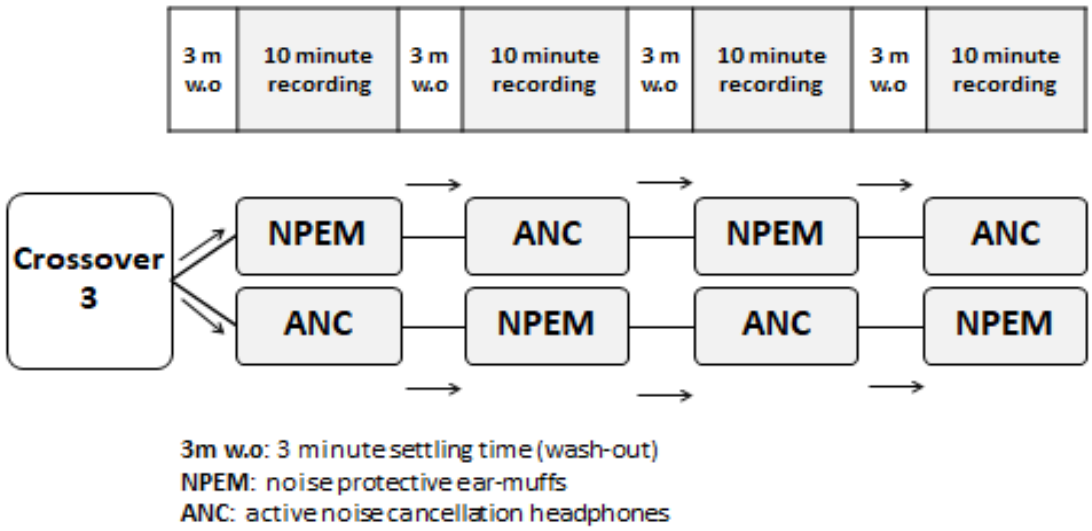

Figure 2.10: Study 3 Crossover 3

Although there is currently no published data available on neonatal studies in relation to noise exposure and noise reduction during neonatal transport, an attempt to calculate sample size for the crossover studies was made through the primary outcome of the study. The power calculations are based on best available evidence on road transfer noise exposure from the published literature. This was calculated from the estimate of mean noise exposure for these studies according to current literature(45). An estimated noise exposure level of 65 dBA during road transfers followed by the reduction of 20dBA when using noise protective equipment, estimated that 10 infants per crossover component would be sufficient to demonstrate significant results for each study. Therefore, a total of at least 30 patients was recruited to the whole crossover study(81).

Study 4: The Effect of Noise protection through Active noise cancellation (ANC) during clinically stable neonatal transfers- a randomised control trial.

This study involved the randomisation of clinically stable neonatal patients undergoing interhospital ground transfers to control and interventional study arms in order to explore the effects of presumably the most effective noise protection application i.e. active noise cancellation (ANC) with standard neonatal ground transport practise (SC) i.e. no noise protection. The patient recruited comprised mainly of neonates who underwent planned return transfers to their local hospital i.e. repatriations or back transfers.

The process of recruitment and the continuous, simultaneous recording of noise levels, physiology and video footage were similar to the observational and crossover studies as mentioned in previous sections. Suitable neonatal patients with informed and written parental consent were recruited. A computer central randomization scheme was used to assign the infants to the two arms in a 1:1 ratio. The patients were randomized and assigned to either:

- **Control group** : standard neonatal ground transport care (SC)

Or

- **Intervention group** active noise cancelling headphones (ANC)

The patients in the **control group** or standard care (SC) arm comprised of the group that received routine NNTP clinical care on ground transport with no noise protection throughout the journey. The patients randomized to the **intervention group** (ANC) arm received the same routine NNTP clinical care during neonatal ground transfer with the added application of active noise cancelling headphones (ANP) throughout

the single journey. Single used sterile headphone covers were applied and disposed after a transport recording was completed for each patient in this study.

The patients were allowed a settling time of 3 minutes after handling and siting of equipment. For each patient in both study arms, continuous and simultaneous recording of noise, physiological data and video footage was performed for a total duration of 30 minutes during the journey (Figure 17). Similar to previous patient studies, all recorded data was extracted and transferred to an encrypted external hard drive using the compatible equipment software, i.e. Svan®PC++ for noise data and Visi Download® for physiological data. Similar to observational studies the data was exported into excel format for further statistical analysis with SPSSv.25 software. Video recording was also transferred and saved to an encrypted external hard drive and assessed for behavioural assessments. Previously validated scores for acute noxious stimuli (NIPS)(72,73) were assessed separately and independently by four separate study investigators to minimise the effect of individual bias.

The power calculation in determining the sample size for this study group was estimated through the primary outcome as the mean noise exposure in the two groups. Active noise cancelling headphones are designed to provide up to a 70% reduction in loudness exposure. Data on incubator noise exposure in a study of in eight simulated road transfers (use of a mannequin) in 2003 demonstrated mean noise exposure levels of 65 (SD2) -75 dBA (SD) for country and urban transfers respectively [(ref)](45,50). As data for the more modern equipment in use in the Irish NNTP does not yet exist, it was estimated that patients without noise protection would be subjected to a mean noise exposure of >55dBA (Standard Arm). The application of active noise cancelling headphones provided an estimate 70% of loudness reduction. Therefore, it was estimated that noise exposure was reduced by

up to 20dBA. An estimate of a 10-dBA reduction in noise exposure in the active noise cancelling group to a mean of 45dBA (estimated SD 10 as data unavailable) required a sample size of 42 patients (n=21 per group) to demonstrate a 10dBA reduction with a power of 90% and an alpha error of 0.05.

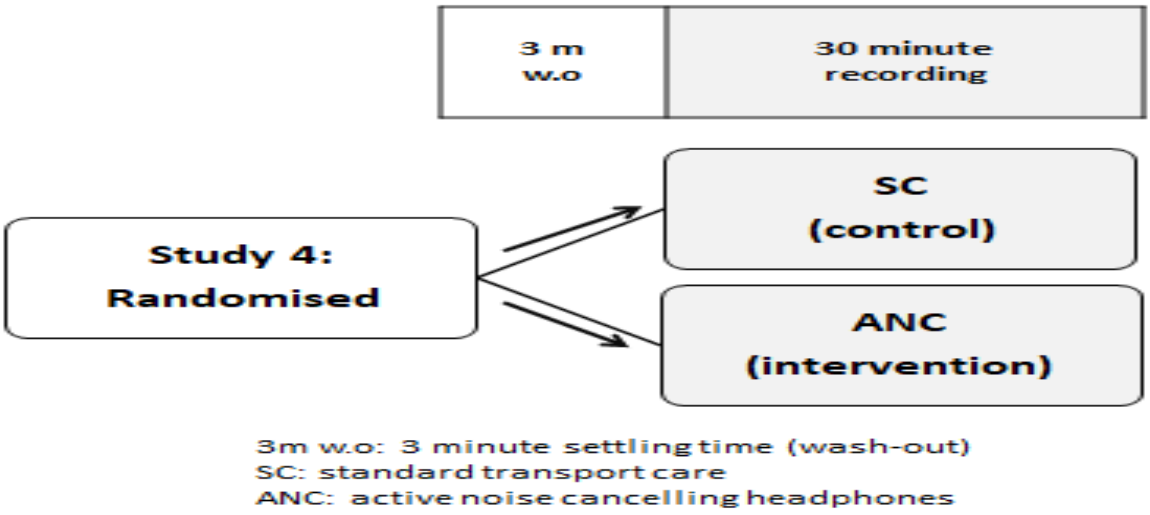

Figure 17: Study 4

Study Arm 5: Noise protection and active noise cancellation during neonatal air ambulance transfers.

The NNTP operate neonatal air ambulance transfers in conjunction with the National Aeromedical Coordination Centre (NACC) and the Irish Air Corps. Distance, criticality, weather and road conditions are factors that influence the decision to transfer neonatal patients via air ambulance. Rotary wing (AW 139 helicopter), fixed wing aircraft (CASA CN235) and the Lear-jet 45 are the range of air ambulance

vehicles that are potentially used; with rotary wing being of most frequently utilised for national or intercounty hospital transfers.

There is limited data on neonatal noise exposure during transport. Older data have been from simulated air transport studies which inform of hazardous noise levels that reach as high as 120 dB(51,52). There have been no data published on neonatal noise exposure in patients in NNTP air ambulance transfers. The baseline study performed at the start of the research allowed for change of practise through escalation of the level of attenuation of exposure in this environment.

This study arm explored the noise attenuation interventions in the Irish Air Corps rotary wing air craft i.e. helicopters that facilitate NNTP air transfers. Patients who required clinically indicated air ambulance transfers conducted by the NNTP were recruited to this study following parental written and informed consent. Patients are then assigned to only one of the following noise reduction interventions (Figure 18):

- Noise protection ear muffs **(NPEM)**
- Active noise cancellation headphones **(ANC)**

A pair of single use sterile headphone covers was applied to avoid cross contamination between patients. All research equipment in contact with patients were cleaned after use. The single noise reduction intervention was maintained throughout the air transfer journey during all flight phases as due to potentially hazardous noise levels during air ambulance transfer. The research team felt that it was potentially unethical to submit patients to an observational trial, apply single layer foam earmuffs or perform crossovers during the air transfers, despite this being the current standard practice for air transfers in NNTP and internationally.

To comply with air transfer safety regulations, the positioning of all research and routine clinical air transport equipment needed to be strictly adhered to. The equipment was securely attached to the air transport rig i.e. trolley. For example, the Svan958A and action camera for video recording was placed securely in the internal aspect of the patient incubator. Therefore, there was limited space to manoeuvre during the recording. The recording of noise levels, physiology, video footage and including the extraction and transfer of data to correlative equipment software was similar to previous prospective patient studies on ground ambulance transfers.

The primary outcome in this study was the mean noise exposure discovered during neonatal air ambulance transfers. An estimated noise exposure level of 90 dBA during road transfer and a reduction to 60dBA when using protective equipment, estimations of sample size required suggest that studying 10 infants per study will be sufficient to demonstrate significant results. However, newborn air transfers happen relatively infrequently in the NNTP service. As data for the more modern equipment in use in the Irish NNTP does not yet exist, it is having been estimated that patients without noise protection would be subjected to SPL >85dBA during air ambulance transfers. In October 2017, airborne electromagnetic testing of our electrical/ electronic research equipment was performed in order to allow its use for the study. We opportunistically measured noise levels and detected peak SPL up to 120 dBA in the transport incubator. Taking in consideration of data from previous studies, an estimated average noise exposure level of >90 dBA during air transfer and a reduction to means of 50-60 dBA when using noise protection, estimated that the sample size required suggests that studying at least 10 infants per study arm was proposed to be sufficient to demonstrate significant results in view of the circumstances. The power calculation as based on the best available evidence on air

transfer noise exposure from the published literature and the levels recorded during electro-magnetic testing of the equipment.

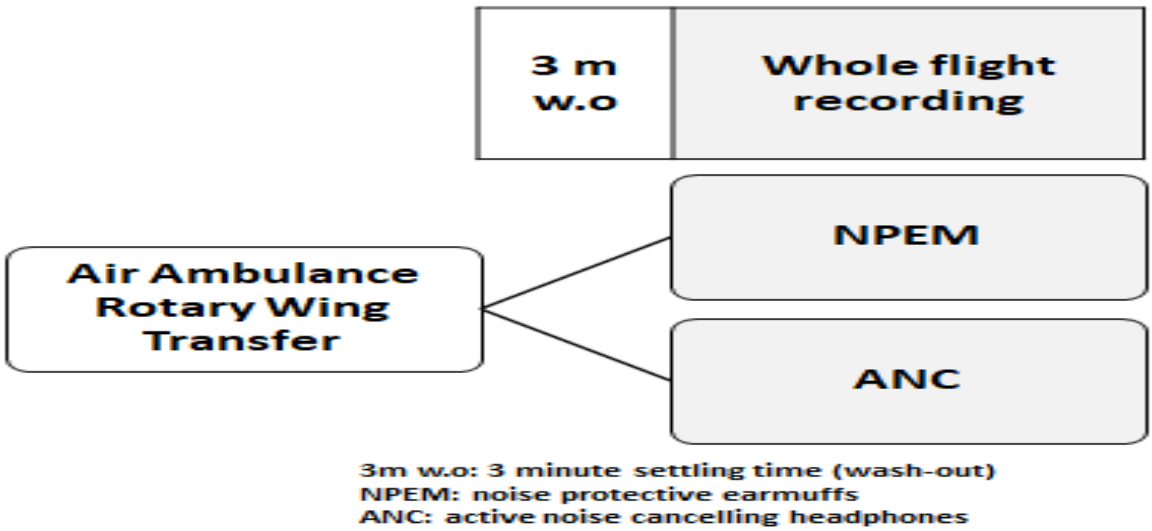

Figure 2.11: Study 5

Neonatal Noise Protection in the Fixed Wing Military Aircraft (CASA CN 235)

Occasionally, NNTP air ambulance transfers will require the use of a fixed wing air craft. Customarily, this modality involves the retrieval of patients internationally to and from specialized tertiary neonatal units overseas. We recruited one case that required the retrieval of a patient from the London, United Kingdom via the Military fixed wing aircraft (Casa CN 235). Following written and informed consent from the parents, the patient was recruited into the research. We applied the noise protective earmuffs (NPEM) throughout the whole return journey. All demographics and

relevant clinical details were documented. The recording of noise levels, physiology, and video footage and including the extraction and transfer of data to correlative equipment software was similar to previous prospective patient studies on ground ambulance transfers. The standard NNTP air transport equipment and clinical care was not disrupted.

Neonatal Noise Protection in the Military Lear jet (Lear jet 45)

Similar to the air ambulance transfers via the fixed wing aircraft, NNTP air ambulance transfers seldom require the use of a jet-stream aircraft for international patient transfers. We recruited one case that required the transfer of a patient to Manchester, United Kingdom via the Irish Air Corp Learjet 45. Following written and informed consent from the parents, the patient was recruited into the research.

The patient was secured in a baby pod due to the size of the jet cabin interior. All demographics and relevant clinical details were documented. We applied the noise protective earmuffs (NPEM) throughout the whole flight. The the recording of noise levels, physiology, video footage and including the extraction and transfer of data to correlative equipment software was similar to previous prospective patient studies on air and ground transport ground ambulance transfers. The standard NNTP air transport equipment and clinical care was not disrupted.

2.13 Summary of study designs

The study components in this research was designed to explore and investigate noise exposure and noise protection that neonatal patients who underwent clinically

indicated interhospital transfer with NNTP. The studies were designed in a pragmatic manner in order to achieve significant results from physiological and non-physiological parameters. The flow-sheet below shows the categories of study components in this research as explained in the previous sections (Figure 19). The next chapter represents results obtained from the studies mentioned.

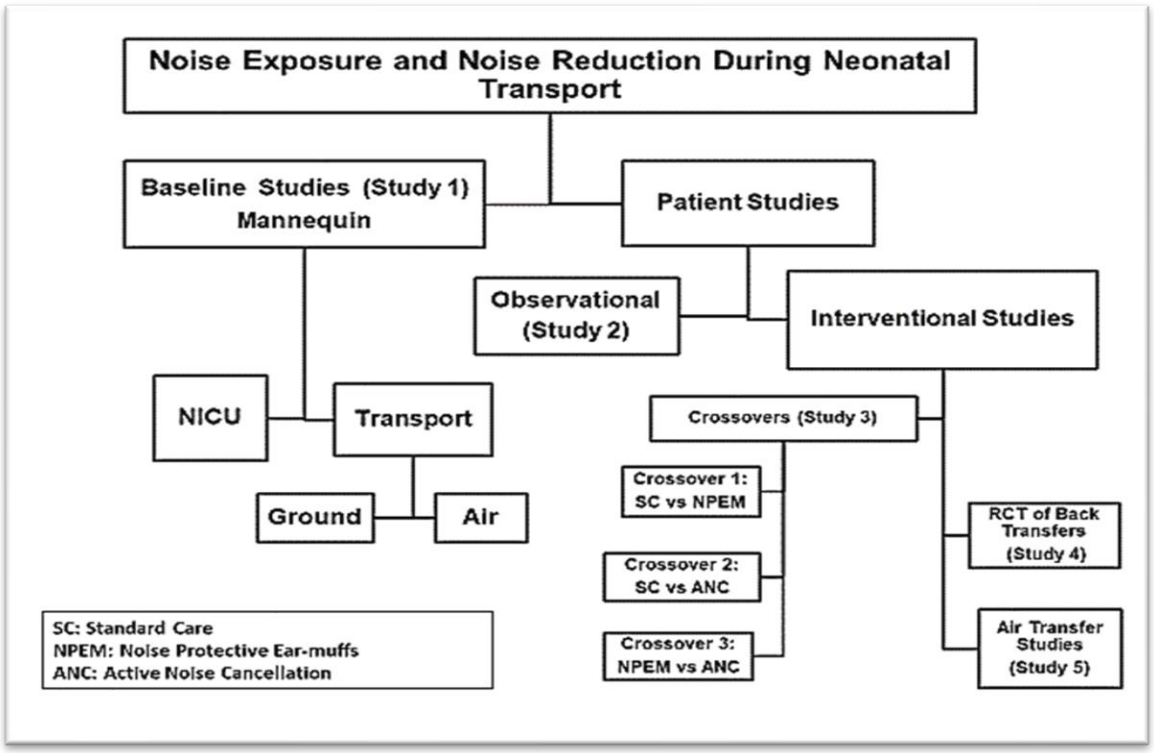

Figure 2.12: Flowsheet of studies

Chapter 3

Results

Recalling the aims and objective of this research, this study involved the quantification of noise levels during neonatal interhospital transfers and investigation of the changes in neonatal physiological and behavioural parameters associated with noise exposure. In addition, I aimed to determine whether noise protective equipment applied during neonatal transfers can reduce noise exposure, and hence lead to greater physiological stability or potentially more comfortable transfers. The research was divided into a mannequin study and patient studies. The **mannequin study** investigated baseline noise levels and noise protection in the NICU and during ground and air transfers. The **patient studies** commenced with observational baseline data during routine neonatal ground transfers of which standard of care did not include noise protection. Noise protection was subsequently applied in crossover studies during neonatal ground ambulance transfers, in a randomised study of neonatal stable repatriation transfers and in an observational neonatal air transfer cohort. I conducted this research in my joint role as neonatal transport clinician and research fellow. I initiated and described the theoretical framework, designed and conducted all the studies and also collected and analysed data for this project. The supervision of this research was provided by a principal investigator and academic supervisor, one primary clinical supervisor and two clinical and academic co supervisors.

The data recording i.e. active conduct of the research commenced on the 15th of September 2017 with the recording of pilot measurements of baseline noise levels and the effectiveness of noise protection on a neonatal **mannequin** in the neonatal

intensive care unit (NICU) and during neonatal ground and air transfers. The first recruitment into a patient study was on the 19th of October 2017 for an observational study that explored the effects of noise exposure to physiological and behavioural parameters in standard neonatal ground interhospital transfers. The interventional phase, i.e. noise protection studies, commenced on 16th January 2018 with the start of crossover studies followed by the randomised study of standard non acute ground transfer. This recruitment was completed on the 3rd of October 2018 with a final recruit in a neonatal helicopter transfer study. The recruitment of neonatal patients into this research was performed by convenience sampling. The researcher was not blinded to the type of study that the patients were enrolled in or to the interventions of noise reduction involved. The figure below is an overview of the timeline of the studies included in the research and the number of patients recruited to each study. (Figure 3.0)

The parents of 67 infants undergoing interhospital transfer were approached regarding recruitment into the research during the time periods mentioned above. One patient was not recruited as consent could not be obtained due to language barrier, i.e. parent could not converse in English. Another parent refused consent due to other unforeseen circumstances. A total of 65 neonatal patients, with clinically indicated interhospital transfers under the NNTP with given parental consent, were recruited in to the research (N=65). 20 patients were recruited in the observational study, a total of 32 patients were recruited into the crossover studies (10 in crossover 1, 10 in crossover 2 and 12 in crossover 3), 7 patients were recruited in the randomised control study and 4 patients were recruited in the helicopter transfer study. The recruitment process for the latter 2 studies (randomised study and air transfer study) is still ongoing. 2 further patients were opportunistically recruited to 2

air transport studies (one in an air transfer in a Lear Jet and the other in a Fixed wing CASA military aircraft).

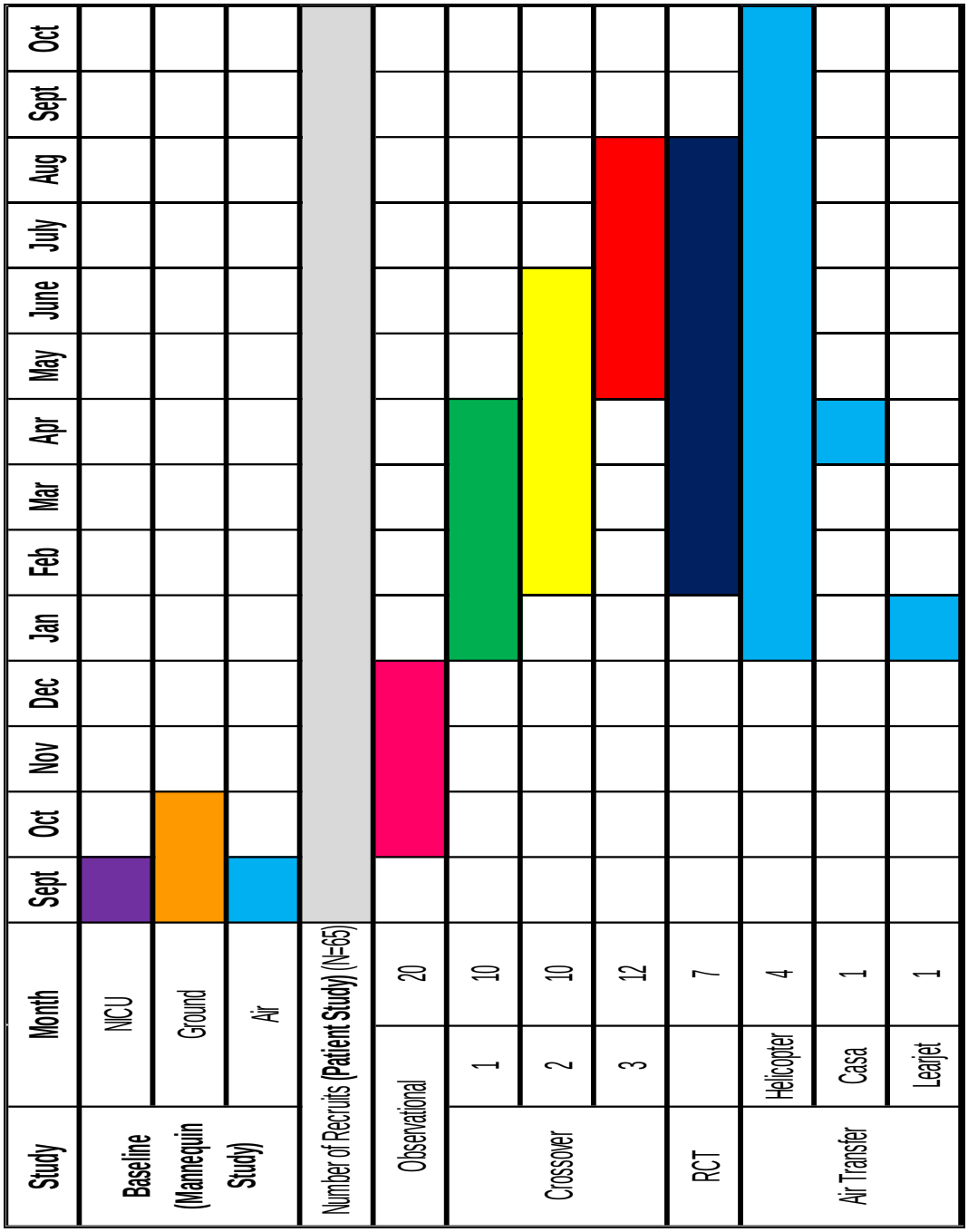

Figure 3.0

3.1 Baseline Noise Levels ï The mannequin study

In order to determine the practicality of using the specialised research equipment and the efficacy of various noise protective equipment; we explored and recorded levels of noise exposure in a NICU and in neonatal interhospital transport environments. This was performed using a neonatal mannequin in an incubator to simulate realistic noise exposure towards to newborn patient in an incubator. The 4-channel sound and vibration level meter were used to measure noise from 3 channel inputs and vibration from one channel as described in Chapter 2: Methodology 2-Equipment.

Throughout all the studies (mannequin and real patients) SPL was measured in 3 positions relative to the neonatal patient in the incubator. Vibration was measured at one position inside the incubator.

Channel 1 (SPL ; microphone): near mannequin ear

Channel 2 (SPL; microphone): inside incubator

Channel 3 (vibration; accelerometer): inside incubator

Channel 4 (SPL; microphone): outside of incubator

The research studies involved measurements of noise as sound pressure levels (SPL), that can be quantified in units of decibel (dB) with varying ‘frequency weighting; for example, ‘A’(dBA), ‘C’ (dBC) or ‘Z’(dBZ). Decibel-A weighted (dBA) was chosen to represent SPL because of its relevance to the response of the human ear to noise. 2 types of SPL were recorded for analysis throughout the whole research; peak SPL (Lpeak) and total sound energy (Leq).

- ¶ Lpeak: (The highest point of the pressure wave, before any time constant is applied)
- ¶ Leq: (An energy average noise level for the period of interest i.e. total sound energy)

Measurements of vibration were obtained with an accelerometer placed in the incubator in a fixed position relative to the mannequin or neonatal patient. Vibration was represented as peak vibration and root mean square (RMS), that are quantified in units of meter per second squared (m/s^2).

With the aim of exploring the effectiveness and feasibility of noise protection equipment use in neonatal patients, we applied 3 types of local noise protection devices on the mannequin; a pair of Natus®Minimuffs ('natus'), a pair of noise protective MRI earmuffs called ems4bubs® ('NPEM) and a pair of active noise cancelling headphones called Bose®QC35 ('ANC).

In order to determine the **level of reduction** from the incubator during standard NICU and transport care and the addition of noise protective devices; we calculated the percentage of noise detected at the mannequin ear (Channel 1) over the external (outside of) incubator noise (Channel 4). The formula for this is demonstrated as:

Percentage of level of reduction (%) = $\frac{\text{[illegible]}}{\text{[illegible]}} \times 100$

As the recommended noise levels should not exceed above 45 dB in the NICU and not more than 60 dB during neonatal transfers, we categorised the noise levels recorded in this baseline study to establish levels of exposure. For the purpose of this

research, the following are the various categories on noise level exposure extrapolated from our data (Table 3.0)

NICU		Transport	
SPL (dBA)	**Noise category**	**SPL (dBA)**	**Noise category**
<45	Recommended limit	<60	Loud / recommended limit
46-60	Loud/ Noisy	61-84	Very Noisy
61-84	Very Noisy	**>85**	**Harmful**
Ó 8 5	**Harmful**		

Table 3.0

3.1.1 Baseline noise levels in the NICU

We obtained SPL measurements from a simulated neonatal patient in an incubator in the NICU. We recorded these levels over period of 3 days in the day time during periods of normal NICU activity i.e. not quiet time. A mannequin was place in an empty incubator located in the middle of the main neonatal intensive care unit. The duration of each recording was approximately 10 minutes each for the 4 noise (protective) environments; standard NICU care (no noise protection application), Natus, NPEM and ANC. I documented the ambient noise level in the NICU environment in relation to the simulated neonatal patient in the incubator in the table below (Table 3.1)

	Peak SPL dBA (Lpeak)			Total SPL (Leq)		
	Ear Channel 1	**Incubator Channel 2**	**NICU Channel 4**	**Ear Channel 1**	**Incubator Channel 2**	**NICU Channel 4**
N	702	702	702	702	702	702
Mean ± SD	61± 4.2	68 ± 4.3	75 ±4.9	45 ±3.3	54 ± 3.1	58 ± 5.6
Maximum	93	96	100	64	69	82
SD: Standard Deviation						

Table 3.1

The mean peak SPL (dBA) detected was 61 ± 4.2 at the ear, 66 ± 4.3 inside the incubator and 75 ± 4.9 outside the incubator i.e. NICU ambient sound. The mean total SPL detected was 45 ± 3.3 at the ear, 54 ± 3.0 inside the incubator and 58 ± 5.6 outside the incubator. The maximum noise level in the incubator in this recording reached to 93 dBA in peak noise (Lpeak) and 64 dBA in total energy (Leq). The figure below represents graphically the mean noise levels (Lpeak and Leq) detected during standard NICU environmental care of the baseline levels experienced by the simulated neonatal patient. (Figure 3.1)

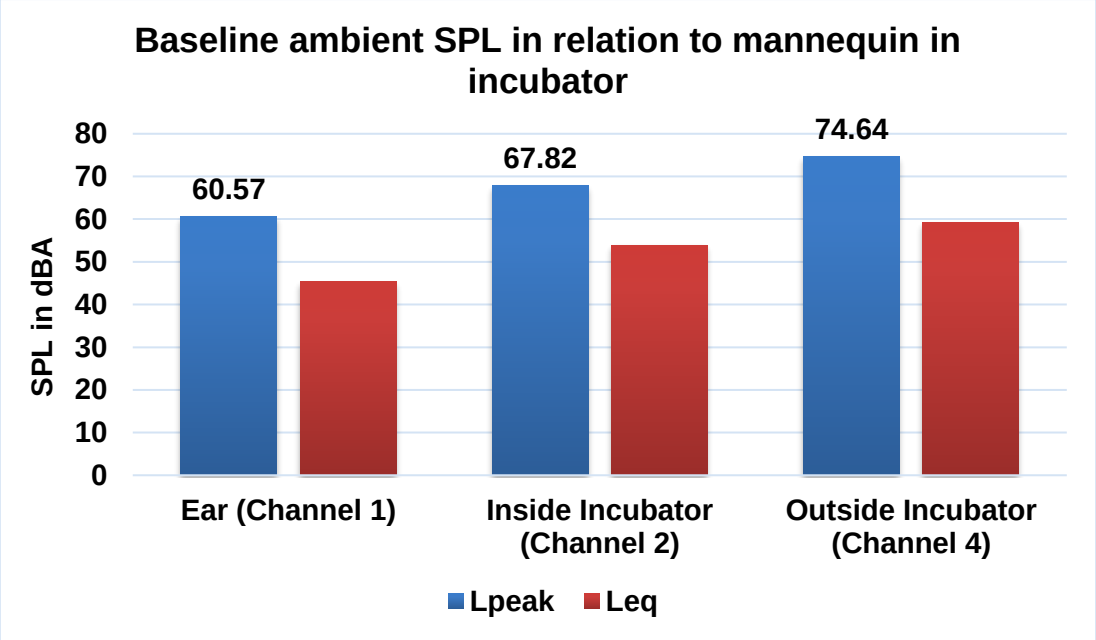

Figure 3.1

The percentage of SPL categories revealed that noise measured from the 3 channels were outside recommended levels in the NICU. Total SPL (Leq) was found to be in recommended levels at the ear 66% of the total recording time. Lpeak sound measured during standard NICU environment was categorised to be 'loud' and 'very loud' from the 3 SPL channels with 6.4% noise in the harmful category (>85dBA) detected from Channel 4 i.e. NICU ambient Noise. Total sound measured (Leq) in this situation revealed noise as 'loud' majority of the recording time from channel 2 (incubator) and channel 4 (NICU). (Figure 3.2)

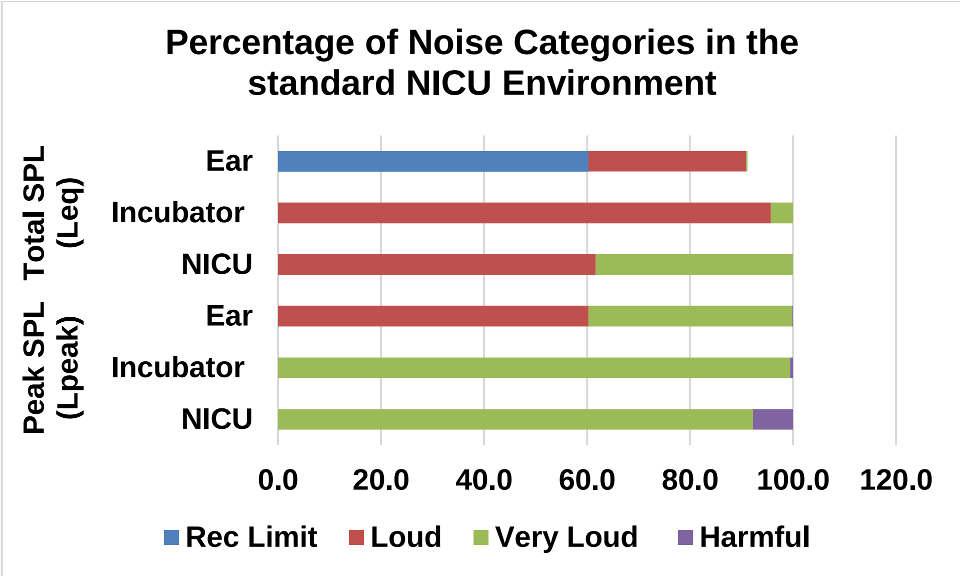

Figure 3.2

It was essential to determine the percentage of noise reduction provided by the incubator wall during standard NICU care. This value was calculated using the formula mentioned:

Percentage of level of reduction (%) = [illegible]

It was discovered from this recording; that the mean incubator noise (channel 2) is 91.2% of the NICU noise in peak dBA (Lpeak) and similarly at 91.3% in total dBA (Leq). This means that the patient in the incubator can potentially pick up 91% of peak and total cumulative SPL (noise) of the outside environment without any other noise protection. (Table 3.2)

Proportion of external NICU sound detected in the incubator (Lpeak and Leq)		
	% incubator/ NICU (Lpeak)	**% incubator /NICU (Leq)**
N	702	702
Mean ± SD	**91± 5.2**	**91.3 ± 5.1**
Maximum	**119**	**108**
SD: Standard Deviation		

Table 3.2

Noise Protective Application in the NICU

We applied 3 types of noise protection to the mannequin ear and compared these with standard NICU care (no protection). The noise protection device applied on the mannequin was (Figure 3.3):

Noise protective device	Abbreviation
No noise protection i.e. standard NICU care	**SC**
Natus®Minimuffs (foam material)	**Natus**
Noise protective MRI earmuffs; ems4bubs®	**NPEM**
Noise cancelling headphones; Bose®QC35	**ANC**

Figure 3.3

SPL was obtained from the simulated neonatal patient during the use of the noise protective devices mentioned above. The table and figure below demonstrate the descriptive statistics of Lpeak and Leq in standard NICU care and with noise protective devices recorded from Channel 1 (mannequin ear). The mean Lpeak SPL

at the ear is 61 ± 4.17 dBA during standard NICU care, 65 ± 7.81 dBA with Natus (higher), 58 ± 2.62 dBA with NPEM and 56 ± 5.17 dBA with ANC. The total sound energy (Leq) detected at is 45 ± 6.26 dBA at the mannequin ear, 50 ± 7.08 dBA with Natus (higher), 43 ± 2.10 dBA with the NPEM and 35± 6.55 dBA with ANC. (Table 3.3)

SPL (dBA) detected from Channel 1 (ear) during standard NICU and with Noise Protection Devices								
	Peak SPL (Lpeak)				**Total SPL (Leq)**			
	SC	**Natus**	**NPEM**	**ANC**	**SC**	**Natus**	**NPEM**	**ANC**
N	702	702	702	702	702	702	702	702
Mean ± SD	**61 ± 4.2**	**65 ± 7.8**	**58 ±2.6**	**56 ± 5.2**	**45 ± 3.3**	**50 ± 7.1**	**43 ± 2.1**	**35 ± 6.6**
Maximum	**93**	**114**	**87**	**112**	**64**	**86**	**70**	**77**
SD: Standard Deviation Natus: Foam ear pads (MiniMuffs) NPEM: Noise Protective Earmuffs ANC: Active Noise Cancellation Headphones								

Table 3.3

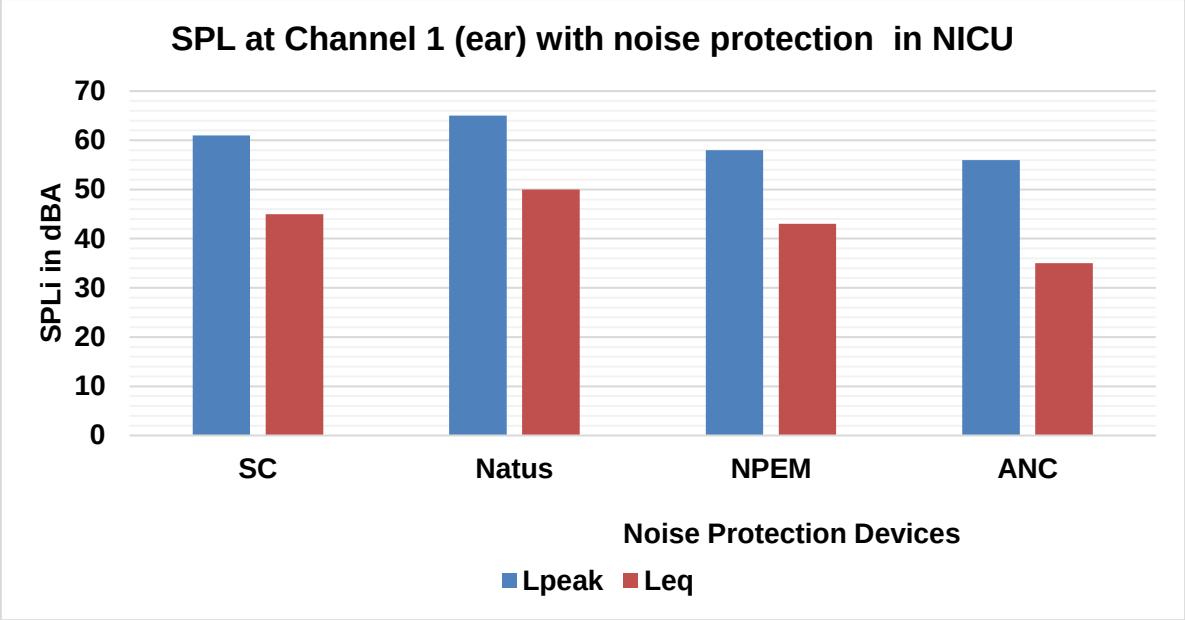

Figure 3.4

A noticeable difference was seen with higher peak and total SPL with the use of Natus compared to the other devices; particularly with standard NICU care i.e. no protection. This was likely due to two probable explanations. Firstly, the amount of activity present in the NICU environment or secondly, the deflection of SPL recorded taking into account the hard surface of the neonatal mannequin. On the other hand, there is an encouraging trend with the use of NPEM and ANC in the NICU which reduced Leq and Lpeak levels detected at the mannequin ear. Therefore, a paired sample t-test was used to calculate the significance of these values of means. We compared mean peak (Lpeak) and mean total (Leq) SPL of standard care with Natus, NPEM and ANC; Natus with NPEM and ANC; and NPEM with ANC which is represented in the table below. (Table 3.4)

N= 702	Peak SPL (Lpeak)		Total SPL (Leq)	
	Mean ± SD	**p-value**	**Mean ± SD**	**p-value**
SC vs Natus	61 ± 4.2 vs 65 ± 7.8	≤0.005	45 ± 3.3 vs 50 ± 7.1	≤0.005
SC vs NPEM	61 ± 4.2 vs 58 ± 2.6	≤0.005	45 ± 3.3 vs 43 ± 2.1	≤0.005
SC vs ANC	61 ± 4.2 vs 55 ± 7.8	≤0.005	45 ± 3.3 vs 35 ± 6.6	≤0.005
Natus vs NPEM	65 ± 7.8 vs 58 ± 2.6	≤0.005	50 ± 7.1 vs 43 ± 2.1	≤0.005
Natus vs ANC	65 ± 7.8 vs 55 ± 5.2	≤0.005	50 ± 7.1 vs 35 ± 6.6	≤0.005
NPEM vs ANC	58 ± 2.6 vs 55 ± 5.2	≤0.005	43 ± 2.1 vs 35 ± 6.6	≤0.005

SD: Standard Deviation
SC: Standard Care
NPEM: Noise Protective Earmuffs
ANC: Active Noise Cancellation

Table 3.4

The paired sample t-test of decibel values in Lpeak and Leq detected at the mannequin ear showed significance in difference of means when Standard Care (SC) was compared with the noise protection modalities i.e. Natus, NPEM and ANC. The calculated percentage of SPL detected at the neonatal mannequin ear compared to the SPL external to the incubator reflected the proportion of capable noise reduction by the noise protective devices applied reminding that the formula used to calculate this is:

Percentage of level of reduction (%) = [illegible]

The following table represents the calculated proportion of noise heard at the mannequin ear in standard care (i.e. no noise protection), with NPEM and ANC compared to the levels detected outside the incubator. (Table 3.5)

	Percentage (%) of SPL (peak dBA-Lpeak) at the external ear with various noise protection interventions compared to NICU SPL				
	N= 702	**SC /NICU**	**Natus/ NICU**	**NPEM/ NICU**	**ANC/NICU**
% Lpeak	**Mean ± SD**	**81 ±4.6**	**91 ± 10.8**	**78.1 ±3.9**	**79± 8.0**
	Maximum	110	164	108	159
% Leq	**Mean ± SD**	**77 ± 3.9**	**90 ± 11.5**	**72 ± 3.6**	**63 ± 11.8**
	Maximum	95	157	113	136
SD: Standard Deviation SC: Standard Care NPEM: Noise Protective Earmuffs ANC: Active Noise Cancellation					

Table 3.5

The percentage of mean peak SPL (Lpeak) detected at the mannequin ear compared to the external incubator SPL (Channel 4-NICU) during this recording was 81.4 ± 4.6% in standard care (SC), 91.2 ± 10.8% with Natus, 78.1 ± 3.9% with NPEM and 79 ± 7.9% with ANC. The percentage of mean total SPL (Leq) detected at the mannequin ear compared to the external incubator SPL during this recording was 76.8 ± 6.9% in SC, 89.6 ± 11.5% with Natus, 71.6 ± 3.6% with NPEM and 62.9 ± 11.8% with ANC. It has been noticed that in this recording in NICU that the Natus ear

foam pads had an increased percentage of detected SPL compared to standard care in both Lpeak and Leq. There was a similar percentage of Lpeak detected with the used NPEM and ANC in this recording. Reassuringly the use of ANC has a distinctly lower percentage of Leq detected compared to NPEM. (Figure 3.5)

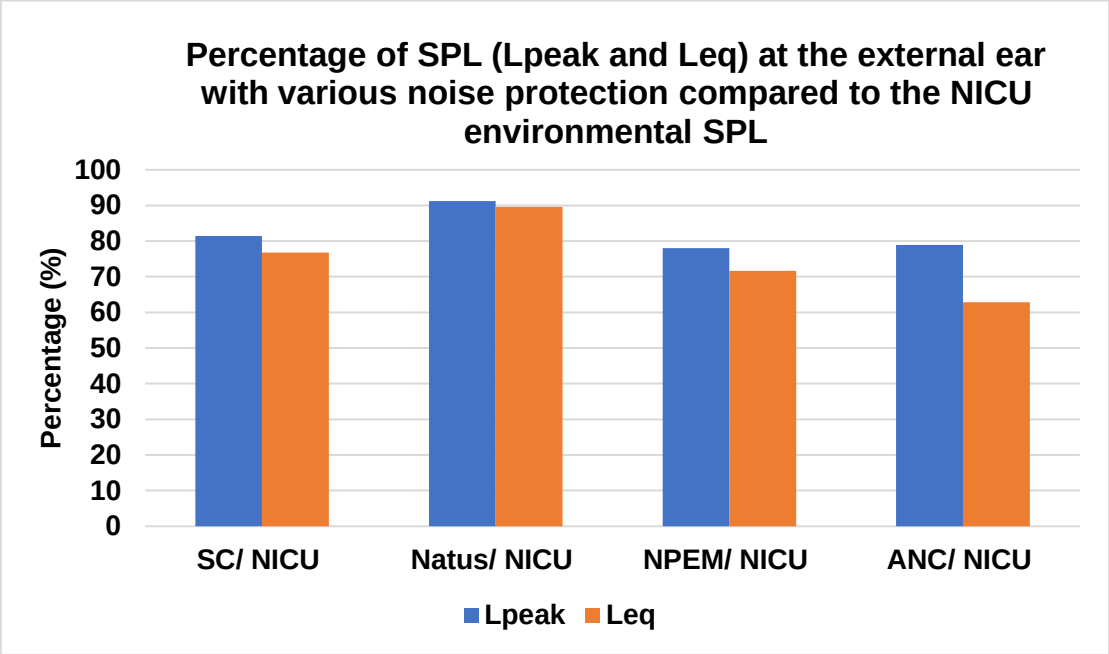

Figure 3.5

The mannequin study on measurement of baseline SPL in the NICU concludes that the noise levels reach above recommended levels in Lpeak and Leq. Noise protective devices reduce the amount of noise exposure to the simulated neonate in the NICU incubator. ANC has the highest noise exposure reduction followed by NPEM. The noise protective devices (NPEM and ANC) evaluated, have reduced SPL exposure at the mannequin ear and was feasible for further evaluation during simulated neonatal ground and air inter-hospital transfers. The research equipment

assembled and used was also effective in the data recording and was further used to evaluate the practicalities in measurements during neonatal transfers.

3.1.2 Results of the Baseline levels of Noise during Neonatal Ground Transfers

The recording of noise levels during simulated neonatal interhospital ground transfers was kept to the similar procedure of assembly of research equipment apart from the transport incubator and trolley. I obtained SPL measurements from simulated neonatal patient in a transport incubator during transfers in a designated ambulance vehicle. I recorded these levels in a period of approximately one month to allow for different types of ground transfer distances e.g. intercity transfers and intercounty (motorway) transfers. A mannequin was placed in the empty transport incubator and the transport trolley was locked securely in the ambulance cabin as per standard clinical practice prior to the commencement of data recording. The duration was approximately 30 minutes per recording for each of the 4 noise (protective) environments. The recorded noise levels of peak SPL (Lpeak) and total SPL (Leq) during standard neonatal ground hospital transfers are represented in the table below (Table 3.6)

	Peak dBA (Lpeak)			**Total dBA (Leq)**		
	Channel 1 (Ear)	**Channel 2 (Incubator)**	**Channel 4 (Ambulance)**	**Channel 1 (Ear)**	**Channel 2 (Incubator)**	**Channel 4 (Ambulance)**
N	1782	1782	1782	1782	1782	1782
Mean ± SD	**70 ± 7.8**	**77 ± 6.6**	**83 ± 6.1**	**53 ± 5.7**	**62 ± 5.3**	**± 5.9**
Maximum	**103**	**118**	**100**	**73**	**83**	**82**

Table 3.6

The SPL recorded in the neonatal transport environment during the recording period has highlighted that mean Lpeak was **70 ± 7.8** dBA at the ear, **77 ± 6.6** dBA in the incubator and **83 ± 6.1** dBA in the ambulance cabin. The maximum SPL Lpeak in the neonatal transport environment is overall above 100dBA from all 3 channels. The total sound energy measured (Leq)was **53 ± 5.7** dBA at the ear, **62 ± 5.3** in the incubator and **67 ± 5.9** dBA in the ambulance cabin. The maximum Leq reached from all 3 channels in the transport environment from our recording was above 70dBA, above recommended safety limits in neonatal transport.

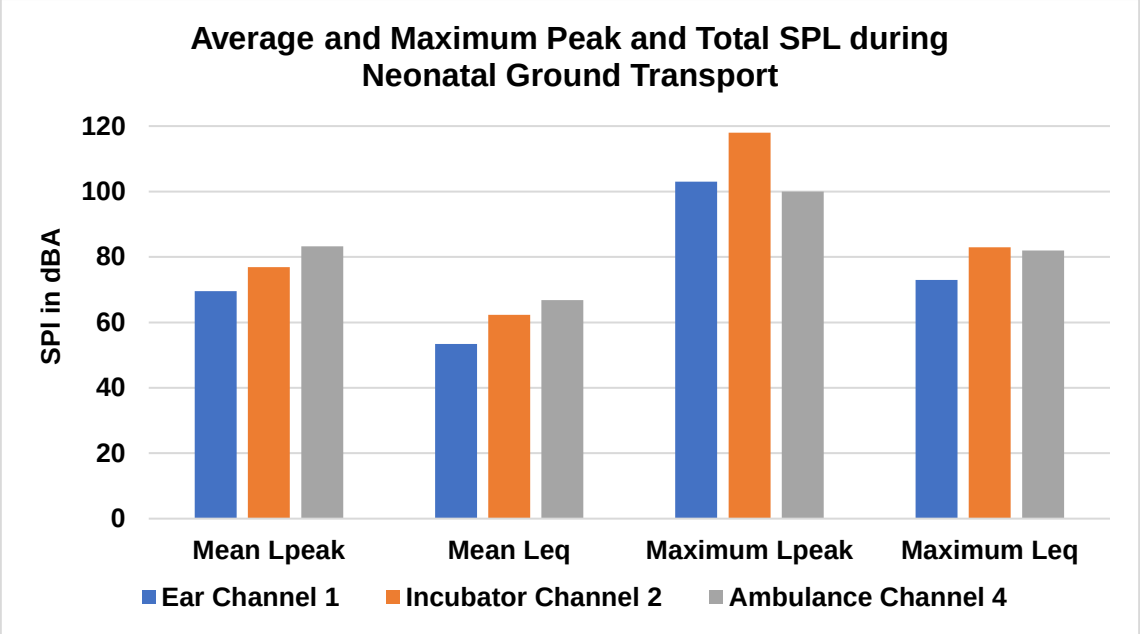

Figure 3.6

The figure above represents the mean and maximum SPL detected from the 3 channels. What was noticeable is the maximum Lpeak reached was louder in the incubator compared to the maximum Lpeak reached in the ambulance cabin. This leads to concerns as to what actually happens to in sound propagation in the neonatal transport incubator.

The percentage of recordings falling within each of the noise categories (Table 3.0) showed that the transport environment in Peak SPL (Lpeak) was in the 'Very Loud' category in more than 50 % of the recording. Total SPL (Leq) were in the harmful range more than 50% of measurements in the incubator (channel 2) and the ambulance cabin (channel 4)

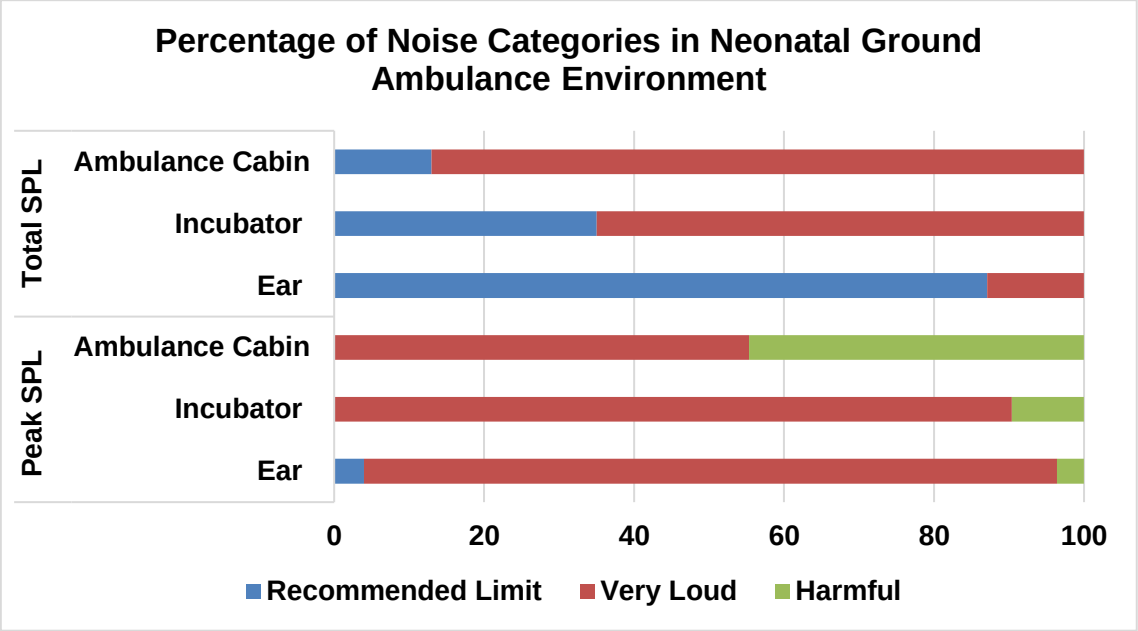

Figure 3.7

Noise Protective Equipment in Neonatal Ground Transport

I applied 2 types of noise protection to the neonatal mannequin ear and compared these interventions with standard NNTP ground transfer care (i.e. no protection). The noise protection devices applied on the mannequin was:

Noise protective device	Abbreviation
No noise protection i.e. standard NICU care	**SC**
Noise protective MRI earmuffs; ems4bubs®	**NPEM**
Noise cancelling headphones; Bose®QC35	**ANC**

Figure 3.8

The mean SPL Lpeak (dBA) detected at the mannequin ear during neonatal transport was 70 ± 7.6 in **SC**, 72 ± 7.8 with **NPEM** and 60 ± 4.0 with **ANC**. In the same recording, the mean total SPL Leq (dBA) at the ear was 53 ± 5.7 in **SC**, 58 ± 5.5 with **NPEM** was applied and 45 ± 3.4 with **ANC**. Both noise protection devices reduced total noise energy exposure (Leq) to recommended SPL limits during neonatal transport while mean peak SPL detected with the use of ANC was at recommended transport limit i.e. 60±0.01 dBA. (Table 3.7, Figure 3.9)

SPL in dBA during standard neonatal (SC) transport and with Noise Protection Devices (NPEM and ANC)						
	Peak SPL Lpeak			**Total SPL Leq**		
N=1782	**SC**	**NPEM**	**ANC**	**SC**	**NPEM**	**ANC**
Mean ± SD	**70 ± 7.6**	**72 ± 7.8**	**60 ± 4.0**	**53 ± 5.7**	**58 ± 5.5**	**45 ± 3.4**
Maximum	**103**	**109**	**104**	**73**	**81**	**73**

SD: Standard Deviation
SC: Standard Care
NPEM: Noise Protective Earmuffs
ANC: Active Noise Cancellation

Table 3.7

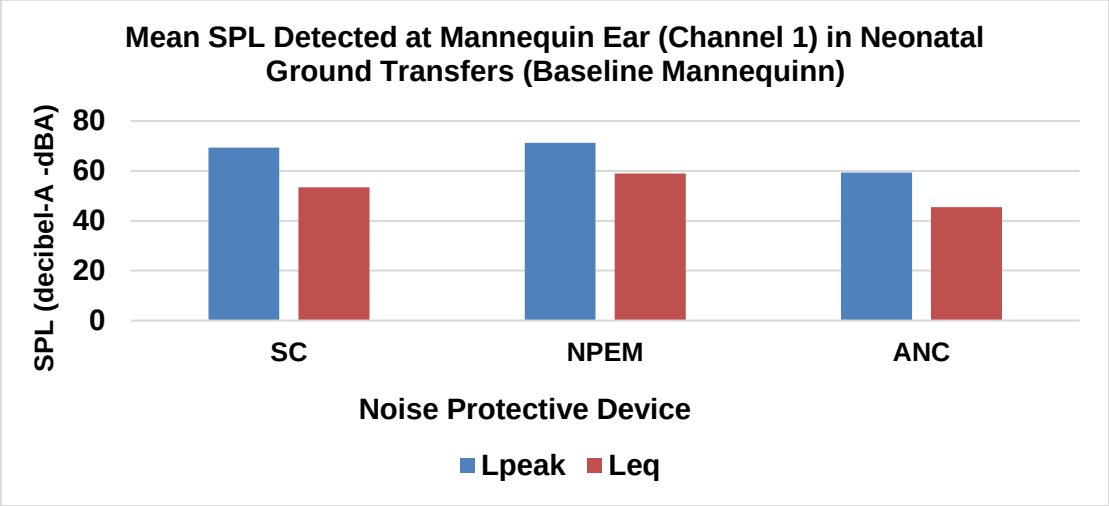

Figure 3.9

Paired sample t-tests were used to calculate the significance of the value of means between standard transport care (SC) with NPEM and ANC. The comparison of means in Lpeak and Leq detected at the mannequin ear showed significance in difference when SC was compared with NPEM and ANC and when NPEM was compared with ANC. (p< 0.005).(Table 3.8)

N= 702	Lpeak		Leq	
	Mean ± SD	**p-value**	**Mean ± SD**	**p-value**
SC vs. NPEM	70 ± 7.6 vs 72 ± 7.8	**Ò 0 . 0**	53 ± 5.7 vs 58 ± 5.5	**Ò 0 . 0**
SC vs. ANC	70 ± 7.6 vs 60 ± 4.0	**Ò 0 . 0**	53 ± 5.7 vs 45 ± 3.4	**Ò 0 . 0**
NPEM vs ANC	72 ± 7.8 vs 60 ± 4.0	**Ò 0 . 0**	58 ± 5.5 vs 45 ± 3.4	**Ò 0 . 0**

Table 3.8

I calculated percentage of SPL detected at the neonatal mannequin ear during neonatal transfers compared to the SPL external to the incubator as this reflected the proportion of capable noise reduction by the noise protective devices applied. I used the previous formula of:

Percentage of level of reduction (%) = [illegible]

The percentage of mean peak SPL Lpeak in the ambulance cabin compared to the mannequin ear was 84 ± 8.7% in SC, 86± 8.2% with NPEM and 73± 8.6% with ANC during neonatal ground transfers. The percentage of mean total SPL Leq for this was 77 ± 10.66% in SC, 82 ± 6.1% with NPEM and 69± 9.6 % with ANC. The application of ANC showed reduced proportion of external ambulance noise exposure detected at the mannequin ear for both Lpeak and Leq.

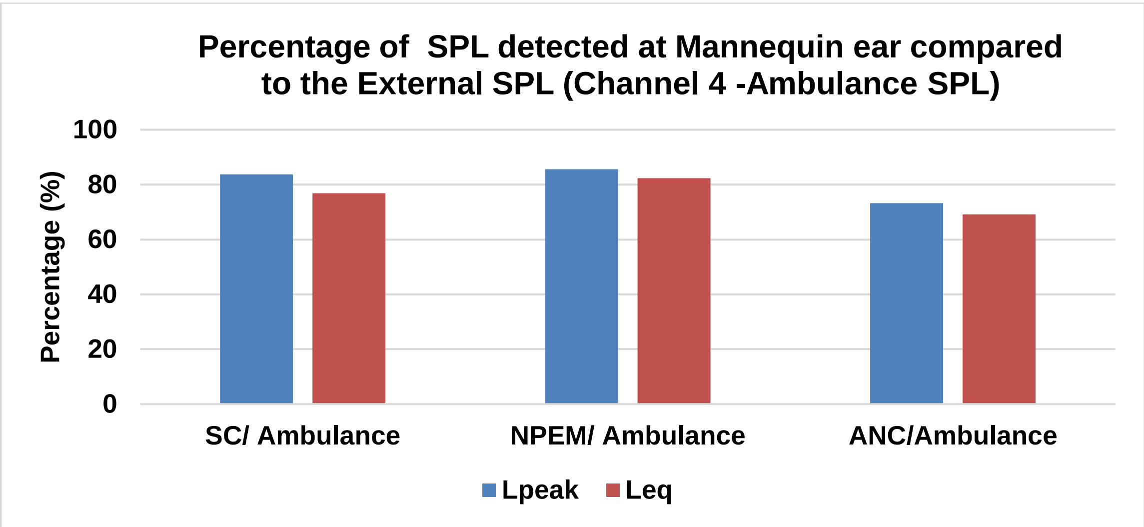

Figure 3.10

The mannequin study on measurement of baseline SPL in neonatal ground hospital transfers showed that the noise levels reached above recommended levels in peak and total SPL. The noise protective devices (NPEM and ANC) evaluated, have reduced SPL exposure at the mannequin ear and were feasible to use for further evaluation during simulated neonatal ground and air interhospital transfers. However, there was an increased SPL level in the use of NPEM compared to standard in mean SPL values and hence the higher proportion of ear SPL (channel 1) detected compared to ambulance cabin SPL levels (channel 4). Therefore, I question reflective and absorbable quality of the neonatal mannequin being used. The research equipment assembled and used was effective in the data recording during neonatal transfers. I then progressed the recording into the next phase and obtained baseline SPL levels during neonatal air transfers.

3.1.3 Results of the Baseline levels of Noise during Neonatal Air Transport

SPL levels in air transfers was measured in a simulated neonatal transfer during the standard in-flight electro-magnetic testing of all research equipment being used for the noise exposure and noise protection. The recording activity of baseline SPL and vibration levels was also facilitated by the Irish Air Corp. The 4-channel sound and vibration meter was assembled; Svan958A® and relevant channels in position relative to the air transport incubator and trolley, in accordance to the Irish Air Corps flight rules and regulations. Any loose research equipment was hand held by the research team through-out the flight.

SPL and vibration recording were performed in a rotary wing (helicopter) military air craft EC 139. Similar to previous simulated recordings, a neonatal mannequin was

placed securely in the air transport incubator. I recorded SPL from 3 channels in relation to the mannequin, i.e. channel 1 (mannequin ear), channel 2 (inside transport incubator) and channel 4 (helicopter cabin). Channel 3 was used for recording of vibration which will be discussed in a further section of this chapter. The constraints of in-flight protocols on movement, limited opportunities to access the mannequin or research equipment while airborne. Each recording in standard and noise protective environments lasted approximately 30 minutes. Channel 1 corresponded to the SPL at the mannequin ear, channel 2 was the SPL recorded in the transport incubator and channel 4 detected SPL outside of the transport incubator which represented the SPL in the helicopter cabin. The recorded noise levels of peak SPL (Lpeak) and total SPL (Leq) during standard neonatal helicopter transfers are represented in the table below i.e. before the application of noise protection on the mannequin. (Table 3.9)

Baseline SPL (total and peak) in Neonatal Helicopter Transfer in dBA						
	Peak SPL (Lpeak)			**Total SPL (Leq)**		
N=1652	**Ear (SC) Channel 1**	**Incubator Channel 2**	**Cabin Channel 4**	**Ear (SC) Channel 1**	**Incubator Channel 2**	**Cabin Channel 4**
Mean	**98 ± 9.2**	**98 ± 14.6**	**86 ± 5.6**	**86 ± 9.7**	**86 ± 14.4**	**74 ± 4.8**
Minimum	81	62	67	70	48	55
Maximum	**116**	**126**	**127**	**103**	**103**	**93**

Table 3.9

The overall mean SPL in peak and total for neonatal air transfers in the helicopter exceeded recommended SPL thresholds (> 60 dBA) during transport. The mean

Peak SPL was 98 ± 9.2 dBA at the mannequin ear, 98 ± 14.6 dBA in the incubator and 86 ± 5.6dBA in the ambulance cabin. The total energy of SPL in this recording was 86 ± 9.7dBA at the ear, 86 ± 14.4dBA in the incubator and 74 ± 4.8 dBA in the ambulance cabin. (Figure 3.11) An astonishing observation of the lower Lpeak and Leq SPL in the helicopter cabin in comparison to the corresponding levels from the mannequin ear and air transport incubator has led to the consideration of whether several internal and external factors led to the amplification in SPL detected in the 2 internal incubator channels. On the other hand, this amplification was also likely due to the high levels of physical vibration transmitted during helicopter transfers to surrounding equipment which led to the amplification of sound.

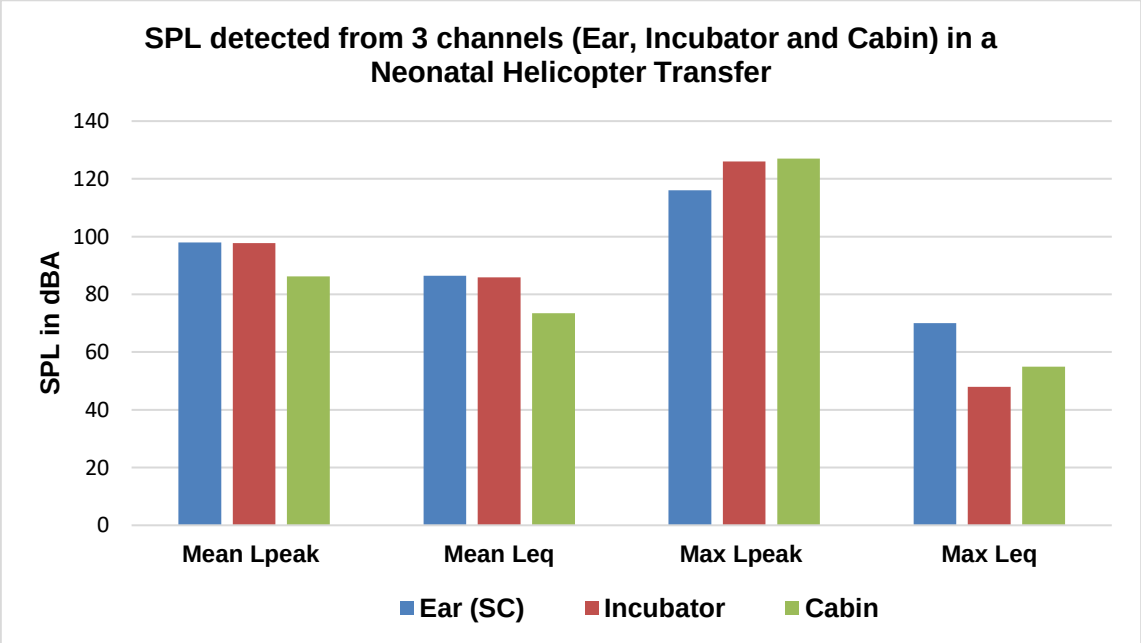

Figure 3.11

Similar to previous baseline level measurements (NICU and ground transfers), the recordings were divided according to SPL category of exposure (acceptable, very loud and harmful). (Table 3.0) The percentages of SPL measurements in each category are represented by the figure below. This showed that in the helicopter environment, harmful levels of >85 dBA were detected in the majority (>75%) of recording of Lpeak and the mannequin was exposed to 'very loud' total SPL levels with very episodes below the recommended limit.(Figure 3.12)

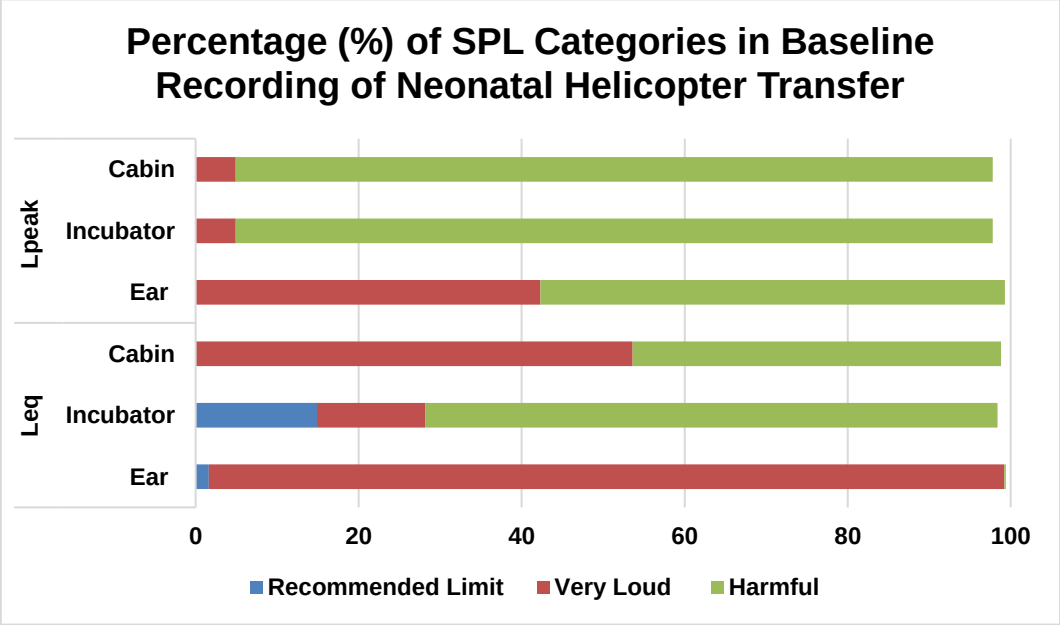

Figure 3.12

SPL in Different Phases of the Helicopter Flight Transfer

Due to the nature of extremely harmful acoustic pressure in the aviation industry I correlated our recording of baseline SPL levels of Lpeak and Leq during the different phases of the helicopter flight. An example of these flight phases with the corresponding recorded SPL Lpeak and Leq is represented in the figure below. The

x-axis represented time and the y-axis represented acoustic pressure i.e. SPL as demonstrated in Figure 3.13 below.

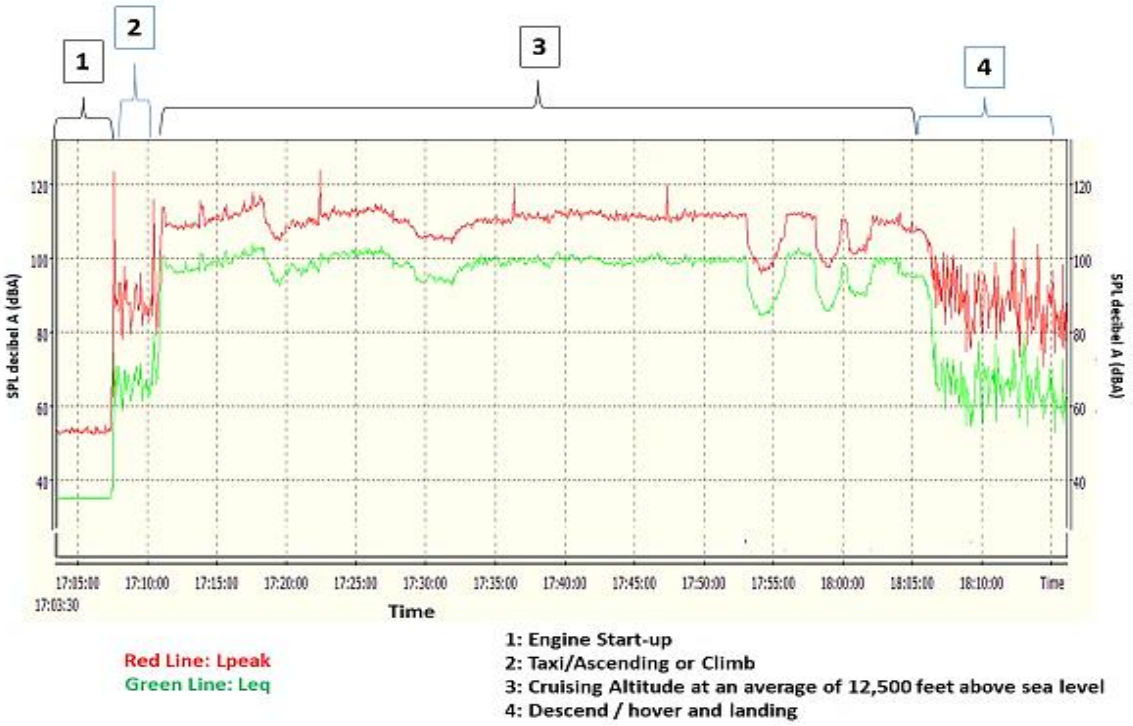

Figure 3.13

Noise Protective application in Neonatal Helicopter transfers.

I applied 2 types of noise protective devices to the mannequin as stated below:

Noise protective device	**Abbreviation**
No noise protection i.e. standard NICU care	**SC**
Noise protective MRI earmuffs; ems4bubs®	**NPEM**
Noise cancelling headphones; Bose®QC35	**ANC**

The SPL measurements was also recorded from the helicopter crew (military headset/ helmet) for comparison with SPL recorded from noise protective devices applied to the neonatal mannequin.

Comparison of SPL in decibel-A (dBA) during Neonatal Helicopter Transfers Detected at the Ear and with other Noise Protective Devices

	Peak SPL (Lpeak)				**Total SPL (Leq)**			
N=1652	Ear SC	NPEM	ANC	CH	Ear SC	NPEM	ANC	CH
Mean ± SD	**86 ± 5.6**	**82± 5.4**	**67 ± 10.3**	**92 ± 7.7**	**74± 4.8**	**71 ± 5.6**	**51 ± 12.3**	**78 ± 6.2**
Minimum	67	63	52	62	55	52	31	50
Maximum	**127**	**94**	**105**	**116**	**93**	**82**	**77**	**90**

SD: Standard Deviation
SC: Standard Care
NPEM: Noise Protective Ear muffs
ANC: Active Noise Cancellation
CH: Crew Headset

Table 3.10

It is important to remind us that the human perception to noise levels is calculated logarithmically (based on powers of 10). For example, an increase of 3 dBA doubles the sound intensity and an increase of 10dBA will be perceived as twice the loudness. Therefore, a small increase of decibel will represent a large increase in intensity. In these recording scenarios, peak SPL (Lpeak) measured in units of decibel A (dBA) was 86 ± 5.6 at the mannequin ear with no noise protection, 82 ± 5.4 with NPEM, 67 ± 10.3 with ANC and 91 ± 7.7 in the crew headset. The total sound energy SPL (Leq) was 74 ± 4.8 with no noise protection at the ear, 71 ± 5.6 with NPEM, 51 ± 12.3 with ANC and 78 ± 6.2 with crew head set. NPEM and ANC were

effective in reducing noise exposure in peak and total sound. ANC displayed a marked reduction of total noise energy (Leq). Both SPL (Lpeak and Leq) that was detected from the military crew head set was higher than standard care, ANC and NPEM. This was due to increased in-flight communication between cabin crew via the military headsets and hence increases acoustic pressure (SPL levels). Lastly, it was essential to make a calculative comparison of mean SPL between these noise protective interventions. (Figure 3.14)

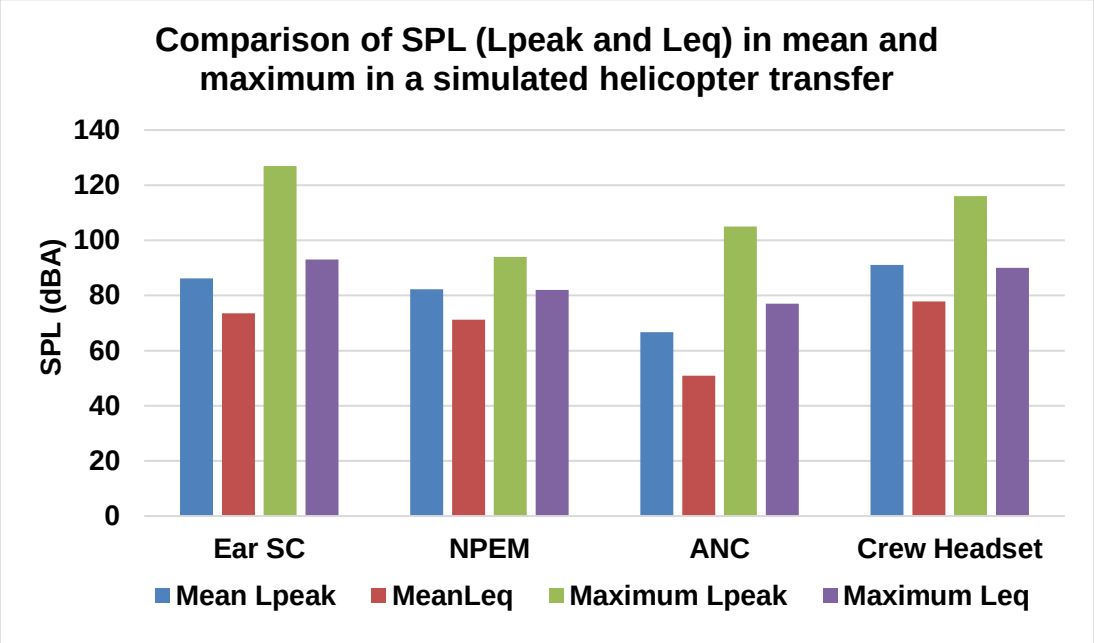

Figure 3.14

An independent sample t-test was used to compare mean SPL (Lpeak and Leq) detected at the ear using NPEM, ANC and Crew Headset (CH). The difference of mean SPL levels detected between these 3 interventions was significant in the recordings of this cohort of the study ($p<0.05$) (Table 3.10).

	Peak SPL (dBA)		Total SPL (dBA)	
N= 702	**Mean ± SD**	**p-value**	**Mean ± SD**	**p-value**
SC vs NPEM	86± 5.6 vs 82± 5.4	≤0.005	74 ± 4.8 vs 71 ± 5.6	≤0.005
SC vs ANC	86± 5.6 vs 67± 10.3	≤0.005	74 ± 4.8 vs 51 ± 12.3	≤0.005
SC vs CH	86± 5.6 vs 91± 7.7	≤0.005	74 ± 4.8 vs 78 ± 6.2	≤0.005
NPEM vs ANC	82± 5.4 vs 67± 10.3	≤0.005	71 ± 5.6 vs 51 ± 12.3	≤0.005
NPEM vs CH	82± 5.4 vs 91± 7.7	≤0.005	71 ± 5.6 vs 78 ± 6.2	≤0.005
ANC vs CH	67± 10.3 vs 91± 7.7	≤0.005	51 ± 12.3 vs 78 ± 6.2	≤0.005

SD: Standard Deviation
SC: Standard Care
NPEM: Noise Protective Ear muffs
ANC: Active Noise Cancellation
CH: Crew Headset

Table 3.10

Similar to baseline NICU and neonatal ground transfers, the percentage of ambulance cabin SPL detected at the neonatal mannequin ear during neonatal transfers reflected the noise reduction capability of the noise protective devices applied in clinical practice. I calculated the percentage of external noise (Peak and Total SPL) that was picked up near the ear and presented this as the proportion of ear versus cabin noise using the previous formula:

Percentage of level of reduction (%) = SPL incubator (dBA) ÷ SPL outside (Cabin) x 100

The percentage of cabin SPL (peak and total SPL) detected at the mannequin ear demonstrated that ANC and NPEM were both effective in reducing peak noise and

even more effective in reducing background noise i.e. total SPL. However, I would like to highlight that there were episodes in the recording where maximum percentage of cabin noise detected at the mannequin ear reached above 100%. The highest maximum percentage reached was without using noise protection i.e. 138% Lpeak and 127% in Leq. . (Figure 3.15)

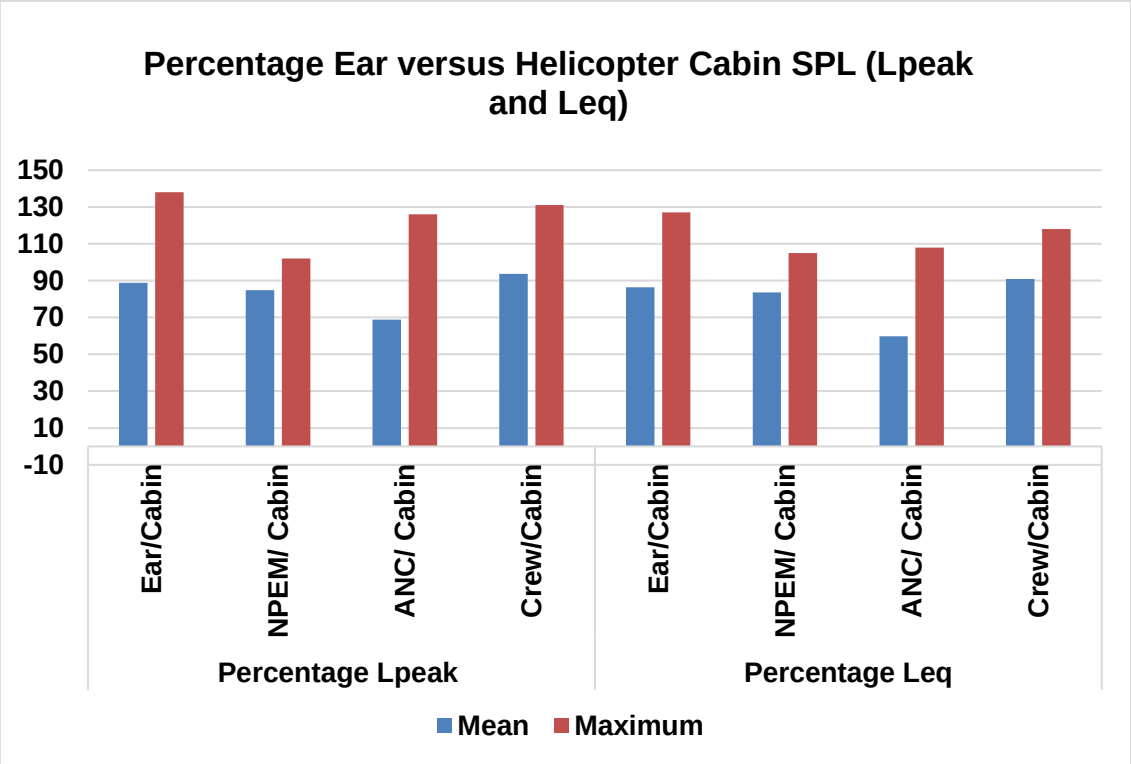

Figure 3.15

The results on baseline measurements of SPL during neonatal helicopter transfers revealed harmful levels detected from all 3 channels and also in the crew military headset. Similar to NICU and ground transport baseline levels, noise protective devices ANC and NPEM applied on the mannequin reduced noise exposure at the ear. However, even with the degree of reduction that these devices can offer, SPL levels detected was still in the 'very loud' or 'harmful' range in the majority of the

recording period. Active noise cancellation was the most effective device in reducing SPL levels, particularly in the total sound energy range (Leq).

3.1.4 Vibration during neonatal transport and its association to noise levels recorded; a crude observation.

Measurements of vibration was not the aim of the overall research but rather an essential element to report in relation to our overall findings. As I did not measure the implications of vibration to the neonatal patient's physiological and behavioural response, the results of vibration were kept at a baseline, observational outlook. Vibration was measured using Channel 3 of Svan 958A and an accelerometer that functioned as the vibration receptor (i.e. a microphone analogue to the Sound Level Meter) was place in a safe location in a vicinity near to the neonatal mannequin (surface of the mattress in the transport incubator).

As previously described in the introductory chapters, the propagation of sound involves the transmission of particles to oscillate to withing 20 –20,000 Hz in order to be perceived in the human hearing frequency range. These are vibratory components that propagate sound. Therefore, any liquid solid or gas particle that vibrate can potentially allow for the transmission of sound to the human ear hence any additional vibration potentially amplifies sound pressure levels in the environment. Like noise, vibration is therefore also considered a stressor in the neonatal transport environment. In occupational health, the vibration exposure limit value (ELV) is the maximum daily level (8-hour period) of vibration an employee maybe exposed to is 5 ms^{-2} in 'Hand Arm Vibration' and 1.15 ms^{-2} 'Whole Body Vibration'.

The table below represents median and range SPL and vibration in 4 environments i.e. NICU, ground transport, helicopter transfers and Fixed wing aircrafts. (Table 3.11) Median peak vibration in m/s^2 was 0.2 in NICU, 1.2 during ground transport , 1.4 during helicopter transfers and 0.9 in fixed wing transfers. Maximum peak vibrations were recorded at 21.38 m/s^2 during ground transport and 62 m/s^2 fixed wing aircraft transfers is currently of great concern. Although the expected results of calculating RMS (root mean square) of vibration in the 4 environmental scenarios lower; the maximum RMS of vibration was high in ground transport and also during fixed wing aircraft transfers.

Median and Range	**SPL (Lpeak) in dBA**		**Vibration Peak (m/s^2)**	**SPL Total (Leq) in dBA**		**Vibration RMS (m/s^2)**
Environment	Incubator	Cabin		Incubator	Cabin	
NICU	67 (62-100)	74 (66-92)	**0.2 (0.13- 0.45)**	53 (49-76)	60 (54-76)	**0.05 (0.03-0.13)**
Ground Transport	76 (66-100)	84 (65-98)	**1.2 (0.19-21.38)**	61 (54-79)	66 (53-78)	**0.3 (0.05-3.76)**
Rotary Wing (Helicopter)	95 (70-110)	105 (67-122)	**1.4 (0.14-2.6)**	83 (59-93)	93 (49-105)	**0.44 (0.03-0.75)**
CASA Fixed wing (N=602)	79 (57-120)	96 (91-114)	**0.9 (0.32-61.66)**	71 (42-91)	85 (80-102)	**0.3 (0.10 -2.11)**

Table 3.11

It was important, in this component of the research to understand the impact of vibration forces toward sound. Therefore, I combined the recording times of simultaneous SPL and vibration in the 4 different environments mentioned. The increase in peak vibration somewhat reflects higher levels of peak SPL. Although the measurement of vibration in this study was a crude recording i.e. dependant on the placement of the accelerometer during the recording phase, the figure below

demonstrates 2 dramatic correlations between SPL and vibration peaks during ground transport and during fixed wing aircrafts. (Figure 3.16)

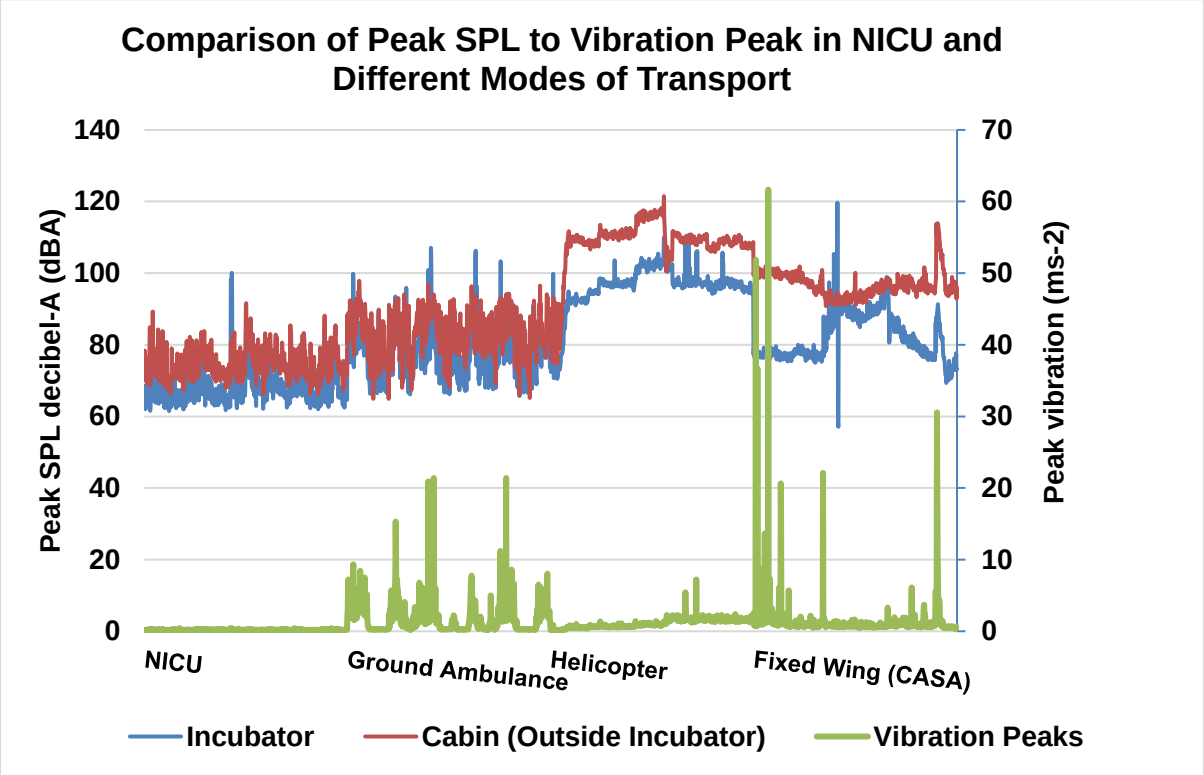

Figure 3.16

The information from baseline noise levels measured in SPL in NICU, neonatal ground and air ambulance transport provided support for progress to patient studies. The following sections will report on patient studies beginning with observational data on physiological responses to noise levels during interhospital transfers.

3.2 Results of Noise Exposure and Noise Reduction : The Patient Studies

The neonatal patient component of this project comprised a series of short prospective studies. As previously discussed in the methodology chapters, these studies involved simultaneous and continuous measurement of 3 main monitoring systems:

1. Noise levels (SPL) with SVAN 95A in similar configuration to the baseline studies. (figure)
2. Pulse oximetry recorded the neonatal heart rate (beats per minute) and percentage of blood oxygen saturation level (%).
3. An action camera (GoPro®) recorded the neonatal patient in the transport incubator for further behavioural scoring by 4 nominated examiners.

The prospective patient studies commenced with an observational cohort of neonates who underwent clinically indicated NNTP interhospital transfers. The interventional studies that subsequently followed involved comparing standard care (without noise protection) with the application of one of two noise protective devices (Noise protective earmuffs -NPEM and active noise cancelling headphones- ANC) in a series of crossover studies, a randomised control study during stable ground transfers and an observational study on noise protection during air transfers.(Figure 3.17)

This section outlines the results of each study , presenting both sound pressure level reduction, the associated physiological measurements during standard care and the use of noise protective devices during neonatal transport.

A separate section in this chapter investigated the behavioural responses of patients during the transfer using a validated behavioural scoring system (NIPS) assessed by experienced neonatal examiners. (72,73)

Overall Demographics of the Patient Studies

The recruitment of patients into the series of prospective research studies commenced in January 2018 and ran until October 2018. A convenience sample of patients was recruited depending on availability of the research team. The parents of 68 neonatal patients who underwent clinical indicated neonatal interhospital transport with the NNTP during this period were approached for consent for recruitment of their newborn infant into the studies. One parent could not provide consent due to language barriers. Two patients were not recruited, as their parents did not give consent. Through convenience sampling 20 patients were recruited into an observational study and 45 patients were recruited to interventional studies. 32 patients were recruited into a series of 3 crossover studies which compared standard ground transport care, the application of NPEM and the application of ANC. 7 patients were recruited into a randomised control study that compared standard care with the application of ANC. A total of 6 patients were recruited into a study involving neonatal air ambulance transfers; 4 of these patients were recruited in the comparison of the application between NPEM and ANC in single journey air transfers. One patient was transferred via a Lear Jet and therefore levels of noise was recorded using NPEM. One patient was transferred via Fixed wing CASA aircraft and SPL data was also obtained from the application of NPEM.

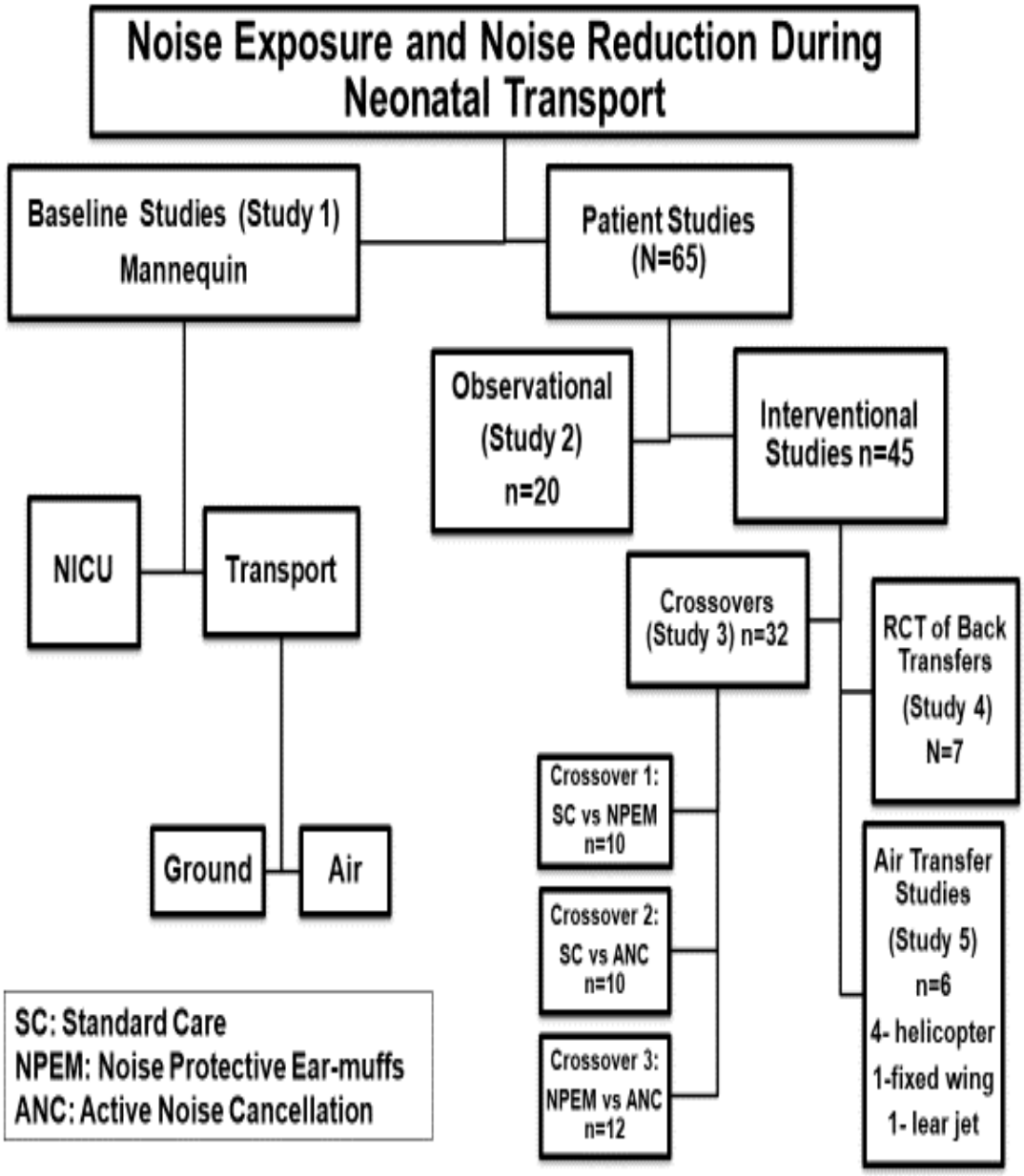

Figure 3.17

The parents of patients who underwent clinical indicated neonatal interhospital transfer under the NNTP were approached for consent prior to recruitment. The patients were recruited through convenience sampling once they have met inclusion criteria and the researcher, who was also responsible for equipment assembly and data collection, was available. Demographic parameters were recorded and

analysed using descriptive statistics (see table below). There were 42 male infants (23 female) recruited. The gestational age during transport was 34.1 ± 5d and the mean transport weight was 2594 ± 1124 grams.

Half of the transport objective was medical (49.2%) and most had fewer than 3 other associated issues or co-morbidities. 1 patient had a family history of deafness (in a paternal grandparent i.e. not a first degree relative) and reassuringly had a normal newborn hearing screen. 2 patients were established to have acquired congenital infection. The majority of the patients were intubated and ventilated during the transfer (53.8%) and needed fractional oxygen requirements (FiO2) of 21-50% (29%). 36.9% of the overall cohort were under sedation and 5 patients in this group had muscle relaxant during transport. TRIPS or transport risk index of physiological stability (a parametric predictive scoring system to reflect the degree of sickness and probable mortality within 7 days of interhospital transfer) was used. The higher the TRIPS score, the higher probability of mortality within seven days of transport. (Figure 3.19) The patients in this research had variable TRIPS scores; highest (35 to 44 = 11.1 to 23.4 % mortality within seven days of transport) and low; (0 to 8 = 0.4 to 0.9 % mortality within seven days of transport . Nearly one third of this patient overall cohort carried the lowest category TRIP score during their transfers. (Figure 3.18)

Demographic Categories		**% (n)**	
Gender	Male	65 (42)	
Birth Gestation (weeks)		34.1 ± 0.71	(23.57 – 41.71-) [b]
Transport Gestation (weeks =w/ days=d) [a]		36.43 ± 0.71	(25- 49) [b]
Birth Weight (grams) [a]		2326 ± 1231	(460 - 5680) [b]
Transport weight (grams) [a]		2594 ± 1124	(690 - 6080) [b]
Diagnosis Category	Medical [b]	49.2(32)	

	Surgical	26.2 (17)
	Cardiac	21.5(14)
	Other	3.1 (2)
Number of associated co-morbidities	<3 issues	55.4 (36)
	3-5 issues	41.5(27)
	>=6 issues	3.1(2)
Family history of congenital hearing loss in first degree relative		1.5(1)
Newborn Hearing Screen Performed		1.5(1)
Establish Congenital Infection		3.1(2)
Respiratory Support [c]	SV	29.2 (19)
	NIV	16.9 (11)
	IMV	53.8 (35)
Oxygen Requirement (FiO2) [d]	room air 21%	32.3(21)
	<50%	44.6(29)
	50-75%	15.4(10)
	75-100%	7.7 (5)
Sedation		36.9 (24)
Muscle Relaxant		7.7 (5)
TRIPS Score [e]	0-8	33.8 (22)
	9-16	15.4 (10)
	17-24	6.2 (4)
	25-34	29.2 (19)
	35-44	15.4 (10)
Transport Distance	< 30 km (intercity)	23.1 (15)
	>30km (intercounty)	73.8 (48)
	international	3.1 (2)
Level of Receiving unit	Level 3 NICU	36.9 (24)
	Level 3 Paediatric Sub-specialty	56.9 (37)
	Repatriation/ Back Transfer	6.2 (4)

Legend:

a. Mean ± Standard Deviation

b. Medical: Comprises of a wide range of neonatal conditions needing specialist neonatal care; including the initial treatment (including surgical and cardiac conditions); For example, prematurity, respiratory diseases and hypoxic conditions et cetera

c. SV (Self Ventilating); NIV (Non-invasive Ventilation); IMV (Invasive Mechanical Ventilation)
d. FiO2: Fractional Inspired Oxygen Concentration (%)
e. TRIPS (Transport Risk Index of Physiological Stability)

Figure 3.18

Transport Risk Index of Physiological Stability (TRIPS)		
Scoring Sheet		
Risk Factors		**TRIPS Points**
Responsiveness	None, Seizures, Muscle relaxants	14
	Lethargy, No cry (2)	10
	Vigorously withdraws, cries (3)	0
Temperature (ºC)	36.1 – 37.6	0
	<36.1 or > 37.6	6
Respiratory Status	None or mild respiratory symptoms	0
	Moderate (apnoea, gasping and not on ventilator)	21
	Severe (on ventilator)	15
	With FiO2 <50%	18
	With FiO2 50% to <70 %	20
	With FiO2 75% -100%	
Systolic Blood Pressure (mmHg)	Under 20	24
	20-30	19
	30-40	8
	>40	0
Pressors/ Inotropes	Not used	0
	Used	5

TRIPS Score Risk	
Points	**Risk of Death within 7 days of Transport**
0 to 8	0.4 to 0.9 %
9 to 16	0.9 to 1.9 %
17 to 24	2.1 to 1.0 %
25 to 34	4.4 to 10.2 %
35 to 44	11.1 to 23.4 %
45 to 70	25.2 to 80.1 %

Figure 3.19

The majority of the patients transferred in the overall patient group were long distance intercounty transfers that were more than 30 km distances (73%, n=48). This was because the study components in this research involved recording times of at least 20 minutes of total duration. 36.9% of the patient cohort were transferred to level 3 neonatal intensive care as the receiving unit. 56.9% were transferred for to paediatric subspecialty (includes cardiac, paediatric surgical subspecialties and other multidisciplinary inputs). There were 2 international transfers of which results are presented in the following sections. The results of each patient study are delivered in the next sections in this chapter.

3.2.1 Observation of Physiological Changes to noise During Neonatal Ground Transport (Study 2)

It was vital to explore if any, physiological changes to noise the neonate experienced during interhospital ground transport during standard NNTP clinical care. This component provided the research baseline information of any physiological changes to noise and established practicalities in the conduct of the patient studies during the research. The methodology can be referred to in the previous chapter of study designs.

20 patients were recruited in the observational study. The demographics of this cohort is displayed in the box below (Figure 3.20):

Demographic Categories of Observational Cohort		**% (n)**
Gender	Male	70 (14)
Birth Gestation (weeks)		33± 6
Transport Gestation (weeks)		37±5

Birth Weight (grams)		2166±1135
Transport weight (grams)		2578 ± 903
Diagnosis Category	Medical	40 (8)
	Surgical	20 (4)
	Cardiac	30 (6)
	Other	10 (2)
Number of associated co-morbidities	<3 issues	55 (11)
	3-5 issues	35(7)
	>=6 issues	10(2)
Family history of congenital hearing loss in first degree relative		5 (1)
Newborn Hearing Screen Performed		5 (1)
External Congenital Anomalies		15 (3)
Establish Congenital Infection		5 (1)
Respiratory Support	self-ventilating	30(6)
	non-invasive ventilation	15(3)
	invasive mechanical ventilation	55(11)
Oxygen Requirement (FiO2)	room air 21%	30(6)
	<50%	45(9)
	50-75%	20(4)
	75-100%	5(1)
Sedation		50 (10)
Muscle Relaxant		10 (2)
TRIPS Score	0-8	30(6)
	9-16	45(9)
	17-24	20(4)
	25-34	5(1)
	35-44	15.4 (10)
Transport Distance	< 30 km (intercity)	75 (15)
	>30km (intercounty)	25 (5)
Level of Receiving unit	Level 3 NICU	35 (7)
	Level 3 Paediatric Sub-specialty	60 (12)
	Repatriation/ Back Transfer	5 (1)

Figure 3.20

More than half of this cohort transferred were male, with mean gestational age during transport of 33 ±6 weeks and the mean weight during transport of 2.58± 0.9 kgs. Half of the cohort were intubated and mechanically ventilated during transfer and 45% of the cohort required fractional inspired oxygen within 20-50%. Half of this cohort was sedated during transport and only 2 needed muscle relaxant during interhospital transfer. The TRIP score for this group of patients represented varying degrees of indexes of physiological stability. (Figure 3.19)

The overall description of mean SPL (total and peak) and oxygen saturation and heart rate were extracted from 19620 seconds of data points in physiological monitoring and 21942 seconds of data points of SPL measurements. **(**Table 3.12)

		N	**Mean ± SD**	Maximum
Physiology	**O2 Sats (%)**	19638	**91 ±4.4**	100
	Heart Rate (bpm)	19620	**143 ±16.4**	234
Peak SPL (Lpeak) in dBA	**Ear**	21942	**74 ±7.9**	129
	Incubator	21942	**78 ±8.7**	146
	Ambulance	21942	**86 ±6.8**	145
Total SPL (Leq) in dBA	**Ear**	21942	**60 ±8.2**	97
	Incubator	21942	**64 ±9.6**	111
	Ambulance	21942	**73 ±7.2**	111
O2 Sats: oxygen saturations SD: Standard Deviation bpm : beats per minute				

Table 3.12

The percentage of noise categories in this study component are represented in the figure below. The majority of the noise category during ground transport environment in this observational cohort is characterised as very loud/ very noisy. Peak SPL

picked up during this recording has reached into harmful category including levels that were picked up near the patient's ear. (Figure 3.21)

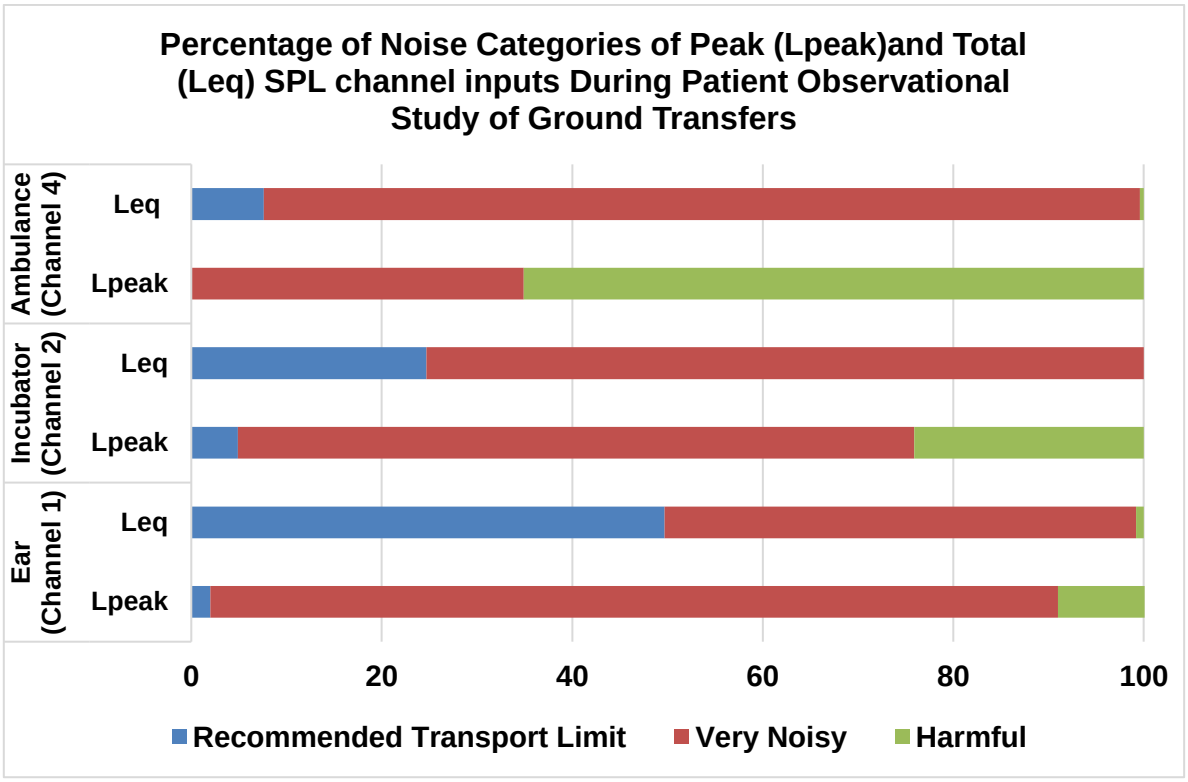

Figure 3.21

With the non-normal distribution of physiological data, the median and range of deviation of oxygen saturation and heart rate in each category is demonstrated in the figure below. I used a non-parametric test (Independent samples Kruskal-Wallis) to demonstrate the differences between the mean physiological values in the noise categories (i.e. Recommended levels during transport, very loud/ noisy and harmful levels). As demonstrated in the table below, a noticeable difference was also detected in oxygen saturation and heart rate in both Lpeak and Leq between the 3 categories ($p<0.005$). High-lighted in this finding is of the increased heart rate

(median and range) in the harmful noise category in both total and peak SPL. (Table 3.13)

A Comparison of Median and Range of Physiological Values in the Noise Categories					
		Recommended Level	**Very Noisy**	**Harmful**	**p-value**
SPL Peak (Lpeak)	**O2 Sats (%)**	N= 398	N=16942	N=1926	
		93 (76-100)	**91 (59-100)**	**94 (59-100)**	<0.005
	Heart Rate (bpm)	N =397	N=16927	N= 1925	
		131 (101-175)	**138 (74-234)**	**154 (85-234)**	<0.005
SPL Total (Leq)	**O2 Sats(%)**	N=8631	N=10080	N=164	
		91 (59-100)	**91 (59-100)**	**95 ± 1.2**	<0.005
	Heart Rate (bpm)	N=8349	N=10077	N=164	
		139 (77-233)	**139 (74-234)**	**170 (143-179)**	< 0.005
O2sats: Oxygen saturation Bpm: beats per minute (heart rate)					

Table 3.13

I analysed the mean heart rate and oxygen saturation and its significance at harmful SPL levels of 80 dBA (above the two-fold recommended limit during neonatal transfer). (82). The graph below demonstrates the distribution of percentage of SPL at 80 dBA; less than (<80dBA) or equal to and above (≥80dBA). Although, mean SPL level as expressed in total sound energy was less than 85dBA, a significant number of measurements demonstrated harmful levels of noise during ground transport (up to 10% of the recording time). (Figure 3.22)

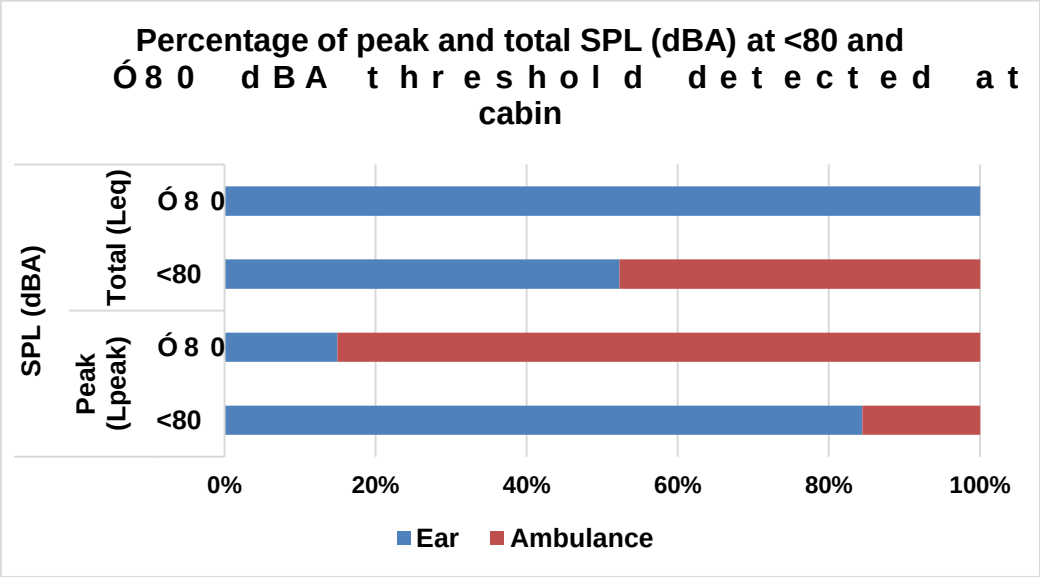

Figure 3.22

In the occupational health setting, hearing protection needs to be provided if there is prolonged, regular exposure to SPL ranges within 80-85dBA. In this study and also in further studies involving neonatal patients in this research; I chose to ascertain information at 80dBA threshold. As the distribution of heart rate and oxygen saturations across the total recording was not normally spread, I performed a non-parametric test (Mann Whitney U) to ascertain the difference of these parameters between the 2 groups (<80 and ≥80) dBA. I compared the differences of heart rate and oxygen saturation levels at 80dBA thresholds for SPL at the patient ear and SPL in the ambulance cabin. (Table 3.14 & Table 3.15)

The median heart rate and oxygen saturations were significantly higher at levels above 80dBA for both peak and total SPL detected at the neonatal ear. There was significant difference between the median oxygen saturation and heart rate between levels below and above Total and Peak SPL of 80dBA. As we expected heart rate to

increase at higher SPL levels, we did not expect to see increase in oxygen saturations overall. Therefore, this leads me to postulate whether there is a compensatory response of increase in oxygen saturation due to an increase in respiratory rate as a response to the perceive higher SPL detected at the ear.

Ear SPL (dBA)		**Oxygen Saturations (%) (Median and Range)**	**Heart Rate (bpm) (Median and Range)**
Peak SPL (Lpeak) in dBA	<80	91 (51-100)	138 (74-234)
	>=80	94 (59-100)	152 (83 -234)
p-value		**Ò0 . 0 0 5**	**Ò0 . 0 0 5**
Total SPL (Leq) in dBA	<80	91 (59-100)	139 (74-234)
	>=80	94 (92-98)	159 (135-179)
p-value		**Ò0 . 0 0 5**	**Ò0 . 0 0 5**

Table 3.14

However, the opposite findings were demonstrated when physiological response was compared at SPL thresholds from **the ambulance cabin** (Channel 4). Results from baseline studies demonstrate SPL levels that are much louder in the ambulance cabin compared to the ear. Median physiological values between the 2 categories (<80dBA and) detected in the ambulance cabin; although had significant difference ($p<0.005$), the heart rate and oxygen level in this analysis was lower at SPL ≥80 dBA (peak and total). (Table 3.15)

Ambulance SPL		Oxygen Saturations (%) (Median and Range	Heart Rate (bpm) (Median and Range)
Peak SPL (Lpeak) in dBA	<80	93 (59-100)	148 (83-211)
	>=80	91 (59-100)	139 (74-234)
p-value		**Ò0 . 0 0 5**	**Ò0 . 0 0 5**
Total SPL (Leq)in dBA	<80	92 (59-100)	142 (74-234)
	>=80	90 (61-100)	136 (77-196)
p-value		**Ò0 . 0 0 5**	**Ò0 . 0 0 5**

Table 3.15

There were significance differences in the heart rate and oxygen saturation at SPL levels less than and above 80 dBA in both Lpeak and Leq ($p < 0.005$). SPL levels above 80dBA detected at the ear and in the ambulance cabin; has demonstrated changes in mean heart rate and oxygen saturation levels. It is thought that increased noise levels increase anxiety, which may increase in baseline heart rate. Whether the elevation in oxygen saturation levels are a reflection of compensatory increased in respiratory rate on this patient cohort is discussed in the following chapters.

The results from this observational cohort provides an understanding of the quantity of noise exposure during neonatal interhospital ground transfers and its effects on neonatal physiological parameters i.e. heart rate and oxygen saturations. SPL was shown to reach harmful levels at times, the aim of subsequent studies was to determine whether noise and hearing protective interventions would lead to improved physiological and behavioural response during interhospital transfers. The results of this is demonstrated in the following studies.

The Application of Noise Protection: The Intervention Studies

3.2.2 Effects of noise reduction Interventions through crossover studies of neonates undergoing ground transfers (Study 3)

This study compared the effects of standard neonatal transport care (SC), noise protective earmuffs (NPEM) and active noise application headphones (ANC) through 3 separate crossover components.

32 neonatal patients who underwent clinically indicated NNTP interhospital transfer were recruited in a convenience sample following parental informed and written consent. A computer-generated system was used to allocate patients to one of the three crossover studies. The starting point was randomised (standard care or intervention) for each case (patient). The researcher was not blinded to the intervention i.e. noise protections or standard transport care that has been applied, as this was not possible in the interhospital transport situation during this period. The number of patients allocated to each study is as follows:

- **Crossover 1**: Standard Care **(SC)** versus noise protective earmuffs **(NPEM) 10 patients** (1 patient excluded in the analysis of heart rate due to low baseline heart rate from therapeutic hypothermia)
- **Crossover 2**: Standard Care **(SC)** versus active noise cancellation headphones **(ANC) 10 patients**

- **Crossover 3:** Noise protective ear muffs **(NPEM)** versus active noise cancelling headphones **(ANC) 12 patients** (The analysis of heart rate was excluded in 3 patients in this crossover)

The results of demographic data were represented in descriptive statistics in percentages. In order to calculate statistical significance, independent Sample t-test was used to compare the means of normally distributed data. Non-parametric test (Man Whitney U) was used to compare median and range values in non-normally distributed data.

The demographic characteristics of the overall crossover study cohort are described in the box below.(Figure 3.23) From the diagnosis category in this cohort, 3 patients were transferred for therapeutic hypothermia and one patient was transferred for level 3 cardiac centre in Supraventricular tachycardia (SVT). Due to the low baseline heart rate in patients undergoing therapeutic hypothermia and the high baseline heart rate in the patient who had SVT we excluded these patients in the analysis of heart rate in their respective groups. However, we included these patients in the analysis of oxygen saturations in their own crossovers.

60% of the patients in this study component were male with an average transport gestation of 36 weeks and an average transport weight of 2.47kilograms. Slightly over half of the cohort in these crossovers were transferred for primarily medical reasons (as opposed to cardiac or surgical), were mechanically ventilated during the transfers and had TRIPS score on the higher end i.e. 25 to 34 and 35 to 44. (Figure 3.19). This information assisted our aims of ascertaining the effects of noise and noise protection on physiology of the unwell/ critical neonate undergoing transport.

Demographic Categories		% (n)
Gender	Male	59 (19)
Birth Gestation (weeks ± SD)		34.3 ± 5.5
Transport Gestation (weeks ± SD)		36.0 ± 5.5
Birth Weight (grams ± SD)		2291 ± 1156
Transport weight (grams ± SD)		2467 ± 1135
Diagnosis Category	Medical	53.1(17)
	Surgical	28.1(9)
	Cardiac	18.8(6)
Number of associated co-morbidities	<3 issues	59.4 (19)
	3-5 issues	40.6 (13)
Family history of congenital hearing loss in first degree relative		0 (0)
Newborn Hearing Screen Performed		0 (0)
Establish Congenital Infection		0 (0)
Respiratory Support	self-ventilating	31.3 (10)
	non-invasive ventilation	12.5 (4)
	invasive mechanical ventilation	56.3 (18)
Oxygen Requirement (FiO2)	room air 21%	31.3 (10)
	<50%	43.8 (14)
	50-75%	12.5 (4)
	75-100%	12.5 (4)
Sedation		37.5 (12)
Muscle Relaxant		9.4 (3)
TRIPS Score	0-8	28.1(9)
	9-16	6.3 (2)
	17-24	6.3 (2)
	25-34	40.6 (13)
	35-44	18.8 (6)
Transport Distance	>30km (intercounty)	100(32)
Level of Receiving unit	Level 3 NICU	43.8 (14)
	Level 3 Paediatric Sub-specialty	56.3 (18)
	Repatriation/ Back Transfer	6.2 (4)

Figure 3.23

Crossover 1: Comparison of Standard Care (SC) versus Noise Protective Earmuffs (NPEM)

I compared the mean and standard deviation of SPL (Lpeak and Leq) in both SC and NPEM using independent t-test. The analysis of physiological comparison in standard care (SC) i.e. no noise protection with the use of noise protective ear muffs (NPEM) resulted in a non-normal distributive data. Therefore non parametric calculations (Man Whitney was used to compare the heart rate and oxygen saturations between the 2 interventions. We excluded one patient (who underwent therapeutic hypothermia) from the analysis of heart rate due to low baseline values of heart rate. However, I included this case in the overall analysis of oxygen saturations.

The table below represents the comparison of mean and standard deviation of SPL (Lpeak and Leq) and median and range of heart rate (beats per minute) and oxygen saturations (%) between the 2 interventions (SC versus NPEM) in an overall group analysis and case by case analysis.

The overall group analysis in Crossover 1 in comparison of means and median values between SC and NPEM showed significant difference ($p<0.05$). Mean SPL (dBA) detected at the ear was lower with the use of NPEM: Lpeak (76 vs. 77) and Leq (64 vs.65); both p -value <0.005. With the use of NPEM; Oxygen saturation (%) was found to be lower (94 vs. 96) and heart rate (bpm) was found to be higher (139 vs 138) with also p-value <0.005. The overall case by case analysis revealed significant difference between SPL and physiology in SC an NPEM . 4.6% (n=2) of our case by case calculations revealed comparisons that are not statistically significant. (Table 3.16)

	Total and Peak SPL in dBA (Median and Range)				Physiology (O2sats in % and HR in bpm)			
		SC	NPEM	p-value		SC	NPEM	p-value
Overall	Lpeak	77±4.1	76 ±4.3	<0.005	O2sats	96 (75-100)	94 (75-100)	<0.005
	Leq	65 ± 5.1	64 ±4.3	<0.005	HR	138 (82-183)	139 (81-206)	<0.005
Case by Case analysis								
1	Lpeak	75 ± 4.8	72 ± 3.2	0.001	O2sats	94 (94-99)	97 (95-100)	<0.005
	Leq	61 ± 4.9	60 ± 2.9	0.005	HR	139 (132-150)	147 (136-183)	<0.005
2	Lpeak	75 ± 3.5	75 ± 2.7	<0.005	O2sats	98 (75-100)	87 (74-100)	<0.005
	Leq	63 ± 3.4	63 ± 2.4	<0.005	HR	165 (138-173)	161 (94-85)	0.014
3	Lpeak	75 ± 3.5	75 ± 2.7	0.033	O2sats	90(87-93)	91 (88-94)	<0.005
	Leq	63 ± 3.4	63 ± 2.4	<0.005	HR	134 (120-156)	131 (116-170)	<0.005
4	Lpeak	78 ± 3.3	77 ± 3.0	0.002	O2sats	96 (85-100)	94 (83-100)	<0.005
	Leq	66 ± 3.0	65 ± 2.2	<0.005	HR	132 (124-142)	130 (124-138)	<0.005
5	Lpeak	80 ±2.1	78 ± 3.3	<0.005	O2sats	95 (92-97)	95 (91-97)	0.672
	Leq	68 ± 1.8	66 ± 3.4	<0.005	HR	152 (141-165)	156 (147-171)	<0.005
6	Lpeak	76 ±3.4	76 ± 4.8	<0.005	O2sats	97 (94-98)	95 (94-98)	<0.005
	Leq	64 ± 3.1	64 ± 4.8	<0.005	HR	137 (127-146)	138 (131-147)	<0.005
7	Lpeak	78±2.9	72± 3.9	<0.005	O2sats	94 (86-98)	90 (77-97)	<0.005

	Leq	65± 2.7	60± 3.9	**<0.005**	**HR**	168 (157-183)	164 (136-186)	**<0.005**
8	**Lpeak**	78± 5.0	78±4.9	**0.042**	**O2sats**	95 (91-97)	95 (92-98)	**<0.005**
	Leq	64 ± 4.1	78± 4.9	**<0.005**	**HR**	137 (118-179)	138 (114-206)	**0.002**
9	**Lpeak**	77± 5.2	77± 3.3	**<0.005**	**O2sats**	97 (94-99)	97 (96-97)	**<0.005**
	Leq	64 ± 5.8	66 ±3.3	**<0.005**	**HR**	134 (126-142)	135 (125 - 162)	**<0.005**
10	**Lpeak**	76 ± 2.9	75 ± 2.5	**0.041**	**O2sats**	99(93-100)	100 (93-100)	**<0.005**
	Leq	64 ± 2.0	63 ± 2.3	0.499	**HR**			

Table 3.16

Similar to the previous observational study, it was essential to compare physiological values at harmful threshold SPL levels of 80 dBA detected at the patient's ear (Channel 1) and also from the ambulance cabin (Channel 4). I performed a two-way comparison of median in this component of the study both using non parametric (Man Whitney U) (Table 3.17):

- ¶ Comparison of median values of physiology for SC and NPEM at SPL threshold level below 80dBA and equal to/ above 80 dBA. (Blue Cell)
- ¶ Comparison of median values of physiology between NPEM and SC for SPL thresholds (>80 and ≥80) dBA separately (Pink Cell)

There is demonstrable significant difference ($p<0.05$) in median oxygen saturation and heart rate detected at peak SPL (Lpeak) of 80dBA **detected at the ear**. However, there is no significant difference in these median values between SC and NPEM at peak SPL equal to and above 80 dBA. Apart from a significant increase in heart rate in NPEM at Total SPL (Leq) <80dBA there is no significant difference in

heart rate and oxygen saturation at 80 dBA thresholds. As total SPL (Leq) levels did not reach >80 dBA, certain parameters in the ear SPL analysis, the statistical analysis was not possible.

The comparison of median physiological values between intervention (SC vs. NPEM) and between above and below 80dBA threshold showed more significant values in total and peak SPL detected from the **ambulance cabin.** There was higher median heart rate picked up at Peak SPL ≥80dBA in the ambulance cabin; but the results were not significance compared to the other variables analysed. Significant results were discovered when median physiological values were compared to SPL thresholds from the ambulance cabin as the SPL levels were generally higher and lead to a more defined distribution for non-parametric calculations of significance.

SPL detected at the patient Ear		**Oxygen Saturations (Median and Range)**			**Heart Rate (Median and Range)**		
		Standard	**NPEM**	**p-value**	**Standard**	**NPEM**	**p-value**
Peak SPL (Lpeak)	<80	96 (75-100)	95 (68-100)	**Ò 0.005**	138 (118-183)	142 (94-202)	**Ò 0.005**
	>=80	95 (75-100)	96 (67-100)	**0.127**	149 (121-177)	143 (95-206)	**0.127**
p-value		**0.001**	**0.005**		**Ò 0 . 0**	**Ò 0 .**	
Total SPL (Leq)	<80	96 (75-100)	95 (67-100)	**0.143**	139 (139-143)	142 (95-206)	**0.003**
	>=80	94 (94-97)	**		142 (139-143)	**	**
p-value		**0.501**	0.108		**0.39**	**	
		Oxygen Saturations (Median and Range)			**Heart Rate (Median and Range)**		

SPL detected at the Ambulance		Standard	NPEM	p-value	Standard	NPEM	p-value
Peak SPL (Lpeak)	<80	96 (90-98)	95 (92-98)	**Ò 0.005**	136 (119-169)	156 (126-161)	**Ò 0.005**
	>=80	96 (75-100)	95 (67-100)	**Ò 0.005**	139(118-183)	142 (94-206)	**0.252**
p-value		**0.03**	**0.118**		**Ò 0 . 0**	**Ò 0 .**	
Total SPL (Leq)	<80	96 (86-100)	95 (77-100)	**Ò 0.005**	137 (118-183)	141 (114-186)	**Ò 0.005**
	>=80	95 (75-100)	95 (67-100)	**Ò 0.005**	151 (122-179)	145 (94-206)	**Ò 0.005**
p-value		**0.018**	**0.02**		**Ò 0 . 0**	**Ò 0 .**	
** no levels > 80dBA in Leq therefore MWU analysis not possible							

Table 3.17

Crossover 2: Comparison of Standard Care (SC) versus Active Noise Cancellation (ANC)

The mean and standard deviation of SPL (Lpeak and Leq) in both standard care (SC) i.e. no noise protection with the use of active noise cancellation headphones (ANC) was compared using independent sample t-test as data was normally distributed. The analysis of comparison of physiology in standard care (SC) with the use of active noise cancellation headphones (ANC) resulted in a non-normal distributive data and therefore non parametric calculations was used to compare the heart rate and oxygen saturations between the 2 interventions. 10 patients were included (none were excluded) in this crossover. SPL (Lpeak and Leq), oxygen

saturation and heart rate were compared between 2 sets of recordings; intervention (ANC) and standard care.

The table below represents the comparison of mean and standard deviation of SPL (Lpeak and Leq) and median and range of heart rate (beats per minute) and oxygen saturations (%) between the 2 interventions (SC and ANC) in an overall group analysis and case by case analysis. (Table 3.18)

	Total and Peak SPL in dBA (Median and Range)				**Physiology (O2sats in % and HR in bpm)**			
N=10		**SC**	**ANC**	**p-value**		**SC**	**ANC**	**p-value**
Overall	Lpeak	76 ± 0.04	69±5.8	**Ò 0 . 0**	O2sats	95 (73-100)	95 (84-100)	**0.258**
	Leq	63 ± 0.04	55± 5.8	**Ò 0 . 0**	HR	137 (109-181)	138 (107-183)	**0.045**
Case by Case Analysis								
1	Lpeak	76± 4.0	69±3.5	**Ò 0 . 0**	O2sats	93 (86-95)	93(90-99)	**Ò 0 . 0**
	Leq	64± 3.7	56± 2.7	**Ò 0 . 0**	HR	129 (123-149)	131(114-159)	**Ò 0 . 0**
2	Lpeak	74± 3.9	73± 6.6	**Ò 0 . 0**	O2sats	94(84-98)	95(90-99)	**Ò 0 . 0**
	Leq	61±3.3	60± 0.2	**Ò 0 . 0**	HR	138 (129-146)	141(125-149)	**Ò 0 . 0**
3	Lpeak	77±3.2	73± 3.8	**0.028**	O2sats	91(73-95)	91(89-94)	**Ò 0 . 0**
	Leq	65± 2.6	60± 2.6	**Ò 0 . 0**	HR	140(109-154)	141(133-153)	**Ò 0 . 0**
4	Lpeak	76± 6.1	66±5.9	**Ò 0 . 0**	O2sats	96(83-100)	97(89-100)	**Ò 0 . 0**
	Leq	62± 6.7	51± 5.7	**Ò 0 . 0**	HR	117(109-147)	118(107-135)	**0.147**
5	Lpeak	75± 3.3	70±4.4	**Ò 0 . 0**	O2sats	96(93-98)	95(93-96)	**Ò 0 . 0**
	Leq	63± 2.6	57± 3.7	**Ò 0 . 0**	HR	133(112-142)	135(124-143)	**Ò 0 . 0**

6	Lpeak	76± 4.4	68±5.0	**Ò 0 . 0**	O2sats	90(84-95)	90(84-94)	**Ò 0 . 0**
	Leq	64±3.4	56 ± 5.1	**Ò 0 . 0**	HR	137(128-145)	140(132-148)	**Ò 0 . 0**
7	Lpeak	77± 2.2	66±4.5	**Ò 0 . 0**	O2sats	97(94-98)	97 (96-98)	**0.279**
	Leq	64± 2.3	49± 4.4	**Ò 0 . 0**	HR	129(118-143)	130(122-141)	**Ò 0 . 0**
8	Lpeak	77± 4.6	66± 5.0	**Ò 0 . 0**	O2sats	95(91-96)	95(89-96)	**Ò 0 . 0**
	Leq	65± 4.7	51± 4.1	**Ò 0 . 0**	HR	150(136-168)	151(140-168)	**0.102**
9	Lpeak	75± 4.0	71±4.0	**Ò 0 . 0**	O2sats	95(92-98)	94(90-97)	**Ò 0 . 0**
	Leq	62± 3.8	58± 3.5	**Ò 0 . 0**	HR	168(154-181)	169(160-183)	**Ò 0 . 0**
10	Lpeak	78± 6.4	72± 6.9	**Ò 0 . 0**	O2sats	97(95-98)	96(90-98)	**Ò 0 . 0**
	Leq	64 ± 5.1	55± 4.5	**Ò 0 . 0**	HR	139(123-156)	135(119-150)	**Ò 0 . 0**

Table 3.18

The overall group analysis in Crossover 2 in comparison of means and median values between SC and ANC showed significant difference ($p<0.05$) in peak and total SPL and median and range heart rate between SC and ANC (137 vs 138). There was no difference in the overall group in median oxygen saturation between SC and ANC. The case by case analysis resulted in significant difference in Peak and Total SPL between SC and ANC. This is and expected result as from previous studies ANC is effective in reducing both peak and total SPL exposure. In the case by case analysis of crossover 2, there was statistical insignificance in 9% of the comparison of median physiological values in heart rate and oxygen saturation between the 2 interventions (SC and ANC). (Table 3.18)

The comparison of physiological median values at harmful thresholds of <80dBA and ≥80 dBA detected at the patient's ear and from the ambulance cabin was

performed. A two-way comparison of median values using non parametric (Man Whitney U) is demonstrated in Table 3.19.

- ¶ Comparison of median values of physiology for SC and ANC at SPL threshold level below 80dBA and equal to/ above 80 dBA. (Blue Cell)
- ¶ Comparison of median values of physiology between ANC and SC for SPL thresholds (>80 and ≥80) dBA separately (Pink Cell)

SPL detected at the patient Ear		**O2 Sats (%) (Median and Range)**			**HR(bpm) (Median and Range)**		
		Standard	ANC	**p-value**	Standard	ANC	**p-value**
Peak SPL Lpeak	<80	95(73-100)	95 (84-100)	0.958	138(109-181)	138(107-183)	**0.088**
	>=80	95(79-99)	95(89-100)	**0.001**	137(109-176)	138(113-183)	**Ò 0 . 0**
p-value		**Ò 0 . 0 0**	**Ò 0 . 0 0**		**Ò 0 . 0 0**	**0.174**	
Total SPL Leq	<80	95(73-183)	95(84-100)	**0.84**	138(109-181)	138(107-183)	**0.0993**
	>=80	**	95(95)	**	**	120(120)	**
p-value		**	0.847		**	0.133	

SPL detected at the Ambulance		**Oxygen Saturations (Median and Range)**			**Heart Rate (Median and Range)**		
		Standard	ANC	**p-value**	Standard	ANC	**p-value**
Harmful Level (Lpeak) (%)	<80	95(89-98)	95(88-99)	**0.004**	139(129-175)	137(112-171)	**Ò 0 . 0**
	>=80	95(73-100)	95(84-100)	**0.794**	138(109-181)	138 (107-183)	**0.182**
p-value		**Ò 0 . 0 0**	**0.96**		Ж л Ф л	Ж л Ф л	
	<80	95(75-100)	95(84-100)	**Ò 0 . 0**	138(108-191)	138(107-183)	**0.527**

Harmful (Total Ear Leq)Level (%)	>=80	94(83-99)	95(84-100)	Ò0 . 0	137(109-180)	137(107-178)	**0.075**
p-value		Ò0 . 0 0	Ò0 . 0 0		Ò0 . 0 0	Ò0 . 0	
** no levels > 80dBA in Leq therefore MWU analysis not possible							

Table 3.19

There is no significance in the comparison of median values in physiology at total SPL (Leq) 80dBA thresholds detected at the ear. This is due to the lack of data recorded at in Leq > 80dBA in this group, hence therefore lacking in comparative distribution. At Peak SPL levels detected at the ear, there is significant difference in median oxygen saturations above and below 80dBA and heart rate in the SC groups at this threshold ($p<0.05$). There is also significance in median physiological values at Peak SPL > 80 dBA between SC and NPEM.

Median physiological values in crossover 2 in comparison of heart rate and oxygen at 80dBa threshold for both Lpeak and Leq in both interventions showed an overall significance ($p<0.05$). However, the comparison of SC with ANC in determining significance between median physiological values was variable. Although ANC is the most effective mode of noise protection, deciding whether it is effective in overall leading to physiological change is currently challenging from both ear and ambulance 80dBA threshold. (Table 3.19)

Crossover 3: Comparison of Noise Protective Ear Muffs (NPEM) versus Active Noise Cancellation (ANC)

The final crossover involved the alternate application of the 2 noise protective interventions (ANC and NPEM). The mean and standard deviation (SD) of SPL (Lpeak and Leq) in both ANC and NPEM was compared by independent t-test as the data appeared normally distributed. Non parametric calculations (Mann Whitney U) was used to compare non normally distributed data of heart rate and oxygen saturation between the 2 interventions.

12 patients were initially recruited to this crossover following consent obtained from parents. Cases that were partially excluded from certain analyses:

- One case was excluded f(or a low baseline heart rate) from analysis of overall heart rate (this patient underwent therapeutic hypothermia). This case was however included in the overall analysis of oxygen saturation.
- A second patient was diagnosed with supraventricular tachycardia and had a baseline heart rate of above 200 beats per minute throughout the whole transfers. This case was excluded from analysis of heart rate and included for overall analysis of oxygen saturation.
- A third case had insufficient recording of SPL data , but had sufficient amount of physiological data. This case was included in the overall physiological analysis for heart rate and oxygen saturations

The overall group analysis in Crossover 3 in the comparison of means and median values between NPEM and ANC revealed significant levels in 94% of overall statistic calculations. Mean SPL (dBA) detected at the ear was lower with the use of ANC: Lpeak (76 vs. 69) and Leq (64 vs.65); both p-values <0.005. there was no significant

difference in oxygen saturation between the two interventions. However, heart rate was higher in ANC (141 vs 147) with p value <0.005. The overall case by case analysis revealed significant difference between all SPL values and nearly all of physiological median values that were compared between NPEM and ANC. (Table 3.20)

	SPL dBA (Mean ± SD)				Physiology (Median and Range)			
N=12		**NPEM**	**ANC**	**P-value**		**NPEM**	**ANC**	**P-value**
Overall	Lpeak	76±6.7	69±9.9	**Ò 0 . 0**	O2sats	96 (47-100)	95 (29-100)	**0.641**
	Leq	64± 4.7	55±8.3	**Ò 0 . 0**	HR	141 (45-187)	147 (49-172)	**Ò 0 . 0**
Case by Case analysis								
1	Lpeak	72 ± 3.9	62 ± 5.0	**Ò 0 . 0**	O2sats	100 (97-100)	99 (95-100)	**Ò 0 . 0**
	Leq	60 ±4.0	47 ±4.98	**Ò 0 . 0**	HR	125 (98-152)	124 (114-140)	**Ò 0 . 0**
2	Lpeak	75 ±2.8	62 ± 3.7	**Ò 0 . 0**	O2sats	98 (96-100)	98 (94-100)	**0.031**
	Leq	64± 2.4	48 ±4.3	**Ò 0 . 0**	HR			
3	Lpeak	77 ± 4.1	69 ±3.6	**Ò 0 . 0**	O2sats	92 (89-96)	94 (82-96)	**Ò 0 . 0**
	Leq	65 ±4.2	57 ±2.8	**Ò 0 . 0**	HR	157 (152-171)	157 (151-172)	**0.065**
4	Lpeak	80 ±5.6	73± 9.1	**Ò 0 . 0**	O2sats	98 (85-100)	98 (86-100)	**Ò 0 . 0**
	Leq	67 ±4.1	58 ±5.3	**Ò 0 . 0**	HR			
5	Lpeak	75 ±5.1	73± 5.5	**Ò 0 . 0**	O2sats	97 (88-100)	97 (92-100)	**Ò 0 . 0**
	Leq	62 ±2.9	59 ± 4.4	**Ò 0 . 0**	HR	130 (111-159)	128 (110-143)	**Ò 0 . 0**
6	Lpeak	76 ±3.0	63 ±3.0	**Ò 0 . 0**	O2sats	89 (82-980	86 (77-970	**Ò 0 . 0**
	Leq	64 ±2.8	49 ±3.1	**Ò 0 . 0**	HR	126 (74-133)	124 (114-129)	**Ò 0 . 0**
7	Lpeak	73 ±2.1	62 ±4.2	**Ò 0 . 0**	O2sats	62 (47-68)	67 (29-75)	**Ò 0 . 0**
	Leq	62 ±2.1	45 ±3.7	**Ò 0 . 0**	HR	156 (137-187)	154 (132-167)	**Ò 0 . 0**
8	Lpeak	75 ±4.1	73 ±2.4	**Ò 0 . 0**	O2sats	94 (87-98)	92 (86-95)	**Ò 0 . 0**
	Leq	63 ±3.4	61 ±1.7	**Ò 0 . 0**	HR	155 (145-159)	153 (149-156)	**Ò 0 . 0**
9	Lpeak	86 ±13.4	72 ± 15.5	**Ò 0 . 0**	O2sats	96 (82-100)	95 (81-100)	**0.46**
	Leq	70 ± 7.6	53.3 ±11.1	**Ò 0 . 0**	HR	145 (116-152)	145 (138-152)	**Ò 0 . 0**

10	Lpeak	76 ± 3.3	79 ±14.3	**0.001**	O2sats	96 (86-99)	96 (86-99)	**Ò 0 . 0**
	Leq	64 ±3.2	63 ±9.6	**0.001**	HR	147 (77-161)	146 (82-159)	**Ò 0 . 0**
11	Lpeak				O2sats	98 (81-100)	98 (91-100)	**Ò 0 . 0**
	Leq				HR	174 (115-179)	174 (168-179)	**0.017**
12	Lpeak	77 ±5.8	74 ± 8.4	**Ò 0 . 0**	O2sats	85 (81-91)	91 (87-94)	**Ò 0 . 0**
	Leq	64 ±4.0	60 ±4.8	**Ò 0 . 0**	HR	174 (168-179)	138 (131-146)	**Ò 0 . 0**

Table 3.20

Similar to the previous 2 crossovers, the comparison of physiological median values at harmful thresholds of <80dBA and ≥80 dBA detected at the patient's ear and from the ambulance cabin was performed. A two-way comparison of median values using non parametric (Man Whitney U) is demonstrated in Table 3.19.

- ¶ Comparison of median values of physiology for NPEM and ANC at peak and total SPL threshold level below 80dBA and equal to/ above 80 dBA. (Blue Cell)
- ¶ Comparison of median values of physiology between ANC and SC for SPL thresholds (<80 and ≥80) dBA separately (Pink Cell)

¶

SPL detected at the patient Ear		**Oxygen Saturations (Median and Range)**			**Heart Rate (Median and Range)**		
		NPEM	**ANC**	**p-value**	**NPEM**	**ANC**	**p-value**
Peak SPL (Lpeak dBA)	**<80**	95(60-100)	95(60-100)	0.532	139(45-187)	136(49-172)	**Ò 0 . 0**
	>=80	96(60-100)	96(82-100)	0.284	145(51-163)	141(50-159)	**Ò 0 . 0**
p-value		**Ò 0 . 0**	**Ò 0 . 0**		**Ò 0 . 0**	**Ò 0 . 0**	
Total SPL (Leq dBA)	**<80**	96(60-100)	95(60-100)	**0.017**	141(45-187)	137(49-172)	**Ò 0 . 0**

	>=80	95(82-100)	96(88-100)	**Ò 0 . 0**	146(136-151)	141(127-148)	**Ò 0 . 0**
p-value		0.051	**Ò 0 . 0**		**Ò 0 . 0**	**Ò 0 . 0**	
SPL detected at the Ambulance		**Oxygen Saturations (Median and Range)**			**Heart Rate (Median and Range)**		
		NPEM	**ANC**	**p-value**	**NPEM**	**ANC**	**p-value**
Peak SPL (Lpeak dBA)	**<80**	95(84-100)	95(70-100)	**0.001**	146(56-162)	146(134-161)	**0.011**
	>=80	96(60-100)	95(60-100)	**0.254**	140(45-187)	136(49-172)	**Ò 0 . 0**
p-value		**0.377**	**Ò 0 . 0**		**Ò 0 . 0**	**Ò 0 . 0**	
Total SPL (Leq dBA)	**<80**	96(60-100)	95(60-100)	**Ò 0 . 0**	142(45-187)	139(49-172)	**0.011**
	>=80	92(60-100)	93(60-100)	**Ò 0 . 0**	139(50-185)	131(49-172)	**Ò 0 . 0**
p-value		**Ò 0 . 0**	**Ò 0 . 0**		**Ò 0 . 0**	**Ò 0 . 0**	
** no levels > 80dBA in Leq therefore MWU analysis not possible							

Table 3.21

At Peak and Total SPL detected at the neonatal ear, there is an overall significance in all median oxygen and heart rate values at comparison thresholds <80 dBA and ≥80dBA. ($p<0.05$) Heart rate was lower in ANC compared to NPEM for both peak and total SPL threshold, with more significant difference at ≥80dBA. ($p<0.05$). Similar to SPL detected at the neonatal ear, the comparison of median physiological values between intervention (ANC vs. NPEM) and between above and below 80dBA threshold showed more significant values in total and peak SPL detected from the ambulance cabin. The median heart rate appeared to be much lower in ANC with significant values in at SPL levels >80dBA. Oxygen saturation between the 2 interventions displayed significant results at threshold of 80dBA in the ambulance

cabin apart from very little difference in oxygen saturation at peak SPL ≥ 80 dBA. This result reflects the effects of ANC towards heart rate in this small cohort; and to a small extent the oxygen saturation is encouraging.

3.23 The Effect of Noise Protection Through Active Noise Cancellation (ANC) During Clinically Stable Neonatal Transfers- a randomised control trial

The randomisation of clinically stable neonatal patients undergoing interhospital ground transfers to a control group i.e. no noise protection and an interventional group of active noise cancellation (ANC); explored the effects of presumably the most effective noise protection application with standard neonatal ground transport practise (SC). The patients recruited were of neonatal patients who underwent planned return transfers to their local hospital i.e. repatriations or back transfers and some stable neonatal patients requiring Level 3 paediatric/ neonatal subspecialty input.

From calculation of power and sampling analysis, a total of 30 patients was required to enable calculation for statistical significance in this study component. The NNTP organisation is an acute neonatal transfer service that provides only approximately one third of its annual transfers for repatriation of stable neonates as most of these cases are retrieved by the patient's local/ referring unit teams. Therefore the 2 factors that led to a much smaller sampling size in this study was a time and paucity of repatriation/ stable transfers during the research period.

A total of 7 patients who were recruited to this study was randomised to 2 types of intervention previously mentioned (SC and ANC). As a result, 4 patients were

randomised to ANC and 3 patients were randomised to SC. The demographics of the patients recruited is presented in the Figure/ box below (Table 3.24)

Demographic Categories		% (n)
Gender	Male	57.1 (4)
Birth Gestation (weeks)		31.7 ± 4.7
Transport Gestation (weeks/days)		34.5 ± 2.8
Birth Weight (grams)		1570 ± 1142
Transport weight (grams)		2000 ± 840
Diagnosis Category	Medical	57.1 (4)
	Surgical	42.9 (3)
Number of associated co-morbidities	<3 issues	42.9(3)
	3-5 issues	57.1 (4)
	>=6 issues	0 (0)
External Congenital Anomalies		14.3 (1)
Respiratory Support	self-ventilating	28.6 (2)
	non-invasive ventilation	42.9 (3)
	invasive mechanical ventilation	28.6 (2)
Oxygen Requirement (FiO2)	room air 21%	42.9 (3)
	<50%	42.9 (3)
	50-75%	14.3 (1)
TRIPS Score	0-8	28.6 (2)
	9-16	42.9 (3)
	17-24	28.6 (2)
Level of Receiving unit	Level 3 NICU	14.3 (1)
	Level 3 Paediatric Sub-specialty	42.9 (3)
	Repatriation/ Back Transfer	42.9 (3)

Figure 3.24

In this group of patients, more than half were male (57%) with a mean gestation during transport of 34.5 weeks and a mean weight of 2 kilograms. 2 out of 7 patients required mechanical ventilation during transfer and one patient needed FiO2 requirements of > 50%. The overall TRIP score in all seven patients were relatively low, the highest being ’17-24’ i.e. 4.4 to 10.2 % risk of death within 7 days of transport. 4 patients required transfer into level 3 units for further intervention and 3 patients were repatriated to their local hospitals.

The comparison between standard care (SC) and active noise cancellation (ANC) groups was analysed with an independent t-test for SPL values as data appeared normally -Non-parametric Mann-Whitney U test was used to analyse any significance in oxygen saturations and heart rate values. The results are demonstrated in the table below.

The parameters analysed between the two groups (SC and ANC) showed statistical significance (p value <0.05). We expected a difference in mean peak and total SPL (detected at the ear) i.e. lower in ANC. The intervention group ANC had higher oxygen saturation and heart rate compared to the SC with significant difference of median values. ($p<0.05$) I did not expect to see any significant difference in SPL from the ambulance cabin as the measurements are external to the transport incubator. However, SPL levels would be more relevant when analysing effects directly on physiology through threshold analysis i.e. <80 or ≥80 dBA. (Table 3.22)

		SC	ANC	
		Mean ± SD	**Mean ± SD**	**p-value**
Lpeak (dBA)	**Ear**	76.45 ± 5.5	72.68 ± 5.3	**< 0.005**
	Cabin	91 ± 5.5	91 ± 5.6	**0.003**
Leq (dBA)	**Ear**	63.41 ± 5.8	59.63 ± 5.0	**< 0.005**
	Cabin	78 ± 6.2	78 ± 6.0	**0.243**
		Median and Range	**Mean and Range**	**p-value**
Oxygen Saturation (%)		92 (70-100)	94 (78-100)	**< 0.005**
Heart Rate (bpm)		144 (84-174)	159 (85-191	**< 0.005**

Table 3.22

Prior to assessing the effectiveness of ANC on physiological parameters, I observed the noise categories detected at the patient ear and its distribution in this cohort between the 2 groups. The figure below demonstrates that ANC group reduced the exposure of the neonate from harmful peak SPL >85dBA. The total noise energy i.e. SPL Leq is calculatively lower than SPL peak levels. Therefore, the amount of SPL measured in the recommended limit category i.e. <60 dBA is higher in SC and even higher in the ANC group. (Figure 3.25)

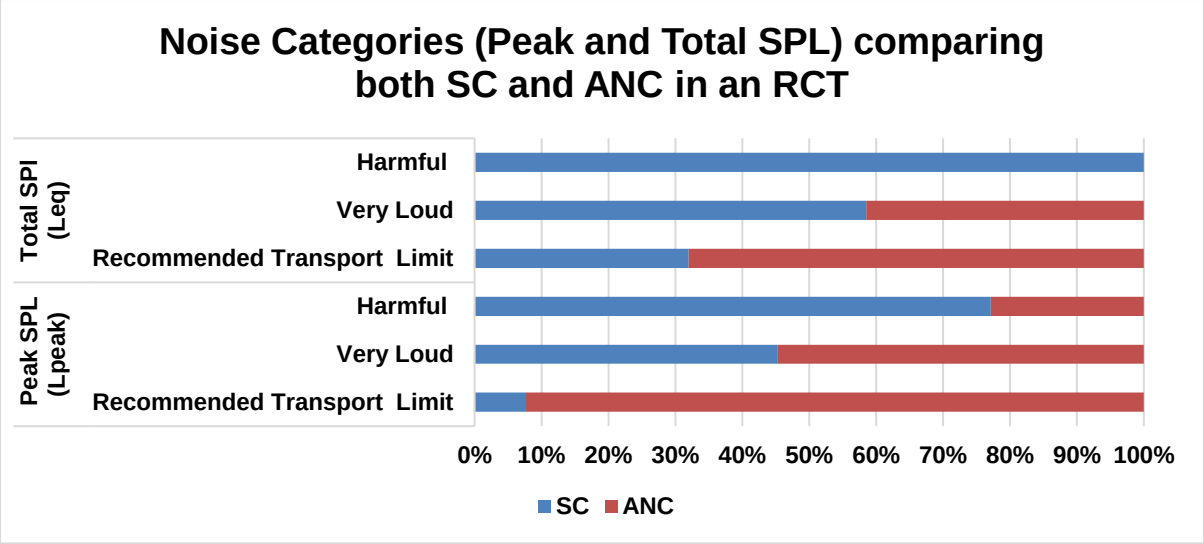

Figure 3.25

In order to compare physiological changes from Peak and Total SPL between SC and ANC in this cohort, I calculated the significance of median physiological values at the harmful 80dBA threshold, similar to previous study cohorts. This was performed at SPL detected at the ear (Channel 1) and also external to the incubator i.e. ambulance cabin (Channel 4). A two-way comparison of medians was performed using non parametric (Mann Whitney U) test; (Table 3.23):

- Comparison of median values of physiology (heart rate and oxygen levels) for SC and ANC at SPL threshold level below 80dBA and equal to/ above 80 dBA. (Blue Cell)
- Comparison of median values of physiology between SC and ANC for SPL thresholds (<80 and ≥80) dBA separately (Pink Cell)

With regards to SPL thresholds of 80 dBA at the ear, there is a significant difference in median distribution between SC and ANC; of which ANC increases oxygen saturation and heart rate in the patients transferred. ($p<0.05$). The comparison of

physiology at the threshold above and below SPL 80dBA (i.e. <80 and ≥80) demonstrates the decrease in oxygen percentage (95 vs 93) and decrease in heart rate (159 vs 151) beats per minute in the ANC group at SPL thresholds above 80dBA. ($p<0.05$). Due to much higher SPL levels detected from channel 4, I compared similar 2-way analysis of median physiological values between the 2 groups (SC and ANC). Although most of my comparison analysis was significant ($p<0.05$) due to the clarity in distribution i.e. more Leq numbers in ≥80dBA thresholds; the difference between 2 entities in nearly all aspects are variable. Therefore, I query the rationality of comparing physiological values with an external channel that has not made a direct impact on reducing noise i.e. via intervention (ANC).

SPL at the Ear		Oxygen Saturations (Median and Range)			Heart Rate (Median and Range)		
		Standard	ANC	p-value	Standard	ANC	p-value
Peak SPL (Lpeak)	<80	92 (70-100)	95 (78-100)	Ò0.50	144 (84-171)	159(86-191)	Ò0.0
	Ó 8	92 (70-100)	93 (78-99)	Ò0.0	145 (109-174)	151(85-191)	Ò0.0
p-value		0.337	Ò0.00		Ò0.00	0.001	
Total SPL (Leq)	<80	92 (70-100)	94 (78-100)	Ò0.0	144 (84-174)	159 (85-191)	Ò0.0
	Ó 8	90 (88-920	*	*	137 (137-138)	*	*
p-value		0.206	*	*	0.06	*	*

SPL at the Ear		Oxygen Saturations (Median and Range)			Heart Rate (Median and Range)		
		Standard	ANC	p-value	Standard	ANC	p-value
Peak SPL (Lpeak)	<80	92 (84-99)	93 (86-99)	Ò0.0	147(108-170)	144 (112-178)	Ò0.0
	Ó 8	93 (70-100)	94 (78-100)	Ò0.0	144(84-174)	160 (85-191)	Ò0.0
p-value		Ò0.00	0.456		Ò0.00	Ò0.00	

Total SPL(Leq)	**<80**	93 (73-100)	95 (82-100)	**Ò 0 . 0**	146 (84-170)	152 (109-190)	**Ò 0 . 0**
	Ó 8	92 (70-100)	94 (78-99)	**Ò 0 . 0**	141 (90-174)	162 (85-191)	≤0.005
p-value		**Ò 0 . 0 0**	**Ò 0 . 0 0**		**Ò 0 . 0 0**	**Ò 0 . 0 0**	
* ANC in harmful levels > 80 dBA for Leq (Total SPL) was N=0 and therefore could not be compared							

Table 3.23

The results from this randomised control study demonstrates the feasibility of establishing the effectiveness of noise protection during stable neonatal interhospital transfers. Although the comparison of median physiological values in the smaller scale showed significance in distribution, the actual values of heart rate and oxygen saturations were variable in nearly every comparison component in the larger scale. This component of the study is potentially ongoing in order to meet the target sampling size for more reliable evidence.

3.2.4 Noise Exposure and Protection During Neonatal Air Transport (Study 5)

This component of the research investigates the physiological effects of noise protection during neonatal interhospital air transport. From the results of baseline SPL levels during helicopter transfers, SPL s detected at the mannequin ear had a mean level higher than mean Peak SPL in the incubator and in the helicopter cabin: Ear 98 dBA vs. Incubator 98 dBA vs. Cabin 86 dBA. Therefore, I made a clinically ethical decision to apply noise protective devices throughout the whole single journey of each participant undergoing air transport in this research.

The main section of this study is the comparison of noise protective devices and its effects on neonatal physiology and behaviour (discussed in a separate section)

during interhospital helicopter transfers as this is the more prevalent form of air transfer used nationally by the NNTP in facilitation with the Irish Air Corps. I will also describe additional findings from opportunistic recruitment and recording of SPL and physiology from 2 other aircraft involved in neonatal transfers i.e. Fixed wing air craft (CASA) and the Lear jet.

Observation of the Effects of Noise Protection and Active Noise Cancellation during Neonatal Helicopter Transfers

This section demonstrates the results of noise exposure and noise protection during neonatal helicopter transfers. Due to geographical and other logistical reasons, neonatal air transfers conducted by the NNTP have been unpredictable with a paucity in frequency. Therefore, I took the opportunity to recruit and conduct the research in nearly all neonatal air transfers operated by the organisations involved. The majority of national neonatal emergency air transfers is operated by the NNTP in conjunction with the Irish Air Corps, the National Aeromedical Coordination Centre (NACC), the National Ambulance Service (NAS). The patients recruited in this study were transferred in the “Augusta Westland 139” (AW 139) Rotary Wing helicopter. The different flight phases and varying SPL levels corresponding to this was described a previous section under baseline results.

Similar to the aims in previous sections, this study has explored the application of noise protection and active noise cancellation in neonates transferred via helicopter and the effects of these interventions on neonatal patient’s physiology during air travel i.e. heart rate and oxygen saturation. The initial aim of this part of the study in the research; following sampling size power calculation was to recruit 10 neonatal participants into each arm of interventions. Due to the paucity of air transfers, the

recruitment of patients into the neonatal transfer air studies was via opportunistic convenience sampling.

From the baseline studies, the SPL throughout the differing flight phases of the helicopter are harmful and potentially detrimental to the human ear let alone an underdeveloped neonatal ear. Air Cabin crew in the helicopter inclusive of medical personnel are required to wear hearing protection during the whole flight.

Until present there has been sporadic use of the Natus Minimuffs ® that provide possibly suboptimal attenuation of noise. Therefore the 2 types of noise attenuators that I used in this study component was:

- Noise Protective Ear muffs (NPEM)
- Bose® Active Noise Cancellation Headphones (ANC).

These noise attenuators were applied throughout the single journey air transfers. I recruited 4 patients in this study and assigned the noise attenuation/ protection types alternately per patient. All the parents of these 4 patients consented their neonatal infant (patient) into the study. 2 patients were applied NPEM and the other 2 were applied ANC. The table below demonstrated the baseline demographics of these 4 patients (Figure 3.26)

Demographic Categories		% (n)
Gender	Male	75 (3)
Birth Gestation (weeks)		38.9 ± 1.8
Transport Gestation (weeks)		
Birth Weight (grams)		3183 ± 596
Transport weight (grams)		3183 ± 675
Diagnosis Category	Medical	25 (1)
	Surgical	25 (1)
	Cardiac	50 (2)
Number of associated co-morbidities	<3 issues	75 (3)
	3-5 issues	25(1)
	>=6 issues	0 (0)
External Congenital Anomaly		25 (1)
Respiratory Support	non-invasive ventilation	25 (1)
	invasive mechanical ventilation	75 (3)
Oxygen Requirement (FiO2)	room air 21%	25(1)
	<50%	75 (3)
Sedation		75 (3)
Muscle Relaxant		0 (0)
TRIPS Score	0-8	25(1)
	9-16	25 (1)
	17-24	0
	25-34	0
	35-44	50 (2)
Level of Receiving unit	Level 3 NICU	25 (1)
	Level 3 Paediatric Sub-specialty	75 (1)

Figure 3.26

Three quarters of this patient cohort were male, mechanically ventilated during interhospital air transfer, needed FiO2 requirement of less than 50% and was sedate for their condition and during the transfer. 2 patients had TRIPS score of ’35-44’ i.e. 11-23.4% of mortality within 7 days of transfer. The equipment configuration was similar to baseline air transfer study (Section 3.1.3);with an added action camera internal to the incubator wall for recording of behavioural responses.

A total recording of 300 minutes of second to second sampling of simultaneous SPL and physiological data between the 4 neonatal patients transferred by helicopter was performed in this patient cohort. Therefore, an average recording time of 1 hour and 15 minutes per patient was performed. A general comparison was made between NPEM and ANC by determining the mean and median SPL (as non-normally distributed SPL data was found in all 4 helicopter transfers) and the corresponding median and range values of heart rate and oxygen saturation level.

I compared peak SPL (Lpeak) and Total SPL (Leq) between ANC and NPEM from both ear (Channel 1) and helicopter cabin (Channel 4). Mean and median peak and total SPL was lower in in ANC compared to NPEM at the ear channel ($p<0.05$). The mean and median peak and total SPL was expectantly higher in the ambulance cabin for both ANC and NPEM groups, although the SPL pick up was external to the ear or incubator. ($p<0.05$). Oxygen saturations were higher (100 vs. 97) and heart rate was lower (111 vs. 116) with the use of ANC compared to NPEM in this small cohort ($p<0.05$). (Table 3.24)

			NPEM	ANC	p-value
SPL (Mean ± SD)	**Ear**	**Lpeak**	84 ± 6.8	79 ± 6.8	≤0.005
		Leq	72 ± 7.3	65 ± 6.7	≤0.005
	Helicopter	**Lpeak**	97 ± 12.3	105 ± 9.2	≤0.005
		Leq	85 ± 14	93 ± 10.6	≤0.005
SPL (Median and Range)	**Ear**	**Lpeak**	85 (62-108)	79 (54-95)	≤0.005
		Leq	75 (50-95)	66 (37-77)	≤0.005
	Helicopter	**Lpeak**	96 (57- 95)	105 (57-124)	≤0.005
		Leq	84 (51-108)	97 (42-105)	≤0.005
Physiology (Median and Range)	**Oxygen Saturation**		97 (51-99)	100 (87-100)	≤0.005
	Heart Rate		166 (70-220)	111(98-192)	≤0.005

Table 3.24

I proceeded to compare percentage of noise categories in Lpeak and Leq the 2 groups NPEM and ANC. The e incubator and helicopter cabin did not have Peak SPL levels that represented the category below recommended transport limits. ANC had less than 5 % exposure of Peak SPL > 85dBA and no exposure of the patient to harmful Total SPL category. (Figure 3.27)

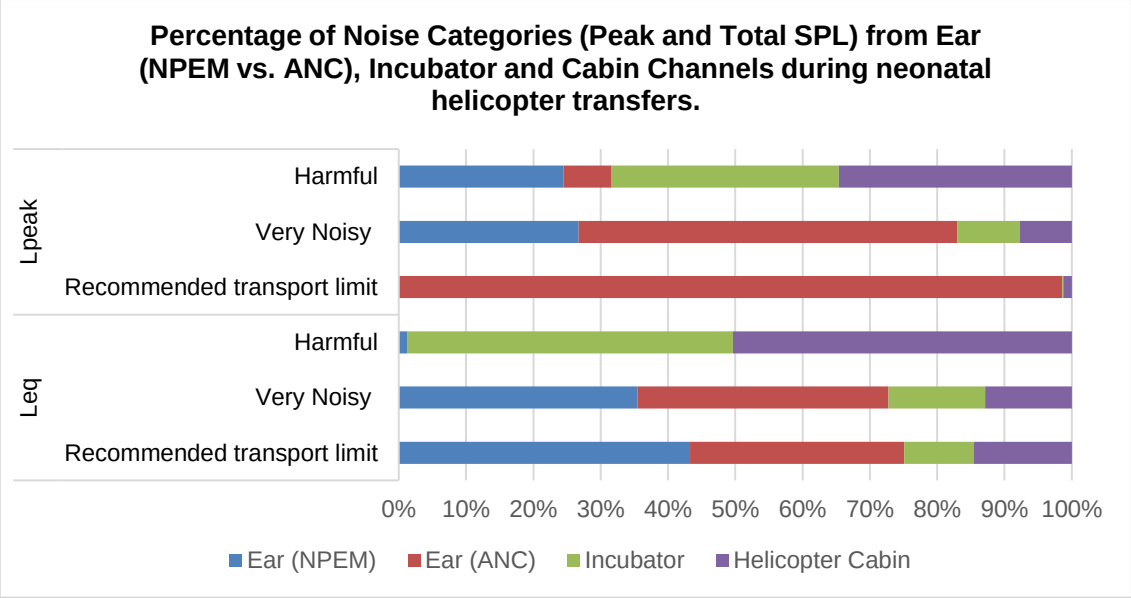

Figure 3.27

The comparison between median and range of physiological parameters at above and below harmful 80dBA threshold was analysed using non parametric Man Whitney U tests. We obtained the significance in the distribution of median valued below and above 80 dBA for both peak and total SPL at the patient's ear (channel 1) and also from the helicopter cabin (Channel 4). I also compared median physiological values between the 2 noise protection groups at the threshold of 80 dBA. Therefore, similar to previous studies, I performed a two-way comparison of median using non-parametric test (Mann Whitney U): (Table 3.25):

- Comparison of median values of physiology for NPEM and ANC at SPL threshold level below 80dBA and equal to/ above 80 dBA. (Blue Cell)
- Comparison of median values of physiology between NPEM and ANC for SPL thresholds (>80 and ≥80) dBA separately (Pink Cell)

SPL at Ear Channel		Oxygen Saturations (Median and Range)			Heart Rate (Median and Range)		
		NPEM	ANC	p-value	NPEM	ANC	p-value
Peak SPL (Lpeak)	<80	97 (56-99)	98 (87-100)	Ò0 . 0	167 (135-198)	160(98-192)	Ò0 . 0
	>=80	96 (51-99)	100(95-100)	Ò0 . 0	166(70-220)	107 (99-179)	Ò0 . 0
p-value		0.508	Ò0 . 0		Ò0 . 0	Ò0 . 0	
Total SPL (Leq)	<80	96 (51-99)	100 (87-100)	Ò0 . 0	166(70-221)	111 (98-192)	Ò0 . 0
	>=80	97(51-98)	**		169 (141-188)	**	**
p-value		Ò0 . 0	**		Ò0 . 0	**	
SPL level at Helicopter Cabin		Oxygen Saturations (Median and Range)			Heart Rate (Median and Range)		
		NPEM	ANC	p-value	NPEM	ANC	p-value
Peak SPL (Lpeak)	<80	94 (66-99)	98 (94-100)	Ò0 . 0	156 (93-198)	168 (101-173)	0.02
	>=80	97 (51-99)	100(87-100)	Ò0 . 0	167 (70-221)	110(98-192)	Ò0 . 0
p-value		Ò0 . 0	Ò0 . 0		Ò0 . 0	Ò0 . 0	
Total SPL (Leq)	<80	93 (66-99)	98 (94-100)	Ò0 . 0	157 (70-221)	168 (70-192)	0.06
	>=80	97 951-99)	100(87-100)	Ò0 . 0	164(99-192)	109 (98-177)	Ò0 . 0
p-value		Ò0 . 0	Ò0 . 0		Ò0 . 0	Ò0 . 0	
* ANC in harmful levels > 80 dBA for Leq (Total SPL) was N=0 and therefore could not be compared/ analysed							

Table 3.25

Although there is a small difference in actual median oxygen saturation between SC and ANC when compared between and at each threshold difference is not large, the

distribution of the median values between 2 tested entities are statistically significant. Oxygen saturation levels are increased in ANC in comparison to NPEM at both peak and total SPL detected at the ear and in the helicopter cabin.

Similarly, the difference in heart rate in both NPEM and ANC at <80 and ≥80 dBA thresholds demonstrates statistical significance in distribution of median heart rate across both groups and also across threshold levels. ($p<0.05$) Heart rate was noted to increase with ANC compared to NPEM ($p<0.05$) . The only decrease in heart rate with ANC compared to NPEM was at helicopter cabin SPL ≥80dBA in both Lpeak and Leq.

Noise protection in fixed wing aircraft (CASA CN 235)

Due to the unpredictable frequency of neonatal air transfers, I opportunistically measured noise levels in the fixed wing military aircraft. This involved the same methodology to the neonatal helicopter transfers. The use of the military CASA aircraft would usually involve international patient transfers. The patient recruited into this study was retrieved from a hospital in London UK. This patient was a full-term male infant who weighted 4.2 kilograms. He developed a lung complication after delivery called ‘meconium aspiration’ and subsequently required extracorporeal membrane oxygenation which is a treatment not available for this situation in the Ireland. During the retrieval transfer back to Ireland he was mechanically ventilated in 50% of fractional inspired Oxygen (FiO2). He was sedated during the journey. His TRIP Score during transfers was ‘35-44’ i.e. 11.1-23.4% of mortality in the first 7 days following transport. Even with a different air craft, configuration of the transport incubator and cabin personnel seating, I followed the same methodology and set-up

of recording as the previous helicopter studies. I applied NPEM to the patient due to its current practicalities. 136 minutes of second to second of simultaneous SPL and physiological data was recorded. As this is an additional measurement, I measured SPL during the CASA flight and demonstrated results from an observational aspect. (Table 3.11) The results below describe the SPL levels, the categories of SPL and the proportion of harmful levels (80 dBA) from 3 channel locations in relation to the patient being transferred. The distribution of heart rate and oxygen saturation level recorded from the patient was normally distributed. Whereas the distribution of SPL from all 3 channels was non-normally distributed. Therefore non parametric test (Man Whitney U) was used to calculate significance between variables. The table below demonstrates mean and median of total and peak SPL from all 3 noise channels in the fixed wing air transfer which shows levels beyond the recommended transport limit. (Table 3.26). Median and maximum Peak and Total SPL shown in the figure below demonstrate that noise levels detected in the fixed wing aircraft do not comply with recommended transport SPL levels, with maximum peak noise levels reaching 120 dBA in the incubator and the helicopter cabin. (Figure 3.28)

		Mean	Median
SPL Lpeak	**Ear**	**80 ± 7.3**	**83 (58-115)**
	Incubator	86 ± 7.0	85.6 (57-120)
	Cabin	95 ± 7.4	98.6 (63-118)
SPL Leq	**Ear**	**69 ± 9.1**	**73.8 (45-91)**
	Incubator	74 ± 7.9	74.3 (42 -99)
	Cabin	83 ± 9.1	87.7 (48-102)
Oxygen Saturation		92 ± 2.5	92 (81-99)
Heart Rate		146 ± 6.8	146 (130-170)

Table 3.26

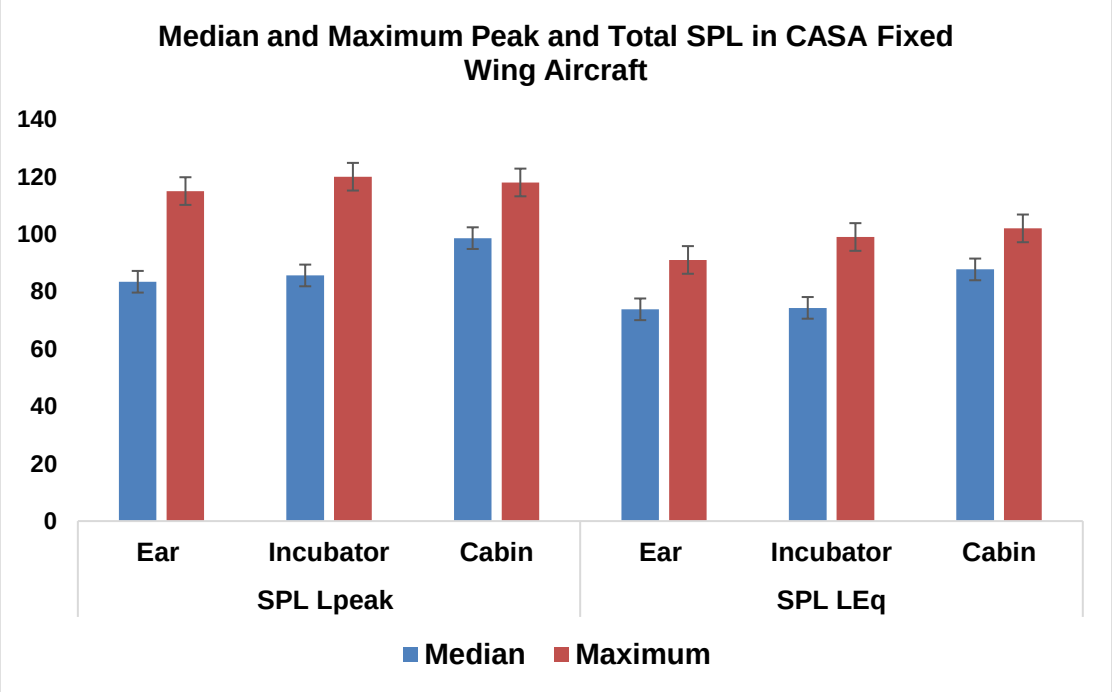

Figure 3.28

The percentage of distribution at below and above 80 dBA thresholds in peak and total SPL was determined to allow for comparison of physiological parameters within these levels. More than half of the recording of SPL has been equal to and above 80dBA in Lpeak in all 3 channels. The total SPL in incubator and at the neonatal ear recorded less than 40% levels جي80dBA (Figure 3.29)

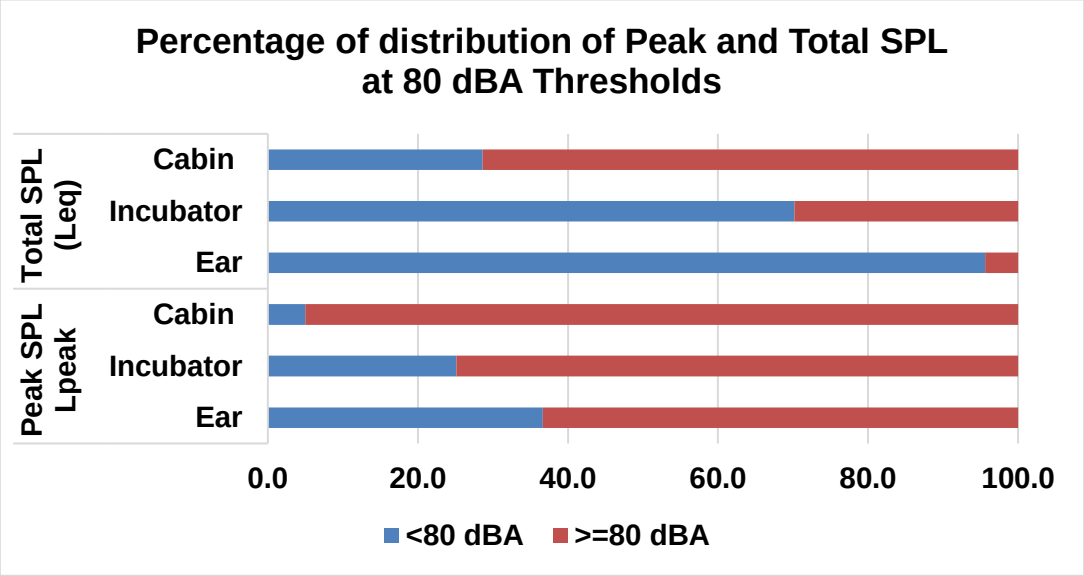

Figure 3.29

Median values of heart rate and oxygen saturations were compared at peak and total SPL of <80 dBA with ≥80dBA detected from the ear with NPEM applied throughout the whole journey, levels from the incubator (Channel 2) and also levels detected from aircraft cabin (channel 4). Non-parametric test for comparison of median values was used to determine significance between these 2 physiological parameters at above and below 80dBA. (Table 3.27)

For all 3 channels recording peak and total SPL; oxygen saturation and heart rate was lower in levels equal to and above 80dBA ($p<0.05$) in nearly all comparisons. The only reported higher oxygen saturation and heart rate, although significant in its difference; was at total SPL recorded at the ear (Leq) of above 80dBA. Similar to previous results in helicopter transfers.

SPL at Ear with NPEM		**Oxygen Saturations (Median and Range)**	**Heart Rate (Median and Range)**
Ear Peak SPL (Lpeak)	<80	93 (86-97)	147 (130-170)
	>=80	92 (81-99)	145 (130-166)
	p-value	**Ò 0 . 0 0 5**	**Ò 0 . 0 0 5**
Ear Total SPL (Leq)	<80	92(81-99)	145(130-166)
	>=80	96(88-99)	147(139-163)
	p-value	**Ò 0 . 0 0 5**	**Ò0.005**
SPL level in Incubator		**Oxygen Saturations (Median and Range)**	**Heart Rate (Median and Range)**
Incubator Peak SPL (Lpeak)	<80	93(86-99)	148(137-170)
	>=80	92(81-99)	145(130-170)
	p-value	**Ò 0 . 0 0 5**	**Ò 0 . 0 0 5**
Incubator Total SPL Level (Leq)	<80	93(81-99)	147(130-170)
	>=80	92(83-97)	143(133-164)
	p-value	**0.102**	**Ò 0 . 0 0 5**
SPL level in Aircraft Cabin		**Oxygen Saturations (Median and Range)**	**Heart Rate (Median and Range)**
Cabin Peak SPL (Lpeak)	<80	93(86-97)	147(137-149)
	>=80	92(81-99)	146(130-170)
	p-value	**Ò 0 . 0 0 5**	**Ò 0 . 0 0 5**
Cabin Total SPL Level (Leq)	<80	93(86-97)	147(133-170)
	>=80	92(81-99)	145(130-166)
	p-value	**Ò 0 . 0 0 5**	**Ò 0 . 0 0 5**

Table 3.27

Neonatal Noise Protection in a transfer with the Irish Air Corp Lear Jet

One patient was recruited for measurement for SPL and physiology with the application of NPEM. This transfer was a retrieval to speed of 445 knots (804km/ha

hospital in Manchester, United Kingdom for further specialist treatment. The mode of transfer involved the Irish Air Corps Learjet 45. This aircraft is a mid-size 9 passenger ‘business jet’ aircraft that has a cruising speed of 445 knots (804 km/h).

The transfer involved a full-term male neonate who needed further evaluation of severe neonatal hypoglycaemia and suspected hyperinsulinism (ref). The patient had no other co-morbidities, did not require any respiratory support and had a low TRIPS score (0.4-0.9%)Even with a different air craft, configuration of the transport incubator and cabin personnel seating, I followed the same methodology and set-up of recording as the previous helicopter studies. I applied NPEM to the patient due to its current and upcoming practicalities. I recorded 136 minutes of second to second of simultaneous SPL and physiological data. As this is an additional measurement, I measured SPL during the CASA flight and demonstrated results also in an observational aspect. The results below describe the SPL levels, the categories of SPL and the proportion of harmful levels (80 dBA) from 3 channel locations in relation to the patient being transferred.

The distribution of heart rate and oxygen saturation level recorded from the patient was normally distributed. Whereas the distribution of SPL from all 3 channels was non-normally distributed. Therefore non parametric test (Man Whitney U) was used to calculate significance between variables. (Table 3.28)

The table below describes the median value of peak and total SPL in all 3 noise channel inputs and the median and range of oxygen saturation and heart rate recorded during transfer. What has been noticeable is the increased median peak and total SPL detected from the baby pod that was used for this transfer. This is also elaborated in Figure 3.30 below.

SPL, Oxygen saturation and Heart Rate (Median and Range)		
SPL Lpeak (dBA)	Ear	72 (57-96)
	Incubator (Baby Pod)	**95 (74-120)**
	Cabin	78 (68-109)
SPL Leq (dBA)	Ear	60(43-73)
	Incubator (Baby Pod)	**83 (56-88)**
	Cabin	67 (57-78)
Oxygen Saturation (%)		96 (92-99)
Heart Rate (beats per minute)		162 (151-198)

Table 3.28

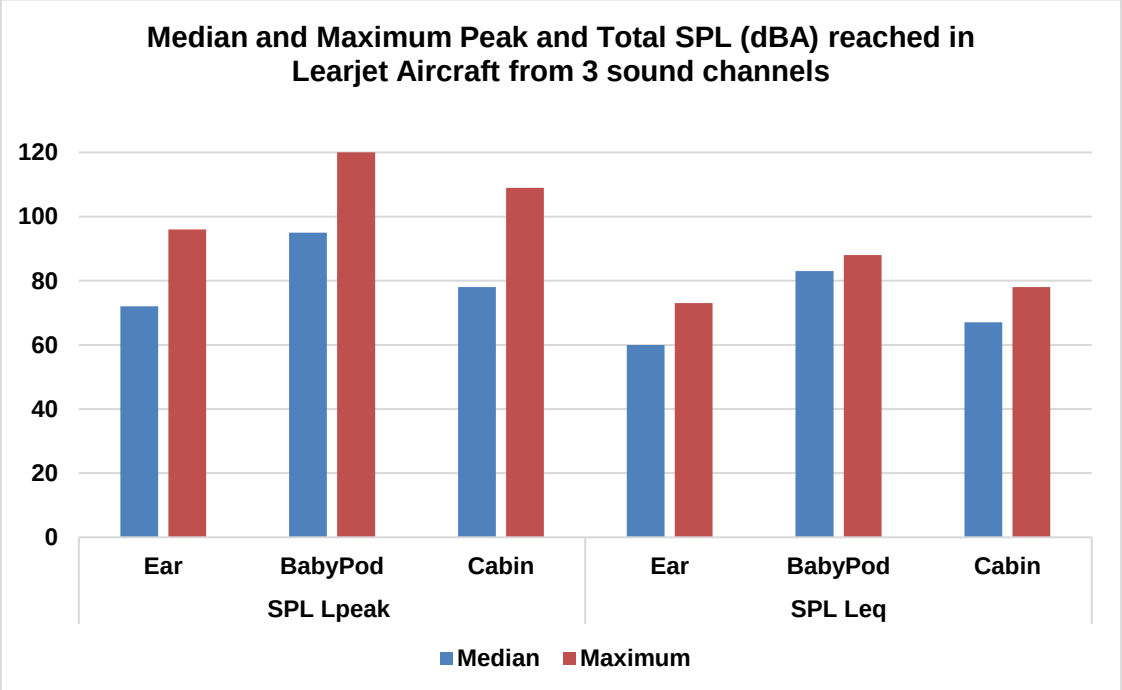

Figure 3.30

Concerning noise categories recorded in relation to the neonatal patient travelling via the Learjet in a baby pod, the amount of harmful peak noise exposure (>85dbA) is demonstrated in the figure below. The majority of noise category in the Learjet and in relation to the baby pod during transfer is in the ‘very loud’ group i.e. within 61- 85 dBA. (Figure 3.31)

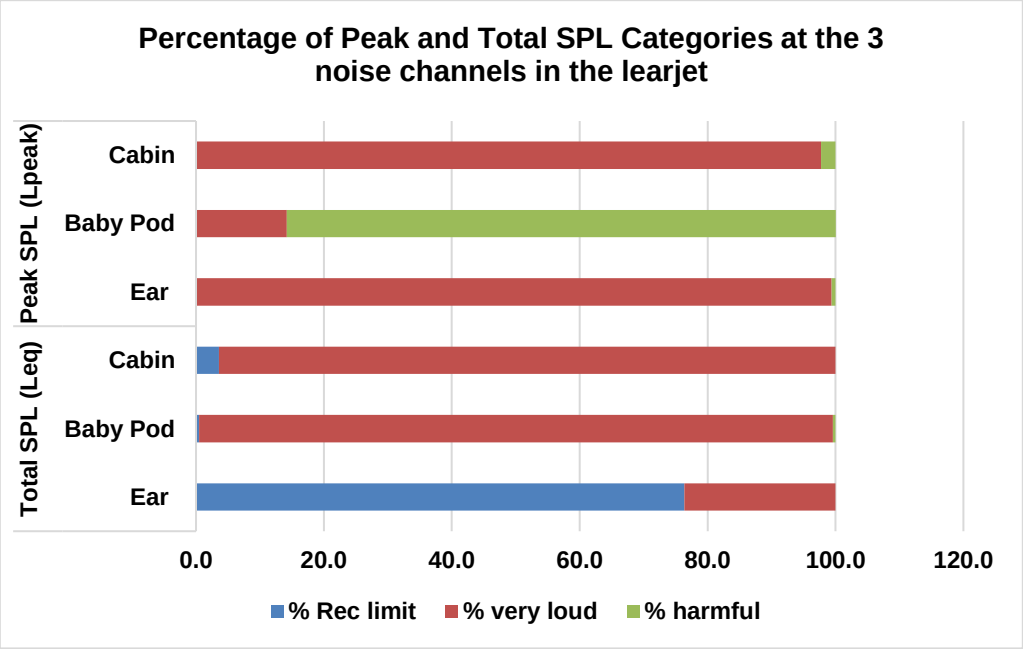

Figure 3.31

Most of the recording of peak and total SPL during Learjet transfer has been under 80dBA. The baby pod demonstrates majority of peak and total SPL recording of 50% more in SPL levels more than 80 dBA. (Figure 3.32)

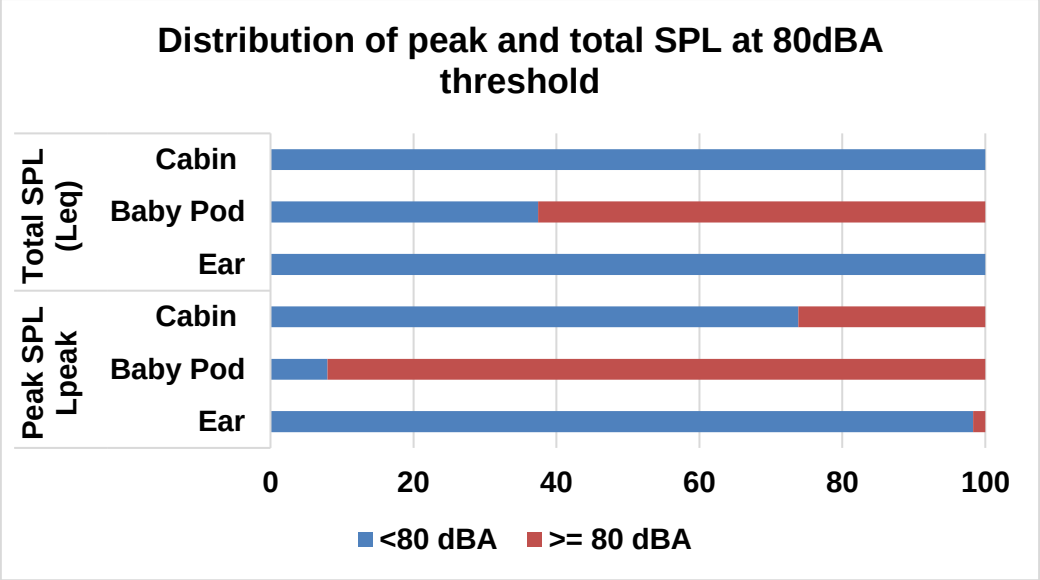

Figure 3.32

Similar to previous study analyses, I compared median oxygen saturation and heart rate at threshold levels of 80dBA in peak and total SPL. Although the values at <80dBA and ≥80dBA threshold demonstrated an overall significance ($p<0.05$) in median oxygen saturation and heart rate distribution, there is not much difference in the actual value between these two groups particularly if the study involves the analyses on one patient. (Table 3.29)

SPL at Ear		Oxygen Saturations (Median and Range)	Heart Rate (Median and Range)
Ear Peak SPL (Lpeak)	<80	96(92-99)	162(151-198)
	>=80	97(95-98)	168(159-183)
	p-value	**0.004**	**Ò 0.005**
Ear Total SPL (Leq)	<80	96(92-99)	162(151-198)
	>=80	**	**
	p-value	**	
SPL in Baby Pod		**Oxygen Saturations (Median and Range)**	**Heart Rate (Median and Range)**
Baby Pod Peak SPL (Lpeak)	<80	96(95-98)	162(157-177)
	>=80	96(92-99)	162(151-198)
	p-value	**Ò 0.005**	**0.043**
Baby Pod Total SPL (Leq)	<80	96(95-98)	161(151-179)
	>=80	97(92-99)	168(156-198)
	p-value	**Ò 0.005**	**Ò 0.005**
SPL in Aircraft Cabin		**Oxygen Saturations (Median and Range)**	**Heart Rate (Median and Range)**
Cabin Peak SPL (Lpeak)	<80	96(92-99)	164(154-198)
	>=80	97(92-99)	161(151-196)
	p-value	**Ò 0.005**	**Ò 0.005**
Cabin Total SPL Level (Leq)	<80	96(92-99)	162(151-198)
	>=80	**	**
	p-value	**	

Table 3.29

3.3 Neonatal Behavioural Response to Noise during interhospital transport

As mentioned in the previous chapters; one of the aims and objective of the research was to investigate the behavioural response of the neonatal patient during transport. Noise is regarded as a noxious stimulus that can potentially be perceived as pain. The Neonatal and Infant Pain Score (NIPS) was used as a practical scoring system in this research.(72)

Behavioural Scoring with NIPS

The NIPS score was provided by watching pre-recorded muted video recordings of each neonatal patient recruited in this study. I assigned 4 examiners (3 NICU nurses and 1 neonatal physician); with appropriate experience in neonatology to provide scores. The examiners observe these recording separately, individually and blinded from any clinical details of the neonate in the video. A NIPS score of more than 3 (i.e. ≥4) indicates pain. The scores recorded for analysis are the highest score of pain (noxious stimulus) demonstrated by the patient observed by the examiners.(Figure 3.33) (73)

Neonatal/Infant Pain Scale (NIPS)

(Recommended for children less than 1 year old) A score greater than 3 indicates pain.

Pain Assessment		Score
Facial Expression		
0 - Relaxed Muscles	Restful face, neutral expression	
1 - Grimace	Tight facial muscles; furrowed brow, chin, jaw (negative facial expression – nose, mouth brow)	
Cry		
0 - No cry	Quiet, not crying	
1 - Whimper	Mild moaning, intermittent	
2 - Vigorous cry	Loud scream; rising, shrill, continuous (Note: Silent cry may be scored if baby is intubated as evidenced by obvious mouth and facial movement	
Breathing Pattern		
0 - Relaxed	Usual pattern for this infant	
1- Change in breathing	Indrawing, irregular, faster than usual; gagging, breath holding	
Arms		
0 - Relaxed/Restrained	No Muscular rigidity; occasional random movements of arms	
1 - Flexed/Extended	Tense, straight arms; rigid and/or rapid extension, flexion	
Legs		
0 - Relaxed/Restrained	No Muscular rigidity; occasional random movements of legs	
1 - Flexed/Extended	Tense, straight legs; rigid and/or rapid extension, flexion	
State of Arousal		
0 - Sleeping/Awake	Quiet, peaceful, sleeping or alert, random leg movements	
1 - Fussy	Alert, restless and thrashing	

Figure 3.33

The behavioural scores recorded was non-normally distributed and highly discrepant (large variability) among the overall patient group and between examiners. Therefore, I used median and range to demonstrate the NIPS scores that represent the neonatal behavioural response to noise during interhospital transport; for the total patient recruited in the research and the sub-categorical studies that each patient was assigned to. It was also important to demonstrate the correlation and accuracy between the NIPS scores provided by the examiners through a reliability analysis using 2 main statistical calculations; Cronbach's Alpha (C-alpha) and an

interclass correlation coefficient (ICC). An acceptable C-alpha and ICC value of above 0.7 is acceptable and any value above 0.8 is considered good. There was a total of 65 patient recruited into this overall research. Due to user error one video recording was unavailable for NIPS scoring for all 4 examiners. One examiner had missed one patient recording and therefore had scored 63 patients in total.

3.3.1 Behavioural Response through NIPS scores in the Overall Research

The NIPS score in the overall cohort resulted in a median lowest score of 1 to highest score of 3 between the 4 examiners. The inter-examiner correlation matrix reflects low correlation between examiner 1 with the other three examiners and somewhat fair correlation between examiner 2 and examiner 4.(Table 3.30)

The NIPS score as a reliable test for the overall patient group in the whole research is fairly good (C-alpha >0.8) but not a reliable test as a single measure. (Table 3.31)

Inter-Examiner Correlation Matrix in NIPS scores overall				
	Examiner 1	**Examiner 2**	**Examiner 3**	**Examiner 4**
Examiner 1	1.000	0.582	0.572	0.536
Examiner 2	0.582	1.000	0.524	0.761
Examiner 3	0.572	0.524	1.000	0.473
Examiner 4	0.536	0.761	0.473	1.000

Table 3.30

		Examiner 1	Examiner 2	Examiner 3	Examiner 4
NIPS		N=64	N=64	N=63	N=64
NIPS Score (Median and Range)		1 (0-4)	1.5 (0-6)	3 (0-7)	2.5 (0-7)
Cronbachô s		0.817			
Intraclass Correlation	**Single Measures**	0.528			
	Average Measures	0.817			

Table 3.31

3.3.2 Behavioural Response through NIPS score in observational cohort

The NIPS score in the observational patient cohort resulted in a median lowest score of 1 to highest score of 2 between the 4 examiners. Therefore, the patients transferred in this category according to the assessors did not appear to be in any discomfort. The inter-examiner correlation matrix reflected low correlation between all four examiners.(Table 3.32) The NIPS score as a reliable test for the observational cohort (Study 3) is acceptable (C-alpha >0.7) (Table 3.33)

Inter-Examiner Correlation Matrix in NIPS scores Observational study				
	Examiner 1	**Examiner 2**	**Examiner 3**	**Examiner 4**
Examiner 1	1	0.678	0.515	0.569
Examiner 2	0.678	1	0.489	0.458
Examiner 3	0.515	0.489	1	0.352
Examiner 4	0.569	0.458	0.352	1

Table 3.32

		Examiner 1	Examiner 2	Examiner 3	Examiner 4
NIPS		N=20	N=20	N=20	N=20
NIPS Score (Median and Range)		1 (0-3)	1 (0-5)	2 (0-5)	2 (0-6)
Cronbachôs		0.785			
Intraclass Correlation	**Single Measures**	0.418			
	Average Measures	0.742			

Table 3.33

3.3.3 Behavioural Response through NIPS score in the crossover studies

I analysed the results of the behavioural score in this crossover cohort by analysing the NIPS scores overall subsequently the 3 crossover studies separately. The median NIPS scores provided by the examiners varied with 1 being the lowest score and 5 the highest median NIP score in the overall crossover. The inter-examiner correlation matrix for the overall crossover cohort was low among all 4 examiners. Examiner 1 correlated well with examiner 2 and examiner 3 was noted to have better correlation with Examiner 4 in certain crossovers. (Table 3.34) The reliability of NIPS as a behavioural scoring system in the crossover overall was low (C-alpha 0.63). (Table 3.35)

		Inter-Examiner Correlation Matrix			
	Examiner	**1**	**2**	**3**	**4**
Overall Crossover	**1**	1	0.337	0.212	0.199
	2	0.337	1	0.472	0.432
	3	0.212	0.472	1	0.261
	4	0.199	0.432	0.261	1
Crossover 1 (SC vs NPEM)	**1**	1	0.685	0.304	0.661
	2	0.685	1	0.138	0.812
	3	0.304	0.138	1	-0.042
	4	0.661	0.812	-0.042	1
Crossover 2 (SC vs ANC)	**1**	1	0.272	0.884	0.045
	2	0.272	1	0.465	0.614
	3	0.884	0.465	1	0.212
	4	0.045	0.614	0.212	1
Crossover 3 (NPEM vs ANC)	**1**	1	0.625	0.744	0.616
	2	0.625	1	0.508	0.971
	3	0.744	0.508	1	0.465
	4	0.616	0.971	0.465	1

Table 3.34

	Examiner	**N**	**NIPS Score (Median and Range)**	**Cronba Alpha**	**Intra-class Correlation**	
					Single Measures	**Average Measures**
Overall	**1**	N=31	1 (0-4)	0.631	0.25	0.571
	2	N=31	2 (0-6)			
	3	N=30	3 (0-7)			
	4	N=31	3 (0-7)			
Crossover 1 (SC vs NPEM)	**1**	N=9	1 (0-4)	0.717	0.221	0.531
	2	N=9	2 (0-4)			
	3	N=9	4 (2-7)			
	4	N=9	5 (0-7)			
Crossover 2 (SC vs ANC)	**1**	N=10	1 (0-3)	0.695	0.288	0.618
	2	N=10	1.5 (0-4)			
	3	N=9	2 (0-7)			

	4	N=10	2.5 (0-5)			
Crossover 3 (NPEM vs ANC)	**1**	N=12	1.5 (0-3)	0.848	0.529	0.818
	2	N=12	1 (0-6)			
	3	N=12	2.5 (1-6)			
	4	N=12	2 (0-7)			

Table 3.35

3.3.4 Behavioural Response through NIPS score in the RCT of stable neonatal transfers

The results of the behavioural score in this the randomised control study cohort by analysing the NIPS scores was analysed in similar manner with the previous study cohort. The median NIPS scores provided by the examiners showed higher scores in the SC group compared with ANC group. Which may reflect the positive response to active noise cancellation during stable transfers. The inter-examiner correlation matrix for the overall RCT demonstrated slightly better correlation between examiner 3 and examiner 4. However, there was better correlation within examiner 2, 3 and 4 in the scoring of SC group. (Table 3.36) Although the reliability of NIPS as a behavioural scoring system in this RCT study was acceptable (C-alpha >0.735) (Table 3.37); it was not a reliable test to perform on single measures.

		Inter-examiner Correlation Matrix			
	Examiner	**1**	**2**	**3**	**4**
Overall RCT	**1**	1	0.194	0.194	0.679
	2	0.194	1	0.475	0.515
	3	0.194	0.475	1	0.745
	4	0.679	0.515	0.745	1

SC	**1**	1	-0.327	0	0.866
	2	-0.327	1	-0.945	-0.756
	3	0	-0.945	1	0.5
	4	0.866	-0.756	0.5	1
ANC	**1**	1	0	-0.229	0.707
	2	0	1	-0.688	-0.707
	3	-0.229	-0.688	1	0.324
	4	0.707	-0.707	0.324	1

Table 3.36

	Examiner	**N (n)**	**NIPS Score (Median and Range)**	**Cronba Alpha**	**Intraclass Correlation**	
					Single Measures	**Average Measures**
Overall RCT	**1**	N=7	1 (0-2)	0.735	0.409	0.735
	2	N=7	1 (0-5)			
	3	N=7	4 (1-5)			
	4	N=7	3 (0-7)			
SC	**1**	n=3	1 (0-4)	-2.667	-0.222	-2.667
	2	n=3	4 (2-5)			
	3	n=3	4 (4-5)			
	4	n=3	4 (3-4)			
ANC	**1**	n=4	0.5(0-1)	-0.395	-0.076	-0.395
	2	n=4	0.5 (0-1)			
	3	n=4	2 (1-4)			
	4	n=4	2 (1-3)			

Table 3.37

3.3.5 Behavioural Response through NIPS score in the neonatal helicopter transfers

The results of the behavioural score through assigned NIPS Score in neonatal helicopter transfers; was analysed similar to previous study cohorts. I observed the

median and range of NIPS scores provided by the examiners and subsequently performed a reliability analysis. The median NIPS scores provided by the examiners showed higher scores in the NPEM group (score within 2-7) compared with ANC group (score 0.5-1.5). Comparable to the RCT study in the previous section, the NIPS score results may probably reflect the positive response to active noise cancellation during stable transfers. The inter-examiner correlation matrix for the overall study; demonstrated all examiners correlated with each other in overall RCT NIPS scoring. This positive correlation between examiners is likely due to the small sample size when analysed separately. (Table 3.37). The reliability of NIPS as a behavioural scoring system in this air transport study cohort was highly reliable (C-alpha 0.934) (Table 3.38); It was also found to be as reliable when measured as a separate entity.

		Inter-examiner Correlation Matrix			
	Examiner	**1**	**2**	**3**	**4**
Overall	**1**	1.000	.926	.981	.724
	2	.926	1.000	.974	.927
	3	.981	.974	1.000	.819
	4	.724	.927	.819	1.000
NPEM	**1**	1.000	1.000	1.000	
	2	1.000	1.000	1.000	
	3	1.000	1.000	1.000	
	4	1.000	1.000	1.000	1.000
ANC	**1**	1.000	1.000	1.000	1.000
	2	1.000	1.000	1.000	1.000
	3	1.000	1.000	1.000	1.000
	4	0.707	-0.707	0.324	1

Table 3.37

	N (n)	Examiner	NIPS Score (Median and Range)	Cronba Alpha	Intraclass Correlation	
					Single Measures	Average Measures
Overall Helicopter Transfer	**N=4**	**1**	1 (0-3)	0.934	0.628	0.871
		2	2(0-5)			
		3	2.5 91-6)			
		4	4.5 (1-7)			
NPEM	**n=2**	**1**	2 (1-3)	0.981**	0.941**	0.98**
		2	4 (3-5)			
		3	4.5 (3-6)			
		4	7 (7)			
ANC	**n=2**	**1**	0.5 (0-1)	1.00**	1.00	1.00**
		2	0.5 (0-1)			
		3	1.5 (1-2)			
		4	1.5 (1-2)			

Table 3.38

Conclusion on the research results

Congregating information from previous chapters and current chapter, the research comprised of various studies with a multitude of analytical constituents designed to investigate the effects of noise exposure on the neonatal patient during transport. The progression of results followed through a succession from the very basic questions at baseline level. I demonstrated the feasibility of obtaining data on noise (and vibration) that opened the windows to exploring the effects of noise on physiology and behaviour of the newborn. Although there are a lot of concerns regarding the high level of noise exposure in modern neonatal practise, the recommended limit of noise exposure in the NICU and during transport that is frequently exceeded; has not changed in the last 2 decades at least. Results of noise levels in baseline studies in NICU, ground ambulance transport and air transport

frequently exceed 80 dBA and occasionally stretch above 100 dBA. Noise levels that I categorised following international standards demonstrated minimal or modest amounts below the recommended limit. The NPEM and ANC are foreseeable applications during transport. While various analysis throughout the research demonstrated changes in physiology and behaviour moreover with the application of noise protection; there is still huge variability within small population groups that was studied.

Chapter 4

Discussion

It is a known circumstance of the constant progress and advancement of clinical research in neonatal medicine; while we expand and pursue our quest into areas in this field, we aim to improve the delivery of care of the vulnerable neonate. This research not only aspires to the purpose mentioned, but enquired into areas of patient care from a different direction i.e. the risk exposure (noise), its effects on the newborn, particularly during interhospital transport, and the effectiveness of eliminating this risk. Noise as described in previous chapters is an unpleasant level of sound that leads to anatomical and physiological; auditory and non-auditory changes in the body which can potentially harm the critically unwell neonate; including the premature. (41)

I hypothesised that neonates who are exposed to detrimentally high levels of noise during interhospital transfers would experience physiological and behavioural changes; which could potentially be alleviated with the use of noise protection. This risk of noise exposure not only is an added stressor; but also leads to changes in the physiology of the neonate and hence could affect clinical stability during a potentially high risk but crucial time in their care i.e. transport. The changes that I anticipated comprised of alterations in heart rate, blood oxygen saturation levels and behaviour during high levels of noise (SPL-sound pressure level). Therefore, the application of noise/ hearing protection devices directly to the neonatal external ear during transport did not just aid in reducing the amount of exposure and minimised injury to the neonatal auditory apparatus, it helped maintain steady physiological state during

transfers and in making periods of transfer more comfortable for the vulnerable neonate.

The research idea originated from a senior colleague/ clinical supervisor of this research; a current national clinical lead in neonatal transport in Ireland who identified, firstly, the need for innovative research and education in the department, and secondly, an aspect of neonatal transport that is essential to explore i.e. noise. The birth of the research began through a list of questions in relation to the project from basic physical science of sound and noise how the newborn physiology manifests the effects of sound to other forms i.e. changes in heart rate, oxygen saturation level and behavioural reaction. I delved into the scientific and clinical literature not only to understand the relation of noise to the environment; but to investigate the impact of noise on health and its implications to the vulnerable neonate in particular.

Therefore, in order to perform this study, a substantial component of the planning process was the pursuit of the most accurate equipment while meeting with allocated costs. This involved communication with various companies that provide parts and equipment for environmental noise monitoring. The noise and vibration meter selected (Svan-958A®) was made by a professional instrumentation manufacturer for sound and vibration measurement and analysis; Svantek Ltd (Poland). The purchase of this equipment and its related consumables was through the company's branch in Bedford, UK. Prior to commencing data collection, I attended seminars on noise and vibration monitoring, received tutorial sessions on how to use Svan-958A® and its correlation software for further statistical analysis and also mostly performed "self-re-education" on the physics of sound, acoustics and noise. This occurred in parallel with the education and training received in conducting clinical research;

performing good clinical practise; training in biostatistics (Microsoft Excel®, SPSS® and Stata®); writing workshops for proposals, ethical committee applications and thesis.

In addition to the noise and vibration equipment I, as the researcher, was required to have competency in operating other relevant clinical and non-clinical apparatus to ensure the success of data collection and analysis. The additional research equipment involved a portable patient vital signs monitor (heart rate and oxygen saturation monitor 'Masimo Rad8'™), an action camcorder to record neonatal behaviour ('GoPro Hero5'™) and various noise protection devices. The equipment was configured to the most achievable and safe positions possible during data collection. Prior to and in the pilot stages of the data collection phase, I developed simpler mechanisms to conduct the research whilst fulfilling the aims and objectives without compromising the potential fulfilment of the hypothesis; and without compromising patient safety and care. This was performed successfully throughout the recruitment phase.

It was fundamental to have the ability to determine the viability of the equipment used for the research. The pilot studies and the data produce were essential to establish its practical use on transport without interfering with existing transport equipment. The data from the baseline or pilot studies aids as a platform and comparison with the results achieved in the patient studies. As the nature of transport medicine is of high turnover phase and increased mobility of staff, the opportunity for data collection for a single patient only happens 'once' in a fraction of the time in the day. Therefore, there is relatively a narrow clinical window for data collection.

Relating Results to Existing Evidence

This research in noise exposure and noise protection; and its journey have explored and identified an under-recognised area in neonatology and neonatal transport that is impactful directly and indirectly to the developmental care of the unwell but growing and developing neonate, and is potentially relatable to future risk i.e. noise induced hearing loss. The first literatures published on the hazardous effects of noise to the environment and health emerged nearly 50 years ago. Governments and international committees world-wide have recognised the detrimental impact of noise pollution to the environment and human health and have set standards limiting excessive noise exposure in the community and also in occupational settings. (23,36,83) The Committee on Environmental Health (USA) back in 1975 have published under the American Academy of Pediatrics the hazardous noise levels that the foetus and neonate are potentially exposed to and therefore have recommended that noise levels in the NICU environment should not exceed 45dB. (36) Evident from the results on baseline studies in the NICU in this research and supported by previous studies, noise measured as sound pressure levels (SPL) frequently exceed this amount. (84,85)

In comparison to the noise levels in the transport environment, results from baseline mannequin and patient studies in this research demonstrate noise levels that surpass the recommended limit of i.e. 60 dBA during transport. (86) The average peak noise levels reach during ground transport was approximately 76 dBA and in air transport was 96 dBA; in this research. It is important to remember that noise levels within 80-85 dBA are perceived to be very loud and uncomfortable, whereas any level that reaches beyond 85 dBA is harmful and not only causes autonomic

changes to the body; it can potentially lead to permanent, irreversible damage to the internal auditory organs following repetitive insults.

The mannequin studies were performed to obtain baseline noise levels in our own research environment. It was essential to be able to target any deficiencies in equipment assembly and operational issues prior to commencing data collection in patient studies. The results demonstrated in the baseline studies in the NICU with the neonatal mannequin revealed mean peak SPL (dBA) of 61 at the ear, 68 in the incubator and 75 outside the incubator. The mean total SPL (an idea of the cumulative sound in the given period of recording time) achieved in the same NICU was 45 at the ear, 55 in the incubator and 58 outside the incubator. These ranges of SPL are equivalent to environmental phenomenon from normal tone conversation up to heavy street noise. The maximum peak SPL (dBA) that was picked up in the NICU in this study was 93 at the ear, 96 in the incubator and 100 outside the incubator.

The importance of applying noise protective devices to the mannequin in the NICU baseline study was not only to demonstrate the extent of noise reduction they can provide; but also, to determine whether they function effectively in neonatal transport research. We discovered mean peak SPL (dBA) detected at the neonatal mannequin ear (that was placed in the incubator) was 61 with no noise protection, 65 with Natus MiniMuffs ®, 58 with NPEM, and 56 with ANC. The corresponding total SPL (dBA) was 45 with no noise protection, 50 with Natus Minimuffs ®, 43 with NPEM and 35 with ANC. The justification with regards to the higher SPL detected with Natus MiniMuffs®, compared to not applying any noise protection in the incubator is with regards to the hard surface of the mannequin that resulted in higher noise reflection in addition to the much thinner material of the MiniMuffs®. In addition to this, the

effectiveness of the foam pads may have been reduced due to a break in the seal to apply the mini-microphone (Channel 1) near the mannequin ear for SPL recording. Although these results have supported previous data on noise measurements in the NICU, the potential noise exposure that can occur towards the neonate in the incubator is concerning. (87–89) Direct application of noise protection to the ear is available i.e. Natus Minimuffs and is applied to infants in some neonatal units. However, they may not be cost effective and not an ideal option for the extremely premature neonate with very friable thin skin. (56,63)

In modern NICU's, attention is given to providing optimal developmental care to the neonate. This includes optimising the right environment that promotes growth and maturity while receiving treatment in the NICU and eliminating stressors or insults that promote physiological instability and affect growth and development. This includes eliminating harmful levels of noise i.e. poor-quality noise. Noise level detectors are placed in most units to alert staff and visitors to reduce the activities that generate high levels of noise. Quiet times which comprise of darkening the intensive care units, limiting the visits from unnecessary staff and avoiding unnecessary conversations next to the patient in the incubator are all being implemented in most modern neonatal units world-wide. Other measure undertaken in the NICUs are the thick incubator covers that are applied outside the incubator that not only acts to block out light and mimic the in-utero environment for the premature infant, it can act as a heat insulator and noise absorber.
Newer incubators have implanted noise detectors and display the amount of noise that is detected near the patient and displays this information on its screen.

Noise protection in the newborn transport environment is much more challenging. It is difficult to control the transmission of vibration and sound from the bumpy road of the ground ambulance and the high pitch sound from the propellers of the rotary wing aircraft. The use of the Natus MiniMuffs are not standard practise world-wide and the guidelines are sporadic even in some air transfers. This study has found that worryingly, the incubator appears to amplify SPL during air transfers and increase noise exposure. Some incubators are padded with multiple rolled up blankets surrounding the baby and acts not just for added protection during transport but also to absorb noise transmitted to the patient. Padded incubator covers are also used to insulate heat and absorb any added external noise. Currently, there is ongoing research on the implementation of active noise cancelling devices in incubators in the NICU. (68,90)

The recording and data collection on patient studies began with recruitment of suitable neonatal patients to an observational study of physiological and behavioural changes to concurrent noise level exposure. The initial sample size suggested following power calculations was 10 participants. The decision to double this number and recruit 20 patients into this observational study allows for more meaningful results about physiological reactions and alterations to exposed noise levels, with added broader variation of patient demographics.

This was supported by our findings on physiological changes as a result of noise exposure to the neonate undergoing interhospital transport. In our observational cohort of neonatal response to noise during interhospital transport during standard care (no noise protection) of 20 patients; the average heart rate was higher in the

harmful noise category (≥ 85 dBA) compared to the heart rate of the patients when noise was under the recommended limit (≤ 60 dBA) i.e. 154 vs 139 beats per minute ($p<0.05$). It was arduous to comprehend whether the slight increase in oxygen saturation at levels in the harmful category; although showed significance ($p<0.05$), indirectly reflected a compensatory increased respiratory rate following exposure to loud noise; 95 vs 91%. Previous studies have suggested that there can be variable response to noise in NICU and during interhospital transport, but are consistent in stating the significant changes noted in physiological parameters. Consistent with this current research, there is an increase in baseline heart rate in neonates who are exposed to noise higher than the recommended limit in NICU and during interhospital transport. (44,91,92)

I obtained a vast amount of second to second data on noise, heart rate and oxygen saturation. Therefore, the decision to apply a threshold of 80 dBA, which is considered harmful for newborns and uncomfortable for adults, was to observe any distinct changes above and below this value. 80dBA is equivalent to very loud sounds where making any normal conversation is difficult i.e. the use of a nearby hair drier, the sound of a factory, milling machine or a freight train 15 metres away. In occupational health 80 dBA would be the lower exposure triggering action or intervention, whereas 85 dBA would be of higher exposure action values. (82) We discovered in this observational study (n=20) the mean heart rate and blood oxygen saturations were higher at peak and total SPL of ≥80dBA which is supporting the evidence in the literature; particularly with respect to elevations in baseline heart rate. In addition to supporting preceding evidence, the results from the observation of

physiological changes during standard neonatal ground transport care provided a platform in interpreting the interventional studies.

The intervention studies

I selected 2 noise protective devices for the application on the neonatal patient participants recruited in the interventional studies; an MRI grade noise protective earmuffs **(NPEM)** –“ems4bubs®” and an electronic active noise cancellation **(ANC)** headphone – “Bose Quiet Comfort 35®”. These noise protection devices were selected for its denser structure which is thought to provide a higher Noise Reduction Rating (NRR) and reduce the exposure of the neonates to high levels of noise. The difference between NPEM with ANC is the mechanism involved in reducing noise exposure to the perceiving neonatal ears. NPEM that was used are made of outer plastic that can deflect noise and any other transmitted noise is absorbed and dampened before it reaches the neonatal eardrum. The ANC headphones are implanted with a microphone that receives external noise and transmits these waves to an analogue filter, which then is programmed to transmit the opposite wave in the opposite direction of the incoming wave, hence cancelling the ‘sinusoidal’ effect of the sound waves. This action is seen to be effective in eliminating high background sounds and to an extent the peak sounds. The ANC headphones are now thought to be the most effective device in hearing and noise protection particularly in the aviation industry. (75)

The intervention studies involving neonatal patient participants commenced with crossover studies; an essential part of the research. As neonatal transport provides clinical care to a diverse patient population, the crossover studies provide for control

over disparities. I achieved slightly more than the target sample size (n=32) following the preceding power calculation for 30 patients. The crossover groups involved comparison of NPEM and ANC with standard neonatal transport care (no noise protection) in 2 separate groups and the comparison of ANC with NPEM in one separate crossover group. This is the first prospective interventional comparison study involving noise protection to neonatal patients during interhospital ground transfers. The aim was to investigate any physiological changes that have transpired from the alternative 'apply- remove- reapply' of noise protection in the crossovers; in addition to ascertain the most effective or even feasible noise protective device in neonatal transport for the future.

In the first Crossover with regards to the overall results, the peak and total SPL (dBA) was effectively reduced with the use of NPEM compared with SC; Lpeak (77 vs 76) and Leq (65 vs 64). The median oxygen saturation was slightly reduced (96 vs 94) and there was not much difference between heart rate (138 vs 139) in when standard care was compared with NPEM; although the distribution of these values was statistically significant. At the 80dBA threshold detected at the ear the overall heart rate actually increased with NPEM protection, which was unexpected. This could have reflected patient discomfort in handling the changes during "apply-remove-reapply" despite including 3 minute 'washout' periods in between the recording phases. The oxygen saturation was unchanged between the 80 dBA threshold remains unchanged despite some statistically significant differences in distribution of means between the 2 groups.

In the second crossover study comparing standard care (SC) with active noise cancelling (ANC) the overall analysis showed no change in oxygen saturation and heart rate between the two groups. However, individual case analysis demonstrated a variable response in heart rate and O2 saturations (increase, decrease or no change; i.e. likely patient dependant). This was unaffected by higher noise levels in detected at the ear or from ambulance cabin (<80dBA or >80dBA respectively). The intervention with ANC reduced both peak and total SPL when compared with SC ($p<0.05$); 76 vs 69 in peak SPL and 63 vs 55 in total SPL. This represents a large reduction in frequency threshold exposure as the decibel scale is logarithmic.(16) Neither this use of ANC during transport nor this level of noise protection have been described in the literature previously, and this represents important data for future clinical practice.

Crossover study 3 compared the application of NPEM and ANC. Active versus passive noise cancelling significantly reduced peak SPL (76 to 69 dBA) and total SPL (64 to 55dBA) and therefore is a more effective potential clinical tool in this setting. Median heart rate was lower in the ANC group compared to NPEM at both above and below 80 dBA thresholds. Heart rate at peak and total SPL detected at the ear at > 80dBA between ANC and NPEM were 145 vs 141 and 146 vs 141 beats per minute respectively. Peak and total SPL levels >80dBA detected at the **ambulance** cabin demonstrated that there was also a reduction in heart rate in the ANC group similarly; (140 vs 136) at peak SPL > 80 dB and (139 vs 131 at total SPL >80. Notwithstanding the higher cost of ANC use, these findings would support the introduction of ANC rather than NPEM into routine clinical practice, although further research may be required. Heart rate was lower in ANC compared to NPEM for both

peak and total SPL threshold, with more significant difference at ≥80dBA. ($p<0.05$). there was not a considerable difference in oxygen saturation between the comparison groups in this crossover despite statistical significance that rather reflected the difference in median distribution across comparison groups.

Patient availability, researcher working hours and both the critical time-sensitive nature of transports and the fact that the service runs 24/;7 all contributed to challenges in completing patient recruitment. I am extremely proud of having recruited 65 patients and obtained detailed real time data on all of them. However, full patient recruitment for the RCT (in addition to the observational and crossover studies) was not ultimately practical within the two year period. Paradoxically, the main difficulty was in recruiting stable repatriated patients, as many were not transported by the NNTP service. This may change for future research as the service evolves and a repatriation service is developed. The RCT compared standard care with ANC. Although only 7 of the planned 30 patients have been recruited to date (ongoing at present), initial analysis showed a significant reduction in peak and total SPL ($p<0.05$ for both) when ANC is used. Oxygen saturations increased slightly with ANC (SC 92% vs ANC 94%), and heart rate was higher in the ANC group (albeit still within the normal range). Further recruitment is required (which is ongoing), but ANC appears to be an effective noise protection strategy. We used the TRIPS score, a validate transport score, to confirm physiological stability. Well infants are not generally sedated, and are more alert and awake which may explain some of our findings. The RCT was not blinded, as it was not possible to conceal allocation. However, the objective nature of the SPL and physiological measurements used in our analysis reduces any risk of bias in my results.

Air transfer

This is novel data within the clinical transport literature. A very recent presentation from March 2019 described the effect of noise and vibration on neonatal TRIPS scoring during air and ground transport without mentioning provision of assessment on noise or vibration protection strategy to alleviate these stressors. The effort to determine duration of harmful, or potentially harmful, noise exposure can potentially be interrogated. (93) In comparison to this research, my work is the first to look at the effectiveness of noise protective strategies in this high-risk group as well as to quantify the cumulative exposure of noise during air transport, as sought by environmental and industrial risk management groups as such in quantifying exposure; but also provides potential solutions for real-life clinical practice. (54,94–96) Recruitment is ongoing for this aspect of the research. However, ANC was better than NPEM at reducing the transmission of cabin noise to the patient (68% transmission with ANC vs 84% with NPEM). However, the simultaneous measurements in the cabin aircraft, in the incubator and beneath the noise protection device also revealed that incubator noise was higher than aircraft cabin noise. This suggests an amplification effect by the incubator system which warrants further investigation with our on-going recruitment in this study. This also requires further intervention and is a potential target for future clinical improvements. Notably, infants using ANC noise protection demonstrated significantly lower heart rates than those using NPEM (111 bpm with ANC versus 166bpm with NPEM). While this analysis will be repeated once recruitment is complete, it suggests that infants may be more settled with ANC protection.

Behavioural scores- were they useful?

The effect of noise exposure on human behaviour has been studied and recognised in the scientific literature. Anxiety, stress and irritability caused by increased exposure to noise and subsequent changes in heart rate and blood pressure have been observed in adult patients, and particularly in noise-exposed occupational settings. (97–99) The neonatal patients have not been excluded from the investigation of the effects of noise as a stressor in the NICU. Studies have hypothesised that neonates have increased behavioural scores as a reflection of their increased reactivity from exposure to high levels of noise. These studies have used behavioural scores to assess neonatal response to noise and results have been variable. (62,100,101)The issue of selecting the appropriate validated behaviour scoring system is important to ensure accuracy and reliability of the assessment results. There are be more elaborate behavioural scoring systems that will require custom trained professionals and time, however feasibility within the busy transport service is an issue. (102) Noise is regarded a noxious stimulus (like pain), so a pain scoring system that was concise and feasible within the time available was felt to be ideal. I selected the Neonatal and Infant Pain Score (NIPS) to assess the behavioural reactions of the patients recruited. (72,77) Four examiners, all experienced in the provision on clinical care to neonatal patients, were nominated. Muted video recordings of 64 patients were reviewed and scored, and one was excluded because of recording issues during transport. Disappointingly, interobserver reliability was low for individual studies, however the scoring system was reliable over the whole research cohort; N=64 (Cronbach's alpha >0.8) despite inter-examiner discrepancy. There is a real need for more robust and yet reliable and feasible transport behavioural scoring systems in the newborn.

The Journey as a Clinical Researcher

As a clinically proficient physician in neonatal medicine the additional journey as a clinical researcher is an important, significant one that I will never regret undertaking. The motivation in pursuing this project stemmed from a pre-existing interest in neonatal medicine and neonatal transport in particular. This project is the first doctorate by research with the National Neonatal Transport Programme (NNTP) in Ireland. Owing to the organisational structure of NNTP, that required buy-in from involved services in 3 separate tertiary level neonatal intensive care units in Dublin in 3 separate hospitals. This research is was a unique arrangement from a variety of factors. Firstly, as an organisation affiliated with 3 hospitals; ethical approval for the studies in the research was sought separately. Although this research was approved by all 3 ethical committees; the challenging factor that I needed to surmount was to do with time. The primary location for the research changed on a weekly basis between the 3 hospitals. The challenges of conducting research in this environment were extraordinary. I, as the researcher, needed to be constantly ready to avail of any opportunity to record for data collection and recruit suitable patients into the relevant study components. I also needed to be equipped and prepared to join any potential suitable transfers while also being prepared to step away or abort the data collection should a patient participant deteriorate or a parent refuse to give consent for their newborn to participate. In addition to this, it was essential for me, as the researcher, to be able to communicate and make all team members aware in all 3 units providing the NNTP service of the potential for recruitment of patients into the studies involved. The research also needed effective time management while conducting the research to inform parents, obtain consent and maintain patient observations and clinical management. As interhospital transport can potentially be a

stressful time for parents who are usually separated from their newborn child, I, as the researcher, needed to be tactful and at the same time informative in order to obtain consent from parents for their child's participation.

I obtained consent from all the parents of the neonatal patient participants that was recruited into this research. 3 patients were assessed and were excluded from this research. There were only 2 parents who did not give consent for their newborn to participate in the research. These 2 parents were too distraught concerning the transport of the children to another hospital. Therefore, due to the high levels of anxiety, the parents were too stressed to understand the nature of the research. The parent of the third patient had a language barrier and therefore the patient was not recruited as there was lack in parental understanding of what the research entailed.

The research involved recording of patient and environmental data during interhospital transport. Therefore, I, as the researcher, remained with the patient and the transport team from the point of arrival at the referring hospital neonatal unit until arrival to the receiving hospital neonatal/ paediatric unit. As previously mentioned in earlier sections, interhospital transport for the neonate, especially if unstable and critical, is a high-stakes environment due to limited staff, mobile environment, limited work space and added external stressor such and extremes of temperature for the neonate when outside, vibration and noise. Whether or not these stressors will affect the patient's transfers, I, as the clinical researcher had a duty of care to assist should any deterioration during transfer occur. One patient deteriorated during transfer and data recording had to cease. Although I was present in a clinical research role, I was able to advise the transport team I was accompanying. Fortunately, I have not

encountered any resistance from any staff members when performing the studies involved in this research. There were also no reported side effects from the application of any research equipment for data recording from any research participants.

The studies were completed in terms of patient recruitment and data collection in the following order: the baseline studies for NICU, ground transfer and air transfer (Study 1); the patient observational ground transport study (Study 2) and the crossover studies (Study 3). With regards to the RCT (Study 4) and the air transfer study (Study 5); the aim was to recruit greater numbers than are currently presented in the results section. The target number of recruits for the RCT was not achieved due to the lack of cases for NNTP repatriation transfer; as most of them are retrieved by staff from their local unit or referring hospital. The air transfer studies were dependant on the time of request and the availability of relevant logistics from the Irish Air Corps. The frequency of air transfers in general are less in comparison to the amount of ground ambulance transfers performed by the NNTP. These latter 2 studies mentioned in the research are still prospectively on-going in order to meet the sample size from preceding power calculations, and the results will be published once recruitment is complete.

Neonatology in general, and neonatal transport in particular, are facing increasing challenges due to changes in the recognised thresholds of viability. Increasingly premature babies are receiving intensive care and require transfer to tertiary centres. These infants are more vulnerable in general, and may be more vulnerable to harmful stressors such as noise. As we increasingly recognise the impact of noise on

neonatal physiology and well-being, we need to tailor our clinical transport service to the needs of these, the smallest patients, and generate robust data to support quality improvement in this area. However, even the methods used in my work may not be tolerated by these extremely small “micro-premmies”, particularly with respect to skin integrity and fragility, and so new and innovative ways of incorporating active noise cancelling into incubators and standard transport equipment may be required.

Chapter 5

Thesis Conclusion

This is innovative and novel research into an area of potential harm that is well recognised in older age groups, but has largely been overlooked in the vulnerable neonatal patient population. My work demonstrates that it is feasible to quantify noise exposure and assess the effectiveness of noise protection strategies in neonatal transport.

There is a lot of published literature on noise and its impact on public and occupational health. (18,103). The auditory and non-auditory physiological effects of noise are recognised as affecting every age range and subgroup of the population, right down to the developing neonate (21,44,84). More research and quality data are needed in order to understand the issues arising from this, and solutions that are required. Neonatal transport is an under-represented area within the wider medical community with respect to the generation of evidence through research in order to improve practise. There is a need to push the boundaries of neonatal research in an area that is seldom “unnoticed”, to continually challenge practices in newborn transport with good research to improve the care of the newborn, and this research on noise exposure and potential solutions to harmful noise levels during neonatal transport in Ireland adds to the knowledge we have, and provides a blueprint for how research can be actualised within the NNTP in Ireland and transport services around the world.

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